A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East

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Glossary of Significant Terms and Abbreviations used in this Study

DPIA – Data Protection Impact Assessment

GDPR – General Data Protection Regulation

HRCDC – Health Research Consent Declaration Committee

HRR – Health Research Regulations

HSE – Health Service Executive

MHC – Mental Health Commission

NICE – National Institute for Health and Care Excellence

NIMS – National Incident Management System

NSSI – Non-suicidal self-injury

REC – Research Ethics Committee

WIT – Waterford Institute of Technology

SETU – South East Technological University

Abstract

Serious untoward incidents, occurring in the context of mental health services and mental disorder, continue to attract widespread concern amongst professionals, policy-makers and the wider population. Such occurrences can range from the most serious incidence of violence and self-harm in communities to more minor but often pervasive and distressing incidents of violence/aggression/self-harm occurring within inpatient or long-term residential health settings. Mental health services, internationally, have sought to reduce or limit such occurrences through the implementation of risk management and patient safety strategies.

This study examined serious untoward incidents occurring within mental health services in the South East of Ireland over an 8 year period. Utilising a database of staff-completed incident report forms and with access to relevant patient charts, the study examined and analysed incident types, prevalence, patterns of activity and contributing/contextual factors. A mixed-method design was utilised, using the established research methods retrospective chart review and content analysis. A sample of 325 patients charts were examined with analysis supported by statistical testing.

Violence and aggression was by far the most widely reported incident type, with occurrences of self-harm mainly limited to acute psychiatric services. Inpatient care was the predominant location for untoward incidents with a pervasive level of violence and aggression relating to longer stay and older adult units. Whilst patient factors such as acute mental disorder, history of trauma and external pressures were recognised as contributory factors in the incident reports studied, a number of other areas relating to clinician-patient interaction and organisational/environmental factors were also considered. The potential for conflict or 'flashpoints' occurring was a significant finding of the study, particular conflict occurring amongst patients and violence and aggression in the context of direct clinical care. Issues of safety, security and risk are considered in relation to the study findings, in addition to an analysis of the various systems in place governing mental health service provision.

Chapter 1 Introduction

1.1 Introduction

This research thesis examines serious and untoward incidents occurring within statutory mental health services in the South East of Ireland. Serious incidents have major significance, not only for those individuals affected by such events, but for all stakeholders involved in the provision or receipt of mental health care. The reporting of serious incidents in Irish healthcare has historically been linked with the areas of risk management and professional indemnity; the creation of a National Clinical Indemnity Scheme (CIS) for services and professionals in 2002 and the establishment of a national incident reporting system (formerly the STARSWeb system) in 2003 formalising the process of incident reporting in Ireland.

The identification and reduction of harm, whilst learning from the occurrence of serious incidents is now part of the patient safety strategy in Ireland (HSE, 2019a). The phrase 'patient safety', itself, has become a global watchword; defined by the World Health Organisation (WHO) (2019: para 1) as "a health care discipline that emerged with the evolving complexity in health care systems and the resulting rise of patient harm in health care facilities."

From a mental health service perspective, it is not only patient harm under scrutiny but also the harm or potential harm posed to others as a result of mental disorder or perceived mental disorder. In Ireland alone, a number of high profile incidents reported in the media over the past 6 years, including cases of filicide (Moloney, 2021); homicide (Reynolds and O'Riordan, 2019) and murder-suicide (Feehan and Anderson, 2017) have examined or questioned the influence of mental disorder in each case.

The frequently reported failure of mental health services to protect service users; families and the public from harm remains a common criticism of mental health services in the media (Tait, 2016; Raleigh, 2017; Reid, 2018). At the other end of the spectrum are critics of frameworks solely focused on managing risk at the expense of personal autonomy and responsibility, whilst serving only to perpetuate the stigma already associated with mental health issues (Slemon et al. 2017; Callaghan and Grundy, 2018). With an estimated one in four people affected by mental health problems globally, (WHO, 2001) such debate has far reaching significance.

Internationally, the transition to community based care over the past decades has been accompanied by the investigation of many high profile cases, leading to substantial changes in the way risk is managed in mental health services. One significant catalyst relates to the Clunis inquiry (Ritchie et al. 1994) which focused on a man with a long history of mental illness who, in 1992, entered a tube station in London and stabbed to death an innocent member of the public. The government inquiry that followed highlighted a 'catalogue of failure and missed opportunity' with responsibility shared by psychiatrists; mental health nurses; social workers; the police; hostel staff and the crown prosecution service. The recommendations, focusing on multidisciplinary communication; organisational governance and risk management emerged as a result of multiple contributing factors as opposed to any single area of blame.

Whilst such extreme examples of harm remain rare, all areas of health service provision, including mental health care, have since developed frameworks to record and examine serious and untoward incidents occurring within their jurisdictions (Kohn et al. 2000; Donaldson, 2000). The central message within these frameworks is that services should be able to learn from adverse events in a supportive climate that does not single out individuals for blame, but considers all influencing factors from a healthcare 'systems' approach.

Clarkson et al (2018; p2) describe a systems view of healthcare as a "product of a complex adaptive system of people, equipment, processes, and institutions working together, where problems can arise with either deficiencies in individual system elements, or in their relationship with each other". Furthermore, Irish Health Service Executive (HSE) guidance on carrying out a systems analysis investigation (HSE, 2016) categorises such systems across several areas; the individual affected or harmed; task and technology related factors;

individual factors (staff); team factors; work environmental factors; organisational and management factors and institutional context factors.

Patient safety, across mental health services, still appears to be very much linked with the dangers associated with mental disorder, notably the areas of violence, suicide and deliberate self-harm. Although alternative notions of risk and patient safety in mental health are being developed to include other categories such as vulnerability, exploitation and sexual violence (Higgins et al. 2016), all incidents can have a direct and indirect effect on the services individuals might wish to access, their self-perceptions and the perceptions of those around them. Whilst neither violence nor self-injurious behaviour exist purely in the context of mental illness, such associations remain a subject of considerable and constantly evolving public and professional debate (Varshney et al.2016; Ahonen et al. 2019).

Suicide, for example, has a long-standing association with mental disorder (Harris and Barraclough, 1997; Nock et al. 2008; Windfuhr and Kapur, 2011) borne out by statistics suggesting a 10 times higher probability when compared with the general population (Bachmann, 2018) and the presence of mental disorder in 90% of suicides (Cavanagh et al. 2003). This is countered by writers such as Pridmore (2015) and Hjelmeland and Knizek (2017) who criticise figures derived from psychological autopsy studies; feel the pathologising of suicide counterproductive in terms of its prevention and argue that mental disorder should not be viewed as the sole cause of suicide but merely a contributing factor.

Similar controversy extends to violence and homicide, where issues relating to the presence of mental disorder have long been debated (Marzuk, 1996; Stuart, 2003; Varshney et al. 2016). Whilst increased risk of violence perpetration has been linked with specific diagnoses such as schizophrenia (Shaw et al. 2006; Thornicroft, 2020), writers have warned against the oversimplification of this association and the need to consider other variables such as environmental stressors and substance abuse (Elbogen and Johnson, 2009).

The assessment of an individual’s diagnosis or mental state is therefore only one area of consideration when carrying out an incident review. People seeking or receiving mental health care are capable, like everyone, of irrational human behaviour. They bring their external lives with them to the services they may access; their family and social relationships; their personal and interpersonal characteristics. As such, this research study sets out to consider serious incidents from all contextual perspectives including how individuals may be affected by the support professionals provide and the organisational/environmental structures in place.

In summary the study presented here proposes to retrospectively examine patient data relating to serious untoward incidents within mental health services in the South East of Ireland. Documents to be reviewed will include incident report forms (completed by staff following an adverse event) and individual patient medical records, where they meet specific inclusion and exclusion criteria (Appendix 1). The main aim is to include the most serious incidents of harm as opposed to accidents, medical/nursing errors or health and safety issues such as slips, trips and falls.

The study proposes to examine both electronic records (incident reports) and handwritten case notes. A manual system of patient files is still used locally. Examining this patient data retrospectively over an 8 year period (2011-2018) will provide the research team with information in relation to:

- The contributing/contextual factors evident in serious incidents
- Any patterns relating to characteristics of those implicated in serious incidents
- Any patterns or differences relating to types of incident and where and when they have occurred

Ultimately the study sets out to examine these factors from a ‘systems’ perspective to identify how incidents may be affected by organisational and environmental structures; resources; staffing; skill-mix; physical environment and numerous other internal and external factors.

1.2 Rationale and catalyst for the study

Mental health services in the counties of Waterford and Wexford were amalgamated in 2011, with the closure of a large Victorian facility in Co. Wexford following a Mental Health Commission (MHC) inspection (MHC, 2011). In line with other parts of the world, many former psychiatric institutions or 'asylums' have been closed down in Ireland over the past 20-30 years as they are no longer seen as fit for purpose (Edwards, 2009). The closure of these institutions was a fundamental element of the Irish government blueprint document 'A Vision for Change' (Department of Health and Children, 2006) (DoHC). The successor to this document since 2016, 'Sharing the Vision' (Department of Health, 2020) continues to promote the expansion of community based services; primary care intervention and alternatives to inpatient treatment.

The amalgamation of local inpatient mental health services and the slow development of community services has been criticised in the media, with local TD's in particularly expressing concern in relation to increases in serious incidents involving users of mental health services. Deputy Halligan (Waterford Today, 2015) highlighted the level of local dissatisfaction with mental health services, referring to the damaging placement of children on adult wards; bed shortages and community service deficits; leading to missed treatment opportunities and increased suicide risk. Similarly, Deputy Wallace (Wexford People, 2016) claimed that there had been a doubling of suicides in Wexford in the year after services amalgamated. Official statistics published by the Central Statistics Office (CSO) show an average increase in Wexford suicides between 2009 and 2012, from 14.8 per 100,000 to 17.8 per 100,000 (HSE, 2019b). Conversely, department of psychiatry staff, working in the single remaining acute adult admission unit left in the Waterford/Wexford area, expressed concern about increased levels of violence and aggression as a result of overcrowding; understaffing and inadequate facilities for patients with longer-term care needs (Brady, 2018).

As such, local mental health services were keen to undertake research that could establish the prevalence of serious incidents; investigate contributing factors and make recommendations that could help improve patient safety and develop services. The project was discussed with Waterford Institute Technology in terms of managing the research study and a proposal was outlined (Appendix 2).

I applied to carry out the research study as I felt it would be interesting and worthwhile in terms of its proposed methodology; its meaningfulness and in terms of my own personal academic development. As a mental health nurse with 25 years' experience, working in both the UK and Ireland, I felt that having witnessed a significant number of serious incidents over this time, I would be able to reflect on some of these and link practice experience with relevant theory.

1.3 Outline of study

This thesis is divided into 3 parts. Part I consists of 6 chapters and is entitled 'Serious and untoward incidents occurring within mental health services.' This section serves as the main review of existing literature. Chapter 2 examines the process of clinical incident reporting, an important element as incident reports play a significant role in the data collection for this thesis. Whilst such reports can provide health services with a wealth of data on the prevalence of serious incidents, their use for audit and research purposes is not without limitations. These issues are discussed further in this chapter, which also includes a historical perspective on how incident reporting has developed; its particular relevance to mental health settings and the different functions it serves.

Chapters 3-5 provide a review of existing literature relating to the antecedents; contextual and contributing factors associated with serious incidents. Violence and aggression; suicide/attempted suicide and non-suicidal self-harm are each discussed individually as these are the predominant areas relevant to patient safety in mental health settings. Four broad antecedent themes were established through this review of literature. Establishing these themes supported later areas of this thesis including data collection and qualitative analysis.

Chapter 6 provides a contemporary view of risk as it pertains to mental health care. This chapter is significant as risk is a central element of this thesis, whilst the management of patient safety and the reporting of serious incidents are key aspects of health service risk policies and procedures. The historical basis of managing risk in mental health services is discussed together with recent developments and debate, particularly in relation to addressing risk from new perspectives.

Part II describes the process of this research study from its outset up to the completion of data collection and is entitled ‘The Research Journey.’ Chapter 7 reviews the research paradigms and design selected for this thesis, examining the use of document/record analysis and discussing the research methods chosen. The chapter also focuses on published mental health research that has utilised medical records in exploring serious incidents. These studies offer insights and learning into the strengths and limitations of document/record analysis as it relates to serious incident research. Chapter 8 examines the complexities in obtaining ethical approval for this study, mainly due to consent issues stemming from the General Data Protection Regulation (GDPR), enacted Europe-wide in 2018. A timeline of these complexities is considered, together with the final consent arrangements and their impact on the study.

Part III incorporates Chapters 9 and 10, presenting the results of the study with relevant analysis and discussion. Recommendations for clinical practice and future research are included.

Part I: Literature review- serious and untoward incidents occurring within mental health services

Chapter 2 Clinical incident reporting

2.1 Introduction

The key data for this research thesis derives from a database of clinical incidents, completed by Waterford/Wexford mental health service employees in the course of their normal clinical duties between 2011 and 2018. Whilst the reporting and retention of such records serves a number of clinical and legal purposes, they also provide valuable data for use in research studies (Shepherd and Lavender, 1999; Kuivalainen et al. 2014; Spaducci et al. 2020). Their use for such purposes, however, needs to be considered in respect of a number of factors highlighted in this chapter, particularly the extent to which incident reports provide an accurate picture of prevalence due to the context in which reporting occurs.

2.1.1 Background

The reporting of clinical 'incidents' has become a firmly established aspect of clinical practice across all areas of healthcare (HSE, 2020; MHC, 2008; European Commission, 2014; NHS England, 2015). The purpose of incident reporting is seen as the "identification of safety hazards in order to develop interventions which reduce the risks of patient harm" (Carlfjord et al. 2018: p1). It is viewed as being central to promoting an organisational culture of patient safety (WHO, 2019); a process of gathering data to facilitate organisational and individual learning (Stavropoulou et al. 2015) and supporting the creation of new policies and procedures in order to prevent incidents re-occurring (Braithwaite et al. 2008).

Incident reports also help to produce published data in relation to the prevalence of serious occurrences. For example, the World Health Organisation (WHO, 2017) suggests that adverse events occur within 8% to 12% of European health services. Similarly, incident report data has been included in media reports citing an increase in some of the most serious incident types, including violent assaults on healthcare staff (Hosford, 2017; Pollak, 2018), and unexpected deaths within health services (Pym, 2016).

Interpreting such figures remains a controversial area due to the nature of incident reporting and some of the limiting factors involved. For example, violent assaults in healthcare are felt to be higher than figures suggest due to incidents going unreported, whilst simultaneously the figures may be seen as unrepresentative of the actual harm experienced, due to the inclusion of no harm and near miss incident reports (Murray, 2020). It has also been suggested that reported increases in incident figures are a result of more open and accessible systems of reporting; ostensibly that staff are simply recording more incidents than they did in the past (Pym, 2016). Conversely, where there is variability in such reporting practices, for example where there is uncertainty about when to report or what exactly constitutes an 'incident,' producing accurate prevalence figures can be problematic (Stravropoulou et al. 2015).

2.2 General history and development of clinical incident reporting

Clinical incident reporting serves a number of service and legal functions, including the identification and elimination of potential risks; as a form of evidence in the case of compensation claims and as a post incident education tool (Cosgrove, 2018). Systems for reporting and collating incident reports within healthcare are, however, not a new phenomenon with UK Department of Health guidance published sixty-five years ago stipulating the action required following an incident: "a brief report should be prepared…as soon as possible after any occurrence of the kind in question, giving the name of any person injured, the names of all witnesses, details of the injuries and the full facts of the occurrence and of the action taken at the time." (NHS, 1955 cited in Donaldson, 2000: p51).

Frequent medical malpractice insurance claims in the 1970's led to the self-indemnification of hospitals and the introduction of formal incident reporting in the 1980's (Singh and

Ghatala, 2012). By the 1990's the UK had introduced a Clinical Negligence Scheme for Trusts which obliged NHS trusts to maintain robust incident reporting systems to comply with risk management standards and keep insurance premiums at a minimum (Dineen and Walsh, 1999). As noted previously, a similar 'Clinical Indemnity Scheme' (CIS) currently operates in Ireland (State Claims Agency, 2020), closely linked with the reporting of adverse incidents and clinical risk management policy.

Viewed in the context of clinical negligence claims, incident reporting serves important legal and economic functions (Bunting, 2010; Lambert et al. 2016). However, it is also seen as a means of documenting and learning from lapses in patient safety. The American Institute of Medicine (IOM) report 'To Err is Human' (Kohn et al. 1999), for example, was published following what it saw as an 'epidemic' of medical errors including adverse drug events; suicides; falls; burns and patient misidentification. It concluded that a mandatory system of reporting (for death and serious harm) and a voluntary system (for other incidents) should be introduced in order to collate and learn from errors; the voluntary system prospectively identifying safety concerns before they reached a critical stage.

A similar UK report, 'An organisation with a memory' (Department of Health, 2000), published a year later, reaffirmed the need for healthcare services to learn from what it saw as organisational failures by encouraging the widespread reporting of adverse events. It was felt that in replicating the safety standards already existent in non-healthcare safety-focused industries such as aviation; military; nuclear energy; oil and rail (Macrae, 2008; Smith and Mahajan, 2009) health services could foster an ethos of learning as opposed to a culture of blame (Hunt, 2016).

Although some differences exist, systems for reporting clinical incidents in healthcare are now well established internationally. Europe wide recommendations incorporate the themes highlighted in 'To Err is Human' and 'An Organisation with a memory' (Box 1) (European Commission, 2014). Similarly, the 'Incident Management Framework' in Ireland references key aspects of these documents in relation to incident reporting, including learning from experience; effective and standardised governance; quality and accountability arrangements; openness; transparency and a culture which supports and encourages clinical staff to report safety issues (HSE, 2020).

Box 1. Incident Reporting Recommendations (Patient Safety and Quality Care Working Group) (European Commission, 2014)

- Use of both mandatory and voluntary reporting systems
- The reporting of all incidents whether serious, near miss, no-harm etc.
- Reporting by any staff member, patient or relative
- A focus on confidential 'sanction-free' systems
- Anonymised distribution of results
- Ensuring the systems are separate from complaints, litigation or disciplinary procedures
- Consistent reporting methods
- The use of electronic reporting systems wherever possible
- Systems clearly explained to staff, patients etc.
- Reporting of incidents leading to visible changes/improvements

2.2.1 Terminology and definitions used in clinical incident reporting

The terminology associated with clinical incident reporting has changed over time whilst defining exactly what constitutes an 'incident' remains a complex area. Terms such as 'critical incident'; 'adverse event' and 'serious and untoward incident' are all still broadly used although 'patient safety incident' is the term favoured in official health service documents (HSE, 2019a; NHS England, 2019). The term is also used by the World Health Organisation (WHO, 2017) with patient safety now seen as a unique healthcare discipline in its own right (Emanuel et al. 2008).

Whilst patient safety guidance applies to all clinical areas, some writers feel that the relationship between mental health services and patient safety tends to be overshadowed by a predominant focus on other more medical areas of healthcare (Brickell and McLean, 2011;

D'Lima et al. 2018; Thibaut et al. 2019). Part of the difficulty in applying patient safety strategies across different clinical specialities is how these translate within unique contexts. Anderson et al. (2013) for example, found that violence; absconding; medication errors; fire risk and self-harm/suicide were the top five reported areas in mental health services as opposed to staff competency; staffing levels; medication errors; system co-ordination and medical devices/IT across general acute services. In terms of defining a patient safety incident, therefore, unique risk factors applicable to each specific clinical area need to be considered. Table 1 offers examples of the different definitions and terminology associated with safety incidents. These varying definitions reflect efforts to differentiate between minor and major incidents, whilst simultaneously aiming to include the potential for harm (e.g. near misses); financial risk and other less obvious risks such as reputation damage.

Table 1. Safety incident terminology and definitions

Example	Definition	Context	Reference
Untoward incident	"A concept which has grown up within the NHS over the years... It is a loosely used term for which there is no standardised definition"	NHS (UK)	Donaldson, L (2000)
Serious and untoward incident	"Any incident where medical treatment was required or death occurred, or where moderate to high financial loss, or loss of reputation might occur"	Mental health inpatient wards (UK)	Bowers et al. (2006)
Serious incident	"act or omission in care that result in; unexpected or avoidable death, unexpected or avoidable injury resulting in serious harm…abuse, 'never' events, incidents that prevent	NHS England	NHS England (2015)

	(or threaten to prevent) an organisation’s ability to continue to deliver an acceptable quality of healthcare services and incidents that cause widespread public concern resulting in a loss of confidence in healthcare services”		
Never events (e.g. wrong site surgery)	“Never Events are serious incidents that are wholly preventable…Each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a Never Event…”	NHS Hospitals, England	NHS England (2015)
Serious Reportable Events (SRE’s)	“A defined list of serious incidents, many of which may result in death or serious harm…a subset of all serious incidents…these are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have	HSE Ireland	HSE 2015

	been implemented by healthcare providers		
Adverse events	"An unintended injury or complication as a result of healthcare management that results in a prolonged hospital stay, disability at the time of discharge from hospital or death"	Acute public hospital wards, Ireland) (Psychiatry excluded)	Rafter et al. (2016).
Sentinel events	"Any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness.	US and Australian hospitals	The Joint Commission (2016)
Patient safety incident	"an incident which occurs during the course of the provision of a health service which: (a) has caused an unintended or unanticipated injury, or harm, to the patient (b) did not result in actual injury or harm to the patient but was one which the health services provider has reasonable grounds to believe placed the patient at risk of unintended or unanticipated injury or harm	HSE Ireland	HSE 2020

	(c) unanticipated or unintended injury or harm to the patient was prevented, either by “timely intervention or by chance”, but the incident was one which the health services provider has reasonable grounds for believing could have resulted in injury or harm, if not prevented …a patient safety incident includes harm events, no harm events and near miss events”		

2.2.2 Limitations and barriers relating to incident reporting

One of the main limitations of incident reporting relates to inconsistent reporting practices, particularly across separate organisations, where clinical staff may be unsure as to when and where they should provide reports or the specific details they should include (Stavropoulou et al. 2015). This is further complicated by various mandatory and voluntary reporting practices in place internationally (HIQA, 2016). Studies comparing incident reporting systems have revealed significant differences in reporting and learning even across departments within the same hospital (Hewitt et al. 2016). Whilst the most serious occurrences such as death or physical injury are likely to have mandatory reporting requirements (HSE, 2015) less serious incidents may fall within the remit of voluntary reporting and therefore go unreported.

The ‘under-reporting’ of incidents, such as those involving minor, no injury violence, has been well documented (Stevenson et al. 2015; Tyler et al. 2022). A number of factors have been attributed to this phenomenon including concern that patients may be negatively affected by the aftermath of any further investigation or action and a perceived lack of management support amongst staff members (Gifford and Anderson, 2010). It has also been associated with a fear of implicating work colleagues in subsequent investigations (Gallagher and Kupas, 2012) and the result of specific incidents being easily resolved and where no visible harm has been caused (Hewitt et al. 2016). Arnetz et al. (2015a) summarises a number of other factors that may influence the reporting of violence, including individual staff characteristics (e.g. age and clinical experience); lack of time; fear of blame or reprisal; a belief that reporting will fail to affect any positive change and viewing episodes of aggression as an expected 'occupational hazard.' " A lack of training has also been identified in terms of highlighting the importance of incident reporting and what exactly constitutes a reportable event (Hamed and Konstantinidis, 2022).

Parmelli et al. (2012) argue that incident reporting requires the endorsement of all clinical staff to make it effective but that this 'buy-in' may be constrained by a lack of knowledge in relation to the incident reporting process or the absence of feedback after reports have been filed. A number of studies have examined staff perceptions of incident reporting, raising a number of further issues and criticisms. Examining the experiences of professionals internationally, Mitchell et al. (2016) highlighted that the high volume of incidents reports generated was often unmanageable in terms of action and feedback. Furthermore, Anderson et al. (2013) note that mental health staff are often less involved in the reporting process, are more sceptical and less likely to submit reports than colleagues in medical/surgical specialities.

Writers also warn against the use of incident report statistics to measure and compare patient safety or organisational performance across different clinical areas and jurisdictions (Pham et al. 2013; Macrae, 2016). The reason for this caution is based on the limiting factors associated with incident reports and the conclusions that can be drawn from simply comparing report based statistics relating to violence, self-harm etc. Provonost et al. (2008) argue that reported incidents should be used to address locally specified risks only and not used as a means of monitoring or measuring patient safety.

2.2.3 Irish national incident reporting system and local protocol

The currently used incident form (NIRF-01) used by the HSE in Ireland has been in circulation since 2018 (Appendix 3). Prior to this date, although guidance existed in relation to the requirements of an incident report (HSE, 2014) no standardised form was available. Hence since the start of the data collection period for this thesis (2011), there have been three different incident recording schemes in use, the National Adverse Events Recording System (NAEMS) and STARSWeb, followed by the current system, the National Incident Management System (NIMS). Data from the previous databases was transferred to NIMS, defined as a web-based system of capturing, investigating and reporting incidents that also supports the management of claims or litigation processes (HIQA, 2020).

The current NIMS system reportedly captures approximately 160,000 incidents a year nationally (HIQA, 2020). Within this system there are four standardised incident forms (National Incident Report Forms 1-4) (NIRF) relating to (i) persons; (ii) vehicle collisions; (iii) property and (iv) dangerous occurrences (HSE, 2020). Only the ‘persons’ report form is relevant to this thesis (NIRF-01).

The incident reporting process is overseen by the HSE national Incident Management Framework (HSE, 2020) which outlines six steps for managing an incident (Table 2). After an incident has occurred a staff member completes a form and forwards this to their line manager. The incident is then categorised in terms of its severity and forwarded to the locally appointed risk manager. The risk manager then reviews all forms for completeness and accuracy before determining what further reporting/investigating requirements are needed such as escalation to the Serious Incident Management Team (SIMT) or the Mental Health Commission (MHC). The content of the forms are then added to a national HSE database and posted to the local HSE management office for inputting on the State Claims Agency (SCA) system.

Table 2. HSE Incident Management Framework step by step guide

Step 1: prevention through supporting a culture where safety is considered a priority	• Ensuring culture where staff feel safe and supported in reporting • Ensuring staff fully understand process and receive appropriate feedback post incident • Having structures in place to anticipate and manage risk
Step 2: identification and immediate actions required (for persons directly affected and to minimise risk of further harm to others)	• First response must be the care of any person harmed to minimise impact and take remedial action • Identify and action any immediate action required • Open transparent discussion with person/s affected after the incident under 'open disclosure' process • Documentation in clinical notes
Step 3: initial reporting and notification	• Direct entry or paper form (NIRF) to be completed within 24 hours of incident • Highest category incidents (category 1) must be reported to Senior Accountable Officer (SAO)
Step 4: assessment and categorisation	• Responsible line manager categorises incident using available risk impact table into one of three categories (Major; Moderate; Minor) • Each category has a number of approaches for further review (e.g. setting up unique review team; MDT review; desktop/casefile review; aggregate analysis)

Step 5: review and analysis	• Ascertain what happened; why it happened and what learning can be gained • Reviews should be overseen by appropriate HSE guidance material • Writing up and publication of findings should be considered on completion of review process
Step 6: improvement planning and monitoring	• Devising an improvement plan to implement recommendations from review • Monitoring of actions identified to aid service improvement

2.3 Incident reporting and mental health services

Box 2 summarises the main components of incident reporting relevant to mental health services in Ireland.

Box 2. Incident reporting in Irish mental health services

Incident reporting fulfils a statutory requirement of the State Claims Agency in Ireland (NTMA, 2022). Managing potential litigation, statutory investigations and compensation claims is one of its main roles. However, the actual number of mental health claims is very low when compared with other specialities. Between 2010-2014, for example, a total of 549 claims amounting to 58 million euro was costed for the area of surgery in Ireland, compared to 23 claims and just over 1 million for mental health services (National Treasury Management Agency) (NTMA) (2017). This also reflects the UK picture, where psychiatric negligence claims amounted to only 0.5% of the total outlay paid to recipients between 2004 and 2012 (Mordue et al. 2012).

Mental healthcare, risk assessment and critical incident reporting exist in a wider framework of patient safety, which has developed considerably over the past 20 years since the 1999 'To err is human' report (Slattery, 2016). It is evident, however, that mental health services contend with specific and often unique risks associated with issues such as self-harm; violence; community based care and mental health act legislation (Brickell et al. 2009).

Writing from a UK perspective, D'Lima et al. (2016) argue that patient safety frameworks and their predominant emphasis on acute medical care may not be easily applied in mental health settings, whilst presenting challenges in terms of patient/staff attitudes to safety and limiting the availability of published literature focusing on mental health and patient safety. The stigma associated with mental disorder and public perceptions in relation to risks such as suicide; violence and homicide are added factors to consider in terms of the role of mental health services in not only managing patient safety, but also the potential risks to staff; other patients and the general public (De Santis et al. 2015).

How these factors impact upon incident reporting practices within mental health services, particularly from an Irish perspective is not widely addressed in the available literature. In their UK based study of barriers and facilitators of reporting in mental health settings, Archer et al. (2020) found that a fear of blame or recrimination can affect incident reporting along with perceived time constraints and a perceived lack of post-report learning and development. Whilst the authors found that these findings were comparable with research findings in other healthcare settings, they noted that issues relating to reporting violence/aggression were particularly evident in mental health services, in addition to a perceived lack of criminal prosecution following the production of reports.

This theme of violence and aggression is also examined by Gifford and Anderson (2010) in their study of assaults in mental health settings. They found that the nurses in their research were influenced by a significant number of factors in terms of reporting, including institutional rules and regulations; the local safety culture; local policies; staffing issues; level of understanding in relation to the reporting process; the degree of support offered after an incident had occurred; relationships with colleagues; individual attitudes and patient characteristics.

The 'fear' that mental health staff experience in relation to blame, recrimination or potential litigation in the context of patient safety and incident reporting (Cutcliffe and Stevenson, 2008; Slemon et al. 2017) is incongruous with EU patient safety recommendations advocating a 'blame-free' reporting culture (Council of the European Union, 2009) and the current Irish incident management framework (HSE, 2020). For some writers, a culture of blame is evident throughout healthcare but specifically affects mental health services in terms of 'rule and compliance' management (Khatri et al. 2009); public criticism of perceived care failures (Morgan, 2007) and professional fears relating to the potential for legal proceedings (Wand et al. 2017).

2.4 Discussion: Clinical incident reporting

Whilst there is a statutory requirement to report the most serious incidents occurring in Irish mental health services in terms of state claims agency requirements and a mandatory serious reportable events (SRE's) policy, the evidence suggests that many incidents, particularly those relating to violence and aggression go unreported. This has implications for the use of incident report data for research purposes, where the number of filed reports may not accurately reveal the actual prevalence of specific incident types, particularly in relation to those perceived as less serious or where no harm appears to have been caused.

The factors that influence the reporting of such incidents are manifold and range from the organisational culture within which professionals work to individual attitudes and personal experience. As such there is likely to be significant variation in the perceptions of staff in relation to the severity of incidents. Similarly, there are likely to be differences in terms of the types of incident that are worthy of reporting and when these should be reported. Furthermore, there is evidence to suggest that incident reporting is almost exclusively initiated by nursing staff, raising the possibility that incidents involving other health professionals, particularly doctors, may go unreported (Kingston et al. 2004; Taylor et al. 2004; Mitchell et al. 2016).

The reporting of incidents has developed significantly over the past 60 years, particularly since the turn of the century when the two reports, “to err is human” and “an organisation with a memory” instilled the notion that healthcare should aim to reproduce the successes in aviation and other safety-focused industries to address the risks of patient harm. Since then, the terminology associated with serious incidents has shifted towards an ethos of patient safety, which has become the maxim internationally and governs strategy incorporating incident reporting in Ireland.

Writers such as Macrae (2016) have been critical of healthcare’s adoption of incident reporting practices from other businesses and industries, suggesting that it has concentrated on the quantity of reports generated as opposed to the quality of individual incident investigations as demonstrated within areas such as the aviation industry. Dodds and Kodate (2012:p.117) argue that incident reporting in the UK, at least, has moved away from its original purpose as a voluntary process of reporting and learning in order to help improve services. They use the term ‘institutional conversion’ to define this change, highlighting how incident reporting has now become the means by which commissioners and patients assess service safety, therefore becoming a mechanism by which funding and resources can be allocated.

If there are organisational discrepancies in relation to how incident reporting systems should be utilised, it is understandable that many of the limiting factors associated at an individual level may derive from a level of misinterpretation and confusion. In Ireland the inclusion of state claims agency requirements within the incident reporting procedure, for example, may arguably result in staff members being more influenced by the threat of litigation and compensation claims than the advocated learning and service improvement elements related to it. Whilst at present there appears to be little or no research literature considering the thoughts and views of healthcare professionals in Ireland it is evident from other countries that there is disparity between the guidance published in official health service policy documents and how incident reporting is perceived and therefore implemented by clinical healthcare professionals.

It is likely that some cultural differences exist in terms of how Ireland as a nation perceives serious incidents relating to reported mental illness, which consequently impacts on practices and protocols. Cultural differences have been demonstrated in studies focusing on attitudes to persons with mental illness (Mehta et al. 2018) and in terms of media coverage of mental health care (Huang and Priebe, 2018). Whereas a long running UK public inquiry, dating back to 1992, continues to focus specifically on homicides and suicides by patients of mental health services (National Confidential Inquiry into Suicide and Safety) (NCISH, 2019), Ireland does not appear to have experienced the same level of political debate; published government/independent inquiries or media and public scrutiny as witnessed in the UK and particularly England. Kelly et al. (2018) cite how the involuntary admission rate in England is more than double the rate here in Ireland; the authors speculating how levels of media concern over public safety may be a factor in this difference.

For all the complexities relating to incident reporting, there is the question as to whether, ultimately, it supports the delivery of safer healthcare. Armitage and Chapman (2006: p.95) describe incident reporting as a ‘curate’s egg’ in that it has both positive and negative aspects. For many writers, however, until the barriers and complexities associated with incident reporting are overcome, the question of ultimate effectiveness is unlikely to be easily answered (Mitchell et al. 2016; Carlfjord et al. 2018; Macrae, 2016).

There is a sense that despite significant limitations associated with incident reporting, it has become a mainstay of healthcare provision; remains of value and is therefore unlikely to be abandoned at any near stage in the future (Carlfjord et al. 2018). There is also a wider feeling that the use of technology plays an important part in the future of incident reporting, including online reporting systems and analytical tools (Macrae, 2015; Mitchell et al. 2016). A number of strengths have been associated with electronic systems including more timely reporting (Walsh et al. 2010); improved legibility, tracking and confidentiality (Elliott et al. 2014) and immediate risk manager scrutiny and response (Levtzion-Korach et al. 2010).

Incident reporting, in a local context, has some electronic elements but not at the point where and when the incident occurs. Whether a fully electronic system would improve the current manual system used locally is not possible to predict at present. Arguably, the barriers and limitations associated with reporting incidents such as violence are likely to apply in the context of an electronic system as they do currently. Similarly, complexities such as under-reporting or lack of understanding over when; where and how incidents should be reported may not be easily resolved with the introduction of an electronic system. Prang and Jelsness (2014) highlight that lack of confidence in the use of technology may also be a limiting factor in individuals using such a system.

2.5 Concluding comments on incident reporting

As it stands, using incident report data to measure the prevalence of serious occurrences has significant limitations, both in terms of clinical measurement and research. At the same time, however, writers appear keen to highlight that the documenting and examination of incidents can have merit in terms of learning and improving patient safety. Even where there are omissions in terms of reporting there appears to be validity in examining the contributing and contextual factors associated with submitted reports. One of the main criticisms associated with incident reporting appears to be their use in measuring levels of patient safety without this analysis of contributory/contextual factors. An overriding theme throughout the literature of 'too many reports and not enough analysis' appears to support the aims and objectives for this thesis.

Chapters 3-5: Specific incident types and their antecedents

3.1 Introduction

As first noted in chapter 2.2.1 there are significant clinical speciality differences in relation to the type and frequency of incident reports completed. This is evidenced by Irish State Claims Agency data (Oglesby, 2012) (Table 3) which reveals the five specialities producing the most reports and the most frequent types of incident logged within each area. Findings in relation to mental health services are comparative with other countries, including England, where reports of self-harming behaviour; aggressive behaviour and absconding feature significantly in similar government department data (NHS Improvement, 2018). It is important to note that some frequently reported incident categories including accidents (e.g. slips/trips/falls); medication errors and medical equipment issues are beyond the scope of this thesis and have been excluded.

Table 3. Top five reporting specialities and their most common incident types (Irish State Claims Agency data) (Oglesby, 2012)

Medicine	Disability Services	Elderly services	Obstetrics	***Mental Health***
Infection control	Unexplained injury	Slips/trips/falls	Peri-natal	***Self-harm***
Treatment incident	Violence and aggression	Equipment/device incident	Peri-operative/peri-procedure	***Violence and aggression***
Medication incident	Self-harm	Inappropriate behaviour	Discharge incident	***Inappropriate behaviour***
Blood transfusion incident	Inappropriate behaviour	Absconding	Consent/confidentiality incidents	***Absconding***

The aim of these chapters is to examine the literature relating to the most commonly reported incident types and present the evidence in terms of possible causes; antecedents and contributing factors. As the literature will demonstrate, there are a significant number of factors discussed in relation to such occurrences. The remainder of Chapter 3 focuses on violence and aggression, whilst Chapters 4 and 5 examine self-harm.

The literature search strategy for each incident type is outlined in Table 4. Search terms were generated from clinical experience and research supervision meetings in order to perform electronic searches of relevant literature.

Table 4. Literature search strategy by incident type

Incident type	**Search terms**	**Databases used**	**Additional sources of evidence**	**Inclusion criteria**	**Exclusion criteria**
Violence and aggression	‘antecedents’; ‘contributory/contributing factors’; ‘violence’; ‘mental health’	Pubmed, EBSCO Host (including Cinahl, Medline, psychINFO and psychARTICLES), Science Direct, Wiley Online and the Cochrane Library	Google scholar; Google search; relevant official websites (e.g. NHS; HSE; NICE)	Focus on mental health patients under active care and treatment Inpatient or outpatient/community mental health settings Statutory reports/documents/guidelines All countries/geographical areas Relating to adult patients 18+	Studies unrelated to patients under mental health care (e.g. general population studies of violence) Patients under 18 Studies where full text not available
Suicide and self-harm with suicidal intent	‘antecedents’; ‘contributory/contributing factors’; ‘suicide’; ‘mental health’; ‘self-harm’	Pubmed, EBSCO Host (including Cinahl, Medline, psychINFO and psychARTICLES), Science Direct, Wiley Online and the Cochrane Library	Google scholar; Google search; relevant official websites (e.g. NHS; HSE; NICE)	Focus on mental health patients under active care and treatment Inpatient or outpatient/community mental health settings Statutory reports/documents/guidelines All countries/geographical areas Relating to adult patients 18+	Studies unrelated to patients under mental health care (e.g. general population studies of violence) Patients under 18 Studies where full text not available
Non-suicidal self-harm	self harm’; ‘‘self injury’; ‘deliberate self-harm’; ‘self-mutilation’; ‘self-injurious behaviour’; ‘contributing factors’; ‘reasons’; ‘causes’ ‘antecedents’	CINAHL; PsycArticles; PsychInfo; MEDLINE; Pubmed; Science Direct and Wiley online	Google scholar; Google search; relevant official websites (e.g. NHS; HSE; NICE)	Research studies relating to the antecedents/contributory factors relevant to self harm Relevance to mental health care/services/providers/service users required	Studies focusing solely on under 18’s Studies not available in English Studies where full text not available

				Official government/statutory reports/documents/guidelines relating to self-harm and mental health services All countries/geographical areas included; Research published between 2012-2020	Research papers before 2012

Existing contributing factor frameworks helped to establish broad headings by which the available literature could be categorised. The Yorkshire contributing factor framework (Lawton et al. 2012) (Appendix 4) and the Safewards contributing factor domains (Bowers et al. 2014) (Appendix 5) are well established and published/validated tools, that have been widely used for the purpose of reviewing serious incidents. The headings used in the following literature review incorporate the categories highlighted in these tools in order to provide a fair and balanced consideration of the antecedents and contributing factors for each incident type. The broad headings 'patient factors'; 'staff factors'; 'organisational/environmental factors' and 'external factors' are therefore used consistently in each chapter.

3.2 Violence and Aggression: Introduction

Risk to others in the form of violence and aggression ranks alongside risk to self in terms of assessment priority for staff working in Irish mental health services (HSE, 2009). As such the management of violence and aggression risk in mental health services remains a significant issue for professionals, service users and their families (Piel and Schouten, 2017; Downes et al. 2016; Slemon et al. 2017). An association between mental disorder and extreme violence such as homicide or more recently, murder-suicide, continues to attract Irish media attention, frequently accompanied by demands for urgent mental health care review (White, 2017; Dunphy, 2020; Riegel, 2020). At the other end of the spectrum, incidents of violence and aggression within mental health services may be perceived as being either minor or so commonplace they fail to be reported at all (Maguire and Ryan, 2007; Arnetz et al. 2015b).

Regardless of severity, many writers continue to challenge the notion that mental ill health equates solely with 'dangerousness' on the service user's part; criticising organisational and professional approaches to risk that are viewed as unhelpful in terms of countering media reports and public opinion (Slemon et al, 2017; Berger, 2018). This dichotomy is further examined in the chapter on risk management (Chapter 7).

However, it is important to note the far ranging scope of violence and aggression risk in question and the problems in defining exactly what constitutes a violent or aggressive act (Dickens et al. 2013). Writers refer to the likely differences existing across international boundaries or amongst different cultures; organisations and individuals calling for common international agreement on the defining of violence in mental health (Dack et al. 2013; Flannery et al. 2014b).

Maguire and Ryan (2007) highlight the complexities in comparing international data on violence due to contrasting definitions which often include or exclude areas such as verbal aggression; property damage; sexual harassment; antisocial or reckless behaviour and attempted suicide. Similarly Higgins et al. (2015) cite a number of areas often neglected in terms of violence and aggression risk including sexual assault and abuse; stalking; intimate partner violence and absconding from hospital. One of the main recommendations emerging from the study by Higgins et al. is that violence and aggression risk should not only be considered from the perspective of an individual’s actions or potential for violence, but from the perspective that he or she, as a result of mental health issues or from their experience of care within mental health services, may be at risk of being a victim of violence and aggression themselves.

Whilst mental health related violence and aggression can be seen to affect service users; their families; members of the public or professionals, the aftermath of such occurrences can be extremely distressing and can result in both short and long term consequences for those affected (Bonner and Wellman, 2010; Yang et al. 2018). Whilst statistical estimates relating to the prevalence of violence in mental healthcare have been widely published, the accuracy of such data has been questioned due to certain limiting factors including under-reporting

(Stevenson et al. 2015); international and cultural differences relating to defining and understanding violence (Duxbury et al. 2008) and consistent/inconsistent incident reporting systems (Iozzino et al. 2015; Anderson et al. 2013).

Health workers across all specialities are considered to be at high risk of experiencing violence, with the World Health Organisation (WHO, 2021) reporting that between 8% and 38% of workers suffer physical violence at some time in their careers. Current definitions of ‘workplace violence’ now tend to include all forms of physical and psychological types of harm, including bullying or harassment from work colleagues (Pagnucci et al. 2022). Registered nurses are considered to be more likely to experience violence in the workplace than other professions whilst mental health nurses and mental health settings are frequently at the forefront of such incidents (Stevenson et al. 2015) with violence occurring up to twice as often in comparison to other specialities (NICE, 2015).

Violence and aggression appears less prevalent in outpatient mental health settings, with acute inpatient care tending to have the highest reporting figures (Choe et al. 2008). Published estimates have placed the rate of aggression on acute mental health wards at between 8% and 44% (Dack et al. 2013; Renwick et al. 2016) whereas estimates of physical assault on mental health staff range from 30% to 100% over an individual’s career (Duxbury et al. 2008; Dack et al. 2013; Hallett et al. 2014; Iozzino et al. 2015).

Such concerns in relation to the incidence of violence and the experiences of healthcare staff are mirrored in Ireland, with 8,667 incidents of violence/aggression recorded in 2020 and nearly half of these directed at nursing staff (Griffin, 2021). Within mental health services, nearly 1500 incidents were reported in 2017, a reported increase over previous years (Pollak, 2018). The reported incidence of violence and aggression in Irish healthcare settings is also reflected in wider Irish society where, since the 1990’s, the rate of homicide has increased, alongside cases of criminal damage and public order offences (O’Donnell, 2009; CSO, 2008). The rate of homicide in Ireland stood at 0.48 per 100,000 population in 1990, rising to its highest point in 2007 (1.80) before falling and rising intermittently thereafter to 2018 where a figure of 0.87 was recorded (Macrotrends, 2021).

The impact of violence and aggression on healthcare staff has been widely reported. In addition to the short and long term risk of physical injury (Renwick et al. 2016) is the potential for psychological difficulties such as post-traumatic stress and increased anxiety (Flannery and Walker, 2008). Such feelings can ultimately lead to job dissatisfaction; 'burn-out'; absenteeism and resignations (Howard and Hegarty, 2003; Kaunomaki et al. 2017). From an organisational perspective there is then the consideration of costs relating to managing violence and aggression; managing staff morale; dealing with rapid staff turnover and vacancies in addition to the potential for legal costs and proceedings (di Martino, 2003; Flood et al. 2008; Flannery et al. 2011; Cutcliffe and Riahi, 2013).

Patient's themselves are also considered to be at risk from violence, both directly and indirectly as a consequence of professional/organisational approaches to managing the phenomenon. Beyond the negative outcomes of societal bias and stigma associated with violence risk and mental ill-health (Corrigan et al. 2004) violence and aggression has also been shown to negatively affect the climate or ethos of mental health services, particularly inpatient units (Bowers et al. 2006) leading to increased use of restraint; seclusion and enforced medication (Renwick et al. 2016). Similarly, patients with severe mental health problems are considered to be vulnerable in terms of experiencing violence as a result of symptomatology and frequent co-related issues such as substance misuse and homelessness (Sells et al, 2003; Latalova et al. 2014). Up to a third of inpatients on mental health units have reported violence and threats from other patients and visitors in the process of receiving care and treatment (Royal College of Psychiatrists, 2007).

Efforts to examine the causes of violence in mental healthcare appear to have historically focused on factors relating directly to the patient themselves in terms of psychopathology; diagnosis; treatment and other demographic factors considered to affect risk such as age and gender. Whilst some acknowledgement of the environmental; political and organisational factors relating to mental health violence appears in older research papers (Depp, 1976; Carson; 1979; Jones, 1985), the exploration of such areas appears to have developed considerably in more recent times.

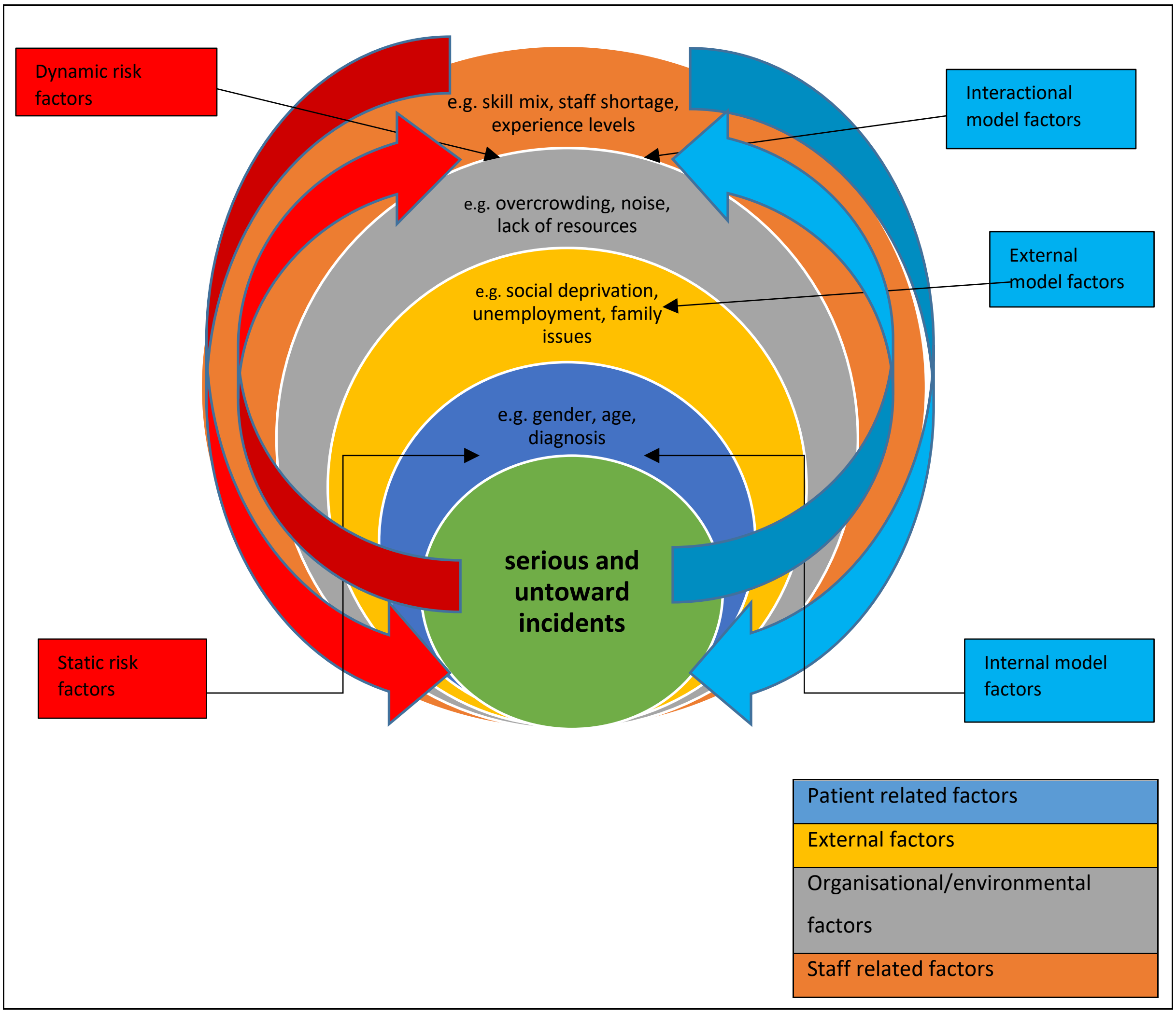
3.2.1 Violence and aggression review: results summary

Figure 1 is a conceptual model outlining the categorisation of contributing factors relevant to violence. The model illustrates the fluid nature and complex interaction between all categories. For example, substance misuse, commonly perceived as a significant contributing factor for violence, can be examined from different perspectives such as the individual's personal habits (patient related); the community where that individual lives (external); policies relating to substance use in a particular unit or clinical environment (organisational/environmental) and how staff might approach this phenomenon in terms of care and treatment (staff related).

Contributing factors can also be viewed in the context of 'static'; 'intrinsic' or 'internal' risks, which tend to be seen as unchanging and offering little in terms of opportunity for clinical intervention and 'dynamic' factors which are fluid and seen as more adaptable (Greer et al. 2020; Bulgari et al.2018). Dickens et al. (2013) theorises that existing aetiological models in terms of internal; external and social/interactional perspectives can be applied to the area of violence and aggression. Fig 1 incorporates these theories, again illustrating the complex and constant interaction between contributory risk factors and where they emerge from.

Appendix 6 is a copy of the original review grid utilised in order to summarise the literature, although more recent evidence has been included since this was produced. The studies included originate from all parts of the world but predominately Europe and America. A broad range of publication dates are included and a number of studies provide a multinational perspective. The majority of papers are primary research studies relating to inpatient mental health wards/units or the period before and after admission to an inpatient area.

Fig. 1 Conceptual model: Contributing factors for violence and aggression in mental health services



The shortfall in community patient based studies on violence is noted by Flannery and Flannery (2014b) and has been highlighted previously by writers such as Bowers et al. (2011). It suggests that inpatient units, inpatients themselves and the periods shortly before and after discharge from hospital are still the main areas of interest for researchers examining serious and untoward incidents. Certainly, from an Irish regulatory perspective, mental health inpatient units appear to experience the greatest degree of scrutiny; an understandable consequence possibly given the Irish Mental Health Commission's role in maintaining standards across 'approved' centres; reviewing the care and treatment of involuntarily detained individuals and carrying out regular, formal inspections (MHC, 2014). Despite this, statistics in Ireland show that violence in non-residential care is, in fact, widespread (Keogh et al, 2016). The development of a more community-based approach to mental health care, including the use of assertive outreach; crisis teams and improved links with social care (HSE, 2012a; O'Shea and Kennelly, 2008) may see more research emerging across these areas in the future.

3.3 Patient related factors in violence/aggression

Violence and aggression in mental health services and particularly the identification of potentially aggressive patients through assessment of risk frequently focuses on individual characteristics; demographics and symptomatology (Price et al. 2018a; Jalil et al. 2020; Giarelli et al. 2018). Whilst past history of violence continues to be seen as the primary predictor of future violence (Chou et al. 2002; Amore et al. 2008; Dack et al. 2013) certain other characteristics prevail repeatedly throughout the literature and are consistently linked with the prevalence of violence or increased risk/likelihood of violence.

Existing systematic reviews of the available literature pertaining to patient factors have found increased risk of aggression linked with male gender; a diagnosis of schizophrenia; young age; being single; being detained involuntarily; having a history of violence; having repeated hospital admissions; having a history of self-destructive behaviour and having a history of substance and/or alcohol abuse (Dack et al. 2013; Iozzino et al. 2015). Whilst such meta-analyses studies provide evidence of the increased risks of violence associated with these factors, there are many complexities and contrasting viewpoints highlighted within the literature. In terms of presenting the available evidence, including studies offering conflicting evidence, the main categories are further examined.

3.3.1 Gender

Historically, general population statistics suggest that men are more likely to commit violent acts (Robbins et al. 2003) although violent offending amongst females appears to be increasing (Heilbrun et al. 2008). Many authors have questioned why this trend does not necessarily extend to mental health services, where the link between gender and violence appears to be much more ambiguous (Lam et al. 2000; Robbins et al. 2003). Although systematic literature reviews report an increased likelihood of violence and aggression amongst male mental health patients (Dack et al. 2013; Iozzino et al. 2015; Bowers et al. 2014) such assumptions of causality are frequently questioned as they tend to discount other contributing factors. Cutcliffe and Riahi (2013: p562), for example, cite the “situational; contextual; historical; interpersonal and cultural phenomena” that are often not considered in violence causation studies.

Aside from literature review data, there is contrasting evidence in terms of gender differences within a number of studies, showing differences in types of violence and settings. A number of inpatient studies report higher rates of violence and aggression amongst males (Shepherd and Lavender, 1999; Amore et al. 2008; Renwick et al. 2016) whilst a study by Lam et al. (2000) found that males and females were equally responsible for causing physical injuries to staff on an inpatient mental health unit.

Outside of hospital-based environments there appears to be wider differences associated with gender and violence. A 12 year study by Flannery et al. (2014a), for example, found that males with schizophrenia were more likely to carry out ‘physical’ assaults but this trend was not reflected in terms of other forms of violence such as verbal abuse; intimidation and property damage. A further community based study examining violence and aggression post discharge from acute inpatient care found the likelihood of violence to be actually higher amongst females (Doyle et al. 2012).

The scope of violence beyond inpatient settings may be a factor in such findings. De Vogel et al. (2016) report that rates of intimate partner violence, for example, are almost identical for males and females, citing females as being more likely to engage in more indirect, reactive types of violence and frequently within social relationships. Robbins et al. (2003) also views the ‘situational’ context of violence as an important factor in gender differences. The writers found women to be more likely to be violent at home towards family, reflecting the notion of increased social relationship risk as posed by De Vogel et al. (2016). However, the writers also found men more likely to abuse substances; to have poor compliance with prescribed medication; to cause more physical injury and to have an increased likelihood of being arrested, reflecting again the multitude of contributing factors that can impact upon violence and gender differences.

Cutcliffe and Riahi (2013) suggest that although it may be naturally intuitive to assume that males pose a greater risk of violence and aggression, a wider appreciation of violence risk is required, incorporating environmental; healthcare system and clinician-related phenomena. Higher rates of male violence in mental health services are sometimes viewed in the context of flawed risk assessment tools and procedures, which can tend to overlook more situational, gender specific risk factors such as partner violence and domestic or sexual abuse victimisation (De Vogel et al. 2016; Sorrentino et al. 2016). Robbins et al. (2003) suggest that the 'unseen' or 'hidden' nature of such phenomena, often incurring less criminal justice involvement than other more visible forms of violence, may explain why violence affecting females is reported less and can be underestimated by clinicians.

3.3.2 Age

Historically, general population studies have shown that those individuals in their late teens and early twenties pose the highest risk for violent and aggressive behaviour (Swanson et al. 1990; Bonta et al. 1998). Considered a less contentious risk factor than gender, young age in both males and females, is also associated with increased risk of violence and aggression in mental health services, particularly when linked with acute illness; a history of schizophrenia; substance misuse and personality disorder (O'Callaghan et al. 2018; Otto, 2000).

Although the risks associated with young age appear to extend from the general population into mental health services, studies have also suggested some variation between community and inpatient settings. Studies by Iozzino et al. (2015) and Ose et al. (2017) indicate that the more factors considered in terms of violence risk (e.g. adding socio-economic factors or co-morbid substance misuse) ultimately reduces the strength of association between violence and age. Renwick et al. (2016) offer three theories as to why the risk of inpatient violence may increase amongst those of a younger age. Firstly, severity of illness may be worse at an early age, particularly in terms of first-episode as opposed to more enduring illness. Secondly, older adults are thought to be better able to self-regulate emotions and thirdly, young adults may be more likely to place importance on themes of independence and liberty; two areas where potential conflict may arise within inpatient mental health services.

Whether in community or inpatient settings, young age is commonly included as a standard risk factor in assessment tools and instruments addressing violence risk. For example, the Sainsbury Clinical Risk Assessment Tool used locally in Waterford mental health services (Morgan, 2000) designates males under the age of 35 as a specific risk category. Similarly the HCR-20 (Douglas et al. 2014), a widely used and validated violence-specific risk assessment tool denotes 'young age at first violent incident' as a specific risk factor. The same tool also refers to 'early maladjustment' as a risk factor, reflecting a wealth of evidence indicating how childhood and adolescent trauma can increase violence risk in later life. Experience of physical abuse in childhood or drug/alcohol misuse amongst parents has been associated with higher rates of post hospital-discharge violence (Monahan, 2002). Other studies suggest that juvenile detention (Varshney et al. 2016); pre-adolescent criminal behaviour (Otto, 2000); witnessing parent on parent violence (Elbogen and Johnson, 2009); experiencing neglect (Van Dorn et al. 2012); and negative school experiences (Rueve and Welton, 2008) can also be contributing factors for adult violence and mental health difficulties.

For many writers the focus on violence risk in younger age groups can detract from the widespread risk of violence amongst older patients. Flannery et al. (2005) suggests two clusters of high risk patients, those of younger age as already noted and an older population, particularly those with a history of organic or psychotic disorders. In terms of assaults on staff, for example, reports indicate that those working on units for over 65's are more likely to be affected than those based in other inpatient areas (O'Callaghan et al. 2018; Royal College of Psychiatrists, 2008). Such instances of violence and aggression have been linked with illnesses such as Alzheimer's disease and other dementias. These extend to community based caregivers or family members living alongside the person affected (Wharton and Ford, 2014; Rosen et al. 2019).

Whilst in this risk context the older person is the acknowledged perpetrator of violence, there are broader areas of potential harm where older persons are perceived as the likely victims of violence and aggression, mirroring some of the other violence risk categories noted under gender. Elder abuse, for example, typified by physical, sexual and emotional abuse, is often perpetrated by family members, is often unrecognised and much like intimate partner violence tends to be directed at females (Culo, 2011; Benbow et al. 2018).

3.3.3 Diagnosis and substance/alcohol misuse

A diagnosis of schizophrenia is frequently associated with increased violence and aggression risk (Chou et al, 2002; Amore, 2008; Dack et al. 2013; Bowers et al. 2014; Flannery et al. 2014a). However, some studies have shown that those with alternative diagnoses of personality disorder or bipolar affective disorder may be as likely (Yu et al. 2012) or more likely to be violent than those with schizophrenia (Carr et al. 2008; Gray et al. 2011; Bulgari et al. 2018). Personality disorder, in particular, has been shown to increase the likelihood of community violence by up to three times compared to those without this diagnosis (Doyle et al. 2012).

Comorbidity is commonly associated with a higher risk of violence than any one diagnosis alone. One exception is antisocial personality disorder where co-occurring disorders have not been found to increase the risks associated (Coid et al. 2016). However, severe mental illnesses such as schizophrenia and bipolar affective disorder are seen as posing a particularly significant risk when closely linked with substance misuse and antisocial personality disorder. Thornicroft (2020) refers to this as ‘triple morbidity’ and views this combination as posing the greatest threat of violence amongst users of mental health services.

Similarly, a systematic review and meta-analysis of schizophrenia and violence studies (Fazel et al. 2009) found that accompanying substance use produced the strongest association for violence, strongly mediating the excess risk of violence initially noted due to schizophrenia. This particular comorbidity was not viewed as posing a greater risk of violence than substance use on its own. In contrast, Doyle et al. (2012) did not find substance use to be associated with an increased risk of violence, albeit nearly two thirds of their patient sample were reported to be misusing substances. Alcohol misuse has also been highlighted in terms of its association with violence both on inpatient units (Kudumija et al. 2014) and in community settings where alcohol itself was associated but substance use was not (Iozzino et al. 2015; Bowers et al. 2009).

For some writers, schizophrenia has become so intrinsically linked with violence that a past history can increase the likelihood of its diagnosis over other mental disorders, therefore perpetuating the associated stigma of violence risk (Clark and Rowe, 2006). Other writers refer to the predominance of violence and mental disorder studies carried out on inpatient units, where results may be skewed as a consequence of other contributing factors such as involuntary detention or severity of symptoms (Choe et al. 2008; Ose et al. 2017). Diagnosis may therefore be less predictive of violence in community settings. Indeed, some studies focusing on community based violence post discharge from inpatient care have failed to establish any association between violence and specific diagnoses such as schizophrenia (Monahan et al. 2001; Doyle et al. 2012).

Borderline personality disorder (BPD) and narcissistic personality disorder (NPD) have both been linked with violence; however as noted previously diagnosis of antisocial personality disorder (ASPD) is reported to have the strongest association (Coid et al. 2006; 2016). Similarly, a systematic review by Yu et al. (2012) found that all personality disorders appeared to increase the likelihood of violence by at least 3 times the general population, but with ASPD producing substantially higher rates. The link between personality disorder and violence is noted to be a complex area, particularly in relation to the blurring that can occur between personality disorder types and the impact of other co-morbid disorders on determining any causal relationship (Howard, 2015). Lowenstein et al. (2016) suggest that personality disorder is often over-simplified for risk assessment purposes, whereby the diagnosis alone is considered rather than the individual traits characterising each case and how these might increase the risk of violence.

3.3.4 Involuntary detention and repeated inpatient admissions

Many studies have revealed an association between involuntary detention; repeated or lengthy hospital stays and violence (Dack et al. 2013; Bowers et al. 2014; Iozzino, 2015; Flannery et al. 2014a). Whether such factors affect the prevalence of violence post discharge does not appear to have been widely debated in the literature. Only one study in this review measured prior detention as a predictor of community violence, finding no significant differences amongst former voluntary and involuntary patients (Doyle et al. 2012).

The association between violence and involuntary detention is considered with some caution in the literature. The high threshold for treatment accompanying involuntary admission may mean that an individual patient has recently partaken in a violent act or is believed to be at high risk of imminent violence. Secondly, involuntary detention, particularly where a patient may lack insight into their treatment needs, may well increase hostility and violence risk (Iozzino et al. 2015).

Bowers et al. (2014: p361) suggest that the link between violence and involuntary detention is "bi-directional" in that it may be enacted in response to risk; acute illness and absence of insight but may also be instigated by the act of confinement on an inpatient unit. Dack et al. (2013) also note that the high degree of variation across the studies they examined was high for number of previous and involuntary admissions, making generalisation problematic. The writers suggest that the differences in how individual units operate in terms of rules; atmosphere; routine and environment may partly account for this variation, highlighting again the importance of other contextual factors in gauging cause and effect.

3.4 Staff related factors in violence and aggression

As noted previously, violence risk assessment has traditionally focused on intrinsic patient factors corresponding with the characteristics and demographic details as discussed in section 3.3.1–3.3.4. Of the other possible variables relating to the prevalence of violence and aggression, factors relating to staff and more significantly the professional-patient interface have been widely discussed. A number of areas relating to staffing are examined including staff shortages and skill-mix; training, supervision and staff support; staff/patient interaction and staff attitudes. The available literature would suggest that demonstrating a link between such issues and the prevalence of violence is a complex area in terms of research planning and the production of reliable/valid results.

3.4.1 Staff-shortages and skill mix

Qualitative studies of staff views and opinions frequently cite staff shortages as a factor in managing and preventing not only violence and aggression but other risks such as suicide and self-harm (Bimenyimana et al. 2009; Stevenson et al. 2015; Hunt et al. 2016; Totman et al. 2011). Even where staff shortages are not directly linked with violence, understaffing has been shown to affect other phenomena such as 'burnout' amongst professionals, which in turn can affect care delivery (Lopez-Lopez et al. 2019; Aguglia et al. 2020; Kang et al. 2020). Staff absenteeism and high turnover, commonly associated with burnout in mental health services (Morse et al. 2012) has historically been seen as both a cause and effect of violence and aggression (Owen et al. 1998).

Growing concern amongst professionals in relation to staffing levels has led to calls for legislation enacting 'safe-staffing' levels in healthcare settings (International Council of Nurses, 2014; Baker and Pryjmachuk (2016). A study seeking the opinions of staff and patients by McKeown et al. (2019) cited the need for sufficient staffing in order to implement alternatives to restrictive practices such as seclusion and physical restraint which, in turn, have been associated with higher rates of violence and aggression.

Whilst staff resourcing issues are widely acknowledged as a major factor in managing aggression, a direct link between the two has been questioned by some writers looking to offer a more objective exploration of staffing problems. For example, in their systematic review of phenomena preceding violence and aggression, Cutcliffe and Riahi (2013) rejected the proviso that increasing staff numbers reduces their prevalence, citing lack of conclusive evidence. Moreover, they suggested that issues such as an excessive male presence, persistent staff sickness/absence and lack of training were equally important factors. In a US study looking at staffing and rates of assaults (Staggs, 2013) greater staff numbers did not appear to have any correlation with reduced aggression, mirroring the previous study. However, the author noted that wards with higher numbers of untrained staff appeared to report more patient-staff and patient-patient assaults, raising issues relating to skill-mix and trained to untrained staff ratios. Bowers et al. (2014) notes that the variation in restrictive practice use within units/environments subject to the same resourcing issues means that other variables are likely to be a contributing influence.

Such findings mirror earlier research underlining the complexities by which staffing ratios and skill-mix may be associated with violent activity. Owen et al. (1998), for example, found that increased staffing numbers and the absence of non-nursing staff correlated with higher risk of violence whereas higher nursing staff absenteeism and having higher numbers of younger staff appeared to decrease the risk. However, the authors felt that these relationships were unclear, raising a number of competing factors to consider. Firstly additional staff numbers may have been introduced in response to high levels of violence in a particular area; higher staff ratios may increase the likelihood of more incidents being recorded and having more staff meant that limit setting and stimulation levels may have increased. In essence, whilst it might be intuitive to assume that lower staff numbers equate with higher levels of violence, this link is far from straightforward, with multiple levels of complexity and contrasting evidence.

3.4.2 Training and staff support

A number of studies make important reference to the training needs of staff, particularly those working on acute mental health units. In terms of managing violence and aggression, recommendations range from straightforward ward induction procedures for new staff (Bimenyimana et al. 2009) to the more complex and ethically contentious use of CCTV footage in ward based educational programmes (Papadopoulos et al. 2012; Pollard et al. 2007). Writers such as Cutcliffe and Riahi (2013) cite a lack of conclusive evidence regarding the effectiveness of formal violence and aggression training for staff citing the importance of other contextual factors such as staff attitudes, degree of ‘burnout,’ utilisation of clinical supervision and level of interpersonal skills.

Although prevention and management of violence/aggression (PMVA) training has been widely recommended for a number of years (Shepherd and Lavender, 1999; Van Wijk et al. 2014) other writers suggest that a greater biopsychosocial understanding and awareness of aggression should accompany the practical aspects of such courses (Chou et al. 2002). Kelly et al. (2015) also advocate the use of ‘resilience’ training for staff, a programme not typically incorporated into PMVA training and useful in supporting staff to cope with the harmful effects of violence.

The emotional impact of violence on staff and the support recommended is discussed intermittently in the examined literature. A common theme is that patient care may be negatively affected by the psychological impact of serious incidents on staff members. Stevenson et al. (2015: p11) highlights factors such ‘‘acceptance’’ of and ‘‘desensitisation’’ to violence, making support for staff a priority. In the study by Bimenyimana et al. (2009) nurses felt unsupported by their managers and other multi-disciplinary team colleagues, citing non-reciprocal supportive relationships and a culture of blame.

Current training practices, particularly within inpatient services, have moved away from traditional violence and aggression response training to a focus on ‘trauma-informed’ care (Muskett, 2014; Wilson et al. 2017; Sweeney et al. 2018) and the avoidance of ‘coercive’ or ‘restrictive’ practices (Duxbury, 2015; Funk and Drew, 2019; McKeown et al. 2019). Many patients of mental health services are deemed to be frequently traumatised by past violence, hence restrictive practices such as physical restraint needs to be minimised in order that ‘retraumatisation’ does not occur; perpetuating further violence (Bryson et al. 2017).

Empirically supported training programmes/models such as the ‘Safewards’ model of conflict and containment (Bowers et al. 2014) have been shown to be effective in reducing coercive and restrictive practices such as physical restraint or seclusion and therefore reducing levels of conflict, violence and aggression. The Safewards programme advocates specific interventions such as clearer; more empathetic communication skills; de-escalation skills and facilitating mutual support between patients. Such models of care appear to advocate staff training that focuses on the proactive nature of violence prevention as opposed to its immediate management. More recent strategies such as ‘safety huddles’ (where staff congregate at set times to briefly discuss safety issues) (Taylor-Watt et al. 2017) and the use of ‘safety crosses’ (publicly displayed daily records of violence and aggression to improve recording and sharing of safety information) (O’Sullivan et al. 2020) reflect such efforts and have proved to be effective in reducing levels of violence on inpatient units.

3.4.3 Staff-patient interaction

The interface between staff and patients is frequently seen as an antecedent of violent behaviour because of the potential for conflict during interaction. Indeed, ‘relational’ factors such as the imposition of rules, the setting of limits and the challenges posed by opposing treatment views have been regarded as more influential in terms of violence than internal patient factors such as diagnosis or personality type (Iudici et al. 2015; Faccio et al. 2020). Bowers et al. (2014), examining documentary evidence on an acute mental health admission unit, found that conflict frequently occurred as a result of staff actions such as setting limits, making requests of or denying the requests of patients.

In carrying out a systematic review of violence antecedents across a number of countries Papadopoulos et al. (2012) reported a similarly strong emphasis on staff-patient interaction, suggesting that such challenges meant staff members ultimately had the greatest influence on ward safety. In acknowledging relational factors some writers have been critical of ‘zero tolerance’ approaches to violence, which tend to consider the phenomenon purely in terms of a patient’s behaviour and not how the clinician; the environment or the person’s situation might be having a significant influence (Paterson et al. 2008; Cutcliffe and Riahi, 2013).

McKeown et al. (2019) suggest that violence in mental healthcare is a result of the interaction between 3 combined ‘actors’ – the patient, the clinician and a potentially oppressive system.

This is not to say that clinicians, themselves, are not aware of the prominent role they play in minimising or contributing to violence risk and the system they operate within. Qualitative studies of nurses’ experiences suggest that clinicians indeed reflect on their authoritative position and the potential for conflict which arises during interaction with patients and during patient-patient interaction (Spokes et al. 2002; Stevenson et al. 2015). It is felt that without reflexivity skills and the ability to see situations from a patient’s viewpoint, clinicians may be more concerned with correcting rather than understanding behaviour (Faccio et al. 2020). Shepherd and Lavender (1999) make the distinction that it is the interactions which occur during crisis or flashpoint situations that are more of a contributing factor in violent and aggressive behaviour as opposed to structured therapeutic interaction during ‘one to one’ support; care plan reviews; therapy sessions etc.

Literature focusing on patient perspectives also highlight the importance of relational factors. A willingness to be flexible in terms of patient requests (Lantta et al. 2016) getting to know a person’s history or back story (McKeown, et al. 2019) or just simply spending more time with patients are frequently cited suggestions in terms of reducing violence and aggression (Kontio et al. 2014). Studies utilising patient interviews have been critical of staff reliance on restrictive practices to manage violence as opposed to de-escalation techniques (Price et al. 2018a) suggesting that staff need to need to be made more accountable for poor practice within a more supportive management framework. Such findings reflect a wider belief that even where staff are willing to learn and develop skills such as de-escalation techniques, they need to be better supported by organisations and leadership who will support staff in trialling or implementing change, within a culture where existing notions of risk management can be challenged (Slemon et al. 2017; Muir-Cochrane et al. 2018; Taylor-Watt et al. 2017; O’Sullivan et al. 2020).

Themes relating to staff ‘consistency’ and ‘flexibility’ are frequently addressed in the literature. Research recommendations suggest that staff members need to include clear, fair and uniform direction in their interactions with patients (Bowers et al. 2014). This consistency is called into question by studies of patient experiences however, where staff ‘inflexibility’ (often over seemingly minor issues) is seen as problematic and can escalate patients’ levels of frustration and anger (Gudde et al. 2015). How consistency and flexibility operate together is clearly a complex area, whilst implementing individualised care (incorporating both these factors) is likely to be a continuous balancing act. Patient narratives suggest, however, that the setting of limits/rules relayed inconsistently, or without adequate communication, can be an aggravating experience in terms of potential violence and aggression (Van Wijk et al. 2014).

3.4.4. Staff attitudes

Research literature also suggests that nurses may have different attitudes in regards to the sources/causes of violence, which in turn can affect its prevalence. Such differences in attitudes may stem from a variety of factors. For example, a study by Duxbury et al. (2008) on the transferability of an aggression and violence attitudes scale found that nurses in the UK tended to focus on environmental factors whereas Swiss nurses tended to focus on more internal patient factors, suggesting cultural differences. Conversely a number of writers suggest that mental health nurses tend to naturally consider internal patient factors as the defining cause of aggressive incidents compared with patients themselves, who are more likely to consider aspects such as ward culture/environment and how staff interact and communicate with them (Duxbury et al. 2005; Gudde et al. 2015; Faccio et al. 2020; Fletcher et al. 2021). Differences have also been found amongst different professional groups. Psychiatrists, for example, who tend to be more exposed to violence than psychologists have been found to have greater levels of job dissatisfaction; emotional exhaustion and cynicism (Pina et al. 2020).

Other research highlights a degree of individual assessment as to the basis of violent or suicidal behaviour (often whether a patient is deemed ‘in control’ or not) affecting the clinicians response and therefore how the incident may be reported (Stevenson et al. 2015).

Price (2018b: p19-20) suggests that such responses stem from “moral judgements” in determining illness versus non-illness related aggression, arguing that the psychological trauma experienced by many mental health patients renders such attitudes redundant as both diagnosed illness and past trauma may similarly dysregulate emotion, leading to increased violence and aggression risk. Clinical judgements regarding patient levels of ‘control’ reflect the complexities within psychological theories of aggression separating ‘instrumental’ forms (intentional and planned) from ‘hostile’ forms (impulsive and not planned) (Green, 2001; Stangor, 2014).

The presence of pre-existing staff attitudes/personalities and their association with inpatient aggression is also examined by Kelly et al. (2015). The writers summarised that individual stress thresholds can impact on levels of physical assaults, where risk is increased or lowered by a combination of exposure to violence and individual tolerance levels. The study also indicated that staff who had the most conflict with patients also tended to experience the most conflict with colleagues, highlighting a further personality-related factor.

Fear and anxiety amongst staff is also seen as a significant influencing factor in terms of preventing and managing violence and aggression. Power et al. (2020) describe a complex relationship between staff emotions such as fear; anger and regret and the prevalence of violence within Australian mental health services. Other studies have sought to examine this intricate area, noting a correlation between continued exposure to verbal abuse affecting the likelihood of restraint use (Jalil et al. 2017) and how staff anxiety, particularly amongst younger clinical mental health nursing members, may increase the use of restrictive practices as opposed to de-escalation (Price et al. 2018b).

3.5 Organisational/environmental factors in violence and aggression

Many antecedents of violence relate to organisational or environmental factors, overseen by mental health services themselves from a structural, cultural and operational perspective. If staff interaction and attitudes can be considered as contributing factors associated with violence then the employing organisations and their settings also need to be considered.

Some of the common elements discussed in the literature include the climate or atmosphere relative to each workplace; safety and security measures; the physical environment and the rules/policies/routines governing the provision of services.

3.5.1 Unit ‘climate’

A positive atmosphere or climate has long been associated with successful outcomes for those receiving mental health care although is often considered a complex phenomenon to clearly distinguish or measure (Dickens et al. 2020). It has been defined as a multifactorial construct incorporating patient and staff perceptions relating to unit safety; approaches to therapeutic care/support and opportunities for the learning/development of new skills (Tonkin, 2015). Studies frequently link unit atmosphere alongside violence risk (Cornaggia et al. 2011; Dickens et al. 2013) with some writers making particular reference to locked environments which can produce a volatile ‘prison-like’ atmosphere (Bowers et al. 2014; Stewart and Bowers, 2011). Emotions associated with such a climate can include fear and oppression (Gudde et al. 2015) and stigmatisation or worsening depression (Bowers et al. 2011).

A negative ward atmosphere can, however, be viewed as both a cause and effect of witnessing or managing the incidence of violence. In a study of nurse views relating to violence and ward climate, Lantta et al. (2016) reported how nurses felt that the increased workload involved in managing frequent violence; the stress endured during such encounters and a developing sense of cynicism could have a negative impact on a unit’s climate or atmosphere. Other studies highlight how staff can overlook the role patients themselves have to play in determining unit climate particularly in terms of how they might relate to staff members and their fellow peers (Hallett and Dickens, 2021).

3.5.2 Safety and security

Many safety and security measures employed by providers of mental health care aim to provide protection from a number of risk factors including the threat of violence and aggression. Some polices, however, such as the locking of unit doors have been regarded as having a negative impact in terms of violence risk (Bowers et al. 2014; Stewart and Bowers, 2011). This finding appears to relate, again, to the type of adverse climate a locked environment can create. Indeed, improved patient satisfaction and reduction in stigma has been linked with a more open unit environment (Lang et al. 2010; Blaesi et al. 2015) and a reduced focus on restrictive practices including restraint; seclusion and a sense of patient 'control' as opposed to patient 'care' (Pollard et al. 2007; Lo et al. 2018; Paterson et al. 2013; Muir-Cochrane and Gerace, 2016).

Absconding or being 'absent without leave' is a frequently reported occurrence on psychiatric wards, estimated to occur at rates of up to 39% and potentially leading to missed treatment, violence to others, self-neglect and suicide (Hunt et al. 2010). Where individuals may be deemed at risk of violent acts towards others or at risk of harming themselves (Ashmore, 2008), the locking of mental health units has been seen as a successful and necessary means of preventing absconding (Nijman et al. 2011). The traditional notion that locked units offer greater safety to patients themselves has, however, been called into question with writers calling for more in-depth research into the impact of locked areas on violence and aggression (van der Merwe et al. 2009). In one example, a 15 year observation study (Schneeberger et al. 2017), the writers established no differences in aggressive behaviour; property damage and bodily harm when comparing different hospitals with open and locked door policies.

There are a significant number of different security measures examined in the research literature with significant variation in terms of specific interventions, local procedure and use of technology across Ireland, the UK and mainland Europe (Cowman and Bowers, 2009; Cowman et al. 2017). Frequently contentious examples include the removal of personal property and the searching of patients and visitors (Bowers et al. 2002; Slemon, 2017); use of CCTV (Desai, 2010; Due et al. 2012); the use of airport-style metal detectors (Laidlaw et al. 2017); the involvement of non-clinical security staff (Lawrence et al. 2018) and the use of body worn cameras (Hardy et al. 2017). This non-exhaustive list illustrates efforts to moderate a number of risks affecting staff and patients and not specifically violence alone. Bowers et al. (2002) refer to the complex task of implementing security measures which aim to protect vulnerable patients from each other; patients from themselves; the public from patients and the protection of patients and property from outside visitors. The issue of illicit drug use on mental health units, for example, reflects this last point and is seen as a major safety and security issue in some jurisdictions (Bowers et al. 2002; Cowman and Bowers, 2009).

As noted previously, the sheer number of potential variables in terms of violence cause makes the isolation of specific security measures through research studies an intricate and complicated process (Duxbury, 2002). Many writers question, however, whether increasing security measures can have a paradoxical effect in terms of confrontation and dissent, leading to more violent incidents and therefore decreasing safety (Cowman and Bowers, 2009). Due et al. (2012) conclude that security measures indeed have a role in moderating violence and particularly in terms of addressing staff safety concerns. However, the writers feel that security measures can be implemented in ways that do not necessarily provoke outbursts of violence (e.g. not placing cameras in areas where they are likely to cause conflict and where there is a consensus of opinion amongst patients and staff in terms of necessity and effectiveness).

3.5.3 Physical environment

A physical environment/ward layout which minimises the risk of violence is another area considered in the literature. The risks associated with overcrowding are emphasised, noting that assaults tend to occur in areas where high levels of contact may occur such as dining rooms and other communal areas (Chou et al. 2002; Cutcliffe and Riahi 2013). Studies examining patient and staff views also suggest that overcrowding and lack of personal space are felt to be significant contributing factors in violence and aggression (Stevenson et al. 2015; Van Wijk et al. 2014).

Some writers, however, suggest that the relationship between aggression and overcrowding is unclear, highlighting research where increased space failed to correlate with a reduction in violent incidents (Cutcliffe and Riahi, 2013). Despite this debate, common environmental recommendations beyond the improved use of space include private rooms as opposed to dormitories; 'quiet' rooms; reduction in intrusive/unwanted noise; involving patients in ward design, smoking areas, temperature and ventilation control and general cleanliness/aesthetic factors (Chou et al. 2002; Cutcliffe and Riahi, 2013; Van Wijk et al. 2014).

In Ireland, the Mental Health Commission (Finnerty, 2021) have produced a report focusing on physical environments within mental health services. The report states that optimal physical environments are associated with a number of positive outcomes including the reduced incidence of aggression due to lower patient stress levels. The author discusses the need for balance in terms of safety measures such as locked doors and damage resistant materials versus the valuing of privacy; noise and crowd reduction. Some of the main features recommended in terms of optimal unit design are noted in box 3. Ulrich et al. (2008) report that architecture can reduce aggression if designs aim to limit overcrowding and excessive noise whilst creating positive distractions which reduce stress such as gardens and natural daylight.

Box 3. Inpatient mental health unit design (Mental Health Commission, Ireland)

- Smaller bedded units (20 beds max.)
- Single rooms with private bathrooms
- Range of communal and private areas
- Noise reducing design
- Room related design that patients can control (e.g. windows/ventilation)
- Accessible gardens
- Daylight and windows
- All areas observable from central area
- Plants, pictures and furniture

3.5.4 Rules; policies and routines

Despite being an essential feature of safe day to day patient care and unit management, the rules; policies and routines evident on mental health units have historically been linked with the prevalence of violence and aggression (Roper and Anderson, 1991; Alexander and Bowers, 2004). This is evident in research suggesting that violent incidents tend to peak at certain times of the day governed by routine and operational policy. For example, mealtimes (particularly lunch and evening times) have been linked with higher levels of aggression as they tend to create a situation where increased patient on patient interaction occurs (Chou et al. 2002; Bowers et al. 2011).

High levels of activity in general terms appear to be linked with patient aggression. For example, Katz and Kirkland (1990) found an increase in aggressive incidents during the high stimulus atmosphere often experienced on Mondays as opposed to the low activity environment normally evident on Sundays. This is contrasted by evidence indicating that a lack of meaningful activity and stimulation, such as regular physical exercise etc., can lead to aggression, with patients frustrated when activities are cancelled or curtailed (Gudde et al. 2015). Another study describes the 'pressure cooker' environment that can prevail on inpatient mental health units, citing a reduction in violent incidents when outdoor activities; computer and gym sessions were introduced (Antonysamy, 2013).

Whilst patient on patient interaction is likely to be shaped as much by environmental factors such as shared sleeping areas and access to personal space it is also likely to be affected by certain rules and routines, for example those governing when patients can eat in a dining area or if they can eat in their own rooms/bed areas. Such arrangements may be affected by factors such as staff availability; wider hospital procedures and schedules and rules governing health and safety. The example of mealtimes demonstrates that rules, routines and policies can create situations where the risk of violence increases, particularly in the context of rules being challenged; policies not being followed/applied or established unit routines not being adhered to. Bowers et al. (2014) suggests that such interactions may lead to 'flashpoints' for violence and whilst they may equally relate to clinician and patient factors (e.g. staff training or patient's level of ill-health), the routine; policies and local rules applicable to each mental health facility are an important contextual factor to consider.

For some writers it is not the presence of rules and policies themselves that can lead to violence but the way in which they are interpreted and applied. A systematic review of inpatient mental health experiences (Staniszewska et al. 2019) notes that patients often feel that rules are either not explained properly or are implemented inconsistently. The authors feel that some of the more welcoming aspects of inpatient environments (such as access to garden/outside space or the making of snacks/hot drinks) are frequently governed by inflexible unit rules. This, in turn, can sometimes create a barrier to successful de-escalation of violence and aggression (Price et al. 2018a). Patient accounts also refer to a number of specific areas where the enforcing of rules are perceived as damaging to the patient-clinician relationship, including rules governing displays of physical affection between patients; access to kitchens/drinking water at night; lying in too long in the mornings and the TV being switched off at bed-time (Price et al. 2018a).

Another contentious example pertaining to rules and service policies concerns the permissibility of smoking and smoking areas. Since 2015 the HSE in Ireland have been committed to making all healthcare sites smoke free (HSE, 2012b), including outside spaces on hospital grounds (McGreevy, 2012). Whilst mental health facilities are exempted from government laws making it illegal to smoke in enclosed workplaces (Public Health (Tobacco) Acts, 2002 and 2004) there has been considerable debate as to what degree smoking should be restricted in such areas and how factors such as violence have been affected.

HSE guidance (Robson and Potts, 2016) reports that staff-anticipated increases in violence; seclusion; absconding and medication use have not occurred across tobacco free campus evaluations in Ireland. International studies appear to concur with this Irish guidance, reporting decreases in violent incidents following the introduction of rigorous smoke free policies (Robson et al. 2017; Huddlestone et al. 2018). Spaducci et al. (2020) consider the reasons why smoking related violence appears to lessen in their study focusing on the introduction of a policy where smoking was entirely prohibited on a mental health unit and its outside spaces. The authors associated a decrease in violence with the cessation of ‘smoking breaks’ where patients were formerly supervised by staff in designated outside areas and at specified times. These breaks tended to create conflict flashpoints where patients were not allowed to go outside to smoke or where they were requesting breaks outside of designated times.

For the HSE in Ireland (Robson and Potts, 2016) such routines reflect a partial or selective approach to smoke free policies, suggesting that a complete ban avoids manpower demands and policy ambiguity which, in turn, decreases the risk of conflict between staff and patients. Studies also suggest, however, that resultant increases in policy breaches and tobacco concealment may increase conflict where staff are required to intervene (Spaducci et al .2019) or where staff facilitation of covert cigarette smoking creates further rule inconsistency (Huddlestone et al. 2018).

3.6. External Factors and violence/aggression

External or outside factors are examined in relation to the antecedents of violence from a direct and indirect perspective. These relate to the outside difficulties than can transfer from people's personal lives to mental health care environments; societal attitudes towards mental health; the provision and availability of appropriate mental health services and the impact of unforeseen events/changes such as the recent COVID-19 (coronavirus) pandemic.

3.6.1 Home; personal lives and society

Bowers et al. (2014) suggest that inpatient wards are not immune to outside influences, citing violent incidents where patients cannot access their finances; where they have significant home responsibilities and following distressing/inflammatory visits from friends or family. In considering the potential risks posed by visitors or members of the public, Raveendranathan et al. (2012) make the important point that a relative's influence may also be supportive and may help to diffuse situations in many cases.

Cutcliffe and Riahi (2013) identify that the community in which a patient lives has a significant bearing on the risk of violence and aggression. They summarise that living in socially disadvantaged communities may increase the likelihood of violence over and above any other potential risk factors. The writers also refer to the attitudes of wider society and how these ultimately impact on violence and aggression by shaping and advocating for the restrictive and stigmatising aspects of some mental health care, which, in turn, can lead to increased levels of violence. They highlight that a connection between mental illness and violence continues to be routinely sought, despite contrary evidence.

3.6.2 Provision and availability of mental health services

The provision and availability of appropriate mental health resources across both inpatient and community services is another factor to consider in relation to violence and aggression. This is exemplified by the current situation in Ireland where maintaining inpatient bed numbers and ensuring access to a 'full continuum' of services such as psychiatric intensive care units (PICU's); specialist older adult units; crisis houses and high support hostels is a main priority for the Mental Health Commission (MHC, 2020).

Certain aspects of violence risk emerge from the dearth of such services in Ireland. PICU's, for example, have historically been seen as effective in terms of reducing violence and aggression (Bowers et al. 2008a), although not always effective in terms of lowering adverse incidents on referring non PICU units (Bowers et al. 2012). Nonetheless, inadequate provision can result in the most severely unwell patients not having access to specialist care, whilst significantly disrupting the therapeutic atmosphere on non PICU units (MHC, 2020). Similarly, violence and aggression risk is the primary reason for PICU referral from adult inpatient units (Cullen et al. 2016).

Other service/resource limitations in Ireland and abroad reveal further examples where violence and aggression can be affected. Patients 'blocking' or failing to move on from inpatient beds due to lack of accommodation options in Ireland is seen as a major cause of overcrowding (MHC, 2020); in itself a predisposing feature of violence and aggression (Virtanen et al. 2011). In the UK, recent media reports have been critical of 'out of area' inpatient stays (where patients are sometimes sent hundreds of miles for inpatient care) noting how individuals’ distress levels may be significantly increased by being far away from their homes and families (Campbell, 2019).

3.6.3 Major external events

Mental health services and levels of mental ill health amongst populations can be affected by events occurring externally across society. Calendar events such as public holiday periods have been traditionally linked with upsurges in mental health problems (National Alliance on Mental Health, 2014; HSE, 2018), whilst major public gatherings throughout the year such as sporting events can precede higher rates of violence-related assault presentations in A&E (Sivarajasingam et al. 2004). However, such findings are contrasted by evidence which suggests that periods such as Christmas might see more mood and alcohol related issues but conversely less hospital/health service presentations (Sansone and Sansone, 2011).

Higher rates of general population violence and homicide have been observed at weekends (Pridemore, 2004) and during the summer months (Tiihonen et al. 1997; Rock et al. 2008). However, such findings do not necessarily translate to users of mental health services. In their UK study, Baird et al. (2019) found that there was no increase in weekend homicides committed by people experiencing symptoms of mental illness. Similarly, a study by Kuivalainen et al. (2017) found no seasonal variation in violence amongst inpatients with psychotic disorder, although seasonal variation did exist in terms of seclusion and restraint use.

Two specific events encountered during the course of this research study serve to illustrate how levels of violence and aggression may be directly and indirectly impacted by wider public events. Firstly, the worldwide financial crisis of 2007-2008 greatly affected mental health in Ireland both in terms of its negative impact on service provision and increased psychiatric morbidity amongst the general population (Nolan et al. 2014; Delaney, Egan & O'Connell, 2011). As noted in previous chapters, both availability of services and level of patient illness have been linked with increased risk of violence and aggression.

Secondly and perhaps less indirectly, the recent COVID-19 (coronavirus) pandemic has been linked with increased levels of violence and aggression on acute mental health units (Payne-Gill et al. 2021). The authors refer to a number of contributing factors related to COVID-19 (coronavirus) rules and procedures: activities being cancelled; further smoking restrictions; prohibited visitor access; limited access to psychological and occupational therapy support; staff redeployment; restricting patients to their rooms during quarantine and greater levels of stress for both staff and patients.

3.7 Discussion: Violence and aggression antecedents

One of the main findings of this review is the significant number of antecedents associated with violence and aggression, with much of the available research literature appearing to focus on the prevalence of violence as it relates to inpatient mental health services. A focal theme arising from this literature is the risk of violence stemming from simply being a patient on an inpatient unit. Although the process of admission may well reduce risk in the community (e.g. to family and the public) it appears to simultaneously increase the scope for violence as a result of issues such as ward restrictions; close proximity of other patients or poor therapeutic environment. The greater number of inpatient studies included in this review as compared to community based studies highlights the extent and multitude of difficulties experienced by patients and staff on such units. However, this may also relate to the ease of access to relevant research data (e.g. access to multiple patients, access to case notes; access to comparison groups/wards and access to multi-disciplinary teams).

A recurring theme throughout the literature is the difficulty researchers experience in scientifically linking violence to any one specific antecedent and the sheer number of factors/circumstances involved. For example, the results from patient-related studies, particularly those examining the link between demographic factors and violence are commonly approached with caution because of the difficulties in discounting other non-patient related factors. In many ways this mirrors the historical limitations associated with mental health inquiries and ‘root cause analysis’ investigations where finding any single, fundamental cause of a homicide or suicide, for example, rarely occurs and should not be anticipated (Neal et al. 2004).

The ability of research evidence to provide only tentative associations between particular antecedents and violent incidents produces somewhat of a quandary for mental health services in establishing where to focus and prioritise valuable resources. Some writers such as Kelly et al. (2014) suggest that services should only focus on those areas which are modifiable; many factors linked with ward violence such as male gender, young age, history of violence and drug use being difficult to control or beyond the control of mental health services alone. Similarly, writers such as Hamrin et al. (2009) suggest that nursing staff need to be aware of the heightened risks posed by factors such as psychosis; younger age and violence history, but that this awareness alone does not stop violent incidents from occurring.

Hansen (1996) makes the point that causative factors do not necessarily need to be explored to reduce violence, suggesting that services should utilise an occupational health paradigm solely focusing on environmental safety. Although written over 20 years ago, this approach to ward safety is arguably evident in many hospitals today, where frequently the aim is to reduce the means and impact of violent behaviour either to self or others as opposed to necessarily investigating every major or minor case and why it may have occurred. Disregarding the investigation of possible causes and replacing with ‘blanket’ measures, however, raises the potential for negative counter-effects. Commonly used methods to control risk including locking ward doors; seclusion; restraint and close observations, for example, may be viewed in terms of harm minimisation. However, as noted in the literature, such practices can perpetuate a negative ‘climate’ on a unit, whereby violence and aggression becomes the expected norm. Writers critical of an over reliance on ‘restrictive’ practices argue that units and staff need to reflect on local practices and to what degree these can be associated with the prevalence of violence and aggression.

In terms of staff-related factors some of the research evidence has aimed to test commonly reported causes of violence such as staff shortages or skill mix. The ability to scientifically research these areas is again limited by other mitigating factors. For example, using a control study to compare staffing numbers on separate units as suggested by Staggs (2013) would be challenging in terms of additional considerations such as patient catchment areas; variable physical environments and ease of access to outside space. Some writers appear critical of nursing staff for only focusing on areas such as perceived staff shortages and not fully considering their interaction with patients, their attitudes and their training/support needs. More in-depth qualitative studies, however, appear to demonstrate that nurses demonstrate an ability to consider the full range of internal and external violence antecedents, including critical reflection of their own practice.

The scrutiny of such nursing practice in the research evidence also appears to contain some contradictory guidance including the complex nature of attributes such as 'consistency' and 'flexibility.' Striking a balance between maintaining consistency during interactions whilst having a flexible approach is, in reality, no easy task. In the same way as incidents may prove to be multi-factorial in relation to their antecedents, the nurse's ability to be consistent or flexible also relies on a number of factors. These may include areas such as numbers of staff on duty; time of day or night; ward culture; level of agreement with the wider multi-disciplinary team or confidence and familiarity around peers. In essence, the nurse-patient relationship needs to be viewed within a wider context of inter-related factors. Indeed, a theme which emerged in the literature was of nurses feeling that they bear the brunt of criticism in relation to violence risk when it is a multidisciplinary issue.

From an organisational perspective, providing individual care in an institutional setting continues to prove problematic, given the sheer diversity of patients; illnesses; complex social issues and behavioural factors evident in all clinical areas. Attempts to provide consistent levels of care and safety for all patients will inevitably result in some expressing dissatisfaction, frustration or aggression at times. A common scenario from practice is the locking of ward doors because of safety concerns about one individual patient, which then has the potential to adversely affect the remaining population on the unit who may not necessarily need the same level of containment.

Significant levels of activity and patient on patient interaction on wards are also linked with the potential for violence and aggression. Although these elements may result in an arguably ‘highly-charged’ or volatile atmosphere, it is not clear that efforts to reduce activity or potential ‘flashpoints’ have an ultimate impact on violence levels. A recent Australian study by Smith et al. (2018) found that having ‘protected engagement time’ (PET) where visitors were restricted at certain times to reduce activity levels, had no impact in reducing adverse events.

There are clearly a significant number of external factors which can influence levels of violence on inpatient units. At a fundamental level, the very fact that a patient is admitted to an inpatient unit stems to a degree, from societal attitudes, which tend to shape policy on service provision. Alternatives to hospital admission such as acute home treatment teams emerged from the progression towards community based mental health policies in the 1990’s. However, writers such as McCrae and Hendy (2018) express caution regarding the further expansion of such services, citing the public and individual safety risks involved where such approaches have become the de facto treatment approach as opposed to use of inpatient care.

From one perspective, community based alternatives to inpatient care provide choice for patients, families and services and can arguably be a means of preventing or diffusing the potential for violence on units, particularly in the context of potential overcrowding; conflict amongst fellow patients and having to conform to rules and policies; all types of antecedent noted in the literature. At the same time, there are many cases where inpatient care is deemed necessary in order to protect the safety of family members and the public as a result of violence risk. Such decisions reflect the ongoing demands on mental health professionals in terms of advocating for the rights of mental health patients in governing their own care needs whilst retaining a role in protecting the wider public.

To a certain extent violence in mental health services does not necessarily differ from outside society. As violence occurs everywhere and predominately without the presence of mental illness, it is reasonable to assume that it can and will, at times, occur in care based settings also. The wide array of factors associated with mental health violence noted in the literature suggests that attributing violence and aggression solely to a person's mental state would be highly presumptuous and would ignore other contextual possibilities.

Chapter 4: Specific incident types and their antecedents (contd.)

4.1 Self-harm

The frequently cited term 'self-harm' is contentious in terms of how it is best conceptualised, particularly in relation to suicide intent (Muehlenkamp and Kerr, 2010; Mars et al. 2014; James and Stewart, 2018). NICE guidelines (NICE 2013: p6) define self-harm as "any act of self-poisoning or self-injury carried out by a person, irrespective of their motivation" arguing that the phenomenon is often too complex and the intention too unclear to be able to differentiate correctly. Whilst 'deliberate self-harm' replaced older terms such as 'parasuicide' and 'attempted suicide' in order to recognise the absence of intent in some cases, the prefix 'deliberate' is often now omitted as it is seen as a judgemental term which belies intent when the behaviour motivation is unclear (Morris et al. 2013).

Other writers, however, suggest that self-harm with intent to die and self-harm without intent should be distinguished from one another as each requires a different treatment approach (Muehlenkamp, 2005). Similarly, there is evidence suggesting differences amongst individuals engaging in respective self-harm behaviours in terms of outlook on life and history of traumatic life events (Whitlock and Knox, 2007). Some similarity and overlap is, however, widely acknowledged, with many individuals engaging in both types of behaviour (Klonsky et al. 2013) and risk factors such as alcohol/substance use; female gender and childhood sexual abuse strongly associated across both categories (Mars et al. 2014). Moreover, those who engage in any form of self-harm are seen to be at higher risk of eventual death by suicide (Morris et al. 2013; Chan et al. 2016).

As such self-harm is often viewed as a fluid phenomenon, occurring on a continuum of severity and fluctuating suicidal intent (NICE, 2011; Morris et al. 2013). For James and Stewart (2018) the fluid nature of suicide intent means that clinicians may be misguided in making distinctions between categories of intent and attributing different levels of risk management. The writers also feel that the diverse nature of self-harm definition is sometimes a barrier to research as studies often apply different criteria, making results comparison difficult.

Whilst acknowledging that there is significant overlap and debate relating to non-suicidal self-harm and suicide/attempted suicide, the two categories have been separated for the purposes of reviewing the literature. This decision was based on the merits of comparing the two categories in terms of any distinct factors and commonalities relating to individuals who frequently self-harm in the absence of suicidal intent. The remainder of Chapter 4 therefore focuses on antecedents directly associated with suicide and self-harm with intent, followed by an examination of the contextual factors relating to non-suicidal self-harm in chapter 5.

4.2 Suicide/self-harm with suicidal intent: Introduction

The most recently recorded general population rate of suicide in Ireland is 9 per 100,000 people, with 437 deaths by suicide recorded in 2018. Just over 76% of these deaths were males and the rate was highest in the 55-64 age category (National Office for Suicide Prevention, 2021) (NOSP). In 2017 Ireland's suicide rate was recorded as the 9th lowest among 33 countries, with a documented average of 11.55 per 100, 000 (Eurostat, 2018). In contrast, earlier Irish research cites a three-fold increase in suicides amongst 15-24 year olds in the last 30 years (8.9–29.7 per 100 000), making Ireland's figures the 4th highest in Europe for this group (Murphy et al. 2015). Male suicide rates are generally higher than females, a recent report indicating that out of approximately 400 recorded suicides in 2017, 8 out of 10 were men (Ryan, 2018).

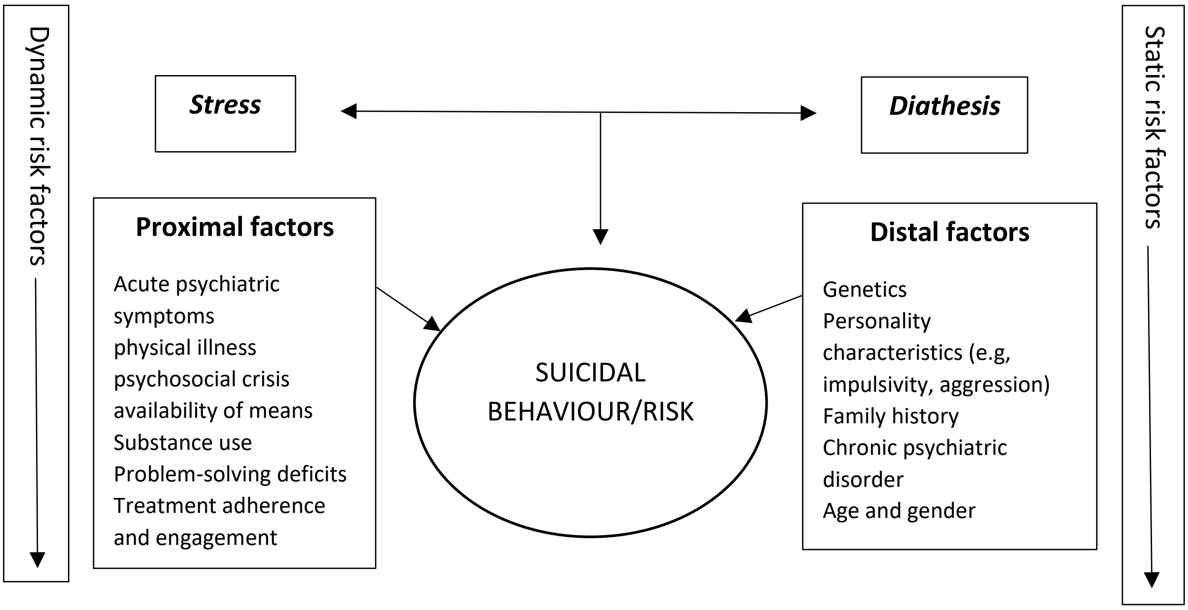
Rates of suicide amongst community and hospital based mental health service users are generally considered to be higher; 2 to 3 times higher (Manuel et al. 2018) and up to five and ten times higher than general population rates (Gaffney et al. 2009; Bakst et al. 2010). Out of 807 recorded suicides in a 2001 Irish report (Departments of Public Health, 2001) half of this group had been referred to a consultant psychiatrist, with two-thirds receiving treatment as inpatients. For the years 1983-1992 in Ireland, Corcoran and Walsh (2014) recorded a rate of 319 deaths by suicide per 100,000 amongst short-stay psychiatric inpatients and 119 per 100,000 for long-stay patients. Recent UK figures by comparison put the rate of suicide amongst those under specialist mental health services at 25 to 30% of all suicides in total (Kapur et al. 2022). The most recent annual report by the National Suicide Research Foundation in Ireland (NSRF) (Joyce et al. 2020) notes that in terms of self-harm presentations to Irish hospitals, homelessness and young age appear to be current risk factors with intentional overdose the most common method of harm, followed by self-cutting and attempted hanging.

Whilst yearly figures are produced by the Central Statistics Office (CSO) in Ireland, these can be imprecise due to delays in coroners verdicts; the fact that all verdicts remain provisional for two years; difficulties with establishing intentionality and a lack of detailed individual information outside of basic demographics (Corry et al. 2016). Malone et al. (2015) argue that establishing deaths by suicide across inpatient and community mental health services remains challenging due to the lack of any centralised national register of suicides in Ireland. To date, a more in-depth suicide information database has been advocated for and piloted in some Irish localities but not widely introduced. The Suicide Support and Information Study (SSIS) aims to incorporate data from multiple sources including families; healthcare professionals and medical records in order to better define the patterns and incidence of suicide in Ireland (NSRF, 2021). This type of resource would mirror the well-established system in the UK where in-depth personal information relating to suicide is contained within a national database (National Confidential Inquiry into Suicide and Safety in Mental Health) (NCISH) (University of Manchester, 2021).

Regardless of questions relating to intent, the experience and aftermath of self-harm is likely to be traumatic for all those connected. Writers such as Takahashi et al. (2011); Bowers et al. (2011) and Morrissey and Higgins (2021) refer to the emotional/psychological impact of completed suicide on inpatient staff, highlighting the need for effective supervision and support. Furthermore, psychological issues can present themselves in the form of feelings of anxiety and guilt, in addition to fears regarding blame and litigation (Bowers et al. 2006; Ballard et al. 2008). For families dealing with loss as a result of self-harm and suicide, long term grief complications can include chronic depression; self-blaming thoughts and feelings of shame/stigma (Pitman et al. 2014; Tal et al. 2017). In financial terms self-harm and suicide have a significant worldwide impact; around 900 million euro a year in Ireland in 2001 (Kennelly, 2007) and the cost to the US economy estimated at 70 billion dollars a year in lifetime medical and work-loss costs (Centers for Disease Control and Prevention, 2021) (CDC).

In terms of contributing factors, evidence in the literature appears to distinguish between the more innate, fixed aspects of a person's background and the changeable events and circumstances affecting their lives. In illustrating this difference, Hawton and van Heeringen (2009) suggest that contributing factors can be categorised as 'trait' or 'state' dependent under the terms 'distal' and 'proximal'. Furthermore, a stress-diathesis model (Mann et al, 1999) seeks to provide an explanatory model of suicide risk where acute stressors and predisposing factors combine to influence suicidal behaviour. This model and the distal/proximal factors noted share similarity with the static/dynamic theory of suicide risk factors (Bouch and Marshall, 2005). Fig. 2 illustrates the interplay between each of these theories.

Fig. 2 Relationship between a stress-diathesis model and risk factors categories (adapted from Hawton and van Heeringen, 2009; Mann et al. 1999; Bouch and Marshall, 2005)



4.2.1 Suicide/self-harm with suicidal intent: Results summary

Appendix 7 is a copy of the original literature review grid used in order to source appropriate evidence. However, newer research findings have been added since the review was initially carried out. The studies included originate from across the world with a broad range of publication dates included. The majority of papers are primary research studies relating to inpatient mental health units or the period after admission to an inpatient area.

As with data produced for violence and aggression, statistical data needs to be examined with certain reliability issues in mind including the problems of ascertaining suicidal intent (Tishler and Reiss, 2009); international and cultural differences relating to defining, recording and understanding suicide (Walter and Pridmore, 2012); the likely under-reporting of suicide due to paucity of evidence, family interpretations and lengthy legal/coronial procedures (Corry et al. 2016) and unreliable incident reporting systems (Iozzino et al. 2015; Anderson et al. 2013).

4.3 Patient related factors in suicide/self-harm with suicidal intent

A number of patient characteristics have historically been associated with increased suicide risk. In common with having a prior history of violence, having a prior history of suicidal/self-harming behaviour (of any severity or intent) is seen as a significant risk factor for future harm (NICE, 2011; Arensman et al. 2019; Royal College of Psychiatrists, 2020; National Institute of Mental Health, 2021) with the World Health Organisation (WHO, 2021) citing any prior suicide attempt as the “single most important risk factor for suicide in the general population.” Also, much like violence risk, having a severe mental disorder such as schizophrenia; being male and having a history of substance abuse are commonly cited risk factors in suicide and self-harm (Bakst et al. 2010; Hunt et al. 2010). The contributing factors affecting for suicide are, however, manifold and complex with contrasting evidence available. A number of areas relating to the patient or individual are examined in further detail.

4.3.1 Gender and age

A widely acknowledged historical paradox relates to gender and suicide/self-harm. Whilst higher rates of non-fatal suicide attempts appear to exist amongst females, males are felt to be more likely to complete suicide (Canetto and Sakinofsky, 1998; Schrijvers et al. 2012). A number of theories have been postulated to explain this paradox. One of the foremost theories relates to lethality, in that males are felt to be more likely to use more lethal means of harm than females (Mosckici, 1994; Varnik et al. 2008).

Why this may be the case raises a second theory relating to gender roles and socialisation. Canetto and Sakinofsky (1998), for example, suggest that societies frequently expect different types of suicidal behaviour amongst males and females, affecting both the harm choices made by each gender and how the behaviour may be interpreted in terms of lethality. Schimelpfening (2020) summarises some of these societal norms including the stereotype of men being seen as ‘strong’ and therefore not allowing for failure in suicide attempts, whilst conversely females may be less inclined to carry out an act of harm seen as violent or ‘masculine.’ Freeman et al. (2017) point to the low rates of suicidal behaviour compared with high mortality rates amongst young males as indicative of this socialisation theory, adding that females may use attempted suicide as a means of seeking help at an earlier stage in their condition than males. For writers such as Callanan and Davis (2012) such findings and theories should be viewed in the context of possible gender bias, which has made the topic of gender and suicide a controversial and complex area of debate.

In terms of age, rates of completed suicide internationally are consistently highest amongst middle aged to older adults (WHO, 2021; Stanley et al. 2016). In Ireland, it is middle-aged men aged between 40-59 who have had the highest rate of suicide in recent years, prompting calls for a targeting of this group in terms of suicide prevention (O'Donnell and Richardson, 2018). Equally, a recent rise in suicides affecting young people, particularly young females (Samaritans, 2021) and with suicide reported as the 4th leading cause of death amongst 15-29 year olds (WHO, 2021), targeting those of younger age is also seen as important.

Past 60 years old, rates of suicide are seen to increase with age (Shah et al. 2016) with males over 75 having the highest suicide rate amongst all age groups in the USA. Older populations are felt to be somewhat overlooked in terms of addressing suicide risk; this despite an expectedly continued rise in the phenomenon over the coming years due to longer life expectancy and an increasingly aged global population (Corcoran et al. 2010; Van Orden and Deming, 2018; Stoliker et al. 2020).

4.3.2 Psychiatric diagnosis

Historically, studies have frequently shown that suicide occurs most commonly among the mood disorders, namely major depression and bipolar affective disorder (Harris and Baraclough, 1997). Although many other disorders including polysubstance abuse, schizophrenia and personality disorder have been linked with elevated rates of suicide (Hunt et al. 2010; Bakst et al. 2010) it has been postulated that rather than the diagnosis in itself, it is the combination of common symptoms present in such diagnoses (depressed mood; severe anxiety and impulsive traits) which increases the risk of suicide (Fawcett, 2012).

The combining of such symptomatology into a formal 'suicide' diagnosis appears to have gained recent traction with the term 'Suicide Behaviour Disorder' being considered for inclusion in the DSM-5 (Fehling and Selby, 2021). This mirrors earlier research by Schuck et al. (2019) who used the term 'Suicide Crisis Syndrome' to define a suicide-specific diagnosis. Both writers refer to the positive aspects of having a specific suicidal behaviour in terms of more accurately assessing risk; the latter highlighting how suicide is currently viewed as a symptom of other mental disorders only and in creating the new diagnosis it would include those who attempt suicide but do not meet the criteria for existing disorders.

4.3.3 Genetics and family history

Suicidal behavioural has been shown to have a strong genetic-familial element (Roy, 1983; Brent, 2010), increasing the likelihood of completed suicide by up to two and a half times (Qin et al. 2002). In their study of suicide amongst 15-29 year olds, Runeson et al. (1996) found that 38% of fatalities had a parent or sibling who had previously completed suicide, whilst twin studies have shown higher rates of congruence for attempted and completed suicide amongst identical pairings compared with fraternal twins (Roy et al. 1991; Glowinski et al. 2001). Qin et al. (2003) notes that whilst familial history of suicide and mental disorder often co-occur (both seemingly increasing the likelihood of suicide), a family history of completed suicide significantly increases risk in its own right, whilst a family history of psychiatric disorder merely increases suicide risk through increasing the likelihood of developing a mental disorder.

Untangling family/genetic history of suicide as a risk factor distinct from a diagnosis of mental disorder and the presence of other environmental factors is clearly complex, and there is an ongoing nature/nurture debate in regards to suicide risk and families. Studies of identical and fraternal twins who have lost a co-twin to suicide, for example, have demonstrated a higher likelihood of attempted suicide amongst identical twins (Glowinski et al. 2001; Segal, 2009). Whilst genome and molecular studies have suggested that up to 50% of suicide risk has a genetic element (Roy and Segal, 2001; Coon et al. 2020) the presence of mental disorder in a significant number of cases and the sheer diversity of factors befalling those who exhibit suicidal behaviour makes controlling for such differences amongst research samples a confounding issue (Mirkovic et al. 2016).

4.3.4 Physical illness and disability

Evidence supporting the relationship between physical illness/disability and suicide appears inconsistent. Recent studies have suggested that chronic conditions such as back pain; congestive heart failure and stroke (Ahmedani et al. 2017; Pompili, 2012); COPD and cancer (Amiri and Behnezhad, 2020; Sampaio et al. 2019); epilepsy and asthma (Singhal et al. 2014) are associated with increased suicide risk. However, there appear to be a number of confounding factors which make such claims questionable. The methodological limitations of controlling for these factors in research is a common critique of evidence directly linking physical illness and suicide (Hawton and van Heeringen, 2014; Onyeka et al. 2020).

The first relates to the well-established link between serious or chronic physical illness and the risk of developing mental health difficulties (Royal College of Psychiatrists, 2016; NIMH, 2021) and the inverse relationship between severe mental disorder and physical illness (Ashworth et al. 2017; MHC 2019). Attributing suicide risk to physical illness alone is, in essence, complicated by co-morbidity, with studies failing to establish any increased risk of suicide emerging as a result of combined physical and mental illness over and above that preceded by mental disorder alone (Lossnitzer et al. 2009; Kavalidou et al. 2019) One study examining a range of physical disorders (asthma; chronic obstructive pulmonary disease (COPD); ischaemic heart disease; hypertension; diabetes; cancer; multiple sclerosis and inflammatory bowel disease (Bolton et al. 2015) adjusted for mental disorder and co-morbidity in their findings and found that only cancer increased the risk of dying by suicide. Furthermore, this risk appeared to relate to the date of first diagnosis with the risk increasing during the first 3 months and dissipating after the first year.

Other confounding issues in the literature include the effects of chronic physical health issues on poor quality of life (Fortin et al. 2004) reduced levels of functioning (Kaplan et al. 2007); diminished socio-economic status (Christiansen and Stenager, 2012) and disruption to daily activity (Onyeka et al. 2020). In each of these cases it is suggested that the social, financial and psychological ramifications of chronic physical illness are more predictive of suicide than any physical condition per se. Additionally, the number of physical issues present is also felt to affect the level of risk (Thomson et al. 2014). This has significance in the older age group, where the frequent presence of increased multimorbidity is seen as a common risk factor (Barnett et al. 2012; Conejero et al. 2018).

4.4 Staff related factors in suicide/self-harm with suicidal intent

The role of healthcare staff in managing suicide risk and the care of people who are suicidal is varied with mental health nurses, for example, having a significant role in both systems and patient level interventions (Smith, 2018). This is illustrated here in Ireland, where the Connecting for Life Implementation Plan 2020-2022 (HSE, 2020) targeting suicide prevention, cites the need for frontline health professionals to be fully skilled in best practice principles and in being able to offer a wide range of therapeutic interventions, whilst also citing the need for their involvement in wider health promotion campaigns such as reducing stigma.

This varied role appears to be a source of conflict when examining staff related issues in suicide risk. This conflict appears to stem from the need for mental health professionals to frequently combine the roles of ensuring patient safety whilst establishing and maintaining a therapeutic rapport with those they are caring for. This is exemplified within inpatient environments where mental health staff frequently provide care for patients deemed at risk of harm to themselves by using containment methods such as close observations, 'PRN' medication and increased environmental security (Bowers, 2004). Whilst such measures can be viewed as therapeutically valuable in certain contexts (Debyser et al. 2017), they can impair professional-patient relationships (Brophy et al. 2016; Riahi et al. 2016) and can lead to unwelcome occurrences such as absconding (Muir-Cochrane et al. 2021). A selection of contributing factors relating to suicide risk and staff members is further examined in this context.

4.4.1 Close observations

Also commonly referred to as 'one-to-one'; 'special'; 'maximum'; 'continuous'; or constant observations (Bowers and Park, 2001; Mackay et al. 2005), close observations typically refer to the temporary allocation of a staff member with a specific patient in order to increase supervision levels and reduce the risk of harm (Stewart et al. 2010). Although there appears to be no overarching national policy in Ireland, the local policy on observation locally in Waterford/Wexford mental health services (HSE, 2018) utilises guidance offered by NICE in the UK (NICE, 2015). As such local policy dictates three levels of observation from general observations (level 3) (the minimum level expected for all patients) up to 'Level 1 special observations' for the highest risk patients (continuously within eyesight and at arms lengths).

For acutely suicidal patients, the use of level 2 (15-30 minute checks) is not recommended in this local policy guidance and indeed clinical experience suggests that this level of observation is not used locally. Writers such as Jayaram et al. (2010) refer to the inherent difficulties in predicting suicide and highlight the number of suicides that have occurred whilst patients have been on 15 minute as opposed to constant observations. A UK study of suicides amongst mental health inpatients under observation reflects this finding reporting the majority of these suicides as occurring whilst patients were under intermittent observation (Flynn et al. 2017).

Staff and patient perspectives in relation to close observations suggest differences in terms of intended purpose and actual lived experience. Best practice tends to emphasise that close observation is an opportunity for 'therapeutic engagement' and not merely a process of maintaining safety (Insua-Summerhays et al. 2018). Local policy guidelines in the South East of Ireland (HSE, 2018: p.4) reflect this line of thinking, citing observation as "one aspect of caring for people during high distress" and adding "It is clearly not enough to simply observe people. The process must be safe and therapeutic." Barnicot et al. (2017) also highlight the value of close observation in facilitating continuous and uninterrupted opportunities for therapeutic engagement, offering unique one-to-one time which may not be readily available otherwise.

In reality, however, there is the suggestion that both staff and patients perceive the process differently. In their study of patient and staff views, Insua-Summerhays et al. (2018) found that the two groups often tended to withdraw from therapeutic engagement as they did not think the other person wanted to fully engage in the process. Barnicot et al. (2017) cites invasion of privacy as a factor in this withdrawal, both in terms of patient experience and staff awareness. Historically, one of the most common negative experiences for patients is the high degree of intrusiveness inevitably associated with the process (Cardell and Pitula, 1999; Bowles et al. 2002; Sakinofsky, 2014), whilst, for staff, it can be a decision making factor in opting for a less stringent observation level (Jayaram et al. 2010) or can be a source of increased stress, particularly where it is felt that patients may respond aggressively to constant monitoring (Stewart et al. 2010).

It is also widely reported that staff may not consistently agree with decisions to commence and maintain close observations; conflict that can lead to widely variable practice (Stewart et al. 2010; Insua-Summerhays et al. 2018; Barnicot et al. 2017). Professionals have also expressed concerns over resource issues in relation to staffing levels and the demands of one on one close observations (Hunt et al. 2016) plus the negative impact on other patients not deemed 'high risk' (Large et al. 2011).

From a patient perspective, there are some clear positives highlighted, including the sense of safety and support that can arise (Cardell and Pitula, 1999; Barnicot et al. 2017) plus a sense of protection from other threats sometimes posed by fellow patients (Warr et al. 2005). However, patient observation is also heavily criticised for a number of reasons. Buchanan-Barker and Barker (2005) feel that patient observation is anachronistic as it is fundamentally based in psychiatric medicine and as such does not advance the nursing profession. The authors refer to observation as one aspect of default risk management strategies, where organisations have to be seen to control risk rather than focus on patients' individual needs.

This concern is not a new phenomenon, however. Ray and Allen (2015), for example, refer to Superintendent of Bethlehem asylum comments from 1884, where a reported over-implementation of observation practices was felt to place too much emphasis on suicide protection and not patient treatment itself. This is further reflected in calls to remove observation as a practice entirely (Barker and Cutcliffe, 2000); the process being seen to lack empirical evidence in support of its efficacy, whilst failing to reflect recovery principles at odds with “restrictive, intrusive and controlling” containment methods (Ray and Allen, 2015: p.381).

Despite the criticisms regarding patient observation, it remains widely recommended as a significant means of preventing suicide. In a suicide prevention study by Bowers et al. (2011) the writers recommended the increased use of patient checks and observation as a primary preventative strategy. Similarly, Hunt et al. (2012), examining inpatient suicide by ligature points, highlighted the importance of observation practices, especially during a patient’s first week in hospital. Further supporting the use of effective observation, Janofsky (2009) has highlighted how ‘incomplete’ or ‘infrequent’ observation is a commonly cited cause of inpatient suicide.

4.4.2 Staff attitudes and skills

A more balanced view of patient observation could be that it is a positive, therapeutic experience when staff members are caring; emotionally supportive and interested/ available to talk; whilst being counter therapeutic when staff act in an opposite manner (Cardell & Pitula, 1999; Ray et al. 2011, Insua-Summerhays et al. 2018). In terms of patient observation as a contributing factor for suicide, therefore, it is not just a question of whether a patient is being observed or not but the inherent skills, attitudes and knowledge of the clinicians involved. This has wider implications in terms of the antecedents of suicide, both on inpatient units and in community settings.

In terms of attitudes towards suicide, a number of general population factors are linked with how suicide and suicide attempts are perceived, including cultural values (Lenzi et al. 2012); gender differences (Poreddi et al. 2016); age and views on mental disorder (Na et al. 2018) and religious beliefs (Lawrence et al. 2016). From a clinician perspective, research literature relating to skills and attitudes suggests that the two aspects are closely linked, with more positive attitudes towards suicide being closely associated with the acquisition of training and knowledge (Herron et al. 2001; Samuelsson & Asberg; 2002; Brunero et al. 2008; Ramberg et al. 2016).

Clinician experience of past patient suicide is another significant factor in attitude formation, seen from a positive perspective in terms of learning from a serious incident (Ramberg et al. 2016) and from a negative perspective in relation to the stress and trauma often evoked, particularly when support or supervision is not forthcoming (RCPsych, 2020; Glodstein, 2021). In their study of professional attitudes to suicide prevention programmes, Brunero et al. (2008) noted that whilst previous experience of working with suicidal patients appeared to have no effect on attitudes, those impacted on a personal level (e.g. family member or close friend) tended to develop a more positive outlook.

Exploration of attitudes to suicide is one aspect of a well utilised suicide prevention programme aimed at healthcare professionals in Ireland, entitled ‘ASIST’ (Applied Suicide Intervention Skills Training), a two day programme aimed at reducing the immediate risk of suicide (HSE 2021). The training has an established evidence base for its effectiveness (Gould et al. 2013) and includes how to understand and interact with people at risk, plus helping those persons to produce a ‘safety plan’ for the future. Safety plans encourage personal strategies for managing suicidal urges such as the use of distraction; reviewing reasons for living and the identification of support persons (friends, family and professionals) with whom they can interact during a crisis period (Turecki et al. 2019). Other formal education and training methods commonly associated with the care of suicidal persons include dialectic behaviour therapy (DBT) and cognitive behaviour therapy (CBT), where personal traits such as low distress tolerance and poor problem solving skills are identified and addressed (Turecki and Brent, 2016).

Availability and uptake of such training is significant considering nursing staff frequently feel that they lack the confidence and skills to care for suicidal persons. (Rebair and Hulatt, 2017).

4.4.3 Suicide risk assessment

The assessment of suicide risk is frequently seen as a pre-requisite skill for staff working in mental health services (McLaughlin et al. 2014; Graney et al. 2020). Successful risk assessment is felt to be achieved through comprehensive clinical interview encompassing the observing of behaviour as well as assessing speech/thought content; past and current risk factors (e.g. past history of self-harm or drug/alcohol misuse); current plans/intent and identifying the person's needs in terms of coping abilities (Harding, 2019). Despite this, the use of suicide risk assessment remains controversial for two main reasons.

The first area of controversy is in relation to its level of effectiveness, especially in relation to risk assessment tools. Systematic reviews of multiple risk assessment tools and their ability to predict future suicides and self-harm episodes frequently cite a lack of evidence for routine clinical use (Chan et al. 2016; Quinlivan et al. 2016; Runeson et al. 2017) whilst NICE guidelines warn against the use of risk assessment tools and scales to predict future suicide or as a means of allocating resources (NICE, 2011). Similarly, a meta-analysis focusing on 50 years of suicide prediction studies found that prediction was only marginally better than chance for all outcomes, whilst this predictive ability had not seemingly improved over the 50 years examined (Franklin et al. 2017).

Critics of suicide and self-harm risk assessment argue that suicide risk is just too multi-faceted and changeable to be able to accurately predict (Bouch and Marshall, 2005; Wand, 2012); made more difficult by a reliance on patient self-reporting (Bolton et al. 2015) where many people die from suicide without ever disclosing suicidal thoughts to a professional (Sheehan et al. 2017) or fail to seek help due to the fear and stigma surrounding the phenomenon (D'Hotman and Loh, 2020). Furthermore, evidence points to suicide being difficult to statistically predict even in 'high risk' groups because of the low base rates of suicide in general populations (Harris and Hawton, 2005; Bolton et al. 2015).

Consequently, where risk assessment tools produce false positives (when patients are incorrectly deemed at high risk of suicide) and false negatives (when patients are incorrectly deemed low risk but go on to attempt/complete suicide) levels of resources may be misdirected (Quinlivan et al. 2017; Runeson et al. 2017). The principal use of demographic risk factors in current risk assessment tools has also been questioned, with such factors seen to increase the risk of suicide amongst a general population over time, but failing to predict individual suicides at any specific time-point (Bolton et al. 2015; RCPsych, 2020).

The use of risk assessment tools is not wholly dismissed in the research literature, however, with risk assessment methods such as 'structured professional judgement' (the combining of unstructured professional judgement and actuarial tool use) seen as a better alternative to risk assessment tools alone (Fagan et al. 2009; Higgins et al. 2015). Similarly, clinicians have expressed how the use of a risk assessment instrument enables a frank discussion on risk and helps develops a trusting relationship (University of Manchester, 2018) whilst at the basic level it can provide a baseline assessment and a checklist of possible risk factors (Fazel and Wolf, 2018). A clinical obligation to assess suicide risk also avoids the widely reported barrier of clinicians choosing not to ask about the subject due to fears it may trigger or worsen a patient's suicidal thoughts (Bolton et al. 2015; Dazzi et al. 2014).

Whether viewed from a positive or negative perspective, current research also suggests that intelligence and 'machine learning' algorithms may help predict and prevent suicide, with results across a number of studies suggesting that AI can outperform clinicians in terms of predicting suicide and suicide attempts (Kessler et al. 2017; DelPozo-Banos et al. 2018). D'Hotman and Loh (2020) reflect on the wide availability of electronic health records (and the linking of this data with other sources to form 'big data') to detect patterns inherent in a person's documented biological, social and psychological health status. Whilst acknowledging the significant ethical issues that may arise, the authors also refer to the use of AI in monitoring suicide risk through online and social media use. For writers such as Franklin et al.

(2017) these strategies should replace more traditional clinician based forms of suicide risk assessment.

Such advances in the use of technology do not necessarily detract from (and arguably may only serve to increase) a notion perpetuated in healthcare that risk assessment can be used to predict and prevent all types of harm including self-harm and suicide (Slemon et al. 2017). This is a second area of controversy in the research literature. Whilst the evidence presented thus far suggests that suicide prediction is an inexact science, this uncertainty is seen as negative and undesirable by clinicians from a risk management perspective, creating significant professional anxiety (Morrissey and Higgins, 2019). Efforts to control this anxiety can lead to what other authors suggest is a form of defensive, risk-averse practice where the process of assessing risk detracts from therapeutic interventions and the supporting of individual care needs (Wand, 2012; Murray, 2016).

When suicide does inevitably occur; clinicians may then experience feelings of professional responsibility; blame and rejection; which, in turn, leads to a repetitive cycle of anxiety and risk-averse practice (Morrissey and Higgins, 2019). If this is indeed the case and the quality of care and support offered to patients by clinicians is detrimentally affected, it could ultimately be deemed a contributing factor in patient self-harm and suicide. Writers appear keen to recommend that organisations focus more on public and population level education/information programmes to encourage a better understanding of risk assessment and its limitations (Walter and Pridmore, 2012; Wand, 2012; Szmukler and Rose, 2013).

4.5 Organisational/environmental factors in suicide/self-harm with suicidal intent

Organisational and environmental factors related to suicide risk are widely examined in the literature and frequently from an inpatient mental health perspective. Areas of safety and security such as the use of locked areas, ligature-free environments and the prevention of absconding are some examples of relevant risk management practices aimed at minimising risk and ensuring patient safety. This also needs to be viewed in the context of available resources/funding and the move from acute inpatient to community-based models of care such as home treatment; challenging conventional methods of suicide risk management. These areas are examined in further detail.

4.5.1 Inpatient safety and security

Literature considering suicide risk and the physical environment tends to focus on reducing access to the means of harm. Some of the most common safety and security measures adopted by healthcare organisations include door locking/access systems; the banning or removal of items (e.g. laces; glass bottles); use of non-breakable/non-sharp windows/mirrors/kitchen utensils; locked bathrooms and ligature point removal (Bowers et al. 2002; Tishler and Reiss, 2009).

The development and maintenance of ‘Ligature-free’ inpatient units is a recurring issue in the literature; writers such as Bowers et al. (2014); Hunt et al. (2012) and Kapur et al. (2022) citing the significant UK reduction in cases of inpatient hanging as a result of removing ligatures and the conducting of regular audits. A US review of inpatient suicide by Tishler and Reiss (2009) also suggests the removal of potential ligatures whilst including a number of other environmental recommendations such as removal of belts, laces etc., restricting visitor items and having non-breakable glass and mirrors. Historically there has been significant variation in the type and degree of safety measures utilised within inpatient units, with inconsistent policies noted in relation to removal or banning of clothing and other items (e.g. glass bottles; mobile phones) (Bowers et al. 2002).

The development of such safety measures is not without criticism or debate however. Walter and Pridmore (2012), for example, note that a ‘hanging point’ is not necessarily required to cause death by strangulation and refer to the many cases of suicide in notoriously secure settings, although it remains a fairly rare occurrence both in Ireland (Malone et al. 2015) and internationally, where the rate is cited as being between 0.1% and 0.4% of all psychiatric admissions (De Santis et al. 2015). In the USA, Simon & Hales (2012) report that approximately 5–6% of all yearly suicide deaths occur in hospital settings.

Given the previously discussed limitations of suicide risk assessment, the implementation of universal safety measures would appear judicious in terms of reducing risk. An occupational health paradigm, as outlined by Hansen (1996) is seen as a way of reducing violence through the use of blanket measures (e.g. removing dangerous items). Such an approach appears to be widely applied from a suicide risk perspective also, where maintaining a safe physical environment for all patients takes into account the unpredictable nature of individual risk prediction (Lieberman et al. 2004)

One of the challenges of this approach, however, is the conflict this creates in terms of organisational safety and security as opposed to maintaining a therapeutic environment. The locking of unit doors, for example, may improve safety but can simultaneously emphasize staff control; reinforce stigma and lead to worsening depression and frustration (van der Merwe et al. 2009). In their literature review of patient safety as it applies to mental health care, Kanerva et al. (2013) suggest that part of the organisational management's role is to maintain a safe environment, but to also understand that environmental safety factors can, in themselves, cause trauma.

In a debate paper by Large and Kapur (2018) the authors highlight the positive and negative aspects of inpatient care as it relates to suicide prevention. The degree of empirical evidence for the effects of hospitalisation is questioned with inpatient care itself being seen as a possible cause of suicide, particularly when linked with the effects of stigma and loss of social role, plus the increased risks arising from long or frequent hospital stays. The opposing view provided is that community based services, such as crisis teams, are now seeing double the number of suicides compared with inpatient services, whilst reduced bed numbers means illness thresholds are higher, but suicide rates have fallen. The authors add that the decreasing rate of inpatient suicide in the UK has been associated with an improved focus on safety, including the removal of ligature points and greater control over people leaving hospital units.

The current focus on ligature points is significant given that hanging is consistently noted as one of the primary causes of inpatient suicide; alongside cutting, strangling and overdose (De Santis et al. 2015; Williams et al. 2018); and jumping from heights or in front of a train (Deisenhamer et al. 2020). Jumping as a means of suicide has been found to be more prevalent than hanging when the person has absconded from inpatient care (Hunt et al. 2016).

4.5.2 Absconding

Absconding is defined in Ireland as “the unauthorised absence of an admitted patient from the boundaries of the care unit without staff knowledge” (HSE, 2015: p10). It has significance in relation to suicide, with research suggesting an association between inpatient suicides and absconding or elopement from psychiatric care (Lieberman et al. 2004; Bowers et al. 2008b; Large et al. 2011). Results from a recent Danish study found that 50% of all inpatient suicides occurred whilst the patient was either on leave or following a person’s absconsion from the unit (Madsen et al. 2020). Similar research studies have put the rate of suicide after absconding at between 36% and 63% (King et al. 2001; Hunt et al. 2010). Varying definitions of absconding internationally and regionally may limit the results of research studies (Voss and Bartlett, 2019). One example is the complexity pertaining to voluntary and involuntary patients, particularly in terms of legal status; seeking permission to leave and failing to return at agreed times (Muir-Cochrane et al. 2021).

A higher prevalence of absconding is reportedly linked with certain patient characteristics such as younger age and involuntary status (Bowers et al. 1998; Gerace et al. 2015) in addition to a higher level of risk being evident within the first 7 days of admission (Muir-Cochrane et al. 2013). The reasons why patients abscond are manifold, with inconsistent findings in terms of staff and organisational factors such as staffing levels; staff experience; levels of observation; type of unit design and the locking of doors (Hunt et al. 2016). A recent study has, however, highlighted a number of individual factors involved including conflict with other patients; conflict with staff including misunderstandings and lack of communication; receipt of bad news and changing to a less acute level of care (Muir-Cochrane et al. 2021).

Whilst acknowledging an association between psychiatric symptomatology and absconding, writers such as Voss and Bartlett (2019) and Muir-Cochrane et al. (2021) see specific reasons for leaving as frequently unrelated to anything other than wishing to attend to external, day-to-day, tasks and needs. The authors suggest that this is reflected in the majority of absconding periods being less than one day and persons opting to return after carrying out their activities.

Organisational safety measures to prevent absconding and suicide risk, such as door locking, tend to be controversial. To illustrate, one recent study found no differences in suicide and absconding rates across open and locked areas (Huber et al. 2016). Similarly, there are ongoing moral and legal perspectives to consider when voluntary patients are, in essence, confined to locked clinical areas (Van Der Merwe et al. 2009). Somewhat counter-intuitively there is also the suggestion that open units may, in fact, reduce the risk of absconding as a result of patients being more satisfied with their surroundings and experiencing a lesser degree of stigma (Lang et al. 2010). Whilst this interpretation was also advanced by Huber et al. (2016), it belies the fact that patients may just be less acutely unwell and therefore at less risk of absconding on open units (Burns, 2016).

It is argued that reduced bed capacity and the availability of acute care alternatives, such as home treatment, has resulted in much higher levels of risk, morbidity and involuntary treatment on inpatient units; thus requiring higher levels of safety and security (Huber et al. 2016; Voss et al. 2019). The brevity of admission stays associated with contemporary psychiatric care also means that there is arguably more of a reliance on safety measures than taking time to develop therapeutic relationships (Huber at al. 2016). Whilst absconding and suicide risk are seen as one of the main reasons for locking doors, it should be noted that these are not the only risks considered by healthcare organisations. The protection of inpatient populations from unwelcome outside influence such as the transfer or sale of illicit drugs being another frequently cited reason for locked doors (Burns, 2016).

4.5.3 Suicide risk and community-based care

As noted, organisational and environmental approaches to suicide risk are often considered from a traditional hospital based perspective. This is despite the international trend towards reducing inpatient bed capacity and developing community services. Shorter inpatient stays and a greater focus on family/carer/peer support involvement are likely to impact on the way risk is managed in community settings, whilst issues relating to funding and resources are likely to be challenging in the context of community based care models.

The care provided on a person's discharge is significant given the higher risk of suicide identified during this period (Bickley et al. 2013; Chung et al. 2017; Madsen et al 2020). Similarly, despite advances in community care, there is evidence that suicide rates among discharged patients have not decreased in the past 50 years. Recent evidence from the UK found that post-discharge suicides made up 17% of all patient suicides (University of Manchester, 2018). Furthermore, writers such as Hunt et al. (2012) and Sakinofsky (2014) have reported higher levels of risk associated with the early period of hospital admission, short admission stays and the immediate post-discharge period. As a consequence, guidance often recommends rapid follow-up once a person leaves inpatient care; within a week in Ireland (where risk of suicide has been identified) (MHC, 2009) and within 3 days in the UK (Bojanic et al. 2020).

The reasons why risk appears higher during this transition are widely debated. Evidence suggests some connection with patient characteristics such as being male (Chung et al. 2019); and being over 40 years old (Bickley et al. 2013). Other evidence supports the absence of employment as a major risk factor in addition to living alone and having low levels of social support (Troister et al. 2008). Using variables such as patient characteristics to identify those most at risk post-discharge is, however, discouraged by writers such as Chung et al. (2017); citing again the inconsistencies evident in assessing suicide risk and favouring a more universal approach to increased support in the immediate period after discharge.

However, from an organisational perspective, greater prevalence has been highlighted where patients have taken their own discharge from hospital (Hunt et al. 2009; Riblet et al. 2018; Bojanic et al. 2020) or where their final inpatient admission was for a short period only (Tseng et al. 2020). This contrasts with other research findings which suggest that lengthy; extended or frequent admissions also increase the risk of suicide (Large et al. 2011). For writers such as Meehan et al. (2006) the fact that patients may take their own discharge presents challenges in terms of patient engagement with follow-up care. Bojanic et al. (2020) refer to the significant number of patients with diagnosed personality disorder who die by suicide within 3 days of hospital discharge, noting a frequent absence of referral or follow-up care options. Such difficulties are further acknowledged by writers such as Grenyer et al. (2018), citing the long waiting times often associated with specialist psychological therapies.

The availability of appropriate community based resources is also discussed in the available literature. Examples, including a US study examining the impact of psychiatric bed reductions by Shumway et al. (2012) have reported little impact on patient wellbeing, including rates of suicide; the writers referring to reductions in lengths of stay as a result of optimal communication/liaison with community and outside agencies. However, a conflicting argument is reported by Yoon and Bruckner (2009) who suggest that the process of bed reduction has in fact increased the rate of suicide in the USA. The writers argue that parallel increases in community care do not provide the same level of 'safety net' as inpatient beds. This theme is discussed by Flannery and Flannery (2014) who feel that community services should be further adapted, using support readily available on inpatient units such as safe holding areas and moving these to day-care settings.

Adapting community services to manage suicide risk, especially post-discharge, clearly presents many challenges in terms of increased risks and available resources. For some writers, involving family and carers is a particular area of emphasis. Wayland et al. (2021), for example, highlight the challenges associated with family or carers becoming the owners of risk in terms of observing for suicidal thoughts and behaviour. How professionals support family and carers with the emotional burden of managing this risk is also discussed. For other authors, there is a risk of family members being drawn into a more custodial or professional role, which in turn may reduce the protective elements associated with family support (Sellin et al. 2017; Morrissey and Higgins, 2019; Vandewalle et al. 2021).

Such challenges are inherent for acute community services such as crisis resolution or home treatment teams. An increasing rate of suicide within UK crisis teams (in comparison to inpatient care) has been highlighted as a cause for concern (Hunt et al. 2014). Furthermore, Hunt et al. (2016) suggest that reduced levels of staff availability and intensive treatment (when compared with inpatient units); high caseloads of acutely unwell persons; taking people home too quickly from inpatient care and the unsuitability of some home environments (in terms of a lack of social support or crisis exacerbation) are possible factors for this increase. However, this is contrasted by evidence highlighting greater satisfaction with crisis teams, particularly in terms of reducing the stigma of admission; addressing social or family issues (where these are a significant contributory factor); the retention or development of coping skills and a more equal power relationship between patients and professionals (Johnson, 2018).

4.6. External factors in suicide/self-harm with suicidal intent

A significant number of antecedents and contributing factors linked to suicide arise from a more social; economic; political or cultural context (Milner et al. 2013). Indeed, the social context of suicide been recognised for over a century, with suicidal behaviour historically viewed as a barometer of socio-economic hardship and societal changes (Durkheim, 1897). Available systematic and narrative reviews suggest there are a multitude of specific factors associated with suicide risk, which although inter-related can be viewed as distinct from patient, staff and organisational/environmental factors.

These include income/financial concerns; low education; employment issues and unemployment; relationship issues; religion and socio-cultural norms; economic crises; place/location of residence; homelessness; access to lethal means and being in a minority group (e.g. LGBT community) (Milner et al. 2013; Coope et al. 2015; Hunt et al. 2016; Turecki et al. 2019; Junior et al. 2020); environmental events (e.g. climate change; forced migration; natural disasters, armed conflicts) (Lund et al. 2018: Knipe et al. 2022) and certain aspects of social or digital media use, particularly in the context of adolescents and young adults (Macrynikola et al. 2021).

Examining all these areas in detail is beyond the scope of this review. However, a number of areas are examined further within an Irish context, where issues such as traveller mental health; rural communities and unemployment/economics have been highlighted as particular areas of concern (O'Donnell and Richardson, 2018). Closely linked to factors such as economics; unemployment and social isolation, the current COVID-19 (coronavirus) pandemic is also examined in terms of its impact on suicide risk.

4.6.1 Traveller mental health

Globally, belonging to a minority ethnic population has been associated with heightened risk of suicide, including a number of indigenous groups such as Aboriginals and Inuits (Bellamy and Hardy, 2015; Chachamovich et al. 2015). Officially recognised as an ethnic minority in 2017 (O'Halloran and O'Regan, 2017) this also applies to the traveller community in Ireland, defined by the Irish Traveller Movement (2019: para. 1) as "an indigenous minority who, historical sources confirm, have been part of Irish society for centuries. Travellers long shared history, cultural values, language, customs and traditions make them a self-defined group, and one which is recognisable and distinct."

Research findings have shown that the rate of suicide amongst travellers can be up to seven times higher than the general population with suicide accounting for 11% of all traveller deaths (Abdalla et al. 2013). Whilst the reasons for this appear varied and complex, there are a number of commonly cited factors attributed to this phenomenon, predominately related to the social determinants of health such as poverty, discrimination and unemployment (McKey et al. 2020). Other cited factors include health inequality and lack of educational attainment (Brady and Keogh, 2018) in addition to frequently overcrowded and sub-standard living conditions (Watson et al. 2017). Discrimination, in terms of negative public and professional attitudes towards travellers, has been highlighted as a significant barrier in the provision of healthcare; housing; employment and education (Commissioner for Human Rights, 2008).

From a mental healthcare perspective specifically, there is a high level of stigma experienced in relation to mental health issues (O'Mahony, 2017) whilst other literature cites a significant degree of mistrust in relation to accessing mental health services (McFaddden et al. 2016) and use of crisis/emergency services as opposed to routine care (Abdalla et al. 2013). The cultural taboo of suicide amongst travellers, in addition to the spirituality embedded in their cultural beliefs, is seen as contrasting with the significant prevalence of suicide; contributing towards a potential contagion of suicide, where young adult peers, in particular, are negatively influenced (McKey et al. 2020). Whilst close knit family groups such as those seen in traveller community can be supportive, they are also viewed as counter-productive after a suicide, where feelings of stigma and an unwillingness to discuss feelings of mental distress are exacerbated by a lack of privacy and the far-reaching familiarity within the community (Keogh et al. 2020).

The juxtaposition between traveller culture and the ever increasing pace of the modern world is also viewed as causative of anxiety and depression (van Cleemput et al. 2007); where reduced freedoms, especially in terms of ability to travel, have been linked to loss of cultural identity (McKey et al. 2020). This conflict of cultures can increase suicide risk amongst ethnic minority and immigrant communities due to 'acculturative stress' or the presence of 'acculturation,' defined as "a process by which subjects acquire the attitudes, values, customs, beliefs, and behaviours of a different culture" (Forte et al. 2018).

4.6.2 Rural communities

Research in Ireland has shown that suicide rates tend to be higher in rural rather than urban communities (NSRF, 2011; Cleary et al. 2012). This phenomenon follows a pattern in Ireland where during the 1980’s rates of suicide in rural areas, especially amongst males, grew significantly whilst rates of male urban suicides remained unchanged (Kelleher et al. 2002). Globally, however, there are mixed results. Mirroring the trend in Ireland, a recent systematic review of literature across 4 countries (UK, USA, Canada and Australia) (Barry et al. 2020) found that persons living in rural areas are indeed more likely to complete suicide. In contrast, a Northern Irish study by Leavey et al. (2016) found no difference in suicide rates between rural and urban communities, whilst higher risk of suicide has historically been regarded as a predominately urban phenomenon (Isometsa et al. 1997; Riva et al. 2009). Furthermore, Nestadt et al. (2017) established that suicide was indeed higher in rural communities but only where a firearm had been involved, whilst Qin (2005) found that suicide risk appeared to increase with levels of urbanicity, but added that rates tended to be similar when adjusted for other confounding factors such as marital status, ethnicity and income.

Some of the suicide risks applicable to the travelling community in Ireland also appear to relate to those living in rural areas. Indeed, travellers, rural dwellers and farmers (particularly where these are middle aged males) are seen as priority groups in Ireland in terms of their vulnerability to suicide (O’Donnell and Richardson, 2018). Like travellers, rural dwellers with low educational attainment, limited job opportunities and dependency on welfare payments are felt to be at higher risk of suicide (Cleary et al. 2012) whilst retaining cultural values and a sense of community has been challenging for many rural dwellers as a result of changes within their communities.

Depopulation; economic recession; the closure of rural pubs and a decline in religious traditions and practices have reportedly led to reduced social contact; increased loneliness; the absence of informal supports during crisis periods and a feeling amongst rural dwellers that their communities have been left behind economically (Hirsch, 2006; O’Donnell and Richardson, 2018). Similarly, people living in rural areas have historically been considered to have a strong; independent, family-orientated work ethic, resulting in feelings of stigmatisation when mental disorder prevails (Hirsch, 2006). Cleary et al. (2012) highlights the sense of emasculation present in males experiencing mental distress in rural Ireland, leading to denial of difficulties or negative attitudes towards seeking help.

Access to lethal means is another risk factor associated with rural and farming communities in Ireland and indeed internationally. Firearm related suicides in Ireland have been reported as six times greater amongst those in rural as opposed to urban environments (Sarma, 2008). Historically, similar differences have been reported in the USA (Hargarten et al. 1996); the UK (Haw et al. 2004) and Australia (Burnley, 1995), whilst more recent research has identified farming communities as being at even greater risk of suicide involving firearm use when compared to non-farming rural dwellers (Kennedy et al. 2020). Similarly, pesticide poisoning is viewed as a largely rural phenomenon, accounting for significant numbers of suicides globally (Hirsch, 2006; Hirsch and Cukrowicz, 2014).

In terms of providing mental health services, geographic location can cause practical difficulties in relation to the availability of staff, appointments and appropriate facilities, whilst the often strenuous and unpredictable elements of rural employment (e.g. caring for crops and animals at unsocial hours) can restrict persons from attending appointments or fully acknowledging mental health difficulties (Hirsch and Cukrowicz, 2014).

4.6.3 Unemployment and economics

A great deal of evidence suggests that economic hardship, such as that experienced during economic recession in the 20th and 21st centuries, is associated with increases in the incidence of suicide (Chang et al. 2009; Luo et al. 2011) and particularly amongst males (Corcoran et al. 2015). Similarly, increased population level rates of suicide appear to correspond with acute surges in unemployment (Stuckler et al. 2009), with a two to threefold increase in the risk of suicide cited for unemployed persons compared with those in employment (Milner et al. 2013).

Whilst job loss and unemployment are key elements of recessionary times and are therefore important contributors in the rise of suicides (Gunnell and Chang, 2016), there are other ripple effect factors resulting from economic downturn, including debt; house repossession and homelessness plus cuts in healthcare funding (Haw et al. 2015). This is evidenced by research citing that suicide rates were increasing even before the most recent global recession (Coope et al. 2015). In Ireland, the effects of this recession (2007-2012) have been viewed as profound (Corocoran et al. 2015); the authors highlighting a doubling in unemployment rates; falling house prices; negative equity; significant personal debt and consequent austerity measures including tax rises and government spending cuts.

The literature would suggest that recession can lead to other known risk factors for suicide such as increases in mental disorders (Gili et al. 2013); self-harm and alcohol abuse (Eliason, 2014). Conversely, those with pre-existing vulnerabilities including mental health issues; relationship difficulties and low income appear to be even more adversely affected by recession (Gunnell and Chang, 2016). As such, writers cite a number of interventions both at government and organisational level to limit the impact of recession and unemployment on suicide. From a mental health perspective, these include service investments such as the expansion of crisis and telehealth services (Deady et al. 2020). From a wider perspective areas such as active employment programmes; the avoidance of spending cuts which affect the most vulnerable; family support; additional welfare benefits and debt relief are also recommended (Gunnell and Chang, 2016; Hensher, 2020). Such interventions have been linked with lower rates of unemployment-related suicides (Haw et al. 2015).

4.6.4 COVID-19 (coronavirus)

Recession and unemployment are closely aligned with the recent coronavirus pandemic, albeit the full extent of the virus's impact has not yet been realised (Devitt, 2020; Deady et al. 2020; McIntyre and Lee, 2020). Since the start of the pandemic, rates of unemployment in many countries appear to have increased steeply (Su et al. 2021) and indeed the rate of suicide is expected to rise accordingly (McIntyre and Lee, 2020; Kawohl and Nordt, 2020). However, recent media reports appear to suggest that unemployment rates are falling again as economies appear to recover slightly, with this trend noted in Ireland (Burke-Kennedy, 2021) the UK (Inman, 2021) and the US (Rubin, 2021).

Whilst it is currently unclear exactly how the virus will continue to play out in terms of economics, its impact on health and specifically suicide risk has been keenly discussed in the literature. Thus far, suicide rates globally do not appear to have been affected by Covid-19 (John et al. 2020) although as Appleby (2021) notes it remains unclear whether this will change, citing a rise in suicides amongst females in Japan and the possibility that nuanced differences could well emerge.

In terms of mental health issues, studies have found increases in psychiatric symptomatology since the beginning of the pandemic, including increased levels of anxiety; depression and post-traumatic stress (Hossain et al. 2020; Hyland et al. 2020; Burke et al. 2020), particularly affecting healthcare workers (Hill et al. 2022). For patients receiving inpatient mental healthcare, increased stress has also been highlighted; exacerbated by the uncertainty of disease progression; strict visitor restrictions and difficulty establishing a rapport with staff members due to personal protective equipment use (Roth et al. 2020). Increased symptomatology, however, has not necessarily translated into a surge in mental health services presentations, with visits to hospital as a result of self-harm, for example, falling by 25% between 2019 and 2020 (Bracken, 2020).

Since the pandemic began a wide number of reasons, including unemployment, have been offered as to why Covid-19 may, in time, affect rates of mental illness and suicide, including anxiety about becoming infected; stress of enforced isolation; increased alcohol use; escalating domestic violence (Appleby, 2021) and the after-effects of severe illness such as traumatic hospital/ICU admission and long-term symptoms (Sher, 2020). Furthermore, Kelly (2020) notes that healthcare workers are significantly more likely to experience severe psychological distress when compared with the general population.

At this stage, however, evidence relating to the pandemic and suicide is based on impending predictions of recession and unemployment (McIntyre and Lee, 2020; Deady et al. 2020) or based on the fact that most significant global crises have resulted in some type of increase in suicides; Devitt (2020) using past examples of violence; natural disasters; epidemics and economic recession to illustrate upsurges in suicide during these periods. Conversely, writers can also reflect on the apparent reduction in suicides observed during wartime, suggesting that the social cohesion and solidarity accompanying Covid-19 restrictions has some similarity with wartime and may well realise itself as a protective factor (Deady et al. 2020; Devitt, 2020).

4.7 Discussion: Suicide/self-harm with suicidal intent antecedents

Suicide and self-harm with suicidal intent, as it occurs in the context of mental health services, is associated with a complex, diverse and often co-occurring range of contributing factors, as illustrated within this chapter where factors have been grouped into patient, staff, organisational and external categories. Whilst some persons who complete suicide are diagnosed with mental disorder or have had contact with mental health services, this is not always the case and the phenomenon remains a major public health issue, affecting all societies. Regardless of whether suicide occurs in the general population or within mental health services, recording accurate rates does not appear to be a straightforward task, given that establishing deaths as suicide can take considerable time to clarify via coroners' reports and is not always clear; for example where the death also occurs in the context of drug/alcohol misuse or where the person has self-harmed, but not in the context of prior suicidal intent.

The concepts of 'suicidal intent' and 'self-harm' and are also areas of complexity, where suicidal intent can vary greatly and alter rapidly at different times and where self-harm is often used as a term to encompass all types of self-injury, intentional or not. Whilst an effort has been made to separate the two phenomena over this chapter and the next (as both types are reported on incident forms) a limitation of reviewing the available literature is that definitions of self-harm may differ, whilst professionals may have different subjective interpretations regarding the nature of each ‘self-harm’ episode. Such differences may affect, for example, the number of incident reports completed and statistical data related to suicidal behaviour.

Identified in the literature are a wide range of personal or patient characteristics and demographics associated with increased suicide risk, including male gender, older age and the presence of mental disorder. Established theories of suicide such as the stress-diathesis model (Mann et al. 1999; Hawton and van Heeringen, 2009) would suggest that these predisposing risk factors bare greater significance when coupled with specific situational or cultural stressors, leading to the development of suicidal behaviour. In applying the model to tangible examples, suicide risk in older age may be exacerbated by physical illness or disability; risk resulting from genetic predisposition to depression/suicidality may be exacerbated by poor socio-economic circumstances or risk relating to being male and middle-aged might be increased as a result of substance or alcohol misuse.

Having knowledge in the contexts of both static and dynamic risk factors is therefore emphasised as important in terms of assessing suicide risk. However, even where patients appear to fit certain risk criteria (e.g. history of suicidality and mental disorder) assessment relies heavily on the “accurate and honest self-disclosure of the suicidal ideation they may be experiencing” (Hoyen et al. 2021: p. 1). This is not always straightforward, with many patients denying ideation before going on to die by suicide (Berman, 2018); or choosing to withhold suicidal ideation for fear or stigma or hospitalisation (Blanchard and Farber, 2020), in addition to the risk changing after assessment has been carried out (Deisenhammer et al. 2020).

Certain risk assessment procedures, particularly those involving tick-box or closed questioning have been criticised in the literature as they may facilitate this withholding or denial of suicidal ideation whilst failing to allow for greater narrative description (McCabe et al. 2017). It can be inferred from the literature that if clinicians take the time to establish a trusting and open relationship with patients over time and use more open questioning there is a greater chance of obtaining a more honest response. Arguably, however, professionals also feel under pressure from an organisational perspective to obtain all information relating to suicide risk instantly and in overly simplistic categorical terms. As such it can become a cursory process, where the answers to questions of suicide risk are often not clear, even to the patient themselves, within such a short timeframe.

Inpatient admission, as outlined by Large and Kapur (2018) is controversial in that the high rate of suicide post discharge is perhaps indicative of its safety value. In contrast it can also be considered damaging in terms of its short–lived effectiveness; the loss of social role which can occur and where it is a traumatic and stigmatising experience. For those patients who stay for long periods in hospital, loss of living and coping skills may occur. Risk of harm may actually increase, as a result of reduced supervision and monitoring and staff focusing on more recently admitted patients (Hunt et al. 2016). Also, in terms of safety measures such as close observations or seclusion, nurses, in particular, can experience some role conflict, where ensuring patient safety through the use of practices sometimes seen as restrictive can be viewed as counter-productive to the establishing and maintaining of therapeutic relationships.

Safety and security on inpatient mental health units remains a major area of concern in the reviewed literature. In terms of preventing suicide, environmental and organisational factors such as removal of ligature points, restricting access to means of harm (e.g. removal of clothing items or banning of certain items such as glass bottles) and absconding prevention are significant areas of focus.

There appear to be contrasting views in relation to such approaches, where safety measures such as ligature removal have been seen as effective in reducing inpatient suicide. Similarly, all-encompassing policies aimed at reducing the risk of self-harm do not appear to be readily reliant on individual suicide risk assessment, which in itself has been seen as flawed in terms of accuracy and producing both false positives and negatives. Such approaches to safety also allow for the fact that many inpatient units (since the development of community services) now tend to admit persons with greater degrees of morbidity and over shorter periods of time. In such instances, there may be high levels of unpredictability and there may not always be sufficient time to develop relationships to a point where suicide risk can be fully explored.

Simultaneously, however, creating environments wholly centred on safety and security can have an adverse effect on patients according to the literature. Rules and procedures focused on security may seem oppressive and restrictive, evidenced in research suggesting that more open environments tend to have little impact on levels of absconding or can even mitigate against it. Not all patients are at risk of suicide and yet measures such as restricted outside access and the locking doors are frequently applied across the board. In these instances, patients may feel traumatised by their hospital experience, leading to undesirable outcomes such as loss of confidence or an increased sense of stigmatisation.

The development of community services has implications for the management of suicide risk. Certainly, there appears to be a wide body of literature citing the interface between hospital and community as a significant meeting point in terms of potential suicide, particularly following discharge. Whilst the options afforded by community based services such as crisis or acute home-based treatment teams allow for more patient autonomy and avoid the negative aspects of hospital admission such as loss of coping skills, there is a sense that family homes may become the new institutions, with family members thrust into the roles of assessing and managing suicide risk.

Suicide also appears to be associated with a significant number of outside or external factors. In mental health services, however, the focus often appears to be on factors relating to the patient themselves (e.g. presence of mental disorder or severity of illness), the care provided by professionals and the organisation’s role in ensuring patient safety. What can be overlooked are the wider stressors in a person’s life; factors that are not always easily altered (e.g. cultural background; unemployment and social hardship; pandemic restrictions) and therefore significant in terms of ongoing suicide risk.

Chapter 5: Specific incident types and their antecedents (contd.)

5.1 Non-suicidal self-harm: Introduction

Self-harm from a non-suicidal context is viewed as a major health issue for many contemporary societies, particularly amongst younger people (Arensman and Kerkhof, 2009; National Health Service, 2018 (NHS); Mental Health Ireland, 2020). Characterised by self-poisoning or self-injury (Saunders and Smith, 2016) it can specifically involve cutting or burning; skin picking; pulling hair; hitting or punching and head banging (Catledge et al. 2012).

Self-harm presents significant challenges for mental health services, not least as a result of the close correlation between self-harm, formal psychiatric illness and increased suicide risk (Mental Health Foundation, 2020; O'Connor et al. 2018; National Institute for Health and Care Excellence, 2011) (NICE). It ranks amongst the most commonly cited risks in mental health services, alongside violence; absconding; medication errors; suicide and smoking/fire risk (Anderson et al. 2013). Whilst there are current health care, social care and economic costs associated with self-harm (Edmondson et al. 2016), the propensity of younger people to engage in self-harm also precipitates concerns in relation to poorer educational outcomes (Saunders and Smith, 2016). Although the primary focus of this review relates to self-harm and mental health services, it is important to note that a significant number of people who self-harm do not seek care or treatment from mental health services (Cerutti et al. 2012; Perry et al. 2012).

Differentiation is often sought between self-harm with and without suicidal intent. For example, NICE guidelines (2011: p.4) define self-harm as "any act of self-poisoning or self-injury carried out by an individual irrespective of motivation." However, self-harm is often demarcated solely in terms of non-suicidal intent. In these circumstances studies may refer to the phenomenon as non-suicidal self-injury (NSSI) (Bresin and Schoenleber, 2015);

Deliberate Self-harm (DSH) (Catledge et al. 2012) or non-suicidal self-harm (Gardner et al. 2016). Although 'non-suicidal self-injury disorder' is now a distinct psychiatric diagnosis in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (Selby et al, 2015), efforts to record and manage self-harm in terms of suicidal or non-suicidal motivation remain a significantly complex area (Stewart et al, 2011; Plener et al. 2015).

Regardless of this motivation, the prevalence of self-harm is believed to be most common amongst younger people. NICE(2011) guidelines report a rate of more than 10% amongst girls and more than 3% amongst boys (aged 15/16 years), whereas the rate across all age groups reduces to around 0.5%. In 2013, over 11,000 presentations to hospital were recorded in Ireland as a result of self-harm (Mental Health Ireland, 2020) with the rate reportedly increasing by 22% amongst 15-24 year olds between 2007 and 2016). Whilst self-harm is thought to increase from the age of 12 and decrease from the mid 20's onwards (Saunders and Smith, 2016) the lower rate of reported self-harm amongst older persons is contrasted with increased suicidal intent and a higher risk of fatality (Cheung et al. 2017; Morgan et al. 2018).

The prevalence of self-harm in terms of gender and ethnicity is diversely estimated. Females are reported to be more likely to engage in self-harming behaviours (Bresin and Schoenleber, 2015; O'Connor et al. 2018; Plener et al. 2015) with research suggesting that lower rates may exist in Asian countries (Carroll et al, 2014). However, specific anomalies can be found internationally with self-harm involving 'cutting' reportedly higher amongst men in Ireland than in other countries (Perry et al. 2012). Similarly, there is research associating higher rates of self-harm amongst, for example, indigenous populations (Dixon et al. 2014) and those living in rural areas (Krishna et al. 2014).

5.1.1 Non-suicidal self-harm: results summary

A literature review grid was used to summarise and analyse the reviewed research studies (Appendix 8). The evidence related to a number of countries including Ireland; UK; USA;

Australia, New Zealand; Germany and India. In comparison to the factors associated with mental health violence and suicide risk, there was less of an emphasis on hospital or inpatient care and a greater focus on younger, female populations. As a result there was less focus on how staff, organisational or clinical environments may impact on the prevalence of self-harm. As suicide and self-harm risk are often categorised together (and as noted are sometimes difficult to disentangle in terms of service user motivation), some of the risk issues within these categories such as ligature free wards, single rooms or staff checks on patients) may indeed be transferable factors.

5.2 Patient-related factors in non-suicidal self-harm

A number of common patient-related risk factors pertaining to non-suicidal self-harm have been examined in the available literature as follows.

5.2.1 Gender and age

As noted, age and gender are two of the most commonly referenced predictors of self-harm. A meta-analysis by Bresin and Shoenleber (2015) found that although the prevalence of self-harm amongst females is frequently higher it remains difficult to understand why this is the case, suggesting that biological factors; gender socialisation and a greater likelihood of seeking help (thus increasing statistical numbers) were possibilities. In addition to having a greater likelihood of seeking help, it is also suggested that females may be more likely to be referred, highlighting wider norms and values in relation to gender (Morgan et al. 2018).

When explored in greater depth, however, gender differences are not always consistent. For example, Cerutti et al (2012) found that gender differences did not exist amongst two of the samples they used in their study (a college and military establishment), whilst greater differences existed in terms of types of self-harm, with females being more likely to engage in ‘cutting’ behaviour. Again, however, this is counterbalanced by alternative studies such as Perry et al. (2012) who found that although males harmed themselves less using the cutting method, they tended to cause more serious injury, therefore utilising more healthcare resources.

A national UK-wide study by O'Connor et al. (2018) found that highest rates of NSSH occurred between the ages of 18-23, with earlier onset associated with greater frequency and repetition. In an Irish national registry study in Ireland, Perry et al. (2012) reported that the highest rates of DSH were amongst 17 year olds, reflecting the findings of other international studies in terms of late teenage years and peak prevalence (Plener et al. 2015; Stewart et al. 2011). Whilst being female and young and seen as frequent risk factors for self-harm, writers studying the phenomenon amongst older adults suggest that risks in other age groups should not be overlooked in terms of addressing care and resource issues (Cheung et al. 2017; Morgan et al. 2018).

5.2.2 Psychopathology and diagnoses

Self-harm has been associated with a number of different psychiatric diagnoses including depression (Plener et al. 2015) and psychotic disorders (Haddock et al. 2013) whilst the psychological basis for the behaviour is widely examined in the literature. A number of writers refer to the four function model of self-harm put forward by Nock and Prinstein (2004) which provides a psychological explanation for why people self-harm based on negative and positive reinforcement and serving intrapersonal or social functions (Box 4).

Box 4. Four function model of NSSI (Nock and Prinstein, 2004)

Reinforcement type	**Negative**	**Positive**
Automatic (Intrapersonal)	Decrease or eliminate aversive affective or cognitive state or states	Increase or generate desired affective or cognitive state or states
Social (Interpersonal)	Decrease or eliminate aversive social event or events	Increase or generate desired social event or events

In their study of male prisoners, for example, Gardner et al (2016) reported that emotion regulation and social functions were central factors preceding episodes of self-harm. Cerutti et al. (2012) refers to the role of self-harm in returning young persons to the ‘present’ from frequently dissociative states, whilst James et al. (2012) refers to self-harm within an inpatient setting, arguing that psychological distress is typically the main antecedent of such behaviour, which in turn serves a coping mechanism function. Bresin and Schoenleber (2015) report that females may be more likely to self-harm for intrapersonal reasons, whilst males tend to self-harm for social function reasons.

In their systematic review of self-reported accounts, Edmonson et al. (2016) provide two further theories in relation to the psychological functions of self-harm. The first suggests that self-harm may have an affirmatory role in self-identity, whilst the second aims to view self-harm as a ‘positive’ experience, describing how some persons find it comforting or even exhilarating in terms of experiencing something new.

A number of studies refer to the association between self-harm and personality disorder, particularly the diagnosis of borderline personality disorder (BPD) and its symptomatology of negative body image; emotion dysregulation and poor impulse control (Cerutti et al. 2012; Larkin et al. 2014). In addition, Gardner et al. (2016) suggest that those with a diagnosis of BPD may be more likely to self-harm for interpersonal as opposed to intrapersonal reasons. Although historically between 65 and 80% of persons with BPD are believed to engage in some form of NSSI (Brickman et al. 2014), the recent DSM-5 inclusion of NSSI as a diagnosis in its own right now allows clinicians to make a distinction between the two disorders (Selby et al. 2015).

5.3 Staff-related factors in non-suicidal self-harm

The impact professionals may have on the prevalence, occurrence and severity of self-harm is widely discussed in the literature. The most prominent areas of discussion are outlined as follows.

5.3.1 Assessment of self-harm and risk

The significance of a thorough biopsychosocial assessment of both clinical and risk profiles is highlighted by a number of authors (Catledge et al. 2012; Haddock et al. 2013; Perry et al. 2012). Whilst 'targeted' assessment of known vulnerable groups such as young females is recommended (Catledge et al. 2012) professionals are prompted not to overlook the possibility of self-harm in other groups such as men (Bresin and Schoenleber, 2015) and older adults (Morgan et al. 2018). In their review of assessment tools relating to self-harm, Borschmann et al. (2012) suggest that a combination of self-reporting methods, objective clinical assessment and medical record review should be utilised. This suggestion reflects research which has shown that in terms of measuring the prevalence of self-harm self-report studies tend to demonstrate a higher rate of self-harm repetition than hospital record based studies (Carroll et al. 2014).

The use of standardised procedures ensuring assessment of risk and the use of validated tools/instruments are also recommended within the literature (Larkin et al. 2014; Perry et al. 2012; Borschmann et al. 2012). Similarly, Quinlivan et al. (2014) note that although there is less consistency in relation to the use of self-harm measurement scales when compared with other risk categories, their use has been demonstrated to reduce the repetition of self-harm. There is a strong consensus related to a history of self-harm being a significant predictor of future harm (Perry et al. 2012; Morriss et al. 2013; Larkin et al. 2014; Plener et al. 2015; Stewart et al. 2011).

Whilst the importance of effective self-harm risk assessment is well documented, the significance of the therapeutic relationship between clinician and service user is also emphasised. For example, Borschmann et al. (2012) refer to the wider stigma often associated with self-harm and the reluctance some service users may have disclosing details without adequate trust and confidence in their care providers. Similarly, Quinlivan et al. (2014) suggest that 'tick box' risk assessment practices can impair therapeutic engagement, a point acknowledged by Catledge et al. (2012) who advocate for a collaborative approach to care and risk planning. The availability and willingness of professionals to allocate time and resources in order to listen, fully explore episodes of self-harm and maintain rapport is also highlighted, particularly within 24 hour care settings (Marzano et al. 2011; James et al. 2012).

5.3.2 Attitudes to self-harm

For some writers a key barrier to the establishment of a therapeutic alliance may be negative attitudes towards persons who self-harm. Clinicians, for example, may adopt a different attitude towards service users they perceive are 'choosing' to self-harm compared to individuals whose behaviour is believed to stem from a clear mental illness (Saunders et al. 2012). The same writers also indicate that females who self-harm are seen from a less negative perspective than males, whilst mental health staff are reported to have less negative attitudes in comparison to non-mental health colleagues.

Smith et al. (2015) suggest that negative attitudes may emerge from the 'system' that professionals work within, highlighting the often narrow focus on risk, diagnosis and preventing serious incidents which can result in staff feeling powerless if service users continue to self-harm. James et al. (2012) advocate for the wider adoption of 'positive risk taking 'amongst clinicians and health service, where service users are empowered to take a greater role in assuming responsibility for their self-harming behaviour.

5.3.3 Knowledge, training and supervision

Effective training and supervision for clinicians has been recommended to counteract the potentially negative attitudes towards self-harm. In a study examining mental health nurses personal opinions, Shaw and Sandy (2016) established that many clinicians they interviewed felt they had a lack of appropriate training and positive attitudes to deal with self-harming behaviour. As a result the authors produced a training model, incorporating various factors associated with attitudes to self-harm, including experience; level of knowledge and perceived seriousness, for use in undergraduate and postgraduate education. According to Saunders et al. (2012) a lack of research exists in relation to the impact of personal factors, such as ethnicity and social class, on overall self-harm attitudes.

Knowledge of interventions in the care of persons who self-harm is another area discussed in the literature. Harm minimisation and positive risk strategies appear to be well supported, particularly in relation to the utilisation of alternative, positive coping methods over efforts to completely suppress the self-harming behaviour itself (Edmondson et al. 2016; James et al. 2012). The experience of caring for persons who self-harm and carrying out such interventions can be anxiety provoking for clinicians, hence the significance of staff support and supervision, where clinicians can discuss their anxieties and concerns (Smith et al. 2015; James et al. 2012).

From an inpatient service user perspective, traditional methods of containing or preventing self-harm have relied upon patient checks and close observations. Whilst some writers continue to advocate for regular patient safety checks, ideally at random and less predictable times (Marzano et al. 2011), others feel that safety and security measures such as absconding prevention strategies or close observations can have a contrary impact in terms of curtailing personal autonomy and responsibility, leading to increased frustration and higher rates of self-harm (James et a. 2012; Stewart et al. 2011).

5.4 Organisational/environmental factors in non-suicidal self-harm

How services are managed and the availability and range of supports may also impact on the prevalence of self-harm. Factors include the organisational culture relating to areas such as harm minimisation approaches (James et al. 2012) and the local system for reporting and recording self-harm (Carroll et al. 2014; Dixon et al. 2019). Access to psychological support in addition to pharmacological treatment is a particular area of discussion in the literature, with therapies such as cognitive behavioural therapy (CBT); dialectical behaviour therapy (DBT) family therapy and other problem solving skills based groups/treatments recommended (Cheung et al. 2017; Perry et al. 2012; Plener et al. 2015).

Certain groups such as older adults may be disproportionately excluded from such therapies and frequently do not receive an appropriate referral to psychiatric services from primary care (Morgan et al. 2018). Saunders and Smith (2016) suggest that there is little evidence from randomised control trials that pharmacological interventions are fully effective in preventing self-harm and express some concerns in relation to the 'contagion' which can emerge from community/school based public health programmes.

The availability of community resources, particularly post discharge from hospital is another organisational factor considered. In their study of community follow up post discharge, Spittal et al. (2017) found that the first four weeks after discharge from hospital presented the highest risk period in terms of repeated self-harm, with poor inpatient/community communication a contributing factor.

Inpatient mental health units are referenced in a number of other organisational/environmental themes relating to self-harm. For example, the high incidence of self-harming in the evenings and in private areas (James et al. 2012) has implications for staffing, unit structure and patient check policies. Similarly, the higher risks associated with the first two weeks of hospital admission and after attempts to abscond (Stewart et al. 2011) have implications for observation, unit layout and risk management policies.

5.5 External factors in non-suicidal self-harm

A number of external factors are closely associated with the prevalence of self-harm. In their study of adolescents and young adults Catledge et al. (2012) cited a number of issues often linked with self-harm in younger people, including a history of sexual abuse; family dysfunction and issues relating to bullying and friendship and intimate relationship problems. In their Irish hospital based Larkin et al. (2014) highlighted a number of the same factors, also including stressful life events and financial problems. However the same authors also noted that, over time, repetitive self-harm tended to become increasingly autonomous, meaning that factors such as financial/relationship problems were not necessarily strong predictors.

Socio-economic deprivation and burden experienced by groups in terms of racial prejudice and their often isolated location is noted in a South Indian study by Krishna et al. (2014), who also highlighted the wider availability of more 'lethal means' in rural areas, such as pesticides. In a similar vein related to racial/cultural differences, western conceptualisations of self-harm may be seen to differ from those in other cultures. A self-harm study focusing on the aboriginal community in Australia (Dixon et al. 2019) found that a higher prevalence of self-harm amongst indigenous groups mirrored higher rates of suicide, when compared with the wider population.

Socio-economic issues and social deprivation are also often closely associated with drug/alcohol misuse difficulties. This, in turn, is associated with a higher prevalence of self-harm and a greater likelihood of repetition (Catledge et al. 2012; Marzano et al. 2011; Larkin et al. 2014; Perry et al. 2012; Cheung et al. 2017). Primary care referral to mental health services for care and treatment has also been reported to be less likely in more deprived communities. Unemployment and living alone have also been linked with self-harm presentations to hospitals (Perry et al. 2012).

Even where individuals are not living in their home communities, external factors can have an influence. In their study involving female prisoners who self-harm, Marzano et al. (2011) found that contributing factors such as bereavement were still a significant issue, often exacerbated by the person's incarceration.

5.6 Discussion: Non-suicidal self-harm

It is clear, from reviewing the literature, that 'self-harm' is a broad and often misleading term. At different points along a continuum, self-harm could mean anything from self-poisoning, serious injury or mutilation intended to end one's life, to minor injury aimed at relieving distress or, as is frequently the case in mental health services, simply a thought or series of thoughts. Reviewing the available literature, it is evident that each research paper requires the author/s to specify exactly how self-harm should be defined for their particular study.

The absence or presence of suicidal intention appears to be a significant factor amidst this complexity but often the intentionality is unclear, or may be interpreted differently from either subjective and objective perspectives. Efforts to distinguish NSSI as a diagnosis and condition from self-harm where suicidal intent is present have, in some ways, sought to address this dilemma. However, whilst the risk of suicide and accidental death remains so closely linked to self-harming behaviour, a degree of ambiguity is likely to endure. For mental health services, the increased risk of suicide associated with self-harming (regardless of intent) plus its frequent manifestation in conditions such as personality disorder, depressive and even psychotic disorders, means that it remains a significant issue in terms of prevalence, care and treatment approaches.

Whilst risk factors and potential predictors of future self-harm are explored in the literature, the majority of these are linked to patient related factors such as age, gender and diagnosis. The contextual role that staff, the organisation and the environment play, particularly within inpatient settings, appears to receive lesser attention. This point is echoed by James et al. (2012) who suggest that characteristic or demographic studies tend to neglect the immediate context of self-harm, the nature of the behaviour and management strategies. Similarly, Stewart et al. (2011) explore the role that containment and detention plays from an inpatient perspective, particularly in relation to frustration levels.

Such factors illustrate that, much like violence and aggression, the contextual factors relating to self-harm are manifold. It may also be that the lesser focus on clinician – service user; environmental or organisational factors may be a result of difficulty demonstrating any specific link. A good example of this complexity is the attitudes of clinicians to self-harm. Whilst it is documented that negative attitudes exist, particularly outside of mental health services, attributing these as a causative factor in episodes of self-harm is likely to be problematic, at least not without considering the significant number of other possible factors.

As clinicians, the most pragmatic approach, under these circumstances appears to be assessing the unique factors relating to each individual case as it presents. Indeed, Borschsmann et al (2012) suggest a process of ‘triangulation,’ whereby the service user’s subjective feelings are considered, alongside objective, professional judgement and medical record review. Clinical experience would suggest that the views of family; carers and close friends may help reveal further contextual factors, although this is not widely explored in the reviewed literature.

A diagnosis of personality disorder, closely associated with self-harm in the evidence, appears to raise two main issues from a mental health care perspective. Firstly, negative attitudes towards persons who self-harm are historically manifest in a well-documented level of wider clinical circumspection towards personality disorder (Chartonas et al. 2017; Day et al. 2018; Attwood et al. 2019). Clinical experience would also suggest that applying a label of personality disorder may then exclude any thorough examination of potential factors for self-harm beyond the diagnosis itself. Similarly, the level of concern; clinical intervention and value applied to the self-harming behaviour may be affected.

Research focusing on self-harm relative to psychotic disorders (Haddock et al. 2013), for example, raises a question as to whether clinicians sometimes apply a more positive, empathetic attitude towards those deemed to have psychosis and are therefore seen as ‘out of control.’ Indeed, negative attitudes towards self-harm have historically been linked to incidents where the service user has been perceived to be fully ‘in control’ (McHale and Felton, 2010). Similarly, clinical experience of inpatient psychiatry, in particular, would suggest that the social or ‘interpersonal’ theory of self-harm may be applied more frequently by professionals. A commonly experienced example can be used to illustrate this, relating to episodes of self-harm which emerge just prior to hospital discharge and may be perceived by clinicians as a manipulative means of triggering concerns amongst the care team.

The second issue related to the association between personality disorder and self-harm is the 'medicalisation' of self-harming behaviour. A number of studies in the review evidence suggest that self-harm should not necessarily be seen as a 'psychiatric' issue and indeed occurs frequently without persons seeking help. It could be argued that by the time a person is referred to secondary mental health services their self-harm is at a level of severity or distress that it naturally becomes a diagnosable medical issue. However, the evidence does at least suggest that self-harm be considered in a less negative way, for example the notion that self-harm may be a protective factor in terms of suicide risk.

Arguably, once self-harm becomes a medical or psychiatric issue, the onus of risk responsibility appears to move from the individual to the care team. Within inpatient psychiatry in particular, this onus of responsibility is discussed within the literature with many authors suggesting that a higher degree of 'positive risk' taking should apply to those who self-harm, returning or at least sharing some of the responsibility for the behaviour. The flipside of this are recommendations based on increasing levels of containment and risk minimisation such as increasing security to prevent absconding; more frequent and irregularly timed patient checks and close observations. Striking a balance between the level of self-responsibility promoted by mental health recovery advocates and adhering to local risk management strategies is an ongoing area of complexity, which is also pertinent to other areas of risk such as suicide and violence.

Clearly, having evidence based knowledge in relation to the main risk indicators associated with self-harm can be valuable, for example acknowledging that previous self-harm; being young and female or having a diagnosed personality disorder can be significant factors. However, there is also the possibility that 'false positives' may emerge from efforts to assess and monitor risk using clinical judgement or actuarial tools, thus raising issues in relation to unnecessary containment measures, a topic correspondingly acknowledged in studies on violence risk assessment (Large and Nielssen, 2017). Even accounting for relevant risk indicators such as age and gender, professionals are advised to remain vigilant to the prospect of self-harm in other groups, such as older populations.

Availability of clinical staff and resources is another issue highlighted in the literature. Access to a full range of treatments, particularly psychological or talking therapies, may be affected by factors such as geographical location, financial or staffing constraints. The often sensitive and personal factors related to self-harm may be understandably difficult to discuss, hence engaging trust and building rapport are clearly important clinical skills. Where difficulties can occur, however, is where staff in teams may disagree or miscommunicate over the best approach to utilise in supporting service users who self-harm. For example, the widely recommended approach of allowing a degree of self-harming behaviour but enabling the service user to seek less destructive/harmful alternative actions may not be successful if different approaches are taken by various team members. Such communication issues can create anxieties where staff may feel reluctant to utilise their skills; feel they lack sufficient knowledge or even seek to avoid direct service user contact.

In striving to manage the anxiety, distress and risks associated with self-harm clinical staff may neglect to acknowledge the outside or external factors which often underpin the behaviour. Clearly associated factors such as a history of childhood sexual, physical or psychological abuse cannot be downplayed in terms of trauma and impact on a person's behaviour. Equally, on a confined inpatient mental health unit it can be easy to overlook a person's home environment or their outside social circumstances when they present with self-harm. Even when seen at home or in a community setting, such factors such as family dysfunction, bullying or financial problems may not be immediately recognised as distinct issues.

Chapter 6: An overview of risk management in mental health services

6.1 Introduction

The assessment and management of risk remains a significant feature of mental health care internationally (Wand et al. 2015; Downes et al. 2016; Coffey et al. 2017; Roush et al, 2018). In Ireland, the concept of risk is integral to all areas of health service provision, including mental health services. This is reflected in a wealth of policy and guidance documents produced over the last ten years (HSE, 2009; Higgins et al. 2015; HSE, 2018; MHC, 2018).

Although Health Service Executive (HSE) guidance on risk applies to all areas of healthcare, there are specific areas of relevance to mental healthcare. These include the commonly cited risks of violence and suicide amongst users of mental health services (Briner and Manser, 2013) and the wider sphere of risk that can extend to other service users, their families, staff members and the general public (Taylor-Watt et al. 2017; Slemon et al. 2017; Robertson and Collinson, 2011).

Despite widespread consensus that risk has become a central component of mental health care, there remains considerable debate in relation to the purpose and effectiveness of risk management practices. At opposite ends of this debate are those who are critical of potentially harmful measures aimed at managing risk such as involuntary detention and seclusion, whilst citing the failure of risk assessment to prevent serious incidents (Szmukler and Rose, 2013; Wand et al, 2015; Callaghan and Grundy, 2018) At the other end of the spectrum there is wide support for the continued expansion of current risk management practices, including the use of actuarial risk assessment tools and risk assessment protocols to successfully identify and manage risk in various mental health settings (Croucher and Williamson, 2013; Carroll, 2014; Coid et al, 2016).

Occupying the middle ground within this contrasting debate is a recognition that both views are relevant and justifiable. Many writers offer a pragmatic view of risk management, acknowledging its merits whilst being awareness of its limitations (Carroll, 2014; Callaghan and Grundy, 2018; McCallum and Eagle, 2015). One example of this is the support for structured professional or clinical judgement (SPJ/SCJ) which incorporates the professional capacity for identifying risk through clinical knowledge and experience, balanced with the use of actuarial risk assessment tools (Downes et al. 2016; Robertson and Collinson, 2011).

Emerging in recent years is a move to alter the language of risk, the need to consider other areas of potential harm and not solely the dangers service users may pose to ‘themselves’ or ‘others’ (Slemon et al. 2017). This is reflected in a departure from terminology associated with traditional risk to a newer culture of patient/service user ‘safety’ (Callaghan and Grundy, 2018). As a result, some writers have reflected on the ‘iatrogenic’ risks of being a service user in mental health services such as harmful use of psychotropic medication and other ‘restrictive’ practices such as seclusion (Higgins et al. 2016a; Slemon et al. 2017).

For many mental health professionals, however, the risks posed by service users in terms of their potential for violence and self-harm/suicide remains a primary focus (Briner and Manser, 2013). An over-emphasis on these risk factors can lead to what some writers describe as ‘defensive’ clinical practice, whereby service users may be unfairly labelled, deprived of individualised care and prevented from making autonomous choices (Slemon et al. 2017). The potential incompatibility between these outcomes and ‘recovery’ in mental health is well documented in the literature (Coffey et al.2017; Downes et al. 2016). How the recovery approach and the assessment/management of risk may successfully co-exist is a source of ongoing debate (Wand, 2012; Grotto et al. 2015; Holley et al. 2016).

Such competing demands can create conflict for mental health professionals trying to support the individual needs of people in their care, whilst complying with employment regulations governing risk management policy and retaining their professional accountability and status (Downes et al. 2016). For many writers a more balanced and sensible approach to risk is required. This needs to be accompanied by greater management support for employees, an onus on the sharing of risk between professionals and service users and better public awareness in relation to mental health and risk (Buckingham et al. 2015; Robertson and Collinson, 2011; Slemon, 2017).

This chapter aims to examine the concept of risk as it relates to contemporary mental health services. It outlines the origins of assessing and managing risk and its later adoption by healthcare providers. It also examines how risk management has evolved since its inception, focusing on the current issues facing mental health professionals, providers and users of services. The main objective in carrying out this review of the literature is to examine and discuss the current ‘state of play’ in relation to risk assessment and management, focusing on published research evidence.

The chapter begins with a brief history of risk and its transition into mental health services. The main body of this chapter is a review of the collated literature. Identified themes are used as headings and within each sub-chapter comparisons and contrasts are made, offering a balanced view of the available literature. A discussion part follows, interpreting the findings in the context of clinical experience within mental health services locally. The chapter ends with concluding thoughts, providing a summary of the review whilst considering the future direction of risk management.

6.1.1 Literature search strategy

Relevant research literature from the past 10 years was chosen for its relevance to contemporary mental health services. In providing an international perspective, no countries were excluded but only those research studies published in English and with full text were retained. The terms ‘risk;’ ‘risk assessment;’ ‘risk management;’ ‘mental health’ and ‘psychiatry’ were used to obtain relevant literature. Abstracts were then screened to ensure that each study was relevant to adult mental health services.

The online databases used were Pubmed, EBSCO Host (including Cinahl, Medline, psychINFO and psychARTICLES), Science Direct and Wiley Online. Relevant literature was also sourced from documents and publications produced by official bodies such as the Health Service Executive (HSE) and Mental Health Commission (MHC).

The evidence was summarised using a literature review grid (Appendix 9). This helped to process and condense the basic details from each paper, alongside main points and recommendations. Organising the literature in this way helped with identifying themes and areas of potential discussion.

6.2 Historical context of risk

The Judgement Support Framework (JSF) (MHC, 2018), is a published guidance document assisting mental health centres in Ireland to comply with regulations under the Mental Health Act 2001. Within this document the term ‘risk assessment’ is used 12 times, across areas as diverse as service users being able to retain their personal property; having access to recreational activities; attending religious ceremonies or being transferred between health care facilities. Combining the terms ‘risk management,’ ‘risk assessment’ and the term ‘risk’ itself produces 115 separate entries.

The degree to which this terminology is used in the document reflects the extent to which risk is now firmly embedded and accepted within the language of modern mental health services. For some writers this central focus on risk within mental health over recent decades mirrors similar developments in other areas of business and industry. This focus on risk appears to be a pervasive and essential organisational/business component, stemming from efforts to reassure the public in terms of strict governance and accountability policies (Flintoff et al. 2019; Power, 2004).

Whereas this pervasiveness, from an organisational or business sense, may be a more recent development, the notion of risk can actually be dated back to the time of the renaissance in Europe and the introduction of numerals and arithmetic to help understand concepts such as odds and probability (Bardi, 2009). Similarly, Large (2013) discusses how probability theory, emerging in the 16th century, ushered in a mathematical approach to assessing the likelihood of harm. The positive contribution to society made by the study of risk is illustrated by Bernstein (1996) who suggests that the ability to balance decisions based on risk and probability has been central to almost all major inventions and innovations over the past 200–300 years.

6.2.1 Risk and mental disorder

Risk and the prediction of harm as it relates to mental disorder can also be traced back a number of centuries. Reporting extensively on violence and risk assessment from the 1980's onwards, Monahan (1988) relates accounts dating back to the 1700's referring to the connection between those formerly described as 'madmen,' their potential for self-harm and a requirement that others be protected from their potentially violent behaviour.

The institutionalisation of those diagnosed with recognised mental disorder in the 18th, 19th and 20th centuries is also closely linked with the concept of risk. Slemon et al (2017), reference the work of Goffman (1961) and Foucault (1965) to argue that societies legitimisation of risk and safety management, which emerged within these former institutions, remains valid today. Furthermore, literature relating to the history of mental disorder in Ireland (Kelly, 2016) cites how many of the practices in early psychiatric asylums emerged from prisons, thus perpetuating a link between mental disorder; risk; dangerousness and a need for confinement.

It is perhaps unsurprising, therefore, that many of the risk assessment practices used in mental health services today emerged from the criminal justice system and the care of 'forensic' service users with mental disorder (Scott, 1977; Monahan, 1981; 1988). The 1976 US 'Tarasoff' case in the USA, (where mental health providers were first legally obligated to protect persons who could be harmed by those with mental disorder) also focused on issues of risk, dangerousness and patient confidentiality (Adi and Mathbout, 2018). Whilst the criminal justice system and the care of mentally disordered offenders can be seen as providing the blueprint for modern risk management practices, their application within general adult populations remains a contentious area (Wand, 2012).

If risk was a major factor preceding and governing the running of large psychiatric institutions, it appears that little changed once 'deinstutionalisation' brought about the closure of many large hospitals. In fact some writers have documented how the emphasis on risk essentially increased with the closure of large hospitals. For example, Cummins (2018) suggests that the liberal ‘counterculture’ ideals of the 1960’s in relation to the ‘community’ care of marginalised people, such as those with mental disorder, never materialised in terms of framing risk in a less punitive way. Similarly, the UK government’s switch from institutional to community care in the 1980’s and 90’s (and the apparent failure of this policy to address risk to the public) is sometimes viewed as a major catalyst of the stringent risk management policies in place today (Flintoff et al, 2019).

6.2.2 Contemporary perspectives on risk and mental health care

The fundamental acceptance of risk as an integral part of health service management strategy continues to be questioned by critics of the concept. Coffey et al (2017: p478) describe the preservation of risk management processes as an “accepted fiction” shared by professionals and service users despite awareness that the concept is severely flawed. Similarly, amidst evidence of widespread support for risk management practices amongst professionals (Wand et al, 2015; Downes et al, 2016) there is concern that continuing to perpetuate the idea of risk as something that can be easily predicted or controlled is misguided; misleading for the public; professionally self-deceptive and ultimately of potential detriment to service users (Wand, 2012; Szmukler and Rose, 2013; Callaghan and Grundy, 2018).

Despite the degree of contrasting views in relation to risk and its place within mental health, it is clear that risk theory and practice continues to evolve. The supposition made by Meehl (1954) that mechanical or actuarial methods of assessing and predicting risk are likely to be more reliable that clinical judgement alone continues to stir debate (McCallum and Eagle, 2015; Coid et al. 2016; Downes et al. 2016). As a result, structured professional judgement (SPJ), a combination of clinical judgement and actuarial measurement is now widely recommended for assessing risk (Caroll, 2014; Croucher and Williamson, 2013).

Whereas SPJ appears to be associated with a degree of pragmatism in relation to potential strengths and weaknesses relating to risk assessment, there is debate and uncertainty in relation to the future direction of risk as a whole. Many countries, for example, have now introduced compulsory treatment orders (CTO's), legislation aimed at reducing risk to self or others by ensuring compliance with risk management plans (Weich et al. 2018). Critics of CTO's point out that service users may be negatively affected by having their liberty deprived, of being denied certain services and of being further marginalised solely because of something that often may or may not happen in the future (Haynes and Stroud, 2019; Rugkasa, 2016).

If general adult services continue to be shaped by developments within forensic mental health services, however, it is then perhaps feasible that recent and controversial innovations such as the use of GPS 'tracking' technology (Tully et al. 2014; Grotto et al. 2015) and the trialling of staff body cameras on forensic and non-forensic inpatient mental health wards (Ellis et al. 2019) may further develop into the mainstream. For many writers, however, risk assessment/management will always have a valuable place within mental health and where developed effectively, particularly with recovery and service user involvement in mind, can improve and enhance care (Holley et al, 2016; Robertson and Collinson, 2011).

6.3 Literature review: Introduction

The studies included in this review originated in various countries around the world, including Europe, Australia, USA and Canada. Their inclusion demonstrates that risk, as it relates to mental health care, is a global issue, despite comparatively different health care systems. As such, a number of themes appear to have a shared significance across different countries. The included literature consists of both quantitative and qualitative primary research plus some review studies and editorial/opinion. Research settings vary between small inpatient unit studies to national research programmes and a variety of inpatient, community and forensic/secure unit locations.

There appears to be significantly more studies offering criticism of risk assessment/management practices than outright support. Even where positive aspects are highlighted (e.g. the effectiveness of certain actuarial assessment measures) these tend to be balanced by the acknowledgement of their potential limitations. Many writers appear to be calling for balance in relation to risk; the need for adherence with organisational procedures to ensure service user, staff, family and public safety, whilst retaining a realistic sense of its shortcomings and not allowing risk to dominate the provision of care.

Four major themes emerged from the review. These are as follows:

I. The changing context and language of risk
II. Risk assessment versus risk management
III. The contrasting priorities of service users and providers
IV. Clinical judgement, actuarial assessment and structured professional judgement

6.3.1 The changing context and language of risk

The context of risk and the language associated with the concept appear to be continually evolving. For many writers this means widening the scope of risk to include new areas of potential harm and considering risk as a 2-way process (the risks posed by service users themselves and the risks they encounter as a result of receiving mental health care). Reflecting these developments is a changing language/vocabulary associated with the concept.

Focusing on violence risk, Callaghan and Grundy (2018: p14) argue that the traditional language of ‘risk’ needs to be replaced by a discourse based on ‘safety,’ whereby stigmatising terms such as “threat” or “menace” are redefined through shared service user involvement. Reflecting this theme, the term ‘safety’ is used frequently throughout the reviewed literature, often alongside ‘risk’ in article titles (Buckingham et al. 2015; Higgins et al. 2016a; Slemon et al. 2017).

Shared service user involvement in the process of ‘safety planning’ is an important area of development for some writers. Higgins et al. (2016a) feel that the ‘tick-box’ nature of many assessment tools needs to be accompanied by closer service user collaboration on risk and safety, an area often not discussed for fear of damaging therapeutic relationships. In a survey of service user perspectives on risk management, Deering et al. (2019) suggest that such relationships between professionals and patients can actually be improved by honest discussions relating to risk, whereby recipients of care feel their thoughts and opinions are being fully considered, especially in terms of their home and community lives. Similarly, in terms of better outcomes for service users and professionals, Harrington et al. (2019) found that greater service user collaboration relating to risk management led to an overall reduction in serious incidents within an inpatient mental health unit.

The focus and content of such collaborative relationships is another area discussed within the literature. As already noted, risk in a traditional sense has tended to focus strongly on harm, either to self or others, originating within service users themselves. More recently, writers have focused on the potential for harm emerging as a result of using mental health services, either in community or inpatient settings. Higgins et al. (2016b) argue that risk assessment should include potential harm from others, sexual victimisation and other ‘iatrogenic risks’ such as the improper use of prescribed medication. Other writers suggest that the consideration of ‘system’ based risks such as abuse from staff and medication/handover/ diagnostic errors is more prevalent in medical specialities but has often been disregarded within mental health services (Briner and Manser, 2013; Slemon et al. 2017).

A number of writers also cite the importance of a ‘strengths-based’ approach to collaborative risk and safety planning, focusing on positive areas such as protective factors and effective coping strategies (Wand 2012; Kivisto, 2016). Focusing on service user strengths is central to the concept of ‘positive risk-taking,’ a recurrent theme throughout the literature whereby service users are encouraged to exercise their own choices and priorities, whilst weighing up potential harms and benefits (Robertson and Collinson, 2011; Downes et al. 2016; Higgins et al. 2016b; Williams et al. 2022). Another major change from traditional perspectives on risk focuses on the multidisciplinary approach. Assessment and management of risk continues to be the primary domain of psychiatrists and nursing staff when, for some writers, a truly collaborative approach should involve all members of the multidisciplinary team (Kaunomaki et al. 2017; Woods, 2013).

Technology and innovation also has a role to play in the reconsideration of risk as it relates to mental health care. The negative risks associated with the use of social media and telehealth often focus on access to misleading information and peer abuse (Naslund et al. 2016; Luxton et al. 2012) whilst informed consent and the protection of service user privacy are other common areas of concern (Kramer et al. 2015).

6.3.2 Assessment vs management of risk

Viewing risk in terms of a complete process of assessment and management is a subject of some debate within the literature*. A* frequent criticism of current risk practice is that appropriate safety or management plans are not put in place after initial assessment or what Woods (2013:p809) describes as a “fragmentation” process occurring between assessment and safety planning. Caroll (2014) cites the significant advances made in terms of assessing risk using actuarial measurement but feels that the real task at present is to translate assessments into tangible management strategies. Similarly, in a study examining mental health nurses’ risk practices, the writers discovered that a high percentage of risk assessments were successfully documented as opposed to a significantly reduced number of associated safety plans (Higgins et al. 2016b).

The absence of safety management plans and failure to consider risk a complete process of assessment and management can lead to ‘reactive’ as opposed to ‘proactive’ management strategies, such as door locking; seclusion; physical and chemical restraint (Woods, 2012; Grotto et al. 2015; Kaunomaki et al. 2017; Slemon et al. 2017). Whilst there is frequent criticism of these types of intervention, it would appear that assessing and categorising potential risk may be a more straightforward process than implementing ‘containment free’ safety/management plans.

For example, in their appraisal of a ‘traffic light’ system to categorise risk into low (green), medium (amber) and red (high) categories, Croucher and Williamson (2013) make no reference as to how each category of risk might be managed. In a similar study by Mullen et al. (2014) specific risk management strategies such as ‘one to one’ time are noted. However, the writers also conclude that although the identification of risk appeared to improve in their study, there were no accompanying improvements in care planning or appropriate clinical interventions.

6.3.3 Risk and contrasting service user/provider priorities

Examining risk from the two perspectives of service user and provider highlights a number of competing priorities. Despite the aforementioned efforts to promote a collaborative approach to risk between service user and professional there are various areas where views and opinions can differ or conflict.

Balancing the long-standing, but still relevant, ethos of ‘recovery’ within mental health services (Anthony, 1993; Slade, 2009; Slade and Wallis, 2017) alongside current perspectives on risk is an area of wide debate. Coffey et al. (2017) suggest that mental health services tend to be risk averse and focused on procedural aspects, therefore detracting from recovery by limiting individual choice and the ability to take ‘normal’ risks. Many of the mental health nurse participants in a study by Downes et al. (2016) expressed concern that limiting freedom and autonomy, a potential outcome of risk assessment, was incongruent with the concept of recovery. Other writers refer to a disparity between spoken views/opinions promoting recovery and what happens in reality as a result of risk aversiveness (Holley et al. 2016).

For service providers there appears to be a level of conflict between organisational responsibility and facilitating a recovery approach. This dilemma is examined by Robertson and Collinson (2011) who feel that mental health staff often find themselves in a bind between ‘support’ and ‘control’ reflecting service user needs, public expectations and the presence or absence of organisational support for ‘positive’ risk taking and recovery. For many writers this conflict can lead to a ‘blame culture’ where staff fear reprisal from within or outside of their own organisation for not controlling risk or failing to prevent serious incidents (Wand, 2012; Grotto et al. 2015; Slemon et al. 2017; Szmukler and Rose, 2013).

Studies from a service user perspective suggest that they can be equally conflicted as a result of the current focus on risk. In one way many service users place a significant emphasis on the therapeutic relationships they form with professionals and wish to play an active, shared role in considering risk (Deering et al. 2019). However, many service users also feel that the therapeutic relationship they value can be marginalised by an excessive focus on risk or may feel obligated to comply with risk assessment/management directives despite not being fully included in the process (Coffey et al. 2017; Holley et al. 2016).

This conflict between support and control, which appears to affect both service users and mental health staff, is evidenced in a study by Buckingham et al. (2015). Examining the use of an integrated service user/practitioner ‘decision support system’ for risk and safety management, the writers found that whilst practitioners favoured a sequential and simplified checklist for checking risk behaviours, service users wanted to examine each area in more depth and context. This gives impetus to the notion that mental health staff, often under time and organisational pressures, may be reducing risk management to a simplified ‘tick-box’ exercise, whereas service users appear to want a much more ‘dynamic’ approach, acknowledging the context of their personal lives.

A number of writers make reference to the development of this dynamic approach to risk management. For example, Coid et al. (2016) suggest that more focus needs to be given to the causal factors of risk, whereas some risk assessments, as they stand, tends to focus solely on prediction of risk. O’Shea et al. (2013) and Kivisto (2016) also suggest that ‘static’ variables alone (e.g. age; gender etc.) are not predictors of risk and need to be examined in the context of other dynamic factors (e.g. unemployment; housing problems; relationship issues etc.)

Mental health nurses are frequently at the centre of debate in relation to the balance between providing therapeutic support and controlling or managing risk. Whilst writers are critical of ‘defensive’ or ‘reactive’ nursing practices stemming from efforts to control risk, acknowledgement is given to the fear of blame and recrimination that currently exists and how this fear may be fuelling management strategies such as seclusion or door locking (Higgins et al. 2016; Grotto et al. 2015; Woods, 2013). Within this perceived climate of blame, some writers are concerned that the nurse’s ability to use their discretion and a level of flexibility is being compromised by strict adherence to risk management guidelines (Slemon et al. 2017).

In some ways this fear amongst mental health nurses and other professionals can be seen to stem from public expectations that risk can and will be controlled by mental health services (Holmes, 2013; Wand, 2012) Szmukler and Rose (2013; p126), for example, refer to the presence of “moral outrage” that prevails amongst the public following a serious incident, where culpability is sought, leading to the blaming of mental health services. Flintoff et al. (2019) propose that responding to such public and social concerns is the main reason risk assessment exists as opposed to the presence of any scientific rationale. It is within this context that organisations are required to balance the sometimes competing demands of supporting service users and clinicians whilst being seen to offer protection and reassurance to the public (Robertson and Collinson, 2011).

Some writers are critical of risk management policies in terms of meeting and placating such public expectations. Callaghan and Grundy (2018), in their review of violence risk assessment, argue that perpetuating the idea of violence as something which can be successfully limited or predicted through clinical risk assessment is misleading for the public. To this end, Carroll (2014: p. 307) suggests that the “limits of foreseeability” relating to adverse events involving users of mental health services needs to be made clearer for the public. Similarly, some writers recommend that organisations need to move away from focusing on individual risk to concentrate more on public and population level education/information programmes prioritising the wider social determinants of risk such as alcohol/drug use and parenting (Wand, 2012; Szmukler and Rose, 2013).

6.3.4 Clinical judgement, actuarial assessment and structured professional judgement

A number of writers have focused on the various means by which risk may be assessed, namely clinical judgement, use of actuarial/evidence based risk assessment tools and structured professional or clinical judgement. Across the reviewed literature, results and opinions differ in terms of the perceived effectiveness or weaknesses of each approach. Regardless of the approach taken however, wide agreement appears to exist in relation to bridging the perceived gap between assessing static risks and dynamic risks (Coid et al. 2016; O'Shea et al. 2013; Kivisto, 2016).

One of the main criticisms of validated actuarial measurement tools is that historically they have tended to focus on static risks only (Downes et al. 2016). However, newer versions of common assessment tools such as the Clinical Risk Management-20 (HCR-20) now include the area of dynamic risk. This has been seen as giving the HCR-20 stronger predictive ability in terms of inpatient violence (O'Shea, 2013). There are a number of other criticisms aimed at actuarial tools within the review literature. These include the exclusion of positive risk taking aspects (Robertson and Collinson, 2011); their poor ability to predict rare events, especially suicide and extreme violence (Flintoff et al, 2019; Wand, 2012; Large et al. 2017) and the limitations of using tools primarily designed for forensic areas within general psychiatric settings (Szmukler and Rose, 2013).

They are also seen to lack predictive efficiency amongst specific service user groups and cultures (O'Shea et al. 2013); can be inefficient in relation to multiple risk factors (Large, 2013); are used too randomly or inconsistently (Higgins et al. 2016; Woods, 2013; Roush et al, 2018) and may have poor application for everyday clinical practice due to their primary purpose as a research instrument (Wand, 2012). Another area of concern is in relation to potential ‘false positives,’ and ‘false negatives’ produced by risk measurement. From a false positive perspective service users may be unnecessarily detained or treated coercively whilst from a false negative standpoint denial or refusal of care could lead to some form of harm (Callaghan and Grundy, 2018; Szmukler and Rose, 2013).

For some writers, however, actuarial measurement can still be a valuable evidence based resource in terms of assessing risk and is at least preferable to using clinical judgement alone (Woods, 2013; Callaghan and Grundy, 2018; Wand 2012). McCallum and Eagle (2015) suggest that risk assessment should not be just about predicting or preventing serious incidents and whilst not dictating practice can assist professionals in their decision making. Similarly, Caroll (2014) feels that any limits to the accuracy of risk assessment should not render it unworthy, comparing its evidence base with that of certain medicines which continue to be prescribed despite a less than 100 percent success rate.

Other studies highlight positive clinical outcomes in relation to the use of actuarial tools. In a study relating to violence risk assessment, Roaldset et al. (2012) found that using a combination of screening tools from physical, clinician and service user perspectives appeared to be more effective in terms of predictive ability than using any one instrument on its own. In a large international study aimed at improving violence risk assessment, Coid et al. (2016) were able to link certain diagnoses with a higher prevalence of violence such as anxiety and antisocial personality disorder, whilst Hvidhjelm et al. (2016) cite a 45% reduction in violent incidents following the introduction of a new risk screening instrument on an inpatient mental health unit.

6.4 Discussion: Introduction

Whilst the concept of risk in relation to mental health care has become an established part of everyday clinical practice, it is also an area that continues to evolve. The evolution of risk as an integral part of operational policies is evident not just within mental health services but across all areas of healthcare, public and private sector organisations, businesses and industries.

Although there appears to be a significant level of criticism in relation to risk and mental health care, its central presence does not appear to have lessened. In a climate of evidence based practice, risk assessment is often seen as lacking a sufficient evidence base, many critics pointing out that serious and untoward incidents do not appear to be decreasing despite the development of rigorous risk management policies over the last 30 years. Similarly there is widespread concern about the ‘false negatives’ and ‘false positives’ associated with risk, where service users may be unduly restricted or conversely denied necessary care and support.

Proponents of the value within risk management do not feel that the concept can be judged in this way, focusing on the unknown number of incidents that may well have been prevented and/or service users successfully supported through evaluation of risk. Similarly, its supporters would argue that consideration of risk is not a new concept nor an exact science, but much like other areas of clinical care has only improved, developed and formalised as a result of extensive research and training.

From a contemporary perspective, there appears to be a widespread sense of pragmatism in relation to risk. This could be summarised as it being both serving an important function in maintaining standards and governance, protecting service users, their families and the public whilst having a strong sense of its evident limitations. Even the harshest critics tend to recognise some requirement for risk management even if this is just acknowledging the status quo in relation to government and organisational policy.

Similarly, those quick to criticise ‘reactive’ risk management strategies such as physical restraint may be in danger of oversimplifying risk in terms of a recovery orientated and non-reactive approach. Particularly within acute inpatient mental health services, the sheer numbers of service users; the presenting psychosocial difficulties and element of 'unknown risk' make these areas 'highly charged' and unpredictable. There are real emergencies where physical intervention and forced administration of medication may be required. Pragmatism would suggest that it may also be unhelpful to hide this fact from service users, families and the wider public.

For every new or innovative area in relation to risk management there are likely to be opposing arguments. Examining the use of bodycams within mental health services to reduce the likelihood and risk of violence is a specific example. Proponents of their use may refer to their successful use in areas of law enforcement and clearly any intervention that may prevent injury to service user or staff member should arguably receive valid attention. However, there are a number of arguments against their use, including the therapeutic basis of mental health care and possible 'function creep,' where the technology originally implemented to deter service users from violence ends up being used by staff, to protect themselves from potential legal or organisational investigation. In many ways, there are similarities here with current attitudes to risk management, its utilisation bridging the two areas of service user care planning and 'defensive' practice.

6.4.1 The changing context of risk

Whilst mental health risk management policy is often included in strategies encompassing all areas of healthcare, there are unique risks applicable to mental health. The ongoing prioritisation of violence and suicide risk signifies two of the most common areas, in addition to factors such as the legal detention of service users; the use of safety control measures such as physical restraint and seclusion; the risks associated with absconding from mental health units; constraints in relation to inpatient care and continued public concern relating to the care of mental illness in community settings.

It is within this unique environment that mental health professionals are being asked to consider alternative and previously omitted areas of risk. A theme evident within the literature suggests a kind of ‘risk reversal’ where rather than seeing risk as only ever emanating from service users themselves in terms of violence or suicide threat, there needs to be an awareness of the risks arising from outside factors such as ‘patient on patient’ violence, prescribed medication, exploitation, sexual vulnerability and homelessness.

Studies involving mental health staff within the literature appear to demonstrate a level of awareness in relation to these areas. Similarly, staff appear to acknowledge the widely supported idea of ‘positive’ risk taking; ‘safety management’ and personal ‘recovery’ where service users are encouraged to take normal risks in their lives, assume a shared level of responsibility for risk whilst making informed but independent and autonomous choices.

6.4.2 Conflicting perspectives on risk

If it is indeed the case that staff members wish to work in a safety and recovery orientated way as recommended, one of the barriers to achieving this may be the sometimes conflicting interests of service users, organisations/employers and the public. Mental health nurses, for example, often appear to be in a difficult position which sees them considering risk from the perspectives of maintaining their own professional status, protecting the reputation of the organisations they work for, ensuring the safety of families and the public whilst working collaboratively with service users in a positive, non-risk averse way.

Despite organisational rhetoric acknowledging the importance of determining risk in positive and service-user centred ways, in reality many staff feel obliged to think of risk mainly in terms of containment, control and compliance. In essence staff appear to be fully aware of the negative aspects of ‘defensive’ practice but feel conflicted in terms of steering away from this approach to managing risk.

One of the main reasons for this, highlighted within the literature, is the ongoing public view of mental health service users as potentially ‘dangerous’ to themselves or others and therefore in need of containment and control. For many writers, mental health services as organisations do not do enough to challenge this opinion whilst published policies on risk promote the unrealistic idea that all forms of harm can be prevented by a systematic process of assessment and management. Whilst one of the aims of risk management policies is to maintain a level of public confidence in mental health services, there is also the question of whether such policies enable unrealistic expectations.

Increasing public awareness of the limitations of risk is therefore seen as one of the ways in which mental health services and professionals can work in a more recovery focused and risk positive way. In many ways, however, the liberal ideology which facilitated the closure of asylums and long term inpatient care has been superseded by an ever increasing public and media focus on risk and 'dangerousness.' Rather than the expected move towards a more inclusive society that values personal responsibility and autonomy, there has been an ever increasing focus on organisational accountability and governance.

6.4.3 Assessment vs management of risk

According to the reviewed literature there has been significant progress in relation to the assessment and categorisation of risk. Whilst these procedures are widely adhered to, there appears to be less documented evidence focusing on the management of risk. In some ways, identifying risks could be considered a more straightforward task than identifying strategies to manage these areas. This is highlighted by the use of 'tick box' checklists which are simple to follow and often quick to complete; a process welcomed by services aiming to produce firm evidence of risk evaluation.

It seems that less emphasis is placed on establishing relationships with service users which allow risk to be fully explored. Similarly producing a suitable management plan, incorporating a service user's views and those around them can take time to produce. Experience would suggest that many service users and their families are reluctant, at least initially, to discuss risk. This places the professional in a difficult position if they feel obliged to produce a risk assessment and plan within a short time span. Service users themselves appear to value a more in-depth and contextually aware approach to assessing and managing risk. This is at odds with the rapid tick-box checklist approach, which could be seen as more valuable to service providers.

In terms of risk management, there appears to be a great deal of debate in relation to ‘defensive’ or ‘reactive’ responses such as seclusion and restraint. Whilst it could be argued that such reactive as opposed to proactive responses may render risk assessment meaningless in the first instance (why assess risk at all if it is only going to be managed via physical restraint and seclusion) producing and maintaining a plan which avoids these responses is arguably not an easy task. This is reflected in the comparative lack of debate in relation to tangible management strategies within the literature. Factors including time, availability of resources, level of service user involvement and capacity are likely to be some of the issues impacting on the management of risk.

6.4.4 Clinical judgement, actuarial assessment and structured professional judgement

According to the available evidence structured professional or clinical judgement is recommended practice in relation to risk assessment, combining clinical judgement with the use of structured/validated measurement tools and instruments. Used in isolation both of these practices have been widely criticised. For example, clinical judgement may often be seen as inconsistent or at worse a form of guesswork lacking any systematic evidence base. Critics of actuarial measurement tools cite a number of concerns, commonly that they are not focused on positive risk; that they are not easily transferred from forensic to general mental health settings and historically have tended to focus on static as opposed to dynamic risk factors. One of the reasons why suicide is commonly cited as one of the most difficult risks to predict appears to be its dynamic nature.

Although validated tools have been shown to be effective in many areas of clinical risk assessment, conclusive evidence is questionable when considering certain aspects of validity. Statistical validity, for example, is often seen as difficult to achieve due to low base rates of serious violence and suicide within inpatient care. Beyond fundamental concerns relating to the evidence for actuarial measurement their use can also be deemed inconsistent or too diverse in terms of chosen instruments.

Clinical experience would suggest that the uptake of any new risk assessment/management tool would need extensive 'buy-in' from any organisations, clinical areas and mental health professionals involved. In the current climate anything that may be perceived as an additional or time-consuming task is unlikely to be fully successful in terms of implementation and evaluation. Mental health nurses, in particular, have expressed concern that a singular focus on structured assessment tools detracts from the traditional nurse-patient relationship, based on interpersonal skills and a level of nurse discretion. Striking a balance between the use of effective measurement tools whilst maintaining the nurse's ability to use discretion and initiative appears to be a key aspect. In essence, there is importance in maintaining the 'human' element alongside innovations such as electronic risk prediction algorithms.

6.5 Concluding comments on risk management in mental health services

Risk management remains a contentious area in the field of mental health care. Despite extensive debate and frequent criticism, there are no indications to suggest that its utilisation or significance is likely to change in the near future. Although theoretical and clinical approaches to risk continue to develop, much of the academic discussion remains unchanged, particularly the evident dichotomy between prioritising risk at the expense of developing therapeutic professional/service user relationships.

Four main themes have been explored within this review; the changing context and language used to define risk; the dual approach of assessment and management to address risk; the competing and sometimes contrasting perspectives of service users; professionals; organisations; the media and the public and perspectives on the use of structured risk assessment over standard clinical judgement.

Risk management is likely to remain a topic of wide debate in the future. Whether services continue to focus on the expansion of community services, or choose to favour increased inpatient capacity is an area to monitor in terms of risk. It is likely, that the views of all stakeholders in relation to the assessment, management and tolerability of risk will be important factors in any decisions made. Future consideration of risk is also likely to be increasingly focused on the impact of technology and innovation within mental health care. Areas such as social media; telehealth; CCTV; tracking and body camera technology have all been recently linked with mental health services. It is also likely that each of these areas will continue to be assessed and evaluated in terms of risk to service users; families/carers; professionals and the public.

Part II: The research journey

Chapter 7: Research paradigms, design and methods

7.1 Introduction

This chapter examines the research paradigms, design and methods used in the study. The overarching philosophical basis of the study is outlined first through the identification of relevant research paradigms followed by description of the chosen research design. Specific research methods are then outlined, focusing on retrospective chart review and content analysis, the two research methods selected for this study. Theory is linked to the aims and objectives of the research study throughout.

7.2 Research paradigms

A research paradigm has been defined as a basic set of beliefs or worldview that guides research action or an investigation (Guba and Lincoln, 1994) or as a “pattern of beliefs and practices and practices that regulate inquiry within a discipline by providing lenses, frames and processes through which investigation is accomplished” (Weaver and Olson, 2006: p.460). From a nursing perspective establishing a research paradigm is of significance as this directs the researcher towards topics of consideration and how research should be conducted (Monti and Tingen, 1999; Parahoo, 2014).

This study is influenced by two philosophical paradigms, empirical and interpretive. An empirical research paradigm focuses on scientific methods of establishing knowledge via the formal statistical testing of hypotheses (Lincoln and Guba, 1985) and by striving to control variables in order to determine their relationship (Monti and Tingen, 1999). In nursing and social science research following an empirical paradigm often encompasses a post-positivist approach which accepts that absolute truths are difficult to ascertain; that contextual factors can affect our understanding of relationships between variables and as such, correlations may be inferred as opposed to any direct 'cause and effect' relationships (Monti and Tingen, 1999; Parahoo, 2014). This has particular relevance in the case of my research study, where contributing factors relevant to serious incidents such as violence and self-ham are likely to be multiple and complex.

In exploring the contributing factors relating to serious incidents an interpretivist paradigm is utilised. Interpretivism is seen as an alternative to positivism in that it relates to personal experience; the different perceptions or interpretations of human behaviour and social environments and therefore does not aim to establish any single, objective reality (Gillis and Jackson, 2002; Parahoo, 2014).

7.3 Research design

This study utilises a mixed-methods design incorporating a quantitative approach (based within a post-positivist paradigm) and a qualitative approach (based within an interpretivist or naturalistic paradigm). In essence this relates to the presenting and comparing of statistical data relating to serious incidents (e.g. type, frequency, comparisons between ages and genders) obtained using a quantitative approach, followed by a qualitative analysis of why such incidents may occur (e.g. patient's level of illness, role of nursing interventions and impact of a person's wider environment).

Mixed-method designs are popular in nursing and healthcare research as they utilise the strengths of both quantitative and qualitative methods, whilst facilitating the exploration of diverse perspectives and relationships (Shorten and Smith, 2017). In relation to the research study, a mixed-method design has been selected as quantitative analysis can only provide descriptive and comparison data in relation to variables such as incident frequency and type. However, quantitative analysis offers little insight into why incidents occur; another important question in the overall research strategy. This process is defined by Halcomb and Hickman (2015) as an 'explanatory sequential' mixed method approach where quantitative data is collected and analysed first, followed by collection and analysis of qualitative data to help explain the quantitative data.

7.3.1 Document analysis

Research involving documentary analysis refers to any written 'texts' studied as "socially situated products" (Scott, 2014: p34). Guba and Lincoln (1992: 228) define documents as "any written material other than a record that was not prepared specifically in response to some requests from the investigator." Whilst synonymous within the disciplines of history and the social sciences (e.g. newspapers; books; official documents) documentary research may also be used in the arts and humanities (e.g. images; diaries; sound recordings) (American Educational Research Association, 2020) (AERA).

Document analysis has been defined as a "systematic procedure for reviewing or evaluating documents; both printed and electronic (computer-based and Internet-transmitted) material." (Bowen, 2009: p27.) O'Leary (2014) provides a summary of the main types of documents examined in such research studies. These are summarised in Table 5. As a qualitative research method it may be used independently but it is often used to complement other methods, both qualitative and quantitative to improve the credibility of findings (Bowen, 2009).

Table 5. Examples of document types used in document analysis research

Public Records	**Personal Documents**	**Physical Evidence**
student transcripts	Calendars	Posters
mission statements	e-mails	Agendas
annual reports	Scrapbooks	handbooks
policy manuals	Blogs	Flyers
student handbooks	duty logs	training materials
strategic plans	incident reports	
Syllabi	Newspapers	

Document analysis research is viewed as a reflexive process, whereby significance is given to the context and theoretical frame of reference underpinning the studied content as opposed to merely recording facts (Ahmed, 2010). The researcher's interpretation and understanding of meaning within the data ultimately results in the acquisition of new knowledge (Corbin and Strauss, 2008). Bowen (2009) provides a summary of the main advantages and disadvantages related to the research method (Table 6.)

Table 6. Advantages and disadvantages of document analysis

Advantages	**Disadvantages**
Manageable/practical	Insufficient data
Accessible/reliable	Not always easily retrieved
Cost and time efficient	Bias (e.g. unwanted organisational influence on corporate documents or record-keeping procedures)
Stable/factual	
Record of information otherwise forgotten	

7.3.2 Document analysis in health research

Historically, research involving clinical documentation has been widely used in healthcare; Hsieh and Shannon (2005), for example, noting a significant increase in the use of document content analysis for health research over a ten year period. More recently, the development of interactive media has meant that a great number of studies now rely on social media sources as opposed to the more traditional documentary evidence found in newspapers and magazines (Skalski et al. 2017).

A selection of published studies from within the last 5 years illustrates the variety of documentation used in health research and the current scope of written information available. For example, Linton et al. (2019) examined both business case and NHS guidance documents to develop a new framework for healthcare related business cases in England, whilst Sturt et al. (2015) analysed clinical notes in relation to the experiences of people attending a diabetes care clinic.

In the USA, Bultas et al. (2016) used health professional students' exam answers to examine views in relation to the US healthcare system, whilst in the UK the public health roles of intellectual disability nurses were explored through the analysis of job description and person specification documents (Mafuba et al. 2018). Lastly, reflecting the use of social media in document analysis, Nastasi et al. (2018) examined opinions on Twitter in relation to breast cancer screening, whilst Hendriks et al. (2018) accessed Facebook and Instagram profiles in order to explore the link between alcohol use and social media.

7.3.3 Document analysis in mental health research

Document analysis in mental health research is viewed as a predominately qualitative technique alongside other common methods in this category such as interviews, focus groups and participant observation (Palinkas, 2014). However, it may also be carried out within quantitative or mixed-method frameworks depending on the information source (Krippendorff, 2013; Robson, 1993).

Relevant examples from published mental health research studies reflect the reported uses of document analysis to include the provision of background and context; additional questions to be asked; supplementary data; a means of tracking change and development and verification of findings (Bowen, 2009).

Viswambharan and Priya (2015) used documentary analysis (of audio-visual material) to explore the mental health of disaster survivors following riots in India. They highlighted the importance of using a specific methodological theory to structure such research and the need for researchers to reflect on their knowledge and opinions whilst acknowledging the context in which the source of information was created (in this case the film-maker’s perspective).

Rasmussen et al (2012) also closely followed an evidence based theory of document analysis to examine documentation relating to the role of the child and adolescent mental health nurse. They also highlighted the benefits of using a specific software programme to help synthesise the collected data into categories and themes.

In their documentary analysis of recovery training in mental health practice, the Scottish Recovery Network (2007) examined a number of different documents including PowerPoint presentations, meeting minutes and emails. They used a framework mapping out a clear focus of the areas they wanted to examine, including specific questions which they felt would be addressed/answered by the documents. Higgins et al (2016) equally used specific questions to frame their document analysis of organisational risk assessment policies and tools used in Irish mental health services. They offer justification for the use of such an approach, noting that the examination of organisation-produced documents can offer an insight into the culture and context of the organisation itself.

7.3.4 The use of medical records in health research

Medical records remain a valuable source of data for various types of clinical research (Cowie et al. 2017; Yim et al. 2018; Husain, 2021). Similar terms can include clinical records; clinical notes; patient casefiles; patient charts and patient notes; each term referring to the “wide variety of documents generated on, or on behalf of, all the health professionals involved in patient care.” (Medical Protection Society, 2012: P5) (MPS).

Their origin can be traced back to the ancient Egyptian, Greek and Roman eras where case histories were retained for teaching purposes (McMillan et al. 2018). The use of clinical notes for educational purposes continued to develop through the centuries but it was not until the

20th century that more purposeful and systematic clinical records were kept for direct patient care (Gillum, 2013). More recent developments relate to patients retaining or having shared access to their medical records (Armstrong, 2017; McMillan et al. 2018; Essen et al. 2018) and the growing use of electronic medical/health records (EMR's or EHR's) for research purposes (Estiri et al. 2021; Wood et al. 2021).

Although the primary purpose of keeping medical records in the modern era remains the facilitation of direct patient care, their usage continues to serve a number of secondary functions. Relevant examples include: the auditing of service provision (HSE, 2017); examination in legal proceedings (Wood, 2015); use in ongoing staff education (Rose, 2000) and serious incident reviews (Mental Health Commission, 2017). Another significant aspect of maintaining medical records is the justification of care delivery in the context of state legislation, professional standards and ethical conduct (HSE, 2011; NMBI, 2015).

Alongside these functions, medical records have, historically, been commonly used to facilitate health research. Beyond the widespread publication of clinical case studies as previously noted, early examples of published material from the early to mid-20th century reflect the use of patient records in a number of research areas focusing on: disease prevalence (Smith, 1913); symptomatology and progression of illness (Burnham, 1915); diagnostic/aetiological trends (Yannet, 1945) and evaluating the quality of hospital/physician care (Rosenfeld, 1957; Sidel, 1966). Later work from the 1970's onwards also utilised medical records in studies focusing on quality assurance in nursing care (Watson and Mayers, 1976); establishing the determinants of service use (Barsky et al. 1986) and the identification of adverse events during hospital admission (Brennan et al. 1990).

Whilst contemporary studies continue to address these areas (Vermeulen et al. 2019; Lawn et al. 2018; Garcia-Gil et al. 2016) they differ from earlier record review research in their use of electronic as opposed to traditional, paper-based patient records. The growing use of electronic/digital record keeping systems within health care has facilitated considerable opportunities in relation to record review research (Coorevits et al. 2013) especially in terms of generating large data sets and cross referencing in relation to patient medical histories (van Velthoven et al. 2016).

Although the computerisation of medical record systems is not necessarily a new phenomenon, with published research dating back 70 years (Ledley and Lusted, 1960), the scope of record review studies has increased in parallel with their continued development (Barick et al. 2018). In the UK, for example, large databases containing patient data are now available for researcher access, in some cases retaining millions of anonymised patient records for research purposes (Su et al. 2014; Herrett et al, 2015; Camden and Islington NHS Trust, 2018).

7.3.5 Medical record review and serious incident research in mental health services

Medical record review is frequently included in research studies examining serious incidents in mental health services. Clinical incident reports, for example, are often the starting point for such research studies. The reviewing of patient records remains a fundamental aspect of research exploring serious incidents occurring in mental health services. Alongside published research utilising record review is a wealth of guidance on performing clinical incident reviews, often carried out to establish contributory factors in the most serious cases. Incident reviews are commonly guided by national protocols defining the management of clinical incidents, allowing health services to learn from adverse events; providing the necessary levels of public transparency and meeting organisational governance and risk liability requirements (HSE, 2018; NHS, 2015).

Some of the most high profile reviews have been published widely in the context of public interest and wider learning, particularly those led by government or statutory bodies (HMSO, 1994; Mental Health Commission, 2009). However, many incident investigations are only undertaken on a local basis and are not widely disseminated, a practice that has faced some historic criticism for failing to support wider learning opportunities (Vincent et al. 2000). Thus, whilst the procedural guidance available clearly has a predominately clinical as opposed to research focus, it does offer some structure and insights into the use of medical records in the context of serious incident research, even if the full extent of recommended investigation techniques relating to any single event may not be easily replicated in multi-case studies.

The main similarities between the methods used in published research studies and official guidance relating to performing investigations is their use of medical records to establish basic factual information followed by a more multi-faceted approach to the various contributory factors. To illustrate, Taylor-Adams and Vincent (2004), outline a protocol for carrying out a 'systems analysis' of clinical incidents which uses medical records and incident forms to firstly establish incident details and timeline. The authors suggest the further use of activities such as interviews with those involved, reviewing the physical environment where the incident occurred and looking at documentation such as staff rotas and local policies/procedures. This advice would suggest that examining medical records alone is unlikely to be sufficient in carrying out a comprehensive serious incident investigation.

Whilst guidance on carrying out clinical incident reviews has altered its terminology over time, from 'root cause analysis' (Neal et al. 2004; MHC, 2016; Haxby and Shuldham, 2018) to 'systems analysis' (Ammenwerth et al. 2002; HSE, 2018); to the more recent 'patient safety incident response' (NHS England, 2020) reviewing patient records or case notes remains a central activity.

Guidance published in Ireland (Incident Management Framework) (HSE, 2020) highlights areas of consideration for serious incident research. The framework offers direction on conducting desk based reviews, particularly where obtaining interviews from relevant staff and patients may not be possible given the passage of time. In such cases the guidance suggests the consideration of independent or expert case review to strengthen the review findings and the presenting of results to relevant parties afterwards in order to ensure factual accuracy and to discuss the issues raised. The guidance also provides direction in relation to carrying out 'aggregate' incident reviews referring to the quantitative elements of collecting data to examine trends/patterns and the qualitative elements of contributing factor analysis. The two step approach described mirrors the framework for this thesis.

Official guidance on clinical incident review also tends to advocate the consideration of a contributing factor framework, another element utilised in this thesis. The four factor framework I have selected (patient factors; staff factors; organisational/environmental factors; external factors) utilises broad categories drawn from existing guiding frameworks; the Yorkshire Contributory Factors Framework (Lawton et al, 2012) (Appendix 4); the Patient Safety Incident Response Framework - contributory and mitigating factors classification) (NHS England, 2020) (Appendix 10); the Adapted Organisational Accident Causation Model (Taylor-Adams and Vincent, 2004) (Appendix 11) and the 'Safewards' model of conflict and containment (relating specifically contributing factors within inpatient mental health services) (Bowers, 2014) (Appendix 5).

7.3.6 Incident reports and mental health research

A number of limitations relate to using incident reports as a source of data in mental health research. As noted in chapter 3, studies relating to the frequency of violent incidents, for example, may be constrained by factors such as staff under-reporting and the variable quality of individual/organisational reporting practices (Kho et al. 1998; Woods et al. 2008; Archer et al. 2020; Spaducci et al. 2020). Additional limitations may include generalisability issues relating to single hospital/unit studies; the absence of a patient perspective (when only staff are completing incident forms) and the possible distorting of violence figures where one person accounts for a significant proportion of occurrences (Kuivalainen et al. 2014). Despite these drawbacks, incident report forms continue to provide a regular source of data for such studies.

At their most straightforward, studies have historically included incident report data to provide descriptive and statistical results. These frequently relate to areas such as prevalence; demographics and prediction of risk behaviour, whereby findings are explored in the context of other research studies (Evenson et al. 1974; Torpy and Hall, 1993; Uppal and McMurran, 2009). Adding intricacy to a violence antecedents study, Powell et al. (1994) used a secondary dataset providing context such as patient risk history; incident location and whether units were locked or 'open door' to accompany their analysis of incident forms.

Further studies have utilised content analysis of incident reports alongside the descriptive/statistical data they can provide. Kuivalainen et al (2014), for example, examined the incidence of physical violence in a forensic psychiatric hospital using a combined qualitative and quantitative approach to study incident prevalence; contributing factors and patient group comparisons (gender, age, legal status etc.). The authors used the narrative descriptions present in each incident form to create contributing factor categories such as 'patient being denied something' or 'patient being asked to do something.'

Other authors have focused in on one particular category and applied content analysis to this sole area. Spaducci et al. (2020), for example, examined violence in the context of cigarette smoking as a contributory factor, selecting only those incidents where violence was preceded by a recorded smoking issue. Whilst the study concentrates on one contributory factor associated with violence in mental health services the authors highlight that such an approach may not take account of other possible moderators. Although areas were pinpointed where smoking related activity preceded violence (e.g. when it was forbidden or when patients were confronted about breaking smoking rules) the authors were cautious to highlight these confrontations as the only causative factors. They also noted that having access to patient records or obtaining patient perspectives may have provided more context in terms of possible contributors.

Retrospective incident reports have also been coupled with staff interviews in order to provide a greater level of context and perspective. Shepherd and Lavender (1999), for example, carried out staff interviews in order to reflect on a sample of incidents where aggression had been present. Whilst such interviews can provide a significant level of perspective on likely antecedents, the authors highlighted certain limitations including recall problems (where delay occurred between incident and interview) and the non-consideration of contextual factors relating to the interviewees themselves (e.g. level of training/experience and organisational culture within their specific work area).

The significance of excluding patient views in serious incident research is illustrated in two contrasting studies, suggesting that patients and staff may view contributing factors in different ways. Ruben (1993) issued questionnaires to a sample of patients following hospital admission requesting positive and negative feedback about their most memorable experiences. Subsequent content analysis revealed that patients valued interpersonal relationships they shared with health care professionals the most. This contrasts with a more recent study by Pelto-Piri et al. (2020) who also delivered questionnaires but to clinical staff, asking for their views on the contributing factors associated with violence within inpatient psychiatry. Conversely, the authors of this study found that staff tended to focus more on internal patient factors than interpersonal relationships.

Prospective studies focusing on serious incidents may aim to implement measures addressing the context often missing from retrospective incident reports. For example, Carr et al. (2008) utilised existing patient records and incident reports to record rates of serious incidents within inpatient mental health services. To further examine correlates and pressures, the researchers requested that staff complete additional daily information logs based on patient activity (e.g. Occupational Therapy attendance; leave from ward; observation levels; visitors) and ward events (e.g. bed numbers; transfers; number of staff on duty; skill mix). Whilst this provided the authors with a better view of contextual/contributing factors than solely examining existing records, limitations still emerged such as varying data recording practices and logs not being completed/returned.

7.4 Research methods

7.4.1 Retrospective chart review

Retrospective chart review offers a well-established; scientific and systematic means of analysing data from medical records (Gearing, 2006; Vassar and Holzmann, 2013), using successfully tested and validated strategies (Gregory and Radovinsky, 2012). Also commonly referred to as retrospective ‘medical record’ review (Van Melle et al. 2018; Vermeulen et al. 2019) or sometimes ‘medical chart/record audit’ (Qui, 2014), it utilises patient data not originally obtained for research purposes and is differentiated from prospective studies by its use of pre-existing records (Sarkar and Seshadri, 2014). Retrospective chart review design may include ‘case-control’ studies, where cases with and without the phenomena of interest are compared and ‘matched case-control’ studies, where subjects in the two groups are matched in terms of certain characteristics such as age and gender (Hess, 2004). For the purposes of this study, a retrospective case-series design is utilised as it focuses on multiple cases, similar in terms of the phenomena examined (i.e. all persons in the case-series being involved in a reported incident) (Hess, 2004).

It can address a diverse range of research aims including the analysis of patient characteristics; patterns of care; patterns of medication prescribing and drug utilisation; effectiveness of care/treatment; identification of unmet clinical need and safety data (e.g. serious adverse events) (Payne and Stein, 2013). The manifold data sources used in such reviews may include demographics, progress notes, prescriptions, laboratory results and other medical procedures/tests (Vasar and Holzmann, 2013; Sarkar and Seshadri, 2014). It is frequently used to answer research questions and explore evidence gaps not easily addressed using other methods (Payne and Stein, 2013).

Table 7 summarises guidance on carrying out retrospective chart review provided by three frequently cited authors in the available literature. There appears to be significant consensus in relation to a number of areas including the need to establish a clear research question; deciding on specific data sources; devising a data collection form, ‘extraction’ or ‘abstraction tool’; addressing ethical issues and pilot-testing. Whilst Sarkar and Seshadri (2014) appear to provide the most straightforward framework, they do not offer advice in relation to sample size and sampling strategy as the other authors have.

Table 7. Guidance on retrospective patient data review. Summaries by main authors.

Gearing et al. (2006)	**Sarkar and Sesahdri (2014)**	**Vassar and Holzmann (2013)**
1. Forming research question and establishing clear hypothesis 2. Literature review 3. Research proposal 4. Establishing a valid tool for abstracting required data 5. Develop guidelines for using abstraction tool 6. Abstracting the data 7. Determining sample size 8. Ethics approval 9. Pilot study	1. Formulating clinical research question 2. Identifying data sources 3. Devising data extraction instrument 4. Consider ethical approval 5. Data extraction 6. Rechecking small set of data for inaccuracies 7. Statistical analysis 8. Dissemination of findings	1. Creating articulate research question 2. Careful consideration of sample size and strategy 3. Attention to the type and use of specific variables 4. Training of data abstractors 5. Use of standardised abstraction forms 6. Use of abstraction manual 7. Addressing inter-rater reliability 8. Perform pilot test 9. Address ethical approval

7.4.2 Strengths of retrospective chart review

A number of strengths are associated with retrospective chart review as a research method. Its use of easily accessible data that has already been collected (Worster and Haines, 2004; Qi, 2014) can produce quicker results than some prospective studies, whilst creating hypotheses for future research studies (Barick et al. 2018). It is viewed as being less resource intensive than prospective studies; can enable access to relatively large samples at minimal cost and over lengthy periods; tends to have minimal impact on patient time/activity and uses information that may have otherwise been forgotten (Gregory and Radovisnky, 2012; Sarkar and Seshadri, 2014). Its low impact on patient involvement can be seen as advantageous when full ethical approval is not required (saving time and available resources) (Vermeulen et al. 2019; Cocoman and Gallagher, 2019). Similarly, no direct patient contact can be seen as advantageous in the study of vulnerable groups such as those in perinatal, neonatal and mental health services (Gregory and Radovinsky, 2012).

In specific relation to the study, it was felt that chart review could feasibly be carried out by a single researcher as a primarily desk based study under the supervision of academic staff. Accessing the data would not place any significant burden on other staff members engaged in clinical duties or directly involve patients and their families in terms of areas such as time; payment; inconvenience or unnecessary anxiety and distress. As such the research would be carried out discreetly with little impact on others schedules and routines. In comparison, survey or interview methods may rely heavily on the time, co-operation and subsequent recruitment of staff and/or patients/families.

The mental health nursing backgrounds of both the researcher (working in clinical practice on a full-time basis locally) and supervisors (working in academia but with extensive clinical experience) meant that the team would have thorough knowledge of the information typically contained within clinical data. Use of a chart review method was supported by the following:

- The researcher would have a clear idea of the nature and type of data retained in patient charts locally (e.g. predominately handwritten as opposed to electronic data; assessment form layout; type of correspondence included; drug charts; blood results etc.)
- As a consequence the team would be able to ascertain the research questions likely to be easily answered by chart review/content analysis and omit questions unlikely to be answered
- Awareness of common problems with information flow in relation to patient data (e.g. missing data, illegible entries; data recorded incorrectly or inconsistently)
- Knowledge in relation to navigating access and security requirements
- Knowledge of processes involved in local incident reporting system
- IT access for relevant electronic resources (e.g. secure HSE email and data storage; local electronic patient information management system)

- Access to restricted clinical sites/chart storage areas
- Able to liaise with key stakeholders/contacts responsible for managing and recording serious incident data and patient charts/data

7.4.3 Limitations of retrospective chart review

A number of limitations are commonly cited in the available literature. Having access to complete and clearly legible information is a frequently cited difficulty including factors such as missing patient charts; missing patient data; amount of available data; poorly archived or inaccessible data and difficulty understanding content (e.g. medical abbreviations and acronyms or undecipherable handwriting) (Gearing et al. 2006; Sarkar and Seshadri, 2014; Puyat et al. 2019).

Similarly, the consistency of documentation can vary amongst clinicians in terms of quality; quantity, collection methods and level of subjectivity (Park, 2013; Gregory and Radovinsky, 2012). Such issues of missing data; inconsistent collection procedures, chart illegibility and differences in subjective clinical interpretations can lead to difficulties in the analysis of documented information, affecting the overall validity and reliability of research studies (Barick et al, 2018; Worster and Haines, 2004). Validity, in the sense of this research study, relates to the degree to which retrospective chart review and the processes/tools used can accurately measure and represent the chosen topic (i.e. serious incidents in mental health services) (Roberts and Priest, 2006). Reliability describes the degree to which the measurement processes involved in retrospective chart review are likely to produce consistent results when used over time (Roberts and Priest, 2006).

Other limiting factors relate to the inappropriate choice of retrospective chart review as a research method from the outset, as opposed to the approaches taken during the process of data collection. Sarkar and Seshadri (2014), highlight, for example, that retrospective studies are more suited to establishing associations between phenomena than exact causal relationships, with prospective studies likely to be more effective where this is one of the main objectives. Gearing (2006) similarly notes the difficulty in establishing precise cause and effect outcomes through use of retrospective chart review alone.

Further limitations do not preclude the use of retrospective chart review but are commonly acknowledged on publication. The limited generalisation of results are acknowledged where sample sizes are small or restricted to single locations (Narita et al. 2019; Panagiouto, 2019). Also, resource limitations sometimes mean that following exact chart review guidelines are impractical. For example, not having sufficient numbers of researchers/reviewers to locate, sort and collect data (van Melle et al. 2018).

Lastly, the omission of patient consent requirements may be advantageous in terms of time, resource and cost savings. However, recent GDPR legislation governing individual consent issues has significantly impacted on retrospective chart review as a research method (Clarke et al. 2019) meaning that increased researcher workload; long delays and financial implications may now be limiting factors (Crowhurst et al. 2019). The areas of consent and ethics approval are discussed further in Chapter 8.

7.4.4 The use of retrospective chart review in recent mental health research studies

An analysis of published mental health chart review studies and theses from the last 5 years provides evidence of its effective utilisation across a number of areas. They provide examples of the broad range of patient data used and the types of data extracted. In essence these examples demonstrate the mutual use of well-defined and specific research questions; the establishing of basic demographic details; the collection of precise data from the charts in response to the questions set and a subsequent analysis/comparison of these results.

Cocoman and Gallagher (2019) examined the charts of patients treated with antipsychotic medication across a number of community mental health teams. They used the charts to record physical health data related to the presence of metabolic syndrome, looking at areas such as weight, blood pressure, BMI and blood results over time. Associations between antipsychotic medication and a high presence of metabolic syndrome were able to be drawn from the study but they noted methodological limitations in the use of paper charts where information was often missing or poorly recorded.

Tang et al (2017) used the 9 step process devised by Gearing et al (2006) to examine the charts of adolescent patients with psychotic disorders. As noted in the guidance discussed, they used chart review to examine the associations between clozapine medication treatment, cannabis use and psychosis. From each chart included in the study they recorded baseline demographics plus presence/frequency of cannabis use and presence/severity of psychotic symptoms over time. The authors appear to demonstrate the use of clear research questions.

Vermeulen et al. (2019) also cite the specific aims accompanying their chart review study, determining the nature and incidence of adverse events and the quality of physical health care for patients with psychosis. The authors in this study used a previously validated checklist screening tool to audit whether items on this list were addressed and recorded in the reviewed charts. The study has similarities with the aims and objectives of my own research dissertation in terms of using chart review to focus on the prevalence of adverse events.

A doctoral thesis by Neil (2019) also examined charts to screen for an aspect of care quality, on this occasion to ascertain the extent to which mental health professionals ask patients about their adverse experiences. Whilst chart review enabled a review of the prevalence of this practice and differences by age and gender for example, a further conceptual and theoretical review was carried out in order to explore why this aspect of care is often neglected.

Another doctoral thesis by Jones (2018) demonstrates the use of electronic medical record review to examine gender differences in the experience of psychosis. In common with my own research study the author uses a combination of quantitative and qualitative methods. Firstly, aiming to establish basic demographic data and the prevalence/type of symptoms recorded in the records and secondly carrying out a thematic analysis to explore these findings in more depth. Whilst chart review was used to identify reported gender differences in relation to psychosis, the thematic analysis was used to provide insights and possible explanations for these variances.

7.5 Application of research method

Applying the three frameworks for retrospective chart review directly to the research study advances the following points:

7.5.1 Formulating research question

The research questions chosen for the study developed from the original research proposal; setting forth the concept of examining serious incidents in Waterford/Wexford mental health services. In order to answer the question 'what are the contributing or contextual factors evident in serious incidents' it was also felt important to identify details relating to:

- the different types of incident that occur
- the number of incidents occurring
- where and when incidents occur
- the characteristics of patients involved in incidents
- any trends or patterns relating to incident types and frequencies, locations and patient characteristics

7.5.2 Identifying data sources

The relevant data sources where this information could be sought were identified as incident report forms (completed by staff members following an incident and entered onto an electronic database); paper-based patient medical charts; a local electronic patient information management system (containing basic patient data such as contact details, appointment times and hospital stays and an electronic folder containing patient letters (outpatient appointment and hospital discharge letters from local mental health teams to patient GP's and other agencies).

It was considered how the data sources could be examined in order of need. The incident report database would need to be viewed first in order to apply relevant inclusion and exclusion criteria for the study. This would consequently reveal details of incident prevalence; types, locations and persons involved. After this stage, the relevant medical charts could be examined for details about the patient and the incident themselves. Where patient charts could not be located or were incomplete, the patient information management system and the electronic patient folder could be accessed to obtain missing patient data. Gearing (2006) suggests that the prospect of missing data should be considered from the outset and strategies put in place to accommodate omissions.

Having clinical knowledge of how patient information is recorded locally also meant being able to specify the exact documents where relevant data could be found (e.g. a risk assessment document for information on previous history of violence or patient summaries detailing diagnosis). Using a consistent approach and having a clear protocol in terms of where and how data is collected is viewed as important from a reliability perspective (Gearing, 2006; Sarkar and Seshadri, 2014). As such, a protocol for carrying out the chart review was drafted (Appendix 12).

Furthermore, in terms of accessing relevant patient charts and data, local service knowledge had a significant influence on the locating and accessing of relevant locations and storage facilities, both electronically (having relevant I.T. access) and in-person (e.g. knowing where old files are stored and knowing where to obtain the necessary permission to gain entry).

7.5.3 Consideration of sample size and strategy

Consultation with a statistician took place in order to consider sample size and how best to select appropriate cases for inclusion. Working from a sample would be required due to the significant number of incidents recorded within the study's parameters and the limited time and resources available to review all the available data. A simple random sampling design was proposed using the randomisation function available on excel. Robson (1993) defines simple random sampling as random selection of the required number of persons from a list of the population. In relation to the study, this would require randomly selecting a sample of incidents from all the valid reports over the period 2011-2018.

The main benefit of randomised sampling is that it provides the best likelihood of an unbiased representative sample (Macleod, 2019). In respect of the study this meant that every incident reported would have an equal chance of being included. Random sampling is seen as the recommended method in terms of chart review studies as it accounts for potential bias and permits generalisation to the population from which the sample was taken (Vassar and Holzmann, 2013). Bias in the case of the study relates to the potential for sampled incidents to be unreflective of the population from which they are drawn (e.g. weighed unfairly in favour of one location, one age group or one gender).

In relation to sample size, the guidance suggests the use of a mathematical process called power analysis to determine the sufficient number of charts needed, based on a specified statistical power, level of significance, and estimated effect size (Hayat, 2013). Statistical power and statistical significance are terms that help quantify how likely a study is to distinguish an actual effect from a chance effect; thereby verifying a hypothesis (Statistics How To, 2021). Studies with larger samples are seen to have greater power whilst sufficient power is needed in order to be able to detect statistically significant differences between variables (Vassar and Holzmann, 2013). Effect size is the magnitude of the differences between such variables, where the larger the effect size, the stronger the relationship (McLeod, 2019).

As such, sample size was calculated using G*Power Version 3.1, a free software tool used to calculate statistical power (Faul et al. 2009). A medium effect size (0.30) (Cohen, 1988) was employed to obtain study power of 80; commonly seen as an acceptable level of power in statistical analysis (Jones et al. 2003; Bhandari, 2021). A minimum sample size of 333 incidents was subsequently proposed for the study. Appendix 13 outlines the process of determining power as discussed with the statistician.

7.5.4 Statistical analysis

In the context of the study, power refers to “the probability that a statistical test will reject the null hypothesis when the alternative hypothesis is true” (Vassar and Holzmann, 2013: p.

2). By way of illustration, a commonly held hypothesis that one might expect to see in this study is more violent incidents involving males than females; a common finding in mental health research literature (Dack et al. 2013; Bowers et al. 2014; Iozzino et al. 2015). In this instance, the null hypothesis would be that there are no differences between males and females in relation to violent incidents. The alternative hypothesis would be that there are indeed more violent incidents attributed to males than females. Confirming this finding would require sufficient power and the use of a statistical test to assess the degree of certainty; the effect size being the difference found between male and female violence. The level of significance relates to the probability of rejecting the null hypothesis when it is true (Jones et al. 2003); a significance level of 0.05, for example, indicating a 5% chance of concluding that a difference in genders exists when there is in fact no difference.

After discussion with a statistician, it was agreed that incident type (e.g. violence) would be the Primary Outcome Measure (POM) of the study. This is the measure felt by the investigator to be the most important outcome amongst the many possible outcomes considered in any research (Andrade, 2015) and as such was one of the first research questions proposed for this study. A chi-square test of independence would be utilised to compare the POM with other variables in the study as follows:

- Comparisons between Waterford and Wexford counties and incident type
- Comparisons between clinical areas and incident type
- Comparisons between genders and incident type
- Comparisons between age groups and incident type
- Comparisons between years and incident type
- Comparisons between voluntary and involuntary patients and incident type
- Comparisons between diagnoses and incident type
- Comparisons between ethnicities and incident type
- Comparisons between months/days/times of the day and incident type
- Comparisons between lengths of stay and incident type
- Comparisons between lengths of time known to mental health services and incident type

- Comparisons between histories of violence/self-harm/suicide/drug or alcohol misuse and incident type

A chi-square test of independence would determine if there is a statistically significant relationship between two categorical variables, where the frequency of each category for one variable is compared across the categories of a second variable. (Statistics Solutions, 2021). Relating this to the study, the first categorical variable would always be incident type followed by comparisons with the remaining variables (e.g. gender, age group) as listed above. A categorical variable (also commonly referred to as a nominal variable) has two or more categories but no discernible ranking or order (University of California, Los Angeles, 2021) (UCLA), differentiating the categories of variables such as ethnicity and diagnosis listed above (which are not ranked) from other variable types such as ordinal or interval data.

7.5.5 Devising data extraction instrument

A simple paper-based data collection form (Appendix 14) was drafted which would allow relevant research data to be recorded on one document per reviewed chart. The choice of questions to include on the data collection form was influenced by the set research questions, the reviewed literature (e.g. the type of patient characteristics known to be associated with serious incidents such as age and diagnosis) and clinical knowledge in relation to the content of data sources (i.e. the type of information likely to be found in patient charts and incident reports and the type of data not available via these sources).

Consideration was also given at this stage as to how the data could be aggregated and further analysed. Robson (1993) considers the role of retrospective studies in experimental research design where a dependent variable is identified (the effect) and further examined in relation to independent variables (the cause). In the context of the research study, incident type was identified as the dependent variable (e.g. violent or self-harming incident) then examined in terms of its relationship to various independent variables (e.g. age, gender, time of day). Gearing (2006) suggests the use of a software package that parallels the data collection form to collate all information gathered. Microsoft Excel was selected for its functionality and ease of use, where the spreadsheet would contain drop-down lists reproducing the variable categories on the data collection form.

7.5.6 Consideration of ethical approval

Chapter 8 focuses on the process of obtaining ethical approval for the study, where the use of patient data for research purposes became a complex issue significantly delaying the chart review process.

7.5.7 Use and training of abstractors; inter-rater reliability and use of procedural manual

The guidance on retrospective chart review advocates the use of more than one abstractor or data collector, ensuring that they are trained beforehand and continually monitored, whilst, ideally, blinding them to the study purpose and research questions (Vassar and Holzmann, 2013; Gearing, 2006). The reasons for this relate to issues of data collector bias where individual assessment may lead to different findings, ultimately affecting the validity of the study. A minimum of 2 data collectors has been recommended (Gearing, 2006) in order to ensure inter-rater reliability, or the extent to which two or more persons agree on the data they are collecting (Fink, 2010).

Having only one data collector, therefore, can be viewed as a limiting aspect of the study. Ethical approval was only obtained for one named person, whilst available resources neither permit the use of multiple researchers. Whilst little guidance appears to be published in terms of solo chart review, efforts have been made to maintain accuracy and consistency by keeping questions close-ended, uncontentious and answered from a short list of available options. Similarly, use of the procedural manual offers a consistent approach to data collection and examining the same sources of data for each incident.

7.5.8 Pilot test

A pilot test was carried out, using a draft data collection form to screen 10 charts (in researcher’s clinical place of work only for ease of access). The pilot test provided the opportunity for any discrepancies or omissions on the data collection form to be amended. Vassar and Holzmann (2013) suggest that pilot tests can help determine the feasibility of data abstraction; determine whether certain variables are frequently missing from charts and provide insight into local practice in terms of accessing and retrieving charts. Specifically the pilot test provided insight into how long each chart review would likely take; the suitability of each proposed data source in providing the necessary information and practice in relation to completing data collection forms and copying these to an excel spreadsheet.

7.5.9 Data collection/abstraction

Data collection was broken down by location and each area contacted. A permission letter was drafted by local HSE management allowing access to different sites and the relevant manager/responsible person in terms of chart storage contacted prior to visiting. Data collection forms were completed (one per incident) by hand and then added consecutively to an excel spreadsheet. The completing of 30 forms per week was estimated requiring approximately 12 weeks in total to collect all the data. A diary was retained over the period to highlight any issues relating to the data collection process (e.g. chart availability; problems accessing certain locations; differences in documentation) and to record any subjective observations or considerations as they arose (Appendix 15).

7.6.0 Analysis and presentation of results

Once completed, the data collected was analysed with statistician support in order to carry out the statistical comparison tests (see chapter 9, results).

7.7 Content analysis

Content analysis aims to translate large amounts of text, visual or verbal communication into organised and summarised data, using a systematic approach (Elo and Kyngas, 2008); Erlingsson and Brysiewicz, 2017). Although typically associated with qualitative methodologies (Gale et al. 2013; Vaismoradi et al. 2013; Bengtsson , 2016) it can also be utilised in quantitative research, particularly where a researcher may wish to quantify the occurrence of particular words phrases in a given text (Hamad et al. 2016; Ash et al. 2017; Grossman et al. 2018).

In relation to the study, whilst retrospective chart review can produce a significant amount of quantitative data relating to patient characteristics (e.g. diagnosis; gender; age); incident details (e.g. location; time; date) and their association with incident types (e.g. violence and self-harm) it does not necessarily examine the contributing or contextual factors associated with serious incidents, or ostensibly why these incidents may occur. A more qualitative approach will therefore enable the detailed examination of events occurring before each recorded incident in order to identify possible contributing/contextual factors.

Qualitative content analysis has been defined as “a research approach for the description and interpretation of textual data using the systematic process of coding” (Assarroudi et al. 2018: p.43), where data analysis leads to the identification of categories, themes and patterns (Hsieh and Shannon, 2005; Elo and Kyngas, 2008). Coding in research refers to “the process of transforming collected information or observations into a set of meaningful cohesive categories” (Allen, 2017: p. 148).

Within healthcare research analysed text may take many forms including transcribed interviews; survey responses; focus groups; observation and print media such as books and manuals (Hsieh and Shannon, 2005). Although approaches to content analysis can differ, studies tend to follow the steps of setting research questions; reading and reviewing chosen texts; the use of coding and category construction and the forming of relevant themes (Bowen, 2009; Erlingsson and Brysiewicz, 2017). Hsieh and Shannon (2005) outline 3 different approaches to content analysis as summarised in Table 8. The authors note that the type of content analysis approach chosen may vary according to the question being addressed and the researcher’s own aims and objectives. Where little or no existing theory is available in relation to a particular area of study, conventional content analysis may be the ideal choice of approach. Recent examples include analysis of nursing managers’ perceptions of workforce managers during COVD-19 (Poortaghi et al. 2021) and a study of Instagram posts by women with breast cancer (Pluta, 2021).

Table 8. Three Approaches to content analysis (Hsieh and Shannon, 2005)

Conventional content analysis	Directed content analysis	Summative content analysis
Aims to describe a phenomenon	To extend or validate existing theory	Tries to understand contextual use of words/text etc.
Where existing theory is limited	Where theory or wealth of research already exists	Finding underlying meaning
On	Existing theory helps to determine coding, research questions etc.	Researchers explore word usage and range of meanings
Flexible approach	More structured approach	
Allows insights to emerge		

Directed content analysis differs in that a depth of existing theory and research already exists, resulting in the validation or extension of concepts and frameworks already established. For example, Wei and Watson (2019) utilise an established theory of human caring (Watson, 2018) to examine interprofessional team members' perspectives on the topic. Summative content analysis uses a more interpretive approach to understanding context in terms of word usage, where an explorative framework aims to discover the underlying meanings of words and content. This is sometimes referred to as latent content analysis, or interpreting meanings that are often 'hidden' or implied within text (Kleinheksel et al. 2020). To illustrate, a recent study focusing on media portrayal of mental illness (Razali et al. 2018) focused on the tone of newspaper reports (as opposed to the stories in themselves) in order to categorise whether mental illness was viewed from a positive or negative perspective.

7.7.1 Strengths and limitations of content analysis

Cited advantages of content analysis include the production of historical insights over time; its flexibility in terms of design; the ability to carry out statistical analysis (once coded); its unobtrusiveness; its ease of comprehension and its relative inexpensiveness as a means of examining text (Columbia University, 2019; Elo and Kyngas, 2007; Bengtsson 2016). Its suitability for analysing the sensitive areas within nursing research has also been highlighted (Vaismoradi et al. 2013).

Cited limitations include a potentially time consuming process; subjective interpretation of data leading to increased risk of error; the applying of incorrect meanings; the over-condensing of text and the disregarding of its original context and difficulty in analysing through automation (Columbia University; 2019). It has, historically, been seen to lack firm definition and procedures (Hsieh and Shannon, 2005) and has been criticised as a process of simply counting words, neither lending itself to statistical analysis nor having a rigorous qualitative framework (Elo and Kyngas, 2007).

7.7.2 The use of content analysis in recent mental health research studies

Recently published studies and academic theses demonstrate the scope of research served by content analysis. Three studies utilised health records content analysis as part of their overall methodologies. Firstly, Goncalves et al. (2019) examined the nursing documentation within mental health patient records. The authors used content analysis to systematically code and categorise 198 different nursing interventions from this data, later exploring these interventions and the terminology used.

Tajabati et al. (2019) also carried out a content analysis on medical records of patients in non-mental health units, in order to explore factors influencing nursing documentation. In this example, the authors condensed the original data into categories and subsequently 12 sub-categories outlining influencing factors. They went on to group these categories and sub-categories under an over-arching theme of 'unsafe documentation.'

A third study applying content analysis to health records was carried out by Morrisson et al. (2018). In this study the authors wanted to identify the type of drug errors that occurred on a mental health ward in Australia and the context in which they occurred. They carried out a content analysis of unstructured text from a clinical incident database to establish categories and themes exploring the nature of drug errors and the associated causative factors.

Two recent doctoral theses also provide evidence in relation to the use of content analysis. Moore (2017) used this method in their study of online resources for perinatal mental health.

The author studied posts on a perinatal mental illness forum over a six month period and established relevant themes as part of their overall research strategy.

Finally, Shannon (2019) examined the use of coercion in mental health practice, carrying out a content analysis of mental health commission inspection reports within an Irish psychiatric hospital. The author used an evidence based protocol to guide them through the content analysis process, focusing on text referring to the involvement of security personnel. The author describes a process of reviewing the text; applying codes; establishing categories and ultimately producing themes for further discussion and analysis.

7.8 Application of research method

This study proposed the use of directed qualitative content analysis (QCA) as outlined by Hsieh and Shannon (2005). The use of this specific approach reflects the presence of well-established contributory factor frameworks for serious incidents occurring in mental health services (as noted in 3.1 and 7.3.5) and the wealth of existing literature relating to contributing factors (as outlined in the literature review). The authors refer to a seven stage process of content analysis which was applied to this research study as follows:

7.8.1 Formulating the research questions to be answered

The enquiry ‘what are the contributing or contextual factors associated with serious incidents occurring in Waterford/Wexford mental health services?’ was the research question in this instance.

7.8.2 Selecting the sample to be analysed

The same random sample obtained for the retrospective chart review was utilised for QCA. If the patient’s chart was not available, however, no analysis was possible as access to handwritten notes was required. This means that the sample obtained for QCA is smaller than the sample obtained for retrospective chart review. In relation to qualitative content analysis, there is no commonly accepted sample size; the sample dependent on the research questions and the purpose of the study (Elo et al. 2014). Therefore, in relation to my research study, all cases where notes were available were used and this appeared to produce sufficient data for contributory factor analysis.

Data ‘saturation’ is a commonly used term in qualitative analysis to describe the point where data collection can stop as no new categories or codes are being discovered (Glaser et al, 1968; Urquhart, 2013). However, in more deductive research (i.e. where pre-determined categories are applied rather than an inductive approach where these emerge naturally) Saunders et al. (2018) refer to a model of ‘a priori thematic saturation.’ This model is the most applicable to my own study as it reflects how incident reports and patient notes were examined in relation to set categories (patient factors; staff factors; organisational/environmental factors and external factors). Using the randomised sample appeared to provide sufficient examples across each set category.

As repeated contributing/contextual factors emerged, these were then coded within the predetermined category framework. Whilst knowing when data saturation has occurred is difficult to predict with no singular method advocated for in the research literature (Fusch and Ness, 2015), consensus exists in terms of reaching a stage where no new codes or themes are emerging and where the data used is rich (relating to quality) and thick (relating to quantity) (Dibley, 2011). It was felt that this stage had been reached once all available charts had been reviewed.

7.8.3 Defining the categories to be applied

The four defined categories applied were the contributing/contextual factors identified during the literature review process (patient factors; staff factors; organisational/environmental factors; external factors). These broad categories are adapted from the research evidence and from existing contributing factor frameworks.

7.8.4 Outlining the coding process

The coding process began with locating and accessing the patient chart for each reported incident in the sample. For convenience, this process took place simultaneously alongside the retrospective chart review part of the study and is incorporated into the data collection form. As such, the following coding instructions were utilised:

- Examine handwritten notes for 7 days prior to incident occurring
- Examine Common Assessment Tool (CAT) document (selecting one closest in time prior to incident if there are more than 1)
- Examine risk assessment tool (selecting one closest in time prior to incident if there are more than 1)
- Examine typed letters and summaries in correspondence section
- Consider which factors may have contributed to incident occurring (maximum of 5)
- Consider these factors in terms of the predetermined categories (patient; staff; organisation/environment; external issues)
- List up to 5 contributing factors on the data collection form (paraphrase from official records as no identifying data should be documented, e.g. patient/staff/unit name)

Each area of text identified in the patient chart as signifying a possible contributing factor was paraphrased and added to columns in the excel spreadsheet; alongside data from the retrospective chart review and a brief description of each incident as it was originally reported. A maximum of 5 contributing factors per incident was used due to time limitations and indeed no cases in the pilot study revealed more than 5 different contributing factors.

7.8.5 Implementing the coding process

Text was coded from charts where there appeared to be a ‘trigger’ event or occurrence, signifying a potential contributing factor. This may have been something that happened during the patient’s care or something relating to the patient’s history. Table 9 is a fictitious scenario used to demonstrate how the coding process was carried out in practice. As the example shows, an incident description was provided alongside the identified contributory factors. As the content analysis progressed and contributory factors began to repeat themselves, these could then be coded into themes. For example, factors relating to the person's illness (e.g. hallucinations and paranoia).

Table 9. Example of coding process

Incident	Paraphrased line of text
Patient punched wall with his hand	Expressing paranoid ideas
	History of physical violence
	Appears to be responding to auditory hallucinations
	Expressing frustration regarding having to stay in hospital
	Upset following visit from family member

Qualitative data analysis software (QDAS) was considered in order to support the coding process. NVivo is one such well-established software package, produced by the company QSR International. QDAS is designed to support the analysis of qualitative data across 5 areas; managing and organising data; managing ideas; querying data; graphically modelling ideas/ concepts and data reporting (Bazeley and Jackson, 2013). Strengths associated with using QDAS include a single storage location with easy access to material and the ability to manage large amounts of data (Bergin, 2011). QDAS has also been endorsed as a means of demonstrating rigour, consistency and trustworthiness in research design (see 7.8.6) (Morison and Moir, 1998; Ryan, 2009; Woods et al. 2016). It has been widely used in published content analysis studies using a range of data sources; including interview transcripts (Haanstra et al. 2013); news articles (Kaefer et al 2015) and medical progress notes (Steel et al. 2019).

Weaknesses of QDAS include the time and effort required for researchers to familiarise themselves with the program (Robson, 2002); the distancing of researchers from their data (Roberts and Wilson, 2002) and an over reliance on the software in terms of reduced critical reflection (Bazeley and Jackson, 2013). Writers have also highlighted how QDAS does not replace the required interpretation and exploration associated with qualitative research design (Ryan, 2009; Kaefer et al. 2015). As the raw data was summarised into manageable, short phrases as noted in table 9, it was felt that QDAS would not be required to support the coding process. As such, Microsoft Word was used to assign contributing factors into different themes, transferring these from the Excel spreadsheet and systematically assigning each one to a particular theme.

7.8.6 Determining trustworthiness

Being able to justify the quality of research design; methods and findings is an important aspect of qualitative research (Noble and Smith, 2015), with qualitative research often criticised for lacking scientific rigour in relation to methods justification; lack of procedural transparency and being biased or merely anecdotal in terms of findings (Rolfe, 2006; Anderson, 2010).

A widely used standard for evaluating aspects of research validity in relation to qualitative content analysis is the concept of 'trustworthiness.' Lincoln and Guba (1985) refined the term to include four components; credibility, dependability, conformability and transferability (Box 5); its aim being the justification of research findings as being worthy of attention. Elo et al. (2014) further suggest that all phases of the research process should address trustworthiness; including preparation, organisation and reporting stages.

Box 5. Four components of Trustworthiness (adapted from Lincoln and Guba, 1985)

Concept	**Description**
Credibility	Concerning the 'truth' of research findings. That the data collected is plausible information; true to its original meaning and correctly interpreted by the researcher
Dependability	Concerning how results are consistent over time. If the study was repeated in the same context, the results would be repeatable
Transferability	Concerning the degree to which the research findings can be applied to other contexts, settings or persons

Confirmability	Concerning the degree to which the results of a research study could be confirmed by others and accounting for objective data retrieval on the part of the researcher

7.8.6.1 Credibility

Credibility is addressed through recommended strategies in the available evidence. Two of these can be applied to the research study. Firstly, Graneheim and Lundman (2004) suggest that credibility should begin with selecting the most appropriate research method. As noted previously, content analysis has been widely used in studies using written documentation (e.g. medical notes) and has a number of defined strengths relevant to this study. Whilst there are clearly other methods that could provide insights into why serious incidents might occur, each of these have strengths and limitations. A comparison of content analysis and structured staff interviews, as another example, raises the following issues relevant to the study (Box 6). Whilst limitations are evident, there are a number of evident strengths for using content analysis.

Box 6. Strengths and limitations of content analysis versus structured staff interviews

Content Analysis		**Structured staff interviews**	
Strengths	**limitations**	**strengths**	**Limitations**
• Unobtrusive • Examines data about events otherwise possibly forgotten • Directly examines source information • Can examine ‘manifest’ content (what’s written) and ‘latent’ content (what can be inferred or is unwritten) • Familiarity of researcher to text being analysed (e.g. context, types of data and where to find required info.)	• Missing data • No cause and effect conclusions • Researcher may misinterpret latent content • Not all contributing factors in serious incidents likely to be referenced in medical notes	• Fixed set of questions that are easy to repeat • A wider range of opinions may be obtained • More reliable approach in terms of successful method outcome (e.g. no missing charts)	• More obtrusive • Lack of recall • Recall bias • Discussing sensitive information may cause distress • Not wishing to criticise other staff members or the organisation employing them

Triangulation is cited as another means of demonstrating credibility. Methodological triangulation can be applied to the study; defined as the use of more than one kind of research method in order to provide confirmation of findings (Bekhet and Zauszniewski, 2012). For this study, retrospective chart review was utilised in order to obtain quantitative data relating to the types and locations of incidents occurring, in addition to the characteristics of those involved in incidents. This data supported the content analysis by providing a level of context and background data. For example, the potential differences between violence as it occurs on an acute admission unit (treating mainly functional illnesses) as opposed to an older adults unit (treating mainly organic disorders) was able to be observed and examined.

7.8.6.2 Dependability

Dependability relates to taking a consistent approach during the research process (Lincoln and Guba, 1985). In terms of the study, this was addressed through adhering to the original research design and, where possible, following the guidelines accompanying each research method. Korstjens and Moser (2018) also recommend that an 'audit trail' be produced during data collection phase, enabling any assessor of the results to endorse consistency and transparency. As proposed, data analysis notes were maintained during the research process, containing reflective thoughts and observations as they emerged (Appendix 16).

7.8.6.3 Transferability

Korstjens and Moser (2018) suggest that any reader of research results should be able to judge whether the findings relate to their specific settings. The writers propose that this is achieved through 'thick description' of the research process and data such as context, settings, sample strategy and demographic/clinical characteristics. In relation to the research study, this type of information has been recorded and made clear to the reader at each stage.

7.8.6.4 Confirmability

Confirmability relates to the level of neutrality maintained by the researcher (Guba and Lincoln, 1985), where the interpretation of results "should not be based on your own particular preferences and viewpoints but needs to be grounded in the data" (Korstjens and

Moser, 2018: p. 122). Whilst strategies to offset researcher bias include data collection by a second researcher and member checks (seeking feedback and validation from respondents) (Elo et al. 2014); these were not factored into the research study due to GDPR issues, degree of resources available and the practical implications of contacting respondents in the case of historical research.

Reflexivity is another strategy recommended in terms of demonstrating confirmability. The process relates to the act of critical self-reflection, particularly a researcher's own preconceptions and biases in relation to the data being obtained (Korstjens and Moser, 2018). In the context of the research study, I strived to focus solely on the content of the data whilst continually reflecting on the degree to which my past experiences could influence the data analysis. I found that maintaining a diary of observations as they emerged helped in terms of keeping true to the data as did discussing issues with my research supervisors.

Chapter 8: Ethics approval and issues relating to GDPR; individual consent and the use of patient data in research

8.1 Introduction

This chapter focuses on the process of gaining ethical approval for this research study. The seeking of this approval was the first major step in the research journey and proved to be significantly more complex than first considered. Whilst many ideas and suggestions pertaining to relevant literature; research methods and data collection had been discussed in supervision sessions prior to ethics committee submission, the consent process overall was key in shaping and informing the eventual strategies/methods chosen. The significance of this chapter is underlined by the study being one of the very first to be assessed within the newly introduced framework of GDPR.

The simultaneous introduction of the General Data Protection Regulation (GDPR) at the very point where ethics approval was initially sought meant that many new and untested areas were encountered, not least a lengthy and labour intensive application process via the Irish Health Research Consent Declaration Committee (HRCDC). It should be noted that the availability of more recent guidance affecting the use of patient data for research purposes (specifically retrospective chart review studies) would likely result in different outcomes were the same research study proposed and submitted for ethics approval in 2023. Nevertheless, the experience was valuable in terms of gaining new knowledge relating to consent requirements. Each stage of the process is examined further in this chapter.

The first section examines broad theories of ethics that relate to the area of healthcare. The historical context of healthcare research ethics is provided in the next section as this aids an understanding of why ethical considerations remain a significant feature of the research process. The next two sections introduce the role of Research Ethics Committees and provide background information in relation to local health research policies/procedures and the General Data Protection Regulation (GDPR); legislation which had a major impact on the process of this research study. Ethics in healthcare research specifically related to retrospective chart review is subsequently discussed, incorporating recent amendments to the statutory guidance for this type of research in Ireland. The remaining sections focus on a timeline of events covering the process of seeking ethical approval. A description of events is outlined first, followed by critical discussion and evaluation, from both local and wider healthcare perspectives. The chapter ends with a final summary and concluding comments. Relevant theory and literature is referenced throughout to demonstrate learning.

8.2 Ethics in healthcare research

8.2.1 Introduction

At its simplest ethics is defined as a “set of moral principles” and the “principles of conduct governing an individual or group” (Merriam-Webster, 2021). The World Health Organisation (WHO, 2021: para.1) states that research ethics govern the standards of conduct for scientific researchers in order to “protect the dignity, rights and welfare of research participants.” They are additionally defined as “the moral problems encountered in connection with scientific or other academic research, by the researcher, their subjects or their social environment” (Berg & Tranoy, 1983; p13). From a healthcare perspective, ethical considerations in relation to patient care have been present since the time of Hippocrates (460-370 BC) (Miles, 2009) but continue to evolve and develop to this day.

8.2.2 Philosophical theories of ethics

Four main ethical theories which have relevance to healthcare include utilitarianism; deontology; virtue ethics and principlism (Rodger and Blackshaw, 2017).

8.2.2.1 Utilitarianism

Utilitarianism is a consequentialist theory in that it determines the morality of actions based on their outcome and seeks the greatest benefit for the greatest number of individuals (Vearrier and Henderson, 2021). From a patient perspective it asserts that the effects of actions on individual well-being and the avoidance of experiences such as suffering are the kinds of outcomes that need to be considered, in addition to the equal recognition of all individual experiences and ultimately choosing options with the highest overall benefit (Felzmann, 2017). Rodger and Blackshaw (2017) note two main major areas of controversy in relation to utilitarian ethics. The first relates to the fact that it may not always be possible to predict or be exact about the consequences of any action. Secondly, as utilitarianism affords some harm where there is benefit to the majority at large (Verarrier and Henderson, 2021), innocent people may suffer as a result. This challenge has been exemplified by the recent worldwide COVID-19 (coronavirus) pandemic where the potential for patient demand outstripping resources led to a utilitarian standpoint whereby those with the greatest chance of survival were prioritised over those less likely to recover; therefore maximising the number of lives saved (Goldhill, 2020).

8.2.2.2 Deontology

Deontology is a duty based approach to ethics that differs from utilitarianism in that consequences of actions are less significant, with emphasis placed on the following of rules, obligations and duties; the deeming of actions as right or wrong and the intentions of the individual as opposed to the outcome of any action (NHS, Scotland, 2018; Copeland, 2019). Rodger and Blackshaw (2017) add that even where certain actions may result in good, these actions should be refrained from if they are intrinsically wrong from a moral perspective. One of the foremost proponents of deontology, Immanuel Kant, coined the term ‘categorical imperative’ to signify the moral obligation of individuals whereby one should “act only in accordance with that maxim through which you can at the same time will that it become a universal law” (Kant, 1997: xviii). In essence, testing the morality of an action by considering its use by everyone in order to create a moral law or rule (Kearns, 2017).

As such deontology is often referred to as duty, obligation or rule-based ethics (Waller, 2010). In the nursing profession the standards set by the Nursing and Midwifery Board of Ireland (NMBI) (Code of Professional Conduct and Ethics, 2021) provide an example of a deontological framework in that rules and standards are applied which should then be followed. Limitations associated with deontological ethics include how strictly rules should be followed when they may in turn cause harm. ‘Lying’ in healthcare is seen as a frequent point of debate as it can create a clash of conflicting roles and duties for professionals (Kearns, 2017). ‘Therapeutic’ lying in areas such as dementia care provides a relevant example of conflicting moral obligations, whereby lying may be undesirable from a professional perspective but can be morally justified in terms of minimising harm and regulating behaviour (Tuckett, 2012).

8.2.2.3 Virtue Ethics

Virtue ethics differs from other theories in that it focuses on the acquisition of good character or ‘virtue’ over time, as opposed to outcome based (utilitarian) or rule based (deontological) theory (Talbot, 2012). The primary aim is for individuals to develop good character in order that they act correctly for the right reasons when required to do so (Rodger and Blackshaw, 2017). The nursing profession, for example, has long been associated with virtue ethics, where morality and being of virtuous character remain intrinsically linked to professionalism (Sellman, 1997; Newham, 2015; Bliss et al. 2017).

Virtue ethics receives a level of criticism in terms of a lack of moral rules or guidance for individual actions and dictating the development of good character over and above merely being seen to do the right thing (Sellman, 2017; Rodger and Blackshaw, 2017). Similarly, the situation or context of any decision to act in a certain way may be a stronger contributing factor than a person's innate character and this should not be overlooked (Sellman, 2017). The UK Mid-Staffordshire NHS report (Francis, 2013), for example, criticised nursing staff for various unethical and inconsiderate practices, recommending a greater focus on improving character virtues such as compassion. However, the existence of poor practice is felt to be more than just a lack of internal personal virtues and needs to be viewed in the context of external or situational factors (Ferkany and Newham, 2019). It is also highlighted that an over emphasis on virtues could indeed cause harm in some cases, especially where it leads to undesirable outcomes such as burnout (Allmark, 2013).

8.2.2.4 Principlism

Principlism is the most widely adopted ethical framework used in healthcare and is an applied ethics approach as opposed to being a theory in its own right (Rodger and Blackshaw, 2017). As such it is an amalgamation of other major ethical theories, bringing each one together to provide a more practical solution to resolving real-world ethical problems (Hain and Saad, 2016). Beauchamp and Childress (2001) introduced the four principle model of ethics (Table 10) which is synonymous with principlism and ethics in healthcare. The writers' work continues to be cited as a major influencing factor in the area of ethics and healthcare today (Gordon et al. 2011; Page, 2012; Shea, 2020). One of the major complexities associated with these four principles is that they can produce a level of contradiction which is not easily resolved (Herring, 2020). Clouser and Gert (1990) argue that contradictions arise as a result of principlism's use of conflicting moral theories.

Table 10. Four principles of biomedical ethics (Beauchamp and Childress, 2001)

Principle	**Definition**
Autonomy	The right for an individual to make his or her own choice
Beneficence	The principle of acting with the best interest of others
Non-maleficence	The principle that "above all, do no harm," as stated in the Hippocratic Oath
Justice	A concept that emphasizes fairness and equality among individuals

8.2.3 Historical context of ethics in healthcare research

Since the 20th century and into the 21st, the ethics governing healthcare research has rapidly developed. Major historical events during this era have served to shape the development of ethical principles in relation to research involving human subjects. None more so than the international recognition of Nazi atrocities after WW2, which involved non-consensual and forced medical experiments carried out in concentration camps. This led to the introduction of the Nuremberg code (1947) which aimed to ensure that all future medical research should involve voluntary human consent; the balancing of risks and benefits and the protection of subjects from unnecessary harm (Gray, 2016).

Despite the set of ethical principles inherent within the Nuremberg code, further studies in the 1950's, 1960's and 1970's came to public attention as a result of patients being exploited or mistreated for research purposes. Relevant examples include the Willowbrook Hepatitis study (1956) where children were deliberately infected with Hepatitis without parents being made fully aware of the risks involved (Krugman, 1986); the Jewish Chronic Disease Study (1963) where elderly patients were misinformed and subsequently injected with live cancer cells (Beecher, 1966) and the Stanford Prison experiment (1971), a controversial psychological study where, amongst a number of questionable ethical activities, participants were prevented from leaving even after expressing a desire to do so (Le Texier, 2019).

Another ethically questionable study, the Tuskegee Study of Untreated Syphilis (1932-1972) (where amongst other ethical concerns African American men were prevented from treatment with Penicillin when it became widely used for the condition in 1947) (Duff-Brown, 2017) led to the publishing of the Belmont report (Department of Health, Education and Welfare, 1978) (DEHW) where terms such as beneficence; justice and respect for persons were first highlighted in relation to healthcare research. This in turn is seen as a precursor to Beauchamp and Childress's 4 principle framework (Beauchamp authoring much of the Belmont report himself) (Kennedy Institute, 2021) as outlined in 9.2.2.4.

8.2.4 Research Ethics Committees (REC's)

Of significant historical note also is the creation of Research Ethics Committees; their origins dating back to the 1960's and the Declaration of Helsinki (1964) (World Medical Association, 2013) (WMA) (last revised 2013) where the international requirement for an ethics review committee, independent of the researcher or team, was first proposed in order to oversee the design and performance of research studies (WHO, 2001). Research Ethics Committees are defined in Ireland as "the international best practice structure for overseeing the conduct of ethical standards in healthcare research" (HSE, 2021: para. 1).

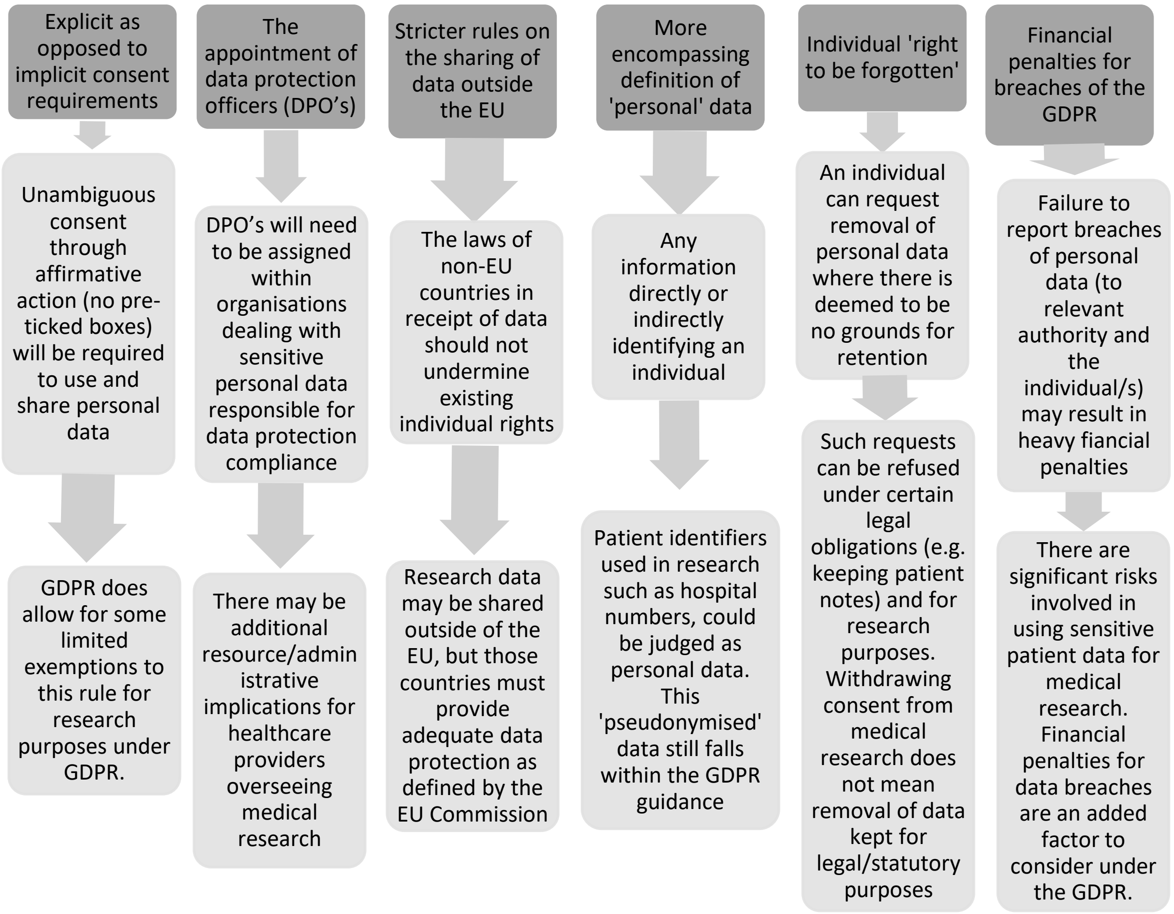
Prior to GDPR in Ireland, REC's worked within the legislation set out in the Data Protection Acts 1988 and 2003. This legislation in terms of accessing patient information for research purposes set out the role of the data controller (e.g. health facility, university) in respecting the confidentiality of such data. This legislation was enacted in data protection guidelines (Data Protection Commission, 2007) (DPC) which outlined requirements for explicit and freely given consent; the use of anonymised data as a first preference; ensuring safeguards to protect confidentiality and where explicit consent was not sought, an undertaking that the health research be carried out for medical purposes and by a healthcare professional or other person owing a duty of confidentiality to the data subject.

8.2.5 The General Data Protection Regulation (GDPR)

GDPR serves as a more recent illustration of how ethics in healthcare research continues to develop in response to changing legislation. The General Data Protection Regulation (EU) 2016/679 came into full effect across the European Union on May 25th 2018, after having been passed by the European Parliament in 2016. Its primary aim is to maintain privacy and facilitate individual control over the use of personal data by organisations (DPC, 2018). Although the law relates to EU member states, compliance is required across organisations throughout the world where data relates to people living in the EU. It emerged primarily in response to developments in technology and the internet, which had driven public concern over the use and sharing of personal data. It also replaced previous EU law dating back to 1995 (European Data Protection Directive) (GDPR.EU, 2021).

Whilst GDPR applies to businesses and organisations across all areas of industry, trade and public services, healthcare has been specifically highlighted in terms of privacy concerns, including the increasing use and development of electronic medical record systems and the potential for sharing this data with unsolicited third parties (Manson, 2014; Williams et al. 2015). Acknowledging these concerns and introduced in the wake of GDPR, Ireland developed its own Health Research Regulations (HRR) which became law in August 2018 (Data Protection Act 2018 (Section 36(2)). These regulations introduced additional regulatory requirements for health research in Ireland, observing an aspect of GDPR which permits some degree of individual member state flexibility in terms of supplementary safeguards and adjustments (Mee et al. 2021). Table 11 summarises the main issues emerging from the introduction of GDPR and the HRR in Ireland.

Table 11. Main areas of GDPR in context of healthcare research



Explicit as opposed to implicit consent requirements	The appointment of data protection officers (DPO's)	Stricter rules on the sharing of data outside the EU	More encompassing definition of 'personal' data	Individual 'right to be forgotten'	Financial penalties for breaches of the GDPR
Unambiguous consent through affirmative action (no pre-ticked boxes) will be required to use and share personal data	DPO's will need to be assigned within organisations dealing with sensitive personal data responsible for data protection compliance	The laws of non-EU countries in receipt of data should not undermine existing individual rights	Any information directly or indirectly identifying an individual	An individual can request removal of personal data where there is deemed to be no grounds for retention	Failure to report breaches of personal data (to relevant authority and the individual/s) may result in heavy fiancial penalties
GDPR does allow for some limited exemptions to this rule for research purposes under GDPR.	There may be additional resource/administrative implications for healthcare providers overseeing medical research	Research data may be shared outside of the EU, but those countries must provide adequate data protection as defined by the EU Commission	Patient identifiers used in research such as hospital numbers, could be judged as personal data. This 'pseudonymised' data still falls within the GDPR guidance	Such requests can be refused under certain legal obligations (e.g. keeping patient notes) and for research purposes. Withdrawing consent from medical research does not mean removal of data kept for legal/statutory purposes	There are significant risks involved in using sensitive patient data for medical research. Financial penalties for data breaches are an added factor to consider under the GDPR.

8.2.6 Healthcare research ethics and retrospective chart review

The examination of retrospective chart review from a research ethics perspective raises a number of issues and complexities relating to the ethical philosophies and legislation changes described thus far. It provides a pertinent illustration of how applying ethical principles in an ever changing healthcare research environment is far from straightforward and as such my personal experience in this area has helped me develop a greater understanding of ethical theory and principles.

Retrospective chart review is a well-established research method typically analysing patient data in order to examine areas such as patterns of care; patterns of medication prescribing and drug utilisation; effectiveness of care/treatment; identification of unmet clinical needs and patient safety data (e.g. for serious incident review) (Payne and Stein, 2013). Patient data may include basic demographics; progress notes; prescriptions; laboratory results and other medical procedures/tests (Vasar and Holzmann, 2013; Sarkar and Seshadri, 2014).

One of the main ethical issue affecting successful chart review studies is obtaining consent from those patients whose charts are selected for review. The right of patients to provide their consent and later their informed consent, emerged from the 1950's onwards in parallel with a number of court rulings in areas such as surgical treatment and a widening public focus on personal liberty and social equality (Beauchamp, 2011). The basic elements of informed consent have historically been its voluntary nature; the disclosure of all relevant information and individuals having the capacity to make an informed decision (Gupta, 2013). In Irish healthcare, it is a standard rule that patient consent is obtained before any treatment, investigation or participation in research; a requirement "consistent with fundamental ethical principles, good practice in communication and decision-making and within national health and social care policy" (HSE, 2021: para. 2).

In retrospective chart review however, there are a number of practical issues which make obtaining informed consent a significantly challenging task. As chart review frequently involves significant numbers of cases, all reviewed retrospectively, there is the difficulty of making contact with high numbers of both current and former patients (Breault, 2013). The writer also refers to the frequently limited time and budget associated with carrying out such research, making this harder to achieve and rendering processes such as anonymisation (which would preclude the need for consent requirements) (DPC, 2019) beyond available resources.

Prior to GDPR, these practical issues specifically affecting the use of historical patient data were acknowledged by the data protection commissioner in Ireland (DPC, 2007). The data protection guidelines issued by the DPC noted that in exceptional cases and after all efforts had been made to gain patient consent, research could proceed without consent as long as appropriate safeguards protecting confidentiality and media notices were organised. As a result REC’s could issue a consent ‘waiver’ in some cases, taking into account the practical issues raised. However, this option was removed by the introduction of GDPR and the HRR in Ireland with the Health Research Board (HRB, 2018) categorically stating that waivers had (and never had) any basis or standing in law.

Not being able to obtain patient consent when it is required raises a number of ethical issues. Firstly, there is a deontological perspective to consider in terms of not adhering to the rules and obligations currently governing consent requirements. A utilitarian argument could be made that the findings of a chart review study are likely to benefit the wider population in terms of increasing clinical knowledge. However, in addition to final outcomes being impossible to predict (an earlier criticism of utilitarian ethics) (Vearrier and Henderson, 2021) it can be contrasted with the principlist rules of autonomy and justice, where individuals have the right to make their own choice and should be fairly treated. For Gupta (2013) one of the fundamental elements of personal autonomy in research is putting participant interests before those of the wider population. Historical research studies such as the Willowbrook case in the 1950’s may have achieved success in benefitting wider society (in this case furthering research on a hepatitis vaccine) but only at the expense of some severely unethical treatment directly harming the research participants (Rosenbaum, 2020).

Whilst the risks involved in retrospective chart or any patient data review are unlikely to endanger physical safety as they did in the Willowbrook study, consideration of patient consent in all Irish health research must include an identification of the risks posed to participants as a result of processing their data (HSE, 2021). In terms of retrospective chart review it is failure to protect confidentiality which poses the greatest risk, as a result of personal data loss or misuse (Sarkar and Seshadri, 2014). Whilst breaches of data may not be the first area considered from a non-maleficence perspective (as opposed to direct physical harm for example) it is recognised as a potential area of patient harm in the Irish HSE Incident Management Framework (HSE, 2017) and is indeed a significant area of public concern and media attention in Ireland alone (Fox, 2020, O’Regan, 2021).

8.2.7 Recent amendments to the HRR in Ireland

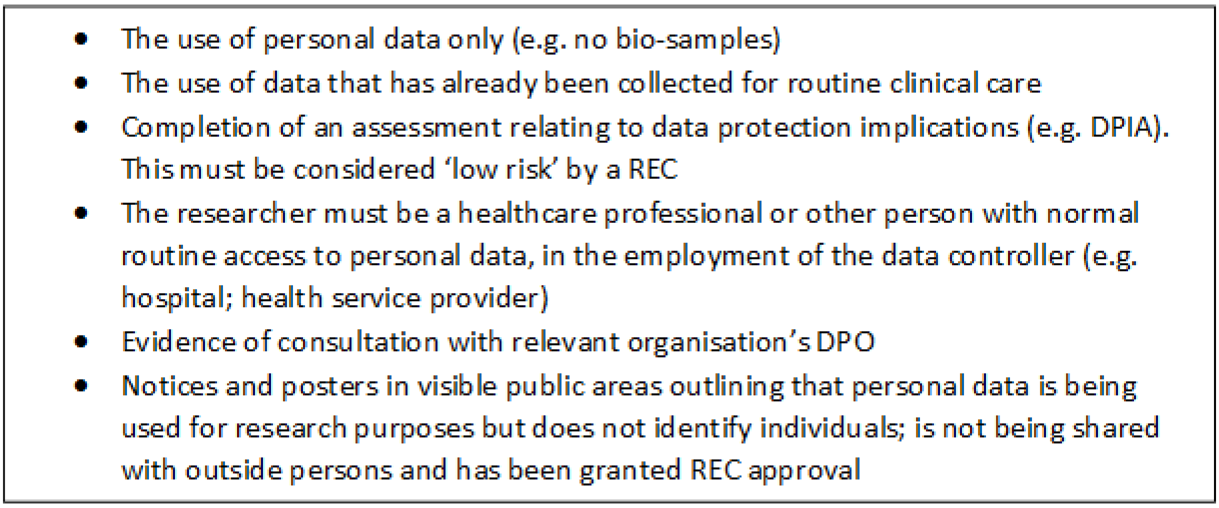
In January 2021, the Minister for Health in Ireland made 5 substantive amendments to the HRR (2018) (HRCDC, 2021) (Box 7). The second of these, relating to retrospective chart reviews has specific relevance to this study. The remaining four amendments provide clarification and guidance in relation to pre-screening (examining personal data in order to establish eligibility for potential studies); the deferral of consent where mental capacity is a significant issue; the honouring of informed consent obtained prior to GDPR and additional transparency in terms of recording consent when obtained (Lennon, 2021).

Box 7. Amendments to the HRR (HRCDC, 2021)

- action to determine eligibility or suitability for inclusion in the research
- retrospective chart reviews
- deferred consent situations
- informed consent obtained during the time of the EU Data Protection Directive
- explicit consent in the context of international best practice in health research
- the appeals process and other technical amendments

The amendment focusing on retrospective chart review sets out that explicit consent requirements may not be applicable if certain criteria are fulfilled (Box 8). The amendment acknowledges the practical difficulties noted thus far in obtaining explicit consent, whilst allowing REC's to determine a study as 'low risk' and worthy of ethical approval without explicit consent requirements. It is possible that if this amendment had been present in the earlier stages of the study, the path to ethical approval may have been more straightforward. Certainly, if the research proposal was presented to a REC now much of the criteria required in order to proceed using the chart review amendment (Box 8) would appear to be present. Although it is not possible to foretell whether a REC would determine the study 'low risk,' the amendment does at least appear to provide greater options in terms of research planning and REC decision-making than was formerly available.

Box 8. Criteria for the omission of individual consent requirements (HRR amendment relating to chart review studies) (HRCDC, 2021)

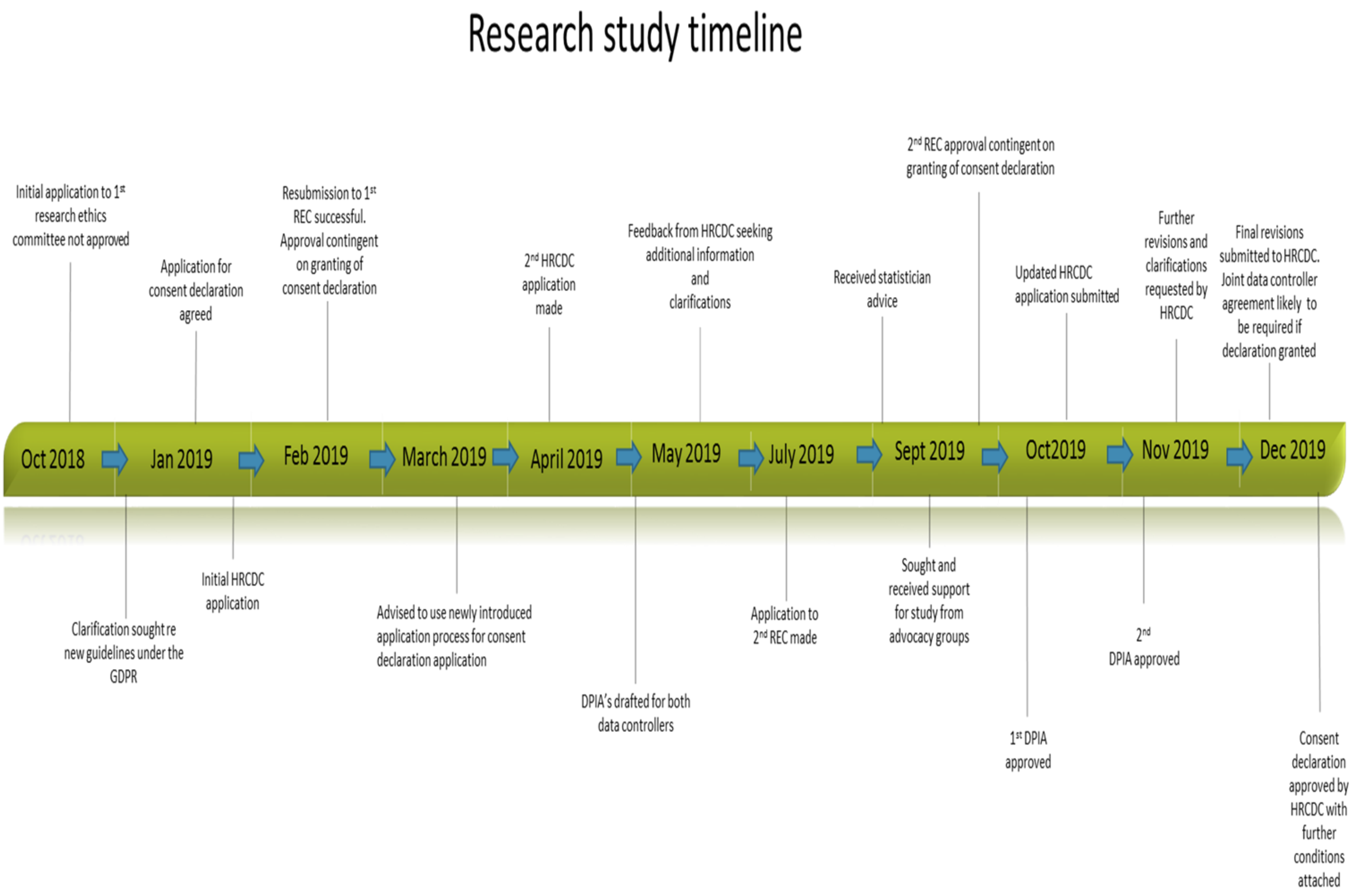


- The use of personal data only (e.g. no bio-samples)
- The use of data that has already been collected for routine clinical care
- Completion of an assessment relating to data protection implications (e.g. DPIA). This must be considered 'low risk' by a REC
- The researcher must be a healthcare professional or other person with normal routine access to personal data, in the employment of the data controller (e.g. hospital; health service provider)
- Evidence of consultation with relevant organisation's DPO
- Notices and posters in visible public areas outlining that personal data is being used for research purposes but does not identify individuals; is not being shared with outside persons and has been granted REC approval

8.3 Timeline of events

Figure 2 is a timeline which serves as a guide for outlining the ethical approval and consent process for this study. This process ultimately took 14 months to undertake and complete. Much of the complexity encountered during this progression stemmed from the introduction of GDPR and the subsequent uncertainty relating to consent requirements in studies using retrospective patient data. There are two main parts to the timeline; the first part outlining events prior to the first ethics committee application and the second describing the application to the HRCDC and the subsequent events thereafter.

Figure 2. Ethical approval and consent requirements timeline



8.3.1 First application to WIT ethics committee

Local protocol dictates that health research undertaken under the auspices of the Health Service Executive (HSE) and Waterford Institute of Technology (WIT) needs to be approved by Research Ethics Committees (REC's) representing both organisations. The WIT REC are required to provide approval before research teams can proceed to the local Health Service Executive REC. As such, separate applications were made to each organisation at different points on the timeline. Appendices 12 and 13 are copies of the completed application forms for WIT and the HSE.

When the study was initially presented to the WIT ethics committee in October 2018, the members felt that they were unable to give the study their approval, suggesting that the research team needed to further clarify how patient consent requirements would be managed. At this stage, the team had incorporated such requirements into the application process, outlining a plan where relevant patients would be contacted in writing for their consent prior to chart review. Available guidance on health research at the time (Data Protection Commissioner, 2007) provided an outline of the recommended process including approaches to care teams to ascertain individual capacity to consent and the contacting of next of kin where such capacity was not felt to be present.

One of the main concerns raised by the WIT REC was that patients or their families could be unduly distressed by any seeking of consent made by the researcher, specifically where the person's involvement in matters of a serious nature (such as self-injury or physical violence) could re-traumatise or unduly affect their mental wellbeing. Furthermore, there were concerns that reminding individuals about certain incidents (e.g. an episode of violence or a suicide attempt) could result in a large number of consent refusals or failure to provide a response either way. Missing responses were also felt to be a likely prospect given the retrospective nature of the study, coupled with issues such as out of date contact details and individuals who had subsequently been discharged from mental health services and could not be traced.

The fact that in some cases seeking consent could result in more harm than good raises certain ethical considerations. From a deontological view, there was a duty and obligation to seek consent as a result of legal and operational guidance but not wishing to cause unnecessary harm (non-maleficence) was clearly a competing consideration. From a virtue ethics perspective, I could understand this argument against seeking consent but also felt conflicted as a result of wishing to comply with the necessary rules, guidance and law. This highlights, again, how healthcare professionals' moral judgements and virtues are likely affected by the complex legal and organisational systems within which they operate (Sellman, 2017).

In considering the way forward following this initial denial of ethical approval, support was sought from the locally organised WIT/HSE research forum which included an ethics committee representative. As GDPR had only been formally introduced in May 2018, there was still a degree of uncertainty regarding how to interpret the new rules in the context of patient data use for research purposes. At the research forum, attention was drawn to a newly formed committee in Ireland, the Health Research Consent Declaration Committee (HRCDC), which had introduced an application process for studies wishing to use patient data in their research but where obtaining explicit patient consent was not feasible. It was agreed that this was the best way forward as it would aim to avoid any unnecessary distress as a result of seeking consent and avoid having to exclude a potentially significant number of cases where persons could no longer be contacted or failed to reply.

8.3.1.1 Anonymisation, pseudonymisation and GDPR

The use of anonymised data was also considered as GDPR does not apply in these circumstances (DPC, 2018). However, the area of anonymisation is complex with Article 13 of the GPDR defining anonymous data as "information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable." (Eur-Lex, 2016: L119/3).

A number of factors prevented the use of truly anonymised data in this study. In order to access and review the medical chart of the person referenced in each retained incident report, I would need to know the patient's full name and their hospital number. Even though these details would not be entered onto data collection forms I proposed the retention of a unique code so that I could cross-reference incident report and chart whenever required. As this code led to the identification of an individual, the data collected could not be considered anonymous under GDPR.

Asking a third party to copy relevant patient notes and remove any reference to the person's identity was also considered but this would not help solve how incident reports and charts would be linked. Similarly, this process, carried out for hundreds of patient charts, would be likely to have significant resource implications in terms of additional staff availability and work hours. Thirdly, entering the content of data collection forms onto a database, as proposed, could reveal a patient's identity, even though their actual name would not be included. If anyone (e.g. other clinician or relative) were to access this database containing details of the incident in question (e.g. date; time; location) and demographic details (e.g. age range; ethnic origin; diagnosis) it is possible that the patient's identity could be revealed, albeit indirectly.

Where data examined and collected cannot be considered wholly anonymous, as highlighted in the points made above, it may be considered pseudonymous. Any process of pseudonymisation is defined under the GDPR Article 4(5) as "the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person." (Eur-lex, 2016: 119/33). Under GDPR, pseudonymous data is considered distinct from anonymised data in that it continues to be defined as personal data and therefore remains within the regulation (DPC, 2018).

8.3.2 Applications to the Health Research Consent Declaration Committee in Ireland (HRCDC) and REC approvals

The next stage on the timeline was an application to the HRCDC. The HRCDC was established in 2018 as part of the newly introduced Health Research Regulations made under the Data Protection Act, 2018 (Government of Ireland, 2018). The committee functions in order to consider applications for a declaration of exemption, where obtaining individual consent is not possible and the public interest in carrying out the research outweighs the need for gaining explicit consent. The committee can ultimately make a consent declaration; attach conditions; refuse a declaration or revoke an existing one and there is a separate appeal process. Attached to the committee is the 'Secretariat' who are responsible for overseeing and co-ordinating the application process and with whom I corresponded throughout (HRCDC, 2021).

The initial application was completed using the guidelines available on the HRCDC website at the time. Unfortunately the introduction of a more formalised application process meant that information needed to be re-submitted with further revisions 2 months later. This was a result of the committee and secretariat only becoming established in terms of process and guideline production. In between initial submission and re-submission to the HRCDC, WIT ethics committee approval was contingently obtained (Appendix 17) pending the granting of a consent declaration by the HRCDC. A great deal of uncertainty was evident around this stage. The new legislation in terms of GDPR and the introduction of the HRR in Ireland introduced an additional level of complexity which all parties involved, including the newly formed HRCDC, were trying to fully interpret. This uncertainty played a major part in my personal experience.

In addition to the written application form (the final version is included in Appendix 18) were a number of other documents and forms required in order to fulfil GDPR and HRCDC requirements. The documentation required for the HRCDC and both REC's is summarised in table 12.

Table 12. Additional information required by HRCDC and REC's

HRCDC	**WIT REC**	**HSE REC**
•DPIA's x 2	•Study proposal	•Study proposal
•REC approval x 2	•CV's of research team	•Data collection form
•Feedback from DPO's x 2	•Data collection form	•Letter to service managers
•Information leaflet	•Publication agreement	•Statement of data protection
•Data collection form	•Information leaflet	•CV's of research team
•Incident report form (blank)	•Statistician comments	•Academic institute REC approval
•Inclusion/exclusion criteria		
•Feedback from advocacy group		
•Evidence of GDPR training		

The level of content and detail required by the HRCDC was labour intensive and time consuming. As one of the first applications to the HRCDC, the process covered new territory and was a learning experience for all involved, particularly in relation to newly introduced aspects of GDPR and the HRR. Data Protection Impact Assessments (DPIA's), used to mitigate and identify data protection risks, are considered mandatory for 'high risk' processing projects (DPC, 2021). High risk in the context of this study stems from GDPR's provision for the use of 'special category data,' which includes areas such as ethnicity; religious beliefs; sexual orientation and physical/mental health history (DPC, 2018). The processing of this type of data (routinely found in medical charts) is prohibited unless at least one out of ten conditions outlined under the GDPR can be met (Box 9).

Box 9. Ten conditions for processing 'special category data' under GDPR

Explicit consent
Employment, social security and social protection (if authorised by law)
Vital interests
Not-for-profit bodies
Made public by the data subject
Legal claims or judicial acts
Reasons of substantial public interest (with a basis in law)
Health or social care (with a basis in law)
Public health (with a basis in law)
Archiving, research and statistics (with a basis in law)

The final DPIA's relating to the HRCDC are found in Appendix 19 (WIT) and Appendix 20 (HSE). Whilst their completion helped to identify and mitigate risks (and as such helping to structure areas of the research study such as the data collection form and storage of confidential information) sections requiring feedback from data subjects (in this case the patients themselves) and relevant Data Protection Officers (DPO's) proved complex. A significant proportion of time was spent trying to source advocacy or patient representative group support as a number of organisations and individuals did not feel that it was their role or that the request fitted their organisation's remit in relation to the study's aim. The first organisation I approached felt that obtaining consent by methods other than directly approaching individuals concerned did not reflect their 'service user' led ethos. Eventually advocacy support was obtained, but it was a challenge.

Liaison with relevant DPO's was also far from straightforward. Who exactly to approach created the first hurdle, followed by many discussions relating to whether it was the responsibility of each organisation's appointed DPO to provide an opinion in terms of a consent declaration. In addition to the time taken to contact each person, each officer required a full account of the study's aims and objectives before they could comment. In the context of the HSE DPO, the granting of approval from the local HSE REC (Appendix 21) was needed before any feedback could be provided. Application to the HSE REC proved straightforward in that approval was given after the first application and presentation, but also contingent on obtaining a consent declaration from the HRCDC.

The process of obtaining a consent declaration from the HRCDC and the necessary ethics approval from both WIT and the HSE took a total of fourteen months. During this time four revised applications were submitted to the HRCDC; 3 REC submissions were made; two DPIA’s were completed and approval obtained from relevant DPO’s, in addition to a local patient advocacy organisation. The issued consent declaration (Appendix 22) contained specific conditions relating to additional ‘transparency’ arrangements, in the form of public notices to be placed wherever data collection would be taking place. A copy of the finalised public notice used for this study is found in Appendix 23. The HRCDC also requested the production of a joint data controller agreement between WIT and the HSE. This was subsequently completed and a copy included in Appendix 24. The consent declaration was validated until March 2023 with an annual progress review required.

8.4 Discussion: Ethics approval and issues relating to GDPR; individual consent and the use of patient data in research

The complexities faced during this 14 month period can be grouped across four broad categories; timing; process; access and resources. As the outset of the study coincided with newly introduced GDPR guidance, the timing was inopportune in the context of uncertainty for the progress of the study as originally conceived; uncertainty amongst REC’s and the absence of clear organisational/online supports and guides. This is exemplified by the first consent declaration application being submitted to the HRCDC before the committee had even fully agreed and published a structured application process.

In terms of process, navigating the order in which documentation was required was problematic during the REC and consent declaration application process. For example, the local HSE REC could not consider an application until it had received confirmation that the

WIT REC had approved the project. Similarly, the health service DPO could not approve the required DPIA until the health service REC application had been approved. The HRCDC, however, required both REC and DPIA approvals before the application could be considered. Other requirements within each application, such as newly added sections of the REC applications in relation to the GDPR and advocacy/patient representative support, meant that the overall process of seeking the necessary approvals and recommendations was significantly complex and time consuming.

This process was in many ways arguably driven by all parties trying to make sense of the newly introduced GDPR rules and rapidly aiming to implement their own rules and procedures. As a result, both REC and HRCDC applications required a great deal of additional detail as noted in Table 12. Each section of the HRCDC application needed to match the information given in the REC applications and the DPIA's with any revisions made to one submission needing to be amended in the others. If a major flaw had been identified in the final HRCDC submission, it is feasible that re-submission to each REC may have been needed, beginning the whole process again.

Accessing consistent advice and guidance also proved difficult as those consulted, including those outside of the study who were asked to provide their support or feedback, were only beginning to fully understand GDPR requirements themselves. Because of its timing the research study proposal became an unforeseen 'test case,' the first of its kind locally where frequent uncertainties; queries and conflicts of opinion arose throughout the REC and HRCDC submission process. Accessing the right information and individuals within large institutions was another area of complexity. Whilst each organisation accepted 'data controller' responsibility, finding specific individuals prepared to 'sign off' on the various application forms was an ongoing difficulty.

The HRCDC suggested that researchers consult with their 'DPO's' or 'legal teams' but this did not prove straightforward. The recent introduction of GDPR meant that data controller responsibility could not be fully established for a number of months, with considerable debate in relation to specific roles and responsibilities. With all stakeholders clearly still trying to adjust their policies and procedures in light of the GDPR, one concern raised related to named data controllers accepting liability should a breach of data privacy occur. Whilst it was eventually agreed that the two organisations in this study were to retain responsibility, identifying and obtaining the support of appropriate representatives proved difficult throughout the process. Difficulties were compounded by a lack of available guidance; the novel situation for all involved and general fears and uncertainties relating to issues of liability.

A significant proportion of time was also spent trying to source advocacy support as a number of organisations and individuals did not feel that it was their role or that the request fitted their organisation's remit in relation to the study's aim. A number of organisations felt that obtaining consent by methods other than directly approaching individuals concerned did not reflect their 'service user' led ethos. Eventually advocacy support was obtained but it was a challenge, only achieved through efforts to promote the positive nature of the study objectives and some personal persistence. Within a context in which many advocacy groups are also campaigning groups, seeking their support for studies which they may oppose in some way can close down research areas that might in the long run be valuable. There have been a number of research areas not popular with the consensus of advocacy groups which later have been shown to have significant patient and public health benefits. For example, advocates of those diagnosed with chronic fatigue syndrome (myalgic encephalomyelitis) continue to question the methodology and findings of the PACE trial (White et al. 2013), which found that exercise and cognitive behavioural therapy can relieve symptoms of the condition (Maxmen, 2018).

The last area of note relates to the considerable resources (time and financial) that were utilised in order to provide the required information under the GDPR provisions. These had not been factored into the study planning and financing pre-GDPR. Research evidence has already highlighted the financial implications associated with the introduction of GDPR, particularly for healthcare institutions (Yuan and Li, 2019) and in terms of funding the necessary changes to health research infrastructure in Ireland (Mee et al. 2020). Similarly, non-compliance with GDPR can result in severe financial penalties for organisations (Clarke et al. 2019); a case in point being the HSE in Ireland who are potentially facing a 1 million euro fine following a recent cyber-attack (Brennan, 2021).

On a personal level, as a part time research student and full-time clinical mental health nurse manager, only a limited number of weekly hours were available to complete the required paperwork. The consequent over-run of the project led to funding issues as the study went past the agreed completion date for the overall project. The funding issue was only resolved by making a case for additional resources to senior local stakeholders, alongside the support of my research study supervisors.

Also from a nursing perspective, it is unlikely that this particular type of research study would be easily carried out if it did not involve a clinician collecting the primary data as any non-employee aiming to access information such as medical charts could face an even greater level of complexity when addressing data protection and privacy issues consequent of GDPR. Indeed, the recent amendment to the HRR in Ireland stipulates that in order to fulfil consent obligations in chart review studies, the researcher needs to be a health practitioner or at least an employee who has access to patient files as part of their normal clinical duties (HRCDC, 2021).

8.4.1 Wider implications of GDPR and patient consent for health research beyond this study

Whilst the most recent amendments to the HRR in Ireland may have helped to simplify or at least shorten the ethical approval process relating to retrospective chart review studies specifically, wider issues remain in relation to the implementation of GDPR and health research. One of the most widespread criticisms of GDPR is that although it is an EU wide directive, each member state has introduced their own interpretation of the regulation, leading to a ‘fragmentation’ in approaches to data protection and difficulties co-ordinating cross border health research projects, even those that remain within EU boundaries (McCall, 2018; Clarke et al. 2019; Donnelly and McDonagh, 2019).

As GPDR only applies to member states within the EU, collaboration with research teams outside of this jurisdiction has also become a significantly more complex task (Laurie, 2018; Timmers et al. 2019). One major difficulty relates to the sharing or transferring of data held within the EU to 'non-recognised' countries (such as the USA) where the European Commission has decreed such states to have insufficient data protection rules (Peloquin et al. 2020). Currently, there are a number of 'adequacy' agreements with non-EU countries for the sharing of data including the UK (European Commission, 2021). However, other major contributors of health research such as Australia and the USA have no such agreement with the EU. In the case of the latter an earlier 'adequacy' decision relating to the EU/US Privacy Shield agreement was subsequently invalidated by the Court of Justice of the European Union (CJEU) as levels of data protection in the US were felt to fall below that expected in the EU, particularly in relation to US intelligence access to personal data and the lack of legal restitution for EU citizens (Hallinan et al. 2021). Such complexities and the imposition of either stricter or looser rules governing areas such as patient consent may lead to inconsistencies in the output and quality of health research across different countries, ostensibly creating an uneven playing field.

The transfer of personal data across international boundaries is one area of controversy rooted in the development of electronic patient data systems. Indeed, the very origins of GDPR are based in the growth of digital personal data collection and the individual's right to control the use of their personal information (European Data Protection Supervisor, 2019) (EDPS). Although technology significantly widens the scope of patient data research, particularly in relation to quantity; accessibility and the ability to link different research datasets (van Velthoven et al. 2016), such developments have been accompanied by public concern over the privacy and security of their digital records (Edwards, 2017).

An example of such controversy exists in relation to the proposed collection and sharing of patient GP data in England for research purposes, (e.g. data on the long term impact of COVID-19) (coronavirus) (NHS Digital, 2021). General Practice Data for Planning and Research (GPDPR) is currently on hold until certain conditions can be met, including a clear 'opt-out' choice for individuals and a full public awareness programme (National Data Guardian, 2021). This follows past controversy affecting the NHS in England where efforts to establish a single database scheme containing all NHS patient medical information (NHS England, 2013) was eventually abandoned in 2016 for poor communication with patients and failing to ensure a clear opt-out choice (Boseley, 2016).

The lack of transparency accompanying the current GPDPR scheme has met with criticism from the British Medical Association (BMA) and the potential refusal of GP's to facilitate data sharing (Clark, 2021). For EU member states the introduction of GDPR means that consent can no longer be assumed where an individual has failed to 'opt-out' (Rumbold and Pierscioneck, 2017) reflecting, for member states, the additional efforts that now need to be made in terms of patient information; informed choice and levels of transparency. GDPR Article 4(11) defines consent as 'any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.'

8.4.2 The perspective in Ireland

From an Irish perspective, 'clear affirmative action' is embedded in an HRR requirement for 'explicit' patient consent. Using explicit consent as the basis for all health research is seen by some writers as the main factor separating Ireland from other EU states, potentially placing the country at a disadvantage in terms of research activity and additional levels of bureaucracy (Donnelly and MacDonagh 2019; Clarke et al. 2019; Dove and Chen, 2020).

Kirwan et al (2021) cite COVID-19 (coronavirus) research as a pertinent example of where the HRR in Ireland has restricted research activity. Whereas the UK suspended its consent requirement under the common law duty of confidentiality for studies relating to the pandemic, no such change was implemented in Ireland due to the rigid nature of HRR explicit consent requirements. The writers further suggest that informed consent, which has always been at the centre of health research, should be the defining factor for researchers as opposed to explicit consent as defined by the HRR. In essence, the writers feel that the current system creates an additional layer of consent requirements over and above the pre-existing ethical/legal requirements embodied by informed consent.

This increase in regulatory activity was arguably one of the main complexities faced during the ethical approval process, particularly in the context of how unprepared the health research system in Ireland was in the wake of GDPR. From a psychological perspective, the level of uncertainty faced by stakeholders can be explained in heuristic terms. Availability and representativeness heuristics refer to cognitive decisions made where reference can be made to similar examples or representative prototypes (Cherry, 2021). The timing of my ethics approval application, meant that pre-GDPR guidance and procedures could be recalled but were no longer applicable. In the absence of any relevant case example post-GDPR, feelings of uncertainty were likely to result. In essence my experience may play a role in future heuristics as it provided one of the first examples of chart review research, post-GDPR.

8.4.3 Summary: the challenge of ensuring ethical conduct in healthcare research

Dove and Chen (2020) argue that GDPR has created some confusion in terms of consent as a research ethics principle and as a lawful basis in data protection law. The writers suggest that consent should always be encouraged but mandating it as the only basis for processing personal data in law is ultimately unhelpful. The recent HRR amendment relating to explicit consent (HRCDC, 2021) appears to go some way in responding to such criticism of the current Irish system, with the most significant modification being the obtaining of consent in accordance with international best practice on the ethical conduct of health research (including informed consent; transparency and independent ethical oversight).

Such changes raise a question as to whether GDPR and the HRR have created additional and unnecessary levels of bureaucracy within a fully functioning system already grounded in consent; transparency and independent oversight. In essence, from a health research perspective, 'fixing something that was not broken.' In their analysis of consenting systems internationally, Dove and Chen (2020) cite the current South African model as striking the best balance between efforts to make consent the starting point for processing data without over-complicating the research process where this is not possible. Under the South African system, researchers themselves (as data controllers) self-assess as to whether consent should be sought or foregone, making an informed and self-determined choice. Presenting this type of self-assessment to a research ethics committee may have avoided many of the complexities and delays that subsequently occurred due to the HRCDC application, whilst still maintaining necessary levels of oversight and supervision.

Furthermore, when considering the 'public interest' argument in terms of foregoing consent requirements, it is likely that a case can be made for most health research studies. The ongoing COVID-19 (coronavirus) pandemic is a timely reminder as to why health research is carried out in the public interest. In terms of my own research study, it was possible to make a strong case as to why research into serious incidents in mental health services might be justifiable from a public interest angle, given the numbers of people affected by mental health issues and the number of incidents occurring in communities and environments outside the hospital setting. However, it is also clear that health research (particularly large scale processing of digital patient data) has been the recipient of significant public scrutiny. As such a balance needs to be struck between safeguarding personal information; reassuring the public; respecting privacy and supporting research which ultimately aims to benefit all members of society.

The ongoing GP data debate in England appears to be as much about transparency as opposed to any misuse of personal data. Ostensibly, it is not the fact that personal data might be used for research purposes which has provoked a public reaction in this case but the lack of explanation and choice offered. As a result, whilst some writers suggest that citizens have an obligation to share their health data for research purposes (Ballantyne and Schaefer, 2018), this is unlikely to achieve much traction within the current social and political climate.

It is possible that researchers may be discouraged from approaching more challenging studies as a result of the current complexities affecting participant consent. Avoiding certain areas due to fears over delays or the burden of complex and additional formalities or procedures may ultimately impact on the quality and degree of health research in Ireland. To some extent the risks associated with breaching GDPR law, including the threat of financial penalties, appears to have contributed to a further strand of risk aversiveness within health research and adding to the existing risk averse culture that often prevails within clinical care.

Whilst GDPR has added a greater degree of regulation to the area of health research, increased management of risk (in this case data protection risk) is unlikely to eliminate harm entirely (Beaussier et al. 2016). Indeed, from a mental health perspective successive efforts to mitigate against risk have not prevented serious incidents from regularly occurring (Holley et al. 2016; Coffey et al 2017). Furthermore, prioritising risk in mental health services has been linked with defensive practice; creating a culture of blame and failing to acknowledge the complexities of day to day clinical care (Royal College of Psychiatrists, 2008).

As opposed to clinical care in this instance, it is the complexities inherent in research ethics decision making that has been impacted by increased regulation and attention to risk. As noted earlier, both legal directives and theories of ethics can overlook the 'grey' areas that can arise in clinical and research settings (Beauchamp, 2011; Herring, 2020); my experience of retrospective chart review and the principle of consent being just one illustration, demonstrating how adherence to policies, procedures and theories alone does not resolve all complexities in healthcare.

Regulatory focus theory (Brockner and Higgins, 2001) a psychological theory of how people approach their goals, might offer that compliance with rules and regulations results in a ‘prevention focus,’ whereby individuals are more likely to focus on safety; security and responsibilities as a result. Furthermore, unwelcome organisational practices such as the passing of responsibility or ‘buck passing’ can be a result of individuals placing more emphasis on avoiding blame for bad outcomes than getting credit for good outcomes (Stefell et al. 2016). If the existing fear of ‘blame’ in clinical care further extends to the field of health research and to those teams and individuals who are now required to endorse consent/data protection proposals, future research projects and the development of mental health nursing practice could be negatively affected.

Conversely, the criticisms aimed at the recent changes to health research regulations, both in Ireland and internationally, may be reflective of the need for professionals to accept change and acknowledge the positive elements of GDPR. Indeed, criticism of informed consent requirements, in the context health research, is not a new phenomenon. Beauchamp (2011: p.516) highlights how the concept met with largely negative commentary in the 1970’s, with healthcare professionals citing the demands of informed consent as “impossible to fulfil and, at least in some cases, inconsistent with good patient care.” Despite this negative commentary, ‘informed’ and later, ‘explicit’ consent, became a mainstay of health research from the 1980’s onwards. It could be argued that the introduction of GDPR and the HRR in Ireland, whilst creating a level of adversity at this present time, will eventually be routinely embodied in healthcare research practice and not to the detriment of research output and quality. The digital age has created an additional need for public reassurance in terms of personal data protection; GDPR and the HRR in Ireland merely reflect this development.

8.4.4 Concluding comments: Ethics approval and issues relating to GDPR; individual consent and the use of patient data in research

In summary, a number of recommendations are highlighted in terms of my experience navigating the ethical approval and consent declaration process (Box 10). Issues of patient consent; personal privacy and the processing/sharing of data are currently very emotive subjects and the landscape within which these areas are considered is rapidly changing. Whilst the timing of this research study was in some ways unfortunate in terms of additional workload and delay, it was also a significant learning experience. For all healthcare professionals, the scope of clinical and research knowledge now needs to be accompanied by a significant legal awareness relating to GDPR and privacy laws.

Box 10. Recommendations for navigating process of consent declaration/ethical approval when not seeking individual patient consent

- Identifying named individuals to assist with data protection issues; GDPR guidance and 'signing-off' duties
- Acknowledging and informing supervisors/funding agencies about potential study delays, particularly in relation to a HRCDC application. Consider placing funding grants/stipends on hold
- Awareness of the time and work involved in a consent declaration application and the resources available to the research team
- Remaining up to date in terms of official guidance on GDPR, retrospective chart review and consent issues
- Check for updated application forms/processes on relevant websites
- Consider how service user/family/advocacy representatives/organisations have been involved in the research study proposal
- Have adequate knowledge of GDPR, particularly in terms of the legal basis for processing data and seeking a consent declaration
- Be able to fully interpret differences between anonymised and pseudonymised data under GDPR guidance
- When carrying out chart review be aware that minimising access to data may mean restricting the number of research team members carrying out data collection. This, in turn may conflict with best practice guidance for carrying out chart review
- The Department of Health may wish to consider a more simplified route for seeking consent declarations as they relate to retrospective chart reviews
- Local organisations may wish to identify senior staff responsible for 'data controller' duties (meeting researchers; signing forms and approval letters etc.)

Part III: Results and Discussion

Chapter 9: Results

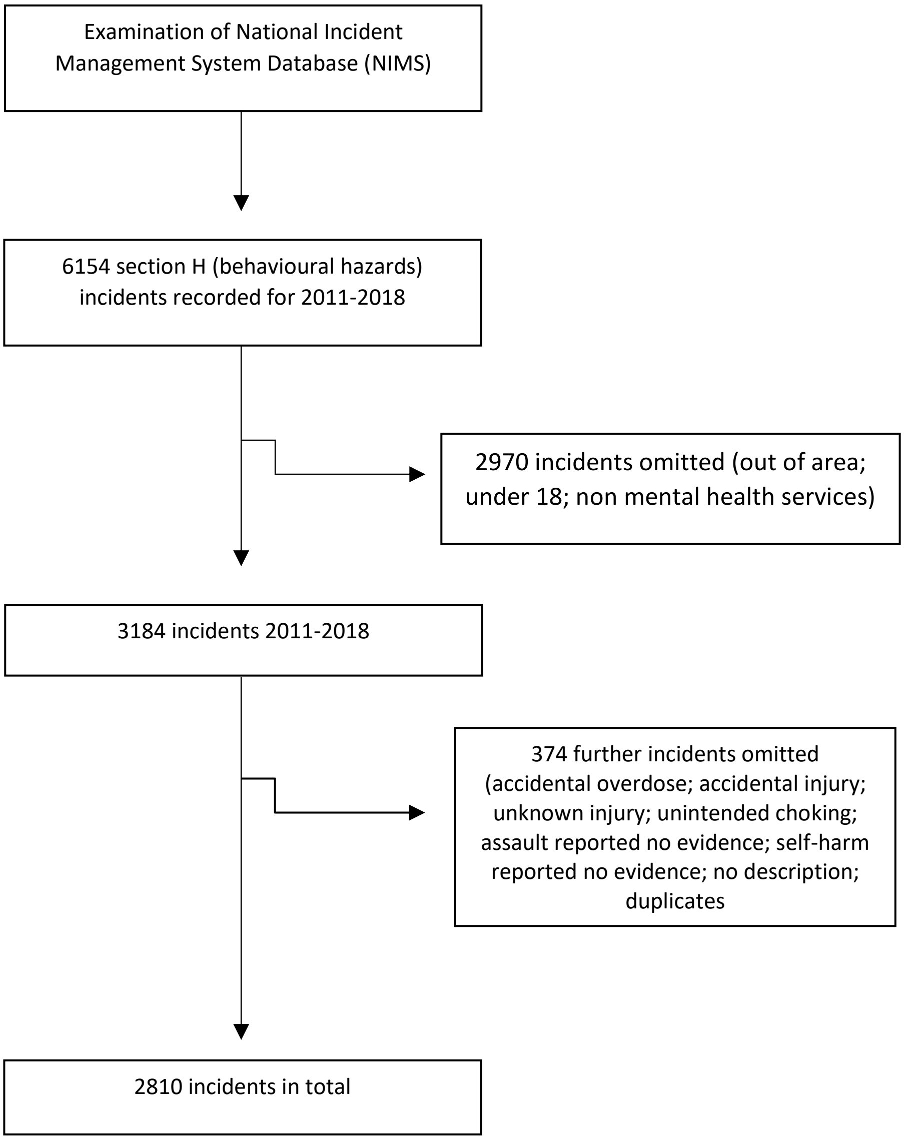
9.1 Introduction

The chapter begins with a description of how the total number of incident reports relevant to the study was obtained, followed by an overview of the basic data. Results pertaining to the sampled data begin with the retrospective chart review element of the study first, followed by results of the content analysis.

9.2 Reported incidents

Figure 3 denotes how the total number of incident reports relevant to the study was obtained. 6154 incidents were found to be logged on the National Incident Management System (NIMS) over the study parameters 2011 to 2018. This was the total number of incidents reported within the behavioural hazards section of the incident report form (section H), the only section relevant to this study. This number was reduced to 3184 on initial application of inclusion and exclusion criteria (incidents not occurring in Waterford or Wexford counties; individuals under 18 years of age and those occurring in non-mental health services). Closer inspection of the recorded incidents yielded additional omissions (incidents deemed accidental or unclear in terms of cause and outcome; those lacking any description of the incident and duplicates).

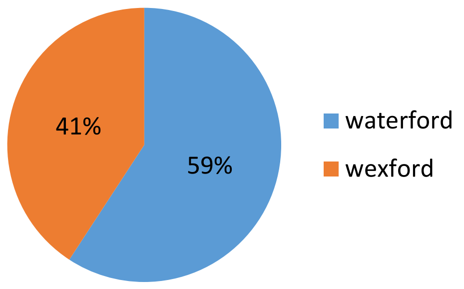
Figure 3. Flow chart: identification of incident reports



9.3 Overview of data

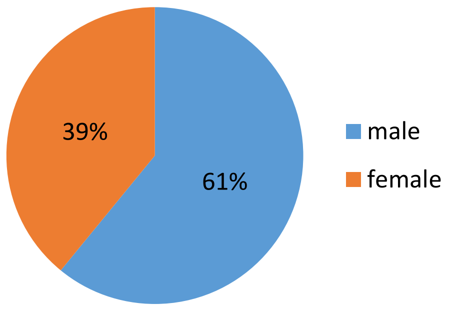
Before obtaining a sample of incidents for chart review and content analysis the total number of incidents were analysed, obtaining the following results.

Figure 4. Incidents by catchment area



A greater number of incidents were reported in the catchment area of Waterford compared to Wexford over the study parameters

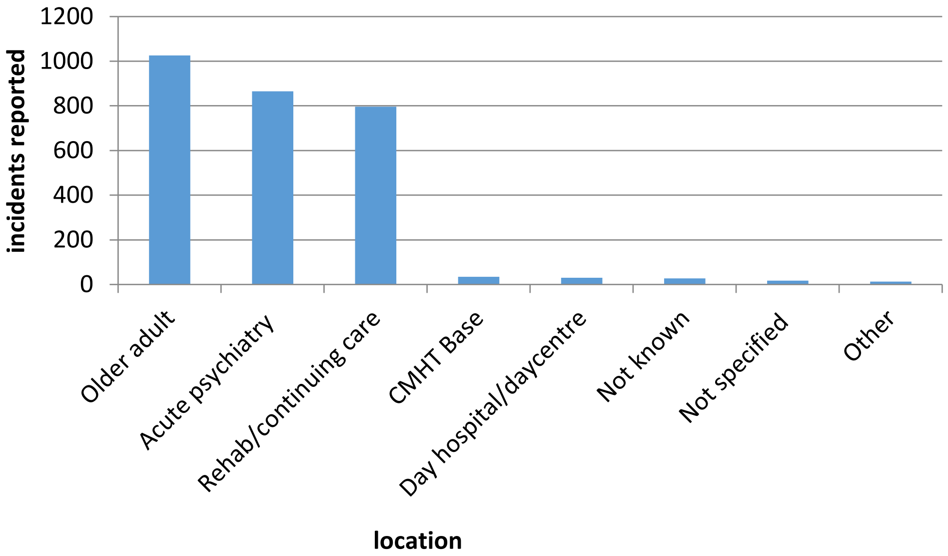
Figure 5. Incidents by gender



A greater number of incidents involved male patients compared with female.

The greatest number of incidents were recorded in older adult services, followed by acute psychiatry and rehabilitation/continuing care. In contrast, a relatively small number of incidents occurring in community/non inpatient services were reported (Figure 6.)

Figure 6. Reported incidents by location



In terms of physical harm, 'no injury' was recorded in the great majority of cases (Figure 7.)

Figure 7. Incident outcomes

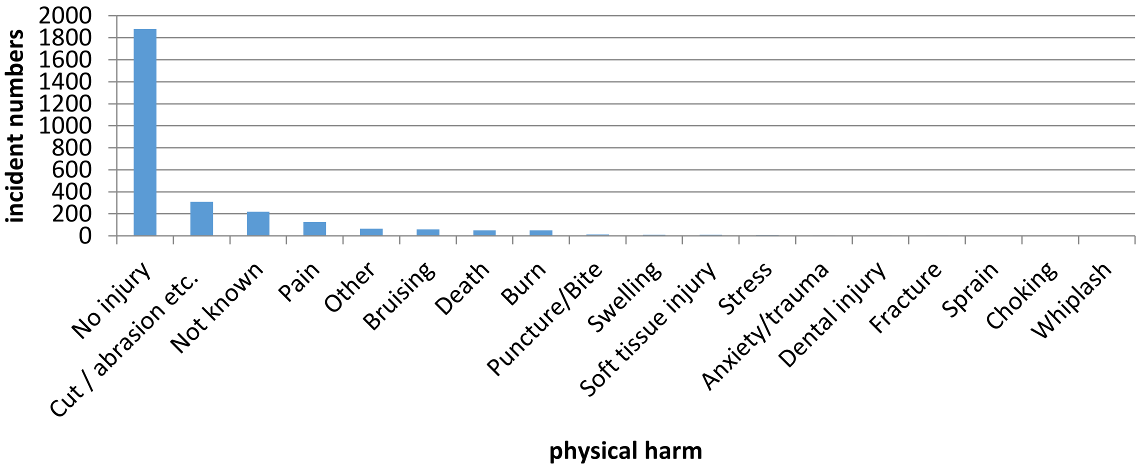
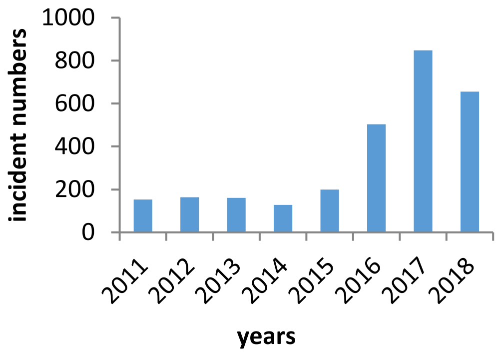


Figure 8. Incidents by years



The number of incidents reported increased by up to 6 times over the study years 2011-2018, with 2017 yielding the most reports. A new national and standardised system for incident reporting (NIMS) was introduced in 2015-2016, which is likely to at least partly explain this increase.

It was noted that a number of patients were frequently referenced in incident reports. 26 patients were referenced 20 times or more in separate incidents over the study period, with one patient referenced in 175 incidents out of the total of 2810.

Figure 9. Patients referenced in 20 or more separate incidents

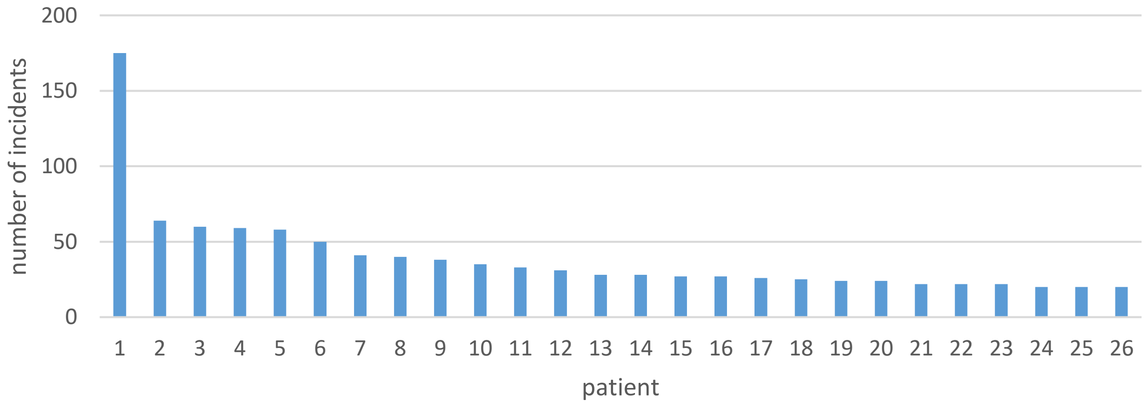
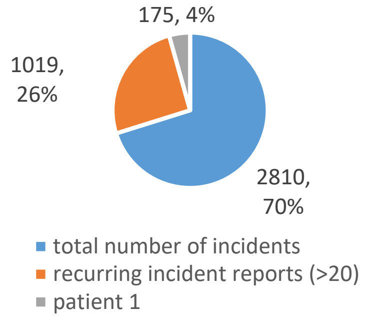


Figure 10. Patients referenced in 20 or more separate incidents

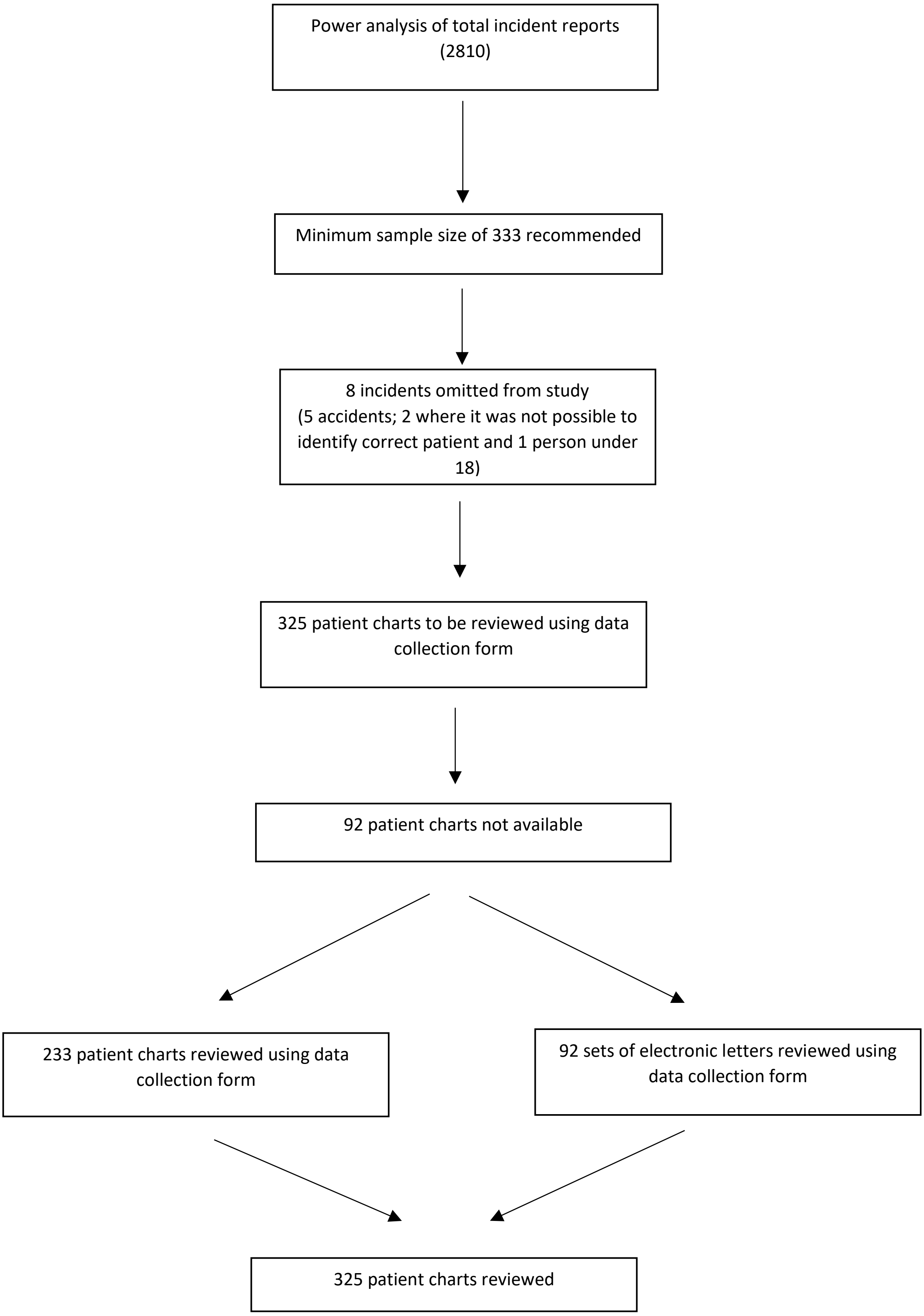


When demonstrated as a percentage, these 26 patients were referenced in over a quarter of all the incidents reported. Patient 1 alone was referenced in 4% of all incidents recorded.

9.4 Sample data analysis

A total of 325 sampled incidents were included in the study. Figure 11 is a flow chart defining how this number was obtained. Where patient charts could not be located, a database of electronic outpatient letters and discharge summaries was examined. These electronically stored letters and summaries are routinely filed in patient notes meaning that this information should be identical across both sources. However, the electronic database does not retain handwritten assessments or progress notes. In 92 cases therefore, handwritten information could not be examined.

Figure 11. Flow chart: Sampled cases



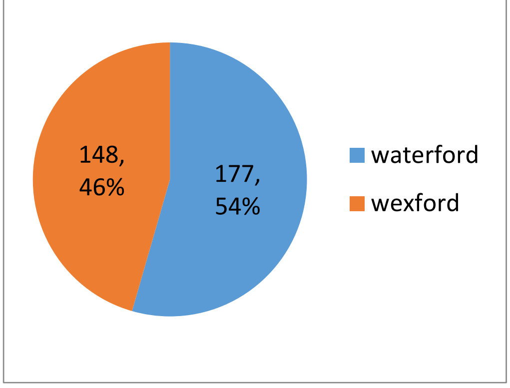


Figure 12. Incidents by catchment area

The randomised sample of incident reports yielded a slightly higher number for Waterford compared with Wexford. This corresponds with the total number of incidents reported over the study period. A chi-squared goodness of fit analysis was conducted between catchment area and incident type. With p<0.001, there is evidence to conclude that there is a statistically significant difference in catchment area across incident types with a higher rate of physical aggression (no injury) recorded in Wexford and a significantly higher rate of self-injury occurring in Waterford.

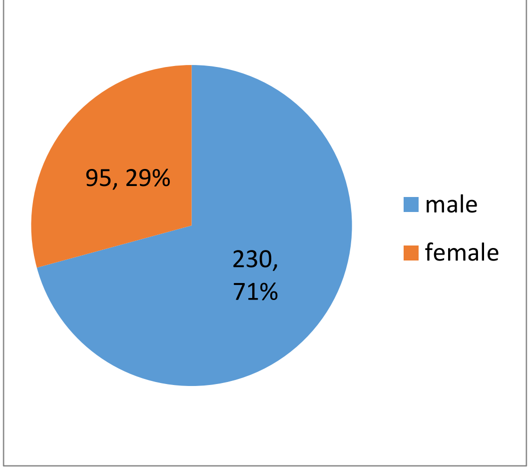
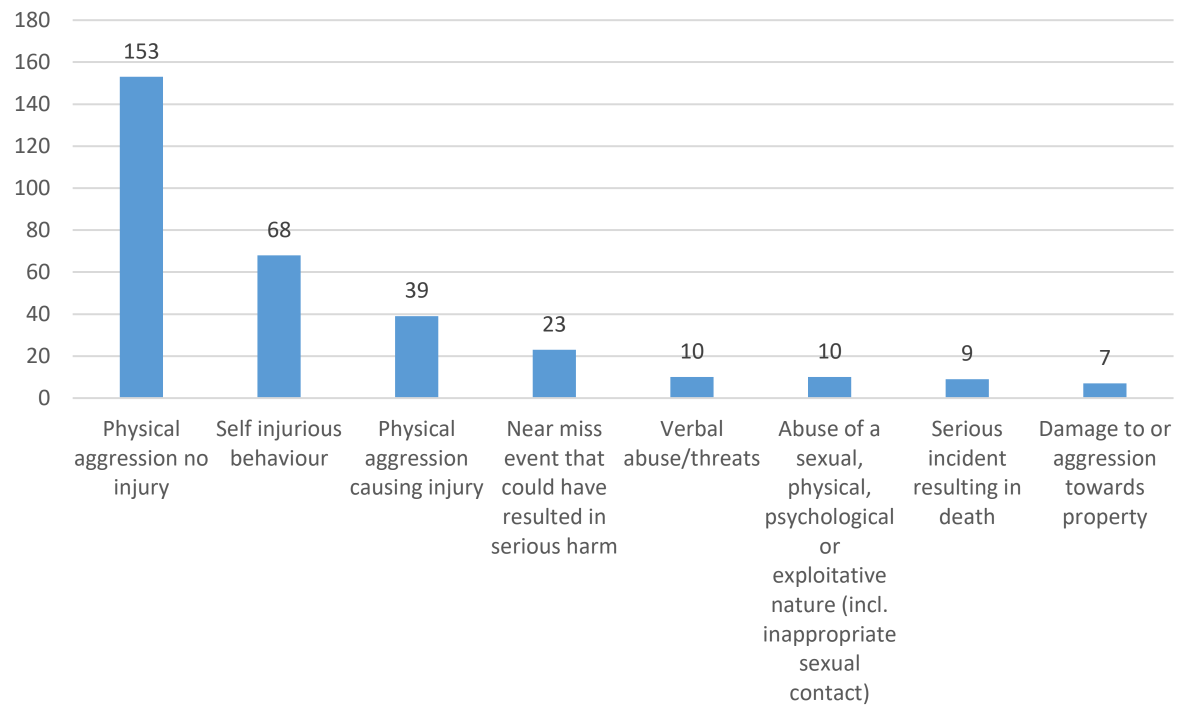


Figure 13. Incidents by gender

The randomised sample of incident reports was heavily weighted towards males. This is reflective of the total study population. A chi-squared goodness of fit analysis was conducted between gender and incident type. With p<0.001, there is evidence to conclude a statistically significant difference in gender across incident types with men far more likely to be associated with acts of outward aggression and females more likely to be associated with self-injurious behaviour.

Figure 14. Incident types



The highest proportion of cases reviewed involved physical aggression where no subsequent injury was reported. Whilst there were much fewer incidents causing injury, violence and aggression was the primary incident type reported in the study, accounting for more than double all the other categories combined. Self–injurious behaviour, more prevalent in acute psychiatry than other clinical areas, was the 2nd most common incident type overall.

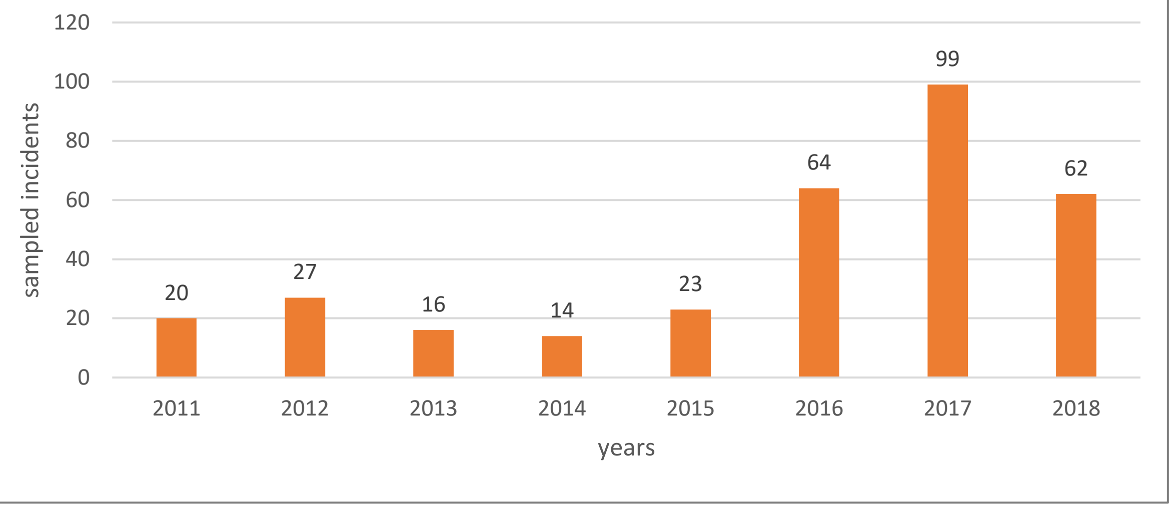


Figure 15. Incidents by year

The sampled data in Figure 15 corresponds with the study population data in that there were many more cases included from 2016, 2017 and 2018 than other years. This does not mean that untoward occurrences such as violence or self-injury dramatically increased over this period; more so this is likely to be explained by observed changes in local and national reporting practices from 2015/2016 onwards. With p=0.027, a univariate linear regression (with time as the interdependent variable) suggests that there has been a statistically significant increase in the number of reported incidents from 2011 to 2018, reflecting the data shown in the total incident numbers (Figure 8).

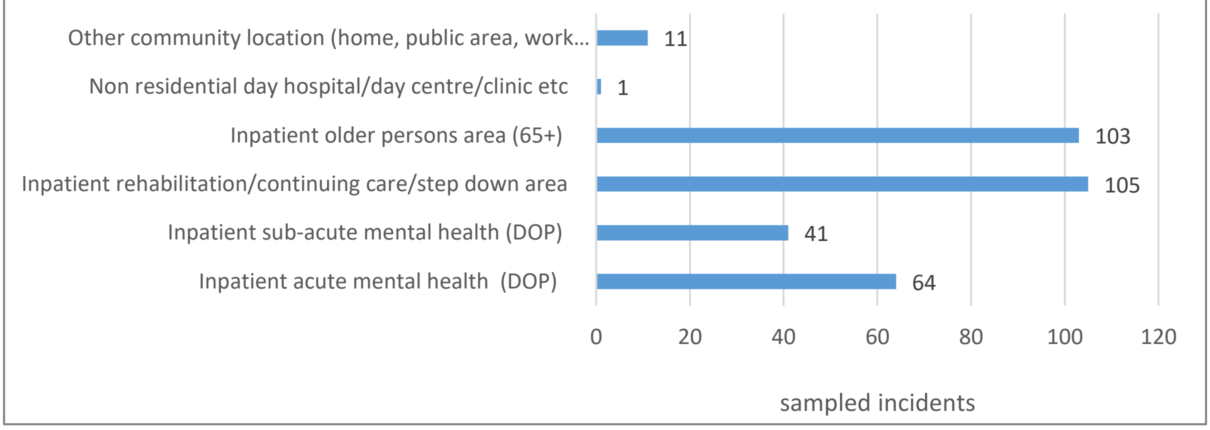
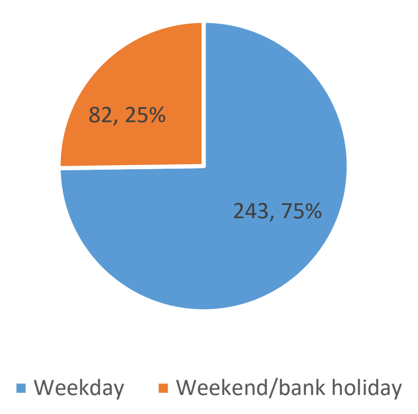


Figure 16. Incidents by location

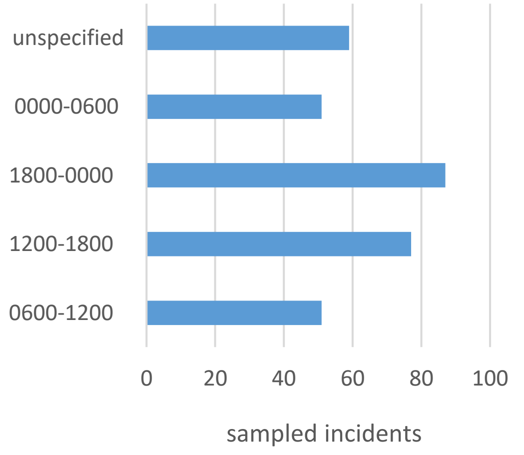
Figure 16 shows the breakdown in location for the sampled incidents and patient data reviewed. Acute psychiatry in Waterford is composed of 2 defined areas, the first an area focusing on a higher degree of patient need, with smaller patient numbers, added security and a better staff/patient ratio. The second area has a reduced staff/patient ratio, more beds and less security measures. Patients move between the two areas on the basis of medical/nursing assessment in relation to risk, treatment needs and available resources. Combining the 2 areas reveals an equal spread of incidents across acute psychiatry, rehabilitation and older adult inpatient areas. Very few incidents occurring beyond inpatient care were included in the study sample, reflecting the population data as a whole.

Figure 17. Incidents by day



The greater majority of incidents occurred on weekdays, compared to weekends and bank holidays. This data was sought in relation to potential patterns or trends affecting resources such as staffing and out of hours services. A chi-squared goodness of fit analysis was conducted between day of incident and incident type. With p=0.059, there was no statistically significant difference found.

Figure 18. Incidents by time of day



Examining the data for trends and patterns also applies to the time of day when incidents tend to occur. As such the highest number of incidents appear to have occurred in the evenings, significantly when smaller numbers of staff (particularly non nursing staff) are on duty. However, the high number of incidents where no time was recorded makes further analysis of incident time tentative.

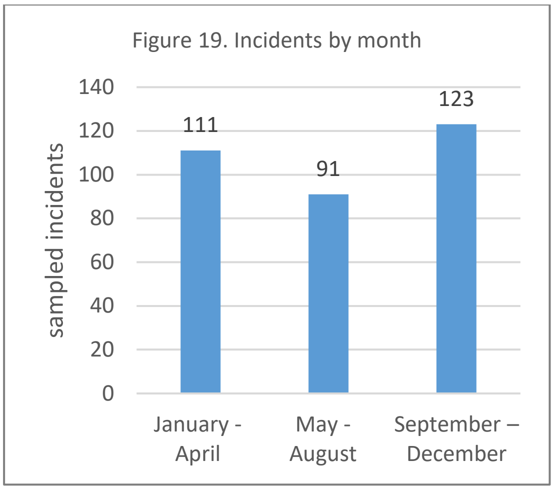


Figure 19. Incidents by month

Incidents were reasonably distributed throughout the year, with slightly fewer occurrences in the main summer months. A chi-squared goodness of fit analysis was conducted between month and incident type. With p=0.474, there is no evidence to conclude any statistically significant difference in month across incident types.

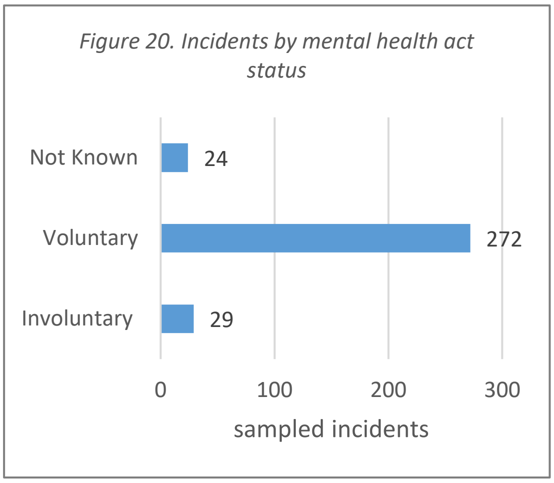


Figure 20. Incidents by mental health act status

The great majority of incidents involved patients not detained under the mental health act in Ireland, which oversees involuntary treatment and detention. This corresponds with national data showing a much greater number of voluntary admissions to hospitals as opposed to involuntary hospital stays.

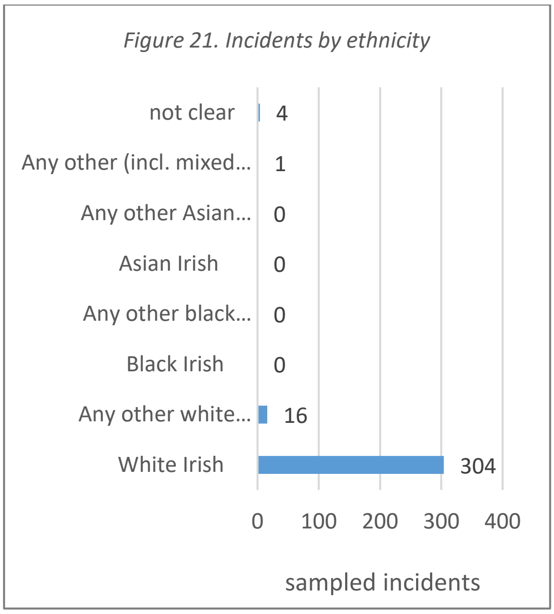
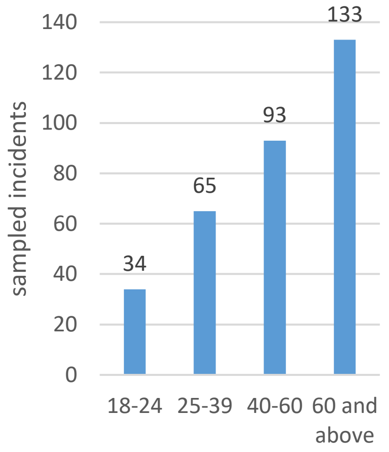


Figure 21. Incidents by ethnicity

A breakdown of ethnicities revealed White Irish as the dominant ethnicity recorded in the patient data, reflecting the ethnic diversity across the two counties.

Figure 22. Incidents by age



The highest number of incidents occurred amongst the over 60's, possibly explained by there being a wider age range in this group when compared with the other categories and the high number of incidents known to be reported across long stay older adult care. Only a very small number of patient under 40 years old were referenced in incidents reports completed in Wexford. A chi-squared goodness of fit analysis was conducted between age and incident type. With $p<0.001$, there is evidence to conclude a statistically significant difference in age across incident types, particularly the 60+ age group being more likely to be implicated in physical aggression whilst the 18-24 and 25-39 categories being more likely to be implicated in reports of self-injury.

Figure 23. Incidents by diagnosis

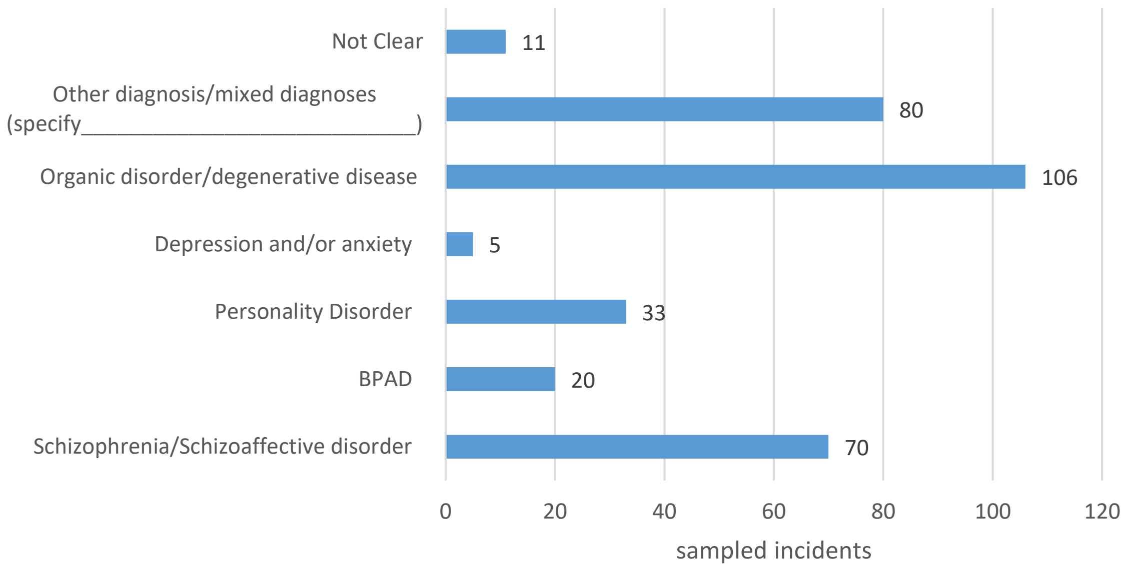


Figure 23 is a breakdown of the patient data by diagnosis. The high prevalence of organic disorders (e.g. Alzheimer's disease) is reflective of the high number of incidents reported on older adult inpatient units. Many of the patient files and letters studied listed more than one diagnosis, maybe indicative of the complexity often accompanying long inpatient stays, lengthy histories of psychiatric care and divergent medical opinions.

Figure 24. Incidents by risk history

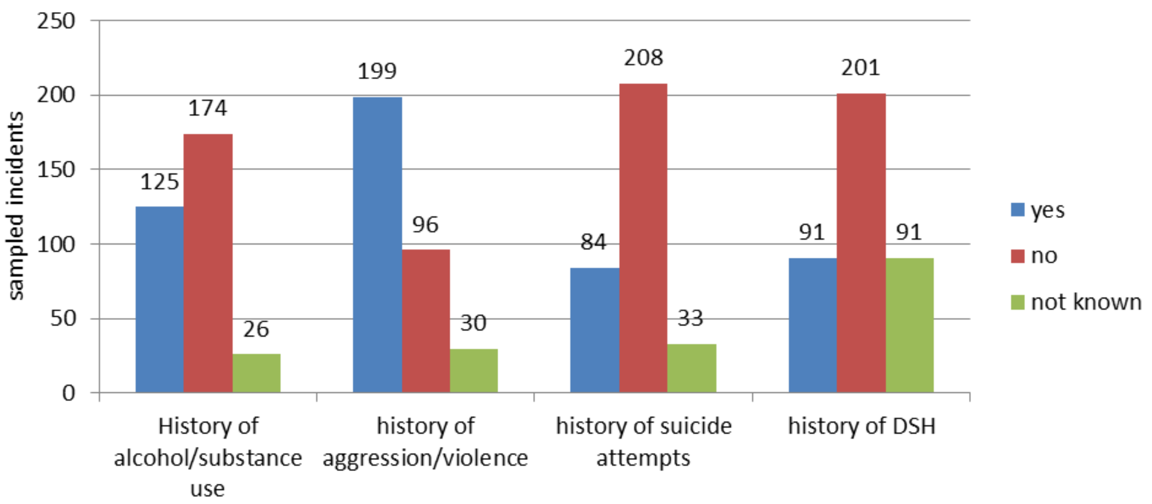


Figure 24 examined risk assessment data as to whether patients referenced in incidents had any risk history across the four main categories as above. In 3 of the categories (alcohol/drug misuse; suicide and self-harm) there was no documented history of risk for the majority of patients. By contrast, in the category of aggression/violence, double the number of patients appeared to have some documented risk history. However, a chi-squared goodness of fit analysis comparing history of alcohol/substance misuse with incident type found, with p=0.05, evidence to suggest more people without a history of note implicated in physical aggression than those with recorded risk histories. In contrast, having a history of alcohol or substance misuse appears to have increased the likelihood of self-injury and being implicated in a near miss event.

Figure 25. Length of time as an inpatient and length of time known to services

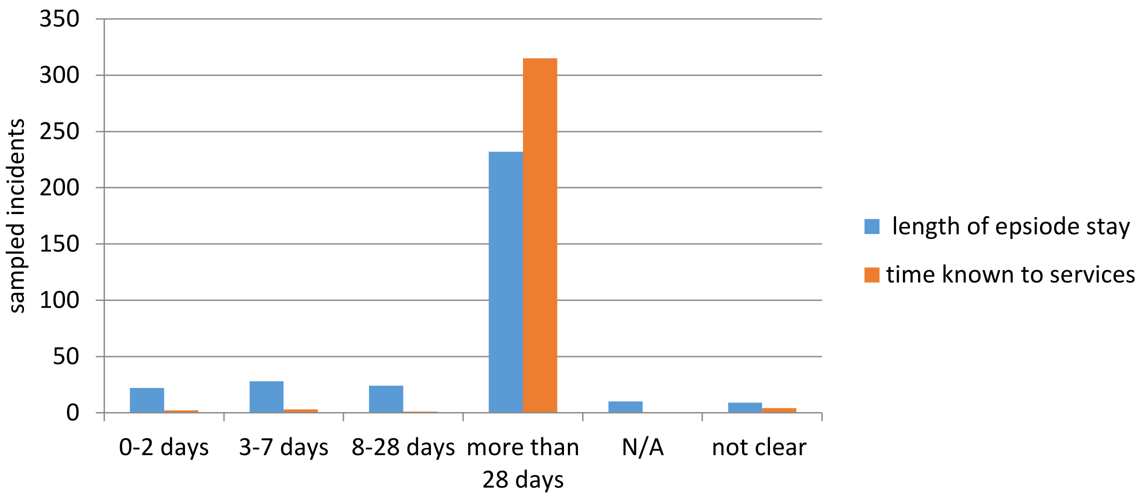


Figure 25 shows that the great majority of patients referenced in incidents were both known to local mental health services for longer than 28 days and had been on an inpatient unit for this length of time also (where applicable). Inpatients with bed stays of less than 28 days and those known to services for less than this time were rarely referenced in reports.

9.5 Qualitative content analysis

All paraphrased lines of text were taken from available patient charts and entered onto an excel spreadsheet during the data collection process. These were subsequently transferred to a word document for further coding. Lines of text were grouped together where they were identical or had similar meaning. This data was then examined and linked together to identify contributing factors and sub-themes, which were further grouped into 8 broad themes. The number of paraphrased lines of text within each theme meant that themes could be then be ordered in terms of the frequency that they appeared in the reviewed patient charts, making number one the most prominent theme in the patient records through to number 8, observed as the least prominent area identified. One or more of the four pre-determined contributing factor categories (patient; staff; organisation/environment; external) was then added in terms of their corresponding relationship to the themes identified.

Table 13 summarises this process. Not all lines of paraphrased text have been added to the table due to their large number. As such, a range of selected entries from the total number available have been included in order to illustrate their relationship with each associated theme.

Table 13 Qualitative content analysis

Theme	Paraphrased lines of text (selected examples)	Contributing factor/s	Sub-themes	Main category /categories
1. Observed and known patient factors	*paranoid and religious delusions* *elated and pressured speech* *medical issues causing discomfort* *major depression after psychotic episode* *complaining of nightmares and flashbacks* *distressing obsessional thoughts* *behaviour significantly complicated by Autism Spectrum Disorder* *complaining of voices telling him to self-harm* *confusion and disorientation*	Acute psychosis Acute mania/hypomania Co-morbid medical issues Acute depression/anxiety PTSD (flashbacks, nightmares) Obsessional thoughts Autism Spectrum Disorder Organic disease/disorder	Symptoms of illness	Patient factors External factors
	history of sexual and emotional abuse *sexual vulnerability noted* *significant forensic history* *significant alcohol and gambling issues* *history of violence to others* *previous history of carrying weapons*	History of physical/sexual/ psychological/emotional trauma Replication of previous behaviour (e.g. known to use physical violence or overdosed previously or absconded before) Use of drugs and alcohol in detriment to mental health Known vulnerability	Historical risk factors	
	not long in new environment *intermittent suicidal thoughts* *complaining of wanting to attack someone* *fully mobile and frequent pacing* *verbally aggressive 4 days before incident* *injured hand punching wall in earlier incident* *episodes of self harm 2 days and 5 days prior to incident* *had taken overdose earlier in day* *self-cutting and attempted hanging prior to admission* *positive for illicit substances on previous day*	Unpredictability (e.g. just admitted and not known; new behaviour; new environment) Expressing suicidal thoughts Expressing thoughts of violence to others Fully mobile (in context of older adults with organic disorders) Drug or alcohol intoxication Similar behaviour recently observed/reported	Behaviour and warning signs	
	citing financial stress *recent relationship break up* *had stressful weekend at home off unit* *being 'bullied' at work*	work or unemployment issues Family concerns Money concerns	External stressors	

	anxious about missing work			
2. Patient-staff flashpoints	*wanting to access kitchen outside permitted hours* *non-compliant with smoking policy* *disagreement over amount of daily cash allowance* *transferred to sub-acute area as sleeping on corridor in acute unit* *not wishing to leave hospital despite team decision to discharge* *demanding to leave* *warned re use of alcohol and cannabis* *refusing medication* *de-escalation not helpful* *involuntary status under MHA affirmed by tribunal*	Challenging unit rules (e.g. gaining access to kitchen, smoking areas) Accessing personal items (cash, drinks/cigarettes in office storage, locked presses etc.) Transferring between clinical areas Wanting to leave/restrictions on movement Refusing to attend to ADL's, eat meals etc. Refusing meds Refusing to leave unsuccessful de-escalation Drug and alcohol use whilst under treatment Involuntary treatment/tribunal outcomes	Rules and regulations Staff experience, training and resources	Staff factors Organisational/ environmental factors
3. Violence and aggression amongst patients	*incident followed verbal altercation over cigarettes* *argument in day area regarding tv and radio use* *previous assault on same fellow resident* *said he hit out in retaliation* *paranoid re other patients in communal dining area* *complaining of other patient harassing her* *perpetrator sleeping in same dormitory* *complaining of severe noise and disruption on the unit* *complaining of claustrophobic/noisy bedroom area* *patient frequently needing to be separated from other patients*	Shared public areas (e.g. day room, dining room, corridors, shared bed areas) Repeat perpetrators Invasion of personal space Arguments about property, cigarettes etc. Noise Shared meal times Entering areas for different genders Retaliation Fear of other patients Efforts made to separate patients	Safety and security measures Unit layout Unit routines and procedures	Organisational/ environmental factors
4. Violence and aggression in context of direct nursing care	*being walked by 2 staff at the time* *in context of receiving help with washing and dressing* *in context of being assisted with shower* *being fed at the time* *frequently resistive to nursing help*	Whilst providing assistance with mobilising (mainly older adult care) Whilst providing assistance with ADL's (mainly older adults care) Trying to mitigate other risks (falls, wandering, disorientation etc.)	Staff interventions Older adult care Manpower and resources	Staff factors

5. Pervasive challenging behaviour in long stay settings	*frequent aggressive unprovoked outbursts* *hostile and threatening on a daily basis* *daily thoughts of self harm* *had physically assaulted 2 other patients in week before incident* *frequently awake and keeping others awake at night* *frequent aggressive outbursts*	Incidents involving the same patient/s Repeated conflict with staff	Long term institutionalisation Staff and team management	Staff factors Patient factors Organisational/ environmental factors
6. Personal and public property used as items of harm	*used hairbrush as weapon* *managed to steal/obtain syringes and needles from the unit* *used and damaged hospital property to harm herself* *removed blade from disposable razor* *use of socks to create ligature* *frequently throwing liquids* *had access to chiropodist tool to use as a weapon*	Availability of items that have potential to cause harm to self or others	Safety and security Specific local policies and procedures Rights and basic needs	Patient factors Organisational/ environmental factors
7. Leave and AWOL arrangements	*was having hours off the unit care of family when incident occurred* *went AWOL 6 days prior to incident* *out on leave from unit most evenings* *says he took drugs whilst AWOL* *in process of being taken for x-ray* *repeatedly not returning at agreed times*	Not returning from leave at agreed time before incident occurred On leave before an incident occurred AWOL before an incident occurred AWOL when incident occurred During escorted leave (e.g. other clinic appointments) During work placement	Safety and security Use of leave in preparing for discharge or other purposes	Organisational/ environmental factors external factors
8. Discharge problems	*lost nursing home placement due to physical aggression there* *awaiting appropriate housing* *two recent hospital stays - the last only 1 week before incident*	Lack of suitable accommodation outside hospital environment Loss of accommodation on admission (e.g. nursing home) Difficulty managing outside hospital environment	Extended hospitalisation	Patient factors Organisational/ environmental factors External factors

The most common theme identified ‘observed and known patient factors’ is unsurprising given the data source and its main function of recording patient histories and progress. As such the first two sub-themes reflect the often dynamic but sometimes long-standing illness/disorder symptoms observed by healthcare staff and the recorded historical risk factors; often associated with a replication of incidents involving self-harm or violent behaviour.

The third sub-theme relates to observed risk factors in or around the time of the incident (i.e. in the week preceding the incident in question) and are associated with the assessment of current risk factors. Included within this sub-theme are cases where there appeared to be a level of unpredictability such as when someone had only just arrived on a unit or where little was known about the person involved. The last sub-theme refers to external stressors; frequently psychosocial in nature and identified in the records as contributing factors. The most common stressors appeared to be associated with families, relationships, work and money.

The next theme, ‘patient-staff flashpoints’ connects all the incidents where some type of staff-patient intervention was involved. These interventions, primarily on inpatient units, appeared to be a contributing factor for incidents in many cases. Nursing experience would suggest that responding unfavourably to requests to leave hospital or omit medication, as examples, can lead to conflict and safety issues. ‘Breaking bad news’ can be seen as a necessary part of the role of healthcare staff, particularly factoring in other contributing factors to the outcome of this, including a temporary lack of insight and understanding on the patient’s part. There was, however, a far reaching number of possible areas for conflict identified, raising not only the role that staff play in how they respond to patient requests but also the role played by organisational rules and policies, which again are often necessary but can create conflict when enacted.

Theme 3 refers to the significant degree of conflict occurring between hospital patients and residents, both in acute hospital settings and in long-term care environments. The theme highlights the frequent difficulties accompanying institutional care in terms of shared facilities such as dormitory style accommodation; shared meal times; noise; retention of personal items and lack of privacy. In long-stay environments there appears to be a particular emphasis on repeat perpetrators, the same patients referenced on recurrent incident forms. Unit layout and local rules and procedures have particular relevance within this theme.

Theme 4 relates to the occurrence of violence and aggression incidents on mainly older adult units in the context of direct nursing assistance and long-term organic disorders. Assisting patients with their activities of daily living such as washing and eating are a significant part of the care provided on these units and incidents appear to be frequently linked to these activities. The theme shares some similarities with theme 2 given that initiating 'hands on' care can create a flashpoint between staff and patients.

Theme 5 refers to the recording of violence and aggression in long-stay environments and the often pervasive nature of such incidents; often involving the same scenarios and the same perpetrators. Despite the logging of incident reports and descriptions in the patient charts of action taken to prevent or manage such incidents (e.g. behaviour plans, use of PRN medication) there is a clear theme of continued, sometimes daily safety issues. Whilst the type of behaviour recorded may simply reflect a particular patient's need for long-stay care, it also raises issues in terms of how staff manage challenging behaviour and the wider complexities associated with institutionalisation.

Theme 6 relates to the wide array of items used as objects of harm, either in terms of harm to self or others. This is significant as there is likely to be differences across clinical units and environments in terms of what is considered a safety risk and therefore in need of monitoring and restriction. The objects described in the analysis, however, demonstrate how complex this assessment is likely to be, given how seemingly innocuous they can appear to be and the degree to which peoples' rights and basic needs have to be met also; access to food, drink and clothing, being examples of this complexity.

Theme 7 refers to incidents where recently sanctioned or unsanctioned leave appears to have had some association. In some cases, patients were accompanied by staff members or family members whereas on other occasions patients had left a unit without informing staff. Policies and procedures for leave and leaving without clinician agreement may clearly differ across different patient groups and clinical environments. However, the whole area of leave, unit security and confinement can be contentious issues, particularly when factoring in the voluntary nature of most hospital stays and the restrictive environments created by excessive security measures such as locked doors and high fences.

The final theme refers to the frequent difficulties in ‘moving on’ patients from inpatient areas to appropriate community settings. In some instances length of time in hospital has been associated with untoward incidents occurring. The availability of suitable nursing home placements, for example, can create extended acute hospital stays in unsuitably resourced environments not necessarily directed towards older adult care. Similarly, the negative effects of extended hospitalisation can in turn create levels of uncertainty and friction towards staff and other patients. In a number of cases, incidents occurred in the context of recent or consecutive inpatient stays, raising issues in relation to the function and capability of available community mental health resources.

Chapter 10: Discussion, recommendations and study limitations

10.1 Introduction

The current study sought to ascertain the nature, type and frequency of reported incidents within mental health services in the south-east of Ireland, including an analysis of the potential triggers leading to such incidents occurring. The study utilised a document analysis based methodology, incorporating the research methods of retrospective chart review and qualitative content analysis.

This chapter presents a discussion of the results, reflecting on the earlier reviewed literature in terms of consensus or divergence from the available evidence. Recommendations relating to local policies and procedures are made as designated in the original research proposal. An overall evaluation of the research study is also provided, including an appraisal of the study's limitations and recommendations for further research.

10.2 Chart review

The findings of this research study suggests that violence and in particular inpatient violence, followed by self-injury remain the most frequently reported incident types, reflecting existing incident reporting data (Oglesby, 2012; NHS Improvement, 2018); their degree of significance within the mental health literature (Piel and Schouten, 2017; Slemon et al. 2017; Gaffney et al. 2009; Bakst et al. 2010; Corcoran and Walsh 2014) and the degree to which nursing staff, in particular, can be negatively affected (Stevenson, 2015, Griffin, 2021). In contrast, other incident types included in the study (near misses; verbal abuse; deaths; sexual assault and damage to property) yielded low numbers of reports.

Whilst the number of recorded violent incidents resulting in death or physical injury were thankfully minimal over the study period, results tend to suggest a level of pervasive low-level violence across local mental health services, either directed at staff or, as observed locally in this study, amongst patients themselves. The high level of patient on patient violence observed is significant as less regard appears to have been given to this phenomenon in the research literature compared to the risks faced by healthcare staff and the general public. The findings of this study appear to support research evidence highlighting the increased vulnerability to violence inherent in both having a mental disorder and seeking mental health care (Royal College of Psychiatrists, 2007; Latalova et al. 2014 Higgins et al. 2015). The significant degree of violence experienced by patients on inpatient units in this study appears to link in with the 'iatrogenic' basis of risk highlighted by Higgins et al (2016b) suggesting that patients are at risk from those around them as a result of their 'patient' status as much as they may be deemed a risk to themselves or others.

Persistent low-level violence appears to occur as much in longer stay settings as it does in acute settings. Indeed, the presence of higher rates of physical aggression across Wexford services may be partly explained by having a greater number of 'long-stay' adult and older adult units with levels of repetitive violence perpetrated by the same individuals. Accordingly, the vast majority of patients implicated in all incident reports were both known to services and had been staying on an inpatient unit for more than 28 days when the incident in question occurred. In contrast, the higher rates of self-injury in Waterford may be explained by the main location of acute adult or 'short-stay' inpatient services within that locality, where self-injury appears to be much more prevalent; affecting a younger age profile and over shorter periods of time.

The higher rates of violence amongst males, in contrast with higher rates of self-harm amongst females appears to correspond with historical findings in the literature (Dack et al. 2013; Iozzino et al. 2015; Bowers et al. 2014; Bresin and Schoenleber, 2015; O'Connor et al. 2018; Plener et al. 2015). Higher rates of violence appeared to be associated with older adults in this study compared with a higher prevalence of self-injury amongst younger patients. Whilst self-injury, particularly non-suicidal in nature, is commonly linked with younger patients (NICE, 2011; Mental Health Ireland, 2020; Saunders and Smith, 2016) the findings across local mental health services in relation to violence in older adults deviate from historical research findings linking younger age with increased violence risk (Swanson et al. 1990; Bonta et al. 1998; Otto, 2000; O'Callaghan et al. 2018).

The high risk of violence associated with organic disorders such as Alzheimer's disease has, however, been previously noted (Flannery et al. 2005; Royal College of Psychiatrists, 2008; O'Callaghan et al. 2018) and is borne out by the results of this study, suggesting a link between essential 'hands-on' nursing care such as assistance with self-care and altercations between fellow residents with organic disorders as contributory elements of older adult violence and aggression.

A significant number of patients were recorded as having some previous history of violence and aggression mirroring the widely held perspective on violence risk which views previous risk as a strong indicator of future behaviour (Chou et al. 2002; Amore et al. 2008; Dack et al. 2013). Again, this needs to be seen in the context of residential settings where the same perpetrators have tended to be implicated across multiple incidents, somewhat skewing results. Similarly, even one episode of violence and aggression noted in the patient charts was enough to establish a 'history' which could be deemed unfair, particularly in the context of severe mental disorder or in some cases, protecting one's own safety.

Not having a history of alcohol and drug misuse was, perhaps surprisingly, statistically associated with incidents of violence, differing from previous results linking a positive history of substance and alcohol misuse with an increase in the prevalence of violence (Dack et al. 2013; Iozzino et al. 2015). However, having a history of substance/alcohol misuse was statistically linked with self-injury and near miss events, reflecting previous studies in relation to self-harm risk (Bakst et al. 2010; Hunt et al. 2010). No other specific themes or trends were identified in the chart review, reflecting missing data (time of day); lack of diversity (mental health act status and ethnicity) not revealing any unexpected results (day of week, month of incident) and frequently unclear or too diverse (diagnosis).

10.3 Content analysis

In examining the contributing factors of each incident report, there appeared to be few differences between the main categories of violence/aggression and self-injurious behaviour. As such, the greatest number of contributing factors noted in patient charts referred to patient risk factors, relating to illness and symptomatology, historical risk factors and observed behaviour. To a lesser extent, external contributing factors in the person's life such as homelessness or loss of unemployment were also highlighted. As noted previously, this focus on patient-related factors is unsurprising given the function of clinical charts and their typical content, which is more likely to focus on how a patient presents or is observed than any outside influences affecting the local environment (e.g. staff shortages or overcrowding). However, despite calls in the literature to consider incidents from other non-patient or non-illness related perspectives (Higgins et al. 2016a; Slemon et al. 2017; Callaghan and Grundy, 2018) research findings from this study suggest that ill health, particularly at its most acute or as in so many cases coupled with other frequently complex historical or dynamic factors, remains a significant contributory factor across many reported incidents.

Whilst diagnosis of a major mental disorder was clearly a contributing element in the incidence of violence and self-harm as noted in the literature (Price et al. 2018a; Jalil et al. 2020; Bakst et al. 2010; Hunt et al. 2010), it is arguably the dynamic nature of these mental disorders which led to incidents occurring. As such, in many of the cases examined it was the acuity by which the person was experiencing symptoms as opposed to the presence of illness itself. Across the 3 main areas where incidents occurred this is again not surprising. Acute admission units admit persons on the basis of the most severe levels of illness and risk, whilst rehabilitative and long-stay environments tend to treat those with symptoms which never fully resolve or those with symptoms illustrative of progressive and irreversible disorders such as Alzheimer's disease.

Findings, then, would appear to support the use of a dynamic approach to risk assessment as advocated for in the literature (Coid et al. 2016; O'Shea et al. 2013; Kivisto, 2016). It appears from examining the charts that this is indeed happening locally, given the attention to levels of acute symptomatology in the context of known historical risk factors, observed behaviour and recent external stressors.

Notwithstanding the significance of patient related factors in clinical incidents, the importance of staff and organisational/environmental factors is also underlined by the research findings. Events preceding reported incidents often included some kind of confrontation between clinical staff and patients, either in relation to the person's treatment plan (e.g. their perceived need to remain in hospital or take medication) or testing local organisational rules or regulations (e.g. access to kitchens or smoking areas). These areas of potential conflict appeared to occur across all clinical areas and were quite varied and contrasting, with encounters such as 'refusing to leave hospital' leading to self-harming behaviour in the same way as 'not being allowed to leave' led to incidents of violence and aggression.

Such findings mirror the work of previous authors highlighting the potential 'flashpoints' that can arise on inpatient units (Bowers et al. 2014; Spaducci et al. 2020). The significant number of areas for conflict identified by this research highlights the need for competent communication and de-escalation skills amongst clinical staff as advocated in the 'Safewards' model of care (Bowers et al. 2014) and a balance of flexible and consistent approaches (Gudde et al. 2015; Lantta et al. 2016; Van Wijk et al. 2014). Similarly, professionals are guided in, wherever possible, trying to assess, gauge and pre-plan for the potential reaction of patients (Taylor-Watt et al. 2017) in order to avoid the type of restrictive or coercive practice criticised in the current literature (Duxbury, 2015; Funk and Drew, 2019; McKeown et al. 2019).

Research findings also point to the significant degree of violence and aggression risk faced by clinical staff in providing 'hands-on' care, which can be seen as another area where flashpoints can occur. This appears to apply particularly to older adult units where full ADL support is often required. Indeed, this mirrors research noting the potential for violence and aggression whilst caring for this cohort of patients (Flannery et al. 2005; Royal College of Psychiatrists, 2008; Rosen et al. 2019).

The potential for conflict and self-harm stemming from unit rules and regulations noted by the research is also reflected in the wider literature (Iudici et al. 2015; Faccio et al. 2020), albeit writers have made the point that it is not necessarily the presence of rules, moreover how these are implemented and upheld (Price et al. 2018a; Staniszewska et al. 2019). It may also be that levels of staff control are linked with increasing the potential for flashpoints. An illustrative example from the research findings is the number of incidents on longer stay units where patient access to money and personal property is restricted. Again, whilst this is often a necessary measure in terms of the person's wellbeing and safety, it can create another potential area of conflict. Elements of staff or organisational 'control' have also been criticised in the literature in terms of managing risk, noting that overly restrictive clinical environments can negatively impact on its management (Barker and Barker, 2005; Ray and Allen, 2015).

Content analysis revealed a significant degree of 'patient on patient' incidents of violence and aggression. This appears to be a less widely discussed area of concern in the available literature, especially when compared with violence and aggression directed towards staff, albeit it is those clinical staff that are often required to intervene in such instances, placing themselves at risk also. Research findings point to frequent conflict but low levels of harm, sometimes relating to patient ill-health, but often appearing to stem from institutional/communal living arrangements (e.g. shared sleeping areas and noise levels). Existing research studies have shown certain areas and times such as dining rooms at mealtimes to be linked with a higher incidence of violence and aggression (Chou et al. 2002; Bowers et al. 2011) in addition to busier times of the week being linked to increases in violence and aggression (Katz and Kirkland (1990). This evidence correlates with the current research findings in terms of close patient proximity being a risk factor for incidents occurring and indeed less incidents being reported on weekends.

It would appear from the findings that environmental factors such as space, privacy and patient numbers are important factors in managing patient on patient conflict. Whilst newer units appear to have been designed with these areas in mind, there are older units that remain unconducive to such aims. The ability of clinicians to predict and plan for such occurrences is still a significant factor (e.g. dining room seating arrangements) but this would appear to be in the context of available organisational/environmental structures in place. As noted previously the Mental Health Commission in Ireland (Finnerty, 2021) have laid out what they feel is the ideal environmental characteristics of an inpatient area. This covers some of the problem areas raised in the research findings such as smaller patient numbers, installing individual rooms and aiming to reduce noise levels.

The research findings revealed a level of pervasive violence and aggression mainly in the context of longer-term care environments. Results also note multiple incidents attributed to many of the same individuals. Over long periods such exposure can lead to what Stevenson et al. (2015: p11) note as ''acceptance'' of and ''desensitisation'' to violence. The danger here, as repeatedly highlighted in the literature, is the risk of staff burnout, leading to absence; high turnover and patient care being negatively affected (Morse et al. 2012; Lopez-Lopez et al. 2019; Aguglia et al. 2020; Kang et al. 2020).

Such challenging behaviour is clearly not isolated to long stay units however. The complexities of moving patients on from acute settings to appropriate placements or homes, as revealed by the content analysis and highlighted in Ireland (MHC, 2020), means that staff in these areas also need to contend with often extended periods of violence, aggression and self-harm. In addition to the physical and psychological consequences of these issues, staff can become disillusioned when discharge is unsuccessful and patients return after only short periods outside the hospital. For many patients themselves, length of time in hospital is likely to be frustrating, debilitating and increasing the risk of an incident occurring due to these factors or simply the length of time they spend in hospital alongside other patients.

Organisational safety and security is a theme revealed throughout the research findings. Obtaining the balance between such measures coupled with the avoidance of overly restrictive or coercive practices as advocated in the literature is clearly a complex and often difficult task. By way of illustration, findings from the content analysis indicate that items of potential harm to self and others can vary significantly and demonstrate how even the most innocuous items can be used to cause harm. Restricting potential items of harm is not a new phenomenon in mental health settings, research over the last 20 years ago discussing the benefits and drawbacks of safety and security measures (Bowers et al. 2002; Cowman and Bowers, 2009; Due et al. 2012).

Similarly, a balance is needed in terms of absconding risk and official leave arrangements which is greatly impacted by safety and security measures. Research findings highlight a number of incidents occurring whilst patients have been on leave or absent from the unit. Whilst this is undesirable, there is the question of the degree to which patients are subjected to safety and security measures akin to detention centre/penal environments. In essence, the evidence for increasing safety and security measures is mixed in terms of preventing incidents from occurring. On the one hand, for example, the research evidence advocates for more open clinical environments in terms of patient satisfaction (Lang et al. 2010; Blaesi et al. 2015) whilst developments in safety and security technology, for example, mean that more measures are being introduced to try and counteract safety concerns (e.g. CCTV, metal detectors and body worn cameras) (Desai, 2010; Due et al. 2012; Laidlaw et al. 2017). The question of whether such measures can exist in an environment that remains open, unrestrictive and therapeutic is a complex area of debate.

Findings from this research study raise a number of aspects for consideration in terms of local service provision (Appendix 25). Whilst accepting the limitations of studies using incident reports and patient data, the research findings highlight the value of incident reporting in terms of examining local services.

10.4 Using a systems analysis approach

In this study contributing factors have been drawn from across the various ‘systems’ in place within mental health services. As noted previously determining any single predominant factor is rarely possible or achievable when examining serious incidents retrospectively, reflecting a wider and ever-present paradox relating to cause and effect observations and clinical research (see sections 4.33; 4.34; 4.62 on contributing factors in suicide and sections and 3.31; 3.33; 3.34; 3.42 on contributing factors in violence).

Even where causes have been defined, acted upon and recommendation processes championed a success there is the ever-present possibility of other 'confounding' factors being at least partly responsible (Ramsey et al. 2022). Ligature removal; 24 hour crisis care and dual diagnosis teams, for example, have all simultaneously been commended for reducing the suicide rate amongst UK inpatients (Kapur et al. 2022), reflecting seemingly positive changes in organisational/environmental systems.

However, reflecting on the other systems identified in this study, a patient-related system explanation may include the changing climate of suicide and mental health, where populations as a whole are now encouraged to positively share and acknowledge their mental health, whilst external factors (e.g. recession, pandemics, poverty and cost of living crises) can never be discounted in terms of their impact on suicide rates. Using a systems approach therefore creates another potential paradox in that whilst it would appear equitable to consider serious incidents from all angles, the identification of too many contributing factors (or indeed the wrong ones) can result in ineffective, 'watered-down' or even potentially unnecessary changes due to false positive or negative findings. In essence it can feel like a case of 'throwing mud at a wall to see what sticks.'

For some writers (Vincent, 2003; Neal et al. 2004; Martin-Delgado et al. 2020), such outcomes reflect the whole ethos of post-incident cause and effect type enquiry (the method on which most healthcare patient safety systems are based) whereby often overly simplistic causes and remedies are put forward in response to significantly complex or unexplainable events. Similarly, organisational or professional systems are prioritised as they are considered more controllable; whilst events not subject to change or alteration can be overlooked. Bhandari et al (2022) suggest a different 'counterfactual' approach to incident analysis whereby events might be perceived as if they did not occur. Suicide, for instance, can create retrospective bias through the investigator evaluating actions in light of the outcome's seriousness. However, from a procedural or organisational perspective the question of whether the professional/s acted or made decisions in the appropriate manner might be more reasonably attested.

In essence there appears to be an endeavour to ensure organisational systems are in place for when serious incidents inevitably occur; the latter being the 'unchangeable' part of the overall patient safety strategy. Whilst it is clearly appropriate for policies and procedures to be in place in anticipation of certain events, it is also evident how such practice could be deemed defensive or risk averse as it places little responsibility on the individual receiving care or how humans (regardless of contact with mental health services or not) are capable of irrational, erratic and unexpected behaviour. Similarly, the fact that organisational and administrative structures obligate mental health services (and indeed nearly all public and private organisations), to examine and learn from serious incidents is in itself part of a wider political system which seeks cause and effect answers when sometimes these are just not easily forthcoming.

The fact that a patient is deemed in need of hospitalisation on a psychiatric unit where he or she then can become the victim of violence is itself a systems issue, albeit resulting from a significant number of factors including how governments organise mental health care; available local resources; levels of family support and even just historical norms and expectations. That the inherent risks of violence might merely move from one environment to another can easily be overlooked. That the majority of people dying by suicide tend not to be under mental health care (Kapur et al. 2022) also reflects a much wider systems issue, far outreaching mental health services alone.

Ultimately, in the absence of any other structured approach to cause and effect patient safety investigations, there is always the concern that professionals within that organisation will be negatively affected by a fear of blame or as Harding (2022: p.44) succinctly states "leads to clinicians doing what is least likely to be criticised rather than what is in the patient's best interest." If such fears lead to increased reliance and use of inpatient care in Ireland (as has reportedly happened in the UK in recent years) (Wessely, 2018), this is also concerning given the risk of patient to patient violence highlighted in this research study. The question of whether such units offer ‘care or custody’ (Jenkin et al. 2022) is an ongoing debate, again reflecting the overriding systems in place to manage mental health services.

10.5 Study limitations and future research recommendations

The use of incident reports and chart review methodology was not a straightforward process and the findings of the study are somewhat limited by the issues experienced. Whilst incident reports have provided the basis for this study, they have certain publicised limitations as discussed in chapter 2.

During the process of carrying out this research study, I found that in linking violent incident forms to patient files there were occasions where the form referenced the victim as opposed to the perpetrator. As such there was no reference to the perpetrator meaning that their file could not be reviewed. This is not an issue for incidents where one person is affected (e.g. self-harm) but in many cases of violence and aggression there are two or even more people implicated. It would be helpful in such instances to ensure that 2 or more forms are completed referring to the perpetrator/s and the victim/s. It is not clear whether this happens after all relevant occurrences.

Some of the options on the incident forms also appear difficult to categorise. Absconding, for example, is categorised as ‘self-harm’ when in essence this behaviour, whilst in some cases, increasing the risk of harm, does not necessarily lead to an actual incident occurring. As such, incidents of absconding (and others noted during the data collection such as dressing inappropriately; giving other people medication; stealing money and taking clothes off) in this research study were categorised as ‘near misses.’ Whilst this is arguably offers a better description of the incident than self-harm, it depends on a level of subjectivity, which could then result in statistics being affected. Indeed, one of the main criticisms of incident reporting is knowing how best to define and categorise incidents (Stravropoulou et al; Murray, 2020).

This is further illustrated by having to remove some incidents (particularly those unwitnessed) where it was not clear whether the occurrence was an accident or a result of violence/ aggression or self-harm.

A number of limitations were highlighted during the process of examining paper files, many reflected in the existing literature (Gearing et al. 2006; Gregory and Radovinsky, 2012; Sarkar and Seshadri, 2014; Puyat et al. 2019). Missing data proved to be the major complicating factor (either wholly or partly missing) but other issues also arose including multiple divergent filing systems across clinical areas and locations; many patients having several volumes of notes (with relevant data not in the current volume) and some progress notes not being updated regularly (e.g. some longer stay units and community services). In some cases it was not possible to link the incident report to the relevant patient notes as the incident itself was not outlined in the patient chart.

In terms of both research methods used, the evidence suggests that data collection should involve more than one person to ensure reliable and consistent results. Due to GDPR limitations and resource availability this was not possible. Having another data collector would have been helpful, particularly in relation to analysing contributing factors, where there was an inevitable degree of subjectivity required.

The success of future research studies utilising patient data is likely to be supported by developments in technology, in particular electronic patient notes. Being able to access all relevant data from a single access point would be a significant advantage, especially considering the time and resources utilised in accessing paper charts during this research study; the problems associated with missing data and the difficulty linking relevant information such as incident reports.

Whilst there is value in carrying out ‘desk based’ retrospective studies using patient data, as demonstrated in this study, future research studies may look to patients, clinicians and carers for their views. These may be sought in relation to their thoughts regarding incident report data and more significantly the contributing factors linked to untoward incidents. Indeed, the involvement of family members in serious incident investigations is now greatly encouraged, where transparency and family experience/input is seen as vital to service improvements (Ramsey et al. 2022).

It would be useful to compare these with the findings of this study in terms of similar or divergent themes. Future research studies may also wish to limit the type of incident and the area in which it occurs to improve transferability outside of local services. Contributing factors could be examined less broadly and more in context with the local environment (e.g. violence and aggression in older adult inpatient care or self-harm within an acute admission unit).

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Appendices

Appendix 1. Study inclusion and exclusion criteria

Research Study

'A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South-East'

Inclusion criteria

- All localities to be included (inpatient/community etc.)
- Waterford or Wexford services only
- All patients over 18 at time of incident
- Suicide/self-inflicted death
- Homicide
- Physical Injury to another patient/s
- Physical injury to a staff member/s
- Acts of self-harm
- Sexual abuse
- Physical abuse
- Exploitation (financial, domestic)
- Property damage (non-accidental)
- Near misses that could have resulted in serious harm (including absconding)
- Any act or omission placing patients, staff or visitors at risk of harm

Exclusion criteria

- Medical emergencies resulting in death or injury
- Drug errors
- Medical ill health/physiological issue (e.g. tissue viability)
- Accidents affecting staff/patients or both
- Slips, trips and falls
- Any other health and safety type incidents (blood spills etc.)
- Data loss (e.g. patient notes/x-rays etc.)
- Patients under 18 at time of incident
- Incidents outside Waterford/Wexford mental health services

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Postgraduate Scholarship Information Sheet

Scholarship title	A Retrospective Case Analysis of Serious Untoward Incidents in Mental Health Services
Reference number	WD_2016_04
Supervisor(s)	Dr Michael Bergin Professor John Wells
Research Group	
Department / School	Department of Nursing and Health Care
Duration	3 Years
Status: Full-time / part-time	Part time
Funding information	MSc Scholarship funded by the Nursing and Midwifery Planning and Development Unit, HSE South-South East
Value of the scholarship (per annum)	Stipend:€9,250 Research postgraduate fees are included in the Scholarship Research costs:€2,000 (Travel and Consumables)
Teaching requirement (if any)	N/A
Closing date and time	10th June 2016
Interview date	
Commencement date	19th September 2016

Post summary

Applications are invited for a student to undertake a part time MSc in Nursing within the Department of Nursing and Health Care on the following project: A Retrospective Case Analysis of Serious Untoward Incidents in Mental Health Services

Background- Over the last 10 years, within the mental health services in the South East there have been a number of serious events and incidents.

The project aim is to undertake a retrospective case analysis of serious events and serious incidents within Mental Health Services with a view to the identification of the nature of the incident as this relates to service structures, levels of contact with services and skill mix utilising a social ecological model.
The study objectives are
1) To identify and analyse contextual factors that may contribute to serious events and incidents within clinical settings in mental health services with reference to theoretical and empirical literature;
2) To utilise a retrospective case analysis design to gather information related to serious events and incidents;
3) Analyse factors which contributes to, or protect from, serious incidents and events occurring
4) Develop an analytical and operational framework that categorises relates the nature of serious incidents, events and outcomes to service structures, levels of service contact and skill mix with reference to the social ecological model;
5) Make policy recommendations based on the above to the Irish Health Service Executive with regard to the development of protective structures to reduce serious incidents and events within the mental health services.

Research Design- This study will use a post ictive case study design. It will be a desk based utilising previously collected data and material.

Standard duties and responsibilities of the scholarship

- Undertake a programme of research leading to the successful attainment of an MSc
- Attend generic skills training provided by WIT and other courses as required.
- Attend and present at agreed conferences and seminars.
- Provide quarterly project updates to MSc Steering Group
- Deliver agreed papers in conjunction with the supervisory team

Person specification

Qualifications

Essential

- Applicants should hold or expect to attain, as a minimum, a 2.2 Honours degree, or equivalent, in nursing or other health care related discipline

Desirable

- First class undergraduate degree in nursing or health care

Knowledge & experience

Essential

- Previous research experience with an understanding of the research process and methods.

Desirable

- Knowledge and experience of data analysis

Skills & competencies

Essential

- Applicants whose first language is not English must submit evidence of competency in English, please see WIT's English Language Requirements for details.
- Excellent communication (written and verbal) and analytical skills.
- The candidate must be highly motivated and self-directed with good time and project management skills.
- The candidate will have the capacity to manage large datasets and display a willingness to travel in order to conduct interviews.

Desirable

- Experience of communicating with health professionals and patients

Further information

For any informal queries, please contact Dr Michael Bergin - email:mbergin@wit.ie or telephone: +00353 (0) 51 845549

For queries relating to the application and admission process please contact the Postgraduate Admissions Office via email pgadmissions@wit.ie or telephone +353 (0)51 302883.

Website: www.wit.ie

Application procedure

Download the Research Postgraduate Application Form and return completed applications to pgadmissions@wit.ie, quoting '(insert reference number)' in the email subject line. Please note that paper submissions will not be accepted.

The Institute may decide to interview only those applicants who appear from the information available, to be the most suitable, in terms of experience, qualifications and other requirements of the post.

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Appendix 3 NIMS incident report form

NIMS
National Incident Management System

HC NIRF 01 – V10
Date issued: 03/05/2018

NATIONAL INCIDENT REPORT FORM (NIRF)
NIRF - 01 PERSON

NIMS record Number: ____________

Incident: An event or circumstance which could have, or did lead to unintended and / or unnecessary harm. Please complete this form to the best of your knowledge at the time of reporting the incident.

SECTION A: GENERAL INCIDENT DETAILS

Date of incident D D M M Y Y Y Y

Time of incident H H : M M *Use 24 hour clock*

Location *E.g. Hospital, Health Centre, Residential Centre, etc.*

Specific Location *E.g. Ward, Theatre, Home etc.* **Offsite?** ☐

SECTION B: PERSON AFFECTED DETAILS

First name ____________

Surname ____________

Date of birth D D M M Y Y Y Y

☐ **Female** ☐ **Male**

Description of incident: ____________

Division (tick one only ✓)

- ☐ **Acute Hospital**
- ☐ **Social Care**
- ☐ **Health and Wellbeing**
- ☐ **Primary Care**
- ☐ **Mental Health**
- ☐ **Ambulance Service**
- ☐ **National Corporate Services (staff only)**

Who was involved...? (tick one only ✓)

- ☐ **Service user** – (Resident/Patient/Client) Go to section **C**
- ☐ **Staff member** – Go to section **D**
- ☐ **Agency / Panel staff** – Go to section **D**
- ☐ **Member of public**-Proceed to section **F**
- ☐ **Volunteer** – Go to section **D**
- ☐ **External Contractor** – Go to section **E**
- ☐ **Student** – Go to section **D**

SECTION C: SERVICE USER DETAILS ONLY

Healthcare Record No ____________

Lead Clinician ____________

This incident involved... (tick one only ✓)

- ☐ **Neonatal Specialties**
- ☐ **Paediatric Specialties**
- ☐ **Adolescent Specialties**
- ☐ **Adult Specialties**
- ☐ **Older Person Specialties**

Incident Occurred under (Service / Specialty) *E.g. Maternity, Radiology, Radiotherapy, Intellectual Disability, Psychology* ____________

SECTION D: STAFF MEMBER / AGENCY / PANEL STAFF / STUDENT / VOLUNTEER DETAILS ONLY

Category of person ____________

Employee no. ____________

Date absence commenced (if known) D D M M Y Y Y Y

Date returned to work (if known) D D M M Y Y Y Y

Work days lost ☐

Note: For employee incidents reportable to HSA that result in an absence from duty for more than three consecutive days, excluding the day of the accident, the date absence commenced and the date employee returned to work should be recorded on the NIMS

SECTION E: EXTERNAL CONTRACTOR DETAILS ONLY

Company Name ____________

Company no. ____________

SECTION F: WHAT WAS THE OUTCOME AT THE TIME OF THE INCIDENT?

✓ Outcome		Body Part Affected
☐ **Near Miss e.g. Nearly given wrong drug**	**Category 3**	*E.g. Arm, Spine, Lung, Other Physiological*
☐ **No Injury** e.g. Wrong drug given but no harm occurred		
☐ **Injury not requiring first aid**		
☐ **Injury or illness, requiring first aid**		
☐ **Injury requiring medical treatment**	**Category 2**	
☐ **Long-term disability / Incapacity (incl. psychosocial)**	**Category 1**	
☐ **Permanent Incapacity (incl. Psychosocial)**		
☐ **Death**		

SECTION G: TYPE OF INJURY (tick one only ✓)

Birth Specific Injury (Baby)	☐ Apgar score <5@ 1 min &/or; 7@5mins &/or pH ≤ 7.0 ☐ Aspiration ☐ Cerebral irritability / neonatal seizure ☐ HIE - Hypoxic Ischaemic Encephalopathy with Hypoglycaemia ☐ HIE Grade 1 - Hypoxic Ischaemic Encephalopathy	☐ HIE Grade 2 - Hypoxic Ischaemic Encephalopathy ☐ HIE Grade 3 - Hypoxic Ischaemic Encephalopathy ☐ Hypoglycaemia - severe ☐ Kernicterus ☐ Neonatal death ☐ Nerve Injury - brachial plexus (incl. Erbs Palsy)	☐ Nerve Injury - face ☐ Other unexpected deterioration ☐ Stillbirth ☐ Sub-galeal / sub-aponeurotic haemorrhage ☐ Unknown ☐ Other ______
Birth Specific Injury (Mother)	☐ Death ☐ Hysterectomy (Perinatal) ☐ Incontinence (faecal) ☐ Incontinence (urinary)	☐ Perineal tear ☐ Post-Partum Haemorrhage ☐ Rhesus iso-immunisation ☐ Incontinence (faecal & urinary)	☐ Unknown ☐ Uterine rupture ☐ Other ______
Blood Specific Injury	☐ Excessive Bleeding ☐ Fainting ☐ Immunological haemolysis	☐ Febrile non-haemolytic transfusion reaction	☐ Non-immunological haemolysis ☐ Other ______
Diagnosed Disease Disorder or Cond.	☐ Asbestosis ☐ Cancer ☐ Acute Radiation Syndrome ☐ Narcolepsy/Cateplexy	☐ Hepatitis ☐ HIV ☐ Brucellosis ☐ Legionnaires	☐ Unknown ☐ Dermatitis ☐ TB ☐ Pleural Plaques ☐ Other ______
Diagnosed Infection	☐ Clostridium Difficle ☐ ESBL ☐ Hepatitis	☐ MRSA ☐ Norovirus ☐ Unknown	☐ VRE ☐ VRSA ☐ Other ______
General Injuries	☐ Allergic Reaction (incl. anaphylaxis) ☐ Brain Injury / Concussion ☐ Burn / scald / corrosion ☐ Choking / asphyxia ☐ Circulatory / volume depletion ☐ Circulatory / volume overload ☐ Pain/Discomfort	☐ Cut / Laceration / Graze / scratch ☐ Death ☐ Dental injury &/or loss ☐ Deterioration ☐ Haemorrhage ☐ Blister	☐ Malaise / Nausea ☐ Nerve injury / Loss of Function ☐ Puncture / bite ☐ Rash / irritation ☐ Unknown ☐ Other ______
Hearing / Sight Injury	☐ Hearing Impairment / loss ☐ Sight Impairment / loss	☐ Tinnitus ☐ Unknown	☐ Other ______
Misdiagnosis	☐ Cancer ☐ Fracture	☐ Infection ☐ Unknown	☐ Other ______
Musculoskeletal / Soft Tissue	☐ Amputation ☐ Bruising ☐ Crushing ☐ Dental Fracture / Tooth loss ☐ Dislocation	☐ Fracture ☐ Repetitive Strain Injury (RSI) ☐ Slipped / Prolapsed Disc ☐ Sprain / Strain ☐ Soft tissue injury	☐ Swelling / Inflammation ☐ Unknown ☐ Whiplash ☐ Other ______
	☐ P. Ulcer Stage 1: Intact skin with non-blanchable redness over bony prominence ☐ P. Ulcer Stage 2: Part thickness dermis loss: blister/open ulcer/no slough ☐ P. Ulcer Stage 3: Full thickness tissue loss: +/- visible subcutaneous fat ☐ P. Ulcer Stage 4: Full thickness tissue loss/necrosis: exposed bone/tendon/muscle		
Personal Loss	☐ Additional / Further Surgery ☐ Limb Deformity ☐ Defamation of Character	☐ Loss of Wages / Income / Business ☐ Loss of Consortium	☐ Unknown ☐ Organ Retention ☐ Other ______
Surgery Specific Injury	☐ Damage to organ / body part ☐ Dental Damage / Loss ☐ Foreign body left in situ ☐ Unknown	☐ Loss of organ / body part ☐ Nerve injury / Loss of Function ☐ Inadequate anaesthesia	☐ Unexpected complication / deterioration ☐ Other ______
Traumatic/Emotional	☐ Anxiety / Trauma ☐ PTSD	☐ Stress ☐ Unknown	☐ Worried Well ☐ Other ______

SECTION H WHAT TYPE OF HAZARD DID THIS INCIDENT RELATE TO? (Tick one option from Steps 1, 2, 3 & 4)

	Step 1.	Step 2.	Step 3.	Step 4.
Clinical Care	☐ **Birth Specific Procedures**	☐ Caesarean Section (Elective) ☐ Caesarean Section (Emergency) ☐ Instrumental Delivery (Forceps) ☐ Instrumental Delivery (Vacuum) ☐ Instrumental Delivery (Multiple Instruments) ☐ Non Instrumental Delivery	☐ Communication / Consent ☐ Diagnosis / Assessment ☐ Documentation / Records ☐ Equipment ☐ General Care / Management ☐ Procedure / Treatment / Intervention ☐ Screening / Prevention ☐ Specimens / Results ☐ Tests / Investigations ☐ Unknown ☐ Other ____________________	☐ Adverse Effect ☐ Failure / Malfunction ☐ Foreign Body left in Situ ☐ Inappropriate for Task / Wrong device ☐ Incomplete / Inadequate ☐ Lack of Availability ☐ Not performed when indicated / Delay ☐ Pre Existing Medical Condition ☐ Shoulder Dystocia ☐ Unavailable / Mislabelled / Lost ☐ Wrong Body Part / Site / Side ☐ Wrong Patient ☐ Wrong Process / Treatment / Procedure ☐ Other ________________
	☐ **Clinical Procedures**	☐ Invasive ☐ Non Invasive		
	☐ **Medication**	*Route of administration* ☐ Oral ☐ Intravenous ☐ Sub Cutaneous ☐ Intra Muscular ☐ Topical ☐ Rectal ☐ Inhalation ☐ Other / Unknown	☐ Administration ☐ Monitoring ☐ Ordering / Supply / Transport ☐ Preparation / Dispensing (Pharmacy) ☐ Prescribing ☐ Reconciliation ☐ Storage	☐ Adverse Drug Reaction ☐ Contra-indicated ☐ Drug Interaction ☐ Failure / Malfunction of equipment ☐ Incomplete / Inadequate ☐ Not preformed when indicated / delayed ☐ Omitted/Delayed Dose ☐ Wrong Dose / Strength ☐ Wrong Drug ☐ Wrong Formulation / Route ☐ Wrong Frequency ☐ Wrong Label / Instructions ☐ Wrong Patient ☐ Wrong Quantity / Duration
		What medication was involved? *Medication One* ____________________ *Medication Two* ____________________		
	☐ **Nutrition**	☐ Parenteral ☐ Enteral ☐ Special Diet ☐ General Diet ☐ Other __________	☐ Communication / Consent ☐ Prescribing / Requesting ☐ Preparation / Dispensing ☐ Administration ☐ Storage ☐ Documentation / Records ☐ Equipment ☐ Supply / Ordering / Transport ☐ Presentation / Packaging ☐ Transfusing blood ☐ Other______________	☐ Adverse Effect ☐ Incomplete / Inadequate ☐ Not performed when indicated / Delay ☐ Wrong Consistency ☐ Wrong Diet / Wrong Blood Product ☐ Wrong Process / Treatment / Procedure ☐ Wrong Patient ☐ Lack of Availability ☐ Wrong dispensing label / instructions ☐ Inappropriate for task / Wrong device ☐ Other____________________
	☐ **Blood / Blood Product**	☐ Whole Blood ☐ Red Cells ☐ Platelet (Apheresis) ☐ Platelets (Pooled) ☐ Other __________		
	☐ **Diagnostic Radiology (DR) & Nuclear Medicine (NM)**	☐ Checking Patient ID procedure ☐ Clinical Details on Referral ☐ Communication / Consent ☐ Documentation / Records ☐ Equipment ☐ Performing procedure ☐ Pregnancy Status ☐ Unknown	☐ Diagnostic Exposure > intended ☐ X-ray Over Exposure ☐ Wrong body part / side ☐ Dose to comforters / carers	☐ Above Notifiable levels ☐ Below Notifiable levels
			☐ Wrong Patient ☐ Inadvertent dose to foetus	☐ <1mSv ☐ >1mSv
			☐ Total dose or Volume Variation ☐ Dose (NM) or Volume Variation (1 fraction)	☐ <10% ☐ 10-20% ☐ >20%
	☐ **Radiotherapy**		☐ Wrong Drug ☐ Wrong Dose ☐ Wrong Process / Treatment / Intervention ☐ Failure / Malfunction ☐ Inadvertent deterministic effects	
Bio Hazards	☐ **Biological Hazards / Acquired Infections**	☐ Bacteria ☐ Fungus / Mould ☐ Prion ☐ Virus ☐ Organism Unknown	⇨	☐ Exposure to Bite (Human) ☐ Exposure to Bite (Insect / Animal) ☐ Exposure to Bodily Fluids ☐ Exposure to Ingestion/Food/Water ☐ Exposure to Needle Stick ☐ Exposure to Skin Contact ☐ Inhalation/Airborne ☐ Equipment, Implements, Facilities, Sharps (Non Needle) ☐ Unknown ☐ Other ________________

SECTION H CNTD: WHAT TYPE OF HAZARD DID THIS INCIDENT RELATE TO? (Tick one option from Steps 1, 2 & 3)

	Step 1.	Step 2.	Step 3.
Behavioural Hazards	☐ **Self-Injurious Behaviour**	☐ Intentional ☐ Unintentional	☐ Absconsion / Missing ☐ Attempted Suicide ☐ Banging Self Against Walls/Furniture/Surfaces ☐ Hitting Body/Slap/Punch Self incl. Scratching & Picking ☐ Inappropriate Eating ☐ Inappropriate Touching ☐ Self-Harm ☐ Stripping Clothes in Public Area ☐ Suicide ☐ Throwing objects ☐ Other ____________
	☐ **Violence, Harassment and Aggression**	☐ By a Family Member / Relative ☐ By a Member of the Public ☐ By a Peer / Student ☐ By a Prisoner ☐ By a Service User ☐ By a Staff Member	☐ Aggressive towards inanimate object ☐ Discrimination/Prejudice/Racial ☐ Intimidation / Threat ☐ Neglect ☐ Non-Compliant / Obstructive / Rude ☐ Physical Assault / Abuse ☐ Physical Harassment ☐ Sexual Assault / Abuse ☐ Sexual Harassment ☐ Unintentional Aggressive Behaviour ☐ Bullying ☐ Verbal Assault / Abuse ☐ Verbal Harassment ☐ Other ____________
	☐ **Child Abuse**		
	☐ **Adult Abuse**		
Physical Hazards	☐ **Slip / Trip / Fall**	☐ From Height ☐ From Equipment / Furniture ☐ Same Level / Ground ☐ On Stairs ☐ On Steps ☐ Other ____________	☐ Unknown ☐ Pre Existing Medical Condition ☐ Inadequate supervision gen health / post op ☐ Obstruction / protruding object ☐ Surface contaminants ☐ Rough terrain / irregular surface ☐ Inappropriate equipment use ☐ Failure / malfunction of equipment ☐ Horseplay ☐ Physical training / sport ☐ Weather Condition ☐ Inadequate Lighting / design ☐ Other ____________
	☐ **Non Mechanical (Incl. Person / Animal)**	☐ Object / Tools (Non Sharps) ☐ Sharps (Non Needle) ☐ Other ☐ Person	☐ Human Use / Error ☐ Obstruction / Protruding Object ☐ Physical Training / Sport ☐ Defective Equipment ☐ Unsafe / Inappropriate system ☐ Unknown ☐ Task ☐ Load ☐ Working Environment ☐ Individual Capability ☐ Other ____________
	☐ **Ergonomics (Incl. manual / people handling)**	☐ Manual Handling ☐ Other ☐ Patient Handling ☐ Restraint / Intervention	
	☐ **Mechanical Components**	☐ Catering equipment ☐ Door / Gate / Barrier ☐ Healthcare Equipment ☐ Lifting Equipment / Accessories ☐ Office / Business equipment	
	☐ **Temperature (Excluding Fire)**	☐ Hot ☐ Cold	☐ Liquid / Food / Steam ☐ Equipment / Utensils ☐ Atmosphere / Environment
	☐ **Fire** ☐ **Vibration** ☐ **Electrical** ☐ **Noise** ☐ **Radiation**	☐ Please Specify ____________	☐ Defective Equipment ☐ Human Use / Error ☐ Unknown ☐ Unsafe System ☐ Explosion ☐ Exposure ☐ Electrical Wiring / installation

SECTION H CNTD: WHAT TYPE OF HAZARD DID THIS INCIDENT RELATE TO? (Tick one option from Steps 1, 2, & 3)

	Step 1.	Step 2.		Step 3.
Chemical Hazards	☐ **Acid / Alkaline** ☐ **Agri Chemicals** ☐ **Gas** ☐ **Other Chemical Products** ☐ **Particulates** ☐ **Petroleum / Synthetic Oil Based Products** ☐ **Sanitation / Cleaning Chemicals** ☐ **Toxic Metals**	☐ Animal Remedy ☐ Arsenic ☐ Asbestos ☐ Bleach ☐ Cadmium ☐ Carbon Dioxide ☐ Carbon Monoxide ☐ Chemical Fertilizer ☐ Crystalline Silica ☐ Detergent ☐ Diesel / Kerosene ☐ Disinfectant ☐ Drain / Oven Cleaner ☐ Drugs ☐ Fungicide ☐ Glue / Adhesive ☐ Grease ☐ Herbicide ☐ Hydrochloric Acid	☐ Insecticide ☐ Lead ☐ Metallic Dust ☐ Motor / Gear / Hydraulic Oil ☐ Natural Gas ☐ Organic Dust ☐ Paint / Paint Product ☐ Petrol ☐ Polish ☐ Radon ☐ Rodenticide ☐ Soap ☐ Sodium Hydroxide ☐ Solvents ☐ Spent / Used Oil Product ☐ Sulphuric Acid ☐ Wrong Patient ☐ Other	☐ Lack of Supervision ☐ Unknown ☐ Human / User Error ☐ Unsafe System

SECTION I: IMMEDIATE ACTIONS TAKEN

SECTION J: REPORTED BY: *person who discovers the incident and unless otherwise stated within the organization, this person is responsible for completing the NIRF.*

First name	
Surname	
Date notified	D D M M Y Y Y Y
Category of person	E.g. Nurse, Catering Staff, Cleaner
Local system reference no.	
Reporter Signature	
Date	D D M M Y Y Y Y
Contact Details	

SECTION K: WITNESS DETAILS (Name, Contact No. etc.)

SECTION L: TO BE COMPLETED BY LINE/DEPARTMENT MANAGER

Has open disclosure happened? (tick one only ✓) ☐ Yes ☐ No

If No, please specify: ____________________

CATEGORY 1 INCIDENTS ONLY

SAO Name [Block Capitals]: ____________________ **Date notified to SAO:** D D M M Y Y Y Y

SAO Email and Contact Details: ____________________

Is there a requirement to report this incident to any external regulators/agencies/insurers (other than the State Claims Agency)? ☐ Yes ☐ No

If Yes: Name regulator(s)/agency(ies) reported/notified to: **Date Notified:**

1 ____________________ D D M M Y Y Y Y

2 ____________________ D D M M Y Y Y Y

3 ____________________ D D M M Y Y Y Y

Line/Department Manager name [Block Capitals]: ____________________ **Title:** ____________________

Signature of Line/Department Manager: ____________________ **Date:** D D M M Y Y Y Y

SECTION M: TO BE COMPLETED BY QUALITY AND PATIENT SAFETY OFFICE

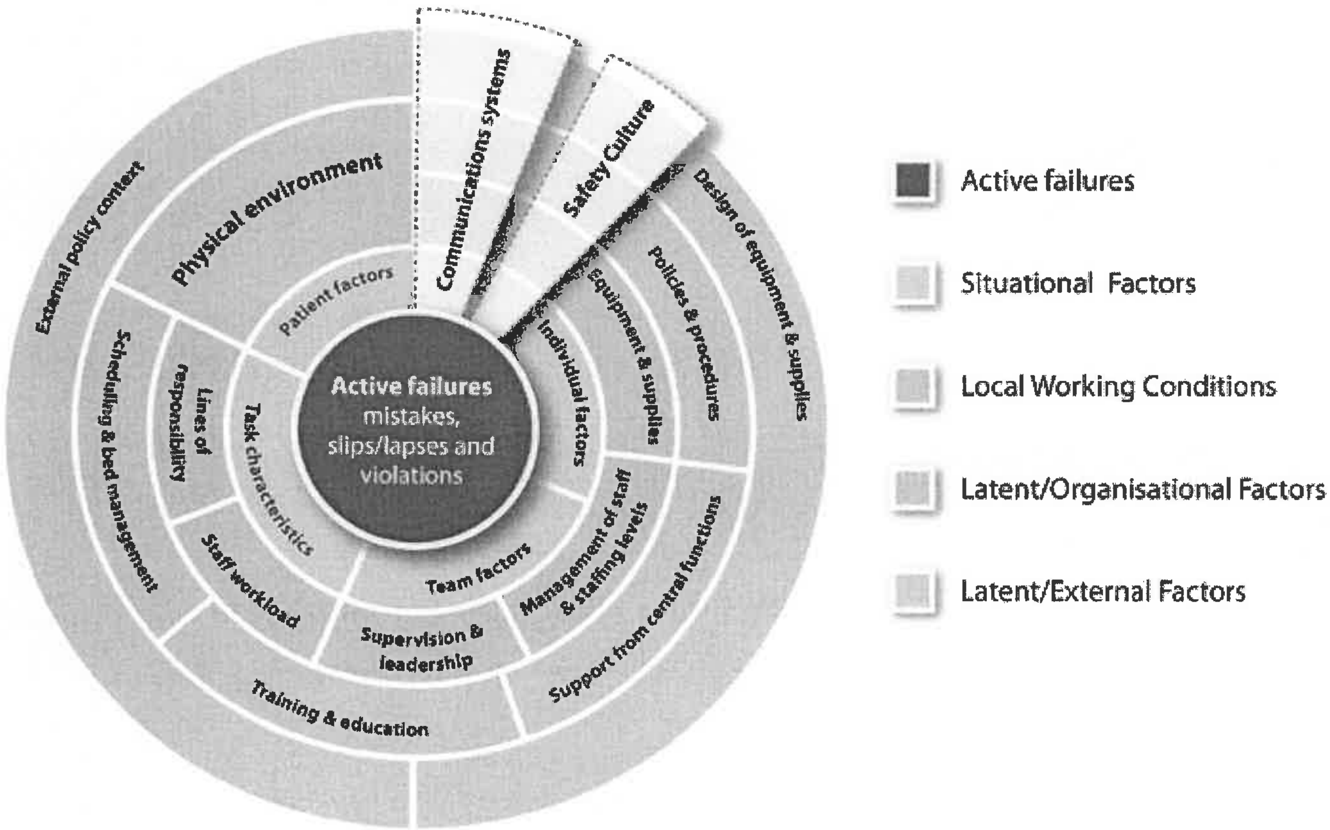
Is this incident a Serious Reportable Event (SRE)? (tick one only ✓) ☐ Yes ☐ No

QPS Advisor Name [Block Capitals]: ____________________

Signature of QPS Advisor: ____________________ **Date:** D D M M Y Y Y Y

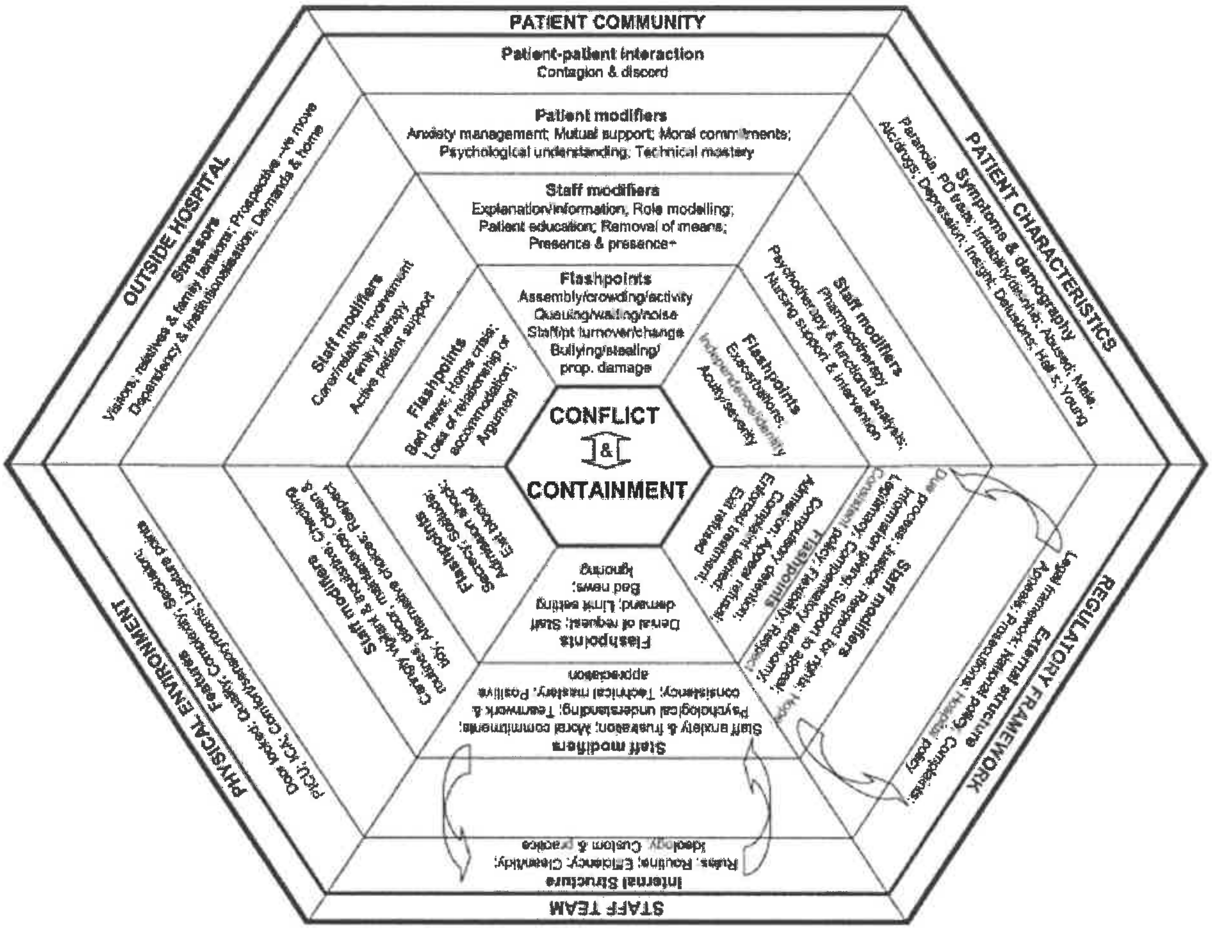
Appendix 4

The Yorkshire Contributory Factors Framework



The Yorkshire Contributing factors Framework (Lawton et al. 2012)

Appendix 5



Safewards model (6 contributory domains) (Bowers, 2014)

Appendix 6 Violence Literature Review Grid

Primary Sources (violence and aggression)

Title	Author and Year	Journal	Purpose	Type of Study	Setting	Data Collection Method	Major Findings	Recommendations	Key thoughts/ Comments
Predictors of violent behaviour among acute psychiatric patients: clinical study	Amore et al (2008) Italy	Psychiatry and clinical neurosciences	Violence risk factors in acute psychiatric patients	Mixed	Locked inpatient unit	Documentary analysis Interviews	1/3 of patients recently physically aggressive Recent aggression associated with history of aggression Aggression during admission predicted by violence in 1/12 before	Past history of violence most important predictor of ward violence Single factors related to predicting violence difficult to isolate but being male, taking drugs and having positive symptoms related	Cementing view of history predicting further violence over all other variables These types of studies are the most common linking demographic and clinical factors to violence/aggression PATIENT FACTORS
The lived experience by psychiatric nurses of aggression and violence from patients in a Gauteng psychiatric institution Planning: Results of a Randomised Control Trial	Bimenyi mana et al (2008) South Africa	Curationis	Exploring the lived experiences of nurses dealing with violence and aggression	Qualitative	South African Inpatient institution	Staff interviews	That staff are faced with 'overwhelming' violence and aggression Staff cite a number of contributing factors including the patient's presentation on admission, the locked environment, staff shortages, lack of MDT support and lack of orientation for new staff Examined the individual effects on staff (absenteeism, drug use etc)	Better guidelines on dealing with violence and aggression especially for new staff	Staff are able to reflect on all variables including staffing and the environment. Positive of qualitative studies Nurses tend to feel alone and unsupported in dealing with aggression internationally. 'we help other MDT professionals, they don't help us.' MULTI-FACTORS
Safewards: the empirical basis of the model and a critical	Bowers et al (2014)	Journal of Psychiatric and Mental Health	Examining the evidence for 6 'safewards' domains using	Review	Inpatient mental health	Documentary analysis	Consistent, clear, fair rules important. Staff consistency important	Quiet rooms could do same job as PICU's/seclusion	Exemplifies the extent to which multiple factors play a part in preventing incidents

appraisal	(UK)	Nursing	a literature review Staff team Patient characteristics Ward environment External environment Regulatory framework Patient community				Patient-staff interaction important in terms of violence (limit setting, staff demands, request denial etc) Locked wards prevent absconding but worsen aggression External factors such as access to money, home responsibilities lead to absconding and violence Young, detained, male, schizophrenic patients more likely to be aggressive Patients clashing with each other leads to violence (meal times, stealing items from each other etc) Detention, locked doors, local and national policies, activity and occupation	Difficulty in providing firm evidence amongst all the very broad variables and they can't be put in priority order Although lack of evidence apparent for many variables, there is scope for implementing a focus on staff led 'modifiers' (interventions to reduce risk)	Helps professionals to consider all elements Some factors both prevent and promote risk (e.g. detention, locking doors) Difficulty of staff to be both consistent and flexible (local smoking garden example) MULTI-FACTORS
Factors Relevant to Patient Assaultive Behaviour and Assault in Acute Inpatient	Chou et al (2002) Taiwan	Archives of psychiatric nursing	Exploring 'interplay' between patient assaults and patient, staff and environmental	Quantitative	7 acute psychiatric wards	Scales and questionnaires	Patient, staff and environmental factors all important Patient factors included history of assaults, psychosis, length of stay and	Staff need to be better trained in managing violence and aggression Training needs to incorporate biopsychosocial view	Why less incidents on weekends when no structured activity at all if structured activity seen as reducing incidents MULTI_FACTORS

Appendix 6 Violence Literature Review Grid

Psychiatric Units in Taiwan			factors				smoking Assaults occurred during busy periods, and in crowded areas Rule setting needs to be carefully considered	of aggression	
Systemic perspective of violence and aggression in mental health care: Towards a more comprehensive understanding and conceptualization: Part 1	Cutliffe and Riahi (2013) multi-country	International Journal of Mental Health Nursing	Using a 'systemic' approach to evaluate all phenomena preceding violence and aggression, aiming to produce a systemic model containing 4 categories Environment Client related Mental Health system related Clinician related	Literature Review	Mental health care	Documentary analysis	Overcrowding/excessive patient contact/noise a problem but not always proved in research studies Mentions socially deprived areas and link with violence Mentions side-effects of medication (restlessness/agitation)	Personal space and privacy Promotion of comfort rooms Not enough evidence to suggest whether doors should be locked or not Psychological theories of violence need to be considered (Freudian, social learning theory etc)	Trying to do what Bowers did earlier – 4 factors instead of six Paper acknowledges difficulty in defining a violent incident and differentiating between 'mad' and 'bad.' Argues that nurses frequently 'blame' patients (not true in some qualitative studies where nurses demonstrate a good awareness of all external factors) Nurses should be able to reflect on their own practice and how this relates to violence/aggression but like all other factors cannot be looked at alone (leading to blame culture) MULTI-FACTORS
Systemic perspective of violence and aggression in mental health care: Towards a	Cutliffe and Riahi (2013) Multi-	International Journal of Mental Health Nursing	Using a 'systemic' approach to evaluate all phenomena preceding violence and	Literature Review	Mental health care	Documentary analysis	That violence and aggression is shaped and viewed by individual systems (hospital, country, culture etc) Increasing staffing	Zero tolerance not suitable for wards as it put all responsibility onto patients and ignores all other factors Staff need post-	MULTI-FACTORS

Appendix 6 Violence Literature Review Grid

more comprehensive understanding and conceptualization: Part 2	country		aggression, aiming to produce a systemic model containing 4 categories Environment Client related Mental Health system related Clinician related				rates to reduce violence/aggression inconclusive Moreover it's the type of staff – too many males, too much sickness and lack of training in v/a linked. Talks again about inconsistencies, rules, meeting demands Includes good table of characteristics related to higher rates of violence/aggression	violence support due to likelihood of re-occurrences Each category can be backed with evidence although not always conclusively Less single intervention research required and more multifactorial studies (same as Bowers et al suggestion) Also need to work with society to change opinions of risk and mental health to reduce restrictiveness (leading to increases in violence/aggression)	
A review and meta-analysis of the patient factors associated with psychiatric in-patient aggression	Dack et al (2013) UK	Acta Psychiatrica Scandinavica	Systematic review of studies examining patient factors associated with aggression and repeated aggression on inpatient wards	Review Quantitative analysis	A review of studies across psychiatric inpatient settings across a number of countries	Documentary analysis	Increased risk of aggression linked to being male, schizophrenia, young age, single, detained involuntarily, history of violence, greater numbers of previous admissions, history of self-destructive behaviour and substance abuse History of violent convictions associated with decreased likelihood of aggression	Future research should focus on longitudinal patient studies. Patient perceptions of violence and aggressive incidents would be helpful so that staff may have greater means of dealing with aggression	Associations found to be statistically small. Study heterogeneity a problem as all wards and services operate with differences Not including other contextual factors such as length of stay, ward environment seen as a limitation PATIENT FACTORS

Appendix 6 Violence Literature Review Grid

Predicting community violence from patients discharged from acute mental health units in England	Doyle et al (2012) England	Social Psychiatry and Psychiatric Epidemiology	Assessment of consecutive patients discharged from acute mental health wards to assess levels of violence up to 20 weeks post discharge	Cohort study	Included all patients discharged from 3 acute wards in Manchester, England.	Baselines interviews with patients and staff plus case notes review to complete various scales and tests Community measures used same data collections methods	Tests and scales used in forensic settings that predict violence also demonstrate risk of violence in acute patients. More than 1 in 4 patients were physically violent on discharge (higher for females) Violence targeted at people known to perpetrator Those with personality disorder 3 times more likely to be violent Substance use not associated with increased violence risk (although those not using substances very small group)	Risk management assisted by use of structured professional guidelines (e.g. HCR-20) Risk assessment focus should be on:- What they have done (history of violence) What they are (angry, impulsive etc) What they have (PD etc)	Best risk scale used includes other dynamic factors such as context and social functioning Schizophrenia related to inpatient violence but not related to future violence post discharge PATIENT FACTORS
The Management of Aggression and Violence Attitude Scale (MAVAS): a cross-national comparative study	Duxbury et al (2008) UK and Switzerland	Journal of Advanced Nursing	Reporting on the transferability of an attitude to aggression and violence scale to another European country noting that nurses attitudes may relate to internal ideas/opinion	Report Quantitative study	Nursing staff from acute psychiatric wards in UK and Switzerland	Completing MAVAS scale Statistical comparison	66% agreement between countries. Swiss nurses more likely to report internal patient factors, UK nurses reported more environmental factors	Differences might relate to rates of aggression, training, policy and management approach	The lead author groups antecedents into 3 models adding to existing theories:- Internal (diagnosis etc) External (ward layout) Situational/interactional (patient/staff interaction etc) International comparison highlights need to consider all of the above model factors If staff attitude can affect rates of aggression, assessing

Appendix 6 Violence Literature Review Grid

			about violence rather than objective evidence						attitudes of staff may highlight whether these are in line with evidence based practice for managing violence and aggression STAFF FACTORS
International Precipitants to Psychiatric Patient Assaults in Community Settings: Review of Published Findings, 2000–2012	Flannery and Flannery (2014) USA	Psychiatric Quarterly	A review of the precipitants involved in community patient assaults 2000 – 2012 comparing results with inpatient assaults	Review	International studies on patient assaults in the community	Narrative review	Many precipitants remain the same as inpatient findings (acute psychosis, substance abuse etc) but context may be changed (e.g. denial of services may continue in home environment by family member/s)	Taking some of the supports in inpatient care into community settings (e.g. safe 'holding' environments when patients feel unsafe)	Very few studies on patient violence based in the community Precipitants should be viewed alongside patient characteristics (e.g. diagnosis can be viewed as both a characteristic and a precipitant in the case of PD) MULTI-FACTORS
Characteristics of International Assaultive Psychiatric Patients: Review of Published Findings, 2000–2012	Flannery et al (2014) USA	Psychiatric Quarterly	A review of characteristics involved in patient assaults 2000-2012	Review Statistical tests	International studies on patient assaults in the community setting	Narrative review Statistical analysis	Results found that male and female patients with schizophrenia presented the greatest risk as opposed to a hypothesis of male, past violence, substance misuse and schizophrenia.	Calls for international research community to have basic, agreed demographic and clinical variables in such studies	No standard operational definition as to what constitutes a patient assault (international differences, cultural differences etc) Some include suicide attempts and criminal behaviour, others don't) PATIENT FACTORS
Service users' experiences and views of aggressive situations in mental health care: a systematic review and thematic synthesis of	Gudde et al (2015) Multi-country	Journal of Multidisciplinary healthcare	Systematic review and thematic synthesis of qualitative studies on patient views and experiences of aggressive	Systematic review	International qualitative studies of patient experiences	Thematic synthesis	Patients more likely to consider environmental factors than staff who mainly consider patient factors Five themes Seeing themselves as	Better user involvement such as 'early recognition method' where incidents can be averted through patients knowledge of their own needs Difficulty balancing this individualisation	Answers research suggestion set by Dack et al (2013) Patients focusing on seemingly minor issues (e.g. cup of coffee outside normal times) seen as staff being inflexible and common bedtime seen as unreasonable – relates back to bowers study and balance of consistency (also seen as

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qualitative studies			incidents				lacking control Frightened re 'locked' environment Lack of meaningful activity Feeling ignored Lack of caring staff patient relationship	with the need for institutional rules	preventing incidents) (making coffee and bedtimes good examples) minor differences in perceptions between staff and patients such as rules on smoking extend to more serious perceptual differences (e.g. staff and aggression v patients and self-defence) MULTI-FACTORS
Prevalence and Risk Factors of Violence by Psychiatric Acute Inpatients: A Systematic Review and Meta-Analysis	Iozzino et al (2015) Multi-country	PLOS 1	Systematic review and meta-analysis of inpatient violence prevalence and risk factors	Systematic review	Psychiatric inpatient wards internationally	Meta-analysis	Prevalence of inpatient violence from collective studies rated at 17% (or 1 in 5 patients) Being male, involuntary, having schizophrenia and alcohol use disorder associated with higher rates of inpatient violence	Recommends areas for research that were not examined in the meta-analysis (e.g. ward layout, is the type of community in which ward is based a violent one? and staffing levels)	Demonstrates how demographic details (age, gender, status etc) are easily identifiable and available for statistical testing whereas other variables are too numerous to include and nearly impossible to identify as antecedents of violence We can link demographic details to violence but we cannot 'modify' these factors so how does it help? PATIENT FACTORS
A cross-sectional survey of factors related to inpatient assault of staff in a forensic psychiatric hospital	Kelly et al (2014) USA	Journal of Advanced Nursing	Examining the staff factors associated with inpatient aggression in a forensic hospital	Quantitative	Forensic hospital institution in California, USA	Online staff survey	First paper to note that staff relationships with each other may increase likelihood of violence Staff who had the most conflict with patients also had the most conflict with colleagues and managers Increased staff risk	Resilience training for staff recommended	Makes point that static factors such as age, gender, history of violence cannot be modified meaning we should be concentrating on modifiable factors such as prevention of violence training Link to Iozzino study Seems to be saying that there are some staff who are very sensitive to conflict who therefore aim to prevent this

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							associated with combination of exposure to conflict and individual stress response		happening and others who are more comfortable dealing with 'high-risk situations' who are therefore at greater risk of assault Also stating the obvious when stating that staff who engage in the most 'core duties' are at the most risk of assault Difficult to follow this paper but appears to be making good point that staff personality and our interaction with each other can affect levels of violent incidents and assaults STAFF FACTORS
Alcohol abuse as the strongest risk factor for violent offending in patients with paranoid schizophrenia	Kudumija et al (2014) Croatia	Croatian Medical Journal	Determining predictive risk factors for violent offending in male patients with schizophrenia	Quantitative	Psychiatric inpatient wards in Croatia	Compared patients in forensic hospital (who had history of violent offending) with same diagnosis patients in acute wards who had no history of violent offending using interviews, questionnaire and patient records	Study found that alcohol was the strongest predictor of violent offending alongside older age and duration of untreated illness before offending	Importance of alcohol prevention strategies highlighted as main recommendation	Older age for offending goes against common idea that young males more likely to be violent This paper relates doesn't relate to violence on wards but violent offending prior to hospitalisation. It only deals with characteristics, not context which is common criticism of these studies. Interestingly looks at characteristics of patients (not seen before) who do not violently offend (extroversion, pleasantness and intellect) PATIENT FACTORS
The antecedents of violence and aggression	Papadopoulos et al (2012)	Acta Psychiatric Scandinavica	Review of antecedents of violence and aggression on	Systematic review	Mixed psychiatric inpatient settings	Thematic analysis and meta-analysis of all extracted	Themes listed in ranking order: - 1 Staff-patient	Too many staff perspective studies not enough patient	59 different antecedents across 71 studies included highlighting level of heterogeneity

within psychiatric in-patient settings	Multi-country		psychiatric wards		across 13 countries	data from existing studies on antecedents of violence and aggression	interaction 2 Behavioural cues (agitation, confusion etc) 3 Patient-patient interaction	perspective Makes several recommendations for staff interventions and more intensive recording of incidents Suggests that staff have the greatest influence in making wards safe (is this fair?)	Relying on staff perspectives only of what the antecedents were Notes how incident forms do not ask staff to record a 'definitive' antecedent and that these are often very difficult to ascertain Reviewing video camera footage recommended (opens up another argument not considered before) Study focuses on staff and what they are not or should be doing Tends to talk in simplistic terms about more readily meeting patient requests – Is it not that requests are denied but how these requests are denied? How do we guarantee individualised attention in large wards with minimum staff where routine/rules are inevitable How do we rate what is reasonable denial and what is unreasonable – subjective to each staff member etc MULTI-FACTORS
Organizational and Unit Factors Contributing to Reduction in the Use of Seclusion and	Pollard et al (2007) USA	Psychiatric Quarterly	Before and after study examining the use of seclusion following an organisational improvement	Quantitative	Psychiatric inpatient ward in veterans service institution, Washington	Data extracted from admin database, nursing records, reports etc. Pre/post statistical tests	Seclusion and restraint was reduced by programme of discussions about alternatives, staff support from management and	Recommending that even by simple process of listening to staff concerns and positively encouraging alternatives can reduce seclusion and	Similarly with critical incidents, factors affecting seclusion and restraint are inconclusive in their significance (e.g. patient numbers, staffing ratios, lengths of stay)

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Restraint Procedures on an Acute Psychiatric Inpatient Unit			programme		State, USA	used to test significance	individual incident review	restraint	Use of videotapes to help staff consider alternatives to seclusion and restraint (2nd mention of CCTV/video as training/debriefing aid) ORGANISATIONAL FACTORS
Explanations for violent behaviour—An interview study among forensic in-patients	Radovic and Hogland (2013) Sweden	International Journal of Law and Psychiatry	Carried out interviews with forensic patients in hospital for violent crimes to examine their beliefs about the causes	Qualitative	46 patients from 6 Swedish forensic units	Semi-structured interviews	Only 4 out of 46 patients felt that mental illness was the sole cause of their crime 15 felt that it had no effect on the crime at all Drug abuse a major contributory factor	Adds experiential data to existing epidemiological studies Limited by factors such as patients not realising their actions were caused by the disorder or not wanting to blame the illness	Raises important point that crimes committed may not automatically relate to presence of mental illness (gives example of man with schizophrenia robbing store as he owes money). This is comparable with critical incidents on the inpatient ward where all contextual factors need to be considered (e.g. would patient have acted the way he/she did in the absence of acute mental illness?) PATIENT FACTORS
Explanations for violent behaviour—An interview study among forensic in-patients	Raveendranathan et al (2012) India	East Asian Archives of Psychiatry	Study looked at 100 consecutive incidents of violence from victims perspective	Mixed	Adult psychiatric wards in Bangalore, India	Interviews with patient relatives and access to patient notes/records	Family members were by the far the most common victim of violence Staff and family mainly agreed on antecedents of violence	Relatives can help prevent violent incidents by providing information about warning signs	India has a tradition of patient relatives staying on the ward with the patient (no staff, poor resources plus strong family bonds) Highlights how we sometimes use family members (e.g. by phone or asking them to bring in items) to diffuse situations. Can also work opposite way in family

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									members provoking patients. Equates with studies where nurses are often largest group affected by violence as they have the closest contact MULTI-FACTORS
Aggression on inpatient units: Clinical characteristics and consequences	Renwick et al (2016) England	International Journal of Mental Health	Examined sequences of aggressive incidents to explore whether there were particular aggression profiles	Quantitative	Patient data from 84 inpatient units in 31 hospitals in the south of England	Case notes review for demographics and details of aggressive incidents	Sequences of aggression could be categorised into 4 groups:- Solo aggression Aggression related to containment Aggression related to medication Aggression related to rule-breaking Aggression related to containment was not dominant as hypothesised Suggesting that the use of containment methods vary in threshold level across different nurses and units Illicit drug use, younger age and history of violence linked to likelihood of aggression again	Patient differences mostly did not explain variation in aggressive incidents leading authors to conclude that differences in staff attitudes may be the reason External factors need to be considered also not just patient factors	Basically establishing that patient factors (clinical characteristics) alone cannot be viewed as the sole cause of aggressive incidents Putting incidents into one of the 4 groupings may prioritise difficulties for individual wards if all incidents of aggression relate to medication or containment etc. PATIENT FACTORS
Putting aggression into	Shepherd and	Journal of	An examination of contextual	Mixed	All violent incidents	Information from 130	Patient characteristics similar to other studies	Organisational differences between	Lots of methodological limitations noted in this study

Appendix 6 Violence Literature Review Grid

context: An investigation into contextual factors influencing the rate of aggressive incidents in a psychiatric hospital	Lavender (1999) England	mental health	issues relating to aggressive incidents		over a consecutive 5 month period in one London NHS psychiatric hospital	incident forms and structured interviews with staff	(age, diagnosis etc) More patient victims than staff Staff most at risk were male nursing assistants (even this could be explained by many different reasons not just absence of training) High-level of patient interaction seen as antecedent of violence but not in context of day hospital or one to ones, highlighting issue of structured activity Incidents more likely to be preceded by external rather than internal events Admission and secure wards did not report higher rates of incidents than others (ward culture, patient profile?) but same wards still had big variations	wards suggest need for staff training in PMVA across all wards All incident reports should consider antecedents and contextual issues Debriefing and consideration of antecedents should occur after each serious incident Influence of the 'medical model' may mean nurses are more likely to report internal rather than external antecedents	but could be attributed to most:- Staff bias (e.g. choosing to ignore external factors where themselves or colleagues implicated) or choosing external as easier to see on a busy unit Under-reporting (only getting a snapshot of actual incidents) Raises good point about when to act physically and use restraint/seclusion (without hindsight we don't know whether this prevents level of seriousness escalating or is enacted too quickly leading to breakdown of relationship with patient etc) Paper raises point that type of ward doesn't relate to number of incidents but more the culture of that ward MULTI-FACTORS
HOVIS – The Hertfordshire/Oxfordshire Violent Incident Study	Spokes et al (2002) England	Journal of Psychiatric and Mental Health Nursing	The views of a sample of psychiatric nurses about the 'staff related' factors contributing to violent	Qualitative	Psychiatric nurses working in 2 NHS Trusts in the South of England	Semi-structured interviews with 108 nurses	Those interviewed were able to see strengths and weaknesses in preventing/managing violent incidents. These were categorised in 3	Highlights importance of selecting right staff and type of deployment Interpersonal skills training and proper	Demonstrates that nurses have good ability to reflect on their own practice (as noted in another study) 'self-awareness' highlighted as very important Raises good point that nurses should be trained as a team as

Appendix 6 Violence Literature Review Grid

			incidents				groups:- Clinical skills Interpersonal skills Personal characteristics	supervision required	'teamwork' highlighted as very important (how plausible is this in reality – is it easier in community teams to sit back, reflect and take stock as a team compared to inpatient wards) Also changes in skill mix (e.g. less trained staff and more HCA's) may have impact on 'modelling' for less experienced staff STAFF FACTORS
Injurious Assault Rates on Inpatient Psychiatric Units: Associations With Staffing by Registered Nurses and Other Nursing Personnel	Staggs (2015) USA	Psychiatric Services	Studied the relationship between staffing (trained and untrained) and rates of inpatient assaults	Quantitative	Data from inpatient adult psychiatric wards across USA	Data on staffing and assaults extracted from national database	Units with higher numbers of untrained staff (non RN's) tended to have higher assault rates for both other patients and staff No evidence that higher staffing rates per se are safer for staff (some studies find the opposite) However, more non-RN's linked to higher numbers of assaults on other patients (trained staff better at defusing situations?) Does higher numbers of staff increase nurse-patient interaction and therefore more violence or do wards with a lot of violence increase staffing levels (chicken and egg	Recommends that staffing level association with violence against staff and patient-patient should be studied separately Recommends control studies (using changeable staffing levels on one ward and remaining consistent on another)	Having the same type wards with different skill mix/staffing levels for research purposes could be seen as unethical/unsafe. Also it would be difficult to control the type of patient admitted (history of violence, level of acuity etc) Special relevance to Ireland where in many units staff are all trained and use of HCA's is a major issue Qualitative studies such as totman et al (inpatient wards) rank lack of staff as biggest threat to morale Is there a basis for adequate staffing that then maintains morale and thus reduces levels of violence? STAFF FACTORS

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							scenario)		
Registered nurses' experiences of patient violence on acute care psychiatric inpatient units: an interpretive descriptive study	Stevenson et al (2015) Canada	BMC Nursing	An exploration of nurse experiences about violence on acute inpatient wards	Qualitative	12 Canadian registered nurses	Semi-structured interviews	Staff highlighted patient factors (diagnosis, history of violence etc) nursing factors (communication between staff, patient assessment) Unit factors (space, nursing numbers and activities) Interpersonal interaction was seen as main antecedent (staff-patient or patient-patient)		Much of paper about experience of violence and aftermath, however part of interview focused on contributing factors and antecedents to violence Nurses tended to make judgement about whether a patient was 'in control' or not during violent incidents MULTI-FACTORS
Environmental and nursing-staff factors contributing to aggressive and violent behaviour of patients in mental health facilities	Van Wijk et al (2014) South Africa	Curationis Journal	Patient perceptions of environmental and staffing factors relating to violence and aggression	Qualitative	Forty inpatients on 2 mental health facilities	Semi-structured interviews over 6 months	Respondents reported a lot of environmental factors as antecedents (overcrowding, hygiene, other patients etc) Also saw limit setting and lack of communication about rules as antecedents	Better staff-patient interaction and PMVA training	Interesting that patient saw difficulty in coming from different wards that have different rules/expectations (relates to merging of Waterford and wexford mental health services) Although environmental factors can't be compared to Ireland, when it came to staffing related antecedents complaints were much the same (rude, impatient

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									etc) MULTI-FACTORS

Non-research literature (violence and aggression)

Title	Author and Year	Journal	Purpose	**Credibility**	Quality	Content	Coherence	Recommendations	Key thoughts/ comments
Workplace violence in the psychiatric setting. An occupational health perspective	Hansen (1996) USA	American Association of Occupational Health Nursing	Author's own perspective using existing literature to examine subject	Peer reviewed article in reputable journal	Good	Provides good historical evidence (older research) on different areas of violence in psychiatry (concept, trends, prevalence, implications etc)	Makes interesting distinction between psychiatric and occupational health paradigms. Psychological interventions look for the triggers/causes of violence whereas an OH approach deals with the prevention of injury (removal of potential weapons etc) without analysing causes	Psychiatric units need to be safe from both a patient and staff safety perspective	Recommendations such as the wearing of protective gear (including helmets) during physical restraint would maybe protect staff but also increase aggression and custodial/coercive nature of ward If we cannot pinpoint the exact antecedents of violence and aggression is this type of approach entirely wrong? Is this the way services are moving anyway? ORGANISATIONAL FACTORS
Zero tolerance and violence in people with mental health needs	Paterson et al (2008) UK	Mental Health Practice	Authors own perspectives and commentary on Zero tolerance approach using political discourse	Peer reviewed journal	Good	Makes argument against zero tolerance policy noting that in the UK, reports of violent incidents rose whilst it was	Suggests that a zero tolerance policy on violence negates research evidence stating that violence stems from the staff-	Basically zero tolerance means that the root cause of violence be it individual or organisational is not	Some aspects have validity. For example is it any harm to let the public know that violence in hospitals is unacceptable?

Appendix 6 Violence Literature Review Grid

			analysis			government policy	patient interaction	considered Recommending a public health model (WHO) of primary (e.g. planning therapeutic environment) secondary (de-escalation methods) and tertiary violence prevention (e.g. debriefing afterwards)	Zero tolerance policy has not really been replaced with any other realistic alternative and it is possible to see why nurses may support such a policy if they do not feel they are being supported in preventing violence (e.g. patients not discharged when frequently intoxicated or drug dealing on the ward) MULTI-FACTORS
Corrupted cultures in mental health inpatient settings. Is restraint reduction the answer?	Paterson et al (2013) UK	Journal of Psychiatric and Mental Health Nursing	Authors own perspectives on areas of 'institutional violence', 'trauma' and 'corrupted culture'. Looking at area of restraint and efforts worldwide to reduce usage	Published in peer reviewed journal	Good	Notes the loss of interest in social psychiatry and the therapeutic milieu When factors such as restraint are legitimised they also run the risk of being misused (*see guns, seclusion, smoking, alcohol etc*)	Suggests that nurses may use their power over patients to restore their own self-esteem (from professional or personal lives) Notes that trauma can affect both patients (e.g. during restraint) and staff (repeated exposure to violence)	Staff need to acknowledge presence and risk of counter transference and that this is normal/expected Elements of recovery in mental health promote reduction of restraint Also recommending model of prevention as noted in earlier Paterson work (2008)	Naïve to think that nurses do not reflect on the power relationship and the risk of counter transference, given the emphasis on reflection throughout training Absence of supervision to think in psychodynamic way (another element that seems to have lost favour) ORGANISATIONAL FACTORS

Appendix 7 Suicide/self-harm with suicidal intent literature review grid

Primary sources (suicide)

Title	Author and Year	Journal	Purpose	Type of Study	Setting	Data Collection Method	Major Findings	Recommendations	Key thoughts/ Comments
Antecedents and Patterns of Suicide Behavior in First-Admission Psychosis	Bakst et al (2009) USA	Schizophrenia Bulletin	Looking at suicidal behaviour of patients with psychosis over 4 years associating demographics and risk factors	Quantitative	Consecutive cohort of patients with first episode psychosis admitted to 12 different hospitals	Interviews and use of patient records	Suicidal ideation and attempts associated with history of attempts, level of depression, presence of insight, substance abuse, thought disorder, and <28 on admission	Patients with first onset schizophrenia are a very vulnerable group in terms of suicide and suicidal ideation	Looked at patient characteristics only, nothing about other external factors PATIENT FACTORS
Suicide Within Two Weeks of Discharge From Psychiatric Inpatient Care: A Case-Control Study	Bickley et al (2013) UK	Psychiatric Services	Identified risk and protective factors for patients committing suicide 2 weeks post discharge from hospital	Quantitative	Retrospctive case control study of 100 mental health patients committing suicide between 2004-2006	Use of national statistics on deaths plus questionnaire completion with control group	49% of patients died before follow-up appointment. Recent life events, short admission (<1/52), older age and comorbid psychiatric conditions were associated with suicides in the study	Highlights importance of discharge planning and awareness of 'external life events' that may be stressful	Paper tries to consider antecedents that may occur outside patient characteristics – experience suggests that this is routinely done at team meetings especially as they are multidisciplinary in nature. Highlights importance of knowledge of patients home situations MULTI-FACTORS
Learning from prevented suicide in psychiatric inpatient care: An analysis of data from the National Patient Safety Agency	Bowers et al (2011) UK	International Journal of Nursing Studies	Attempted to examine the mechanisms by which inpatient suicides are prevented	Quantitative	Used published reports on attempted inpatient suicides from national patient safety agency	Statistical analysis of data and use of rating scales	Out of 244 incidents most were female using strangulation or suffocation (plastic bags, shoe laces etc) Common areas were bedrooms, bathrooms and toilets Evening and midday nursing handovers	Increased use of patient checks and observation	Having the means of committing suicide (e.g. ligature points) has been the focus of services for some time Asks whether locking ward doors prevents suicides or increases depression? Leading to more self-harm? No daytime handover in Irish units as staff work long shifts

Appendix 7 Suicide/self-harm with suicidal intent literature review grid

							were frequent times Most incidents discovered by staff (routine checks or particular concern)		(positive in terms of safety but could be negative in terms of tiredness/stress) ORGANISATIONAL FACTORS
Characteristics of people dying by suicide after job loss, financial difficulties and other economic stressors during a period of recession (2010–2011):A review of coroners' records	Coope et al (2015) England	Journal of Affective Disorders	Examined mental health, social and economic factors associated with suicides over 2 year period	Quantitative	Used coroner's inquest reports re suicides in 4 parts of England	Data collection proforma to analyse relevant material within inquest reports	13% of suicides in study associated with money, recession and employment problems Generally confirms that suicides rise with recessionary times	People should consider help from other agencies (besides GP, mental health teams) to help during recession	Such information only recorded if someone (e.g. relative thought that it was important post suicide) Relates to Bickley et al study in that we can only record what patients or their families tell us. EXTERNAL FACTORS
Suicide amongst psychiatric in-patients who abscond from the ward: a national clinical survey	Hunt et al (2010) UK	BMC Psychiatry	Examined the antecedents of suicides where patients had absconded from inpatient care (social/clinical characteristics and clinical care)	Quantitative	Used collective sample of suicide deaths via ONS over 10 year period	Questionnaires (sent to consultant psychiatrists)	14% of patients in study inpatients at time of suicide – 30% on ward Absconders more likely to be younger, schizophrenic, using substances and being non-compliant with meds	Recommending staff and external factor improvements (e.g. better door security such as swipe card access or attempts to make ward less oppressive, risk assessment training, close observation etc.)	Consequences of absconding include suicide and harm to others (hence not included in lit review) Absconding can be considered an antecedent in itself Majority leaving ward to commit suicide raises important issue of locked doors/absconding although majority were actually on official leave Authors do acknowledge the difficulty balancing security with ward milieu MULTI-FACTORS

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Ligature Points and Ligature Types Used by Psychiatric Inpatients Who Die by Hanging	Hunt et al (2012) UK	Crisis – Journal of Crisis Intervention and Suicide Prevention	An examination of ligatures and ligature points used in inpatient suicides looking at trends and patient characteristics	Quantitative	Used collective sample of suicide deaths via ONS over 10 year period	Questionnaires (sent to consultant psychiatrists)	Most ligatures brought by patients (mainly belts) – use of doors, hooks, handles and windows. Use of doors and windows had increased 80% died in single rooms, toilets, bathrooms (links to Bowers, 2011 study) Hanging patients differ from other suicides by history of self-harm, drug use, alcohol use and violence. Detention under MHA more common plus suicide in 1st week Half were on special observations	Mainly recommends closer scrutiny of ligature points and access to ligatures (e.g. audits, liaison with estates department re plumbing etc) Also notes importance of observation, especially in 1st week, plus staff training in emergency medical care etc.	This type of approach relates to occupational health paradigm (Hansen, 1996) that causes and antecedents can be offset by blanket security measures Does this affect milieu of ward seen as important in other studies given the 'ethical and practical' implications involved? ORGANISATIONAL FACTORS
Suicide after absconding from inpatient care in England: an exploration of mental health professionals' experiences	Hunt et al (2016)	Journal of Mental Health	Sought the perspectives of clinical staff in relation to suicide after absconding	Mixed methods	21 staff interviewed regarding 18 separate suicides following absconding	Semi-structured questionnaires	Being homeless added to list of characteristics already produced Staff raised 4 themes: - Ward design problems Staffing problems Problems assessing risk Individual patient problems (e.g. potential	Clinical characteristics highlighted including male, homeless etc. and times of risk elevation (delayed discharge) can be used in risk assessment procedures Environmental measures need to be closely considered (e.g. door access, exit points)	Highlights controversy of locking doors (previous research indicates less absconding due to satisfaction/reduced stigma) Issues around staffing numbers and skill mix repeated again Demonstrates that clinical staff consider all angles (safewards domains) Homelessness and delayed discharge often go together are frequent problems. These patients, considered to be high

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							homelessness or external life situations) Delayed discharge is a time of increased risk		risk of absconding and committing suicide are often the least assessed as a result of being judged clinically well, given free range to come and go from ward and tend not to take priority over more acute cases MULTI-FACTORS
Psychosocial Risk Factors Associated With Suicide Attempts and Violence Among Psychiatric Inpatients	Krakowski and Czobor (2004) USA	Psychiatric Services	Examined the association between psychosocial problems and suicide attempts or violent behaviour	Quantitative	216 assaultive inpatients (study group) vs 81 non-violent patients (control)	Patients followed over 4 week period and assessed for violence, suicide and psychosocial factors	Study found no link between likelihood of violence and suicide attempts Discipline, parent illness and head trauma associated with suicidal behaviour School truancy and foster home placement associated with violence	Further study required – acknowledges limitations and non-generalisation of results	Coming from the premise that a lot of violence and suicidal behaviour stems from drug problems, broken homes, physical abuse etc Does not really suggest how knowledge of psychosocial factors helps risk assessment process on the ward – some of the information would not automatically be asked on assessment (e.g. truancy) suggesting more in-depth assessment or length of time required. Obtaining info also difficult if patient too acutely unwell EXTERNAL FACTORS
Systematic review and meta-analysis of the clinical factors associated with the suicide of psychiatric in-patients	Large et al (2011) Multi-country	Acta Psychiatrica Scandinavica	Examining the association between inpatient suicide and demographics history, treatment, symptoms and diagnosis	Systematic review	29 studies included where patients who committed suicide were assessed against same type patients who did not	Strict quality guidelines used for inclusion/exclusion and meta-analysis software used in examination	Patients with schizophrenia or affective disorder alongside prominent depressive symptoms more likely to commit suicide Discounted being male, single, unemployed, having forensic history or	Feels that inquiries that view suicide as avoidable probably succumb to hindsight bias Feels inquiries might highlight some hospital system problems but: - Recommends (likes staggs violence study)	Only found a 'modest' number of scientific controlled studies amongst all the literature on inpatient suicide Risk of hindsight bias raised (deciding cause after event from the notes or from interviews) interesting point, is it worth looking for a cause if the outcome can be put down to hindsight bias and dismissed? How do we ensure evidence is

Appendix 7 Suicide/self-harm with suicidal intent literature review grid

							using drugs	comparing groups on different wards to test causes such as staffing, observation etc) Also suggests comparing suicides in different care settings Does not feel that simply putting patients into high risk groups prevents suicide	scientific? Criticises shortfall of possible causes in most studies (how practical is it to include all?) Suggests that the prediction of suicide in hospital compared to community is more difficult because of lower base rate and short admission time Basically dismissing risk assessment and advocating preventative measures such as removing means of suicide – Is risk assessment then effective for violence but not suicide? MULTI-FACTORS
Preventing Suicide Among Inpatients	Sakinofsky (2014) Multi-country	Canadian Journal of Mental Health	Analysis of inpatient suicide literature examining knowledge and evidence on prevention	Qualitative literature review	Selected literature worldwide	Systematic search of literature relating to inpatient suicide	Concludes with points that most suicides occur off ward after discharge or early in admission whilst on leave/absconsion	Recommends:- Safer environment Better visibility Better supervision Better assessment Awareness of suicide risk Good teamwork/communication Adequate treatment	Plastic bags not routinely removed in locally as suggested Mentions legal consequences of not implementing close observation Agrees with Large et al that just concentrating on high risk patients puts others at risk If concentrating then on making ward safer by locking doors etc is this unfair on non-suicidal patients? Does there not have to be some form of risk assessment? Very general recommendations MULTI-FACTORS

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Impact of Capacity Reductions in Acute Public-Sector Inpatient Psychiatric Services	Shumway et al (2012) USA	Psychiatric Services	Tested hypothesis that reducing inpatient bed capacity would have negative impact on patients including higher suicide rate	Quantitative	'Impact indicators' (e.g. overcrowding, length of stay recidivism levels etc) from admin databases in San Francisco General Hospital, USA	Use of patient databases for required info over 3 year period Statistical analysis of data used	50% reduction in acute beds and 23% reduction overall had no negative impact Mainly achieved by concerted effort to reduce inpatient length of stays (thus treating same number of patients as before)	Bed reductions can work but maybe not in the long-term and only by utilising all existing community supports	Inpatient services were cut without any expansion of community services Acknowledges study limitations in longer term effects of reductions. Also no qualitative evidence from staff and patients Describes much greater level of community services than available locally including good liaison with housing providers (temporary community placements rather than waiting for longer term accommodation in hospital – a huge problem locally) ORGANISATIONAL FACTORS
Absconding and locking ward doors: evidence from the literature	Stewart and Bowers (2011) Multi-country	Journal of Psychiatric and Mental Health Nursing	Examined relationship between absconding and locking ward doors	Review	26 studies included from 7 different countries	Narrative literature review	Open wards tend to report higher levels of absconding Only a few studies could be included as authors wanted to compare study findings where absconding rates were similar	Recommends more hospital wide security (e.g fences, locked doors) but has to be weighed up against negative impact (more aggression, more self-harm) Although difficult to substantiate alternatives to locking doors (sign in out books etc) may be as effective	Highlights again the blanket security measures that may protect some patients but antagonise or negatively affect others (one set of problems replaced by another in the case of suicide prevention for violence cause?) ORGANISATIONAL FACTORS
Inpatient suicide: preventing a common sentinel event	Tishler and Reiss (2009) USA	General Hospital Psychiatry	Examined rates of inpatient suicide, risk factors, methods and contributing	Review	Unspecified electronic and manual search of evidence	Review	Main antecedents appear to be environmental safety issues, patient assessment problems and staff/training	Makes many recommendations under headings of Environment	Mentions apparent ineffectiveness of 'no suicide' written contracts (not used locally) Lists all diagnoses as profile for

Appendix 7 Suicide/self-harm with suicidal intent literature review grid

			factors				factors	Patient screening Patient Treatment Staff training Hospital policy	suicide Is suicide risk assessment sometimes based on numbers of staff available as suggested? What about numbers of suicidal patients as a result of inpatient wards becoming much more acute? Threshold for implementing stricter risk assessment practices reduce or increase? In addition to the need to discharge patients quickly, do we also hold on to them too long as there aren't other services in the community (become neglected and suicide risk increases?) MULTI-FACTORS
Does Deinstitutionalization Increase Suicide?	Yoon and Bruckner (2009) USA	Health Services Research Journal	Examined whether bed reductions in USA increased suicide rate (also examined impact of private bed usage and availability of community services)	Quantitative	Examined data on changes in mental health service provision from inpatient to community relating these to suicide rates	Official records from all states in the USA	Suggests that reducing inpatient care may lead to increased suicide rates Increases in community care have not replaced 'safety net' capability of inpatient beds	Approaches results with caution but feels inpatient type facilities still required even if these are available in more community-type settings	Generally considers role of deinstitutionalisation in rate of suicide asking whether community services can adequately care for those at risk of suicide Includes studies from around world where suicide rates have increased when beds have been reduced What about re-configuration of beds or re-location of beds? ORGANISATIONAL FACTORS
Suicide prevention in mental health	Manuel et al (2017)	International Journal of Mental Health	Investigation of coroner report recommendatio	Qualitative	Discussed the coroners recommenda	Interviews with 16 clinicians and 9 support	Recommendations related to: -	Mental health nurses need to balance risk containment and	Author raises important point that coroners recommendations are rarely disseminated through

Appendix 7 Suicide/self-harm with suicidal intent literature review grid

services: A qualitative analysis of coroners' reports	New Zealand	Nursing	ns on suicide prevention for mental health services		tions and then sought views of clinicians and family support workers	workers followed by qualitative content analysis	Communication Risk containment Service delivery Family involvement Evidence tends to agree with 3 out of 4 recommendations aside from risk containment. Clinicians raised the difficulties associated with: - Risk assessment Therapeutic treatment vs risk management Conversely, MHS are more likely to implement risk containment measures than any of the others	therapeutic treatment but need to be supported by their organisations The involvement of family needs to become more of a reality and less rhetorical More of a balance between pharmacological and evidence based psychological treatment required	mental health services. Highlights issue of constructive learning process as opposed to blame How do we change the myth that suicide risk assessment and containment are a panacea - goes back to argument of public health education/promotion MULTI-FACTORS

Non-research literature (suicide)

Title	Author and Year	Journal	Purpose	**Credibility**	Quality	Content	Coherence	Recommendations	Key thoughts/ comments
Reducing Inpatient Suicide Risk: Using Human Factors Analysis	Janofsky (2009) USA	Journal of the American Academy of Psychiatry and the Law	Author gives description of a process to improve observation practices (to reduce suicide risk) on an	**Special article** in peer reviewed journal	Good	'incomplete' or 'infrequent' observation commonly cited as cause of suicide Many studies and	Author reporting on proposed best practice as he could not find existing evidence in the literature	Terminology should be standardised and simplified ('constant or 'intermittent' observation) Problems may arise	Appears to be wider strategy of standardising care processes away from clinical judgement alone

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to Improve Observation Practices			inpatient ward			inquiries are critical of individual nursing care rather than systems approach Observation practices an terminology varies greatly across different countries (arms-length, in sight etc)		at handover times of because of miscommunication	(includes quite complicated patient flow diagram) STAFF FACTORS
Suicide is preventable, sometimes	Walter and Pridmore (2012) Australia	Australasian Psychiatry	Examines the principle that suicide is preventable	Viewpoint (opinion) piece in peer reviewed journal	Good	Saying that 'suicide is preventable' can lead to 'witch hunt' of staff and blame for responsibility Provides examples of suicide that have occurred in places with highest degrees of security and observation (e.g. Guantanamo, Wakefield Prison etc) Not all suicide results from mental illness and not all mental illness is detected	Authors are providing a counter-argument to a govt inquiry paper in Australia with the title 'suicide is preventable' claiming the this is misleading and not possible	Does not think suicide can be stopped by clinical means alone Again suggests that suicide risk assessment does not work but similarly highlights that good care can prevent suicide Suggests wider public health approach	Raises important point that issues such as culture, social disadvantage and loss are not easily removed from equation of suicide prevention Retrospective studies of suicide tend not to look at what is working well and the cases where it has been successfully prevented (like many critical inquiries and many staff criticisms of their own work places) Public health approach raises issue of whether an inpatient suicide is purely a hospital problem or a wider societal one (historically kept

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									quiet when the responsibility should be shared with society?) ORGANISATIONAL FACTORS

Appendix 8 Non-suicidal self-harm literature review grid

Deliberate self-harm

Title	Author, Year and Country	Data Collection methods	Major Findings	Recommendations	Key thoughts/ Comments
Measuring self-harm in adults: A systematic review	Borschmann et al (2012) UK	Systematic review to evaluate instruments used in self harm measurement	7 instruments met inclusion criteria Considerable variation in length etc. SAS II seen as most comprehensive	Self-report measures should be used in conjunction with non-self report measures (reporting bias issues) Self reports can be helpful in terms of comfort divulging information Validated measures should only be used Authors highlight that given stigma and SH not being seen as a helpful behaviour it may be more difficult to measure than other phenomena Study recommends use of medical records in 'triangulation' approach to measurement Lack of 'versatile' effective tools to measure self-harm behaviour	In order to work out where self-harm emerges from we first need to reliably assess and measure its prevalence - Medical records can help with self-harm particularly as it is historically difficult to evaluate through self-reporting alone From a serious incident perspective – sometimes identifying differences between suicide attempts and dsh without intent is difficult. Experience suggests that patients may say they were trying to kill themselves where professionals disagree and vice versa. We are often reliant on self-reporting (where incidents unwitnessed for example) and this is anecdotally indeed not reliable or at least lacking clarity as the authors suggests

Appendix 8 Non-suicidal self-harm literature review grid

Gender differences in the prevalence of nonsuicidal self-injury: A meta-analysis 2	Bresin and Schoenleber (2015) USA	Meta analysis to examine gender differences and prevalence of self-injury	Women slightly more likely to engage in NSSI but effect size small No gender differences across ages (hypothesised that gender difference would be greater for younger females compared to males) Gender difference greater in terms of clinical cases as opposed to community/college groups (maybe men do not seek treatment as actively?) Women more likely to draw blood	Still not clear why women are more likely to self harm than men (authors suggest gender socialisation; differences in dealing with emotions and biological factors) Multifaceted factors likely to be in play Authors suggest that men may be more likely to self-harm for interpersonal reasons whilst females harm themselves for intrapersonal reasons Self harm assessment should not be neglected in men	Author cites NSSI (non suicidal self injury) differentiating phenomena from 'wanting to die' intention Can NSSI stem from inability for all other known 'treatments' to provide relief in the same way? Professionals would often feel that self-harm from inpatient perspective is often about the 'interpersonal' as opposed to intrapersonal perspective (e.g. competing with other clients; threat of discharge etc.) Is it more likely to be intrapersonal if it takes place in the community setting? Viewed by professionals as a very maladaptive behaviour and always arising from 'the person themselves' as opposed to environmental or staff factors etc.
Hospital Presenting Self-Harm and Risk of Fatal and Non- Fatal Repetition: Systematic Review	Carroll et al (2014) UK	Review and meta-analysis to examine the incidence of repeated self-harm in hospital presentations (and the factors	Major differences in estimates internationally Lower rates in Asian countries Overall 16% rate of repeated	1 out of 25 repeated self-harmers will go on to die by suicide within 10 years. Greater in males and older patients	Linked with author 1 in that published self report studies show a higher rate of repeating self harm than hospital record studies (18

Appendix 8 Non-suicidal self-harm literature review grid

and Meta-Analysis		influencing differences)	self-harm within year one 1% fatal repeated self-harm but higher in males	Rates of self-harming and repeated self harm do not seem to have changed over past 30 years Study also recommending better system of reporting self-harm than self report alone	vs 11%) Study continues to highlight the difficulties In accurately recording and assessing prevalence of self harm All prevalence studies do not really look at the contextual factors involved in its occurrence other than gender, age, ethnic origin etc. (all coming from patient perspective and not considering other factors such as environment and family)
Assessment and Identification of Deliberate Self-Harm in Adolescents and Young Adults	Catledge et al. 2012 USA	Provides guidelines from the available literature in relation to assessing and identifying DSH in young adults and adolescents	Factors associated with DSH include: Sexual abuse Family dysfunction Psychosocial factors Psychological factors Friendship Intimate Relationships Drugs/alcohol Schoolwork Bullying	Recommendations for support include: Targeted assessment Establishing rapport Physical/suicide/psychosocial and psychological risks to be assessed Collaborative care plan	The term DSH is also defined as harm without suicidal intent (similar to NSSI) Most listed factors are external to hospital/clinical environments
Deliberate Self-Harm Behavior Among Italian Young Adults: Correlations With	Cerutti et al (2012) Italy/USA	Explored rates of DSH with psychological and psychopathological correlates using self-report questionnaires	Rates of DSH may be just as high between clinical and non-clinical samples No gender differences among	Importance of examining factors relating to DSH amongst non-clinical groups highlighted	Paper concentrates solely on personality traits and psychopathology to explain DSH

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Clinical and Nonclinical Dimensions of Personality		with college students	certain samples (college, military, adolescents) Gender differences in form of cutting where higher rates amongst females Self-harm sometimes used to return to 'here and now' from dissociative states Borderline personality traits and DSH show an association Negative body image associated with DSH but not necessarily the frequency Poor urge/impulse control Emotion regulation deficits Some personality traits (neuroticism and high impulsivity) associated not only with self harm but alcohol problems, gambling and eating disorders		DSH alone may not lead to psychiatric referral – in clinical enviroments it then becomes a psychiatric or medicalised problem
Predictors for repeat self-harm and suicide among older people within 12 months of a self-harm presentation	Cheung et al (2017) NZ	Study to characterise older people who present to ED with self-harm and to determine the predictors for repeat self-harm and suicide	Older persons presenting after self-harm more likely to have intended to die Repetition rate falls within 9 and 18% 13 to 23% use of alcohol before self-harm More likely to have psychiatric histories or be/have been with	Older persons presenting with self-harm should be seen as unsuccessful suicide cases Limited guidance on treating self-harm in older persons Structured psychological interventions should be used as an adjunct to	Study does not define self-harm as omitting suicidal ideation in this example Locally professionals linked to ED departments would try to ascertain level of 'intentionality' to differentiate between self-harm and suicidal intent. The term self-harm would be more likely used in a

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			mental health services Overdose the most common form of self-harm Association between physical factors and suicidal behaviour	psychopharmacology	non-suicidal context Some factors associated with self-harm may be related to age (e.g. physical health) Are staff more likely to have different thresholds for assessing self-harm in young and older persons? More staff support/assessment/closer monitoring for older persons?
A Systematic Review of the Antecedents and Prevalence of Suicide, Self-Harm and Suicide Ideation in Australian Aboriginal and Torres Strait Islander Youth	Dixon et al. (2019) Australia	Systematic review of antecedents of self harm and suicide in relation to aboriginals in Australia	Indigenous rates of suicide higher than non-indigenous groups, plus self-harm and suicidal ideation Greater risk associated with incarceration, social stress, racial discrimination but not substance use Regional and remote areas associated with greater risk No evidence for differences in gender risk	Paper refers to socio-economic antecedents (e.g. economic deprivation) and psychological antecedents (e.g. beliefs, coping strategies) Western conceptualisations of 'self-harm' may be different amongst other ethnicities Better reporting systems required to capture data on self-harm	Paper defines self-harm in introduction demonstrating the different meanings often attached Some links could be made with other ethnic groups in Ireland (e.g. travelling community; refugees) and different cultural ideas about self-harm or greater likelihood of socio-economic deprivation
Self-harm in a primary care cohort of older people: incidence, clinical	Morgan et al (2018) UK	Used anonymised data to examine incidence of self-harm amongst 65+ age group	Referral rates to mental health low with females more likely to be referred Less deprived areas more likely	Care needs to be taken in terms of GP's making the necessary referrals, being careful with potentially harmful medicines and	Link with Cheung (2017) self-harm in older adults likely to be more related to actual suicide intent

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management, and risk of suicide and other causes of death			to refer High level of TCA prescription	improving treatment rates in more socially deprived areas	From mental health inpatient perspective, we may not assume that older persons can and will self-harm. Are we likely to assess someone older or younger as high risk in terms of self harm?
Assessing risk of suicide or self harm in adults	Morriss et al (2013) UK	Review piece aimed at GP's and non-specialist mental health services in terms of assessing suicide and self-harm	Antecedents may include history of mental illness or self-harm; unpredictable behaviour, active depressive symptoms; unstable social situation; recently discharged from hospital; under 25; taking medication; ease of access to lethal means Increased self-harm may be precursor to imminent suicide risk Risk factors can change rapidly		Paper talks about self-harm mostly in context of suicide risk as opposed to DSH – does reference increased risk of completed suicide emerging from self-harm behaviour
'Near-lethal self-harm in women prisoners: contributing factors and psychological processes'	Marzano et al (2011) UK	Examined the contributing factors relating to self-harm amongst female prisoners	Suicide or self-harm often seen as a one off event as opposed to a culmination of factors over time Contributing factors included: problems with prison staff and other prisoners adverse events outside prison (e.g. bereavement) psychiatric disorder psychological problems (e.g.	Female prisoners have significant therapeutic needs often in terms of early abuse and violence More staff availability Less predictable check times	Some of these findings could be linked to inpatient care especially locked acute areas Interesting that paper looks at environmental, personal and social aspects as contributing factors

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			burden on loved ones) drug problems missing those outside prison being incarcerated		
Non-suicidal reasons for self-harm: A systematic review of self-reported accounts	Edmonson et al (2016) UK	Systematic review of self-reported non-suicidal reasons for self-harming	Authors categorised reasons into: Responding to distress (affect regulation and interpersonal influence the 2 most commonly cited reasons) defining the self Self harm as a positive experience	The third category of being a positive experience is often overlooked People do not self-harm necessarily as a result of emotional or social distress but getting themselves and others to 'affirm' behaviour Qualitative accounts of self-harm are frequently interpreted in different ways by researchers Research may be biased from it all coming from specific areas such as clinical practice Suggests looking for alternative positive strategies as opposed to changing negative behaviour	Points out that the distinction between suicidal and non-suicidal behaviour frequently unreliable Interesting that self-harm and suicide often classed in same group but people who choose to self-harm may do so because they trying to avert from suicide and suicidal thoughts themselves
Reasons for Non-Suicidal Self-Harm in Adult Male Offenders With and Without Borderline Personality Traits	Gardner et al 2016 UK	Looked at reasons for self-harm amongst male prisoners	Cites the 2 main reasons of affect regulation and interpersonal/social functions Reasons may cross all categories Suicide risk may be downplayed	Intrapersonal reasons have more significance than interpersonal functions Rarely performed solely for one specific reason	Also cites conflict between distinguishing suicidal and non-suicidal forms of self-harm Cites much of the former paper's findings (use of

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			as not seen as serious or genuine but more calculated manipulation Diagnosis such as BPD should be considered as this may affect reasons for self harming (particularly affect regulation)	Having BPD increases likelihood of endorsing interpersonal functions	clinical samples; deliberate over emphasis on affect regulation) Although suicidal ideation may not be present or even acknowledged by service users, they should still be viewed in a high risk category? Being seen as willing manipulation may lead to less support (e.g. don't feed into it) and ignoring of risk?
Psychotic symptoms, self-harm and violence in individuals with schizophrenia and substance misuse problems	Haddock et al (2013) UK	Looked at links between schizophrenia, substance use and self harm/violence	Psychotic symptoms particularly related to self-harm in people with schizophrenia/co-morbid substance use problems Specifically severity of delusions and distress caused by delusions but also command hallucinations	Clinical interventions should include careful assessment of symptom content and risks associated	Contrary to patients seen as manipulative, are this group likely to garner more sympathy (as they are seen as genuine) and therefore more careful consideration of risk/more support Usually behaviour of shorter timescale and relative to acuity of illness? Easier to manage/have empathy for as a result? No deep psychological reasons to try and fathom in this scenario – almost easier to understand?
Severity of suicidal intent, method and behaviour antecedent to an act of self-harm: A	Krishna et al (2014) India	Looked at antecedents of self-harm amongst patients in India	More suicidal intent in unskilled labourers and professionals than those in between Pesticide poisoning common in	Cites need for more studies which may help predict likelihood of self harm	Although the study does not differentiate in terms of self- harm it does make a good point about access to lethal means in rural

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cross sectional study of survivors of self-harm referred to a tertiary hospital in Mysore, south India			rural areas (ease of access) Rural dwellers generally scored higher than non rural in terms of self harm behaviours Mental disorder linked to greater intent		communities Some comparison with rural Ireland (possible to see how access to lethal means could take NSSH and turn this into a suicide statistic as opposed to accidental) - then impossible to tell retrospectively without guessing Removing the means of self-harm has become more important than understanding why people self-harm?
Risk Factors for Repetition of Self-Harm: A Systematic Review of Prospective Hospital-Based Studies	Larkin et al (2014) Ireland	Systematic review of the risk factors associated with repeated self-harm from hospital bases studies	Statistically significant associations for: previous self-harm, personality disorder, hopelessness, history of psychiatric treatment, schizophrenia, alcohol abuse/dependence, drug abuse/dependence, living alone. Lesser associations for: impulsivity; comorbidity; problem-solving ability; sexual abuse; current psychiatric treatment; stressful life events; work or school problems relationship problems family relationship problems; financial problems	Such risk factors can be easily included in risk assessment procedures/risk factor scales which include many of the main risk predictors Resources can be directed towards those most at risk Risk factors for repeated self-harm match initiation factors The most consistent predictor of repetition relates to long-standing psychosocial vulnerabilities Also suggests that repeated self-harm becomes increasingly autonomous meaning that factors such as financial/relationship	Paper seems to summarise that vulnerability is the key from a biopsychosocial perspective Only briefly mentions self-harm in the context of obtaining support from services Notes that risk assessment tools are good at capturing those who will self-harm but poor at predicting those who won't Challenges some of the innate beliefs people have about the causes of self-harm Mainly includes personal,

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			attitude towards self-harm episode; involvement of self-cutting.	problems are not necessarily strong predictors	psychiatric, psychological and social characteristics Not much of note in relation to how far the therapeutic relationship is a protective factors
Suicide attempts and non-suicidal self-harm: national prevalence study of young adults	O'Connor et al (2018) UK	Interviews with young adults across Scotland to examine prevalence of suicidal and self-harm thoughts	16% of the 3500 people interviewed reported NSSH Women reported NSSH 1.8 times more than men Self harm often precedes suicide attempts (by 2 years on overage) Mean age was 16 for onset Majority referenced repeated NSSH Rates of NSSH higher amongst 18-23 year olds Earlier onset linked to more frequent NSSH Young and female main risk factors for repeated and frequent NSSH	Services need to focus carefully on young adults as greatly affected by NSSH and suicide risk	Paper cites the lack of consensus about how to conceptualise self harm referring to the reported distinction between suicidal self harm and non suicide self harm on one side and the belief that self-harm is much more fluid and multifaceted good intro section on prevalence study looks at prevalence as opposed to causes – does compare rates between England and Scotland noting possible health inequalities study highlights how difficult it is to separate the 2 types of self-harm
The Incidence and Repetition of Hospital-Treated Deliberate Self Harm: Findings from the World's	Perry et al (2012) Ireland	Review of findings from national registry database of self-harm presentations in Ireland	Only a minor number who self harm present to hospital Few countries keep reliable data Highest rates of DSH amongst	Need for careful risk assessment Mentions efficacy of CBT; problem solving and	Can we always class self harm as a psychiatric problem? Especially away from hospital – what about tattoos, piercings?

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First National Registry			17 year old females Repetition rates similar for men and women Risk of repetition highest in days and weeks following each presentation to hospital Patterns of DSH mirror other countries (women, young, drug overdoses) Rates of self-cutting amongst men higher in Ireland than other countries Self-cutting patients tended to be unemployed, single, living alone, using drugs and having a history of self harm Men tend to be more risk of cutting severely (? Leading to more hospital presentations) Repetition rate after 1 year around 30%	interpersonal therapies DBT for BPD patients	If only fraction seeking help very difficult to truly estimate numbers DSH rate went up with the suicide rate amongst men in 2008/2009 - ? recession Are all social factors implicated in rise in both suicide and self harm? Many similarities with findings on suicide (e.g. greater risk on discharge) Most severe types of self-harm seen in hospital (post medical treatment) Are men and women who self harm perceived differently?
The longitudinal course of non-suicidal self-injury and deliberate self-harm: a systematic review of the literature	Plener et al (2015) Germany	Systematic review as title (32 studies)	Vast heterogeneity making comments about longitudinal course and predictors complex – not helped by different definitions of self harm, comprehensiveness of assessment tools Studies on adolescents showed upwards prevalence Studies on older persons shown	Given rapid changes in behaviour probably wise to only diagnose for short periods Repeated incidents within a year to diagnose correctly Early intervention aimed at person and families	Highlights problems with definitions Being female, depression and adolescence comes up a lot Past self-harming behaviour increases

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			downwards trend Peak at 15-17 Past self-harming behaviour the strongest predictor of repeated self harm Depression Female Social and family factors		informal monitoring of these patients in an inpatient area? Probably is helpful to define intent – however staff need to be aware of risks (sometimes accidental too?) and that intent needs to be checked each time?
Scales for predicting risk following self-harm: an observational study in 32 hospitals in England	Quinlivan et al (2014) UK	Observational study on the number of risk scales used to assess self harm in emergency and mental health depts. Looked for associations between scale use, service quality and repeat self-harm <6 months	Scales to assess self-harm not as common in risk assessment Little consistency in frequency, type and validity of tools used SAD PERSONS most commonly used scale (however seen to have poor predictive capability) Descriptive study but where scales used repeated self harm may be lower No differences in service quality scores between those that used scales and those that did not	Lack of a gold standard for repeat self harm assessment ? whether tick box exercises help engagement or hinder	Local tool and risk assessment document has a whole page dedicated to self harm Interesting that scale use did not affect quality Use of scales no guarantee of quality service (more focused on governance and risk aversity than therapeutic care and support?) Having scales for every possible presenting feature probably not realistic – usually part of wider assessment in mental health services

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Attitudes and knowledge of clinical staff regarding people who self-harm: A systematic review	Saunders et al (2012) UK	Systematic review as title	Service user who self harm often report a negative experience in relation to mental health services In general medical services the attitudes towards self harm are negative – no difference between newer and older studies Self harm up and mental health beds down so more self harm in general areas Conflict of choice to self harm vs mental health problems (ie not choice) Self destruction is highly challenging Females favoured more positively More negative attitudes amongst medical as opposed to nursing staff Attitudes of psychiatric staff tend to be more positive Notes practical difficulties assessing self harm (e.g. interview rooms and referral to psych services delay)	Training is seen as vital in terms of more positive attitudes Suggests that little is known about how things like ethnicity or social class affect staff attitudes	Self harm is 'bread and butter' to psychiatric staff but not to general medical staff (perceive self harm as preventing them from helping 'really' unwell people?) Study mentions waiting times being a priority – care of self harm patients may not be a rapid process Very difficult to assess attitudes – unless observed first hand and without staff members knowledge? Even then there could be any number of factors affecting that person on the day Very difficult to assess how much nursing intervention for example helps prevent or nurture self harm – most studies in this review look at person characteristics and behaviour as predictors
Interventions to prevent self-harm: what does the evidence say?	Saunders and Smith (2016) UK	Review of RCT evidence on interventions	Majority of self harmers do not present to hospital Many methodological challenges involved in designing	Observational studies may be more successful that RCT's in assessing efficacy of interventions (e.g. lithium)	Has good definitions and basic stats First paper to raise issue of 'contagion' in that school based interventions may

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			RCT type efficacy studies Little evidence from RCT's but things mentioned as interventions Antidepressants Mood stabilisers Antipsychotics (in BPD) Ketamine ECT CBT, DBT, MBT, group psychotherapy School based and public health interventions (mental health programmes)		do more harm than good – reflects current thinking on mental health promotion Open conversation about things that used to be unspoken - positive and negatives of 'cat being out of the bag'
Nonsuicidal Self-Injury Disorder: The Path to Diagnostic Validity and Final Obstacles	Selby et al (2015) USA	Review discussing the recent addition of NSSI to the diagnostic manual	Researchers calling for NSSI as a condition since the 1970's Authors weigh up the arguments for and against validating the condition as a valid diagnosis Against: Setting diagnosis apart from other diagnoses Lack of clarity in terms of condition development (timescale, stability etc.) On suicide continuum rather than a distinct disorder in its own right Not having accurate and consistent diagnostic criteria	Authors feel that: It does exist and does have clinical implications beyond BPD Is distinct from other disorders and suicidal behaviour Is a major problem over time for adolescents Validating the diagnosis would have beneficial clinical elements	Link with Plener 2015 Cites 4 function model – experience suggests that staff would mainly consider the social function model (see medical staff response in Saunders et al 2012) In mental health services (esp. inpatients) most patients would have existing diagnoses (psychosis or EUPD/BPD?) Have never seen someone admitted just for self harm alone without suicidal intent

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			Whether it is actually clinically useful to diagnose the condition in its own right		
Mental health nurses' attitudes toward self-harm: Curricular implications	Shaw and Sandy (2016) UK/South Africa	Interviews and focus groups with mental health nurses in order to examine attitudes towards self harm	Wide number of terms used by staff leading to some confusion 'Mismatch of motivational attributions' between nurses and patients Many respondents felt they lacked knowledge skills, training and positive attitudes to deal with self harm Also felt by service users More negative than positive attitudes generally	Need for greater training and education FASH (factors affecting attitudes to self harm) and TPB (theory of planned behaviour) might be good frameworks for education curriculum on self harm care Curriculum based on the application of positive attitudes to positive outcomes (ie less self harming) Discussion groups, role plays and case studies	Each paper has to start with an agreed definition of self harm Staff and patients sometimes not singing from same hymn sheet in terms of motivation – often not explored fully? Particularly in inpatient mental health (reactive psychiatry?) Use of TBP interesting as talks about the other areas that form staff attitudes both formal (e.g. local policies) and informal (e.g. going against the grain etc.) How much does training really change engrained attitudes – what about bad experiences (e.g. constantly dealing with self harm on night duty or inquiry following serious incident)
Health services, suicide, and self-harm: patient	Smith et al (2015)	Personal view looking at how health services often respond negatively	Tries to firstly understand the context of the workplace 'system' and the impact on staff	Three main factors	Subject of 'fear' in services an interesting concept – more focused on

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distress and system anxiety	Scotland	towards suicidal and self harming patients	attitudes and anxieties Staff may feel powerless if patient not helped or continues to self harm *'person in need who does not behave like a patient, and a health system that feels obliged to intervene, yet isn't always clear how to do so'* talks about coping strategies/thoughts (difficult and contradictory feelings) can't think negatively about a patient wasting resources	Ambiguity about the sick role Need to respond with uncertainty about what to do exactly That there may be potentially fatal outcomes whatever the intervention …leading to dysregulated zones: negative feelings about patients, an inappropriately narrow focus on diagnosis and risk assessment, and ad-hoc, abrupt, and inconsistent decision making. We need to think more about how staff manage anxieties in these circumstances	protecting reputation of self and hospital than the patient themselves Self harm can be a protective factor against suicide (never considered this before) Mirrors work on managing risk in health services; expectations; policies etc. Lottery of who gets/deserves support and who does not If patient doesn't conform with support offered – help could be taken away completely as we feel we just cannot help at all Who's stress – ours or theirs?
Community mental health care after self-harm: A retrospective cohort study	Spittal et al (2016) AUS	Study looked at post inpatient discharge take up of mental health care and treatment on self harm patients	41% had contact with mental health teams post discharge for self harm Not clear what the other 59% did Those with no prior contact	Period post discharge important given statistics on higher risks of repeat in first 4 weeks post D/C	How much does 'lethality' impact on support planning and community follow up Locally most patients offered follow up – left as their choice whether they want to attend or not – 'well we offered them care

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			most unlikely to be referred – know patients 5 times more likely to be seen Explanations for shortfall: Poor inpatient/community communication Patient reluctance Carer reluctance Increasing age was associated with poor follow up uptake Patients staying in hospital a long time often not followed up surprisingly		so we've done our bit' Therefore is it always actually helpful to provide follow up? or just because we feel we could be criticised if something happened and we did not offer follow up service
Self harm and attempted suicide within inpatient psychiatric services: a review of the literature.	James et al (2012) UK	Lit review looking at prevalence of self harm within inpatient psychiatry in the UK	Most studies looked at characteristics and demographics associated with self harm as opposed to the antecedents, the nature of the behaviour or management strategies (very few) Few conclusive risk factors despite a great deal of papers focusing on these Differing rates of incidence not likely to be about demographics alone but about care delivery methods and organisational factors Although many studies do not differentiate between self harm and suicidal intent, they probably benefit from different	More regular safety checks particularly in the evenings Unique reasons for each episode of self harm should be fully explored Staff working in 24hr care have a good opportunity to achieve this Studies with service user feedback have reported having the opportunity to talk about their feelings in regard to self harm as important Positive risk taking required in order to provide the patient with a sense of control and empowerment rather than restrictions and	Appears to contradict in some ways other studies that suggest that self harm is a very personal thing and does not respond to prof intervention well Does however note that separating suicide intent and self harm may be helpful in this regard How do we really demonstrate care delivery and organisational methods effect self harm without controlling for all other factors? Paper seems to call for more balance from control methods (e.g. safety checks and ligature free wards) to

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			management strategies and should be viewed separately People more likely to self harm in private areas (eg. Bathrooms) on inpatient units and in the evenings Head banging, cutting and strangulation the most common forms of harm Psychological distress the most common antecedent – primarily as a coping mechanism Points out that things like restriction or control (often involving nursing staff) can lead to self harm Nurses also feel emotional distress, lack of knowledge and understanding – some develop negative attitudes	control Some interventions don't focus on self harm at all but the behaviour can be reduced by how nursing staff interact with patients in general terms Observation can be helpful in terms of reducing self harm but few studies have looked at harm minimisation where direct self harm prevention is replaced with looking at alternatives and self-responsibility Staff need greater support and supervision Much more research required in nursing-patient relationship in terms of managing self harm	a greater focus on the nurse patient relationship Letting people self harm may be therapeutic in a sense but where does this fit in with the current risk/safety focus in healthcare Staff may wish to work more in this way but may feel reluctant to do so without support around them from management and the organisation they work for
Patient characteristics and behaviours associated with self-harm and attempted suicide in acute psychiatric wards	Stewart et al (2011) UK	Retrospective case note analysis of before and after self harm and suicide attempts plus characteristics of those involved	1 in 10 patients self harmed within 2 weeks and 4% attempted suicide Over half of patients who attempted suicide also self harmed Patients who self harmed or attempted suicide tended to be younger and have an established history of self harm	Complex relationship between self harm and suicide Self harm could be an alternate way of expressing distress and frustration because of not being able to leave the ward Some links between self harm and aggression in terms	Again raises issue of public safety versus targeted and individual treatment plans which may allow for some self-empowerment and responsibility on the patient themselves Absconding is a risk but so are overly zealous containment measures (which can lead to refusal

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			Patients who attempted suicide were more likely to be female Absconding a risk factor for completed suicide but not self harm – most occur off the ward and after absconding Self harm tended to follow attempted absconds Refusing meds more associated with suicide antecedents than self harm Consequences of self harm and attempted suicide were prn meds and de-escalation Not entirely clear how effective close observations are – other areas such as ward layout need to be considered	of preceding aggression towards objects Measures to reduce absconding may help but balance needs to be taken in terms of just locking doors (can lead to problems like medication refusal) (e.g sign in book, targeted nursing time, MDT review etc.) Withdrawing from interaction or meds should be seen as a sign of increased self harm risk Early stages of admission pose the most risks	of meds, wanting to leave, break down in therapeutic relationships, social withdrawal etc.) If self harm without suicidal intent – is hospital admission always required? Particularly if hospital admission can lead to greater frustration and increased risk of self harm – iatrogenic problems again Close obs extremely labour intensive and directs care away from other patients – however it is justified in the risk averse environment we work in and provides some level of protection and reassurance for patients, families and staff – trouble is how long do we continue?

Patient factors	Staff factors	Organisational/environmental factors	External factors
Gender (differences across specific types of self harm and suicide risk)	assessment	Measuring and assessing self harm (assessing history)	History of sexual abuse
Age	Rapport/collaboration	Reporting system	Bullying
Psychological dysfunction	Risk assessment (self harm vs	Availability and use of psychological	Schoolwork

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	suicide risk)	treatment in addition to psychopharmacology plus family work and early intervention	
Body dysmorphia	Patient checks and close observations	Incarceration and increased risks on discharge	Family dysfunction
Personality disorder (emotion dysregulation; poor impulse control)	Attitudes towards people who self harm (manipulation etc.)	Other patients (inpatient wards)	Racial prejudice
Drugs/alcohol	Training	Flexibility and tolerance to harm minimisation approaches	Economic deprivation
	Supervision	Safety and security measures (absconding etc.)	unemployment
Cultural/ethnic differences		Community/inpatient links	Availability of means
			Stressful life events (incl. debts etc.)
Psychosis			

Appendix 9 Risk management in mental health services literature review grid

Narrative review – contemporary risk assessment and management in mental health

Title	Author, Year and Country	Data Collection methods	Major Findings	Recommendations	Key thoughts/ Comments
Clinical risk management in mental health: a qualitative study of main risks and related organizational management practices	Briner and Manser (2013) (Switzerland)	Staff Interviews	Risks prioritised by interview results 1. Risk of violence and self-destructive behaviour 2. Treatment errors (patient abuse from staff, diagnostic errors and medication risks) 3. Specific risks related to diagnosis – psychosis, lack of insight etc)	Hospital leaders can use findings to address their own clinical risk management systems	Patient safety inconsistent in mental health compared to medical Mental health has to consider patient and STAFF safety more so than medical Violence and suicide still top of risk priorities Risk number 2 highlights that staff are indeed able to think about risk in different ways
Integrating service user and practitioner expertise within a web-based system for collaborative mental-health risk and safety management	Christopher D. Buckinghama,*, Ann Adamsb, Laura Vailb, Ashish Kumarc, Abu Ahmedc, Annie Wheland, Eleni Karasoulie (2015) (UK)	Staff interviews, focus groups, software development	Study aimed to see if a DSS (decision support system) could be utilised by both professionals and service users alike in terms of assessing and managing risk	Can help with the shared risk approach	Not clear how feasible it is for mental health services internationally to use the interface – costs involved Fits into category of recovery and sharing risk Interesting that professionals want to be able to assess risk quickly and systematically whereas service users want to look at everything that effects risk – e.g. life history and social context)
Health Training, Education and Practice Violence risk assessment and	Callaghan and Grundy (2017) (UK)	Narrative literature review	Prevalence of violence remains high but risk management process has done little to reduce this. Risk assessment focuses on individual only,	We need to talk about safety as opposed to risk Based on recovery principles	Removing our own innate beliefs about risk before assessment using actuarial methods is arguably not

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management in mental health: a conceptual, empirical and practice critique			ignores wider societal issues. Stigmatises mental illness and falsely allows public to believe that mentally ill are dangerous whilst perpetuating idea that threat can be reduced by managing risk clinically	and process of collaboration These things required together:- • Patient self-perception • Clinical judgement • Electronic risk algorithms • Evidence based management plan Opposing positivist vs social constructionist views on risk Society has 'constructed' the view that patients are dangerous High risk = involuntary detention Low risk = difficulty accessing care and treatment	possible from social constructionist perspective Some writers suggest that patients acknowledge contextual antecedents of violence better than staff as they mention environment, staff attitudes etc. Do staff think of individual risk only? If we are getting to a point where we understand that risk assessment is limited as suggested this needs to be 'marketed' properly to the public as they have been previously misinformed
Risk management in public mental health	Carroll (2014) Australia	Opinion letter critique of other research paper	That structured risk assessment has its place, is valid, evidence based and preferable to pure intuition alone (SPJ – Structured Professional Judgement) That we only know so much about the risks in mental health as a result of empirical research over many years	Mental health services need to relay to the public 'limited foreseeability' Risk is similar to other parts of medicine such as prescribing where we use EBP from 'group' research as opposed to 'individual' (the fact that medication does not work **everytime** with **everyone** does not stop us using the evidence en masse)	Counter-argument to critics of risk and 'defensive' practice – important to remember that much of this **planning** work is routine and would exist/did exist before the whole risk assessment agenda (consider asylums and blanket risk management for all patients) With modern risk assessment practices we can be much more specific and

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				That we are entering a new phase – we have improved assessment, how can we improve management	individualised
Ordinary risks and accepted fictions: how contrasting and competing priorities work in risk assessment and mental health care planning	Michael Coffey PhD RN,* Rachel Cohen PhD,† Alison Faulkner MSc,‡ Ben Hannigan PhD RN,§Alan Simpson PhD RN and Sally Barlow PhD (2017) England and Wales	Cross national mixed methods study	'contrasting' priorities of patients and staff Staff wish to engage with patients and families but are fearful that frank discussions about risk will damage these relationships Staff do not consider social/environmental context, only risk coming from the person, are risk 'averse' and only concerned with procedural aspects	Focus on risk detracts from recovery approach – can limit liberty whilst simultaneously trying to protect them Workers are fully aware this is happening however What families want is a firm management plan (who to contact and a prompt response) 'Accepted fictions' – we all know it is flawed but follow this path anyway Overt control using mental health legislation and covert control using un-shared risk assessment procedures Uses neoliberalism vs restrictive practice argument	Surmises that all patients are fully insightful and 'want to be safe' at all times – relate this to acute patients and those antisocial/violent/drug using patients – is this true for them? Idealistic and sometimes not clear for staff how much responsibility can patient accept for risk.
Risk Assessment in Mental Health: Introducing a Traffic Light System in a Community Mental Health Team	S. Croucher and Graham R. Williamson (2013) UK	Action research using focus groups and qualitative data collection	Discussing the benefits of introducing a 'traffic light' system for high risk, medium and low risk patients Involved staff members in focus groups examining the feasibility of a proposed TLS	Traffic light systems are easy to understand, easy to implement and are cost effective Teams may assess risk differently as they are made up of individuals from different cultures, races,	Opposite of previous study in its simplicity – using SPJ and team approach to risk assessment Previous study looked a lot at forensic patients and offenders whereas this study focused on community

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				ethnicities etc.	mental health where supervision occurs far less - highlighting difficulties in establishing same risk assessment/management procedures across all mental health services
From Hero of the Counterculture to Risk Assessment: A Consideration of Two Portrayals of the "Psychiatric Patient"	Cummins (2016) UK	Comparative thematic analysis of two famous fictional portrayals of psychiatric patients – related to development of risk management strategies	That the ideals of 1960's 'counterculture' relating to the care and treatment of marginalised society never materialised with the advent of 'community care' Asylums have just been reproduced in community settings (community hostels, homelessness, prisons, housing estates etc.) The staff in cuckoos nest were controlling and heartless – in contrast staff in the modern novel are tired, resigned and focused on bureaucracy and managing risk		Comparisons with accepted fictions work by Coffey in that both staff and patients 'go along' with risk management 'game' despite serious misgivings about its effectiveness and worthiness Was it easy to worry about civil rights and dignity before patients began living on our doorsteps? Quite a bleak view of current services - isn't necessarily all negative Is our education in relation to institutionalisation wrong – we have community care but does this still takes place just in peoples homes, hostels, on the streets etc
Improving risk management for violence in mental health services: a multimethods approach	Coid, JW; Ullrich, S; Kallis, C; Freestone, M; Gonzalez, R; Bui, L; Igoumenou, A;Constantinou, A; Fenton, N; Marsh, W; Yang, M;	Multi-methods international research – very large study incorporating a number of sub-studies	A) Anxiety, ASPD, drug/alcohol misuse strongly linked to violence. Depression, ASD and psychosis 'unrelated.' Socioeconomic deprivation linked to violence in young men. Higher intelligence	Future risk management needs to combine actuarial and dynamic factors. Challenge to find causal factors and not just predictors continues	Highly statistical, very difficult to understand in lay terms – writers themselves note time and training difficulties in establishing new systems Study highlights sheer

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	DeStavola, B; Hu, J; Shaw, J; Doyle, M; Archer-Power, L; Davoren, M; Osumili, B; McCrone, P; Barrett, K; Hindle, D; Bebbington, P (2016) UK		'protective' factor B) Violence easier to predict in females as opposed to males with first episode psychosis. Mental illness more strongly associated with violence in females	Proposing use of 'Bayesian networks' to assess and manage risk	number of actuarial tools available
Survey of mental health nurses' attitudes towards risk assessment, risk assessment tools and positive risk	Downes, Gill, Doyle, Morrissey, Higgins (2016) Ireland	Survey of nursing attitudes about recovery, positive risk taking and risk assessment using anonymous feedback	Majority felt that risk assessment was a personal responsibility and not just 'fulfilling' an organisational task Majority were in favour of actuarial tools to back-up decision making, however conflict arose at times in relation to 'mechanical' nature of tools and preventing therapeutic relationships, their being too generic and possible restricting freedom when recovery approach suggests the opposite Majority positive about 'positive' risk taking but acknowledge the competing demands of safe patient care whilst respecting autonomy whilst protecting themselves and their organisations from liability claims etc.	Organisations should continue to promote recovery and positive risk taking Allowing staff to be at ease with allowing positive risk and support their concerns about 'personal, professional and public accountability' Limit the idea that 'instinct' is preferable to SPJ	How do organisations go about mending the dichotomy between positive risk and accountability? We seem to be moving even further away from this goal from organisational perspective – difference between what's written and reality for staff
Risk assessment and absconding: Perceptions, understandings and responses of mental health nurses	Grotto, J., Gerace, A., O'Kane, D., Simpson, A., Oster, C. & Muir-Cochrane, E.	Semi-structured interviews with 11 mental health nurses	Discussed nurses views and feelings about risk assessment/management and patients absconding Discusses how nurses tend to rely on containment methods to address risk of absconding (locking doors,	Balancing risk of preventing absconding with patients rights Consideration of recovery approach	Exemplifies the difficulties nurses face in considering risk and trying to maintain therapeutic relationships with patients and climate of blame

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	(2015) Australia		medication, close observations etc.) Nurses used own judgement as actuarial tools for assessing absconding risk not present Nurses can experience a great deal of anxiety dealing with absconding risk and if/when it does occur - Coroners court - Bothering police - Being blamed by management - Feeling negligent	More consideration of why patients abscond than merely trying to contain it Having awareness of the counter-arguments for risk containment methods (increased risk to patient and others of jumping fences, breaking doors etc. in absconding example)	Focus on risk appears to have made it much harder for nurses, in particular, to use their discretion in areas such as locking of ward doors. Discretion arguably linked to maintaining of therapeutic relationships
Documentary analysis of risk-assessment and safety-planning policies and tools in a mental health context	Agnes Higgins, Louise Doyle, Jean Morrissey, Carmel Downes, Ailish Gill and Sive Bailey (2016) Ireland	Documentary analysis of risk and safety management policies across Ireland	Wide variation in tools/definitions used Missing risk categories (e.g. harassment, victimisation) and focus on violence/suicide/self-harm Positive risk and patient/family involvement absent Lack of validated tools and not enough use of discussion between nurse and patient to accompany 'tick-box' approach utilised	Managers in mental health to be aware of these shortcomings and address them Importance of risk plan following risk assessment Strategy to pilot the same risk 'tool or template' across all parts of the country Negative risk language can 'alienate patients'	If certain tools are validated for 'specific service user groups' this creates difficulty for acute admission wards with huge variety of patients to care for (e.g. older adult, adolescent, substance misuse etc etc. Could be difficult to establish one risk template
There is more to risk and safety planning than dramatic risks: Mental health nurses' risk assessment and safety-management practice	Agnes Higgins, Louise Doyle, Carmel Downes, Jean Morrissey, Paul Costello,Michael Brennan and Michael Nash (2016)	Self-completed survey of mental health nurses in Ireland	Nurses continuing to focus on violence suicide and self-harm and not iatrogenic risks or physical risks Not creating safety plans another criticism Staff on wards and in community	As previous study with addition of education in risk management at undergraduate and postgraduate levels	Issues with lack of 'care co-ordinator' approach in Ireland where these issues of positive risk could be more easily addressed – sometimes a case of engaging someone first before really exploring risk fully and openly

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	Ireland		settings differed on risk focus (wards=containment, de-escalation vs community=social, family context) Lack of service user/family involvement – staff not wishing to address issues with patients for fear relationship will be affected, meds compliance affected etc. Lack of positive risk focus Staff requesting greater education around use of tools and positive risk taking		(e.g.drug/alcohol use, speaking frankly to family etc.) The crisis management nature of acute wards make the shared care/risk planning approach difficult at present Creating risk plan might not always be immediate given stages of health status (acute, recovering, stable etc)
Risk assessment practice within primary mental health care: A logics perspective	Flintoff et al. (2018) UK	Analysed telephone interviews assessing risk	Risk assessment 'Base rate' problem with actuarial methods of risk assessment (low rate of these occurrences amongst the general public makes them difficult to predict) Risk assessment exists and is wholly accepted not because of the science/evidence behind it but because it serves a social function (in response to major public concerns) Secondary risk assessment exists (Power, 2004) where professionals manage their own risks. As such we become 'experts' in defending reputation and use of admin practices Clients only presented as risks not people Admin processes detract from clinical judgement The problems with risk assessment	Problems with risk assessment need to be examined internationally At present, we spend time protecting ourselves (managing our own risks) and the service by carrying out assessments where patients tell us that they present no risk	Written from psychoanalytic viewpoint making it difficult to follow at times General points reflect other literature so far particularly that risk assessment is used to reassure and placate as opposed to really helping and is an 'accepted myth'

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			remain hidden		
The impact of risk management practice upon the implementation of recovery-oriented care in community mental health services: a qualitative investigation	Holley et al. (2016) UK	Semi structured interviews with staff and patients	Difference between what professionals feel and say about recovery and risk and what actually happens as a result of risk averse culture we work in Similarly patients do not truly feel that risk management is shared but that they need to go along with conditions set by professionals	More guidance at policy level for implementing 'roc' and 'rmp' together More support at clinical level due to risk aversive culture	Demonstrating the gap between policy guidance and reality – some way to go to fully realise recovery IS recovery like risk becoming another thing we 'do' to patients rather than with them?
Is risk assessment the new clinical model in public mental health?	Holmes (2013) Aus	Opinion/review	Anxiety created in health professionals due to level of public expectation about preventability Risk assessment can create more anxiety rather than reduce it due to fear of coroners court etc. Neither unstructured assessment, actuarial methods or SPJ are evidence based (or are too difficult to test statistically) Any litigation defence extends well beyond a risk assessment form Over-focus on risk affecting clinical care; wrong use of risk to prioritise or refuse care; risk assessment sometimes separated from rest of assessment Pychiatrists end up just dealing with risk (don't have the capacity for this role) Concern re defensive practices and	Attention to risk as it arises – discussing and documenting the management plan and the arguments for and against – rather than focusing on magnitude of risk However, to some extent, we all have to work within the organisational understanding of risk	Makes good point about lack of evidence for risk assessment and a risk assessment form not telling us everything about the patient - yet we still pursue this route Aus paper but could easily apply to UK and Ireland Consultants seem to be burdened with risk management – deflecting from using their skills in the best way?

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			burnout		
Aggression in Psychiatric Wards: Effect of the Use of a Structured Risk Assessment	Hvidhjelm et al (2016) Denmark	Evaluative study to see whether a risk assessment tool (BVC) could reduce frequency of patient aggression	Estimated reduction in violent incidents of up to 45%	Lacking statistically significant reduction in violence Issues with carrying out research across many wards (all different in terms of staff, levels of ill health, management etc.) Many wards declined to involve themselves in research	Highlights difficulty in 'proving' interventions when trialled across many different and independent areas (too many mitigating factors) Many wards/areas likely to be quite cynical about risk assessment tools (too busy, too much focus on risk, lacking evidence etc.) See ambivalence in Kaunomaki
Interventions following a high violence risk assessment score: a naturalistic study on a Finnish psychiatric admission ward	Kaunomaki et al (2017) Finland	Study to see how many risk management strategies were used following initial risk assessment (on the basis that many staff feel the results of these assessments are not used properly)	PRN meds came top followed by seclusion and then focused discussion with a nurse Daytime activity came low but highest in terms of reducing perceived risk of violence Hardly anyone mentioned OT, social worker, psychology or psychiatrist input as helpful interventions	Non coercive approaches need to be used more (these have most impact in reducing perceived threat) Nurses need to be able to utilise other MDT members in using interventions to manage violence risk	Is actuarial risk assessment required if main interventions available are prn medication and seclusion? (both could be deemed more reactive rather than proactive approaches)
Violence Risk Assessment and Management in Outpatient Clinical Practice	Kivisto (2015) (USA)	Literature review in relation to violence risk in outpatient settings	Risk needs to be assessed and managed dynamically Risk assessment has not historically focused on protective factors with equal weight as risk factors	Recommends that all cases receive the same violence risk approach Assessment of risk and protective factors Assessing of patterns in	US example not easily transferable to Europe (access to weapons, more strict duty to protect) Forensic services in USA warned away from wearing '2 hats' of law enforcer and

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				previous violent incidents Where person has avoided violence protective factors should be considered	therapist What about other risks beyond violence?
Legal, Regulatory, and Risk Management Issues in the Use of Technology to Deliver Mental Health Care	Kramer et al (2014) (USA)	Opinion/information piece looking at risk management considerations related to mobile health apps and social networking	In terms of clinical risk areas covered include: Informed consent Security and privacy considerations Plan for dealing with technical, medical and clinical emergencies Telecare can be managed safely in the home Concerns about data going missing via mobile health apps Concerns about the accuracy/safety of advice guidance offered (anyone can create an app)	That risks involved in telehealth can be managed effectively and that potential benefits equal the risks (e.g. rural communities, disability, avoiding stigma) Some feel that telehealth will become the default standard of care for all patients regardless of these issues	USA paper A lot of detail about insurance/governance issues, loss of data, privacy issues and avoiding litigation Appears to be less concern about clinical 'damage' that could be caused A lot of guidance refers to having a 'local' person on hand to deal with crises, technical matters etc. How far, realistically, is mental health care going to move away from traditional face to face appointments? Especially in respect of managing risk and BEING SEEN to manage risk by authorities Home based telehealth can be positive in terms of risk (person not impacted by others, can maintain independence etc.) but exacerbate risk (lack of supervision, self-neglect, isolation etc.)
The relevance of the	Large (2013)	Review taking historical look at	Compares risk assessment to	Limitations of probability	Makes interesting point

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early history of probability theory to current risk assessment practices in mental health care	Australia	probability theory and relating this to modern risk assessment practices	insurance business (these companies don't try to pinpoint individuals but 'group' risks – clinically we group in high and low risk categories Concentrating on one risk only not helpful (e.g. violence) and can be detrimental (suicide risk ignored or locked on ward/restricted etc.)	theory can be equated with limitations in clinical risk assessment Risk assessment is often about modifying our initial beliefs Suicide and homicide so rare as to be 'non-computable' Actuarial risk not set up to deal with multi-risk	about probability of self-harm contrasting with low probability of violence and vice versa – makes management plan quite difficult - can be compared with inpatient wards unknowingly reducing risk of self-harm (e.g. locked ward) but increasing risk of violence Risk assessment takes cues from probability theorists (these theorists never claimed to be able to predict particular outcomes)
Suicide risk assessment among psychiatric inpatients: a systematic review and meta-analysis of high-risk categories	Large et al. (2017) (AUS)	Review and meta-analysis of suicide risk assessment for high risk categories		Suicide risk models not suitable for clinical decisions Many high risk patients do not suicide and many low risk do – therefore interventions for preventing suicide should not be addressed solely towards high risk categories On many occasions we are not relying on probability but what the person is actually saying	
Risk Assessment: A Reflection on the Principles of Tools to Help Manage Risk of Violence in Mental Health	McCallum and Eagle (2015) (AUS)	Literature review focusing on violence risk assessment tools	Actuarial tools cannot pinpoint exact incidents but merely place clients into high risk groups. They should not be seen as dictating clinical practice, as solely deciding on involuntary detention, to solely prevent deaths Risk assessment should not be seen as aiding the prediction of future	Author argues that just because critics of risk assessment point to failure of RA in preventing deaths – this does not mean it is not helpful – we should not be thinking of RA as just predicting an preventing	We need to be using tools because they are helpful not because this is the likely outcome of any serious incident inquiry Staff, patients, carers and the wider public need to be aware that just having a risk

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			violence but as a first step Setting up a RCT on risk management for high risk patients would be unethical given that the high risk control group would not get necessary support	deaths Risk management of 'high risk' groups should be the outcome not prediction	assessment serves little purpose Really reflects the shift from risk assessment to management
Care zoning in a psychiatric intensive care unit: piloting a model of care in clinical risk assessment	Mullen et al (2014) (AUS)	Pilot study of care zoning on a PICU – involving an audit and staff questionnaires	Proposing use of a 'traffic light' model of risk into high, medium and low categories. Also proposes use of 'protected' one to one nurse time where required	Introduction helped to improve risk documentation but not necessarily the implementation of strategies to manage risk Protected time not adhered to – nurses busy with other admin tasks etc. Concept of protected time misunderstood to mean spending time close to patient as opposed to being available (e.g. may not be clinically helpful to interact continuously with some psychotic patients)	Demonstrates difficulty of introducing new but well-meaning concepts to some clinical areas, particularly where staff already feel overburdened Easy to categorise risk but then what happens with those areas identified? What are the clinical interventions? We hospitalise to reduce risk but also increase risk by this act – same for inpatient ward to PICU?
Moderators of the predictive efficacy of the Historical, Clinical and RiskManagement-20 for aggression in psychiatric facilities: Systematic review and meta-analysis	O'Shea et al (2013) (UK)	Systematic review and meta analyses of predictive efficacy of the HCR-20 (aggressive behaviour)	Stronger effect sizes amongst those diagnosed with schizophrenia as opposed to personality disorder Stronger effect sizes amongst women and Caucasians Significant predictive effect but not across all categories/groups	The tool definitely helps to predict aggression but has not be shown to reduce the occurrence of aggression More predictive efficacy research needs to involve more diverse populations	Again the management of risk needs to follow assessment otherwise the process is futile Are small effect sizes for physical aggression down to 'preventative success' or false

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			(diagnosis, gender etc.)	Static and dynamic risks need to be identified together. Static variables alone are not necessarily predictors of risk	positive prediction Tools mainly used in forensic areas – application to general psychiatry? Used mainly to predict risk on release/discharge from forensic institutions Are tools to be judged by how well they predict or meaningful reductions in aggression – how do we know that use of the actuarial tool is the reason?
A multifaceted model for risk assessment of violent behaviour in acutely admitted psychiatric patients	Roaldset et al. (2012) (Norway)	Naturalistic study examining whether use of three risk assessment tools (physical screening, self-reported and violence risk assessment) helped to predict violence	Multifaceted risk assessment appears to be more effective than violence risk assessment alone More accurate predictions means less 'false positives,' where patients are unnecessarily detained	Large amount of variables in play when assessing efficacy of such models for predicting violence - Does violence get reported? - Patients not self-reporting - Too much variation in acute psychiatry "However, understanding and assessment of violence risk will remain limited if they are conceptualised as caused by or related to only a single aetiology"	Asks whether a 'ceiling' has been reached in developing risk assessment tools or whether there is benefit in biopsychosocial approaches to assessing risk So little is known about many of the patients admitted to acute psychiatry – difficult to obtain histories etc. as compared to forensic settings. Also forensic settings have legal obligations (involving the legal system) to predict future offending (or risk of violence etc.)
Mental Health Professionals'	Roush et al (2018)	Self-report questionnaires completed by staff around the	30% of respondents only asked about	More research to explore why staff feel uncomfortable	Despite extensive training – actual suicide prevention

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Suicide Risk Assessment and Management Practices	USA	area of suicide risk assessment and management	suicide some of the time Fewer than half were able to cite evidence based strategies to reduce risk of suicide Large variability/inconsistency in utilisation of risk strategies Staff fear of suicide does not impact on usage of evidence based assessment and management (EBAM) Fear of suicide is a normal reaction and may not be related to training needs or ability to implement EBAM If staff are 'comfortable' working with suicidal patients, they are more likely to implement EBAM	working with suicidal patients – to increase consistency	training is not always provided for mental health staff Difficult to estimate the effect that suicide can have on staff (sometimes the only professional working with an individual) and managing risk (can create positive and negative outcomes?) Where is the human element? Difficult to deal with risk of suicide in such a systematic/formulaic way – leading to inconsistencies?
Safety in psychiatric inpatient care: The impact of risk management culture on mental health nursing practice	Slemon et al (2017) (Canada)	Review examining risk culture's effect on mental health nursing	We assume that we (system) can cause harm in general nursing areas (meds errors, handover errors) but in mental health it is solely the patient that creates risk through their own actions Risk extends to staff, other patients, themselves and the general public Safety was a the heart of the 'institution' and remain so today in the guise of 'containment' Risk management strategies are seen as even more justifiable when considered 'treatment' Nurses end up in contradictory bind of not supporting seclusion but feeling	Discourse of safety in mental health is all about the identifying and managing the risks posed by patients Dominance of this means we are not seeing the harmful nature of some nursing practices (e.g. seclusion; locked doors etc.) Nurses should have more control and autonomy to be 'flexible' with risk and 'bend the rules' where deemed therapeutic (and not just saving nurses time) Equal attention needs to be given to therapeutic	All well meaning but nurses cannot attain these recommendations alone (requires organisation, governments, the media and the public to change thinking on mental health and risk) Constant fear is of public inquiry or coroner or being blamed Can a comparison be made with other outside organisations in terms of mechanisation and automation – one non flexible approach – dynamic human interaction replaced with 'one size fits all' safety

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			that a patient is not being 'treated' or that the environment is not safe unless it is utilised Same for locked vs unlocked wards (patients absconding vs increased risk of violence) Nurses feel 'powerless' to be effective (e.g. interpersonal skills) within a 'system' based on 'safety' Strategies to deal with risk to self (constant obs) ; risk to others (seclusion) and risk to the public (locked doors) are based on safety discourse Fear of blame and litigation amongst staff leading to 'defensive' practices (by their nature non-therapeutic)	engagement – safety cannot be the only priority There needs to be more sharing of responsibility as nurses are fearful they will not be supported or will experience recrimination	approach Unprecedented level of scrutiny paid to safety measures over everything else and nurses in the cross-fire
Risk Assessment in Mental Health Care: Values and Costs	Szmuckler and Rose (2013) (UK)	Review/opinion concerning current thinking on risk	Risk assessment involves a 'trade off' with costs attached Public concern around risk is not rational, straightforward or even based on evidence (e.g. risks associated with plane vs car journeys) Some risks associated with 'moral outrage' (e.g. terrorist attacks) – violence perpetrated by those with mental illness creates 'moral outrage' and the aftermath such as public inquiries reflect this thinking where someone must be to blame Questions whether we can learn anything from post incident inquiries where general recommendations are	Resources to resolve issues of risks go way beyond what services can do Public engagement required Population level interventions (drug and alcohol interventions, parenting etc.) Staff need to take back control and consider how much they should let the risk agenda affect professional practice	Ties together points about the isolation of mental health staff and the wider approach required How did we arrive at this point considering lack of evidence ? (in climate of everything being evidence based) Moral outrage is dynamic (leaves mental health and returns periodically) How much if current thinking on risk is to placate and satisfy public demand for 'safety' and general

			made to very complex and highly individual situations A significant amount of UK mental health staff have little faith in risk assessment other than necessary 'bureaucratic/defensive' purposes – not helped by lack of evidence associating risk assessment with reduced untoward incident statistics No one RA tool outperforms any other – furthermore base rates for violence in general psychiatry make PPV and the application of instruments impractical Instruments need to consider particular settings and provide details of 'missed' adverse outcomes Serious violence is rare and therefore not statistically predictable – could be replaced with term 'uncertainty' but would the public be happy with this? Easier for the organisation to use the term 'risk' instead In the past dangerousness may have been noted post incident – now it is pre and post incident widening scope for applying culpability Effective treatment may be undermined by the process of risk assessment (affecting patient trust in services) Process of risk 'colonisation' (supervisor to understudy, manager to supervisor etc etc.) where focus is risk		confidence in public (are we in fact leaving the public hoodwinked?) Selling something to the public that we actually don't believe in ourselves The performance of and confidence in actuarial tools lost in statistical jargon that most cannot understand Culture of risk now normalised and endemic throughout mental health

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			management and not actual clinical practice It is discriminatory to believe that people should be risk assessed just because they are mental health patients when there is no evidence that they pose a greater risk (e.g. for violence) than the general population Also discriminatory for the public to only consider false negatives (those missed) and not the false positives (those incarcerated for example)		
Can electronic monitoring (GPS 'tracking') enhance risk management in psychiatry?	Tully et al (2014) UK	Editorial review examining the use of electronic monitoring in forensic psychiatry	Aim was to increase public protection Introduced in 2010 No patient obliged to wear one Used in the early stages of leave to facilitate return to the community Already used in dementia and could be compared with other tech developments (smartphones and mood monitoring – telepsychiatry etc.) Clear ethical issues incl. concerns about "21st century shackles" and other human rights issues Should be balanced with positives though (more patient autonomy; quicker return to the community etc.)	Needs to be thoroughly examined and researched – still a very new area Technology likely to improve in the future Should only be as part of a wider care plan	Awareness that the article refers to forensic psychiatry and not general adult Risk of coercion down the line though – i.e. "you can go home/on leave but only if you agree to electronic monitoring Then becomes the norm where all patients are monitored electronically – formal assessment of risk would have been considered unusual once upon a time Also risk of services getting criticised post-serious incidents for not using it if it is widely available Is this the next step after compulsory treatment orders (e.g. monitoring 'kicks in' if patient goes past due date

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					for meds administration) If worn with informed consent – are there benefits? (e.g. freedom away from highly charged inpatient ward – less stimulus for violence?) Ultimately would not prevent patient from harming themselves or others
Investigating the Evidence for the Effectiveness of Risk Assessment in Mental Health Care	Wand (2012) Aus	Lit. review examining effectiveness of risk assessment	Little overall evidence that it reduces risk to self or others Culture of blame; coercion; poor patient engagement; organisation and not patient centred; Despite efforts to educate public – fear amongst public continues to drive policy SPJ more successful than other approaches according to evidence Poor evidence for association between psychosis and violence once drug use and psychopathology are removed from equation Cites link between severe mental illness and social deprivation in terms of violence risk Predicting suicide is even more difficult – risk is too dynamic. Also low prevalence of suicide makes prediction virtually impossible	Mental health legislation needs to be changed – invol treatment only as a last resort and short duration Risk and recovery are conflicting areas More focus on strengths needs to take place - protective factors, coping skills etc. Suggests use of solution focused therapy	Also mentions by trying to reduce staff anxiety it creates a great deal more (form filling etc.) Also points out the flaws in actuarial tools (only prediction not management) and the misuse of primarily forensic tools in general settings No NICE guidance on best actuarial tool to use RCP warning against risk in 2008 – but does not appear to have changed anything Something nobody wanted but now a significant aspect of standard care Seems to acknowledge need to review risk but not at expense of all other areas

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Surveying clinician perceptions of risk assessment and management practices in mental health service provision	Wand et al. (2015) AUS	Survey of mental health staff perceptions	Considerable agreement that risk assessment is necessary Respondents felt confident in their ability to judge Respondents felt under pressure to comply with organisational directives but felt supported 65% felt that there was good evidence for risk assessment/management practices	Author concerned that staff are misinformed – suggesting managers have a duty to provide staff with real evidence for risk practices	Basically disagrees with the respondents and wonders are they victims of misinformation - comparisons with Brexit? ie people who want to leave must be misinformed/stupid Staff reportedly ignoring evidence but author ignoring the evidence that many staff feel it is helpful
Risk assessment and management approaches on mental health units	Woods (2013) (Canada)	Exploratory study (focus groups) of selected mental health units in Canada and how risk assessment and management is used	Risk assessment not considered as a whole process (assess, manage etc.) Mainly carried out by nurses and psychiatrists Risk assessment tools used inconsistently Staff concerned re legal ramifications of using or not using tools Reactive or crisis intervention risk management highlighted (meds, seclusion etc.) Little consideration given to involving patients in managing risk Staff highlighted issued with consistency and different thresholds for managing risk	Reliance on clinical judgement alone not recommended Needs to be a whole process otherwise becomes reactive approach More staff training required More patient involvement required	Suggests more of an MDT approach required Seems to demonstrate staff awareness re need for assessment but again lacking management plan Thresholds amongst staff may be different in different areas, units etc. Always likely to be an issue in the same way as individual and diverse nature of risk amongst patients

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			Lack of training and resources		
Patient perspectives of helpful risk management practices within mental health services. A mixed studies systematic review of primary research	Deering et al. (2019) England	Looking at patient views in relation to risk management	Joint decision making is part of policy advice Risk should also include positive elements of taking risks to improve lives Removing coercive practices (restraint, seclusion etc.) requires patient involvement When patients can become more involved better practices emerge Openness and exploring risk helpful Bringing in patients ordinary lives to the risk context helpful Disagreements need to be acknowledged but discussion and openness better than ignoring or bypassing Importance of involving friends and family	Risk management more observable and more inclusive	We sometimes do not want to discuss risks with patients (e.g. violence) and sometimes families do not want us to discuss risks either Risk assessment often takes place without any knowledge on the patients behalf The relationship can feasibly be improved by being open and honest re risks Peer support may be helpful where staff are conflicted by patient vs public safety scenario
Evaluation of an alternative model for the management of clinical risk in an adult acute psychiatric inpatient unit	Harrington et al. (2019) (AUS)	Evaluation of a new risk management strategy (basically replacing close observations with frequent engagement and individual risk management plans) on an acute admission ward and its effect on adverse incidents	Introduction of new procedures reduced occurrence of serious incidents		Risk management approaches that engage more with patients have potential to reduce serious incidents Links with previous paper acknowledging need to engage more with patients

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					Comparisons with traffic light system and strict risk management plan for each category Difficult to maintain given level of dynamic as opposed to static risk, staffing levels etc.
Positive risk taking: Whose risk is it? An exploration in community outreach teams in adult mental health and learning disability services	Robertson and Collinson (2011) UK	Interviews with staff examining experiences of working with positive risk	Risk can be perceived as either a danger or a positive opportunity Staff often do not feel supported by their organisations in terms of positive risk taking (only focusing on narrow definition of risk) Staff acknowledged that organisations need to act in the public's interest and maintain public confidence (sometimes wrongly informed by the media) Risk has to be considered from person, patient, organisation and public perspectives Coercion inadvertently arises as a result of conflict between "support" and "control" Staff unsure to what degree they should pursue positive risk approach Staff can have very different perspectives on risk taking creating inconsistencies Risk assessment tools best used to pinpoint positive risks as opposed to	In recovery approach, risks should be minimised where there is potential for 'personal harm' but otherwise should be left for service users to experience Cites need for balance between safety and opportunity	Is there not potential for harm in every risk? Stopping meds Getting a job

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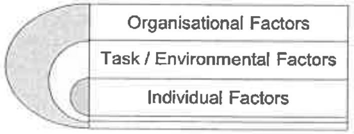
			negative risk (citing failure of risk assessment tools in predicting rare events)		

Appendix 10 Patient Safety Incident Response Framework Contributory and mitigating factors classification

Patient Safety Incident Response Framework

Contributory and mitigating factors classification – Print only in A3



External context factors	Components
National guidelines and policies	• Impact of national policy/guidance (DHSC/professional colleges, etc) • Locum/agency policy and usage • Contractor related
Economic and regulatory context	• Service provision • Bed occupancy levels (opening/closures) • Private finance initiative related • Equipment loan related • Financial constraints • Resource constraints
Societal factors	• Values • Beliefs

Organisational and strategic	Components
Structure	• Hierarchical structure (discussion, problem-sharing, etc) • Roles, responsibilities and accountability • Multidisciplinary working • Clinical/managerial approaches • Maintenance • Service-level agreements/contractual arrangements • Safety terms and conditions of contracts
Priorities/resource	• Safety focus • Finance focus • External assessment focus • Workforce resource management • Estates and technology resource management
Safety culture	• Safety/efficiency balance • Commitment to safety • Openness of culture and communication • Risk tolerance • Approach to escalation of concerns • Leadership response to whistleblowing
Policy, standards and goals	• Organisational processes (formal) • Organisational processes (informal) • Processes between/spanning organisations

Operational management factors	Components
Safety focus	• Rule compliance • Dealing with risks from past incidents • Awareness of current practice • Adherence to current practice • Empowerment of staff to act
Work planning and delivery	• Risk management plans • Scheduling • Incentive schemes • Contingency planning
Staffing levels and skill mix	• Skill mix • Staff to patient ratio • Workload/weighting/dependency • Temporary staff • Staff turnover
Workload, shift patterns, hours of work	• Working hours • Work breaks • Workload (under/over/balanced) • Extraneous tasks • Social relaxation, rest and recuperation
Training design	• Training needs analysis • Training design • Training/education content • Targeted training • Style of delivery • Time of day provided
Training availability/accessibility	• Training availability/accessibility • Core skills training • On the job training • Emergency scenario training (skills drills) • Team training • Refresher training
Staff supervision	• Orientation • Personal supervision • Monitoring of supervision (assessment) • Mentorship
Staff competence	• Knowledge • Skill • Experience • Familiarity with task • Competence testing and assessment

Workplace factors	Components
Environmental factors	• Capacity • Fixture or fitting • Separation • Safety • Cleanliness/hygiene • Temperature • Lighting • Noise levels • Distractions (audio) • Distractions (visual) • Ligature/anchor points
Design of physical environment	• Work area design (eg size, shape, visibility, screens, space, storage) • Security provision • Lines of sight • Use of colour contrast/patterns (walls/doors/flooring, etc) • Space design (adjustable furniture, panic buttons, positioning, etc)
Administrative factors	• Administrative work systems • Administrative infrastructure (phones, bleep systems, etc) • Administrative support

Equipment and technology factors	Components
Displays	• Information/feedback available • Information clarity • Information consistency • Information legibility • Information Interference • Information displays (colour, contrast, anti-glare screens, etc)
Integrity and maintenance	• Working order • Reliability • Safety features (fail to safe, etc) • Maintenance programme • Emergency back-up services (power, water, piped gases, etc)
Positioning and availability	• Availability • Accessibility • Position/placement • Storage • Emergency backup equipment
Usability/design	• Controls • Intuitiveness • Use of colour • Use of symbols • User manual • Detectability of problems • Use of items which have similar names or packaging • Compatibility

Team and social factors	Components
Culture	• Approach to newcomers • Approach to adverse events • Approach to conflict • Approach to rules/regulations • Approach to seeking support • Approach to interprofessional challenge • Interpersonal relationships • Power relationships
Team structure and consistency	• Shared understanding • Familiarity • Mutual respect • Clarity of roles and responsibilities • Congruence of roles and responsibilities • Informal support networks
Leadership	• Clinical leadership • Managerial leadership • Leadership impact • Leadership decision-making • Timeliness of leadership action • Respect for leadership • Formal support networks for staff
Communication management	• Communication strategy and policy documents • Involvement of patient/family/carers in treatment and decisions • Communication of risks to patient/family/carers • Communication of risks to staff • Communication of risks to the board • Information from patient/family/carers • Communication flow to staff up, down and across • Communication with other agencies (partnership working) • Measuring effectiveness of communication
Verbal communication	• Tone of voice • Style of verbal communication delivery • Use of language • Specificity • Direction • Channel/route • Verbal communication aids/equipment
Written communication	• Readability • Accessibility/availability • Collated • Completeness • Contemporaneous • Accuracy • Currency • Circulation of written information • Patient identification • Information to patients
Non-verbal communication	• Body language/gestures/facial expression

Task factors	Components
Clinical condition	• Pre-existing co-morbidities • Complexity of condition • Seriousness of condition • Options available to treat condition
Plans, guidelines, policies, procedures and protocols	• Informative • Instructional • Representative • Routine use • Usability • Currency • Accuracy • Availability • Accessibility (ambiguous, complex, irrelevant, incorrect) • Monitoring • Review • Targeting/focus (ie audience)
Decision-making aids (information/results/ tools/machines, etc)	• Available • Accessible • Working • Accurate • For prioritisation of tasks • Access to specialist advice • Access to technical information, flow charts and diagrams
Procedural or task design and clarity	• Task complexity • Task memorability • Understandable • Agreed with staff (feasibility) • Time allocation • Task sequencing/stage sequencing • Workload (under/over/balanced) • Compatibility of tasks/task stages • Competing task demands • Feedback from the task • Transferability to/from other situations • Influence on task/outcome • Automation • Audit, quality control, quality assurance

Individual patient factors	Components
Physical factors	• Physical health/condition • Nutrition/hydration • Age related • Body mass related
Social factors	• Cultural/religious beliefs • Language/communication • Lifestyle choices • Life events • Living accommodation • Support networks • Social protective factors (relevant to mental health services) • Risk tolerance • Engagement/motivation/compliance/concordance • Interpersonal relationships (staff-patient; patient-family; staff-family)
Psychological factors	• Mental health • Mental capacity • Learning disability • Intent (relevant to mental health services)

Individual staff factors	Components
Physical health	• General health (nutrition, hydration, wellness, fitness) • Health related conditions (eg eyesight, dyslexia)
Psychological/mental health	• Mental health • Mental alertness • Motivation level (boredom, complacency, low job satisfaction)
Social domestic factors	• Domestic (family related) • Lifestyle (financial, housing, etc) • Language
Personality factors	• Confidence • Risk awareness/risk tolerance
Social factors	• Motivation and values • Beliefs and expectations • Attitudes • Habits
Cognitive factors	• Focus/attention • Perception • Reasoning and decision-making • Group influence • Workload (underload/overload/well-balanced)

Appendix 11 The Adapted Organisational Accident Causation Model

Factor types	**Contributory influencing factor**
Patient factors	Condition (complexity and seriousness) Language and communication Personality and social factors
Task and technology factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results Decision-making aids
Individual (staff) factors	Knowledge and skills Competence Physical and mental health
Team factors	Verbal communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership etc.)
Work environmental factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support Environment Physical
Organization and management factors	Financial resources and constraints Organizational structure Policy, standards and goals Safety culture and priorities
Institutional context factors	Economic and regulatory context National health service executive Links with external organizations

Framework of contributory factors influencing clinical practice (Taylor-Adams and Vincent, 2004)

Appendix 12 Chart review protocol

Procedural manual for data collection

Chart review

- Type, date, year, month, day and location of incident to be obtained via the selected sample database of incident reports
- Locate the chart for each patient identified in the sample
- Using the chart, find the date and record the time where the incident in question took place
- Examine the common assessment tool (CAT) (a comprehensive assessment document completed for every patient seen in mental health services locally). Where there are multiple assessments, select the one closest to the date and time of the incident. Obtain details of gender, age, MHA status (voluntary patient/involuntary patient/not applicable), ethnicity, diagnosis and length of time known to services
- Examine the risk assessment tool (Sainsbury risk assessment form within the common assessment tool) for details of previous risk (violence, self-harm, suicide, alcohol/substance misuse)
- Examine the patient progress notes for details of admission lengths (where applicable)
- Examine typed correspondence within the chart (letters, summaries) if any details missing from CAT, risk assessment and progress notes

If the chart is missing or incomplete:

- Access patient information section of the patient information management system (standardised data relating to patient demographics)
- Access inpatient ward stay information in the patient information management system (dates of admission and lengths of stay)
- Access electronic patient correspondence folder (GP letters, correspondence and patient summaries that are duplicates of those stored in patient charts)

Appendix 13 Power analysis: determining sample size

Purpose:
The purpose of this paper is to re-evaluate a sample required in order to provide the study with 80% power, as is typically minimally required. A 5% level of significance shall be employed, and G*Power Version 3.1 shall be used for all calculations.

Scope:
This sample size calculation shall be employed for the Serious Incident Study data as provided by Neil Crowhurst.

Statistical Approach:
With Incident Type, a categorical variable, being the Primary Outcome Measure (POM) of this study, much of this analysis will require a chi-square test of independence. That is, to investigate the POM in the following ways,

- Comparisons between Waterford and Wexford;
- Comparisons between different clinical areas
- Comparisons between genders
- Comparisons between age groups
- Comparisons between years
- Comparisons between voluntary and involuntary patients
- Comparisons between diagnoses

a chi-squared test will need to be employed.

The Chi-square test for independence in a contingency table is the most common Chi-square test. Here individuals (people, animals, or things) are classified by two (nominal or ordinal) classification variables into a two-way, contingency table. This table contains the counts of the number of individuals in each combination of the row categories and column categories. The Chi-square test determines if there is dependence (association) between the two classification variables. Hence, many surveys are analyzed with Chi-square tests.

Of note, before we begin, it is important to determine the "degrees of freedom" for the chi-square test. With n=8 groups, as suggested, the degrees of freedom are d=n-1=8-1=7.
For correlation measurements, a sample size will not be explored as it is assumed that the large sample sizes noted for the chi-squared test of association will provide more than enough power for correlation analysis. A justification for this can be found in Appendix 1 where minimum sample size is calculated as n=85.

Appendix 13 Power analysis: determining sample size

Effect size, w:

It is possible to make an a priori calculation of the minimum sample size required, using $n = \lambda/w^2$. For the χ^2 distribution, the values of non-centrality λ that correspond to significance level 5%, power 80% with degrees of freedom df (df = (Number of Columns -1)*(Number or Rows -1)), can be found in tables (Haynam *et al.*, 1970) or can be calculated using relevant software. For this analysis, we shall be using G*Power Version 3.1. The only remaining problem lies in providing a predetermined estimate of effect size that is significance within the framework of the hypothesis.

The determination of effect size (magnitude by which one would expect results to statistically significantly differ) could be achieved either through pilot research project or from previous related studies on the same research subject.,Cohen's convention can also be used in relation to what can be considered as a small, medium, or large effect size within the framework of Pearson Chi-square test of independence (Cohen, 1988).

Table 1: Cohen's convention of classification of effect size

Effect size	Classification
Small	$w = 0.10$
Medium	$1.0 < w \leq 0.30$
Large	$0.30 < w \leq 0.50$

An effect size, w=0.3 shall be employed for all analysis; that is, a medium effect size is expected. This can be amended if you feel this is unreasonable. A larger effect size (i.e. an expectation of seeing large differences between groups) would reduce the sample size required, while a small effect size (i.e. an expecting that the magnitude of differences shall be subtle) would result in higher sample sizes.

Sample Size Calculation:

Below, in Table 2, we outline the number of datapoints required for each analysis to assess against incident type.

Appendix 13 Power analysis: determining sample size

Table 2. Sample Size Recommendations

Comparison of Incident Type between:	**Sample Size recommendation for 80% Power**	**Total Degrees of Freedom (= (r-1)*(c-1))**
Waterford and Wexford	160	7
Different clinical areas	291	35
Gender	160	7
Age groups	238	21
Years	333	49
Voluntary and involuntary patients	160	7
Diagnoses	291	35

Conclusion:
For a study with 80% power, at the 95% confidence level, a minimum sample size of 333 randomly selected datapoints shall be required to explore all research questions above. Of note, the following assumptions have been made throughout this analysis:

- A medium effect size is noted. If a large effect size is expected, then there may be potential to reduce the sample size further;
- For the POM, eight (8) categories have been assumed for comparison;
- Sample sizes are large enough for correlative analysis. This seems reasonable as for even a weak correlation (with r=0.3), an appropriate recommended sample size is n=85 (See Appendix 1).

Recommendations:
A minimum sample size is recommended from this power analysis as n=333.

Appendix 13 Power analysis: determining sample size

References:
Cohen, J., 1988. Statistical Power Analysis for the Behavioral Sciences. 2nd Edn., Lawrence Erlbaum, Hillsdale, New Jersey, USA., ISBN: 0-8058-6283-5, Pages: 128.

Haynam, G.E., Z. Govindarajulu and F.C. Leone, 1970. Tables of the Cumulative Non-central Chi-Square Distribution. In: Selected Tables in Mathematical Statistics, Harter, H.L. and D.B. Owen (Eds.). Vol. 1, Markham Publishing Co., Chicago.

Appendix 1:

The standard normal deviate for $\alpha = Z_\alpha = 1.9600$
The standard normal deviate for $\beta = Z_\beta = 0.8416$

$C = 0.5 * \ln[(1+r)/(1-r)] = 0.3095$

Total sample size = $N = [(Z_\alpha+Z_\beta)/C]^2 + 3 = 85$

Appendix 14 Data Collection Form

A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East

Patient Data Collection Form (version 5)

Please review:

- *handwritten notes 7 days prior to incident occurring*
- *common assessment tool booklet (referring to specific episode only)*
- *risk assessment (referring to specific episode only)*
- *Any typed summaries/letters (referring to specific episode only)*

Incident type

- ○ Serious incident resulting in death
- ○ Self injurious behaviour
- ○ Physical aggression causing injury
- ○ Physical aggression - no injury
- ○ Verbal abuse/threats
- ○ Abuse of a sexual, physical, psychological or exploitative nature (incl. inappropriate sexual contact)
- ○ Damage to or aggression towards property
- ○ Near miss event that could have resulted in serious harm

Catchment area where incident took place

- ○ Waterford
- ○ Wexford

Gender

- ○ Male
- ○ Female

Year of incident

- ○ 2011
- ○ 2012
- ○ 2013
- ○ 2014
- ○ 2015
- ○ 2016
- ○ 2017
- ○ 2018

Clinical area of incident

- ○ Inpatient acute mental health (DOP)
- ○ Inpatient sub-acute mental health (DOP)
- ○ Inpatient rehabilitation/continuing care/step down area
- ○ Inpatient older persons area (65+)
- ○ Non residential day hospital/day centre/clinic etc
- ○ Other community location (home, public area, work placement etc.)

Month of incident

- ○ January - April
- ○ May - August
- ○ September – December

Day of Incident

- ○ Weekday

Appendix 14 Data Collection Form

○ Weekend/bank or public holiday

Time of incident

○ 0600-1200
○ 1200-1800
○ 1800-0000
○ 0000-0600
○ Unclear/unspecified

Age

○ 18-24
○ 25-39
○ 40-60
○ 60 and above

MHA Status

○ Voluntary
○ Involuntary

Ethnic/cultural background

○ White Irish
○ Any other white background
○ Black Irish
○ Any other black background
○ Asian Irish
○ Any other Asian background
○ Any other (incl. mixed background)
○ Not clear

Diagnosis

○ Schizophrenia/Schizoaffective disorder
○ BPAD
○ Personality Disorder
○ Depression and/or anxiety
○ Organic disorder/degenerative disease
○ Other diagnosis/mixed diagnoses (specify________________________________)

History of Alcohol/drug abuse

○ Yes
○ No

History of Aggression/violence

○ Yes
○ No

History of attempted suicide

○ Yes
○ No

History of self-harm

○ Yes
○ No

Length of stay

○ 0-2 days
○ 3-7 days
○ 8-28 days

○ More than 28 days
○ N/A

Known to services

○ 0-2 days
○ 3-7 days
○ 8-28 days
○ More than 28 days

Qualitative content analysis

What factors do you think may have contributed to the incident occurring? (max 5)

Think of these factors in the context of:

- ***The patient (e.g. level of illness, symptoms, alcohol/drug issues; personality etc.)***
- ***The staff (e.g. nurse/patient relationship, skill levels, close observations, level of verbal and visual contact etc.)***
- ***The organisation/environment (e.g. unit rules; locked doors, safety and security etc.)***
- ***External issues (e.g. unemployment, homelessness, family dysfunction etc.)***

1. ______________________________

2. ______________________________

3. ______________________________

4. ______________________________

5. ______________________________

Appendix 15 Data collection process notes

Data collection diary

March 2020

1. Met David Green in Lacken Kilkenny – assisted with using NIMS system to obtain database of recorded incidents – able to apply some inclusion exclusion criteria:
   -Description of incident
   -Mental health division
   -No child and adolescent service users
   -Behavioural hazards section only (self injury; violence, harassment and aggression; child and adult abuse)

2. Despite adding these criteria – database still had to be explored fully. Further cases were removed (out of catchment area; under 18's and non mental health (primary care, ID, substance misuse)

3. Further cases were removed after this process (Minus accidental OD; accidental injury; unknown injury; unintended choking; assault reported no evidence; self-harm reported no evidence; no description; duplicates). Many taken out as cannot be fully established what happened or whether anything happened at all. Additionally very difficult to prove whether self harm type incidents were intended or not – obviously a contentious area and indeed widely discussed in the literature). Little other option than take reports at face value otherwise exploring antecedents and causes when not warranted. Study of 'accidental' incidents and injuries another research study in itself?

April 2020

1. Covid restrictions commenced – impacting on staff availability in terms of setting clinical and public health priorities - ability to visit sites outside immediate workplace restricted
2. Had to quarantine for 3 weeks after positive test myself

June 2020

1. Pilot study carried out on 10 cases locally (within Covid restrictions)
   - Notes had to be obtained from archives in 6 out of 10 cases
   - particularly as research spreads from 2011-2018
   - last year being 2018 means that most notes archived
   - system in St Otterans not ideal – lots of notes still in boxes awaiting filing on shelves
   - building very old, dark and not easily accessible (damp, ceilings falling in etc.)
   - managed to find all but one set
   - most time consuming element was finding notes
   - quantitative data straight forward
   - changes to data collection tool made – added free text for diagnoses and most have more than one
   - added more incident types to include aggression towards visitors on inpatient units

Appendix 15 Data collection process notes

  - listing possible triggers limited to 5 (time, resources, higher number not required for pilot study)
  - ideally would have asked colleague to look at triggers to see if ideas match but not possible given resources, availability and limited access to files as a result of GDPR/consent declaration restrictions

2. Linked up again with statistician to discuss sampling issues (numbers and type of sampling from 2000+ recorded incidents)
3. Established contact in Wexford in preparation for medical record review particularly as most areas unfamiliar (relevant staff, notes storage, access issues etc.)
4. Data entered onto Excel spread sheet and qualitative data added to NVivo
5. Basic online guidance for NVivo utilised plus guidance in supervision re keeping personal notes about each entry made

July 2020

1. Ongoing discussion with statistician – clarified sample size calculation basing all results on incident type. Reduced number of incident types to bring down total sample size required. Advised to consider number of categories on some questions of data collection form to further reduce highest sample number. Advised to consider the hypothesised outcomes relating to each comparison area as these could limit need for large sample numbers

August 2020

2. Relooked at number of categories in each group – further reductions made in order to reduce sample size numbers. Final minimum of 352 from 2809 population. Discussed random sample generator (software). Used widely used and available randomizer.org.

September 2020

1. Database found to contain a number of staff names as opposed to patient names (raises issue of whether incident report should reference the victim or assailant where applicable – policy suggests that an incident report should be completed for both and indeed incident reports are generally collated separately) Research population reduced to 2423. 333 final minimum sample of casefiles required on recalculation.
2. Whilst notes in Waterford are archived locally the archive is not carefully maintained with many sets of notes yet to be filed, making the job of finding files difficult. Wexford archive contacted and permission granted to review notes – however these are old files dating back to 1950's. More recent files located in various places across Wexford.
3. With many sets of notes missing, qualitative record review not possible in every case. However, necessary quantitative data taken from old outpatient letters and discharge summaries (diagnosis; admission dates etc.) (available electronically on HSE G Drive using A number) and/or IPMS system. Issues pertaining to risk history (substance use, violence, self harm, suicide) not formally recorded electronically meaning some "don't know's" within these categories). Qualitative analysis does not necessarily require a statistical number of cases to achieve outcomes

4. Inability to find old records is a well documented outcome of such research. The number of casenotes not found will inform the overall research and subsequent HSE feedback report.
5. Some incident reports relate to the victim as opposed to the perpetrator of violence and aggression – raises issue of confusion when completing incident form (official line is one form for each person) and examining antecedents without perpetrator's details.
6. Diagnoses amended to include cognitive disorder which was overlooked before. Many patients with various diagnoses relating to dementia etc.
7. Added comments column to excel spreadsheet – at the end of collection the whole document can be uploaded to Nvivo
8. Running list of themes on word document

October 2020

1. IPMS commenced in 2013. Info on admissions/patients prior to this date available on older PAS system which is also accessible on HSE terminals using password details

November 2020

1. Asked 3 colleagues (nursing, OT and social work) to collect data on 3 cases from pilot study to compare reliability. 2 agreed, one had to decline for being a student and not being an HSE employee
2. Sometimes when patient notes not available there are relevant electronic notes – however these do not always relate to exact episodes – things like diagnosis or risk history not entered from older or newer summaries in case they have changed

January 2021

1. Encountered different system for filing older adult notes (by surname rather than A number) adding time to task of locating files
2. Wide range of areas where notes may be stored for older adults

February 2021

1. Discussed holding on Wexford charts in supervision due to COVID
2. 08/02/21 – 72 charts missing out of 178 in total – going back to DOP with missing list to check if any still stored there and not sent to archives yet

March 2021

Appendix 15 Data collection process notes

1. 179 incidents charted; 2 omitted; 68 missing charts in Waterford
2. Commenced Wexford data collection – made contact with ACNO and relevant administrator. Records kept in various areas. Beneficial to find helpful and informative member of staff
3. Extra ID requirements needed for unfamiliar areas/staff – letter obtained from NMPDU
4. Different patient ID numbers in Wexford and filed alphabetically – more organised and less files to manage

May 2021

1. Early completed Wexford patients. Files not stores centrally (should be but time constraints etc. prevent this). Meaning that files located in several different places (8 different locations) with an equal number of contact persons. Having familiar colleague in Wexford and support of management really helpful in accessing charts
2. Having central location not helpful if charts are just left there and not correctly archived, maintained etc. Might as well stay with the appropriate service/unit/ward/secretary
3. ? whether access to outpatient letter database for Wexford can be obtained via IT support for patients where charts missing
4. Obtained access to Wexford outpatient letters for missing files
5. Wexford files sometimes kept in parent units, sometimes with secretary and some archived

Appendix 16 Data analysis process notes

- Incident form queries –referencing an incident involving 2 or more people? Some of incidents refer to victims only (there might be separate forms for the perpetrators – limitation of random sampling in this instance) ; some incidents not documented in notes themselves (so commonplace?)
- Categories of incident types on forms not fitting behaviour (e.g. absconding and self-harm; taking clothes off, dressing inappropriately etc., being found in another person's room with possible sexual contact; giving other people medication; stealing money; self-harm when it is threatened rather than actual)
- Differences between Waterford and wexford – different filing system; different paperwork/forms/assessments – e.g. risk assessment documentation not standardised or consistent
- Patients with long inpatient stays may have several volumes – reader may need to refer to earlier volumes to find relevant assessment/risk assessments/letters/summaries etc. (particularly in rehab settings) – issues of time; missing earlier files etc.
- Unwitnessed events – eg. Self-harm or accidental harm? Allegations of violence
- Community vs inpatient incidents – last entries in notes for community incidents may have been made some time ago rendering them limited in terms of examining any immediate antecedents
- Some rehab units don't write progress notes everyday
- Ward safety and security measures and balancing risk – fences; access to outside space; smoking areas (particularly risks in unsupervised long term rehab settings); private areas; mixed sex wards; single rooms vs dormitories; noise and disruption; blindspots; safety checks; close observations; ligature points and access to ligatures/sharps etc; damageable property; clothing or objects as a means of self-harm/aggression (pyjamas' trouser cord; bra hook; plates/cups/hot tea/cutlery; hair clips; cigarettes; walking frames etc. (older adults); cleaner's mop/buckets; shoes; other liquids
- Patient/staff interaction – refusing medication; dealing with money/property issues (e.g. cigarettes and weekly allowance (mainly rehab settings and violence and aggression; direct 'hands on' care required in dementia care that increases risk of physical aggression
- Home vs therapeutic area with rules (rehab settings)
- Self-harm – differentiating between those who self report and those discovered by staff
- Patient/patient interaction (communal living and violence/aggression particularly in long term residential; arguments re food/cigarettes etc; patients who are mobile vs those who are immobile; balance between allowing patients to mobilise freely (maintaining physical wellness) and ward safety; close proximity of patients in day areas/dining rooms – staff resources in terms of monitoring multiple patients vs risks – not always possible to supervise patients in several different areas or in individual rooms to reduce risk of violence and aggression)
- Patient/family interaction
- Older adults on acute mental health units
- Clients awaiting residential placement
- Client complexity – e.g. those with co-morbid physical difficulties
- Clients with non-mental health issues – e.g. Intellectual disability

Appendix 16 Data analysis process notes

- Absconding and not returning at agreed times (becoming AWOL)
- Leave arrangements
- Transfers between different clinical areas (e.g. not wanting to move between acute to sub-acute and vice versa)
- Discharge and proposed discharge difficulties (e.g. not wishing to leave - Self-harm activity; suicidal ideation; re-admission within 7 days)
- Behaviours that repeat themselves either on the ward or before admission and then on the ward

Appendix 17 WIT ethics approval

rge Waterford Institute *of* Technology

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Waterford, Ireland.
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REF: WIT2018REC0007

15th February, 2019.

Mr. Neil Crowhurst,
Ballydowane,
Kilmacthomas,
Co. Waterford.

Dear Neil,

Thank you for submitting your amended documentation in relation to your project *'A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East'* to the WIT Research Ethics Committee.

Based on our discussions with you we note that corrections have been made to the documentation but some minor inconsistencies still appear. Please amend as outlined below:

Application form:

- (a) Data management section:
  - (i) Ensure files are password protected, encrypted where possible and use OneDrive for storage of files.
  - (ii) Amend storage of data to reflect 5 years post publication.
  - (iii) In relation to the destruction of electronic files, please liaise with Computer Services.
- (b) Remove all reference to informed consent.

Information leaflet:

- (c) Rename the information leaflet 'general information leaflet'.

Supporting documentation:

- (d) Rename the data collection tool 'data collection form'.
- (e) Consider a data sharing agreement between WIT and the HSE. (Corina will send you on a sample template).

We are pleased to advise that we are granting **contingent approval** to the project subject to: (i) correction of the minor amendments outlined above, (ii) approval from the HRB; including a letter from the HRB which sets out the authority under which they operate and provides a reference pathway to the associated policies under which they operate and have made their assessment.

In due course, we therefore invite you to please re-submit the revised documentation for final approval by desk review highlighting the amendments in red and attaching HRB approval and the HRB letter to the secretary of the WIT Research Ethics Committee, Ms. Suzanne Kiely (skiely@wit.ie)

We will convey this decision to Academic Council.

Yours sincerely,

Philip R. Walsh

Dr. Philip Walsh,
Acting Chairperson,
WIT Research Ethics Committee

cc: Prof. John Wells
Dr. Michael Bergin

Appendix 18 Final HRCDC application

CDCAF1

HRCDC
Health Research Consent
Declaration Committee

APPLICATION FORM

TO PROCESS OR FURTHER PROCESS PERSONAL DATA FOR THE PURPOSES OF HEALTH RESEARCH COMMENCING ON OR AFTER 8 AUGUST 2018

PART A: APPLICANT DETAILS

1. Name and address details (including website, if any) of data controller:

i. Health Service Executive
Waterford/Wexford Mental Health Services
Administrative HQ
Ross Road
Enniscorthy
Co Wexford

2. Lead contact person to receive correspondence in relation to this application:

Neil Crowhurst
Acting Clinical Nurse Manager 2
Health Service Executive
Brook House
Cork Road
Waterford
051 354804/087 9489105
neil.crowhurst@hse.ie

3. Principal business of data controller:

i. Healthcare (mental health services)

4. If there are joint data controllers, please specify the name, address and principal business of joint data controllers and set out the division of responsibilities between them:

i. Health Service Executive
Waterford/Wexford Mental Health Services
Administrative HQ
Ross Road
Enniscorthy
Co Wexford

ii. Waterford Institute Technology
Cork Road
Waterford

The project is a jointly managed study involving the HSE and a local third level education institution. This is a frequent occurrence in relation to post-graduate research projects linked to healthcare, under the funding and guidance of the local Nursing and Midwifery Planning and Development Unit (NMPDU). The principal researcher is employed, supervised and guided by both organisations policies and procedures in relation to data protection.

The HSE have responsibility for what happens to patient data. WIT will have responsibility for managing data collected during the research project, although for this research study no identifying data will be managed or processed by WIT.

5. Name of addresses of data processors, if any –please attach a copy of the contract or draft contract that will be used:

No other processors involved

6. Research site/s involved in processing activity:

All hospital/clinic/day service sites in Waterford/Wexford mental health services where patient data is stored. Addresses as follows:

Department Of Psychiatry, Waterford
Waterford Primary Care Centre
Tramore Primary Care Centre
St Otteran's Hospital, Waterford
Ard Na Deise, Waterford
Springmount House, Dungarvan, Waterford
Carn House Community Mental Health Centre, Enniscorthy, Wexford
Summerhill CMHC, Wexford Town, Wexford
Maryville CMHC, New Ross, Waterford
Wexford Mental Health Admin HQ, Enniscorthy
St John's Hospital, Enniscorthy, Wexford
Selskar House, Wexford Town

Commented [JB1]:
Secretariat: Can these sites be named? If not please indicate why not.

7. Name of and contact details for Principal Investigator. If the Principal Investigator is regarded as the data controller, this should be made clear and information provided to support that view.

Neil Crowhurst
Acting Clinical Nurse Manager 2
Health Service Executive
Brook House
Cork Road
Waterford
051 354804/087 9489105
neil.crowhurst@hse.ie

8. Co-Investigator name and contact details:

There are 2 supervisors also involved in the research study, both academic staff within WIT. They will have no access to any information which could identify patients. Only the principal investigator will have access to this type of information. Only anonymised data will be reviewed and discussed in supervision meetings.

Dr. Michael Bergin
Head of Department of Applied Arts, School of Humanities
Waterford Institute of Technology
Cork Road
Waterford

i. Professor John Wells
Head of the School of Health Sciences
Waterford Institute of Technology
Cork Road
Waterford

9. Collaborator name and contact details (and role in project):

There are no other collaborators involved in this study.

10. (a) Is it proposed to process any personal data outside of the State?

Yes: No: X

(b) If Yes, please specify the countries that this will take place in.

N/A

(c) If any of those countries are outside of the European Economic Area what is the legal basis for the transfer of the personal data?

N/A

11. Please specify any person, organisation or group from whom funding or other material support has been sought or is intended to be sought and indicate where such funding or support has been provided or committed at the time of this application.

Funding for the study comes via the Nursing and Midwifery Planning and Development Unit (NMPDU) who are a department within the Health Service Executive (HSE).

12. Please specify any sponsor for the research activity (where appropriate)

No other funding/sponsorship has been sought for this project.

13. Please specify any person (other than a joint data controller or data processor) with whom it is intended to share any of the personal data obtained or further processed (including where it has been pseudonymised or anonymised), the purpose of such sharing and the country that the person is located in.

Only the principal investigator will have access to personal data. No personal data will be shared with any other person.

14. Please list (below) all Research Ethics Committees involved in approval and attach copy of outcome letter from each of those RECs.

Commented [JB2]: Secretariat: HSE and WIT ethics committee approval/ provisional approval letter is required as they are joint data controllers

WIT Research Ethics Committee has issued 2 letters in relation to this study. The first not granting approval (Appendix 1) (hence the decision to apply for a consent declaration) and the latter granting contingent approval (Appendix 2). Recently granted HSE ethics committee approval is also attached (Appendix 3).

PART B: NATURE OF HEALTH RESEARCH AND PERSONAL DATA INVOLVED

1. Provide a lay summary of what the research is about and why the application is being made (Max 500 words)

Commented [JB3]: Secretariat: Outline in this section why the application to the HRCDC is being made: i.e. to retrospectively review patient charts without requiring their consent

The study proposes to retrospectively review patient charts without the individual consent of individual patients. Two main reasons have been established for the seeking of a consent declaration:

1. It is felt that the public interest in carrying out the research outweighs the potential for unnecessary distress or anxiety caused by seeking individual consent in particularly sensitive cases (e.g. cases of serious self-harm, attempted suicide or serious assault)

2. There are likely to be major logistical difficulties associated with gaining patient consent for this retrospective study (where patients may have since moved, been discharged, refused further contact etc.)

In terms of background, mental health services in the counties of Waterford and Wexford were amalgamated in 2011, with the closure of a large Victorian facility in Co. Wexford following a Mental Health Commission (MHC) inspection. The subsequent redesign of local inpatient mental health services and the slow development of replacement community services was heavily criticised in the media, with local TD's in particularly expressing concern about care deficits and increases in serious incidents involving users of mental health services.

Similarly, mental health staff working within acute services in Waterford have expressed concern about increased levels of violence and aggression as a result of overcrowding, understaffing and inadequate facilities for patients with longer-term care needs. The available research evidence would suggest that these concerns are not merely a local phenomenon and are, in fact, mirrored worldwide. International research literature also highlights a significant number of issues which may contribute to serious incidents and not solely the organisational limitations of mental health services, such as those cited locally. Additionally, significant media exposure relating to homicide, violence and suicide (and their association with mental illness/mental health care) continues to attract public and political interest.

It is clear that the aftermath of such serious occurrences such as physical violence can be far-reaching. For mental health nursing staff the emotional and psychological impact of experiencing violence can lead to work absence; 'burnout;' depression/anxiety; poor job satisfaction and seeking of alternative employment. From a patient perspective, some writers feel that the users of mental health services may be negatively affected by systems put in place to prevent and counteract factors such as physical violence, describing the use of practices such as chemical restraint and seclusion as restrictive and coercive. Similarly, mental health services have been criticised for an over-emphasis on violence 'zero tolerance' and a reliance on security measures over effective clinical care.

The project therefore proposes to examine, retrospectively, the mental health service notes of those patients implicated in serious incidents. These are logged in report form by staff members following adverse events such as accidents, assaults, suicides and property damage.

The project aims to look at the collective issues which may contribute to these incidents occurring as opposed to any in-depth examination of specific cases. It is not in the aims and objectives of the research study to publish identifiable data in relation to people or individual incidents. As such the study is concerned with looking at general contextual issues with examples likely to include areas such as levels of psychiatric morbidity, use of alcohol and drugs, overcrowding, staff numbers, skill-mix, physical environment and external issues such as homelessness. Fundamentally, the proposal is a systems-based study, where trends and patterns across a number of serious and untoward incidents will be examined.

There is a significant onus on mental health services to 'learn from experience' in relation to serious and untoward incidents, whilst research focusing on this area could provide the impetus for better patient services and improved patient outcomes.

Commented [JB4]: Secretariat: this is certainly relevant here but should be reinforced in the public interest case section of the application form

It is strongly felt that such research would be in the public interest. We have consulted with local HSE, research and ethics stakeholders throughout the proposal process and we have been advised that the safeguards highlighted in this application are sufficient in relation to data protection requirements. There is full support from local HSE management and contingent ethical approval has been given by the WIT ethics committee.

2. Describe the nature and objective of the health research project for which the application is being made.

The research study is purely 'desk-based' in that it will not involve any interviews, questionnaires or any other involvement of patients, families and staff. It will solely involve the principal investigator reviewing patient data in the form of incident reports and patient notes. A proportion of this data is available electronically and the remainder is available in handwritten casenotes (traditional file-based medical records). No identifying data will leave any clinical area as all relevant data collected will be pseudonymised at the point of data collection.

3. Indicate the start date and expected duration (months)

September 2019 – 3 years (principal investigator is a full-time mental health nurse, employed by the HSE, who will carry out the research study on a part-time basis.

Commented [JB5]:
Secretariat: please see comments on seeking confirmation on data retention periods as they aren't aligned

4. Specify the study endpoints/deliverables

The proposed endpoint of the study covers 3 areas: -

i. Published research findings (adding to the existing literature relating to mental health services, serious incidents and risk management)
ii. A report provided to the HSE in relation to the findings and recommendations
iii. A MSc by research/PhD qualification for the principal investigator

Commented [JB6]:
Secretariat: It would be beneficial to describe the way the findings will be published i.e. considering the type of information that may be collected, such as homicides and suicides in this geographic area, will they be presented in such a way that would allow a data subject to be identified?

This could be referenced here or in the methodology section in PART B Q5, Q6 or Q8.
In Q8 it is noted *'It is not the intention of the research study to examine any details of specific incidents. As such no personal data, long descriptions of events or any other identifying information will be discussed'* – perhaps it this answer could be built upon

The published findings will include:

- Presenting the contributing/contextual factors evident in serious incidents
- Presenting any patterns relating to characteristics of those implicated in serious incidents
- Presenting any common patterns or differences relating to types of incident, where they have occurred and the times

Each category of incident on the data collection form will be mapped against the other questions posed (e.g. age range, time of incident etc.) to determine any significant patterns or trends. The incidence of self-harm, for example, will be presented in terms of age profile, gender, location of incident, diagnosis etc. Descriptive statistics relating to just one area such as self-harm could be presented in table form as shown in Fig.1. Statistics for each incident type will be presented followed by overall statistics across all incident categories (Fig.2)

Fig. 1 self-harm (example table format)

Variables	number	%
Age		
18-24	3	18.75
25-34	5	31.25
35-44	4	25
45-54	3	18.75
55-64	1	6.25
65 and above	0	0
Gender		
Male	6	37.5
Female	9	56.25

Fig.2 all incident types (example table format)

Variables	number	%
Age		
18-24	21	
25-34	16	
35-44	14	
45-54	07	
55-64	18	
65 and above	22	
Gender		
Male	46	
Female	40	

Rare occurrences have been grouped together on the data collection form to reduce the risk of data subject identification. Therefore suicides and homicides fall within 'incidents resulting in death' whilst sexual abuse falls within the wider category of 'sexual, physical, psychological or exploitative abuse.' To further reduce the risk of identification, if 2 or less incidents are recorded under any single incident category no variables will be presented as per Fig.1. They will, however, be included in the overall statistics.

The qualitative aspect of the results will be presented as codes, categories and themes only. Direct quotes from patient charts will not be reproduced. An example table is provided for illustrative purposes in Fig. 3. The four headings outlined in the table emerged from an earlier literature review in relation to the study. Each code will be generalised without any reference to specific events/people/places etc. The codes below are common entries for a mental health unit and many will be categorised under some or all of the headings. If we take 'patient requesting to leave' as an example, it raises the question of whether they are requesting to leave because: -

a) They are acutely unwell (patient factors)
b) They do not feel staff are helping them or have time to talk with them (staff factors)
c) They do not like sharing a room with other patients (organisation/environmental factors)
d) They are worried about something at home (external factors)

Clearly these are just examples and there could be any number/combination of factors involved. These are the type of areas that will be addressed through the research study and demonstrates how it will address the 'systems' in place as opposed to individual incidents themselves. If, for example, 'patient upset by visitor' is recorded frequently, it maybe highlights an issue that needs addressing from an organisational/environmental or staff perspective.

Fig. 3 content analysis

Codes	PATIENT FACTORS	STAFF FACTORS	ORGANISATION/ENVIRONMENTAL FACTORS	EXTERNAL FACTORS
Patient requesting to leave	X	X	X	X
Patient refusing medication	X	X	X	X
Patient hearing voices	X	X		
Patient upset by visitor			X	X
Patient worried about homelessness			X	X

5. Provide an overview of the proposed design and methodology (3 pages max to be attached).

Methodology

Commented [JB7]: Secretariat: for ease of HRCDC review the methodology section should be non technical if possible.

Method

The required research evidence for the proposed study will be obtained from existing patient data, namely incident report forms and medical charts. In terms of research investigating serious incidents within mental health services, this is a unique approach that has not been widely used. However, this type of methodology is well-established and a frequently used research design within other areas of health care and nursing research. Commonly referred to as retrospective 'chart' or 'medical record' review, it utilises patient data not originally obtained for research purposes and is differentiated from prospective studies by its use of pre-existing records.

Its strengths include access to available data without the need for participant recruitment; minimal intrusion on patient/staff time and the inclusion of information that may have otherwise been forgotten. Limitations include inconsistent documentation practices and missing or unavailable data.

The proposed research study will follow the methodological steps recommended in the existing literature for this type of approach. Common elements of this include establishing a clear research question; deciding on the specific data to collect from the patient record and using a data collection form to achieve this. The data collection form proposed for this study is included in Appendix 4.

Commented [JB8]: Secretariat: Please include as an appendix and reference appropriately

Data collection

Commented [JB9]: Secretariat: please provide a sense of the numbers of medical charts to be reviewed: DPIA states 100

Firstly, submitted incident reports dating back to the amalgamation of Waterford/Wexford services in 2011 will be reviewed. In discussions with staff in the risk management office in Lacken, Kilkenny (HQ for Waterford/Wexford services) I have been informed that each section of the current National Incident Report Form (NIRF) (Appendix 5) is available to be used as a heading for the summary they will produce and forward to me. The team proposes to request Sections A, C, F, H, I and an incident description. Fig. 4 shows the expected summary headings in table form.

Fig. 4 Summary of incident reports

A		C	F	H	I
Description of Incident	General incident details	Service user details	Outcome at time of incident	Type of injury	Immediate action taken

Only the 'behavioural hazards' aspect of section H is relevant to this study. This will help to reduce the number of incident reports that need to be reviewed for inclusion. On average there are around 950 incidents reported in one year across Waterford and Wexford. Therefore being able to exclude irrelevant areas such as slips, trips and falls before applying inclusion/exclusion criteria will drastically reduce this number.

Commented [JB10]: Secretariat: Please confirm what HSE database you are referring to and who will be producing the summary of reports and applying the 'A' number.

Please describe the level of detail contained in this summary of reports (are names of staff and patients noted for example)

In terms of detail included in the summary report, the service user's healthcare record number (A number) should appear in section C. Only HSE employees with access to the electronic patient information system (IPMS) would be able to match this unique number with a patient's personal details. This is necessary for the lead researcher to be able to access relevant patient charts at a later stage.

The name of the lead clinician (generally the service user's consultant psychiatrist) will appear in section C. The incident description and section I (immediate actions taken) do not generally refer to service users or staff names. However in my own clinical experience I have seen patient or staff initials used and there is no guarantee that service user or staff names will not appear in these sections. Similarly, it is not feasible for the staff working in the risk management office to read/review every incident and remove such data before forwarding to me. I would propose that I delete any service user/staff names upon receipt of the data, however, as only the A number is required.

Each incident report will have specific inclusion/exclusion criteria applied in order to pinpoint those that are relevant to the study. The specific inclusion/exclusion criteria will be established using mental health service definitions of a 'serious and untoward incident' across three countries (Ireland, UK, Australia) forming an aggregated set of common principles. The main aim is to include the most serious incidents of harm as opposed to accidents, medical/nursing errors or health and safety issues such as slips, trips and falls, which are beyond the scope of the study. A current list of inclusion and exclusion criteria is attached in Appendix 6.

The retained incident reports will direct the research team to the individual psychiatric notes for each individual patient. This data will be then be reviewed in order to obtain demographic information and to examine events leading up to the incident in question. The demographic information will provide statistical quantitative data in relation to each serious incident (e.g. patient gender, diagnosis, time of incident etc.) whilst a qualitative content analysis of the recorded information, particularly the clinical progress notes, will examine events leading up to the incident in question. It is envisaged that up to 100 patient charts will be reviewed during the study.

Data analysis

The aim of the content analysis will be to establish all the possible contextual issues contributing to the resulting incident. This will be achieved by locating 'triggers' categorised under four separate incident antecedent themes, established during the literature review process. These are:

- Patient factors (e.g. severity of ill health, violence history etc.)
- Staff factors (staffing numbers, skill mix, education and training etc.)
- Environmental/organisational factors (ward layout, work culture, access to physical activities etc.)
- External factors (unemployment, outside family issues, social deprivation etc.)

Commented [JB11]:
Secretariat: confirm in PART B Q6 what personal data on patients and staff will be collected for analysis – if no data on staff is to be collected please state so

Some of these 'triggers' will be clearly documented (e.g. the patient's clinical state at the time) whilst others may not be explicit within the notes (e.g. staff shortages/absence, short-term environmental changes due to building work etc.). A main hypothesis of the study is that a significant number of contributing factors are not referenced within patient notes. This is likely to be an important aspect of the overall research discussion.

As recommended in the guidance on patient data review, a data collection form to extract both the quantitative and qualitative elements of the study will be utilised. A pilot exercise, reviewing 10 charts selected randomly from the summary of incident reports will be carried out for reliability/research quality purposes. A process of reflexivity and researcher supervision will be utilised throughout the study to counteract possible bias. This could potentially emerge as a result of the lead researcher being the only member of the team accessing notes and records but this is an unavoidable scenario due to confidentiality issues. It is proposed that the collected data from each abstraction sheet will be entered onto a database software system (such as Microsoft access) for further analysis. Only pseudonymised data will be recorded on data collection sheets and the proposed electronic database.

Commented [JB12]:
Secretariat: As you will be piloting the tool please describe what this will look like, for example how may charts and how will subjects be selected?. This pilot may also need to be within the scope of the declaration being sought (PART B Q15)

Commented [JB13]:
Secretariat: Unless the data is irrevocably anonymised and can not be liked back, then the statement should be corrected as 'pseudonymised'. As a result data retention and data analysis may also need to be within the scope of the declaration (PART B Q15)

6. Describe the personal data which will be obtained and used.

The personal data obtained and used in the study will be as per the data collection form and the headings contained within the incident report summary. No staff data will be retained or used.

Commented [JB14]:
Secretariat: The list of personal data being collected and used in this project should be consistent across all documents associated with the application form. (as mentioned this can be scope of information rather than specific data fields). Recommended that you note the personal data in the draft data collection tool as well as others in this section of the application form. Please also note the scope of any personal qualitative data to be collected if possible. (This relates to Q1 in Secretariat letter)

The Secretariat also recommend that data that won't be collected e.g. a natural person's sex life' are not recorded on the application as Committee will require applicants to justify why it is needed for the research (PART B Q9)

7. Explain why the health research requires that personal data be obtained and processed rather than anonymised data.

Commented [JB15]:
Secretariat: Your answer focuses on why it is not possible to anonymise the data – however the questions relates to why anonymous data cannot be used. In this case it may be the nature of the study (extracting demographic data and information from patient charts) that would likely suggest why anonymous data cannot be used.

The nature of the study is to access information that can only be sourced from demographic data and information contained within patient charts. This type of information is unique and not available in any anonymous form.

The research study is a local project with limited access to resources and staffing. Practically and logistically, it would be extremely difficult to anonymise all personal data that could be included in just one page of a patient record. Even removing a patient's name from the top of a page would not be sufficient as other personal references may be made within the bodies of texts (assessments, clinical progress notes, typed reports etc.)

The principal investigator will be the only research team member who has access to personal information. This information will be pseudonymised in relation to accessing relevant incident forms and medical notes. All data collection will be carried out within HSE establishments with no data removed from manual or electronic storage. All data collected will be anonymised before it leaves these areas.

Commented [JB16]: Secretariat: as noted data is unlikely to be considered anonymised so recommend removing such references

8. Describe how you will ensure, in relation to the research, that personal data already held and to be obtained will not be processed in such a way that damage or distress is, or is likely to be, caused to the data subject.

The research aims to examine common themes and trends relating to serious incidents within mental health services. It is not the intention of the research study to examine any details of specific incidents. As such no personal data, long descriptions of events or any other identifying information will be discussed. Conversely, it is felt that attempting to obtain consent from individuals previously involved in serious incidents is likely to cause more distress than obtaining and processing data in the manner described.

Commented [JB17]: Secretariat: Please state clearly how the findings of the analysis are to be presented/disseminated

9. Describe how you will ensure that the collection and use of the personal data will go no further than is necessary for the attainment of the research objective (data minimisation principle).

Commented [JB18]: Secretariat: the focus of this question is for the applicant to describe/justify why the extent of data being used is required to achieve the research objective. Your current answer mainly relates to security of the data and the data collection process as well as exit strategy for the data collected. This information would be more relevant in PART B Q10 and/or PART E.
(This relates to Q4 in the Secretariat letter)

The type and quantity of data required has been carefully considered by the research team. Each aspect of data collection is intended to support the study's overall aim, which is to examine trends and patterns relating to serious incidents within mental health services. Without personal data such as age, gender or ethnic origin (as examples) trends and patterns will not be able to be fully examined.

The research team's clinical background ensures that the information being asked in the data collection form is readily available in the patient charts being reviewed, meaning that there are no questions that cannot be feasibly answered. From all the sections of the NIMS incident report form, the team have only requested what is necessary for the study.

Timeline

Task	Sept - January 2019	January - April 2020	Apr - Dec 2020	Dec - Apr 2021	Apr- Sept 2021	Oct- Dec 2021	Jan- Apr 2022	Apr- Sept 2022
Obtain HSE ethics approval (team)	■	■						
Apply to HRB for consent declaration (team)	■	■						
Meet with local service managers and staff to introduce study (Neil)		■						
Access and review incident forms from 2011 applying incl/excl criteria (Neil)		■	■					
Pilot exercise and review (10 charts) (team)		■	■					
Carry out chart reviews (neil)				■	■			
Data analysis (team)					■	■		
Write-up results and discussion (neil)						■	■	
Edit for HSE report and journal submission (team)							■	■

10. Describe the data processing activities (data lifecycle and research lifecycle), focusing on access, storage, analysis, sharing, transfers, archiving and destruction

Firstly the lead researcher will request a summary of incident reports from 2011-2018 (see Fig. 4) from an agreed contact person (Mairead Kavanagh) working in risk management administration in Waterford/Wexford mental health services headquarters (Lacken, Kilkenny). This will be sent by email to the lead researcher who will store the summary on his personal HSE drive which is not accessible to anyone else and only accessible through an HSE computer).

Commented [JB19]: Secretariat: as referenced previously in comment 13 please describe

Commented [JB20]:
Secretariat: please provide as more detail on this: at what date is it likely to happen and by whom? For example at the end of the three year study or at the end of the 5 year retention period that is noted elsewhere in the application.

Commented [JB21]: Secretariat: In the interest of the Committee's review process we recommend that applicants use consistent and 'lay-mans' terminology in their application – in this case what is meant by HSE domain?

Commented [JB22]: Secretariat: as noted the data is unlikely to be considered anonymous

Commented [JB23]:
Secretariat: Please provide specific details on timeline and who is responsible for doing so; it is noted that this is described elsewhere in the application but for clarity it is useful to have the information in one place.

Commented [JB24]: Secretariat: Please describe in more detail the data processing to be undertaken – much of this is described elsewhere in the application, for example the methodology section (for the benefit of Committee review describing this in one section would be very useful)

Commented [JB25]:
Secretariat: Please confirm what HSE database you are referring to and who will be producing the summary of reports and applying the 'A' number.

Please describe the level of detail contained in this summary of reports (are names of staff and patients noted for example)

Initially, for the purposes of a pilot exercise, 10 incident reports on this summary will have specific inclusion/exclusion criteria applied. Any incidents not meeting the inclusion criteria will be deleted immediately. Similarly, any patient or staff names/initials will be deleted as incidents are reviewed. The retained incident reports will direct the lead researcher to the individual psychiatric notes for each individual patient. After obtaining permission from relevant managers, the lead researcher will visit the site where the chart is kept to review the chart on-site and complete a data collection form. Once completed each of the 10 data collection forms will be brought back to the lead researcher's normal place of work and retained in a locked filing cabinet (again not accessible to anyone else).

The data collection forms will be entered manually into an Excel spreadsheet which will be stored, encrypted and password protected on the lead researchers WIT laptop. This spreadsheet will mirror the questions being asked on the data collection form. Once the pilot exercise is finished the team will meet to discuss any difficulties in relation to the use of the data collection form/excel spreadsheet. Once agreed the process will start from the inclusion/exclusion criteria stage once again, reviewing up to 100 charts as noted previously.

Commented [JB26]: Secretariat: as referenced previously in comment 13 please describe

- Incident reports summary will be held for 1 year from receipt. At this point the lead researcher will delete this from storage on his personal HSE desktop computer 'G' drive
- Data collection sheets will be held for duration of study (3 years). At this point, the sheets will be removed from their storage (locked HSE filing cabinet) and shredded securely by the lead researcher
- The database/spreadsheet will be retained for duration of the study (3 years). At this point, the lead researcher will delete this from storage on his WIT computer
- The lead researchers academic dissertation will be kept for 5 years post publication of the research results (as per WIT policy)

No patient charts will be removed from site locations. The data recorded from these charts will be the minimum amount of information required to answer the study questions. All of the pseudonymised data will be password protected, encrypted where possible and WIT OneDrive/HSE personal drive ('G' Drive) will be utilised for storage of relevant files. Handwritten data collection sheets will be kept in a secure filing cabinet.

Commented [JB27]:
Secretariat: recommend that consistent terms and language are used throughout the application. As noted in previous letter the Secretariat are unsure what this refers to

Commented [JB28]:
Secretariat: recommend that consistent terms and language are used throughout the application. As noted in previous letter the Secretariat are unsure what this refers to

Commented [JB29]:
Secretariat:
A) does this mean the completed analysis? Again please use consistent terminology
B) for clarity please confirm in your application the proposed retention periods for the personal datasets – at the moment it is unclear; for example in Q9 above the database and collection forms are to be retained for duration of the study, however PART E Q2(iv) only refers to the incident report list being kept for duration of the study.

11. Confirm that there will be no disclosure of the personal data unless that disclosure is required by law or the data subject has given his or her explicit consent to the disclosure.

I can confirm that there will be no disclosure of the personal data unless that disclosure is required by law or the data subject has given his or her explicit consent to the disclosure.

12. Identify the data sources from which the personal data will be obtained and any engagement, general or specific, with those sources on the likelihood that they will provide the personal data should a consent declaration be made.

As noted, the data sources required for this study are incident report forms and patient medical notes. No other forms of data are or will be required in terms of the study outcomes.

13. If the research involves data linkage between different sources of information, you must describe what is involved and its purpose.

The principal investigator will need to be able to link incident forms and medical notes together and will be the only member of the research team who is able to do this. As noted, this will be achieved by the use of a unique patient identifier number, which only reveals patient data when entered into the electronic patient information management system – a secure system currently operating within HSE clinical services.

14. Describe your exit strategy with timelines to address the issues that led to this application, such that the research described will no longer require support under the consent declaration process. If you will continue to require the support of a declaration over a number of years, you must set out the reasons why that is the case.

Commented [JB30]: Secretariat: as noted previously the declaration would likely need to be beyond data collection

It is proposed that a consent declaration would be required until all retained identifying data has been deleted after 3 years, as noted in question 10

The incident report summary needs to be retained for one year to allow the lead researcher sufficient time to access individual patient charts

Data collection sheets need to be kept for 3 years as the lead researcher needs sufficient time to enter these manually onto an excel spreadsheet. They need to be kept for the duration of the study to check for consistency between data form and spreadsheet and for reference should a query relating to a particular answer arise

The spreadsheet needs to be kept for the duration of the study as the lead researcher will need time to write up the results and discussion, using the data in the spreadsheet to inform this results/discussion section of his dissertation

15. Identify the particular part(s) of the research for which the consent declaration is sought.

Commented [JB31]: Secretariat: would also potentially include piloting the data collection tool, data analysis and subsequent data retention (This relates to Q3 in the Secretariat letter)

- Piloting the data collection tool
- Data analysis
- Data retention of 3 years

Commented [JB32]: Secretariat: would also potentially include piloting the data collection tool, data analysis and subsequent data retention (This relates to Q3 in the Secretariat letter)

16. Following on from 15, you must set out fully-

(i) why you claim it is not practicable to seek consent from the data subjects.

Firstly, seeking individual consent from relevant patients was part of the original proposal. However, concerns were raised (on WIT ethics committee application) in relation to the potential distress to patients and their carers from the informed consent procedure, especially for those that had been implicated in serious incidents. For example, if we took the case of someone who had self-harmed causing injury (within the inclusion criteria for the study), a subsequent request for consent to review their chart could trigger a number of unnecessary worries. In this scenario, the person may not want to be reminded of a particularly stressful time in their life or may be experiencing acute mental health problems. Any mental health symptoms they may be experiencing could feasibly be exacerbated by efforts to gain their consent, whilst it may not always be possible to know their level of 'wellness' before contacting them.

Commented [JB33]: Secretariat: please provide as much information and rationales here, which should be informed by evidence. This should include both patient and staff consent where relevant. Some of the information provided in PART D may be relevant for this section

Commented [JB34]: Secretariat: further information on this point may be useful for the Committee

Commented [JB35]: Secretariat: please provide as much information and rationales here, which should be informed by evidence. This should include both patient and staff consent where relevant. Some of the information provided in PART D may be relevant for this section

Secondly, there are practical considerations to gaining individual consent for this study because of its retrospective nature. Clinical experience suggests that many patients will not be contactable because of changes to their circumstances over time. Such circumstances include subsequent discharge from services following a serious incident, changes of address/telephone numbers where mental health services have not been notified, periods of homelessness, changes in personal capacity to give informed consent, physical illness and death.

Thirdly, poor uptake in relation to individual consent could greatly limit the number of incidents included in the review and therefore the overall quality of the research. In reaching a goal of identifying patterns relating to different categories of incidents for example, it is important that as many serious incidents as possible are included in the study.

These three areas are frequently cited in the international research literature as reasons for seeking consent waivers/exemptions. For example a literature review of 115 different studies by Rebers et al. (2016) found that decreases in data quality, distress or confusion amongst participants and practical problems were the three most common categories noted.

(ii) in what way was consent formally considered at the design or any stage of the research.

The need for individual consent from patients was discussed with supervisors and local ethics advisors from the outset of the study. At the time, we consulted with our local HSE ethics committee co-ordinator, Caroline Lamb, who indicated that individual consent would be required.

We then proposed a plan for obtaining individual patient consent using the available guidelines at the time produced by the Data Protection Commissioner (DPC, 2007). These guidelines, focusing on data protection in the health sector specifically, included a section on the use of historical data such as patient files. Guidance in this document suggested that researchers should write to the patient twice, try to telephone once and then refer to local ethics committees if no response was elicited. This procedure was included in the first ethics committee proposal to WIT (local guidelines state that health research must achieve ethical approval in the relevant educational institution before applying for HSE committee approval).

WIT considered this proposal but would not give ethical approval based on the plan to obtain individual consent (see Appendix 1). One of the main issues affecting the thoughts of those involved at the time was the arrival of GDPR and some uncertainty in relation to the best way forward. At a subsequent Clinical and Academic Research Excellence (CARE) meeting (the local forum for discussing health research matters), Caroline Lamb made the team aware of newly updated guidelines on the HRB website, including the option of applying for a consent declaration. This information was then considered by the research team who felt that it would be an appropriate step to take, gaining agreement from CARE meeting attendees first.

The research team submitted a journal paper for publication addressing some of the issues noted above. The paper entitled 'Implications for nursing and healthcare research of the general data protection regulation and retrospective reviews of patients' data' was accepted in the journal, Nurse Researcher, in March 2019.

The article highlights some of the advantages of retrospective patient data research such as minimal intrusion on staff/patient time and access to information that may otherwise have been forgotten. It also highlights limitations which include inconsistent documentation (such as ineligible notes) and missing data (e.g. patient charts that cannot be located easily).

One of the main conclusions noted in the article is that whilst more innovative ways of engaging patients in health research (and resolving consent issues) are required, there are currently few options locally in terms of the research proposed. As time is required to develop such processes and procedures, applying for a consent declaration is one of the only options open to the team at present.

Commented [JB36]:
Secretariat: in the interest of Committee review process please pull refer to the relevant elements from this paper in the application form

(iii) what consultations have you undertaken on the feasibility of obtaining consent: for example, focus groups?

As noted, obtaining consent was discussed at length in supervision and research stakeholder meetings which regularly take place within WIT. As the research planning for this study coincided with the introduction of GDPR and new rules/regulations, it proved difficult to obtain definitive advice/guidance in relation to consent issues.

Commented [JB37]:
Secretariat: consultations, in particular with public and patient representatives is an important area for the Committees. If possible please describe relevant consultations and feedback received ((This relates to Q8 in the Secretariat letter)

The request by the local ethics committee (see letter dated 25th October 2018) (see Appendix 1) for an 'independent person outside of the HSE who would be able to give assurance to the committee...' was also discussed but it was felt that this was not possible given the studies limited resources and an absence of any direction or guidance on who to approach or who would be able to offer such assurance.

(iv) the extent to which you have involved patient and user organisations/representatives in the development of the research.

The public have been represented by appointed 'laypersons' on both the ethics committees (HSE and WIT) giving their approval to this study. In addition, the local patient advocacy service for Waterford/Wexford was consulted and their feedback is included in appendix 7. They are supportive of the study and the ethical issues addressed, whilst making some helpful comments. As noted, there is scope for the research study to be expanded at a later date, to further address the direct views of service users and advocacy representatives.

Commented [JB38]:
Secretariat: As noted in comment 28 please describe details and feedback received from Public/Patient involvement, such as advocacy groups

Commented [JB39]:
Secretariat: Please provide any other relevant information or evidence here to enhance your rationale for not seeking consent

PART C: LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA

1. Identify the legal basis under Article 6 and the relevant condition under Article 9 for the proposed processing of the personal data.

Reference is given in relation to GDPR Article 6 point E – 'processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.'

Reference has also been made to GDPR Article 9(2) (j) 'processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject'

PART D: THE PUBLIC INTEREST CASE

Commented [JB40]:
Secretariat: please build on the public interest case here. For example what will happen with the findings of this project, due to the type of data that may be collected in this research the public interest case needs to be described in detail

1. Describe fully why you believe that the public interest in carrying out the health research significantly outweighs the public interest in requiring the explicit consent of the data subject and provide any supporting evidence for your case.

As noted in the lay summary (part B) there is significant public interest in carrying out the research, which can be seen to outweigh public interest in requiring explicit consent. Serious incidents can have a major impact, not only on patients themselves in terms of physical health, mental wellbeing and in extreme cases, life itself – but also on families, carers and professionals alike.

Any simple 'Google' search of news reports pertaining to 'mental health incidents' will produce an extensive list of cases which can be viewed as 'within the public interest.' The following examples are taken from one basic search and highlight the media focus on mental health, patient care and incidents occurring publicly and within mental health services.

https://www.irishtimes.com/news/health/number-of-police-incidents-caused-by-mental-health-crises-doubles-1.3890875

https://www.bbc.com/news/uk-47927704

https://www.thejournal.ie/inquest-death-2-4745335-Jul2019/?utm_source=shortlink

https://www.plymouthherald.co.uk/news/plymouth-news/former-mental-health-worker-took-3206447

https://www.irishtimes.com/news/crime-and-law/courts/coroner-s-court/hse-admits-failings-over-death-of-man-30-by-suicide-in-its-care-1.3695487

https://www.irishtimes.com/news/health/patient-assaults-on-psychiatric-health-staff-on-the-rise-1.3465935

As a result of such incidents, health services in this country and internationally continue to develop risk assessment/management strategies aimed at managing and ultimately reducing the likelihood of such events occurring. Current evidence on managing risk dictates that we, as health service providers, learn from serious incidents in the same way as other professions (e.g. airlines) whereby an open and transparent, 'blame-free' system of reporting exists and where serious incidents are reviewed and acted upon in terms of maintaining public safety at all times. What many incident investigators have found is that very often it is not any individual at fault but rather the 'system' in which individuals work - thus the focus on organisational 'systems' relevant to this research proposal.

There has been an ever increasing demand for patient safety over the last 30 years, not only in mental health but across all areas of healthcare. For example two landmark reports from 1999 and 2000, in both the USA and the UK, focused on the importance of incident reporting, patient safety and learning from serious occurrences. Similarly, a long running inquiry in the UK continues to place mental health suicides and other patient safety incidents within the public domain.

http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf

https://webarchive.nationalarchives.gov.uk/20130105144251/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4065086.pdf

https://www.rcpsych.ac.uk/docs/default-source/improving-care/nccmh/suicide-prevention/safer-services_a-toolkit-for-specialist-mental-health-services_updated-nov-2018.pdf?sfvrsn=f6620787_2

The findings of this study should ultimately lead to improvements in patient and public safety, whilst adding to the research literature on serious incidents. As such, local HSE management have requested a final report on the research findings and the study will be submitted for publication in a relevant healthcare journal.

Commented [JB41]:
Secretariat: it is likely that this information is more relevant in PART B Q16.

Also in this section the Secretariat is unsure of the relevance of some of the text in italics - for example italics in No.1 and No.3 seem to suggest it is proposed to provide a patient information leaflet or seek consent from next of kin. No. 5 reference to 2007 guidance is also outdated – this may not be clear to members of the Committee

PART E: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS AND TRAINING

1. Specify the transparency arrangements you have/will put in place to ensure that personal data are processed in a transparent manner.

Commented [JB42]:
Secretariat: could you provide information on who this is for, how it will be disseminated and attach a copy of the leaflet?

Commented [JB43]:
Secretariat: are patients included under stakeholders? Would need to outline transparency measures for patients as well as staff

The lead researcher will contact all the managers/team leaders of the various HSE locations relevant to this study. Staff will be briefed verbally on the study and the researcher will be available to answer any queries. A staff information leaflet has been created, outlining the study and providing the lead researcher's contact details (Appendix 8).

The researcher will undergo regular supervision (monthly) where security arrangements and data processing transparency will be continuously reviewed and monitored. Only data relating to questions set on the data collection form will be collected. No other questions will be added at any point.

2.Identify the controls in place to-

(i) limit access to the personal data undergoing processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data;

Commented [JB44]:
Secretariat: as noted this is unlikely given the nature of the data to be collected

Controls in place to limit access are:

- Secure HSE email system in place
- Secure electronic storage via HSE and WIT owned computers
- Secure, locked filing cabinet – only accessible to lead researcher
- Only data collection forms will be taken from relevant HSE sites, not any medical charts themselves. They will be transported manually by the lead researcher and placed in the locked filing cabinet immediately after completion

(ii) log persons who access personal data;

Only the lead researcher will be authorised to access data for research purposes

(iii) technical, organisational and physical measures to protect the security of the personal data concerned;

Commented [JB45]:
Secretariat: only the list of incident reports are noted here; security of other data (including those on the data collection form and the database for analysis) is noted elsewhere. Would be useful to have details on security measures to be in one place in the application form. What security is there for the data collection forms?

Commented [JB46]:
Secretariat: who is sending it?

Personal data relates to three areas of the processing - the original incident report list, the data collection form and the electronic database for analysis. Security measures for each area are proposed as follows:

1. Incident report list
   The list will be compiled by Mairead Kavanagh working in local HSE headquarters in Kilkenny (risk management office). This will be sent by secure HSE to my work email address. This list will then be retained on my secure HSE personal drive – only accessible from a work password protected computer terminal and only accessible to me.

2. Data collection forms
   Data collection forms will only be completed within the listed HSE sites. No patient charts will be taken away. On completion, I will immediately return data collection forms to my usual work location, where, when not in use, they will be stored in a lockable filing cabinet. This cabinet is only accessible to me and I retain the key.

3. Electronic database
   The database will be retained as an excel file on my WIT laptop. The file will be encrypted and the laptop is password protected.

(iv) arrangements to anonymise, archive or destroy personal data once the health research has been completed;

- Incident reports summary will be held for 1 year from receipt
- Data collection sheets will be held for duration of study (3 years)
- Database will be retained for duration of the study (3 years)

Commented [JB47]:
Secretariat: please confirm the retention periods for the personal data collected (summary of incidence reports, extracted from patient charts, data collection sheets and the database, completed data analysis files).
As noted previously it is unclear and in some cases it may be contradictory: earlier it says that the database will be retained for end of study, in this section it would seem it is 5 years. ((This relates to Q6 in the Secretariat letter)

(v) any other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation, together with processes for testing and evaluating the effectiveness of such measures.

3. (a) Set out below a summary (max 750 words) of the findings of the Data Protection Impact Assessment that has been carried out and ensure that you have attached a copy of the DPIA.

Commented [JB48]:
Secretariat: as discussed it would be beneficial to utilise the institutions template for completing a DPIA and subsequently updating this section. The current DPIA may be considered insufficient by the Committee – for example data protection solutions are noted but data risks are not

Separate forms were completed for both WIT and the HSE using the templates provided by each organisation (appendices 9 and 10)

The 2 forms helped to identify the types of data that would need to be collected and the steps that would need to be taken to achieve this. It helped to identify the legal basis for processing the data, namely using a public interest perspective, overriding the potential distress emerging from seeking individual consent.

Data processors and data controllers were identified – data collection has been restricted to one person as a result, whilst the controller role is shared between WIT and predominately the HSE. The team were able to consider each aspect of personal data and whether it was essential to the study. As a result only data specific to the study needs and requirements will be collected.

The means of collecting data is a manual system of hand-completed forms. Other than this, all other parts of storage and analysis will be carried out using electronic means (computer storage and electronic patient management system).

Security measures are as documented within the attached DPIA's and include use of the secure HSE email system, safe locked storage, accessible only to the lead researcher, laptop password protection and use of encryption. Patient notes will not be removed from their usual, secure, place of storage.

The main risk identified by the DPIA's is illegitimate access to personal data. The sources of such unwanted access and the controls proposed are listed within the HSE DPIA. In complying fully with these controls, we propose that the overall risk of any deviation from legitimate access to personal data is in the low category.

(b) Indicate the steps you have taken to address any risks identified in the DPIA with particular reference to the possibility of data linkages and details of any consultations undertaken with data subjects.

The risks identified via the DPIA's were considered in research supervision, via the 2 local ethics committees and via DPO's for WIT and the HSE. The steps to mitigate these risks are outlined in the DPIA's themselves and resulted from these consultations.

Commented [JB49]:
Secretariat: This statement is quite general

(c) Please attach the advice of the Data Protection Officer on the research and any action taken in relation to that advice. Where the application is from joint data controllers, the advice of each data controller's DPO must be attached.

Commented [JB50]:
Secretariat: please summarise and attach DPO advice from HSE and WIT on the DPIA

Please see attached DPIA's from the HSE and WIT. Unfortunately, the DPO for WIT has declined to provide feedback. The reasons for this are due to a different interpretation of rules relating to DPO advice and are summarised as follows:

- WIT DPO does not see WIT as a data controller and feel it should only be the HSE providing the advice required
- The DPO does not feel that giving formal advice is necessary given that the data will be pseudonymised at the point WIT become involved
- WIT are not determining the processes of how and what happens to the initial data
- The DPO contacted the DPC who provided the following advice: -

"This assessment is entirely a matter for the actors involved and should be based on the factual circumstances of the relationship of the parties while reflecting the reality of the underlying data processing with regard to specific sets of data or operations.

WP29 pointed out in its opinion 1/2010 on the concepts of "controller" and "processor" that "the first and foremost role of the concept of controller is to determine who shall be responsible for compliance with data protection rules, and how data subjects can exercise the rights in practice. In other words: to allocate responsibility." These two general criteria responsible for compliance and allocation of responsibility should be borne in mind by the parties involved throughout the analysis in question.

I enclose a link to the High Court Judgement In the Matter of Mount Carmel Medical Group (South Dublin) Limited (In Liquidation) for your information:

-

http://courts.ie/Judgments.nsf/09859e7a3f34669680256ef3004a27de/a91ac72770acace880257e88004d178f?OpenDocument

As you will note from same the Court confirmed that "the question of whether a person is a data controller is primarily a question of fact, conditioned by the application of the definition contained in the DPA.

It is entirely the responsibility of the actors involved to determine who is responsible and liable for any personal data that is processed and for each distinct data processing operation. Without a clear allocation of responsibilities there is an increased risk to the rights and freedoms of data subjects and how they can exercise their rights in practice. This could run the risk of making the processing unlawful due to a lack of transparency and also breach the fair processing principle. As per Article 5(2) of the GDPR, accountability for the lawful processing of personal data lies solely with the controller or processor involved.

I enclose the following detailed analysis on the concept of controller and processor for your information"

https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2010/wp169_en.pdf

The DPO for the HSE South, Mary Deasy, was provided with a copy of this application and the relevant DPIA. Her comments were provided via email and are included in appendix 11.

4. Provide information on the training in data protection law and practice that has been provided to those individuals involved in carrying out the health research.

Both the HSE and WIT have issued advice and guidance in relation to data protection and specifically GDPR. All team members have had access to this information, using online resources where required. The lead supervisor on this study, Professor John Wells is also chair of the local WIT ethics committee and has undergone specific training in relation to data protection law.

I have undertaken an online teaching module relating to GDPR via 'HSEland' (HSE facility for staff training and development). I have attached a certificate (appendix 12).

PART F: SIGNATURES - DATA CONTROLLER(S)

DATA CONTROLLER
I certify that I have been duly authorised by the data controller to forward this application by the data controller to the Health Research Consent Declaration Committee APPLICATION TITLE: 'A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East.' PRINCIPAL INVESTIGATOR NAME:

Commented [JB51]: Secretariat: Please sign (on behalf of both joint data controllers)

Name: Neil Crowhurst

Organisation: HSE South

Original signature: ____________________________

Date:

DATA CONTROLLER (where there are joint data controllers)

I certify that I have been duly authorised by the data controller to forward this application by the data controller to the Health Research Consent Declaration Committee

APPLICATION TITLE: 'A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East.'

PRINCIPAL INVESTIGATOR NAME: Neil Crowhurst

Name: Neil Crowhurst

Organisation: WIT

Original signature: ____________________________

Date:

If there are more than two joint data controllers, the above box should be copied as necessary.

Appendix 19 DPIA for WIT

Waterford Institute *of* Technology
INSTITIÚID TEICNEOLAÍOCHTA PHORT LÁIRGE

Data Protection Impact Assessment Template

Background:
Data Protection Impact Assessments ('DPIAs') can be used to identify and mitigate against any data protection related risks arising from a new project, which may affect Waterford Institute of Technology. DPIAs are mandatory for any new high risk processing projects.

When to use a DPIA:
Under the GDPR, a DPIA is mandatory where data processing "is likely to result in a high risk to the rights and freedoms of data subjects (the person to which the data relates). However, carrying out a DPIA is required as a standard practice in WIT and will serve as a useful tool to help comply with data protection law. The DPIA should be carried out prior to the processing of data.

Who must carry out the DPIA:
It is the responsibility of the project team to ensure that a DPIA is carried out for any new data processing projects.

DPIA Process:

1. **Need for DPIA:**
   Summarise the need for a DPIA

2. **Describe the information flows:**
   Describe the collection, use and deletion of personal data here and it may also be useful to refer to a flow diagram or another way of explaining data flows. You should also say how many individuals are likely to be affected by the project.

3. **Identify data protection and related risks**

Identify the key privacy risks and the associated compliance and corporate risks.

4. **Identifying data protection solutions to reduce or eliminate the risks**
   Describe the actions you could take to reduce the risks, and any future steps which would be necessary.

5. **Signing off on the outcomes of the DPIA**
   Ensure appropriate sign off of outcomes is formally documented and retained.

6. **Integrating data protection solutions into the project**
   Ensure the controls and actions identified are tracked through to completion to ensure the rights of the data subject are upheld.

Template

1. Need for a DPIA Please answer the below questions	
Will the project involve the collection of information about individuals?	The title of the study is a 'retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East.' The main aim of the study is to examine all the contextual issues relating to serious incidents within mental health services in the Waterford/Wexford area. This will be achieved through the retrospective review of patient data (in this instance patient medical records and incident report forms). Concerns relating to serious incidents across mental health services are not confined to local services alone, however. Studies examining areas of risk and untoward incidents within mental health services are commonplace, particularly focusing on areas such as violence, aggression, self-harm and suicide. Despite far reaching efforts to

	reduce the risk of harm to patients, families, staff and the wider public, mental health services continue to be criticised for failing to foresee and prevent serious incidents. Conversely, the current climate of risk is felt to have potentially damaging consequences for some patients in terms of their human rights, freedom and choices.
Will the project compel individuals to provide information about themselves?	No
Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information?	No
Are you using information about individuals for a purpose it is not currently used or in a way it is not currently used?	Yes – in this instance patient medical records are being used for historical research purposes and not clinical care
Does the project involve you using new technology that might be perceived as being privacy intrusive? For example, the use of biometrics or facial recognition.	No
Will the project result in you making decisions or taking action against individuals in ways that can have a significant impact on them?	No
Is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For example, health records, criminal records or other information that people would consider to be private.	Yes – the research study proposes to collect data from health records
Will the project require you to contact individuals in ways that they may find intrusive?	No as consent is not being requested directly

2. Describe the information flows	
Date of Assessment:	04/06/19
Assessment performed by:	Neil Crowhurst
Function/Department:	Researcher/ACNM2 – WIT and HSE South
Process Name:	‘A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East.'
Description of the envisaged processing operations: (Including collection, deletion and use)	The first step of the research project will be accessing incident reports relating to mental health services in Waterford and Wexford, dating back to 2011. These will be obtained via the regional health service office (based in Kilkenny) where they are stored electronically. The research team have liaised with the relevant staff working there to be sent, by HSE email, an electronic list of all the incident reports collated sine 2011 for the areas of Waterford and Wexford. This list will only be kept electronically in a folder within the lead researcher’s personal HSE ‘G’ drive which is only then accessible from an HSE computer terminal. It will not be transferred to any other storage device outside of the HSE. The only identifying information in this list will be a patient identifier number (known locally as an A number) - a six digit code which then only reveals patient information when entered

	into a system known as IPMS (an electronic database only accessible to relevant healthcare staff).The lead researcher is the only member of the research team who will have access to this code number and who has the necessary login credentials - as a result of being a current HSE clinical employee. The reason that the identifying number needs to be known relates to the second step of the research project which is the proposed accessing of the medical record/chart. In practical terms these records/charts will not be able to be accessed without the lead researcher knowing patient identities. Once the identity of the patient is established, the lead researcher will be able to locate and review relevant charts - stored in their normal locations within Waterford and Wexford mental health services. Files will not be removed from any HSE location and will be reviewed ‘on-site.’ Data will be extracted from the file using a patient data collection form (Appendix 1). This form will be pseudonymous as although there will be no reference to patient identity outright, a person with knowledge of a particular case might be able to establish identity from age, gender, place of incident etc. Similarly, the lead researcher will need to be able to link the original data collection sheet to the data entered on the database meaning that identities will be discoverable for the lead researcher only. Data will be collected manually and then entered onto an electronic database, using the lead researchers academic institute laptop which is password protected.

	During and after the adding of data to the electronic database, the data collection sheets will be kept securely in the lead researchers HSE place of work (locked filing cabinet only accessible to lead researcher).
Purposes of the processing:	For research purposes
Legal basis for processing:	Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the HSE.
Necessity of the processing (Justification)	GDPR article 9-2(j) "processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject" Whereas explicit patient consent would commonly be the best way forward in terms of gaining access to personal data, in this instance it was felt more appropriate to seek a consent declaration from the Health Research Consent Declaration Committee. Two main reasons were established in terms of seeking a consent declaration: - 1. It was felt that the public interest in carrying out the research

	outweighs the potential for unnecessary distress caused by seeking consent in particularly sensitive cases (e.g. cases of serious self-harm, attempted suicide or serious assault) 2. The logistical difficulties associated with gaining consent in retrospective studies (where patients may have since moved, been discharged, refuse further contact etc.) was also noted
Proportionality of the processing (Estimated number of Data Subjects Affected)	Up to 100 records are expected to re be reviewed
Individuals consulted during the performance of DPIA (Include internal and external consultations held)	Members of CARE (care collaboration group forum involving WIT and HSE representatives) Members of the research team (myself, Dr Michael Bergin and Professor John Wells) - Patient advocacy - Statistician - HSE and WIT ethics committees A similar DPIA form to this one has been sent to the DPO office for the HSE South (awaiting comments and feedback) An application to the Health Research Consent Declaration Committee for a consent declaration (exempting study from seeking patient consent) is currently in progress. They have requested feedback on DPIA's from both WIT and the HSE

3. Identify data protection and related risks			4. Identifying data protection solutions to reduce or eliminate the risks				
No.	Privacy Issue	Risk	Existing Controls Identified	Risk Rating L x I	Additional Controls/ Actions Required	Action Owner	Deadline Date
1	*Unauthorised access to clinical/personal data.*	*The main risk impacts relate to breach of patient privacy (improper use/storage/sharing of data) and potential detriment to clinical treatment (if notes were to be lost/misplaced)* *Although the data collected will not include patient or family names, the collation of certain characteristics (as defined in the data collection form or the incident report summary) could lead to an outside person being able to identify an individual (e.g. through combining persons age, gender, time of incident,*	*Use of secure email system* *Use of secure electronic and manual storage within HSE place of work* *Use of password protection and encryption on WIT laptop* *No additional data to be added to data collection form/electronic database besides*	*3*	*None at present*		

		type of incident, ethnic origin etc.) However, the identifying person would need to have prior knowledge of the specific incident	*what is being asked* *Patient charts not to be removed and put back promptly in their usual location* *Adherence to the data protection plan outlined* *Following professional protocols and guidance relating to data protection and patient confidentiality (HSE and WIT policies)*				

5. Signing off on the outcomes of the DPIA

DPIA Assessment result: (Pass- risk eliminated, avoided or accepted; Fail- risk unavoided)	

Approved by:	C. Power
6. Integrating data protection solutions into the project	
Next steps/Actions	

Guidance

Example Risks to Individuals:

- Inappropriate disclosure of personal data internally due to a lack of appropriate controls being in place.
- Accidental loss of electronic equipment may lead to risk of disclosure of personal information to third parties.
- Breach of data held electronically by "hackers".
- Vulnerable individuals or individuals about whom sensitive data is kept might be affected to a very high degree by inappropriate disclosure of personal data.
- Information released in anonymised form might lead to disclosure of personal data if anonymisation techniques chosen turn out not to be effective.
- Personal data being used in a manner not anticipated by data subjects due to an evolution in the nature of the project.
- Personal data being used for purposes not expected by data subjects due to failure to explain effectively how their data would be used.
- Personal data being used for automated decision making may be seen as excessively intrusive.
- Merging of datasets may result in a data controller having far more information about individuals than anticipated by the individuals.
- Merging of datasets may inadvertently allow individuals to be identified from anonymised data.
- Use of technology capable of making visual or audio recordings may be unacceptably intrusive.
- Collection of data containing identifiers may prevent users from using a service anonymously.
- Data may be kept longer than required in the absence of appropriate policies.
- Data unnecessary for the project may be collected if appropriate policies not in place, leading to unnecessary risks.
- Data may be transferred to countries with inadequate data protection regimes.

Appendix 19 DPIA for WIT

Corporate Risks:

- Failure to comply with the GDPR may result in investigation, administrative fines, prosecution, or other sanctions. Failure to adequately conduct a DPIA where appropriate can itself be a breach of the GDPR.
- Data breaches or failure to live up to customer expectations regarding privacy and personal data are likely to cause reputational risk.
- Public distrust of organisation's use of personal information may lead to a reluctance on the part of individuals to deal with the organisation.
- Problems with project design identified late in the design process, or after completion, may be expensive and cumbersome to fix.
- Failure to manage how your company keeps and uses information can lead to inefficient duplication, or the expensive collection and storage of unnecessary information. Unnecessary processing and retention of information can also leave you at risk of non-compliance with the GDPR.
- Any harm caused to individuals by reason of mishandling of personal data may lead to claims for compensation against the organisation. Under the GDPR the organisation may also be liable for non-material damage.

Compliance Risks:

The organisation may face risks of prosecution, significant financial penalties, or reputational damage if it fails to comply with the GDPR. Individuals affected by a breach of the GDPR can seek compensation for both material and non-material damage.

Failure to carry out a DPIA where appropriate is itself a breach of the legislation, as well as a lost opportunity to identify and mitigate against the future compliance risks a new project may bring.

Examples of data protection solutions:

- Deciding not to collect or store particular types of information.
- Putting in place strict retention periods, designed to minimise the length of time that personal data is retained.
- Reviewing physical and/or IT security in your organisation or for a particular project team and making appropriate improvements where necessary.
- Conducting general or project-specific training to ensure that personal data is handled securely.

- Creating protocols for information handling within the project, and ensuring that all relevant staff are trained in operating under the protocol.
- Producing guidance for staff as reference point in the event of any uncertainty relating to the handling of information.
- Assessing the need for new IT systems to safely process and store the data, and providing staff with training in any new system adopted.
- Assessing the portability of using anonymised or pseudonymised data as part of the project to reduce identification risks, and developing an appropriate anonymisation protocol if the use of anonymised data is suitable.
- Ensuring that individuals are fully informed about how their information will be used.
- Providing a contact point for individuals to raise any concerns they may have with the organisation.
- If using external data processors, selecting appropriately experienced data processors and putting in place legal arrangements to ensure compliance with data protection legislation.
- Deciding not to proceed with a particular element of a project if the data privacy risks associated with it are inescapable and the benefits expected from this part of the project cannot justify those risks.

Risk Assessment Guidance:

Likelihood/Potential for an Incident to occur	**Impact/Outcome of Incident**	**Risk Level Calculation L X I**	**Guideline Action Timetable**
1 - Rare: No history of event occurring over period of years. This event may occur but in exceptional circumstances.	**1.** Minor compromise of privacy (e.g. un-sensitive personal data such as helpdesk ticket compromised)	1 – 2 Acceptable	No Action
2 - Unlikely: The event would be expected to occur annually	**2.** Minor data breach (e.g. inappropriate contact of data subject via email)	3 – 5 Low	Prioritise after medium risk actions complete
3 - Possible: This could occur monthly, as such it has a reasonable chance of occurring.	**3.** Moderate data breach (Sensitive data e.g. payroll compromised)	6 – 10 Medium	Prioritise after high risk actions complete
4 - Likely: Expected to occur at least weekly, the event will occur in most situations	**4.** Significant data breach (Financial loss, severe stress for a data subject or data	11 – 15 High	Prioritise Action as soon as Practical

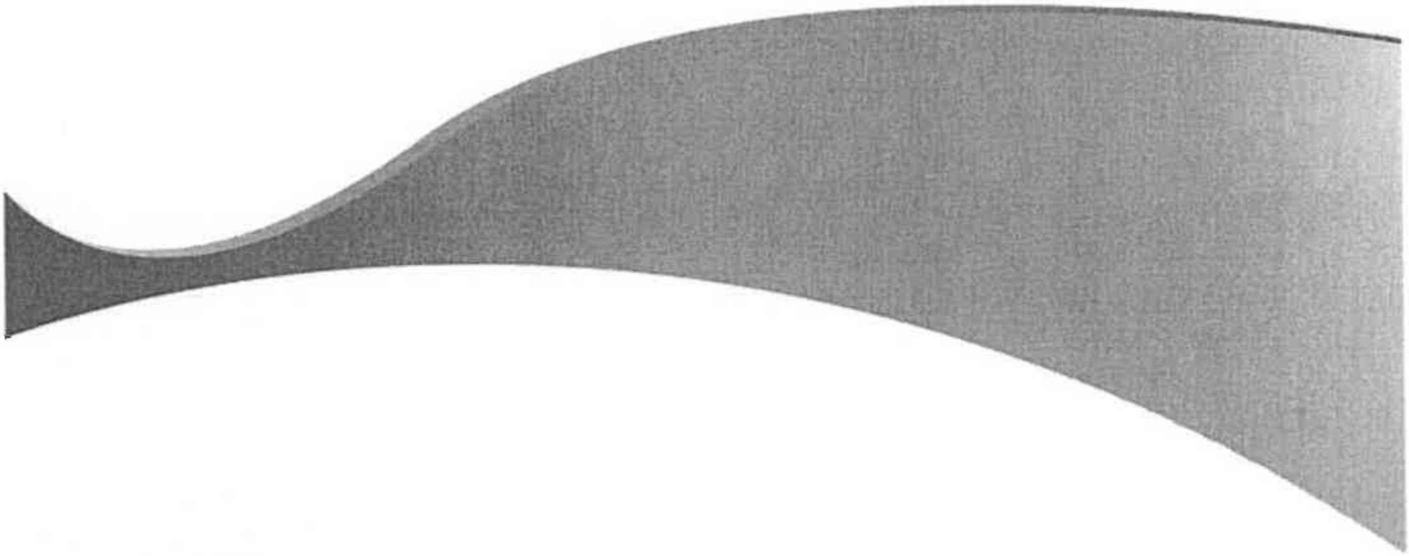
	subjects		
5 - Certain: Expected to occur almost daily, it is more likely to occur than not.	**5.** Major data breach (Risk of severe financial loss to a large number of data subjects)	16 – 25 Very High	Action Urgent

Appendix 20 DPIA for HSE

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Privacy Impact Assessment (PIA) Form

Private & Confidential



This form should be completed with reference to the HSE Privacy Impact Assessment Process Guidance Document

Version 1.0
August 2018

Seirbhís Sláinte
Níos Fearr
á Forbairt

Building a
Better Health
Service

Document Information

Title:	HSE Privacy Impact Assessment (PIA) Form
Purpose:	A PIA is a process to help identify and minimise the data privacy risks of a project or activity so as to ensure that patients and service users' rights to privacy and confidentiality are appropriately protected.
Author:	Joe Ryan
Publication date:	August 2018
Review Date:	August 2020

Contact Details

Data Protection Officer **HSE**	Email: dpo@hse.ie Phone: 01-635-2537
Deputy Data Protection Officer West • **CHO 1 – Cavan, Donegal, Leitrim, Monaghan, Sligo** • **CHO 2 – Galway, Mayo, Roscommon** • **Mid-West Community Healthcare** **Saolta Hospital Group**	Email: ddpo.west@hse.ie Phone: 091-775819

Deputy Data Protection Officer Dublin North-East (excluding voluntaries) • **Midlands, Louth, Meath Community Health Organisation** • **Community Health Organisation Dublin North City & County** • **CHO 6 – Dublin South East, Dublin South & Wicklow** • **RCSI Hospital Group** **National Children's Hospital**	Email: ddpo.dne@hse.ie Phone: 049-4377343
Deputy Data Protection Officer Dublin mid-Leinster (excluding voluntaries) • **Dublin Midlands Hospital Group** • **Ireland East Hospital Group** **Community Healthcare Dublin South, Kildare & West Wicklow**	Email: ddpo.dml@hse.ie Phone: 057-9357876
Deputy Data Protection Officer South (excluding voluntaries) • **Cork & Kerry Community Healthcare** • **CHO 5 – Carlow, Kilkenny, South Tipperary, Waterford & Wexford** • **UL Hospital Group** **South South-West Hospital Group**	Email: ddpo.south@hse.ie Phone: 091-775819

Document History

Version	**Owner**	**Author**	**Publish Date**
1.0	HSE	Joe Ryan	August 2018

Privacy Impact Assessment Form

Section 1 – Initial Details (Threshold Assessment)

Title of the activity: Research project - Retrospective case analysis of serious untoward incidents

Name of person completing this form: Neil Crowhurst

Title: A/CNM2

Service Area: Waterford/Wexford Mental Health services

Is personal data being collected or used? Yes ☑ No ☐

Are special categories of personal data being collected or used? (as listed below) Yes ☑ No ☐

If yes, indicate the categories involved:

☑ Health data
☑ Data revealing racial or ethnic origin
☐ Political opinions
☐ Religious or philosophical beliefs
☐ Trade union membership
☐ Sex life data
☐ Genetic data
☐ Biometric data

If you answered 'No' to both of the questions above you do not need to complete the remainder of the form as a PIA is not required

If you answered 'Yes' to any of the questions above you do need to complete the remainder of the form as a PIA is required

Section 2 – Activity Details

Briefly outline the activity (name, purposes, context of use, etc.)

The title of the study is a 'retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East.' The main aim of the study is to examine all the contextual issues relating to serious incidents within mental health services in the Waterford/Wexford area. This will be achieved through the retrospective review of patient data (in this instance patient medical records and incident report forms).

Concerns relating to serious incidents across mental health services are not confined to local services alone, however. Studies examining areas of risk and untoward incidents within mental health services are commonplace, particularly focusing on areas such as violence, aggression, self-harm and suicide. Despite far reaching efforts to reduce the risk of harm to patients, families, staff and the wider public, mental health services continue to be criticised for failing to foresee and prevent serious incidents. Conversely, the current climate of risk is felt to have potentially damaging consequences for some patients in terms of their human rights, freedom and choices.

Describe how the activity generally works (from data collection to data destruction, different processing stages, storage etc.) give a detailed description of each of the processes carried out.

The first step of the research project will be accessing incident reports relating to mental health services in Waterford and Wexford, dating back to 2011. These will be obtained via the regional health service office (based in Kilkenny) where they are stored electronically. The research team have liaised with the relevant staff working there to be sent, by HSE email, an electronic list of all the incident reports collated sine 2011 for the areas of Waterford and Wexford. This list will only be kept electronically in a folder within the lead researcher's personal HSE 'G' drive which is only then accessible from an HSE computer terminal. It will not be transferred to any other storage device outside of the HSE.

The only identifying information in this list will be a patient identifier number (known locally as an A number) - a six digit code which then only reveals patient information when entered into a system known as IPMS (an electronic database only accessible to relevant healthcare staff).The lead researcher is the only member of the research team who will have access to this code number and who has the necessary login credentials - as a result of being a

What is the legal basis for processing the data?

☐ Consent from the data subject.

☐ Processing is necessary for the performance of a contract.

☐ Processing is necessary for a legal obligation to which the HSE subject.

☐ Processing is necessary to protect the vital interests of the data subject.

☑ Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the HSE.

If processing special categories of data what is the legal basis?

☐ Explicit Consent

☐ For the purposes of preventative or occupational medicine, for the assessment of the working capacity of an employee, for medical diagnosis, for the provision of medical care, treatment or social care, for the management of health or social care systems and services. Or pursuant to a contract with a health practitioner.

☑ Other (please state)

GDPR article 9-2(j) "processing is necessary for archiving purposes in the publi

If applicable describe the relevant legal obligation (act, regulation, article etc.):

Whereas explicit patient consent would commonly be the best way forward in terms of gaining access to personal data, in this instance it was felt more appropriate to seek a consent declaration from the Health Research Consent

Describe the Role of data controller(s) for the activity:

For the purposes of this study the joint data controllers are the two organisations (HSE and WIT). Both organisations have been asked to give advice in relation to the data protection aspects of the study.

Describe the Role of data processor(s) for the activity:

The sole data processor in this instance is the lead researcher, Neil Crowhurst. He will access and process personal data only within the specified parameters of the study aims, objectives and methods and only after gaining

Does the activity use automated decision making? Yes ☐ No ☑

Briefly describe the automated decision making

N/A

If yes, what are the consequences of the automated decision making for the data subject:

N/A

Explain why all personal data collected is necessary for the purposes of your processing:

The type and quantity of data required has been carefully considered by the research team. Each aspect of data collection is intended to support the study's overall aim, which is to examine trends and patterns relating to serious incidents within mental health services. Without personal data such as age, gender or ethnic origin (as examples) trends and patterns will not be able to b

List the data supporting assets (hardware, software, networks, people, paper or paper transmission channels):

HSE personal 'G' drive and HSE computer terminal
HSE 'IPMS' patient database
WIT password protected laptop
Microsoft excel
Data collection forms (paper)

Is the personal data going to be shared? Yes ☑ No ☐

If yes, list the recipients (or categories of recipients) of the personal data and for what purpose is it being shared:

For supervisory purposes, it may be necessary for the lead researcher to discuss the pseudonymised personal data collected with the two research supervisors for this study. Neither the 'in progress' or 'final' electronic database

Provide details of all data processors:

Neil Crowhurst - lead researcher

There will be not other data processors

Provide details of all data sub-processors:

None

Is the data being sourced from another source? Yes ☑ No ☐

If yes, please state where the data originates from and if applicable, did it come from a publicly accessible source:

The data collected will be obtained from clinical incident reports and patient medical charts. These are not routinely accessible beyond the relevant care team, health services managers and administrative staff.

What is the retention period for the different items of personal data:

Incident reports summary will be held for 1 year from receipt
Data collection sheets will be held for duration of study (3 years)
Database will be retained for duration of the study (3 years)

Describe the steps taken to ensure that the personal data is kept up to date and accurate:

No personal data will be removed from its normal place of storage (within the patients medical chart and in its usual clinical location). It is the responsibility of the researcher to keep files in their present condition and to return them immediately after data collection.

How are data subjects informed of the processing?

In this instance the research team are not seeking individual consent but applying for a consent declaration. However, an information sheet will be made available to anyone wanting to know about the study and the researcher will be available at all times to answer queries relating to the study and the processing of personal data.

How can data subjects exercise their right to access and to data portability under Article 15 and Article 20 of the GDPR?

This is not applicable as a consent declaration is being applied for.

How can data subjects exercise their right to rectification and erasure under Articles 16 & 17 of the GDPR?

This is not applicable as a consent declaration is being applied for.

How can data subjects exercise their right to restriction and object under Article 18 and Article 21 of the GDPR?

This is not applicable as a consent declaration is being applied for.

For each data processor, describe their responsibilities (duration, scope, purpose, documented processing instructions, prior authorisation, contracts in place) for this activity:

The sole data processor will contact administrator (based in CHO5 HQ) to request electronic list of all incident reports for Waterford and Wexford mental health services dating back to 2011. A contact person is in place who is aware of the research study.

This list will contain a description of the incident without reference to patient names. However, each patients 'A' number, a 6 digit code which allows access

Is the personal data being transferred outside of the Republic of Ireland? Yes ☐ No ☑

If yes, list the countries where the personal data is to be transferred:

N/A

For each country outside of the EEA (European Economic Area) where data is stored or processed, name it and describe the provisions concerning the transfer:

N/A

Describe the organisational security measures:

The HSE maintains a secure email system which will be utilised appropriately. The data processors personal 'G' drive is only accessible from an HSE workplace. Safe storage (locked filing cabinet for personal use only) is available to the data processor in his usual clinical location. This will be used to store the handwritten data collection forms.

Describe the technical security measures:

The data processor's laptop was provided by WIT and is password protected. The database containing pseudonymised data will be stored on this laptop but will also be encrypted.

Describe the additional measures taken to ensure data security:

Required incident reports will be stored electronically and only accessible with HSE login details and from an HSE computer terminal.

The only privacy identifier on the incident reports will be the patient's unique 'A' number. A patient's identity can only be known by entering this six digit code

Section 3 – Risks and Risk Mitigation

Is there a risk of:

a. ☑ Illegitimate access to personal data

b. ☐ Unwanted modification to personal data

c. ☐ Personal data disappearance

d. ☐ Other (please state)

Section 3 (a) – Illegitimate access to personal data

Complete the following questions if you selected a. (Illegitimate access to personal data)

What are the main threats that could lead to the risk?

The main threat is unauthorised acccess to clinical/personal data.

What are the potential impacts on data subjects arising from the risk?

The main risk impacts relate to breach of patient privacy (improper use/storage/sharing of data) and potential detriment to clinical treatment (if notes were to be lost/misplaced).

Although the data collected will not include patient or family names, the collation of

What are the risk sources?

- email correspondence going to wrong persons
- electronic list of incidents being misplaced, lost or removed from secure area
- medical notes being misplaced, lost or taken from their usual location
- data collection forms being misplaced, lost or removed from secure area
- database containing data from collection forms being misplaced, lost or removed from secure area

What controls are in place to address the risk and are these controls adequate?

- use of secure email system
- use of secure electronic and manual storage within HSE place of work
- use of password protection and encryption on WIT laptop
- no additional data to be added to data collection form/electronic database besides what is being asked
- patient charts not to be removed and put back promptly in their usual location

How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?	☐ 1 – Rare ☑ 2 – Unlikely ☐ 3 – Possible ☐ 4 – Likely ☐ 5 – Highly Certain
How do you estimate the potential impact of the risk on data subjects?	☐ 1 – Negligible ☑ 2 – Minor ☐ 3 – Moderate ☐ 4 – Major ☐ 5 – Critical
What is the overall risk rating (likelihood x impact)?	☑ Low ☐ Medium ☐ High

Section 3 (b) – Unwanted modification to personal data

Complete the following questions if you selected b. (Unwanted modification to personal data)

What are the main threats that could lead to the risk?

What are the potential impacts on data subjects arising from the risk?

What are the risk sources?

What controls are in place to address the risk and are these controls adequate?

How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?

- ☐ 1 – Rare
- ☐ 2 – Unlikely
- ☐ 3 – Possible
- ☐ 4 – Likely
- ☐ 5 – Highly Certain

How do you estimate the potential impact of the risk on data subjects?

- ☐ 1 – Negligible
- ☐ 2 – Minor
- ☐ 3 – Moderate
- ☐ 4 – Major
- ☐ 5 – Critical

What is the overall risk rating (likelihood x impact)?

- ☐ Low
- ☐ Moderate
- ☐ High

Section 3 (c) – Personal data disappearance

Complete the following questions if you selected c. (Personal data disappearance)

What are the main threats that could lead to the risk?

What are the potential impacts on data subjects arising from the risk?

What are the risk sources?

What controls are in place to address the risk and are these controls adequate?

How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?

☐ 1 – Rare
☐ 2 – Unlikely
☐ 3 – Possible
☐ 4 – Likely
☐ 5 – Highly Certain

How do you estimate the potential impact of the risk on data subjects?

☐ 1 – Negligible
☐ 2 – Minor
☐ 3 – Moderate
☐ 4 – Major
☐ 5 – Critical

What is the overall risk rating (likelihood x impact)?

☐ Low
☐ Moderate
☐ High

Section 3 (d) – Other

Complete the following questions if you selected d. (Other)

Describe in detail the risk

What are the main threats that could lead to the risk?

What are the potential impacts on data subjects arising from the risk?

What are the risk sources?

What controls are in place to address the risk and are these controls adequate?

How do you estimate the likelihood of the risk, especially in respect of threats, sources of risk and planned controls?	☐ 1 – Rare ☐ 2 – Unlikely ☐ 3 – Possible ☐ 4 – Likely ☐ 5 – Highly Certain
How do you estimate the potential impact of the risk on data subjects?	☐ 1 – Negligible ☐ 2 – Minor ☐ 3 – Moderate ☐ 4 – Major ☐ 5 – Critical
What is the overall risk rating (likelihood x impact)?	☐ Low ☐ Medium ☐ High

Section 4 – Data Subject Consultation

Were data subjects (or a representative) consulted as a part of the PIA process? ☑ Yes ☐ No

If Yes, state the number of data subjects consulted, method of consultation and describe the outcome of the consultation:

- The data processor has met with the relevant local patient /representative advocacy service (see feedback attached).
- The research study has been given contingent HSE and WIT ethics committee approval. Patient representatives were present on both research ethics committees.

If No, explain the reasons for not consulting data subjects:

Section 5 – DPO/DDPO Consultation

DPO opinion (please ensure the previous questions are completed fully before the DPO can provide an opinion):

Many thanks for forwarding the application form with comments and the completed HSE DPIA. My apologies for the delay in responding to you.

I note that you have outlined the difficulties in obtaining the consent of data subjects in the application form and the requirement for the consent declaration to continue the research. I note that you are satisfied that the public interest in carrying out this health research significantly outweighed the public interest in obtaining explicit consent in order to do so. Having perused these documents and, in particular, the DPIA, I am satisfied that such risks as there may be to the processing of the personal data have been sufficiently mitigated in the circumstances.

Please treat this communication for the purposes of fulfilling Part E.3(c) of the HRCDC Application Form.

(copy of email from Mary Deasy, HSE DDPO - see appendix 10 of HRCDC application)

Section 6 – Approval

To be completed by the data controller

Outcome:

☑ Approved
☐ Denied
☐ DPC Consultation Needed
☐ Further Updates Needed

Signed: ____________________ **Date:** ____________________

Ospidéal Ollscoile Phort Láirge
University Hospital Waterford
Regional Cancer Centre South East

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

Research Ethics Office Old School of Nursing
University Hospital Waterford
Tel: 051- 842026/051-842391

2nd September 2019

Mr Neil Crowhurst
Mental Health Department
Primary Care Centre
John's Hill
Waterford

STUDY

STUDY TITLE: "A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE south east."

STUDY STATUS: **APPROVED**
(Contingent on a Consent Declaration being granted by the HRCDC)

Dear Mr Crowhurst

The Research Ethics Committee, REC, HSE, South East reviewed the above study at their meeting on the 8th July 2019.

Full ethical approval is granted by the REC to proceed with this study. This approval is contingent upon a Consent Declaration being granted by the Health Research Consent Declaration Committee (HRCDC).
You must inform the REC of the outcome of your application to the HRCDC before commencing this study.

The following documents were reviewed and approved:

1. Research Ethics Standard Application Form
2. Research Proposal
3. Staff Information sheet
4. Letter to Director of Nursing
5. Declaration Form
6. CV of Principal Investigator – Mr Neil Crowhurst

It is a requirement of the REC, HSE, South East that you inform the REC of the outcome of the HRCDC prior to commencing this study.

Yours sincerely,

Caroline Lamb.

Ms Caroline Lamb
Research Ethics Committee Coordinator
Health Service Executive, South Eastern Area

The Research Ethics Committee, HSE, South East is a recognized Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human use) Regulations 2004 and as such is authorized to undertake ethical review of clinical trials of all descriptions and classes for the Republic of Ireland.

The Research Ethics Committee, HSE, South East issues ethical approval on the basis of information provided. It is the responsibility of the researcher to notify the Research Ethics Office of any changes to a study to ensure that the approval is still relevant.

Appendix 22 HRCDC approval

HRCDC
Health Research Consent
Declaration Committee

Teach Grattan
67-72 Sráid an Mhóta Íochtarach
Baile Átha Cliath 2
D02 H638
Éire

Grattan House
67-72 Lower Mount Street
Dublin 2
D02 H638
Ireland

T: 353 1 234 5000
F: 353 1 661 2335
E: info@hrcdc.ie

www.hrcdc.ie

PRIVATE AND CONFIDENTIAL

Neil Crowhurst
Acting Clinical Nurse Manager 2
Health Service Executive
Brook House
Cork Road, Waterford

20th December 2019

Dear Neil,

Application: "A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East'"
Reference ID: 19-002-AF1
Data Controller(s): Health Service Executive & Waterford Institute of Technology
Decision: Conditional Declaration

Thank you for your application to the HRCDC seeking a consent declaration on behalf of the Health Service Executive and Waterford Institute of Technology. The HRCDC convened on 16th December 2019 and reviewed the above referenced application. After careful consideration, we are pleased to inform you that the following decision was made by the HRCDC;

- The HRCDC has exercised its right under Regulation (8)(4)(b) and has made a **Conditional Declaration** that the public interest in carrying out the health research significantly outweighs the requirement of the Applicant(s) to seek explicit consent of the data subject, whose personal data is being used for the above referenced health research study.

- The following specific conditions have been attached to the Declaration as follows;

Condition 1. In addition to the staff and patient information leaflets developed, to further enhance the data protection principle of 'transparency', the Applicant is requested to ensure more robust transparency arrangements are in place to inform staff and patients about this study and the data being used for the study. Transparency can be enhanced by way of providing public notices at the relevant mental health services sites involved in this study. These notices should include relevant contact information and practical steps for individuals who may wish to withdraw from the study, if they believe their personal data may be included. The notices should be clearly visible at each site and in place prior to data collection commencing at that location. Other means of making the information about the study publicly available, should be considered, as appropriate.

NOTE: Further information on providing transparent information can be found on the Data Protection Commission's website; https://www.dataprotection.ie/en/organisations/know-your-obligations/transparency. It is advisable to consult with your Data Protection Officer as needed.

Condition 2. As the Health Service Executive & Waterford Institute of Technology have now been confirmed as Joint-Data Controllers, an appropriate Joint Data Controller arrangement also should be in place between these parties. It is advisable to discuss this with your Institution's legal office and Data Protection Officer, as appropriate.

- The Declaration is made solely to the Applicants who are the Data Controllers and not to any other third party.

- The Declaration is made commencing 16th December and shall be valid until 31st March, 2023

In addition to the decision made by the HRCDC, the following standard conditions of the Declaration shall apply;

- the Applicant must complete an Annual Review to the HRCDC on the anniversary date of this decision letter and for every year, or part year, the Declaration is valid;
- the Applicant must have any necessary contractual obligations in place;
- all activities being carried out are in compliance with the General Data Protection Regulations, the Data Protection Act 2018 and Health Research Regulations, for the duration of the Declaration;
- any breaches that occur that affect the integrity of the Declaration and the protection of data subjects, must be reported to the HRCDC.

Please confirm acceptance of the Declaration within 30 working days of receipt of this letter, or the Declaration will lapse.

On behalf of the HRCDC and Secretariat, we wish you the very best of luck with the research study.

Kind regards,

Emily Vereker, PhD
Programme Manager, Secretariat
Health Research Consent Declaration Committee

Cc by email

Appendix 23 Research study public notice

Public Notice

Notification of Research Study

Research title

'A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE South East'

Background

HSE mental health services in the south-east are constantly aiming to improve the care provided to service users and their families. Research is an important part of this process and we are continuously engaging with service users; families and staff members in order to achieve this.

The aim of the above study is to examine the various issues which can lead to serious incidents both on inpatient wards and in community settings across Waterford and Wexford services. Unfortunately, there are times where service user, family member or staff safety has not been maintained because of actions such as verbal or physical abuse and self-injury. Although incidents of a very serious nature rarely occur, it is really important that, as providers of care, we try to find out why these things happen and what we can do to prevent them happening again in the future.

In this research we will look at things like staffing levels; staff training; HSE policies; the clinical environment; the safety of service users/family/staff in hospitals and some other wider social issues, which can affect life inside and outside the hospital, such as unemployment and homelessness.

Data collection

Part of the research study involves examining patient medical charts and collating relevant patient data. However, this data will not directly identify any patient, family or staff member and all efforts have been made to ensure that there is no breach of data protection at any stage. The only researcher who will access patient charts is also a clinical member of staff and therefore bound by a strict code of confidentiality.

Consent and ethical approval

The study has been approved by the local Research Ethics Committee (REC) and has the consent of the Health Research Consent Declaration Committee (HRCDC). This means that individuals will not be approached for their consent. This decision was taken as contacting patients and families in relation to past serious incidents could cause unnecessary distress and indeed they may have moved on from services or no longer be contactable.

Appendix 23 Research study public notice

Patients, however, still retain certain rights under the General Data Protection Regulation (GDPR):

- Confirmation of whether or not personal data concerning them is being used
- An explanation of the reasons why their data is being used
- Confirmation of the types or categories of data being examined
- Confirmation of whom I intend to discuss personal data with
- An explanation of where I will be collecting their data from Explanation of the length of time that I will be keeping their data
- Change, remove or correct the data collected
- Object to the research team in relation to any aspect of the research
- Object to the Health Service Executive in relation to any aspect of the research (see details below)
- Complain to the Data Protection Commission if they are unsatisfied with any activity or response from the research team or hospital management (see details below)

If you would like to discuss any of these issues, have any further concerns or queries, please feel free to contact the Lead Researcher at the following location:

Neil Crowhurst
Clinical Nurse Manager 2
Mental health department
Primary Care Centre Waterford
051861148

Complaints and feedback to the HSE
The procedures for making any complaint to the HSE are explained on their website at: https://www2.hse.ie/services/hse-complaints-and-feedback/your-service-your-say.html

Complaints to the Data Protection Commission (DPC)
The procedures for making any complaint to the DPC are explained on their website at: https://www.dataprotection.ie/en/individuals/raising-concern-commission

Appendix 24 Joint data controller agreement between WIT and the HSE

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

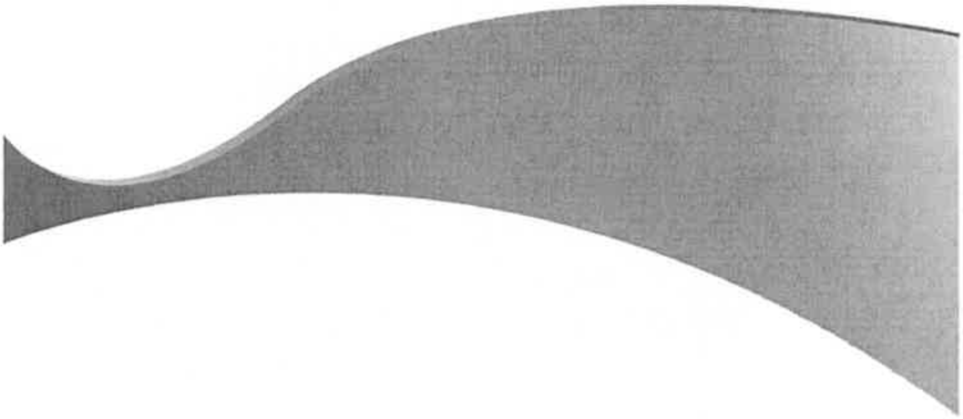
Data Sharing Agreement

Between

Health Service Executive

And

Waterford Institute Technology



1. Introduction

The purpose of this Agreement is to define the arrangements for the sharing of data between the Health Service Executive (HSE) and the specified organisations.

2. Definitions

In this Agreement, unless the context otherwise requires:

Anonymised data shall mean data which has been manipulated so as to irreversibly remove all personal identifiers from the data so that it is impossible to identify an individual whom the data relates to.

Consent has the meaning given to that term in Article 4 of the GDPR.

Data shall mean any information (irrespective of the format it is held - paper, electronic or otherwise) of whatever nature that, by whatever means, is shared by the Parties to this Agreement with each other.

Data Controller *or* ***Controller*** has the meaning given to that term in Section 1(1) of the Data Protection Acts and (when effective) in Article 4 of the GDPR;

Data Protection Acts means the Data Protection Act 2018 and the European Communities (Electronic Communications, Networks and Services) (Privacy and Electronic Communications) Regulations 2011 (S.I. 336/2011) and every statutory modification, re-enactment, replacement and/or amendment thereof for the time being in force (or, where the context so admits or requires, any one or more of such Acts) and all orders and regulations/statutory instruments made thereunder.

Data Subject has the meaning given to this term in Section 1(1) of the Data Protection Acts;

Freedom of Information Acts means the Freedom of Information Acts 1997, 2003 & 2014 and any amendments to or replacements thereof, including by means of directly effective EU Regulation;

GDPR means the EU General Data Protection Regulation, Regulation (EU) 2016/679, the effective date of which is 25th May 2018;

Party, Parties shall mean each any organisation that has signed up to this Agreement (i.e. the HSE and the specified organisation(s)).

Personal Data has the meaning given to that term in Section 1(1) of the Data Protection Acts and (when effective) in Article 4 of the GDPR, and includes Sensitive Personal Data and Special Categories of Data;

Process has the meaning given to those terms in Section 1(1) of the Data Protection Acts and (when effective) in Article 4 of the GDPR;

Pseudonymisation, Pseudonymised and like words, have the meaning given to those terms (when effective) in Article 4 of the GDPR;

Sensitive Personal Data has the meaning given to this term in Section 1(1) of the Data Protection Acts;

Special Categories of Data has the meaning given to this term and/or such Personal Data as referred to in Article 9(1) and/or Article 10 of the GDPR.

3. Parties to the Agreement

3.1 The following organisations are party to this Agreement [The **Parties**]:

a) The Health Service Executive, a body corporate with perpetual succession established by the Health Act 2004 [the **HSE**], and

b) [the **Specified Organisation**] which has its principle administrative offices at **Waterford Institute Technology, Cork Road, Waterford**

3.2 This Agreement shall be managed by the following authorised officers from each of the participating organisations:

a) The Health Service Executive
Gerry Maley
General Manager,
Waterford & Wexford MHS,
South East Community Healthcare

b) Waterford Institute Technology
Corina Power
Data Protection Coordinator
WIT
dataprotection@wit.ie

Reason(s) for sharing data

1. The data is being shared for research purposes in the public interest
2. The specific objective of sharing the data is to provide service user details in relation to historical incidents of a serious nature within mental health services
3. The benefits of the sharing the data include:
   a. The production of research results which can be used by the HSE to improve safety measures aimed at reducing the prevalence of serious incidents
   b. Benefits to WIT in terms of research output
   c. Benefits to the wider research community on publication of results

   d. Academic and professional achievement/development of the lead researcher and supervisory team
4. The final results will be summarised in HSE report and publication formats

4. Description of data shared

1. The type of data shared will be of a sensitive and personal nature, originating from serious incident reports and patient medical files. The data will be classed as pseudonymised on collection for two reasons:
   a. The lead researcher will need to be able to retain the ability to trace collected data to its original source
   b. Patient identities could be identified through the collated data when examined across a number of categories (e.g. age range, gender, ethnicity, diagnosis
2. The source of the shared data will come from centrally stored HSE electronic files containing serious incident reports and patient medical files (stored across various sites in Waterford and Wexford)
3. The type of data being shared is best defined by attention to Appendices 1 and 2. Appendix 1 is a blank copy of the incident report form currently being used in the HSE South (a summary of multiple forms will be sent electronically for the study). Appendix 2 is the data collection form which will be used on reviewing medical files

5. Legal Basis for Data Sharing

Reference is given in relation to GDPR Article 6 point E – 'processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.'

Reference has also been made to GDPR Article 9(2) (j) 'processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject'

Patient consent is not being sought due to the potential distress that may arise from approaching individuals or families in relation to serious incidents of a historical nature. As a result, a consent declaration has been ~~applied for from~~issued by the Health Research Consent Declaration Committee, Ireland.

The provision of a consent declaration does not exempt patients from certain rights enshrined within GDPR (see Appendix 3). Neither does it result in any diversion from existing protocols relating to European human rights or healthcare/academic staff codes of professional conduct.

6. Methods Used for Sharing Data

1a A summary of Incident reports will be sent via internal HSE email to the lead researcher. These will have inclusion and exclusion criteria applied with those not deemed suitable deleted immediately.
b. This incident report summary will be retained in the personal HSE 'G' drive of the lead researcher – only accessible via an authorised, password protected HSE workstation
c. The relevant medical files identified through this process will be reviewed by the lead researcher in their regular, secure place of storage. Files will not be removed. A structured data collection form will be completed for each reviewed file. These forms, containing pseudonymised data will be taken back to the lead researcher's regular place of work and stored in a locked filing cabinet, only accessible to the lead researcher himself.
d. The pseudonymised data from these forms will be transferred to an excel spreadsheet on the lead researcher's WIT issued laptop. The laptop is password protected and the spreadsheet itself will be encrypted.
2. The data collection period is one year from commencement of the study. The retained data will be held for 3 years. The final academic dissertation will be held for 5 years.

7. Data Quality

8.1 Each Party to this Agreement shall be responsible for the quality and accuracy of the Data, personal or otherwise, they share with the other Parties.

8.2 Data discovered to be inaccurate or inadequate for the specified reasons (as outlined in clause 4 of this Agreement) will be brought to the notice of the Party that supplied the Data. The Party that supplied Data will be responsible for correcting the Data and notifying all the other Parties of the corrections.

8. Legal Responsibility

9.1 When the HSE shares Data with the other Parties, the other Parties become the Data Controllers for this copy of the Data which they have received from the HSE.

9. Data Protection & Freedom of Information access requests

10.1 If one Party to this Agreement receives a data subject access request, and Personal Data is subsequently identified as having originated from the another Party, it will be the responsibility of the receiving Party to contact the Party that supplied the data to determine whether the supplier wishes to claim an exception under the provisions of either the Data Protection Acts, GDPR or the Freedom of Information Acts.

10. Restrictions on the use of data shared

11.1 All Data shared by the Parties, personal or otherwise, must only be used for the reason(s) specified at the time of disclosure(s) and as outlined in clause 4 of this Agreement. The Data must not be used for any other reason(s) without the permission of the Party who supplied the Data, unless an exemption applies within the Data Protection Acts, the GDPR or the Data is required to be provided under the terms of the Freedom of Information Acts or under the instructions of a court of law.

11. Responsibilities of the Health Service Provider

In consideration of the HSE sharing Data with the other Parties, the other Parties agrees to:

12.1 Comply fully with all their obligations as Data Controllers under the Data Protection Acts and GDPR, and Process all Personal Data shared in accordance with the these Acts and any guidance issued by the Data Protection Commissioner;

12.2 Maintain the security and confidentiality of all Personal Data shared;

12.3 Ensure Personal Data is only accessible to their staff on a need to know basis;

12.4 Ensure their staff, that need to access Personal Data are given appropriate training and are made fully aware of their responsibilities to maintain the security and confidentiality the Personal Data;

12.5 Implement appropriate human, organisational and technical controls to protect against unauthorised access, accidental loss, destruction, damage, alteration or disclose of the Personal Data;

12.6 Ensure the security of all Personal Data stored by them and their staff on fixed and mobile devices, including desktop computers, servers, mobile computer devices and removal storage devices;

12.7 Ensure that non-electronic copies of the Personal Data are managed and stored securely.

12. Monitoring & Review

13.1 If a new organisation joins the Agreement, a new version of the Agreement will be issued as soon as is possible, certainly with one month, and circulated to all the Parties.

13.2 If an organisation leaves the Agreement, a new version of the Agreement will be issued as soon as is possible, certainly with one month, and circulated to all the Parties.

13.3 If any organisation is replaced by a successor body or have their relevant powers and responsibilities transferred to another body, a new version of this Agreement shall be issued as soon as is practical, certainly within one month, and circulated to all the Parties.

13.4 This Agreement will be formally reviewed on an annual basis by the HSE and the other Parties, unless legislative changes necessitate an earlier review.

13.5 This Agreement may not be supplemented, amended, varied or modified in any manner except by an instrument in writing signed by a duly authorised officer or representative of each of the Parties hereto.

13. Indemnity

14.1 The HSE and the other Parties, agree to indemnify each other, against any action arising out of their failure to act within the terms of this Agreement, or in relation to wrongful or negligent disclosure of Personal Data generally relating to actions taken in the context of this Agreement

14. Governing Law

15.1 This *Agreement* will be governed by and construed in accordance with the laws of Ireland, and the Parties submit to the exclusive jurisdiction of the Irish courts for all purposes connected with this *Agreement,* including the enforcement of any award or judgement made under or in connection with it.

15.Severance & Unenforceability

16.1 If any provision, or part thereof, of this agreement shall be, or is found by any authority, administrative body or court of competent jurisdiction to be, invalid, unenforceable or illegal, such invalidity, unenforceability or illegality shall not affect the other provisions, or parts thereof of this Agreement, and of which shall remain in full force and effect.

16.2 If any invalid, unenforceable or illegal provision, or part thereof, would be valid, enforceable or legal if some part were deleted, the provision, or part thereof, will apply with whatever modification is necessary to give effect to the intention of the Parties as appears from the terms of this agreement.

16. Termination

17.1 The HSE or any of the other Parties can terminate their participation in this Agreement by providing the other party with one month's written notice.

IN WITNESS where of this *Agreement* has been entered into the day and year first herein written.

SIGNED on behalf of the **Health Service Executive**	**In the presence of**
.... Signature	.... Signature
GERRY MALEY Name (printed)	Name (printed)
General Manager Title	.... Title

SIGNED on behalf of the Waterford Institute Technology	**In the presence of**
.... Signature	.... Signature
Corina Power .... Name (printed)	.... Name (printed)
Title Data Protection Co-ordinator....	.... Title
Date: 29-11-19......................	Date: ....

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Appendix 25

Local service comments and recommendations

- As Ireland moves towards the introduction of electronic health records, it will be important to consider how and where the existing part-handwritten system of reporting can be integrated and improved. Having access to and being able to easily link incident reports and patient data via the same electronic access route is likely to assist with research and audit in the future and certainly would have been beneficial for this study, arguably reducing the amount of missing data.

- From an environmental perspective, it is evident that the design of current acute services need to be improved and may be impacting on the number of incidents occurring. The proposed relocation/refurbishment of the department of psychiatry in Waterford is welcomed and it is hoped that the MHC recommendations in terms of space, noise, private areas and single rooms can be introduced to limit the degree of patient-patient conflict currently occurring. It would be interesting to review, in time, the number of incidents of violence and aggression occurring in Waterford older adult inpatient services, now that these have moved to new purpose built premises, rectifying the previous difficulties with space and shared bedrooms/facilities.

- It is also hoped that the proposed introduction of home treatment/crisis resolution services in Waterford may reduce some of the bed capacity issues that have occurred locally, which can lead to overcrowding and conflict amongst patients, in addition to stretching the resources of clinicians in terms of ensuring adequate care and patient safety. Whilst there is the possibility of incidents occurring more frequently in community settings given the increased acuity of persons being cared for; providing an alternative to inpatient treatment where a person's privacy is respected, where they are more unlikely to be affected by other person's mental wellbeing and behaviour and where they are not strictly bound by safety and security rules may well reduce the number of incidents occurring at an inpatient level. This is particularly relevant, considering the degree of patient on patient conflict observed in this study and the number of opportunities for conflict arising between staff and patients.

- Training and staff support are also areas that need to be addressed on an ongoing basis. Research findings would suggest that this is best targeted towards issues relevant to individual clinical areas. For example, self-harm appears to be a phenomenon predominately occurring within acute psychiatry whereas violence and aggression occurs across all areas. However, even within violence and aggression, there are differences in the type of short term episodic aggression that can occur in relation to acute mental disorder and the type of pervasive violence and aggression occurring in longer stay units. Whilst preventing and managing violence through PMVA training is applicable to all clinicians, dealing with long standing issues is often more complex and requires a team approach in monitoring and managing such cases. Staff need support in terms of not accepting that such occurrences are routine, expected or just a part of their daily work life.

- Knowledge and sharing of information would appear to be the important factor in managing such cases, as opposed to exact numbers or grades of clinicians, albeit clinicians need to feel supported by colleagues when extra presence is required and feel that their work environment is safe. Whilst data was incomplete, it may be that evening times are a vulnerable time in terms of incidents occurring but this would need to be further investigated before any final conclusions can be drawn.

- In the research findings the significant number of patients referenced in incident reports were known to services for more than 28 days, outlining the importance of getting to know patients' backgrounds, how their illnesses manifest themselves and their vulnerabilities or tendencies towards risk behaviours. Whilst, as noted in the literature, assessing and managing risk is not the panacea for preventing incidents from occurring, there is still room for considering their likelihood. Review of the patient charts suggests that a level of dynamic risk assessment is indeed occurring on a daily basis and of course it is likely that many incidents are prevented or managed because of this process.

- However, in addition to regular formal and informal MDT risk reviews of individuals, it would also be advisable for organisational rules and procedures to undergo regular review. One example would be the banning, confiscation or limiting of different 'items of harm', which as noted in the research are multiple and sometimes innocuous, but nevertheless can create additional complexities when too strictly enforced or followed inconsistently. Rules and procedures relating to AWOL patients and discharge planning also need to be regularly reviewed.

- Finally, mental health services should also advocate for patients in terms of encouraging a recovery based ethos, whereby more than just lip service is paid to important factors such as autonomy and positive risk taking. As noted previously, making inpatient mental health units more confined, restrictive and security conscious does not tend to mirror the rhetoric offered in numerous statutory documents and in the available research literature. Services still have a role in educating families and the public in supporting patient decision making and how they wish to live, whilst continuing to repel the notion that mental disorder equates to risk or 'dangerousness' in every circumstance.