A study into the adverse event data required by the Mental Health Commission to support the regulation of in-patient mental health services in Ireland.

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Author Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university. I further declare that this research has been carried out in full compliance with the ethical research requirements of the School of Computer Science and Statistics.

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Summary

Patients invariably are at their most vulnerable when under admission to an in-patient facility. This is even more so for mental health service users who in addition to reduced capacity for self-advocacy, are more likely to engage in harmful behaviour when admitted during acute episodes of their illness. It is important, therefore, to measure, monitor and report on risks in mental health services to ensure vulnerable service users are cared for in a safe environment.

In its role as the regulator of mental health services in Ireland, the Mental Health Commission (MHC) has oversight of patient safety in services to ensure accountability and public assurance. A crucial part of this role involves assessing risks and making decisions based on patient safety data. The quality of data is therefore critical to the effective function of the regulator. The data collected for assessing patient safety is data relating to adverse events in the services.

This research project used a qualitative approach to examine the data needs of the MHC in the context of the regulation of in-patient mental health services with a view to proposing an appropriate data set. Semi-structured interviews were carried out with key stakeholders to identify current challenges and perceived opportunities for improvement. Thematic analysis was then carried out to define common themes. The interview data was also analysed using an iterative process for data development based on the highly-regarded Australian Institute of Health and Welfare (AIHW) data development guide.

In the dissertation, a minimum data set for adverse events has been identified that can be put in place to address challenges identified by the key stakeholders interviewed. Furthermore, themes emerged in the interviews that have identified opportunities for additional improvements such as standardisation and data reuse.

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Abbreviations

AHRQ: Agency for Healthcare Research and Quality

AIHW: Australian Institute of Health and Welfare

COE   Council of Europe

CQC: Care Quality Commission

DOH: Department of Health

HIQA: Health Information and Quality Authority

HSE: Health Service Executive

IOM: Institute of Medicine

JC: Joint Commission

MHC: Mental Health Commission

NHS: National Health Service

OECD: Organisation for Economic Cooperation and Development

SCA   State Claims Agency

WHO: World Health Organisation

Glossary

Adverse Event
An incident which resulted in harm.* (also known as a harmful incident)

Adverse outcome
An adverse outcome includes prolonged hospitalization, disability or death at the time of discharge **

Adverse serious event
An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes the loss of limb or function.**

Ameliorating action
An action taken or circumstance altered to make better or compensate any harm after an incident.**

Approved centre:
An in-patient facility for the care and treatment of those suffering from a mental illness or a mental disorder.****

Benchmark
A measure of comparative performance.**

Child
A person under the age of 18 years other than a person who is or has been married.****

Circumstance
A situation or factor that may influence an event, agent or person(s).**

Class
A group or set of like things.**

Classification
A taxonomy that arranges or organizes like or related terms for easy retrieval.   An arrangement of concepts into classes and their subdivisions to express the semantic relationships between them **

Concept
A bearer or embodiment of meaning**

Conceptual model
A model of the main concepts of a domain and their relationships.**

Contributory Factor
A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.**

Data element
The basic unit of information having a unique meaning and subcategories of distinct units or values.**

Dataset
A set of data collected for a specific purpose.****

Degree of Harm	The severity and duration of harm, and the treatment implications, that results from an incident.**
Detection	An action or circumstance that results in the discovery of an incident.**
Diagnosis	The determination of the nature of a disease, injury, or congenital defect… made from a study of the signs and symptoms of a disease.**
Disability	Any restriction or limitation resulting from an impairment of ability to perform an activity in an manner or with the range considered normal for a human being according to the International Classification of Impairments, Disabilities, and Handicaps (1980) published by the World Health Organization (WHO). The term disability reflects the consequences of impairment.**
Error:	The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning) Errors may be errors of commission or omission, and usually reflect deficiencies in the systems of care.**
Event: *see also incident*	Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards** something that happens to or involves a patient.**
Harm	Harm to a person: Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury* Death, disease, injury, suffering and/or disability experienced by a person. **
Incident reporting	A system in many health care organizations for collecting and reporting adverse patient occurrences, such as medication errors and equipment failures based on individual incident reports.**
Incident type	A descriptive term for a category made up of incidents of a common nature grouped because of shared, agreed features **

Incident:	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention and staff or service user complaints which are associated with harm.*
Mental disorder	means mental illness, severe dementia or significant intellectual disability where—(a) because of the illness, disability or dementia, there is a serious likelihood of the person concerned causing immediate and serious harm to himself or herself or to other persons, or (b) (i) because of the severity of the illness, disability or dementia, the judgment of the person concerned is so impaired that failure to admit the person to an approved centre would be likely to lead to a serious deterioration in his or her condition or would prevent the administration of appropriate treatment that could be given only by such admission, and (ii) the reception, detention and treatment of the person concerned in an approved centre would be likely to benefit or alleviate the condition of that person to a material extent.****
Mental health facility:	In-patient facility is a hospital or other facility for care and treatment of persons suffering from mental illness or mental disorder in approved centres as defined by the Mental Health Act 2001 and residential mental health services.****
Mental health services	Services which provide care and treatment to persons suffering from a mental illness or a mental disorder under the clinical direction of a consultant psychiatrist.****
Mental illness	A state of mind of a person which affects the person's thinking, perceiving, emotion or judgment and which seriously impairs the mental function of the person to the extent that he or she requires care or medical treatment in his or her own interest or in the interest of other persons.****

Metadata	Data about data that we need to help us understand and accurately interpret information***
Minimum dataset	The core set of data that have been identified by users and stakeholders as the minimum for collection for a specific purpose.****
Near Miss:	An incident that did not cause harm.**
No Harm Incident:	An incident occurs which reaches the patient, but results in no injury to the patient. Harm is avoided by chance or because of mitigating circumstances.**
Nomenclature	A set of specialized terms that facilitate precise communication by eliminating ambiguity.**
Open Disclosure:	An open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the patient informed, providing feedback on investigations and the steps taken to prevent a recurrence of the adverse event.*
Outcome	The result of the performance (or non performance) of a function(s) or process(es).**
Patient	A person who is a recipient of healthcare.**
Patient *(Mental Health Act 2001)***:**	In the context of the Mental Health Act 2001 a person to whom an admission order relates is referred to in this Act as ''a patient'' as specified Section 14(1). Any person who is the subject of an admission order is involuntary detained.****
Patient Characteristic	Selected attributes of a patient.**
Patient outcome	The impact upon a patient which is wholly or partially attributable to an incident.**
Patient safety	Freedom, for a patient, from unnecessary harm or potential harm associated with healthcare.**
Patient safety data	The broad and heterogeneous information that includes, but is not limited to, the description of incidents with medical errors or near

	misses, their causes, the follow-up corrective actions, interventions that reduce future risk, and patient safety hazards.**
Process	A series of related actions to achieve a defined outcome.**
Public accountability	The obligation or duty of specific individuals and/or institutions to make information about their actions or performance available to the public or a public organization or agency (or its designee) that has responsibility for oversight and is answerable to the general public.**
Reportable occurrence	An event, situation, or process that contributes to, or has the potential to contribute to, a patient or visitor injury or to degrade [practitioners'] ability to provide optimal patient care. Reportable occurrences can generally be divided into the following types based on severity: sentinel events, patient and visitor injuries (adverse events), nears misses, and safety concerns.**
Resident:	A person receiving care and treatment in a centre (in-patient, mental health service).****
Risk	The probability that an incident will occur. The combination of the probability of occurrence of harm and the severity of that harm.**
Risk Management Process	The systematic application of management policies, procedures and practices to the activities of communicating, consulting, establishing the context, and identifying, analysing, evaluating, treating, monitoring and reviewing risk
Risk Management:	A continuous, proactive and systematic process to understand, manage and communicate risk from an organisation-wide perspective. One of a number of organizational systems or processes aimed at improving the quality of health care, but one that is primarily concerned with creating and maintaining safe systems of care.*
Safety	Freedom from unacceptable risk. The reduction of risk of unnecessary harm to an acceptable minimum.**

Safety Concern	Protocols, procedures, products, or equipment that are problem-prone, or risk generating processes that may degrade [practitioners'] ability to provide optimal patient care.**
Safety Culture	An integrated pattern of individual and organizational behaviour, based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the processes of care delivery.**
Semantic Relationship	The way in which things (such as classes or concepts) are associated with each other on the basis of their meaning.**
Sentinel Event	Any event that has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition.*
Serious Harm:	Serious injury to a person, or serious damage done to a thing. An injury which creates a substantial risk of death or which causes serious disfigurement or substantial loss or impairment of the mobility of the body as a whole or of the function of any particular bodily member or organ.*
Serious Incident:	An incident that results in death or serious harm.*
Serious Reportable Event:	Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers.*
Service User:	Members of the public who use, or potentially use, health and social care services as patients, carers, parents and guardians. This also includes organisations and communities that represent the interests of people who use health and social care services.*
Severe dementia	A deterioration of the brain of a person which significantly impairs the intellectual function of the person thereby affecting thought, comprehension and memory and which includes severe psychiatric or behavioural symptoms such as physical aggression.****

Significant intellectual disability	A state of arrested or incomplete development of mind of a person which includes significant impairment of intelligence and social functioning and abnormally aggressive or seriously irresponsible conduct on the part of the person.****
Stakeholder	An individual who has an interest in the activities of an organization and the ability to influence it.**
Standard	A statement that defines the performance expectations, structures, or processes that must be in place for an organization to provide safe and high-quality care, treatment, and service.**
Structure	The supporting framework or essential parts. It includes all elements of the healthcare system that exist before any actions or activities take place**
Sudden, Unexplained death:	An unexpected death that may have been a suicide or that has occurred in suspicious circumstances as a result of violence or misadventure on the part of others or from any cause other than natural illness or disease.*****
System	A set of interdependent elements (people, processes, equipment) interacting to achieve a common aim.**
Taxonomy	System for naming and organizing items into groups that share similar characteristics.**
Terminologies	Terminologies define, classify, and in some cases code data content.**

Source of definition:

* HSE Incident Management Policy 2014

** WHO Conceptual Framework for and International Classification for Patient Safety

*** Mental Health Act 2001

**** Australian Institute of Health and Welfare (AIHW) Guide to Data Development

***** Mental Health Commission (MHC)

1. Introduction

1.1. Introduction

Mental illness is characterised by "a state of mind of a person which affects the person's thinking, perceiving, emotion or judgment and which seriously impairs the mental function of the person to the extent that he or she requires care or medical treatment in his or her own interest or in the interest of other persons;" (Department of Health, 2001).

According to the WHO, one in four people will experience a mental illness at some point in their lives (WHO, 2001). In line with national policy (DOH, 2006) which advocates for the deinstitutionalisation of mental healthcare, the majority of service users in Ireland will access mental health services in out-patient or community settings, however, some may require in-patient care and treatment in an 'approved centre' (a facility registered to operate by the Mental Health Commission) during acute episodes of their illness. In 2013, there were 18,457 admissions to approved centres in Ireland (HRB, 2014) and 12% of those admissions were involuntary detained (MHC, 2014a).

In mental health services there is a complex interaction between the environment and the patient population which makes patient safety unique. When service users are acutely unwell they may have reduced capacity for self-advocacy. During this period individuals are at their most vulnerable and are more likely to engage in harmful behaviour. Absconding, self-harm and suicide, difficult and non-compliant behaviours and aggression are likely to co-occur in the same patients (Brickell and Tomita, 2009).

The deinstitutionalisation of mental health services has resulted in a higher threshold for in-patient admissions. As the complexity of care increases in inpatient units, so too does the likelihood of patient safety incidents. It is, therefore, of critical importance that risk management, underpinned by good clinical governance, is a key focus of service providers. Occurrences of patient safety incidents should be monitored and reported and steps taken to reduce the possibility of recurrence. The reporting of patient safety data to a regulatory body allows for an analysis of issues and patient safety performance in services from a national perspective ensuring transparency and accountability.

This research study was focused on the data needs of the Mental Health Commission (MHC) the regulator of in-patient mental health services (approved centres) in Ireland. It examined the role of a regulator particularly in relation to oversight of safety in services, how adverse data can be used to support regulatory activities. It explored the current adverse data reporting requirements for in-patient mental health services to the MHC, if the data currently collected by the MHC are fit for purpose and any challenges and opportunities in relation to the collection of the data.

1.2. Context

The MHC is charged with regulating and monitoring care and treatment provided in approved centres. Its mission is "To safeguard the rights of service users, to encourage continuous quality improvement, and to report independently on the quality and safety of mental health services in Ireland"(MHC, 2013). As specified in the Mental Health Act 2001 (Department of Health, 2001), in-patient facilities providing care and treatment to persons suffering from a mental illness or a mental disorder must be registered to operate by the MHC. They must comply with standards to ensure they provide quality care in a safe environment.

To support its statutory remit as a regulator, the MHC is charged with ensuring accountability and public assurance. This includes monitoring and reporting on the safety of approved centres. Under this duty of care to service users the MHC needs to monitor service user risks and safety concerns. Monitoring past harm in a service through the collection of incident data is one method a regulator may use to assess how safe a service is.

An incident which results in harm to a service user is known as an adverse event. Adverse events resulting in serious harm or death are of particular concern to the MHC as they may reflect issues in relation to the structure or process of care in a particular approved centre which may impact on the service user's outcome.

There were 61 approved centres on the 'Register of Approved Centres,' at the end of 2014, with a combined bed capacity of 2,702 (MHC, 2015). The majority, 88% (54/61), of

in-patient mental health services in Ireland are managed by the HSE and this study is focused on the collection of data from HSE managed services. It is the responsibility of the HSE to collect data relating to incidents and provide the data to the MHC on a pre-defined schedule to enable the MHC to identify potential risks in services.

1.3. Rationale

Patient safety is high on the agenda for healthcare services in Ireland. Recent high profile cases in maternity care highlighted the vulnerability of service users across the healthcare sector.

The role of the healthcare regulator in overseeing the quality and safety in healthcare services is vital, particularly in Ireland where there is no single agency with national oversight of risk management and patient safety issues (Holohan, 2014). This work relies heavily on good quality data which provides a complete and accurate picture of the risk environment in services to ensure appropriate regulatory action can be taken if there are concerns in relation to the safety and welfare of service users.

The MHC collects various data from in-patient mental health services, including data on deaths, incidents, child admissions, use of restrictive interventions and Electroconvulsive Therapy treatment. Mental health services have been submitting summary incident reports to the MHC on a six-monthly basis since 2008 in line with reporting requirements in the MHC's Code of Practice for Mental Health Services on Notification of Deaths and Summary Incident Reporting (MHC, 2008).

The key data elements that are collected by the MHC are the category of incidents and the level of severity of the incident. In the past there was no nationally agreed incident reporting classification system in use in Ireland, which resulted in heterogeneous incident reports. This has presented a challenge for the MHC as it has meant that it is difficult to interpret or interrogate the data and that the data cannot be used to benchmark, compare services or carry out any trend analysis. All of these things are important in the context of regulation, which is intended to ensure that services are accountable and

provide assurance to service users and the public. Therefore, the current data is not fit for purpose.

The MHC is currently reviewing its regulatory process and is adopting a more responsive risk-based approach to regulation. This model of regulation, which is more focused on the poor performing services, is heavily reliant on good quality data to support intelligent monitoring of services. Patient safety policy has evolved in Ireland since 2008 and there have been a number of developments in the HSE. These have resulted in improvements in incident and risk management and with it the standardisation of incident data and the introduction of an agreed incident reporting classification system in the HSE. It is therefore an opportune time to review the data requirements of the MHC to identify whether any improvements can be made in relation to the adverse event dataset collected to support the regulation of approved centres.

1.4. Research aim, question and objectives

The aim of this research study was to generate a body of knowledge in order to answer the following research question:

What are the challenges and opportunities relating to the completeness of adverse event data, required by the Mental Health Commission, to support the regulation of in-patient mental health services?

The main objectives of the research study were:
1. To describe the adverse event data required by the MHC.
2. To examine if the current dataset is fit for purpose.
3. To propose an appropriate adverse event dataset.
4. To document any challenges that exist in relation to the data required by the MHC.
5. To document any opportunities to improve the dataset required by the MHC to support its regulatory activities.

1.5. Overview of dissertation

This dissertation is broken down into six separate chapters, which are briefly described below. It contains a glossary and list of abbreviations at the beginning of the document and includes appendices at the end.

This chapter provides an introduction to the research topic, the background, context, the research question, the research aims and objectives and the structure of the dissertation.

Chapter two is focused on the findings in the literature which are relevant to answering the research question and includes information in relation to how adverse event data fits into supporting a healthcare regulator in monitoring and measuring safety in order to inform regulatory activities.

Chapter three describes the research methodology. It maps out the research approach, the process which was used to complete the research study and the research methods. It includes details regarding the search strategy for the literature review and the procedures for the semi-structured interviews that were conducted with key stakeholders.

Chapter four describes the findings from the interviews; including the key themes and sub-themes that emerged from the interview process.

Chapter five includes the analysis and results of the research study which is based on a synthesis of the literature review and analysis of the results of the interviews.

Chapter six contains the conclusion which includes the limitations of the study, the key findings, personal observations, contribution to the research, final thoughts and future work.

1.6. Summary

This chapter has set the research context, identified the rationale for the study and the research aims, objectives, and the research question. It also provided an overview of the layout of the document.

2. Literature Review

2.1. Introduction

This chapter presents the findings from the literature review. It maps out the role of a healthcare regulator in the context of patient safety. It highlights some of the unique patient safety areas of concern in mental health services. It examines how adverse event data is used to monitor and measure safety and what are the current adverse event reporting requirements to the MHC. Finally it describes the importance of data quality in relation to the use of data to support regulatory decisions.

2.2. Healthcare regulation

As this research study was focused on the data needs of the MHC (the regulator of in-patient mental health services in Ireland), it was essential to examine the role of a regulator, the objectives of institutional healthcare regulation (the MHC's domain) and the associated regulatory activities, particularly those which are informed by data.

Regulatory agencies are established by governments in an attempt to influence behaviour, indirectly through arm's length bodies, over organisations providing public services. (Sutherland and Leatherman, 2006, BRTF, 2005, Lewis et al., 2006). Selznick describes regulation as "sustained and focused control exercised by a public agency over activities which are valued by a community" (Selznick, 1985). In the healthcare context, regulation has been described as "any set of influences or rules exterior to the practice or administration of medical care that imposes rules of behaviour" (Brennan & Berwick, 1996) and can be focused on professional, market or institutional regulation. Professional regulation involves licencing of medical professionals and market regulation manages supply and competition. Institutional regulation, the MHC's domain, is concerned with organisations that provide health services whereby the regulator attempts to influence the nature of the service offered to the service user.

Regulatory agencies typically draw their statutory authority from legislation and are responsible for the external oversight of organisations which they regulate. The role,

functions and activities of healthcare regulators are grounded in their statutory remit and driven by efforts to achieve the objectives of regulation which are:

- accountability of healthcare organisations to service users;
- assurance that minimum standards are met and
- quality improvement.

(Sutherland and Leatherman, 2006, Walshe, 2003, Koornneef, 2010)

In order to meet the objectives of healthcare regulation, regulators are involved in three main types of activities which are: direction, surveillance (external oversight); and enforcement. These regulatory activities drive a regulator's data needs and are discussed in more detail below.

Direction activities involve the communication of expected levels of performance by the regulator to the regulated organisation through issuing standards. Standards are used to make assessments of performance through surveillance activities and are the foundation of a regulator's data requirements. (Walshe, 2003).

Surveillance activities are focused on assessing performance and compliance with standards. They are central to achieving accountability of healthcare organisations to service users; play a key role in assuring that standards are met and to inform quality improvement. Monitoring is carried out through inspections and the collection of data. As inspections only occur at intervals, the collection of data is key for ongoing measurement of quality and safety performance in services. A range of data may be collected by a regulator either directly from the regulated organisation or from other external organisations that have information of relevance. (Walshe, 2003, Adil, 2008, Sutherland and Leatherman, 2006, HIQA, 2014, Berwick, 2013).

Enforcement actions are informed by surveillance activities including data collected from services. Enforcement involves the use of regulatory powers (such as sanctions or rewards) to change the behaviour of regulated organisations and support the objectives of regulation (assurance, accountability and quality improvement). Therefore, effective

regulation is reliant on standards which are measurable and reliable (consistent measurement process). (Walshe, 2003)

The principles of good regulation underpin the work of a regulator, the Better Regulation Task Force identified five principles of good regulation as follows:

- proportionate to the risk;
- accountable to government and the public;
- consistent;
- transparent and
- targeted (BRTF, 2005).
-

In line with these principles, many healthcare regulators internationally, have adopted a responsive risk-based regulatory approach (HIQA, 2014). In this model of regulation the regulator is responsive to culture, context and conduct of regulated organisation (Ayers and Braithwaite, 1992) and risk-based focusing on poor-quality providers applying regulation proportionately based on risk posed by the service to the safety and welfare of the service users (Adil, 2008).

Data collected through surveillance activities has a critical role in a responsive risk-based model of regulation. Data are analysed and the information is used to:

- measure compliance with standards,
- identify poor performing organisations,
- compare compliance over time and between organisations,
- trigger other detection activities such as investigations or inquiries,
- report on publically for accountability and
- inform enforcement actions.

(Berwick, 2013, HIQA, 2014).

The measurement of patient safety risks in services is important to ensure that regulatory activities are proportionate and targeted in line with a responsive risk based model of

regulation which is focused on poor-quality providers, particularly services where there are patient safety risks. It is therefore critical to have quality data.

The next section explores the concept of patient safety, risks in mental health and the methods a regulator may use for measuring and monitoring safety for a regulator.

2.3. Patient safety

The research question was concerned with the collection of adverse event (harmful incident) data to support regulation of in-patient mental health services, therefore, it was important to explore the concepts of patient safety in healthcare, safety risks in mental health services and the ways in which data can be used by a regulator to monitor safety. The WHO defines a quality health service as one which increases the "likelihood of desired health outcomes" (WHO, 2005b). Quality is multi-dimensional and safety is widely recognised as one of the key domains, others include effectiveness and patient-centeredness (IOM, 2001, Commission on Patient Safety and Quality Assurance, 2008, Arah et al., 2006, WHO, 2005b, Department of Health, 2012). The concept of safety has been defined by the AIHW as "the avoidance or reduction to acceptable levels of actual or potential harm from health care or the environment in which health care is delivered" (AIHW, 2009b).

Freedom from harm is common to many definitions of safety, but what is harm? The WHO defines harm as "an outcome that negatively affects patient's health and or quality of life, including illness, injury, suffering, disability and death and may thus be physical, social or psychological" (WHO, 2009). Berwick indicates that harm can occur as a result of neglect; failures in the system or errors (Berwick, 2013).

Preventing harm and thereby ensuring patient safety is complex as it is an outcome of many factors which relies on safe healthcare structures and processes. (Kristensen et al., 2007). Risk management is an integral part of ensuring a safe service and minimising service user harm. It is widely recognised that patient safety and risk management are the responsibility of services, however, healthcare is complex and if there are poorly organised delivery systems it can affect the process of care. This may lead to unsafe care

environments and poor outcomes for service users. (IOM, 2000). Regulators require oversight of the risk management process to monitor safety with a view to detecting any areas of concern in relation to the safety and welfare of service users.

Risks may vary depending on the clinical setting and the patient population, therefore a regulator needs to identify the patient safety areas of concern in their clinical domain to ensure effective regulation (Vincent et al., 2013b). Although many of the same safety risks and incidents apply to both acute general health and mental health, there are some patient safety risks and incidents which are particular to mental health services and these are discussed below.

2.3.1. Patient safety in mental health services

Patient safety incidents are common in mental health services. A study in the UK found that mental health settings had the third highest rate of death and the fifth highest rate of severe harm from across nine medical settings (Scobie, 2006). A study in the US found that psychiatric hospital and psychiatric units were the second and third most common domains respectively for patient safety incidents, following general hospital (Chang et al., 2005). The State Claims Agency in Ireland reported that 12.5% of all incidents reported to the Clinical Indemnity Scheme in 2012 were from mental health services, the third highest of the clinical specialities (SCA, 2013).

A report by the Canadian Patient Safety Agency found that patient safety in mental health is unique due to both the patient population and healthcare environment (Brickell and Tomita, 2009). Mental health service users especially when acutely ill are vulnerable to a number of potential risks due to the following factors:

- their own behaviour (self-harm, absconding, aggression and violence or sexually uninhibited);
- the behaviour of others (aggression and violence or sexually uninhibited);
- instability as a result of their mental illness and
- from care and treatment being provided.

(Scobie, 2006, O'Rourke and Hammond, 2005)

Healthcare environment patient safety risk factors identified included the work environment, high bed occupancy rates and staffing. (Anderson et al., 2013, Baker et al., 2010). Brickell and Tomita also highlighted that the use of seclusion and restraint posed safety risks to patients (Brickell and Tomita, 2009)

The types of incidents which frequently occur in mental health settings include incidents due to slips, trips and falls and medication errors. These are also common in general health but incidents due to behaviour which include violence, harassment and aggression, absconding, self-harm and suicide also account for a large proportion of incidents in mental health services internationally (Shaw et al., 2005, SCA, 2013, Scobie, 2006). The Canadian Patient Safety Agency identified that medication safety, suicide, slips and falls, aggression and violence and patient absconding were the primary patient safety issues in mental health (Brickell and Tomita, 2009). In Ireland, the State Claims Agency (SCA) reported that, in 2012, violence, harassment and aggression were the most frequently reported incidents in mental health, accounting for 36% of all incidents, followed by slips, trips and falls (29.9%) and self-harm (10%) as shown in figure 1.
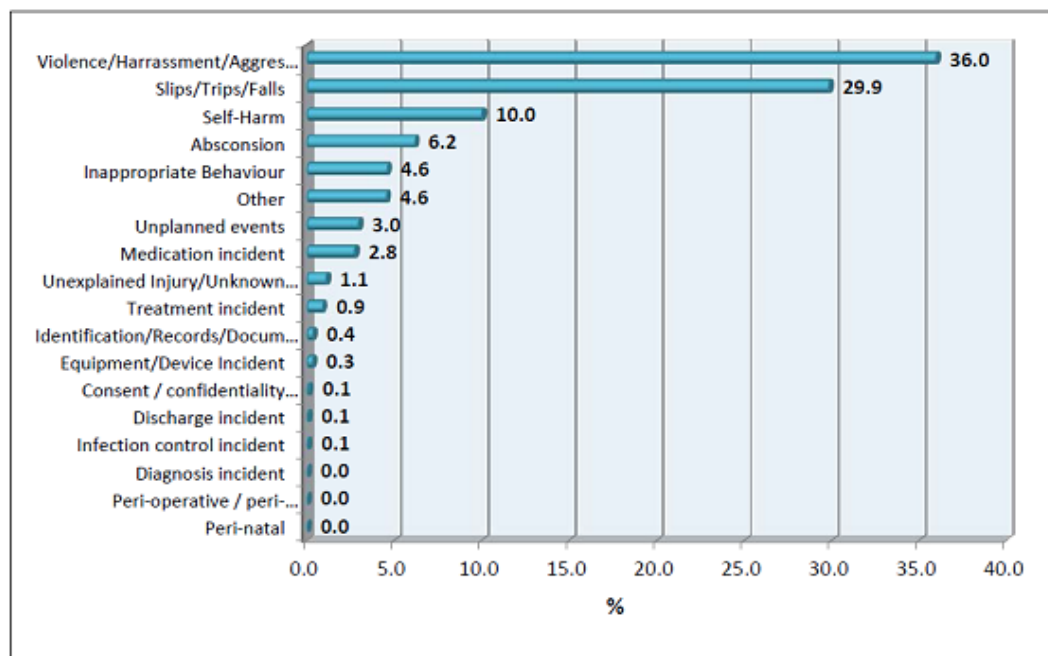
Figure 1: Adverse Event Type Reported by Mental Health Services in Ireland. 2012 (SCA, 2013)

The section has provided an overview in relation to patient safety and risks and incidents in mental health. The next section examines methods that may be used to measure and monitor safety.

2.4. Monitoring and measuring safety

Reporting patient safety data to a regulatory body allows for an analysis of issues and patient safety performance in services from a national perspective ensuring transparency and accountability. (Adil, 2008, IOM, 2001, Berwick, 2013, Scarpello, 2010, Sutherland and Leatherman, 2006). Regulators use data to benchmark services (measure comparative performance) and to detect failings when unacceptable standards of care are identified (Boxwala et al., 2004).

The National Quality Forum defines a measure as "a standard: a basis for comparison; a reference point against which other things can be evaluated"; and that to measure is "to bring into comparison against a standard" (NQF, 2015). Vincent et al posits that measuring safety is challenging as it involves trying to quantify 'a dynamic property of an organisational system' (Vincent et al., 2013b). Donabedian's classic paradigm for assessing quality indicates there is no single measure of safety, it can be measured based on ''structure'', ''process'' or ''outcome' (Donabedian, 1988):

- Structure measures: try to evaluate the physical (facilities and equipment) and institutional (staffing and organisational structures) attributes of a service.
- Process measures: assess the interactions between service user and structural elements.
- Outcome measures: assess the change patient's outcome including functionality, mortality and patient satisfaction.

Outcome measures are widely used to measure patient safety, but must be risk adjusted to ensure they account for factors outside the health system which may impact on outcome and need to be valid (well founded) and reliable (provides consistent results). (Kristensen et al., 2007, Zhan et al., 2005, Gaebel et al., 2012, Vincent et al., 2013b, AIHW, 2009a, Berwick, 2013).

One, commonly used, outcome measure of safety is the rate of adverse events in a service (Hauck et al., 2012). An adverse event is defined by the WHO as "an incident which resulted in harm" (WHO, 2009) and more comprehensively by Runciman et al as "an incident which resulted in harm to a person receiving health care, resulting in additional treatment; prolonged hospital stay; disability at the time of discharge, or death" (Runciman et al., 2006). As we can deduce from Runciman's definition, there are various levels of harm which can range from low harm to serious or severe harm or even death. The HSE defines serious harm as "an injury which creates a substantial risk of death or which causes serious disfigurement or substantial loss or impairment of the mobility of the body as a whole or of the function of any particular bodily member or organ" (HSE, 2014).

2.4.1. Patient safety data standardisation

There is a consensus that national adverse event and incident reporting should be based on a standard patient safety terminology, agreed concepts, standardised definitions, risk and harm measures, clear data definitions and complete information that capture the what, who, when, where, risk and consequences in relation to incidents. (Runciman et al., 2006, Berwick, 2013, Donaldson, 2002, WHO, 2005b).

Many patient safety experts propose that the classification of an event is the foundation of analysis of patient safety data but variation in terminologies act as a barrier to analysis, comparability and interoperability. (Berwick, 2013, Chang et al., 2005, Leape et al., 2005). The WHO Patient Safety Alliance launched in 2004, has been a driving force behind the development of a universal classification system for patient safety data. They first published *The Conceptual Framework for an International Classification for Patient Safety* (ICPS) in 2007 and released an updated version in 2009 (WHO, 2009). The ICPS has been internationally recognised as a movement towards the standardisation of patient safety data. It is used by the Health Quality & Safety Commission in New Zealand as the basis for categorising incidents in its National Reportable Events policy (Health Quality & Safety Commission, 2012b) and was endorsed by the Commission on Patient Safety and Quality Assurance in Ireland. One of the recommendations in the Commission's 2008 report was that the ICPS should be adopted on a national basis to overcome the disparate adverse

event reporting systems in place in the Irish health service. (Commission on Patient Safety and Quality Assurance, 2008).

This conceptual framework, which is founded on a consensus of leading patient safety experts, presents "standardised sets of concepts with agreed definitions, preferred terms and the relationships between them to facilitate the description, comparison, measurement, monitoring, analysis and interpretation of information to improve patient care." (WHO, 2009). It is based on ten high level classes (included in Appendix B) and includes 48 key concepts and provisional descriptions of concepts and links to existing classification systems. Vincent et al posits that a regulator needs to identify the types of incidents and level of harm of concern for their clinical domain to ensure effective regulation (Vincent et al., 2013a) which relate to the incident type class and a patient outcome class in the ICPS. As previously discussed, behavioural incidents, such as self-harm and aggression and violence are, are the most frequent incidents in mental health settings. Figure 2 shows the conceptual representations of behavioural incidents and figure 3 displays how harm is represented including the five point level of harm rating proposed in the ICPS. The WHO representation demonstrates how standardised categories may be applied to ensure consistency.
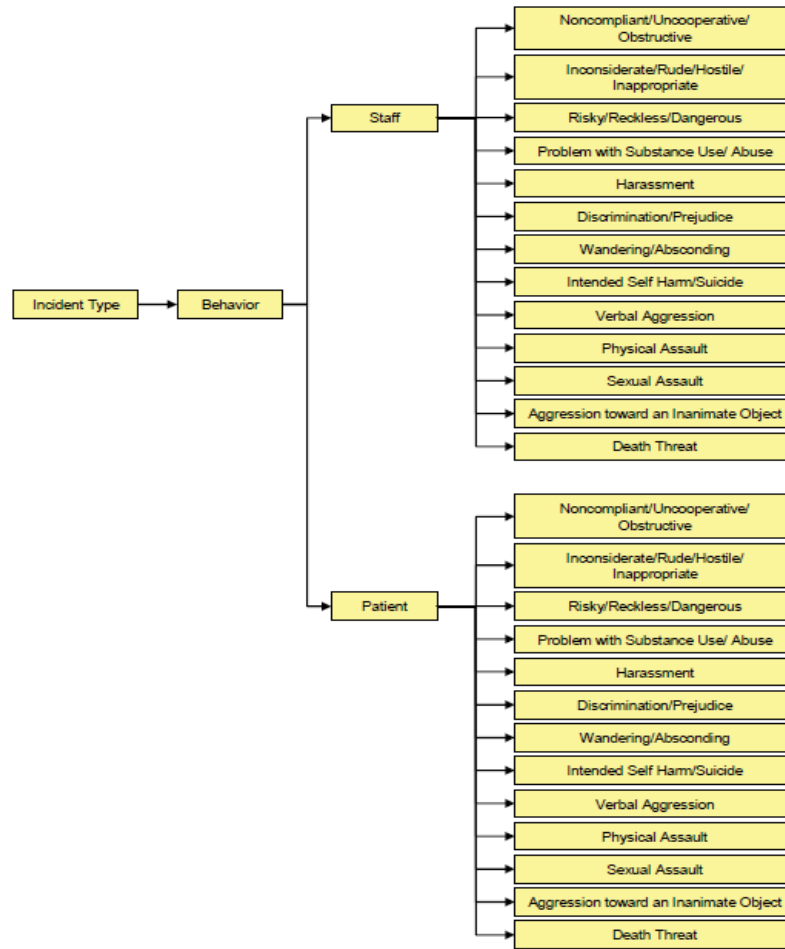
Figure 2: WHO ICPS. ICPS Class: Incident type - Behaviour and Associated Concepts. (WHO, 2009)
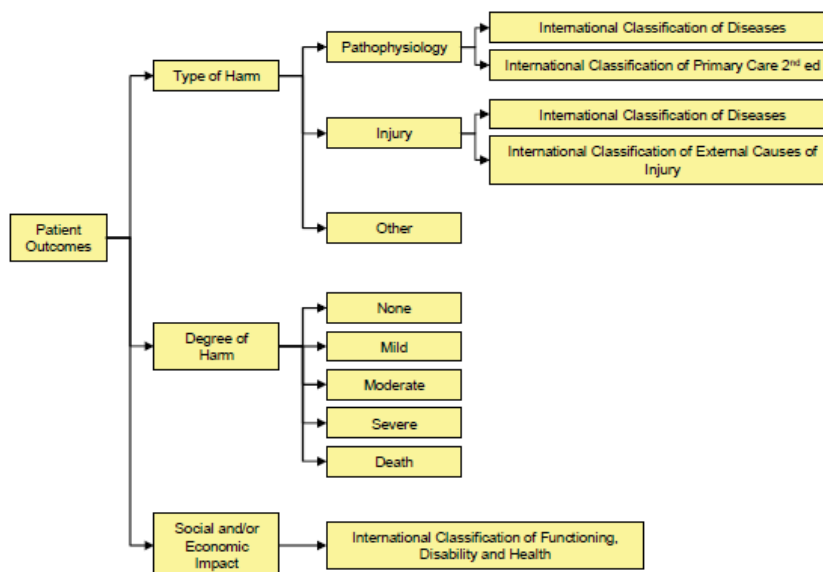
Figure 3: WHO ICPS. Patient Outcomes Class and Associated Concepts.(WHO, 2009)

Sherman et al identified that one limitation of the WHO's ICPS is that it is an information model rather than a fixed classification and further definition of key concepts need to be fully defined (Sherman et al., 2009). The WHO are continuing to validate the classification system and push for standardisation of data. They recently published a draft Minimal Information Model (MIM) for Patient Safety to "strengthen effective reporting by identifying the key data features that can provide minimal meaningful learning"(WHO, 2014). The MIM (shown in figure 4 below) is presented as the core concepts that are essential for information and comparison purposes (both national and international) of incident reports and form part of a more comprehensive information model. An EU Project is underway to validate the MIM and to identify preferred terms for the most frequent incidents.

THE DATA CATEGORIES OF THE DRAFT MINIMAL INFORMATION MODEL FOR PATIENT SAFETY ARE:
- Incident identification
  - Patient
  - Time
  - Location
  - Agent(s) involved
- Incident type
- Incident outcomes
- Resulting actions
- Reporter
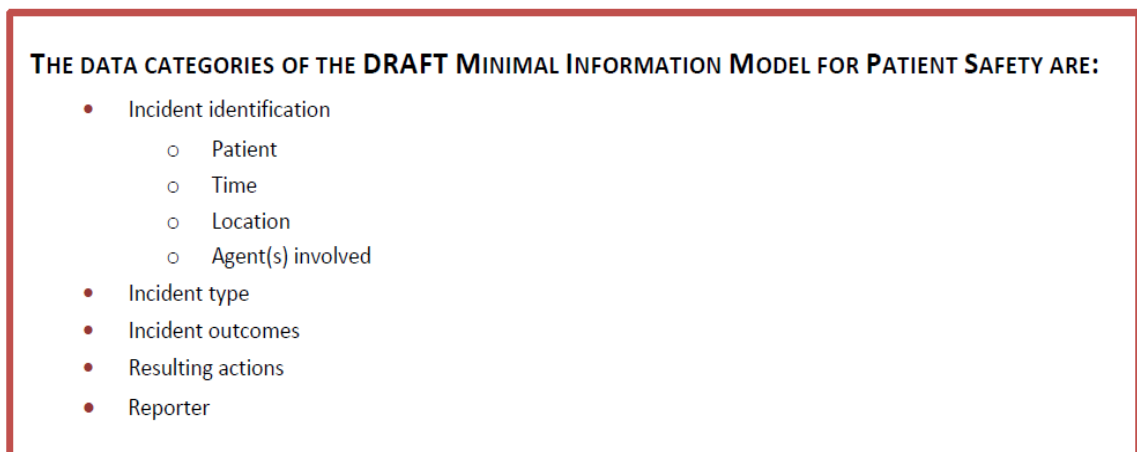
Figure 4: WHO Minimal Information Model for Patient Safety (WHO, 2014)

In Ireland, the HSE have been working towards standardising patient safety data. The HSE's *Incident Management Policy* (HSE, 2014) contains comprehensive procedures in relation to reporting of incidents, including the introduction of a standardised incident reporting and escalation form. The HSE is also in the process of implementing the State Claims Agency's National Incident Management System (NIMS) nationally to support the incident management policy. This end-to-end incident management system, which replaces the STARSWeb claims based system, is designed using the WHO's ICPS. The STARSWeb system was a claims-based system and more focused on risk rating that service user outcome. Another issue was the high level of incidents that were not risk rated in the system, accounting for almost half of all incidents in 2012 (SCA, 2013). The

new NIMS system is based on a single standard interface and common reporting form which will result in homogeneous data in the system (SCA, 2015).

2.4.2. Measures of harm

As previously discussed, data standards including classification of incidents is a key area for consideration for a regulator when collecting patient safety data but they must also consider the different measures of harm associated with the collection of adverse event data. There are a number of recognised measures of harm which include incident reporting systems; safety indicators; mortality statistics and systematic record review and regulators should triangulate evidence from various sources where possible (Vincent et al., 2013b, Schulz et al., 2009). Each of the four measures is discussed in more detail below.

Incident reporting systems

Sir Liam Donaldson, WHO Envoy for Patient Safety stated that " reporting is fundamental to detecting patient safety problems." (WHO, 2005b). Incident reporting is widely described as the cornerstone of quality and risk management systems for patient safety. Systems for reporting of incidents to regulatory agencies are primarily to ensure public accountability (WHO, 2005b). National reporting to a regulator or patient safety agency can facilitate triple-loop learning where the learning experiences from services can be disseminated at national level. (Runciman et al., 2006). The information gained can be utilised at both a local and national level to identify trends, patterns and gaps in the system. (Woloshynowych et al., 2005, Larizgoitia et al., 2013). With adequate data, an incident reporting system can develop information about risk and harm caused by incidents and facilitate data analysis and dissemination of findings to support a learning environment develop (WHO, 2005b, Leape et al., 2005, Benn et al., 2009) (WHO, 2005b).

The WHO highlights that effective adverse event reporting and learning systems need clear objectives, a clarity around who should report, the scope of what is to be reported and a classification system to allow for analysis, aggregation and comparability. A key part of any reporting system is analysis and dissemination of findings. Regulators need to

have mechanisms for receiving reports and managing data, expertise for analysis and a capacity to respond to reports or the opportunity for learning may be lost. If reports from services elicit no response then services may perceive that reporting is all risk and no gain which can lead to under-reporting. (Leape et al., 2005, Evans et al., 2006, WHO, 2005b).

Challenges associated with incident reports include timeliness of data, under-reporting and high reporting associated with a good safety culture. The issue of timely of incident report data can be a particular challenge for a regulator. Incident reporting tends to be retrospective and therefore does not inform real-time regulatory activities the data can also be out of sync with the inspection cycle which limits targeted activities on inspection. Therefore, a regulator may need to access more current intelligence to support a responsive risk-based approach. (Adil, 2008).

Evidence suggests widespread under-reporting of incidents. A number of studies have found that a lack of clinical engagement has lead to under-reporting in both general health and mental health settings. Reasons cited for lack of engagement included fear of punitive action, poor safety culture, time constraints, lack of understanding among clinicians about what should be reported, lack of feedback to clinicians resulting in them being sceptical of its value. (Gifford and Anderson, 2010, Shaw et al., 2005, Anderson et al., 2013, Larizgoitia et al., 2013). It is important that regulators feedback directly to clinicians for their continued engagement (Mahajan, 2010).

In many cases the service that has a high rate of reporting has a good safety culture and is open and transparent in relation to patient safety, however, due to inappropriate attribution they may be the focus of more negative attention which is a limitation of incident reporting (Raleigh and Foot, 2010, Anderson et al., 2013, Zhan et al., 2005).

Safety indicators

HIQA's international review in relation to the use of information for regulation found there was a consensus amongst regulators that reporting on patients safety indicators is valuable (HIQA, 2014). The AIHW define an indicator as "a key statistical measure

selected to help describe a situation concisely, track progress and performance, and act as a guide to decision making" (AIHW 2008a). The WHO is a proponent of the use of indicators as part of a mental health information system (WHO, 2005a). The AIHW in their publication *Towards national indicators of safety and quality in health care* suggests that reporting on indicators can serve two main purposes: to provide transparency (a key principle of good regulation) and to inform decision-making. (AIHW, 2009b)

Indicators are used for comparison and therefore risk adjustment is required to ensure comparison is fair and equal. National reporting generally includes comparisons over time, by population or service and can be used for comparisons against standards or international comparisons and can therefore be useful for regulators. Key criteria for selection of indicators include relevance, validity, reliability, evidence based, comparability and feasibility (HIQA, 2013a, Pencheon, 2008, Kristensen et al., 2007). Evidence concludes that indicators are not direct measures of safety but alerts to possible risks of harm and are useful for measuring specific policy objectives. (AIHW, 2009b, WHO, 2005a).

Data in relation to specific adverse events identified as 'never events' or 'sentinel events' are commonly used by regulators (HIQA, 2014). The WHO defines a sentinel event as "any event that has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition" (WHO, 2009). In Ireland, the HSE recently introduced a list of Serious Reportable Events (SREs) (akin to the AHRQ's list of Never Events) which they define as "serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers"(HSE, 2014). The most recent list issued in January 2015 includes some mental health specific events. Although many countries have implemented systems for reporting of never events it is recognised that by their nature these adverse events are rare which limits their sensitivity to changes in safety (AIHW, 2009b).

The development of mental health specific indicators has lagged behind work in relation to general health, however there has been some work in this area in Australia, Scotland,

England, the US and at a European level in the OECD shown in table 1 below. Excess mortality and in-patient suicide are common indicators used in many jurisdictions. However, it has been identified that accurately measuring rates of suicide can be difficult due to under-reporting, misclassification and the complex procedures that are associated with suicide registration (Nordentoft et al., 2011). Due to the infrequent nature of in-patient suicides related indicators are of limited value for monitoring changes but can be useful at the system level for national and international comparisons (Kristensen et al., 2007)

Table 1: Mental health patient safety indicators

Jurisdiction	Organisation	Indicator Type
Australia	AIHW mental health indicators	Intentional self harm Seclusion amongst admitted patients (AIHW, 2013)
Scotland	*Scottish Mental Health Dashboard Indicators*	suicide rates per 100,000 (Information Services Division, 2014)
England and Wales	NHS Outcomes Framework	excess mortality in adults <75yrs with serious mental illness (NHS, 2014)
US	IHI Whole Systems Evaluation	rate of adverse events expressed per 1,000 patient days as an appropriate indicator safe domain (Martin et al., 2007)
Europe	OECD Health Care Quality Indicators for mental health	in-patient suicides, excess mortality and deaths after discharge (OECD, 2015).

Mortality statistics

Hospital standardised mortality rates (HSMR) are a widely used type of mortality statistic. A recent example of their use was the Mortality Review Outcome Report in the UK (Keogh, 2013). They measure outcomes by a combination of the patient's underlying condition and the care they actually receive. Proponents for use of mortality rates advocate that an unexpected rise in mortality might indicate underlying clinical problems (AIHW, 2009a, Dr Foster Intelligence, 2014) whereas opponents indicate that an increase in mortality on its own is not an accurate measure of safety issue and data is liable to misinterpretation. The consensus is that mortality rates used should be risk-adjusted and

only used as 'smoke detectors' rather than to produce patient safety league tables. (Raleigh and Foot, 2010)

Systematic record review

Systematic record review such as selective case note reviews, have been used in many large scale studies into adverse events (Baker et al., 2004) and are useful when gathering detailed information about an incident. Tools such as the internationally recognised *IHI Global Trigger Tool* (Griffin and Resar, 2009) can be used during record reviews and can be effective mechanisms to identify adverse events and measure harm using medical record reviews (Health Quality & Safety Commission, 2012a).

Other sources of patient safety information

Vincent et al's recently published framework for measuring and monitoring safety identified that past harm is only one class of information which should be considered by regulators. Other dimensions, shown in figure 5 below, include reliability, sensitivity to operations, anticipation and preparedness and integration and learning (Vincent et al., 2013a). There is growing support which acknowledges the value of using information from different sources, such as patient experience, complaints, staffing levels and reliability of critical processes to inform assessments of quality and patient safety as recently advocated. Also, combining data from different sources and looking at similar events from multiple perspectives (for example a combination of incident report, Systems Analysis Investigation reports and malpractice claims data) may lead to a better understanding of what happened. (The Health Foundation, 2014, Berwick, 2013, Adil, 2008).

Figure 5: A framework for measuring and monitoring safety. (Vincent et al., 2013a)

2.5. MHC's adverse event data reporting requirements

The concept of healthcare regulation and the role of a regulator were discussed earlier in this chapter. This section of the literature review investigates the specific role of the MHC and the current adverse event data that approved centres report to the MHC. It examines the regulatory basis for and background to the current data requirements and reporting arrangements. Finally it highlights some of the challenges experienced by the MHC in relation to use of this data. The main source of evidence for this section was relevant legislation, policy and organisational documentation.

2.5.1. MHC role

The MHC is an independent statutory body, responsible for the regulation of approved centres (in-patient mental health services) in Ireland. It was established under provisions in the Mental Health Act 2001 (the Act) and its functions as set out in Section 33(1) are "to promote, encourage and foster high standards and good practices in the delivery of mental health services and to protect the interests of persons detained in approved centres" (Department of Health, 2001). The core regulatory activities of the MHC include registration (licensing of in-patient services), surveillance (inspection and data collection), enforcement and quality improvement (MHC, 2013).

In line with international thinking which was previously discussed, the MHC recognises that safety is a key dimension of a quality service: "ensuring that there are appropriate structures and systems in place to effectively manage risks posed to patient safety is considered central to the creation of high standards and good practices in mental health services" (MHC, 2007). In its role as regulator the MHC has identified that "reporting independently on the quality and safety of mental health services in Ireland" is an integral part of its overall mission (MHC, 2013).

One key method of surveillance which the MHC uses to monitor and measure quality and safety in approved centres is the collection and analysis of activity data from services, which is the focus of this study. Data collected from services are used, in conjunction with inspection data, to support the MHC's regulatory process which includes:

- To assess compliance with standards and create a risk profile for each approved centre;
- to drive good practices and quality improvement in services;
- to identify areas of concern in relation to the safety and welfare of service users and
- to prompt regulatory action in response to poor performing services (MHC, 2013, MHC, 2014b).

The MHC adopts a responsive regulatory approach which may result in further investigation; an inquiry (as mandated under Section 55 of the Act) or enforcement actions such as sanctions (e.g. conditions attached to registration) or prosecution (specified under Section 66 of the Act) where the MHC identifies a risk to quality and service user safety. Therefore, the MHC is reliant on good quality data to measure safety risks in services to support its decisions in relation to regulatory activities.

2.5.2. Current adverse event reporting requirements

The Mental Health Act 2001 (Approved Centres) Regulations 2006 (Department of Health, 2006) are the fundamental standards against which an approved centre's performance is assessed and therefore, the foundation of the MHC's data requirements. The concept of safety is embedded in the regulations. Specific provisions under *Article 14 Care of the Dying* and *Article 32 Risk Management* are the basis for the current adverse event

reporting requirements. They provide for reporting of deaths (including deaths due to natural illness or disease and sudden, unexplained deaths which may have been as a result of an result of an adverse event) and incidents to the MHC and are discussed further below.

Firstly, requirements in relation to notification of deaths are prescribed in *Article 14 Care of the Dying*; 14(4) which states that:

> "The registered proprietor shall ensure that the Mental Health Commission is notified in writing of the death of any resident of the approved centre, as soon as is practicable and in any event, no later than within 48 hours of the death occurring."(Department of Health, 2006)

Although the regulation makes it a legal requirement to notify the MHC of all deaths it does not define the data elements which must be provided. This dataset has been developed iteratively, by the MHC, since 2006, when the regulations came into effect. The MHC Death Notification Form specifies the required data elements of the dataset. This dataset was reviewed, in consultation with service providers, in 2014, a revised dataset and associated form have been place since January 2015.

Secondly, A*rticle 32 Risk Management* prescribes that it is a statutory requirement for approved centres to have a comprehensive risk management policy in place which must include "arrangements for the identification, recording, investigation and learning from serious or untoward incidents or adverse events involving residents". Section 32(3) of the regulation specifies the requirement for approved centres to report incidents to the MHC, it states that:

> "The registered proprietor shall ensure that an approved centre shall maintain a record of all incidents and notify the Mental Health Commission of incidents occurring in the approved centre with due regard to any relevant codes of practice issued by the Mental Health Commission from time to time which have been notified to the approved centre." (Department of Health, 2006).

Article 32 Risk Management does not specify the types of incidents or data elements which must be reported but defers to the MHC to determine these requirements in a

code of practice. The Article does however highlight some particular risks of concern which include:

- a service user absent without leave (absconding);
- suicide and self harm;
- assault;
- abuse of children and vulnerable adults.

The MHC's *Code of Practice for Mental Health Services for Notification of Death and Incident Reporting* (MHC, 2008) communicates the incident reporting requirements for approved centres in line with provisions in Article 32(3). It highlights the MHC's position which is that incidents should be managed and investigated locally and that the MHC's role is to monitor corporate governance and ensure effective risk management systems are in place. The code of practice states that the purpose of reporting deaths and incidents to the MHC "is to improve the quality and safety of care and treatment provided to service users by identifying and correcting any problems as they arise, and in doing so creating a learning environment which supports ongoing quality improvement" (MHC, 2008). It indicates that the MHC aims to do this by providing feedback to services on information received and identifying trends or patterns occurring in services.

The code of practice defines an incident as "an event or circumstance which could have resulted, or did result, in unnecessary harm to a service user" (MHC, 2008). Section three of the code of practice specifies that approved centres are required to send an aggregate summary incident report to the MHC on a six-monthly basis. The dataset required is at enterprise level (with no individual patient data collected) and includes the types or categories of incidents and the severity of injury. Approved centres are required to report all incidents including near misses (no harm incidents) and adverse events (incidents resulting in harm which may range from low to severe harm or death). Reporting requirements are flexible; no incident reporting classification system or taxonomy is defined (services are instructed to use their own) and services can use either the MHC Summary Incident *Reporting Template* or other extract data from their own local risk management system as long as it contains category of incident and severity of injury.

2.5.3. Challenges in relation to use of the incident report data

It was intended that the summary incident report required under the code of practice would provide the MHC with a high level overview of incidents in services while trying to minimise duplication of effort and adding value to existing risk management systems (MHC, 2008). However, it has become evident, through the limited use of the data by the MHC, that there are issues with the current data reported. The reasons for these issues include: the heterogeneous nature of the data, limitations of data extracted from STARSWeb and issues with the MHC template. Each of these is discussed further below.

The heterogeneous nature of the data is the primary challenge in relation to use of the summary incident reports. The reason for this variation is due to the non-prescriptive nature of the MHC reporting requirements. Services are instructed to use their own classification systems, however, historically there has been no nationally agreed incident reporting classification system in use in Ireland. This has resulted in local variation in terminologies and taxonomies. The current reports are limited as the data is not comparable, therefore the MHC cannot benchmark approved centres or report nationally on the data to provide assurance to the public or feedback to services. The data is currently only used to provide a snapshot of incidents in an approved centre which may inform the inspection process (MHC, 2015).

All HSE services are legally required to report incidents to the State Claims Agency (SCA) through the Clinical Indemnity Scheme's STARSWeb claims system. In order to avoid duplication of effort collating data, the MHC liaised with the SCA to facilitate services being able to extract their incident data from the system to fulfil the MHC requirements.. The fact that STARSWeb is a claims based system has been an issue as it has been focused on risk rating rather that level of harm to the service user. There have also been issues with data not being fully completed on the system, in 2012, there was no risk rating logged for 50.6% of incidents reported in that year (SCA, 2013).

Finally , the current MHC incident reporting template is flawed. It does not request a breakdown of severity of injury for each category of incident. The current layout requests the number of incidents under each category of incident and the number of incidents

under each level of severity of injury, but they are not correlated. Therefore, it is not possible for the MHC to interrogate the data and analysis is limited. For example the MHC cannot identify the types of harmful incidents (adverse events) which resulted in the most severe harm in individual services or on a national basis.

2.6. Data quality

The research question was focused on the challenges and opportunities in relation to the quality of adverse event data to support regulatory activities. To understand data completeness we must first understand data quality.

There are many definitions of data quality; a common theme is that the data should be 'fit for purpose' as is specified in the definition by Arts et al:

> "data quality is the totality of features and characteristics of a data set that bear on its ability to satisfy the needs that result from the intended use of the data" Arts et al. (2002)

A number of data quality frameworks have been developed for the healthcare context. For the purpose of this research study the HIQA's data quality framework has been adopted. The HIQA framework was chosen because of HIQA's prominent role in developing national data standards for health in Ireland. The framework consists of seven internationally recognised dimensions of quality: accurate, valid, reliable, timely, relevant, legible and complete. The domains of quality need to be balanced with the use of data, which means that depending on the use of the data some domains will be more important than others. The dimension of completeness is of particular relevance to this research study "complete data is data that has all those items required to measure the intended activity or event" (HIQA, 2013b).

Regulators are charged with monitoring the performance of regulated organisations and making regulatory enforcement decisions based on how they measure up against the standards. Therefore, data completeness is important. The completeness of data provided plays a key role in informing decision making.

The Audit Commission in the UK identified that good quality decisions are reliant on good quality data and that in order for data to be complete "data requirements should be clearly specified based on the information needs of the organisation and data collection processes matched to those requirements" (Audit Commission, 2007).

Regulators need to adopt a strategic approach to the collection and quality assurance of data. The principles of regulation include consistency and transparency, regulators should not collect data simply because they can. Only the most essential data should be gathered as irrelevant data become distractions during the data analysis and decision-making processes. (WHO, 2005a, Martin et al., 2007). Therefore, regulators should explore the use of minimum datasets which capture the core, most essential data for a required purpose. HIQA have identify the steps involved in establishing a minimum data set which include to define the level of data required and the frequency of collection, to document data collection processes, identify the data sources, assess compliance with information governance and plan data quality (HIQA, 2013a).

One of the biggest factors underlying poor data quality is the lack of understanding among clinical staff of the reasons for, and benefits of, the data they are collecting. (Raleigh and Foot, 2010). Risks to data quality include changing information needs, the burden of data collection on services and failure to re-use existing data.(Rajendran, 2007, HIQA, 2013a). Therefore, datasets should be reviewed periodically to ensure they are meeting their purpose, existing data should be used where possible to avoid duplication and conflicting data (Rajendran, 2007).

Challenges which are particular to the regulatory context are imperfect mapping of requirements to regulatory standards, organisations may not have the data required themselves, regulated organisations may manipulate or distort the data, it may be difficult for inspectors to obtain accurate information, validity and reliability of indictors, regulator's staff may lack the expertise and time to interpret the data, (Walshe, 2003, Sutherland and Leatherman, 2006, HIQA, 2014, Rajendran, 2007). Variation in terminologies also affect data quality and act as a barrier to analysis and comparability (Leape et al., 2005).

The AIHW's data development guide advocates the use of data standards which describe the agreed meaning and acceptable representations of data for use in a defined context to ensure consistency and comparability of content and to avoid duplication and diversity and highlight the following principles of good data development:

- "create data standards

- use national and international standards

- be clear about the purpose of data collection

- data included must be required to meet the objectives of the data collection

- create once and use often

- acknowledge the limitations of the data

- data development may be incremental

- should be system independent

- should be mindful of privacy concerns

- should minimise collector/recording burden

- should reflect not drive practice (data collected as a by-product of service delivery and should be relevant to those collecting the data and be of benefit to service providers)" (Rajendran, 2007)

They advocate that a data dictionary is a key document to ensure consistent data collection processes. It defines the requirements for the dataset and associated data elements, attributes and metadata within a dataset. A data element is the basic unit of data and metadata is the data that describes the characteristics of data. Metadata is important for data quality as it removes ambiguity and helps to interpret data accurately and consistently. The data dictionary is a dynamic document which should be frequently reviewed and validated. (Rajendran, 2007, Johnson et al., 2013).

As highlighted in the research data quality and completeness are reliant on clearly specified requirements where only the essential data elements are collected and that a data dictionary is a key tool to assure data quality. These literature findings informed the work which was undertaken to meet objective three, to propose an appropriate adverse event data set.

2.7. Summary

This section included a review of literature in relation to healthcare regulation, patient safety, the MHC current reporting requirements and data quality. It has provided an overview in relation to some of the existing challenges in relation to reporting of adverse events both internationally and specifically for the MHC in the Irish context. It has also summarised some of the key developments since 2008, which may be opportunities for the MHC to improve the current dataset. The current MHC adverse event reporting requirements have been in place since 2008 and are out of date in the current policy context and this is a motivating factor for this research.

3. Research methodology

3.1. Introduction

This chapter contains information in relation to the research methodology which was adopted for this research study. It describes the rationale for selecting the research approach and design, the process which underpinned the research and the methods used to collect data to answer the research question.

3.2. Research approach and design

The focus of this research study was to understand the adverse event data requirements of the MHC in the context of the regulation of in-patient mental health services. In order to explore the MHC's data requirements "participants' views of the situation being studied" (Creswell, 2012) were sought in line with an interpretivist philosophy .

Following a review of the different types of research approaches a qualitative approach was adopted. Qualitative research is described as "an inquiry process of understanding based on distinct methodological traditions of inquiry that explore a social or human problem The researcher builds a complex, holistic picture, analyses words, reports detailed views of informants, and conducts the study in a natural setting." (Creswell, 2012). Kaplan and Maxwell identify that a qualitative research approach is appropriate where the researcher is "trying to make sense of what is happening" and is associated with the how and why questions. Quantitative research on the other hand is an approach best suited when testing objective theories by examining the relationship between variables that can be measured (Creswell et al., 2003). As the goal of the study was to explore and understand the research topic rather than test or measure a hypothesis, a qualitative approach was identified as more appropriate.

A case study design of inquiry is commonly used in qualitative research. Yin describes a case study as "an empirical inquiry that investigates a contemporary phenomenon within it's real-life context." (Yin, 2014). As the study required an in-depth understanding of the MHC's adverse event data requirements, based on participant's views, a qualitative case

study design was identified as a flexible research design which could best answer the research question.

Once the research approach and design were selected, a research process was developed to provide structure and focus to the research activities and research methods were explored. The process and methods employed for this study are discussed further below.

3.3. Research process

The aim of this research study was to generate a body of knowledge in relation to adverse event data required by the MHC to support the regulation of approved centres. It was identified that there are gaps in the current dataset and that there is a need to develop a dataset which is 'fit for purpose'. Therefore, as the main focus of the study was around data development (the process of building a dataset for a specific purpose), best practice guidelines on which to base the process were sought. From the available material, the Australian Institute of Health and Welfare (AIHW) publication *A Guide to Data Development* was identified as providing a good structure on which to base the data development process (Rajendran, 2007). The AIHW are highly regarded in relation to data development in the health domain, with particular expertise, in relation to data standards and metadata. Their Guide outlined the key stages in the data development process from the early stages of data development through to authoritative endorsement of the dataset. Therefore, the process outlined in this guide was identified as a sound evidence base on which to underpin the research study.

The AIHW describe data development as a methodological iterative process which results in the production of a set of data standards to ensure consistent collection and use of a dataset. The research evidence for this study was gathered, through the collection of primary data from interviews and secondary data from the literature review which was aligned to the requirements gathering process identified in figure 6 below. This five stage process (adapted from the AIHW data development process) was iterative with each stage being informed by the interviews and literature review. The purpose of each stage of the data gathering process and the outputs were identified. This was done to ensure

clarity in relation to the research methods that would be used to complete the process.

Table 2 below shows the framework that was used.
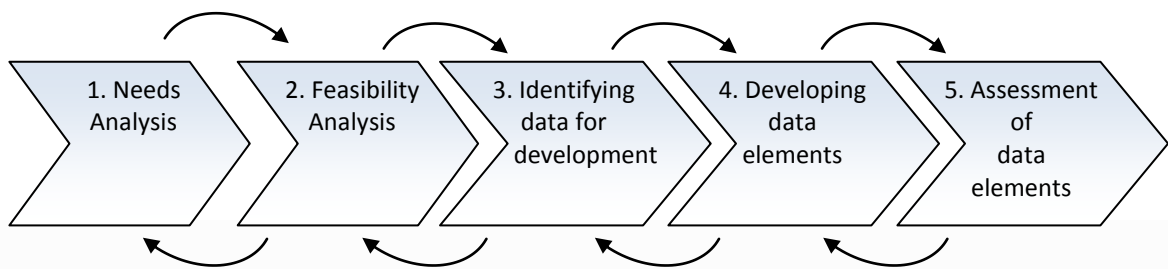
Figure 6: Stages in the research process, adapted from (Rajendran, 2007)

Table 2: Stages in the research process. Purpose, outputs and research methods (adapted from (Rajendran, 2007)

Stage	Purpose	Outputs	Research Methods
1. Needs Analysis	To be clear about the purpose of the data development and its benefits. To obtain an understanding of the business context within which the information is needed.	Identification of: • The business context and requirements for the data. • A problem statement (the issue the data needs to address). • The target population (subject of the data). • The service environment. • Data priorities. • Expected benefits. • How the data will be used.	• Literature review: healthcare regulation, patient safety, MHC requirements. • Interviews with key stakeholders: questions regarding the types of events that need to be reported, challenges using data for regulation, information also obtained from across other questions.

Stage		Purpose	Outputs	Research Methods
2	**Feasibility Analysis**	To provide an indication of the scope of the data development. To identify operational constraints of the systems and people who need to record the data results.	Identification of: • Data that currently exists, their usefulness, how they are collected and if there are existing standards. • Performance indicators or benchmarks.	• Literature review: patients safety, MHC data requirements. • Interviews with key stakeholders: questions regarding challenges, frequency, what adverse events, data quality, gaps, information also obtained from across other questions.
3.	**Identifying data for development**	Analysis of data that are required to support the business requirement, how the data can be collected in practical terms and the priority of the data.	Identification of: • The questions the data needs to answer • The problem that the data needs to address • The data for collection • The data elements and how they will be collected. • Definition and standardisation of	• Literature review: regulation, patient safety, data., MHC data requirements. • Interviews with key stakeholders: questions in relation to data elements, challenges, opportunities and information also

Stage		Purpose	Outputs	Research Methods
			core concepts. • Limitations of the data.	obtained from across other questions.
4	**Developing data elements**	Definition of the characteristics that describe the entities identified and defined.	Documentation which identifies the data elements which will be used including: • new data elements that are being created including their definition and associated rules (including the metadata • existing data elements that are being used or modified	• Literature review findings. • Results of interviews with key stakeholders.
5.	**Assessment of data elements**	To identify if the data elements are fit for purpose.	Evaluation of the data elements to assess if they are fit for purpose.	Assessment against WHO Patient Safety Minimal Information Model.

3.4. Research methods

Research methods include data collection, analysis and interpretation activities used by a researcher to answer a question (Creswell, 2012). Multiple sources of data were collected to ensure robust evidence. Secondary data was sourced from the literature review and primary data was sources from semi-structured interviews with key informants. This section describes each of the research methods in more detail.

3.4.1. Literature review

The literature review was an iterative process that was carried out over the lifecycle of the research study. Firstly, to ensure that literature retrieved was relevant, the main areas of interest to the research study were identified. This was done by examining the research question, the aims, the objectives (identified in Chapter 1) and the business need for the data. Four main areas of interest were selected as follows: healthcare regulation; patient safety; data quality and MHC data requirements. A number of search words were identified under each area of interest. Table 3 below describes the four areas, the key objectives of each and the search terms that were used.

Table 3: Literature Review. Areas of interest, key objectives, search terms

Areas of Interest	Key objectives	Search Terms
Healthcare Regulation	To understand the objectives of regulation and the role of a healthcare regulator and how data is used to support regulatory activities, particularly in relation to patient safety.	healthcare, regulation, regulator.
Patient Safety	To define patient safety and to examine ways to measure safety in healthcare.	adverse events, healthcare services, incidents, indicators, measuring, mental health services, mental health, monitoring, patient risks, patient safety.
Data Quality	To investigate the concept of data quality in the context of data that is used for measurement. To identify relevant patient safety and incident reporting data standards.	classifications, data quality, data standards, taxonomies terminology.
MHC Data Requirements	To capture the MHC adverse event data requirements.	regulations, standards, legislation, policy.

Literature searches were carried out using three academic databases (PubMed, Science Direct and PsychInfo), GoogleScholar, websites of leading organisations with a remit in relation to patient safety or healthcare regulation and key Irish organisational and government documents. Literature was critically appraised based on the inclusion and exclusion criteria and the search terms used. Table 4 below shows the primary data sources and inclusion and exclusion criteria. Documents were also identified from reviews of references lists in reports and articles that were selected for inclusion. The Trinity Library was the primary source of articles and books as it provided comprehensive access.

Table 4: Literature. Sources of evidence, Inclusion and exclusion criteria

Sources of information	Inclusion criteria	Exclusion criteria
Academic Databases:	English	Non English
PsychInfo		
PubMed	Since 2000 with a particular	Pre 2000 (international
Science Direct	focus on literature since	literature, unless
Search Engine:	2008 when the MHC's Code	document with key
GoogleScholar	of Practice for Notification	definition)
International Websites:	of Deaths and Summary	Pre 2006 (Irish
AIHW	Incident Reporting was	literature, pre full
Canadian Patient Safety Agency	published.	implementation of the
Care Quality Commission (CQC)		Mental Health Act
OECD		2001).
The Health Foundation		
The King's Fund	Patient safety classification	Near miss reporting,
WHO	systems, incident reporting	individual hospital
Irish websites:	taxonomies, patient safety	incident reporting
Department of Health	measurement tools,	systems, market
HIQA	healthcare regulators role	regulation, product
HSE	in relation to patient safety,	regulation.
MHC	data quality frameworks.	

3.5. Semi-structured interviews

Primary data was collected through semi-structured interviews. Interviews are common practice in qualitative research as they are considered to be an efficient method for the collection of rich empirical data, providing an interviewee's interpretations of the phenomenon in question (Kvale and Brinkmann, 2009). Interviews can be structured, semi-structured or unstructured. For the purpose of this research a semi-structured approach was taken to allow for flexibility in terms of the topics discussed and to allow the interviewee's knowledge, experience and views to emerge in the course of the interview (Lee, 2012).

The objective of the interviews was to obtain stakeholder input in relation to adverse event data requirements to support regulation. A small number of key informants were purposefully selected from within the MHC and the HSE, participant information and the rationale for their selection are included in table 5 and discussed further below.
The MHC participants were selected as they are the key decision makers who manage the regulatory activities of registration, inspection and enforcement. It was identified that they were best placed to identify the business need for the data as it forms part of the intelligence they use to inform decisions in relation to regulatory actions. Another criteria for selection of the participants was their knowledge of the subject under study and the relevance of their experience.

As the focus of this study was on the collection of data from HSE managed approved centres, the HSE were identified as a key stakeholder. The HSE participant was selected due to her seniority and specialist role in relation to overseeing quality and service user safety in all HSE managed mental health services in Ireland and her expert knowledge and experience of the research topic.

Table 5: Interview participants. Organisations, name, job titles, rationale for selection.

Organisations	Name	Job Title	Rationale for selection
MHC	Ms Patricia Gilheaney	Chief Executive	Responsible for enforcement of statutory powers in relation to registration and quality improvement of mental health services.
MHC	Ms Rosemary Smyth	Director Standards and Quality Assurance	Overall responsibility for registration, enforcement, direction (developing rules and codes of practice), monitoring activity in mental health services and quality improvement activities.
MHC	Dr Susan Finnerty	Acting Inspector of Mental Health Services	Overall responsibility for the inspection of mental health services and reporting on inspection findings
HSE National Office -Mental Health Division	Ms Margaret Brennan	Lead for Quality and Service User Safety in the HSE (reports to the National Director for Mental Health)	Oversees the development and supports the implementation of comprehensive frameworks in the areas of quality, service user safety, risk and incident management, standards and compliance within mental health services.

Four semi-structured qualitative interviews were conducted, three face-to-face and one over the phone. Interviews were based on a self-designed questionnaire (included in Appendix D) with eight questions to capture the various requirements associated with each stage in the research process (identified in Table 6 above) as a source of evidence to answer the research question. Interviewees were provided with the participant

information sheet and questions in advance of the interview. The interviews ranged in length from 20 minutes to 45 minutes. All interviews were audio recorded and transcribed into MS Word. Each interviewee was provided with a transcript of their interview and were provided with the opportunity to add an addendum if required. Thematic analysis was carried out on the interview data using a process previously used by Braun and Clarke which is shown in figure 7 below The analysis was an iterative process. Firstly, each interview question was coded based on the study parameters (data needs, gaps and challenges and opportunities) using MS Excel. Second round analysis involved the identification of broader themes which spanned multiple questions. Themes were identified through the initial coding and categorisation process as well as reading and re-reading the interview transcripts and referring to the stages of the research process. Once themes were defined, relevant quotes were identified to support them.

Phase 1	• **Become familiar with the data** though the process of transcription and initial review and examination of the data
Phase 2	• **Generate initial codes** systematically across the data set, collating data relevant to each code
Phase 3	• **Begin to identify themes** by reviewing codes and grouping related codes together
Phase 4	• **Review themes** both relating to sections of the data and at the level of the entire dataset
Phase 5	• **Define themes** based on a process of reflecting on the themes and the overall analysis, and clearly name each theme
Phase 6	• **Produce the report** though a process of selecting quotes and/or examples and drawing the results back to the research

Figure 7 Thematic analysis process (Braun and Clarke, 2006)

3.6. Ethical considerations

Due to the requirement for human participation in this research study ethical approval sought from the School of Computer Science and Statistics Ethics Committee at Trinity College Dublin. Ethics approval was received on 20th April 2015.

3.7. Summary

This section described the research methodology which included information about the research approach, the study design, the data gathering process and research methods (literature review and interviews) that were selected for use in the research study. It described the rationale for adopting this approach and provided information in relation to the research methods employed. It also discussed ethical considerations.

The next section presents the results of the interviews.

4. Interview findings

4.1. Introduction

The purpose of the interviews was to obtain input from key stakeholders (which were selected based on criteria outlined in the Methodology section) as a source of evidence to answer the research question. The study was focused on the adverse event data required by the MHC to support the regulation of in-patient mental health services in Ireland. Interviews were conducted with personnel from the MHC who were identified as the key users of the data due to their decision making roles in relation to regulatory activities. They included: the Chief Executive (PG), the Director of Standards and Quality Assurance (RS) and the Acting Inspector of Mental Health Services (SF). In order to obtain information in relation to the current HSE policies and operations, of relevance to the research study, the National Lead for Quality and Service User Safety (MB) in the Mental Health Division was also interviewed.

Interviewees were asked eight questions (included in Appendix D). This included three questions which asked for specific information in relation to the types of adverse events that the MHC needs to be notified of; the data elements required and the frequency of reporting. There were a further four questions which covered broader topics including: gaps in the current data; challenges in relation to using the data; issues with the quality and opportunities to improve data quality. Finally, there was an open question to capture the expert knowledge of the interviewees. Thematic analysis was carried and the following six main themes emerged from across the eight interview questions:

- Business requirements for the data.
- Current issues and challenges.
- Dataset requirements.
- Data limitations.
- Data standardisation.
- Data quality.

4.2.   Thematic analysis

This section expands on each of the six main themes and describes the sub-themes that were identified. Direct quotes are provided to support the analysis and the interviewee and question number are identified after each quote in brackets.

As discussed in detail in the literature review (Chapter 2), approved centres are currently required to report adverse events to the MHC in two main formats which are individual deaths notifications (within 48 hours of the death occurring) and aggregate summary incident reports (on a six-monthly basis). The dataset in relation to notification of deaths was recently reviewed by the MHC in consultation with service providers and a revised dataset and associated notification form has been in effect since January 2015. All interviewees expressed that the new dataset was meeting their requirements but that incomplete forms was an on-going challenge which prohibited effective use of data in determining if a service is safe. Interviewees identified that the current data captured on the incident reports is not fit for purpose and this data was the main focus of the interviews and the analysis below .

4.3.   Business requirements for the data

A dataset is a set of data collected for a specific purpose. One of the main themes that emerged from the interviews was the business requirement for the data. Interviewees from within the MHC and HSE perceived that the MHC, as the regulator, requires adverse event data to have oversight of safety in services; to get assurance that there are effective risk management structures in place; to support the MHC's regulatory process; to prompt regulatory action when the standards are not being met and to benchmark services nationally. The role of data in supporting quality improvement was also identified as an overarching purpose of the MHC collecting data.

> "From a regulator's perspective it is important for us to have an overview and be able to aggregate data to provide a full picture of how services are operating."
> (PG, 2)

"I think they (the regulator) need high level assurance that they know about things when they need to know..." (MB, 2)

"The intention being that it would form part of the intelligence that the inspectorate team are armed with when they go out on inspection so that they can actually look to see are there any issues that have emanated from the particular (incident) reports and follow up on them." (PG, 4)

"... there is a new regulatory process being developed in the Commission and it is intended that active use will be made of the reports that we receive...." (PG, 4)

"...I think there is a point where you (MHC) need to call it if we (HSE) are not achieving the standard because that is very helpful to me..." (MB, 8)

 "We all want to have a safe healthcare system as a bare minimum but that's not good enough we also want to have a quality healthcare system. We can only do that if we have good, reliable, accurate, data that is relevant and that we have in a timely manner that we actually can use to provide us with information to meet the needs in terms of quality improvement." (PG, 8)

4.4. The current issues and challenges

Information in relation to the current issues and challenges emerged from across a number of questions and five sub-themes (which are discussed below) were identified as follows:

- Dataset currently notified;
- Lack of standardisation in the reports;
- Ad hoc reporting of serious adverse events,
- Disparate systems for collection of data;
- Privacy and confidentiality.

4.4.1. Dataset currently notified

Interviewees were in agreement that the MHC should be notified of adverse events resulting in serious harm on an individual basis and that the current summary incident report dataset and reporting arrangements are not fit for purpose to support the regulatory process. The level of detail or the data elements in the current dataset and the quality of the data were also perceived as a challenge.

> "So I actually believe that the Mental Health Commission should be notified of all serious incidents which result in death or serious harm to service users. The current system where there is only notification of deaths I think is limited and doesn't necessarily assist you with getting a sense around the quality issues and perhaps areas that might need regulatory attention." (MB, 1)

> "The challenges would be the detail that we have on the form to make a determination if that service is safe, the quality of the data we get in and what we do with the data when we get it in." (RS, 6)

4.4.2. Lack of standardisation in the reports

All interviewees indicated that the lack of standardisation in the reports was an issue which prevents effective use of the current data reported to the MHC. (Standardisation emerged as one of the principal themes from the interviews and is expanded on in great detail later in this Chapter.)

> "One of the challenges in the six-monthly summary reports is that they are all different. There is no standardisation in terms of what is reported to us so therefore how we use that data to provide information we are actually quite compromised and that's evident that over the years that we have been collecting this data we haven't been in a position to provide very detailed significant reports arising from the data." (PG, 4)

4.4.3. Ad hoc reporting of serious adverse events

Another issue which was identified by all the interviewees from the MHC was the ad hoc reporting of serious adverse events. The lack of an explicit requirement for services to notify the MHC and the absence of a formalised process within the MHC for dealing with

these notifications have lead to incomplete reporting of serious adverse events and an inconsistent regulatory response in relation to these ad hoc notifications.

> "The ad hoc way in which they can report (serious incidents) to us. If it was more structured and a uniform process we could do more of an analysis on it and it would be more useful to the Inspectorate in their function....They would be able to make better use of their resource and it may inform their reports more. It would be good to see what people are actually submitting to us is reflected in the reports" (RS, 4)

4.4.4. Disparate systems for collection of data

The disparate systems for collecting adverse event data by the MHC and the absence of an organisational policy in relation to processing of this information was identified by PG who expressed that this has resulted in fragmented adverse event data within the MHC which is not being effectively utilised to support regulation.

> "…apart from the notification requirements in the COP (Code of Practice) whereby services report on certain matters to the Mental Health Information Officer in the Commission, it would be helpful if there was a specific policy and protocol internally within the Commission that addresses the sharing of information gathered on inspections regarding adverse events and serious incidents. This would ensure that all relevant information is captured centrally to provide an enhanced picture of the safety profile of services." (PG, 1)

4.4.5. Privacy and Confidentiality

Issues in relation to privacy and confidentiality were raised by all interviewees which included challenges regarding data protection and inappropriate data being collected. One interviewee highlighted the importance of the MHC having clarity in relation to the purpose of collecting the data, to support regulatory activities, to ensure only appropriate data is collected.

> "Issues with confidentiality and I know there is such a small number they are instantly identifiable. We had one in the last six months of one patient killing another patient I mean that is totally identifiable" (SF, 8)

"…. it is not so much about the individual information because I think you have a lot of issues around data protection and transfer of information. Whereas I think high level, fairly well anonymised but which you have clear location and follow-up if required." (MB, 2)

" Yes, as regulator it is not our role to identify what the cause was…Our role is in relation to the safety and we need to get that home. And it has resulted in a considerable amount of detailed personal data of individuals in our systems that we never had any involvement in their care and treatment." (RS, 6)

4.5. Dataset requirements

As highlighted under the current issues and challenges interviewees identified that there was a specific gap in the current incident reporting data in relation to notification of adverse events resulting in serious harm. There was a consensus that these incidents should be reported on an individual basis. Interviewees described the types of adverse events that should be notified, the required data elements and the frequency of reporting which are discussed in this section.

4.5.1. Types of adverse events

Question one asked *What adverse events does the Mental Health Commission need be notified of in order to support regulation of approved centres?* This section describes feedback from interviewees in relation to this question which includes the types of adverse events that were identified and why it is challenging to define a definitive list of the categories of incidents which are required.

There was a consensus that it is difficult to identify a specific list of adverse events that should be notified to the MHC but that the level of harm (as an outcome of the event) was the key area of concern. It was agreed that all adverse events resulting in serious harm, in addition to those resulting in death, should be notified. Interviewees did identify some specific types of adverse events of concern which included sexual assault, physical assault and adverse medication events. There was a particular emphasis on adverse medication events due to the prevalent and long-term use of medication, in mental

health services, which has known side effects. There was also reference to a requirement to notify any adverse events which are directly related to the approved centre regulations (the standards for services) to use in conjunction with evidence from inspections to judge a service's level of compliance. Finally, the HSE's list of Serious Reportable Events (SRE) was also referenced as a sub-set of the adverse events which should be reportable to the MHC for the public good. Table 6 provides an overview of the areas identified by each interviewee.

Table 6 : MHC requirements in relation to the individual notification of adverse events. Types of events identified by interview participant.

Adverse event type	SF	RS	MB	PG
Adverse events resulting in death	•	•	•	•
HSE Serious Reportable Events		•	•	•
Adverse events resulting in serious harm	•	•	•	•
Adverse events of relevance to the approved centre regulations		•		•
Specific event types were identified as follows:				
• Adverse medication events	•	•	•	•
• Sexual Assault/Abuse	•		•	
• Physical Assault	•			
• Pressure Sores				•
• Adverse event as a result of Electroconvulsive Therapy treatment	•			

4.5.2. Data elements

Question two asked '*What are the data elements that should be included in adverse event reports?'* All interviewees agreed that the management and investigation of incidents is the responsibility of the HSE and that the MHC requires data on adverse events to have an oversight of safety in services, to get assurance that incidents are being investigated and to identify if further regulatory action is required (e.g. targeted inspection, investigation or enforcement). There was a general consensus that the dataset should be small but there was variation in relation to the specific data elements required (as shown

in table 7 below). A variety of individual data elements were identified either specifically or in more general descriptive terms. Different terms were used to describe the same data elements and for the purpose of this section a single data element name is used.

Two data elements were identified by all interviewees as key pieces of information. They were the location where the incident occurred (as a means of identifying risks such as ligature points) and the type of investigation which the service was going to carry out (to get assurance that risk management procedures were being adhered to). Corrective and preventative actions were also identified by most interviewees. Again this was identified as important in relation to oversight of risk management procedures. There was some variation in relation to service user information; age and gender were identified as important but due to small numbers and issues of confidentiality the preference was for a unique identifier rather than patient name or initials.

Table 7: Data elements identified by each interviewee

Data element	Interviewee			
	SF	RS	MB	PG
Service User Initials/Unique ID	●			●
Age	●		●	●
Gender/Sex	●		●	
Diagnosis				●
Medication				●
Treating Team				●
Location where incident occurred	●	●	●	●
Date of occurrence	●	●		
Time of occurrence	●	●		
Circumstances surrounding incidents	●	●		●
Level of harm			●	
What other Agencies were notified		●		●

Data element	Interviewee			
Type of Investigation	●	●	●	●
Corrective and Preventative Actions		●	●	●
Service User & Family informed/Open Disclosure?		●		
Form completed by	●			

4.5.3. Frequency of Reporting

Question three asked '*How frequently do you think that in-patient mental health services should report adverse events to the MHC?*' All interviewees had similar views in relation to the frequency of reporting. They all indicated that the preference would be for adverse events resulting in serious harm to be notified in a timely manner as close to real-time as possible. MHC interviewees felt that an outer limit of one week from the date of the occurrence was appropriate in cognisance of what services can cope with.

"In an ideal world, we would have one national reporting system and that would gather data in real-time. …. Obviously that is not where we are at currently so we have to look at what the system can cope with. (PG, 3)"

"...we need to define the taxonomy for the serious incidents and close to real-time, within 72 hours, let's think about that in terms of timeframes with weekends, anyway within a week." (RS, 3)

4.6. Data limitations

Data limitations emerged as an overarching theme. All interviewees perceived that there are limitations to using adverse event data in terms of informing regulatory activities and that these limitations need to be acknowledged and accounted for when using the data. Five sub-themes (discussed below) emerged under data limitations which included:

- Constraints of adverse event reporting;
- Uniqueness of the mental health domain;
- Other measures of safety;
- Other ways to improve safety, and
- The limited scope of the data collection.

4.6.1. Constraints of adverse event reporting

One of the main sub-themes that emerged in relation to the limitations of the data was the constraints of adverse event reporting. A variety of reasons were identified as follows:

- **The positive correlation between a good safety culture and high reporting.**

  "I tell you the biggest challenge for me at the moment, which I think would transfer in to the regulator... a good culture and safe area will probably have more reported incidents than an area where we should really be putting the spotlight. So adverse event reporting has a lot but it is intrinsically flawed because good culture of reporting usually does not necessarily equate to poor patient safety." (MB, 6)

- **The difficulty defining some adverse events** (e.g. long-term adverse effects of medication).

  "...there are some that we may never capture Deirdre like the long term effects of medication for someone who is on it would be considered an adverse event. That is something that could go on over a number of years, but is that reportable to us? We can't capture that but yet it is something that a patient may come back on and that is down to the interrogation of the data and the information you have available to make that decision whether it is an adverse event or not." (RS, 1)

- **How the data should be used** (having a clear purpose for collecting the data).

  "So I think a regulator has to be very careful that the data that is collected and used is just that. It is a trigger, a smoke signal or it is a signpost to say look there may be something here that is of particular concern.." (PG, 6)

- **High numbers of adverse events may be skewed by one service user** which is difficult to determine in the aggregate reports.

  "One of the things is around the slips trips and falls or assault is whether it was the same patient all the time." (SF, 6)

4.6.2. Uniqueness of the Mental Health Domain

The uniqueness of the mental health domain was noted by one interviewee who highlighted that the care process in mental health doesn't always lend itself to a systems

approach in terms of incident management. This can result in gaps in the data which limits how adverse event data can be used to inform regulation.

> "Mental health services by their very nature don't lend themselves to and I will use the word simplistic, even though they may not view it as a simplistic approach, because in essence mental health services do not use procedure to a great extent...the majority of interactions or therapies provided .... are about human interactions between individuals and at a point in time and the record of those interactions are case notes which will not in any way capture the entire session because they are not going to be taped so there is no way of going back to look at everything that has transpired. So that of course lends itself to challenges in terms of using adverse event data to inform regulation." (PG, 6)

4.6.3. Other measures of safety

Looking at other measures or indicators of safety was identified by two interviewees as important to overcome the constraints of adverse event data. One interviewee referred to the measures of safety identified by Vincent et al in their publication *Monitoring and Measuring Safety* (Vincent et al., 2013b).

> "That circle stuck in my mind, from Vincent, is there past harm, future harm. Is that the way the inspectorate when they are looking at things, should be looking at in their processes. How many incidents here today, has it occurred in the past, will it occur in the future. " (RS, 8)

> "We are always going to struggle with the challenges of using adverse event data to inform regulation in terms of safe care if that was the only tool we were going to use. It is important but it is one tool in an armoury of other tools that we must use. Complaints for example I would purport is a tool that in association with the adverse event data would provide a fuller picture about safety of care that is being provided." (PG, 6)

4.6.4. Other ways to improve safety

Another sub-theme that emerged under limitations of the data was that reporting adverse event data is only one means of driving safety improvement. It was acknowledged, by those interviewed, that adverse event data can be used to provide a snapshot of the risk environment in a service which may prompt regulatory action, however, there are also other ways to ensure and improve safety including quality and safety initiatives, service user empowerment and good clinical governance, which the MHC should also focus on.

> "So putting it back on the services so the people who actually deliver care and we should be actually supporting initiatives...Very simple things involving the service user in their own safety do you feel safe here and what do you do if you don't, who do you tell...empowering patients in relation to their own safety." (RS, 8)

> "But to me it is about the wider improvement of mental health services, good clinical governance, having good quality and patient safety systems and structures in place, having their clinical governance committees in place or quality and patient safety committees.. So that all incidents from the slip, trip and fall to the very serious maybe homicide/suicide go through a process, ok, and that there are incident management teams established and that they are managed as part of the day-to-day quality patient safety management." (MB, 8)

4.6.5. Limited scope of the data collection

All those interviewed indicated that they would like to see data collected from the broader mental health services as the majority of mental health services are delivered in the community and that only collecting data from in-patient services was limited. However, it was also acknowledged that the MHC currently has limited regulatory powers in relation to community mental health services and this was a constraint.

> "...well you could be on a home-based treatment team where you are seen every day but you would still be classified as an out-patient. Or a nurse could be visiting you every day to give you injections or giving you medication and there is potential there for incidents." (SF, 4)

4.7. Data standardisation

The most prominent and overarching theme which emerged, from the interviews, was the standardisation of the data. Data standards were identified as important in relation to data quality particularly in terms of the consistency, completeness and comparability of data. Four sub-themes (discussed below) emerged under data standardisation which included:

- Defining the data requirements,
- Standardising collection of data;
- Using existing standards;
- Using data from existing systems

4.7.1. Defining data requirements

Clearly defined data requirements were identified as important to ensure services are clear regarding reporting requirements; that data is being classified and interpreted in a consistent manner and data completeness is in line with MHC requirements.

> "it's defining it....it is back to what is harm, what is safe and what does it mean to people........in most recent times there was an omission of medication where we had to attach a condition.... They (the approved centre) didn't consider it a risk and they didn't report it and then when they did do their risk analysis of it they rated it as a minor risk which we wouldn't perceive as a minor risk but then they didn't use the new HSE incident management policy." (RS, 1)

> "I just wonder about the definitions of the different types of events. I am just not sure about this whether or not the services are clear about what they are reporting on, do they have a definition of each of a category to be absolutely sure of what they are reporting on... Sometimes you see incidents reported at verbal assault and you look at the seriousness of it and you see that it seems to be quite minor.." (SF,5)

4.7.2. Standardising collection of data

When discussing the key issues in relation to the quality of adverse event data MB highlighted work in the HSE to standardise the collection of data to improve the quality:

"...there will be a new standardised form issued for the HSE in coming months in line with the new NIMS system so that is something which hopefully improve the data."
(MB, 5)

4.7.3. Using existing data standards

Interviewees identified that it was a challenge to identify a definitive list of the types of adverse events and the specific data elements that should be reported to the MHC but that linking in with national and international standards is imperative as a starting point to ensure consistency and comparability.

"Then it is back to what is harm, what is safe and what does it mean to people.. if you look at how it is defined is medical harm only related to the treatment being given or an omission in relation to that care and treatment, that's what it says then where do you go in relation to the homicides, the self harm and violence and aggression, which we get a lot of but we don't define that either....... So I suppose again its ensuring that we link in on what the service providers are considering serious risk and the Clinical Indemnity Scheme as well." (RS, 1)

"If we don't link in with international taxonomies we are not in a position of comparing like with like, so we are not in a position to compare our incidents or deaths to other international countries unless we utilise the internationally recognised taxonomies."(PG, 2)

4.7.4. Using data from existing systems

The State Claims Agency's recently upgraded IT system (NIMS, previously STARSWeb) was identified as a potential source of existing data which would provide standardised data to the MHC.

"So I would be suggesting that with the new version of STARS which is being rolled out across the country that there should be a requirement that a report which is a nationally agreed report with the Commission and with the State Claims is agreed on what type of report, how it looks and what data is on it..." (MB, 4)

4.8.   Data quality

Data quality was another overarching theme which emerged from the interviews. The four sub-themes were identified:

- Data quality challenges
- Domains of quality
- Opportunities to improve data quality
- Data Quality Assurance

A number of data quality challenges and opportunities to improve data quality were identified and are described below.

4.8.1. Data Quality Challenges

Issues such as the limitations imposed by the paper-based nature of reporting, which is a burden for services and the limited resources that the MHC has were identified as challenges which affect data quality.

> "Absolutely the learning that we have gained is, that because of the paper-based system, that less is more in terms of the less frequent we put the burden, and I use that word deliberately because it is a burden on services, the better chance we have of receiving the data." (PG, 3)

4.8.2.   Data quality attributes

Data quality is multidimensional, however, interviewees emphasised some domains of data quality are key to the MHC. Data completeness was identified as a core data quality attribute. Incomplete forms result in the MHC going back to the service and forms lacking clinical input can result in pertinent information not being provided. Timeliness was also perceived by all interviewees as a key item in relation to the data. Legibility was also highlighted as an important aspect of data quality.

> "I continue to notice that despite our best efforts we still receive forms with incomplete data, with fields left blank... if what we are looking for was filled in correctly in the first place there would be no need for a second return to the service at all." (PG, 4)

"I go back if they don't give me enough information on the form. If they give me enough information on the form, if they do a Systems Analysis review or some other kind of investigation I don't go back to them I just request a copy of that. But in a number of them they don't tick the box so I don't know what they are doing about that." (SF, 4)

"there is a level of professional discernment that can only be provided by the mental health professional because of their particular knowledge and competencies that they would be able to identify that it is pertinent information that they need to include in the form." (PG, 5)

"The delay in it, it is really more real-time information we need. " (RS, 4)

"The ability now for people to type on the form has been fantastic because it means that some of the forms now are very legible whereas deciphering hand-writing in the past was also a challenge. But unfortunately some are still in hand-writing and we have to scan in the forms. The quality is compromised as a result, as it can be very difficult to read." (PG, 4)

4.8.3. Opportunities for improved data quality

A number of developments and current projects were identified as potential opportunities to enhance the quality of adverse event data required by the MHC. They included a national IT system, the safety culture in the HSE and collaborative working. Standardisation of data (one of the main themes to emerge) was also identified as a key driver in relation to data quality.

The redesign of the State Claims Agency's claims system (STARSWeb) to a risk management system (NIMS) was highlighted as an opportunity to improve data quality (as well as under the data standardisation theme). The system was perceived as a possible direct source of adverse event data for the MHC, subject to authorisation from the HSE. It was also highlighted that the revised system, which must be used by all HSE

services, will implement national incident reporting taxonomy which will standardise the data for all HSE services.

> "So at the point of input no matter where it is in the service that information would be stored centrally in a system something like the system in terms of adverse event reporting in the CIS. So that regulators, including ourselves would have access to the information that is pertinent to us. Central, so that services would only have to input data once and that anyone who required the data to assist them carry out their functions would have access to it. So collect once and use multiple times..." (PG, 3)

> " We really need to be more dependent on a more objectified manner of getting a report from a system of what is actually reported. I think it is very difficult to trust data that isn't pulled from a report because at the end of the day the State Claims Agency system is a legislative requirement that the incidents are reported there so I think you can definitely expect a level of quality from taking information from that system (NIMS)." (MB, 8)

The current safety culture in the HSE was perceived by all interviewees as a major external development which could support the collection of better quality adverse event data. The HSE's *Incident Management Policy* (HSE, 2014)and the training that has taken place to support its implementation have introduced a comprehensive and systematic approach to incident management and the standardisation of data throughout the HSE.

> "So the HSE have a robust, strong incident management policy in place, people have all been trained up in the HSE and they are all aware of it. The National Office have a strong handle on it and it is an opportunity for us to link in with them and improve our systems on the back of that..... So there are lots of opportunities with the current culture within the HSE" (RS, 7)

Collaborative working was a common theme which was mentioned by all interviewees in relation to addressing data quality issues and improving systems for reporting of incidents. PG highlighted one development to address the data collection issue in relation to data on suicides and homicides in mental health service users whereby a steering group had been established to discuss the feasibility of setting up a system akin to The

National Confidential Inquiry into Suicide and Homicide by People with Mental Illness in the UK, to provide more robust data in relation to suicides and homicides among mental health service users in Ireland.

> "...in relation to one of the issues and challenges at the moment in relation to collection of information regarding suicides and homicides, in Ireland, and there is some discussion in that regard. Ideally, the Commission would like to be in a position to have a system in place, something perhaps akin to the National Confidential Inquiry in Scotland or perhaps in the UK. ... and a steering group has been established by the HSE to bring relevant key individuals to look at scoping out how it might be possible to move forward with a project like that. So that it would be done in collaboration." (PG, 7)

4.8.4. Data quality assurance

It was acknowledged that the MHC are reliant on services for the data and therefore the quality of the data is not totally in the MHC's control. Two interviewees identified that communication with services was important to improve the quality of data by providing comprehensive guidance on reporting requirements, feedback on the data and to highlight the value of reporting the incidents which is about quality improvement rather than compliance. Validation of MHC data against an external system was also identified as a way to assure data quality.

> "We can ask for whatever we want under the sun but we are not in control of the information that is notified to us. I think it is important that we have a communication strategy with the system that is very robust...to inform services why this isn't just a form filling or a paper exercise it actually does make a difference to patient safety. Which is the whole basis of why we are working in the fields that we are, in mental health."(PG, 7)

> "I wondered about how much guidance goes out to services about filling out forms or getting information back to us. Maybe a guidance document or something like that." (SF, 7)

"I do believe that when we couch something as an improvement and safety and learning and making it better rather than you have to do it because it is a compliance issue you do get people more engage and it is less threatening...I think it is better to couch it as good governance, good quality and good patient safety and as part of doing that you will achieve your compliance and a lot more." (MB, 7)

"Take what we know from the system and then going back and bouncing that to the areas where they are not reporting...and I think it will improve the quality very quickly." (MB, 7)

4.9 Summary

This section presented the findings from the interviews based on the thematic analysis which was carried out.

The next section includes the results and analysis from the literature review and the interviews.

5. Results

5.1. Introduction

This chapter presents the body of knowledge, which was generated through a synthesis of the literature review and the interview findings, to meet the research aim and objectives. The aim of this study was to answer the following research question:

> What are the challenges and opportunities relating to the completeness of adverse event data, required by the Mental Health Commission, to support the regulation of in-patient mental health services?

Research activities were focused on meeting the following five objectives:

1. To describe the adverse event data required by the MHC.
2. To examine if the current dataset is fit for purpose.
3. Propose an appropriate adverse event dataset.
4. To document any challenges that exist in relation to the data required by the MHC.
5. To document any opportunities to improve the dataset required by the MHC to support its regulatory activities.

The research approach involved a five stage iterative process as shown in figure 6 and table 2 in chapter three: methodology. It included a needs analysis; a feasibility analysis; identifying data for development; developing the data elements and the assessment of the dataset.

5.2. Results

The results are presented for each of the research objectives. Information is presented by objective and the findings are displayed in tables which show the associated stages and outputs in line with the process described previously.

1. To describe the adverse event data required by the MHC

The first objective of this study was to describe the adverse event data required by the MHC. The research activities were focused on the needs analysis which identified the business context and requirements for the information. It also captured the problem that the data needs to address.

Table 8 below presents the results based on literature and interview findings. Literature in relation to the role of a regulator, how adverse event data is used to monitor and measure patient safety and the MHC current reporting requirements were the key sources of information under this objective. The results were also informed by findings from the interviews, particularly under themes in relation to the business requirements and the current issues and challenges.

Table 8: Results for objective 1: Describe data required. Needs analysis, outputs and results

Outputs	Results
Identification of the business requirements for the data	Adverse event data is required by the MHC: ● To provide oversight of safety in services and to provide intelligence to support a responsive risk-based model of regulation in line with the principles of good regulation. ● To measure compliance with standards in relation to quality and safety. ● To benchmark services. ● To report independently on the quality and safety in mental health services to ensure public accountability.
Problem statement	The MHC's current adverse event dataset is not aligned to their new regulatory process and is not reflective of the evolution of national policy and HSE operations in relation to the collection of patient safety data.
The target population	Service users availing of in-patient mental health services. The MHC has a regulatory role to oversee the delivery of quality, safe services to the target population.

Outputs	Results
The service environment	In-patient mental health services (approved centres). The MHC is responsible for regulation of mental health services.
Data priorities	Adverse events resulting in serious harm to service users. To be able to have oversight of these incidents in a timely manner.
Expected benefits	More targeted and proportionate regulation in line with a responsive risk-based model of regulation. More timely and complete overview of serious adverse events in approved centres. Benchmarking of services and trend analysis as the data will be comparable.
How the data will be used	To identify occurrences of serious adverse events in approved centres. To assess the performance of services in relation to patient safety and risk management. To prompt for more timely regulatory action when areas of concern are identified.

2. To examine if the current dataset is fit for purpose

The second objective of this study was to examine if the current adverse event dataset is fit for purpose. This involved understanding what data is currently collected, reviewing against the business need and documenting the gaps in using the data to support regulation. This centred around the feasibility analysis.

This section was informed by literature in relation to measuring and monitoring patient safety, MHC current reporting requirement and data quality. The main source of information from the interviews came from a number of themes including the current issues and challenges, data standardisation and data quality. The findings in relation to this objective are presented in table 9 below.

Table 9: Results for Objective 2: Examine if the current data is fit for purpose. Feasibility analysis: outputs and results

Outputs	Results
Data that currently exists, how they are collected their usefulness, and if there are existing standards	**MHC data currently collected:** • Death notifications: notified in line with requirements in the approved centre regulations. They provide oversight of all deaths and what proportion was as a result of adverse events. The dataset is specified in a prescribed form however there is no accompanying data dictionary. Limitations of the data include the inability to report on the number of deaths due to suicide as this can only be determined by a Coroner's inquest. • Summary incident reports: reported on a six-monthly basis. They include basic information regarding incident category and severity of injury. They provide a snapshot of incidents in an approved centre. The use of the data is limited as there are no data standards and the information in the reports is not comparable.

3. Propose an appropriate adverse event dataset

The third objective of the research study was to propose an appropriate adverse event dataset. The proposed dataset was based on findings from identifying data for development, developing the data elements and the assessment of the dataset. The data development was also founded on the outputs from the needs analysis and feasibility analysis. Dataset development was informed by literature in relation to patient safety risks in mental health services, measuring and monitoring patient safety and MHC adverse event reporting requirements. Dataset requirements were also extracted from the interview findings The dataset was assessed against the WHO Minimal Information Model (MIM) (WHO, 2014) discussed in the literature review.

The proposed dataset was designed to capture the core data elements for adverse events resulting in serious harm to a service user. Table 10 shows the outputs and results

associated with this objective. Tables, 11, 12 and 13 include details of the data elements in the dataset

Table 10: Propose an appropriate adverse event dataset. Identifying data for development, outputs and results

Outputs	Results
The questions the data needs to answer	How many serious adverse events have occurred in the approved centre. What types of serious adverse events occurred. The circumstances surrounding the adverse event. The corrective and preventative actions taken by the service including the type of investigation that is planned.
The problem that needs to be addressed	To formalise reporting of serious adverse events to the MHC. To propose a complete dataset to ensure consistency and comparability. To align MHC reporting requirements to current policy.
The data for collection	Data on adverse events resulting in serious harm. Serious adverse events as a result of self-harm, assault, absconding in line with the risks identified in the regulations and medication events.
Limitations of the data	The proposed dataset only relates to collection of adverse events data from in-patient mental health services.
The data elements and how they will be collected	The data elements are presented in tables 11 and 12 below. The data would ideally be extracted from the SCA NIMS system but otherwise direct reporting from services to the MHC.

Table 11 shows the proposed dataset for individual reporting of adverse events resulting in serious harm from approved centres to the MHC. It includes the data elements, the rationale for inclusion and the optionality of each data element. In line with good data development practices, identified in the data quality section in the literature review, a core minimum dataset was developed and a data dictionary was developed to clarify data requirements (shown in table 12). The data dictionary includes definitions for the data

elements and indicates the data type, value domain and if an existing data standard has been used.

Table 11: Proposed adverse event minimum dataset. Developing data elements. Data elements, rationale for inclusion and optionality.

Data element	Rationale for inclusion	Optionalilty
Unique patient identifier	To be able to identify the same person was involved in more than one adverse event. Identifier versus full patient name to minimise privacy risks.	Mandatory
Sex	To identify any sex specific risks.	Mandatory
Date of birth	To identify risk due to age e.g. child in an adult unit.	Mandatory
Incident Category	To capture standardised information in relation to the type of incident in order to enable comparability.	Mandatory
SRE Type	To capture standardised information in relation to adverse events which meet the HSE's definition of a Serious Reportable Event (SRE).	Optional
Date of occurrence	To identify when the event occurred, measure compliance with reporting requirements and to assess if an investigation took place in a timely manner.	Mandatory
Time of occurrence	To identify the time when the event occurred and if there risk management issues within a service at a particular time.	Mandatory
Location where event occurred	To obtain information in relation to where an event occurred to identify any environmental risks.	Optional
Circumstances surrounding event	To qualify information provided in relation to the category of incident.	Optional
Corrective and preventative actions	To identify if there are effective structures for investigation and learning in line with requirements in the regulations (Department of Health, 2006)	Mandatory
Reported by	To provide a point of contact to go back to if more information is required.	Mandatory

Table 12: Proposed adverse event minimum dataset. Data dictionary.

Data element	Definition	Data type	Value domain	Existing Standard
Unique patient identifier	The number or code assigned to a subject of care by a health or social care provider.	Unique identifier	Not applicable	HIQA National demographic data set (HIQA, 2013c)
Sex	Sex is the biological distinction between male and female. Where there is an inconsistency between anatomical and chromosomal characteristics, sex is based on anatomical characteristics.	Coded text	Male Female Intersex or indeterminate Not stated/ inadequately described	HIQA National demographic data set (HIQA, 2013c)
Date of birth	The date of birth of the subject of care as per the birth certificate. Age to be provided is date of birth not available.	Date	Valid dates	HIQA National demographic dataset (HIQA, 2013c)
Incident Category	Classification of incident including the Hazard/Sub Hazard/ Process/ Problem/ Cause	Coded text	Categories n the NIMS	NIMS incident reporting classification system (based on WHO ICPS (WHO, 2009))

Data element	Definition	Data type	Value domain	Existing Standard
Serious Reportable Event (SRE) type	SRE Type and sub-category	Coded text	Categories as per the HSE SRE list.	HSE SRE list (HSE, 2014)
Date of occurrence	Date of occurrence (If exact date not known then approximate date)	Date	Valid date	Date of incident (NIMS)
Time of occurrence	Time of occurrence.	Time	Valid time	Time of incident (NIMS)
Location where event occurred	The exact location where event occurred for example the name of the ward.	Text	Not applicable	None
Circumstances surrounding event	A description of what was observed when the person was found, physical state, others involved, ligature points etc.	Text	Not applicable	None
Corrective and preventative actions	Provide details regarding the type of investigation planned.	Coded text t	System Analysis review Multi-disciplinary review Other type of review	none
Reported by	The person reporting the event	Coded text	Name Job title Medical Council Number	none

The MHC proposed dataset was mapped to the WHO MIM in order to assess the dataset against an international standard (see table 13). Based on this assessment there was a strong correlation between the two datasets. There was some variation in relation to terminology (for example 'Circumstances Surrounding Event' in the proposed dataset versus 'Agent(s) Involved' in the WHO MIM) but for the most part the data element and definition were the same. There were only two data elements that were not present in both datasets. Patient identifier was included MHC proposed dataset as a means of identifying if more than one event is associate with an individual. Incident outcomes was included in the MIM as a means of describing the consequence of an incident for the patient in detail. As the MHC proposed dataset only relates to adverse events resulting in serious harm patient outcome is in part captured through this focused reporting.

Table 13: Mapping of MHC proposed adverse event dataset against the WHO Minimal Information Model (MIM) for Incident reporting (WHO, 2014)

MHC proposed data elements	WHO MIM data elements	Mapping of datasets
Patient Identifier		X
Sex	Sex	√
Date of birth	Age	√
Date of occurrence **Time of occurrence**	Time (date and time when incident occurred)	√
Location where incident occurred	Location (physical environment in which a patient safety incident occurs)	√
Circumstances surrounding incident	Agent(s) Involved (product, device, person or any elements involved in the incident)	√
Incident type **(SRE type)**	Incident type (incident types as per the ICPS report)	√
	Incident outcomes (patient outcomes such as ICD and ICF codes)	X
Corrective and preventative actions	Resulting actions : Ameliorating action and Preventing action	√
Reported by	Reporter (role of reporter)	√

4. To document any challenges that exist in relation to the data required by the MHC.

The fourth objective of the research study was to document any challenges that exist in relation to the data required by the MHC. Challenges were captured through the needs analysis, the feasibility analysis, identifying data for development stages and the assessment of data elements. The findings drew on literature relating to regulation; monitoring and measuring safety; MHC reporting requirements and data quality. The key sources of information from the interviews came from the themes in relation to current issues and challenges, data standardisation and data quality. The results in relation to this objective are presented in table 14 below.

Table 14: Objective 4: Document any challenges in relation to the data required by the MHC. Stage(s), outputs and results.

Stage	Output	Results
Business Requirements	Problem Statement	Approved Centre regulations are not prescriptive in relation to adverse event reporting requirements, regulations form the basis for a regulator's data needs and therefore it has been difficult to obtain a complete dataset. The current MHC dataset does not provide a timely view of serious adverse events in approved centres. The MHC reporting requirements are out of sync with current policy and practice. Ad hoc reporting of serious adverse events has resulted in an incomplete picture of these incidents in approved centres.
Feasibility Analysis	Any gaps that may indicate difficulties in obtaining	The SCA STARSWeb reported high percentage of incidents were not risk rated in the past. This may indicate that there is difficulty in determining the severity of an incident. Incomplete death notification forms returned to the MHC may indicate that it may be difficult for services to

Stage	Output	Results
	data	obtain complete data to meet the MHC's needs.
Identifying data for development	Limitations of data	Adverse event data is only one measure of harm, and serious adverse events can be rare so they may not be a good indicator of safety.
		Incident reporting is flawed as a good safety culture can result in higher rate of reporting.
		It can be difficult to identify all relevant adverse events as some may be an outcome of long-term treatment.
		Small numbers and sensitivity of the data prohibits detailed national reporting on serious adverse events.

5. **To document any opportunities to improve the dataset required by the MHC to support its regulatory activities**

The fifth objective of the study was to document any opportunities to improve the dataset required by the MHC to support its regulatory activities. This objective was met through the needs analysis, the feasibility analysis, identifying data for development stages and the assessment of data elements. The findings in relation to this objective are presented in table 14 below. They include information from the literature review in relation to monitoring and measuring safety, standardisation of patient safety data and from the interview themes in relation to data standardisation and data quality.

Table 15: Objective 5: Document any opportunities to improve the dataset. Stage(s), outputs and results

Stage	Outputs	Results
Business Requirements	Performance indicators or benchmarks	Mortality rates
		Never Events/Sentinel Events
		OECD mental health indicators
Feasibility Analysis	Safety culture	HSE National Incident Management Policy
		Quality and Safety Division in the HSE
Feasibility Analysis	Existing data	HSE incident data on the NIMS
		HSE as Serious Reportable Events (SREs).

Stage	Outputs	Results
Feasibility	Existing data	WHO ICPS
Analysis	standards	WHO MIM
		HIQA National demographic dataset

5.3. Summary

This chapter presented the research results. It presented the findings in the context of the research objectives which were linked to the aim of the research to answer the research question.

6. Conclusion

6.1. Introduction

This section of the document provides a summary of the research study. It highlights the key findings in relation to the research question. It also includes personal observations, contribution to the research and final thoughts. It also includes some recommendations for future work and acknowledges some limitations of the study.

6.2. Key findings

- The research highlights the data challenges and ultimately presents some key opportunities to improve data collection in support of regulatory activity.

- The role of a healthcare regulator is heavily dependent on good quality data which provides a complete and accurate picture of the risk environment to inform appropriate regulatory action.

- It is clear from the research that good processes which are based on data standards, agreed classifications and concepts both in general data terms and adverse event data are key to achieving good data quality that is fit for purpose.

- The research has highlighted a move towards a more standardised approach to the reporting of patient safety data. A key message is that there is no single measure of safety however using classifications and concepts that are widely accepted will result in comparisons both nationally and internationally resulting in a learning environment, the ultimate objective of any incident reporting system.

- The current frequency of incident reports (on a six-monthly basis) means the data are not timely and this limits the effectiveness of regulatory action when there are areas of concern in relation to service user safety and welfare.

- The quality of the data in relation to all incidents is also challenging for the MHC. When collecting any data the objective must be clear and the purpose for which it will be used and communicate this to the providers of the data to ensure buy-in and the return of complete data. A dataset should be reviewed regularly to ensure it is fit for purpose and to address any data quality issues.

- The MHC should use data and information that is already being generated. The implementation of the NIMS system which will standardise incident reporting in all HSE services is a welcome development. There may be an opportunity to access data from NIMS rather than burdening services with additional reporting requirements.

- Adverse event data is only one component of measuring patient safety in approved centres. In order to achieve a comprehensive picture of patient safety and the overall quality of a service the MHC should look to integrate multiple sources of data to feed into the development of dashboard to support regulatory activities. Other sources as identified in the literature include near miss data, service user surveys, complaints and malpractice claims data .

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6.3. Personal observations

Patient safety policy evolution and refinement at a national level in conjunction with operational developments in the HSE have resulted in a more favourable environment for the collection of standardised adverse event data from mental health services in Ireland. Continued collaboration with the HSE will improve collection and use of data to benefit patient safety.

6.4. Contribution to the research

The research generated a body of knowledge to answer the research question which reflects current data standards, existing data for re-use and opportunities to improve data quality. It examined the MHC's business requirements for adverse event and identified gaps in the current MHC dataset which has not been updated since 2008.

One of the research outputs was a minimum dataset to collect serious adverse event data, including the HSEs SREs, on an individual basis. This dataset was developed in line with good data development practices and could may form the basis for a specification of requirements of data from the NIMS system once it has been fully implemented in mental health services.

Available evidence suggests that this research includes the first assessment of an adverse event dataset against the WHO Minimal Information Model (WHO, 2014) in Ireland.

6.5. Limitations

As with any study, there are some limitations to this research that are outlined below.

The focus of the research has been based on acute care settings. The majority of service users access mental health services in community settings and therefore there is scope to extend the study to ensure the challenges and opportunities which may specific to community services are also captured.

Patient safety in mental health is still an emerging field. The advancement of the field will require a move to more rigorous methodologies includes validated indicators and measures and consistency in terminology.

6.6. Final thoughts

To quote Perneger "problems do not lie with the words we use but rather with the underlying concepts" (Perneger, 2006). Data should be collected for a specific purpose and linked to clear objectives. Where possible datasets should use agreed national and international data standards to minimise data quality challenges.

6.7. Recommendations for future work

The dataset should be validated with users and the data dictionary should be further developed.

The proposed dataset should be further developed to support the collection of adverse event data from community mental health services, particularly community residences.

The MHC has gone to tender for a new IT system and the SCA NIMS is being rolled out nationally. The MHC should explore the use of a messaging tool to interface between the two systems or liaise with the SCA and HSE in terms of developing a dashboard on the NIMS to provide direct access to relevant data.

6.8. Summary

This chapter provided a high level overview of the key findings of the research including personal observation and recommendations for future work.

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Appendices

Appendix A: Conceptual framework for international classification for patient safety (ICPS)
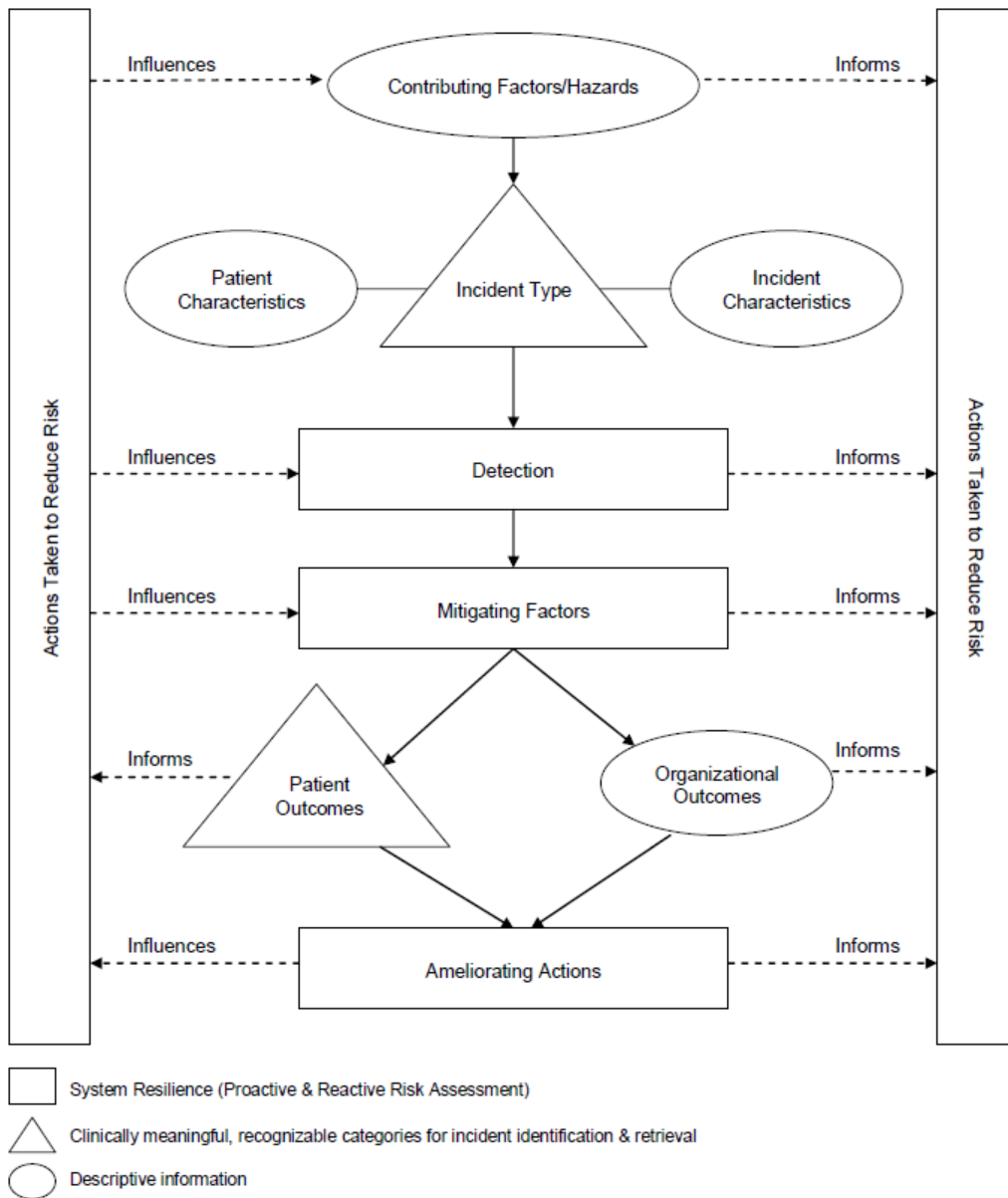
Figure 8 The Conceptual framework for the international classification for patient safety (ICPS)(WHO, 2009)

Appendix B: Information sheet for prospective participants
TRINITY COLLEGE DUBLIN

INFORMATION SHEET FOR PROSPECTIVE PARTICIPANTS

Lead Researcher: Deirdre Hyland

Student Identification Number: 12323826

Timeframe & duration of research: April-May 2015

Dear Participant,

I would like to invite you to take part in a research study entitled 'A study into the adverse event data required by the Mental Health Commission to support the regulation of in-patient mental health services in Ireland'. This research study is being undertaken in part fulfilment of an MSc in Health Informatics in conjunction with the University of Dublin, Trinity College, Ireland.

Please read the following information carefully. It introduces the nature of the project and   provides a procedural outline for participation. Please contact me if you require clarification or further information.

What is the purpose of the research study?

The purpose of the study is to answer the following research question: What are the challenges and opportunities relating to the completeness of adverse event data, required by the Mental Health Commission, to support the regulation of in-patient mental health services?

Why have you been chosen?

You have been selected to participate in this study due to your role, knowledge of the subject under study and relevance of your experience. You have been identified as a key informant who can provide views, based on your expert knowledge, regarding the challenges and opportunities in relation to AE data completeness.

Voluntary Participation

Your participation in this study is voluntary and you are free to withdraw at any time without penalty. If you do not wish to answer any specific questions, these wishes will be respected by the researcher.

Who is organising the research study?

This study is being organised by the lead researcher Deirdre Hyland. There are no external collaborators involved in this study. The study is being supervised by a Trinity College supervisor.

Conflict of interest

The researcher has no conflict of interest to declare.

What will happen if I take part?

If you choose to take part in this study, I will contact you to arrange a time to conduct a semi-   structured interview. The interview will take place face to face or over the telephone and last for approximately 30 minutes. A series of lead questions have been prepared and will be supplied in advance of the arranged time to allow questions or clarifications to be dealt with in advance of the interview.

The intention is to audio record the interview and also to make notes. No audio recordings will be made available to anyone other than the researcher/research team, nor will any such recordings be replayed in any public forum or presentation of the research. If you do not wish to be recorded I will only take notes during the interview. Informed consent will be requested for the study. Subsequent to the interview you will be contacted to review the transcribed document. Prior to publication, you will be contacted for your feedback on a proposed dataset from the research. You will be afforded the opportunity to verify the accuracy of direct quotations and their contextual appropriateness in advance of any publication and presentation of resulting data and findings. You will be provided with a copy of the completed research report. Anonymity is not guaranteed as you will be identified by name and your role. There are no anticipated risks/benefits for you.

If you make any illicit activities known, these will be reported to appropriate authorities.

How will data be stored and protected?

Data collection, storage and analysis will be in line with the Data Protection (& Amendment) Acts and Best Practice in Scientific Research.

Research Ethics Approval

The Research Ethics Committee of the School of Computer Science & Statistics, University of Dublin, Trinity College granted ethical approval for this study.

What will happen to the results of the research study?

The results of the study will be presented in my dissertation for submission to the University of Dublin, Trinity College. Results may also be presented at conferences or published in scientific publications.

Procedure to be used if assistance or advice is needed

If you require clarification or further information about this study please contact me by email (hylandde@tcd.ie).

Thank you for taking the time to read this correspondence and for considering   taking part in the research study.

Yours sincerely,

Ms. Deirdre Hyland

Appendix C: Informed consent form

<div align="center">

TRINITY COLLEGE DUBLIN

INFORMED CONSENT FORM

</div>

Lead Researcher: Deirdre Hyland

BACKGROUND OF RESEARCH:

One of the Commission's principal statutory functions is to promote, encourage and foster high standards and good practices in the delivery of mental health services'. Ensuring that there are appropriate structures and systems to effectively manage risks posed to patient safety in mental health services is considered central to the creation of high standards and good practices. The MHC requires reliable, factual information in relation to adverse events (AEs)/incidents to monitor risk management and patient safety in services, inform the regulation of MHS and to carry out data analysis so that it can provide feedback to services to facilitate a learning environment. Issues in relation to AE data quality, in particular, the completeness of the data returned to the MHC, have been particularly challenging and have prohibited the effective use of the data to date(Liaw et al., 2013). AEs involving service users are a patient safety concern; data is being collected nationally by the MHC but is not being used or disseminated to optimise its benefit and this is a motivating factor for this research.

The research will attempt to answer the following research question:

> What are the challenges and opportunities relating to the completeness of adverse event data, required by the Mental Health Commission, to support the regulation of in-patient mental health services?

The research will attempt to identify the challenges in relation to the collection and effective use of AE data returned by MHS to the MHC and any opportunities to improve this data to ensure it is fit for purpose.

The research objectives are:

- To describe the adverse event data required by the MHC.
- To examine if the current data are fit for purpose
- To propose an appropriate dataset.

- To document any challenges that exist in relation to the data required by the MHC.

- To identify any opportunities to improve the dataset required by the MHC to support its regulatory activities.

PROCEDURES OF THIS STUDY:

No individual patient data will be collected as part of this research it will be informed by a review of documentation and interviews with key informants,. You have been selected as a participant due to your key role, knowledge of the subject under study and the relevance of your experience.

Participation in the interview is on a voluntary basis, and you retain the right to withdraw and to omit individual responses without penalty.

Interviews will not be anonymous. You, the participant will be asked for your opinion based on your expert knowledge. There are no perceived risks to you arising from the interview.

If you agree to participate in this research you will be contacted to arrange a face-to-face semi-structured interview. The interview is expected take 30 minutes. It is the intention that interviews will be audio-recorded. However, you may decline to be recorded, and in this instance, notes of the interview will be taken instead. Additionally, you may request recording to be stopped at any time during the interview, and you may also request the destruction of the recording at any time after the interview. No audio recordings will be made available to anyone other than the researchers/research team, nor will any such recordings be replayed in any public forum or presentation of the research. All audio recordings will be deleted upon publication of the dissertation.

You will be asked to take part in a debriefing session (face-to-face or email) to ensure contextual appropriateness of results and information obtained following the interview. Prior to publication, you will be asked to provide your feedback (face-to-face or email) in relation to any proposed dataset identified.

PUBLICATION:

The report, based on the results from interviews and any other research carried out, will be submitted as a masters dissertation in partial fulfilment of an MSc. Degree in Health Informatics at Trinity College Dublin.

DECLARATION:

I am 18 years or older and am competent to provide consent.

I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.

I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.

I understand that my participation will not be anonymous and will be named as the interviewee in the researchers study.

I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications.

I understand that if I make illicit activities known, these will be reported to appropriate authorities.

I understand that my interview will be audio recorded however I have the option to request not to be recorded, in which case manual notes will be taken instead.

I understand that I may stop electronic recordings at any time, and that I may at any time, even subsequent to my participation have such recordings destroyed (except in situations such as above).

I understand that no audio recordings will be replayed in any public forum or made available to any audience other than the current researchers/research team.

I understand that audio recordings will be made and stored at the researchers place of residence for transcribing purposes.

I understand that audio recordings will be permanently deleted by the researcher following submission of dissertation to Trinity College Dublin.

I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.

I understand any direct quotes will be clarified with me before including them in the final report.

I have received a copy of this agreement.

DECLARATION:

Participant's Name:

Participant's signature:

Date:

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

RESEARCHERS CONTACT DETAILS:

Deirdre Hyland

hylandde@tcd.ie

Investigator's signature:

Date:

Appendix D: Template for interviews

Introduction:

Interview with (Name, Job Title, Organisation) on the (date) as part of a research study looking into adverse events data required by the Mental Health Commission for the regulation of in-patient mental health services in Ireland.

Before we start I would like to thank you for agreeing to take part in this research. Just to let you know that each of the questions, which you've been provided with in advance of this interview, are optional you're free to omit a response at any time, without penalty, however I'd be grateful if you could respond to all questions. Also to remind you that this interview is being recorded, are you agreeable to this?

Question 1: In your opinion, what adverse events/serious incidents does the Mental Health Commission need be notified of in order to support regulation of approved centres?

Question 2: What are the key pieces of information or data elements that you think should be included in adverse event reports which are used to inform regulatory decision-making?

Question 3: How frequently do you think that in-patient mental health services should report adverse events to the Mental Health Commission?

Question 4: Do you think there are any gaps in the current adverse event data reported to the Mental Health Commission?

Question 5: What are the key issues in relation to the quality of adverse event data reported to the Mental Health Commission?

Question 6: Are there any challenges in relation to using adverse event data to inform regulation of in-patient mental health services?

Question 7: Do you think there are any opportunities to improve the quality of the adverse event data reported to the Mental Health Commission?

Question 8: Can you provide me with any further information that may assist with this research study?

Thank you for your time and input in this research study. I will be providing you with a copy of the transcript in due course.

Appendix E: Coding framework for interviews

Themes	Sub-themes
Business requirement for the data	
Current Issues and Challenges	• Dataset currently notified • Lack of standardisation in the reports • Ad hoc reporting of serious adverse events • Disparate system for collection of data • Privacy and Confidentiality
Dataset requirements	• Types of adverse events • Data Elements • Frequency of Reporting
Data Limitations	• Constraints of adverse event reporting • Uniqueness of the mental health domain • Other measures of safety • Other ways to improve safety • Limited scope of the data collection
Data Standardisation	• Defining data requirements • Standardising collection of data • Using data from existing systems
Data quality	• Data quality challenges • Data quality attributes • Opportunities for improved data quality • Data quality assurance