

What do we tell the Coroner? Clinicians understanding of reportable deaths in Victoria

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Abstract

Title: What do we tell the Coroner? Clinicians understanding of reportable deaths in Victoria

Background

Coroners in Australia have the important role of investigating unnatural and unexpected deaths, collectively referred to as "reportable deaths". While there is some guidance in the legislation that governs the Coroners' death investigations and associated processes, the cause and circumstances of deaths that occur in the healthcare setting can be particularly complex. A clear and unambiguous understanding of what equates to a reportable death is integral to clinical practice and it is the nexus between the Coroner's expectations and the practises and understanding of clinicians which has inspired this study.

The central aim of this research study was to determine clinicians' reporting and understanding of deaths which meet the criteria for reporting to the Coroners Court of Victoria.

Methods

A sequential explanatory mixed method research design was utilised, involving the collection of quantitative and qualitative data. There were three studies performed in this research endeavour

In study one, a retrospective audit of the medical records of deceased inpatients in one healthcare organisation over a 12-month calendar year was undertaken. Bivariate descriptive analysis of the data was completed, with identification of whether there was a reporting error or not. This information was utilised to inform the development of the semi structured interview questions and clinical scenarios for study 2.

Study two comprised two parts; in the first part, 22 clinicians were interviewed to determine their understanding and responsibilities and the role of the coroner regarding reportable deaths. Following thematic analysis the data highlighted six individual themes. The second part of study two included examination of the same 22 clinicians of 10 clinical scenarios and whether the death met the legislative reportable criteria. In study 3, an in-depth review of the cases that were identified in study 1, as having a reporting error was performed.

Results

In study 1, the findings reflected contemporary society in view of demographics and gender distribution. The majority of the cases were reported by registrar level of clinical staff, and deaths most frequently occurred between 1201 - 1800 hours in both groups.

The themes that were identified following review of the data obtained from the semi structured interviews in study two included: Timing of reporting of deaths; Lack of awareness/knowledge;

Fear/blame/stigma regarding reporting deaths; Educational requirements; Accountability-transparency of any contributing factors to death and Practicality of reporting deaths.

In the second part of study 2, the clinical scenarios there was little consensus across all of the scenarios with the "correct" answer. In study 3, 5.1% of deaths were identified with a reporting failure indicating that the death was not reported or was inappropriately reported.

Conclusion

This study found that there was a lack of consistency in the clinician's understanding in which deaths meet the reportable criteria and are reportable under the *Coroners Act 2008* (Vic). The implications of this study for clinicians, health services, the Coroners Court of Victoria and patient outcomes were described. It is acknowledged that despite the relatively small number of cases in this study where there was a reporting error it is relevant and the opportunity for deaths to undergo independent review is invaluable for informing patient safety.

Declaration

This thesis is an original work of my research and contains no material which has been
accepted for the award of any other degree or diploma at any university or equivalent
institution and that, to the best of my knowledge and belief, this thesis contains no materia
previously published or written by another person, except where due reference is made in
the text of the thesis.

Signature:
Print Name: Amanda Charles
Date:7 th July 2020

Thesis including published works declaration

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes two original papers published in peer reviewed journals. The core theme of the thesis is clinicians' understanding of deaths reportable to the coroner. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the student, working within the School of Nursing and Midwifery under the supervision of Professor Debra Griffiths, Associate Professor Lyndal Bugeja, and Professor Wendy M Cross.

Publications

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Thesis Chapter	Publication Title	Status (published, in press, accepted or returned for revision, submitted)	Nature and % of student contribution	Co-author name(s) Nature and % of Co- author's contribution*	Co- author(s), Monash student Y/N*
6	What do clinicians understand about deaths reportable	Published	75% Concept and collecting data, Writing first draft	Wendy M Cross - input into manuscript (15%)	No No

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6	What do clinicians understand about deaths reportable to the coroner-Using clinical scenarios to enhance learning	Published	75% Concept and collecting data, Writing first draft		Wendy M Cross - input into manuscript (15%) Griffiths- input anuscript (10%)	Yes No

NB I have not renumbered sections of submitted or published papers in order to generate a consistent presentation within the thesis.

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I hereby certify that the above declaration correctly reflects the nature and extent of the student's and co-authors' contributions to this work. In instances where I am not the responsible author I have consulted with the responsible author to agree on the respective contributions of the authors.

Main Supervisor name: Professor Debra Griffiths

Main Supervisor signature: Date: 7/7/2020

(The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.)

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Personally, to say this thesis has been a journey is an understatement. At times it has tested my resilience and my resolve, but I am very pleased and satisfied that I have now completed the work and have made a contribution to an area of practice that is important in protecting and providing a safe environment for our community.

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Chapter 1 Introduction to the study

1.1 Introduction

This thesis examined clinicians' understanding of their role in reporting deaths to the coroner. The study explored any identified barriers, real or perceived, to this process. There is also reference to the delivery of safe patient care and the contribution that an independent and objective mortality review can make. This study involved health professionals who work at a tertiary hospital in Melbourne, Victoria, and applied a mixed methods research design to determine the level of reporting of deaths to the Coroners Court of Victoria (CCOV).

In this chapter, the role of the coroner will be described, from its medieval roots to the modern-day mandate. The influence on patient safety, death prevention and the benefits of independent mortality review will also be discussed. There will also be reference to the study setting and significance of the study. In Chapter 2, the discipline of patient safety and its application to the coroner's death investigation will be explored.

1.2 Background to the study

The role of the coroner in Victoria emerged from medieval times and has evolved to include the adoption of the English coroner's system at the time of English settlement. The role and duties of the coroner today, under the *Coroners Act 2008* (Vic.), include specific criteria and circumstances for reporting deaths to the CCOV.

The data for the study was drawn from the calendar year 2015 and was, therefore, contextualised with other Victorian statistics for the same year. In 2015, there were 39,955 deaths registered in Victoria with the Registry of Births, Deaths and Marriages (BDM). It is a legal requirement that a death must be notified to BDM within 48 hours of it occurring. Of these deaths, over 6,000 cases are reported to the CCOV (Annual Report Coroners Court of Victoria, 2015). This number has increased, with over 7,000 deaths reported to the CCOV in 2017-2018 (Annual Report, Coroners Court of Victoria, 2018). Deaths that are reported to the CCOV and meet the reportable death criteria require investigation. This investigation is not only to fulfil legislative requirements to determine the person's identity, cause and, in some cases, the circumstances of the death but also as a means of identifying the preventability of deaths. This is one way that the reporting of deaths to the coroner, and the subsequent investigations, can assist with determining if there are systemic issues of concern within health care organisations. These can be addressed by coroners through recommendations directed to public statutory authorities and entities. If these deaths are not reported to the CCOV, then a valuable opportunity for review and for making potential

recommendations to inform patient safety may be missed. To gain some understanding of the role of the coroner in patient safety, it is important to understand how the role has evolved, including the specific functions of the modern coroner.

1.3 Origin and history of the Coroner's role

Medieval times

An early reference to the role of coroner (or crowner, as it was known in the tenth century) occurs in the Articles of Eyre. The Eyre is the term given to the judicial circuit followed by itinerant judges. Primarily, the role of these judges was to settle disputes and to hold court, in a process that was known as "holding the pleas of the crown" (McKeough, 1983, p191). This was a suboptimal process which ceased to be effective, due to a lack of transparency and under-reporting of deaths. As a result of this, during the reign of King Richard, in 1194, there was a new group of officers, consisting of three knights and one clerk, appointed. Their role was "custos placitorum coronas" or "keeping the pleas of the Crown", in other words, to protect the Crown's fiscal interests from corrupt sheriffs (Cordner & Loff, 1994). The coroner, at this time, had both judicial and financial responsibilities and was appointed to the role by the counties where he resided. Within this role, the Coroner was also required to record the revenue that may be owed to the King following a death, as part of the legal administration applicable at that time.

An unexpected, violent or unnatural death that occurred provided a potential source of revenue, as the Crown was able to claim the perpetrator's estate (Dorries, 2004; Freckelton & Ranson, 2006). Similarly, people who died from suicide had their death investigated, in anticipation of being found guilty of the crime of "felo de se" or "self-murder" (suicide). Such a finding ensured that the goods and chattels of the deceased also became available to the Crown (Freckelton & Ranson, 2006,). Deaths which occurred due to shipwreck or fires, or any discovery of "buried treasure" in the community, all contributed to the Crown's revenue. Death due to suicide and fire are two areas of investigation into death that the coroner continues to have jurisdiction over today (Freckelton & Ranson, 2006). It is of note that a sudden or unexpected death in the community was reviewed by coroners in the early days, albeit for different reasons than contemporary death investigations, which today determine if there are any preventable factors that contributed to the death. In previous times, the emphasis was very much directed towards financial interests.

1.4 Registration of deaths

Historically, the coroner's role also comprised record keeping, where monies owed to the King from the administration of justice were all documented (Dorries, 2004). This provided an additional source of revenue for the Crown and ensured that the Crown's financial interests were kept

protected during criminal proceedings. Indeed, this is where the first recordings of what were deemed reportable deaths are documented, as any person who became aware of someone who had died, either suddenly or unnaturally, was expected to raise a "hue and cry" and, effectively, be responsible for notifying or reporting the death to the coroner, so that the coroner could attend the scene of death (Dorries, 2004; Freckelton & Ranson, 2006). The process to be followed, according to the law, involved the notification of four local neighbours (people who lived nearby) and also the bailiff. Following these notifications, the coroner would be summoned, and this would be considered to be the emergence of a reportable death. There was considerable incentive to follow this expected procedure, as there were financial penalties if it did not occur (Freckelton & Ranson, 2006). Notably, the statute De Officio Coronatori, in effect in 1276 in the United Kingdom (UK), formed the basis of the coroner's duties in death investigations for ongoing times (Freckelton & Ranson, 2006).

As society developed, the need to accurately and adequately record births and deaths led to the enactment of specific legislation to record both births and deaths, and later marriage. In the UK the key legislation was the *Births and Deaths Registration Act 1836* (UK). The Act was in response to concerns raised by the public regarding the level of review of the medical causes of death. There were also concerns that deaths due to homicide may not have been reported (Martin, 2016). Prior to the legislation being enacted, the responsibility for recording births, deaths and marriages was held by the local church parishes. Under this Act, the coroner was obligated to inform the local registrars if a death had occurred, and supply information to the registrar following an inquest, if one had been held, referring to what was the cause of death. English Coronial practice was guided by the Coronial manual. During the 19th century these manuals evolved with versions written in Canada, New Zealand and the colonies of Van Diemans Land and New South Wales. (Trabsky, M 2016). This contributed to the increased importance in the coroner's role in determining the circumstances of deaths, which is a core component of the role today (Freckelton, 2006; Dorries, 2004).

1.5 Qualifications and Mandate of Coroners

Although, historically, the English legal system was imposed on many nations, the role of the coroner has further evolved, both in England and internationally. While the work of the coroner has its origins in English society (Dorries, 2004), the business of the coroner has been adapted and shaped in different directions. There were no formal qualifications required to be a coroner, and landowners performed the role in the UK until 1926 (Martin, 2016). Changes, at this time, to the Act required the coroner to be an experienced physician with legal qualifications or formal legal qualifications. In Australia, due to the practicalities of availability, appropriately qualified personnel, police magistrates or local justices performed the role of coroner (Pudney & Grech, 2016). In the United States, there has been discussion regarding the optimal model between the medical examiner and

the coronial system. Coroners are elected to their role, but the role is not clinically based and, therefore, they are unable to perform medical investigative procedures, such as autopsy. Conversely, medical examiners have a background more suited to physical examination and, therefore, are able to perform the procedural requirements. There is ongoing debate as to which is the more appropriate or preferred professional to oversee the medicolegal investigation (Hanzlick & Fudenberg, 2014). Over time, the responsibilities of the coroner have changed. For example, coroners today do not have any financial responsibilities (Freckelton & Ranson, 2006).

Modern coroners' responsibilities have retained the mandate to determine the deceased's identity and cause of death and have expanded to include a mandate to consider injury and death prevention opportunities that arise from a coroner's investigations, which include making recommendations or comments, where deemed appropriate, to prevent future similar deaths (Sutherland, 2014). These changing directions and developments culminated in the most recent legislation in Victoria, made in 2008, in which the Coroner's role now includes an explicit focus on injury and death prevention (Bugeja & Ranson, 2017; Hinchey et al, 2016).

1.6 Modern Day Coroner

1.6.1 Appointment of Coroners – International perspective.

In Canada, coroners are appointed to their positions whereas in the United States (US), they may be elected or appointed, depending upon the jurisdiction. Canadian coroners are generally medical practitioners, with some discrepancies between provinces. Juries are used and recommendations are formulated that assist in death prevention and learning. Medical examiners are sometimes physicians, experienced in pathology or forensics, who may act as coroners and are usually appointed (Freckelton & Ranson, 2006). In the UK, in the past, a coroner must be a lawyer or a doctor with at least five years' experience (Dorries, 2004). More recently, in the UK, a medical practitioner must also have a legal qualification to be a coroner (Dillon & Hadley, 2015). The role of the Coroner is to determine the name of the deceased, the cause of death, and whether an autopsy and/or an inquest is required. This position is usually appointed and recompensed by the local authority, usually the county (Dorries, 2004).

Internationally, the investigations into deaths are performed by different professional groups. For example, in France, the police are actively involved in the review of deaths, in Italy all suspicious or unnatural deaths must be reported to either the judicial or public health authorities and, in Japan, unexpected deaths, including those that occur in hospitals, are reported to and, subsequently, investigated by the police (Kamishiraki et al, 2010).

1.6.2 Effectiveness of the role of the Coroner

In the UK, concerns have been raised, previously, in relation to the effectiveness of the Coroner's role, including the transparency of death reviews, in the light of two significant events. These events were the Bristol Royal Infirmary Inquiry in 2001 and the criminal investigation into Dr Harold Shipman in 2003 (Middleton & Buist, 2014). In the 1990's, the Bristol Infirmary investigation noted that there was an increased mortality rate of infants post cardiac surgery, compared to other National Health Services (NHS). There were 53 paediatric cardiac surgery cases examined, of which 29 children had died and four had suffered severe brain damage. As a result of that review, the need to improve clinical governance systems, such as mortality reviews and audits of quality, was recognised (Walshe & Offen, 2001).

In 2000, a general practitioner in the UK, Dr Harold Shipman, was charged with having murdered 15 patients. It emerged that the doctor had murdered up to as many as 200 patients with fatal injections. The relevant issue that emerged concerned the doctor's claims and subsequent documentation in which he noted that all the patients had died of natural causes, which he recorded on the death certificates. This alerted the authorities to the ease in which records, such as death certificates, could be falsified, which led to a resultant lack of public confidence in the system of death review (Freckelton& Ranson, 2006; Middleton, 2014).

Similarly, in 2008, concerns were raised by the Healthcare Commission in the UK regarding the Mid Staffordshire Trust and their mortality data. Within this health service, the mortality data were considered unreliable, which was attributed to coding errors. However, this was later proven to be an incorrect assumption and a Royal Inquiry was commissioned to review the deaths and the care of patients within the health service. The inquiry, known as the Francis report, also exposed concerns regarding the coronial service in the UK and information supplied on death certificates.

The monitoring of mortality rates within hospitals has long been recognised as a valuable measure of quality and safety of care. There is a belief that an important link or opportunity to review the preventability of a death may be missed if deaths are under-reported or not reported at all. This is particularly evident where deaths occur in settings such as the community or within healthcare organisations (Higginson et al, 2012).

1.7 The role of coroner in Australia

Historically, in Australia, the coronial system is based on the UK system, with key legislation introduced in 1865, known as the Coroner's Statute (Hinchey, 2016; Freckelton & Ranson, 2006). This legislation designated the roles of the coroner and the powers that were included within the jurisdiction. The coroner did not require any specific qualifications at this time (Freckelton & Ranson,

2006). Under the *Coroners Act 1865*, and then under succeeding acts until 1985, there was a requirement to hold an inquest to determine the cause of death of any person who was shown to have "drowned, died suddenly or died whilst detained in any lunatic asylum, mental hospital or prison". Inquests at this time were performed as quickly as possible, as they were held with the physical presence of the body throughout the entire the process. In Victoria, the practice of having a jury as part of the inquest ceased in the early 1900s. Members of the police force have always been actively involved in the Coroner's investigations, and this is a practice that continues today. Of interest in the mid-19th century, is the storage of bodies during the investigation, which occurred in hotels and public houses until a central city mortuary was established in Melbourne in 1855 (Freckelton & Ranson, 2006).

In 1841, the first coroner of Melbourne, Dr William Wilmot, was appointed, and he served in this role until 1857. Following Wilmot, the Melbourne coroners were magistrates, with the last Melbourne city coroner being Mr Hal Hallenstein in 1985. Following a review of the *Coroners Act*, in 1985, Mr Hallenstein was appointed as Victoria's first State Coroner in 1986, until he resigned in 1994.

There are eight jurisdictions in Australia, each with its own legislative coronial requirements, including variable definitions of what is considered to be a death that must be reported (a 'reportable death'). In all the jurisdictions, deaths that occurs in a violent or unnatural way, or are related in some way to health care, are deaths that are reportable to the coroner's office. There are some discrepancies between the jurisdictions, with the precise descriptions of healthcare-associated deaths, including the timing of hospitalisation, for example (refer to Table 1.1 for a comparison of the criteria for reportable deaths, according to jurisdiction).

Both New South Wales (NSW) and the Australian Capital Territory (ACT) are the only jurisdictions in Australia that refer a person who has not been cared for by a doctor for six months prior to the death as meeting the criteria for reporting to the coroner. Four of the jurisdictions, South Australia (SA), NSW, Queensland (QLD) and ACT, refer deaths defined as 'suspicious' or 'unusual circumstances' 'as also being reportable. When referring to healthcare-related deaths, the terminology is variable. In Western Australia (WA) and the Northern Territory (NT), it is stated that a death which occurs during or as a result of an anaesthetic is reportable, as defined by the *Coroners Act 1996 (WA)* and the *Coroners Act 1993 (NT)*. In SA, reporting criteria are met if a death occurs during, as a result of, or within 24 hours of a surgical procedure or an anaesthetic. Additionally, if the death occurs within 24 hours of inpatient discharge or following treatment in an emergency department, it is also reportable *(Coroners Act 2003* [SA]). South Australia is the only Australian

jurisdiction that refers to deaths that occur on an aircraft during a flight or a vessel during a voyage as being reportable (*Coroners Act 2003* [SA]).

Table 1.1 Criteria for reportable deaths in Australia, according to jurisdiction

Jurisdiction and year of Act	Victoria (Vic) 2008	New South Wales (NSW)2009	South Australia (SA) 2003	Western Australia (WA) 1996	Queensland (QLD)2003	Tasmania (TAS)1995	Northern Territory (NT) 1993	Australian Capital Territory (ACT) 1997
Unexpected	Yes	No	Yes	Yes	No	Yes	Yes	No
Violent or unnatural	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Suspicious or unusual circumstances	No	Yes	Yes	No	Yes	No	No	Yes
Resulted directly or indirectly from an accident or injury	Yes	No	No	Yes	No	Yes	Yes	Yes
Health care related	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
No death certificate able to be signed	Yes	No	Yes	No	Yes	No	Yes	Yes
Not seen by doctor within previous 6 months	No	Yes	No	No	No	No	No	Yes
Unknown identity	Yes	No	No	Yes	Yes	Yes	Yes	No
Held in care/police/custody/mental health	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Unknown Cause of death	Yes	Yes	No	No	No	Yes	No	No
	(Coroners Act 2008 (Vic),	Coroners Act 2009 (NSW),	Coroners Act 2003 (SA)	Coroners Act, 1996 (WA	Coroners Act 2003 (QLD	Coroners Act 1995 (Tas),	Coroners Act 1993 (NT),	Coroners Act 1997 (ACT),

1.8 Reporting deaths in Victoria

In Victoria, the *Coroners Act 2008* (Vic.) outlines the functions expected of coroners. The office was renamed in 2009, from State Coroner's Office (SCO) to Coroners Court of Victoria (CCOV). This change was one of several that were a result of a thorough review and were implemented in 2009 (Annual Report Coroners Court of Victoria, 2015). Furthermore, coroners' rules were created, relating to the practice and procedures of CCOV, to support the *Coroners Act 2008* (Vic.), which came into operation in November 2009. There were also Coroners Regulations established in 2009, which were made under section 117 of the *Coroners Act 2008* (Vic). The objectives of these Regulations, which described the requirements, are to:

- "(a) to provide forms and machinery provisions for -
 - (i) Investigations and inquests into deaths; and
 - (ii) Investigations and inquests into fires; and
- (b) to prescribe various matters necessary to be prescribed under the Coroners Act, 2008". (Coroners Regulations, 2009)

According to the *Coroners Act 2008* (Vic.) it is a legal requirement that the coroner will determine a number of factors regarding the death. These include the identity of the deceased person, the cause of death, and, in certain cases, the circumstances in which the death occurred. The coroner has jurisdiction if the body is in Victoria or the death occurred in Victoria or the cause of death occurred in Victoria or the person ordinarily resided in Victoria at the time if death.

The process in Victoria when a death occurs is that a death certificate is commonly completed and forwarded to the Registry of Births, Deaths and Marriages (BDM). The Registry operates under the auspices of the Victorian State Government and is responsible for the registration of all births, deaths and marriages that occur in Victoria. The information on the death certificate is examined and may be referred to the CCOV for further review if there has been something documented on the certificate that suggests the death is reportable. If this occurs, the circumstances surrounding the death is then reviewed by the office of the CCOV and further review may be indicated. In a study by Neate et al. (2013) evidence presented showed that 48% (n=320) of deaths reviewed had information on the completed death certificates that indicated that the death met the reportable criteria (Neate, 2013). This indicates that there was minimal linking of the reportable criteria and documentation of contribution to deaths within the death certificate and therefore potentially not recognising which deaths meet the reportable criteria. The process that is followed following a death occurring is outlined in the flow chart below.

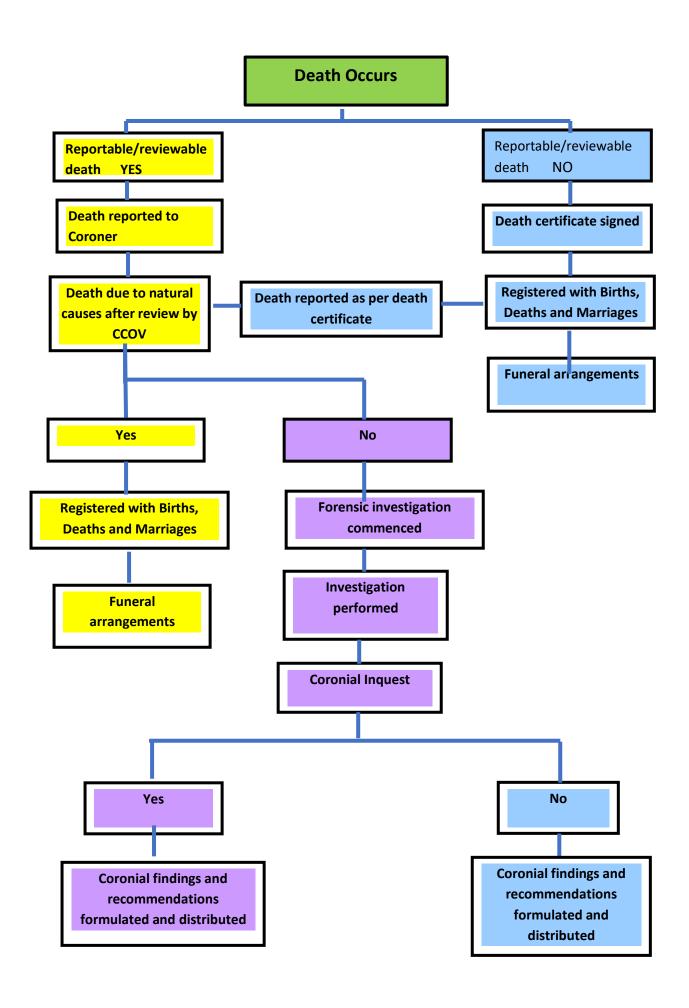


Figure 1.1 Flow chart of coronial process in Victoria. Source: Modified from CCOV www.coronerscourt.vic.gov.au

In the healthcare context, if a death meets the reportable criteria, a phone call is made to the COCV. This is usually the role undertaken by the medical practitioner within the healthcare setting.

According to Victorian legislation, however, any person who believes that a death is reportable has a legal responsibility to report the death to the CCOV. When the report is accepted by the CCOV, the deceased is given a unique case number and the medical practitioner then completes the electronic medical deposition form. Details of the deceased are recorded on the form, including demographics, a brief clinical history and any particular area of interest to be raised with the forensic pathologist regarding the autopsy.

With the reform of the Act in 2008 (enacted in 2009), there was a strengthening of the prevention component of the Coroner's role. The legislation in Victoria also states that findings where the Coroner makes recommendations must be published on the CCOV's website, to aid with the promotion of public health and safety activities within the community. These recommendations are also required to be responded to publicly, within determined timeframes, according to Section 73 (1) of the *Coroners Act 2008* (Vic.) (Bugeja & Ranson, 2017).

1.9 Reportable deaths in Victoria

In Victoria, a reportable death includes a number of situations. The criteria for reportable deaths in Victoria are described in Table 1.2.

Table 1.2 Criteria for reportable deaths in Victoria.

- where the death was unexpected, violent or unnatural.
- if the death occurs as a result of an accident or injury, either directly or indirectly, it is reportable. Moreover, there are no time frames attached to this criterion; or example, trauma deaths, falls that result in a complication such as fractured neck of femur, or drowning.
- a death that occurs (i) during a medical procedure, and is unexpected (<u>criteria one</u>) or (ii) following a medical procedure where the death is or may be causally related to the medical procedure-and a registered medical practitioner would not, immediately before the procedure was undertaken, have reasonably expected the death (<u>criteria two</u>); *
- if the medical certificate cause of death is not signed, or it unable to be signed.
- if the identity of the person is unknown.
- people who are held in custody, or in care, such as guardianship under the Department of
 Human Services, in the legal custody of the Department of Justice or Chief Commissioner of
 police, or in the custody of a police officer or protective services officer, or in the process of
 being taken into custody or being detained or in the process of being taken into custody to
 be detained all are criteria for reportable deaths. People who die whilst admitted or

committed to an assessment or treatment centre under the *Alcoholics and Drug Dependent Persons Act, 1968* (Vic) must be reported to the coroner, as must any person in an approved mental health service *(Coroners Act 2008* (Vic).

Notes: The term "medical procedure" is defined to mean a procedure performed by or under the general supervision of a medical practitioner and includes imaging, internal examination and surgical procedure.

In determining whether the death meets <u>Criteria One</u>, the medical practitioner should consider the following

questions: Would the person have died at about the same time if the medical procedure was not undertaken? Was the medical procedure necessary for the person's recovery? If 'no' to any of the above (and the death meets criteria two) - the death is reportable

In determining whether the death meets <u>Criteria Two</u>, the medical practitioner should consider the following question: Before the medical procedure was performed, was the person's condition such that death was foreseen as more likely than not to occur? *If 'no' to the above question (and the death meets criteria one)* - the death is reportable (Coroners Act 2008 (Vic).

Death investigation or review within the healthcare sector can be an extremely valuable tool for the provision of safe patient care. The actual number of preventable deaths is very difficult to determine. For example, in England, the figures are estimated to be anywhere between 800-400,000 deaths per year (Hogan, 2014). The under-reporting of deaths may be an indication of wide-spread system-based issues, such as the review of deaths and informing patient safety initiatives at a local level with broader themes identified by the CCOV. Whilst it is unavoidable that people will die in hospital, the information that can be obtained following review of these deaths is very valuable. The value at an organisational level is gained through promoting reflection on practice and effecting any potential changes to practice and care delivery to patients (Hogan et al, 2015).

1.10 Study setting

The study setting is a tertiary referral facility of over 980 beds, with 400 acute beds across several sites in Melbourne, Australia. Australian public hospitals are funded by Medicare, which covers almost all costs incurred in the hospital, with a mixed funding model. In 2016-2017, Australian spent \$181 billion on healthcare, which was 10% of the gross domestic product (GDP). This comprised Commonwealth funding (41%), State funding (27%), and the remainder funded by individuals, private health insurers and non-government organisations (Victorian Government Health Information, 2019).

Healthcare is offered under a three-tiered health system in Victoria. These tiers include:

- Primary care: care offered by general practitioners and nursing and allied health clinics;
- Secondary care: the provision of specialist services, usually following referral from primary care providers; and
- Tertiary specialist care, especially of complex medical or surgical procedures.

Across Victoria, the hospitals are categorised as specialist, tertiary, major, outer metropolitan, regional and sub regional. Figure 1.2, below, illustrates the spread of hospitals across the Melbourne metropolitan area in 2015. (Victorian Government Health Information, 2019).

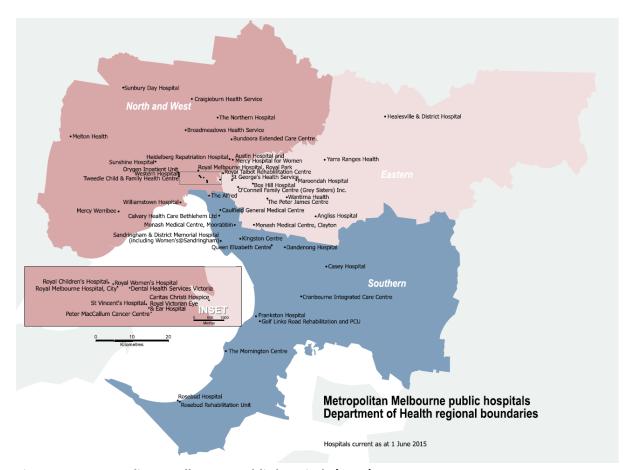


Figure 1.2 Metropolitan Melbourne public hospitals (2015)

The hospital in this study is a long-established, major academic, public health service providing healthcare, health professional education and health research. It provides a comprehensive range of acute, sub-acute, mental health, outpatient and outreach services to the local community. There are almost 97,000 separations with approximately 1,200 deaths annually within the facility. Separations are defined as episodes of care, which are completed when the patient is discharged, dies, transfers to another hospital or changes the type of care (AIHW, 2016). It is the state-wide provider of a range of services, some of which include specialist work in cancer, neurology, endocrinology, mental health, infectious diseases, rehabilitation, sleep medicine, intensive care, emergency medicine and a range of other specialties. There are no neonatal or obstetric services offered at the hospital.

The local government area that the facility services has a population of over 126,000 people, with 885 births and 1,531 deaths recorded in 2015 when the data for the study were collected (Australian

Bureau of Statistics, 2015). Of this population, just over 11% of the population was aged over 70 years, which reflects the aging population.

1.11 Study aim

The aim of this study was to determine clinicians' understanding of the types of deaths that meet the criteria to be reported to the CCOV.

1.12 Study objectives

The objectives of this study were to:

- 1. examine the frequency and characteristics of deaths at one healthcare facility during one calendar year;
- 2. examine factors that impact on a clinician's decisions to report a death to the coroner; and,
- 3. determine a clinician's knowledge of the legal requirements of reporting a death in the healthcare facility to the coroner.

1.13 Significance of the study

Much of the available literature regarding coronial processes has been directed towards the use of autopsy for investigation and the review of deaths. This study describes other perspectives, such as the role of a mortality review to inform and influence safe patient care delivery. A local mortality review is recognised as being beneficial, however, the independent review by coronial services is also very useful. Within contemporary patient safety frameworks, there is reference to the need for capability for independent mortality and morbidity reviews of deaths within health care settings and the opportunity for shared lessons across the sectors for healthcare professionals (Duckett et al, 2016). Following the investigation of reportable deaths, coroners have the opportunity to identify procedural and systemic improvement to clinical care. There is also the chance for state-wide oversight and identification of any "clusters" or groups of death. The identification and investigation of these cases, to determine any commonalities, can also contribute to patient safety, with the information being feedback to the clinical areas and more widely. The importance of these findings to influence clinical practice, assist in policy change and support review of standards of practice cannot be underestimated and allows for lessons to be learned. The importance of the prevention component that may be identified in the review is one factor that remains very valuable to society and, indeed, can serve as catalyst for change to health and safety practices.

The contribution of the discipline of patient safety is further described in Chapter 2. The understanding of clinicians, however, regarding their legal requirements to report deaths to the coroner and the lessons that may be learned from this independent review have not been established.

This study, therefore, is significant, as it will contribute to the body of knowledge pertaining to the role of the coroner and mortality review. This study will also determine the understanding of clinicians' regarding their responsibilities to report deaths to the CCOV and identify any real or perceived barriers to this process.

1.14 Structure of the thesis

This thesis is organised into seven chapters. The study has been introduced in Chapter 1, with discussion regarding the history and evolution of the coronial services, internationally and nationally, and their influence on patient safety, particularly within healthcare. Chapter 2 will describe Donabedian's framework, as a theoretical basis. The evolution of the concept of patient safety from an international, national and then state-focussed perspective will be presented. A scoping review of the available scientific research literature on clinicians' practices and understanding of reporting inpatient deaths to coronial services and the impact of the medico-legal death investigation process on patient safety is presented in Chapter 3. In Chapter 4, the research strategy that was utilised, mixed methods, will be described. The methods used for data collection and analysis in both the quantitative and qualitative phases of the research will also be presented. The results and discussion of Study 1, the retrospective audit will be presented in Chapter 5. Chapter 6 will present the results of Study 2, the key informant interviews and clinical scenarios with discussion of the findings. In Chapter 7, the findings of Study 3, which is the cases where a reporting error was identified, and the discussion of these cases will be presented. The final chapter, Chapter 8 will present the recommendations and conclusions of the study.

Chapter 2 The concept of patient safety

"It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm. It is quite necessary nevertheless to lay down such a principle."

Florence Nightingale, 1860.

2.1 Introduction

This chapter-explores the concept of patient safety, which underpins this study's aim and questions. This study seeks to examine issues relating to reportable deaths and factors that may impact clinicians' reporting of such deaths and the influence that this has on patient safety. In this context, there has been an increased attention to patient safety, due to the awareness that patients were being harmed whilst they were in hospital and that this harm was preventable (Emanuel et al., 2017). Likewise, this potentially preventable harm may result in the death of a patient and so there is a need to ensure that there are appropriate measures in place to monitor and prevent this harm.

Following a review of the available literature on the topic of patient safety frameworks, one framework was identified as forming the basis of contemporary quality assurance for patient care. The model or framework that was identified was developed by Dr Avedis Donabedian. The method of assessment of quality patient care was described by Donabedian (Donabedian, 1966) and this will be discussed as forming the foundation for the theoretical framework for this thesis.

There will be further reference to Donabedian's framework, particularly regarding the outcome measures of adverse events and deaths. These domains are used to describe how identification and review of adverse events and the mortality review process informs patient safety.

2.2 Development of patient safety

Patient safety has evolved through the recognition that patients in hospitals were at risk of harm. This harm was usually due to system issues or system breakdowns. Once this was acknowledged, it allowed for insights and the subsequent expansion of knowledge following specified events (Emanuel et al., 2017). These insights highlighted an ongoing reference to a concept referred to as patient safety and this led to the need for a clear definition of patient safety. Within the literature, the definition of patient safety is broad. It is considered a philosophy or a way of *doing things*, with its own framework, ethical principles and methods (Emanuel et al., 2017). It can also be considered a discipline, with its own body of expertise or, even, as an attribute of health systems (Emanuel et al., 2017).

Emanuel et al. (2017, p. 6) describes patient safety as:

... a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute

of health care systems; it minimises the incidence and impact of, and maximises recovery from, adverse events.

Other accepted definitions include that provided by the Institute of Medicine (IOM), which defines patient safety as freedom from accidental injury (Kohn et al, 2000), and that of the World Health Organization (WHO), which refers to the absence or reduction of risk of preventable harm to a patient (WHO, 2019). Other terms refer to patient safety as a field, or a framework for quality health care delivery (Australian Commission on Safety and Quality in Health Care (ACSQHC), 2019). Broadly, patient safety is the extent to which patients are protected from actual or potential harm whilst they are receiving care (Hibbert et al, 2016).

One measure of determining whether there is safe delivery of care, and freedom from preventable harm to patients, is an open and transparent mortality review process. The value of mortality review in the pursuit of safer patient care cannot be underestimated as a tool to provide potential lessons for treating clinicians (Hogan et al., 2015). Similarly, the role of an independent review of the circumstances surrounding a death, as provided by a Coroners' investigation, is also beneficial as a review of system-level issues. Of course, the deaths that are reportable to the CCOV provide an opportunity for a broader perspective on deaths across the state of Victoria and for the identification of any clusters of deaths. One component of the role of the CCOV is prevention of deaths, which is also very useful. For the review of the circumstances of deaths, the deaths are required to be reported to CCOV if they meet the specified criteria. For these deaths to be reported, therefore, requires a clinician to have a clear understanding of which deaths are reportable, especially from a healthcare delivery perspective.

Donabedian is regarded as the founder of quality assurance (Ayanian & Markel, 2016; Best & Neuhauser, 2004). He recognised that quality healthcare could be assessed and evaluated. For this to occur, Donabedian also recognised that there was the need for ongoing governance and processes to be in place to describe the delivery of quality healthcare (Ayanian & Markel, 2016). There were three concepts that Donabedian described in his seminal paper, published in 1966, which aimed to assist in the evaluation of quality health care. These concepts are structure, process, and outcome (Figure 2.1).



Figure 2.1 Donabedian's concepts for evaluation of quality care

The *structure* concept includes the setting and context of the care being delivered. When referring to the setting, here, this includes the resources that are within the setting, together with factors, such as infrastructure, the health providers' capacity to deliver care, staff qualifications and the administrative systems that support and direct healthcare delivery to patients.

The *processes of care* concept measures the way systems or processes deliver healthcare; for example, incident identification and management, and communication with patients regarding delays for appointments. It also includes the appropriateness of information gathered, how it is utilised and the culture of organisation.

The *health outcome* concept measures are not always easily quantified but relate to whether goals of care are achieved, including recovery, survival and restoration of function. Putting it simply, to achieve good patient outcomes, health services need the right inputs as well as reliable processes and monitoring of these indicators to assist them with keeping the quality of care high (Donabedian, 1966). Examples of measures include the percentage of patients who have died as a result surgery or the rate of surgical complications.

Within Donabedian's original framework there are also six domains used to evaluate the outcomes of healthcare delivery (Donabedian, 1966). Some are easily measured, such as the number of deaths as an outcome of management, the number of adverse events during patient management, and the number of re-admissions to hospital following discharge. Outcome assessment, however, is not particularly scientific or research-based, and not very easily measured (Donabedian, 1966).

The six domains used to evaluate the outcomes of health care delivery are:

- death,
- adverse events,
- resource use,
- re-admission,

- quality of life; and,
- activities of daily living.

Outcome measures, such as the quality of life or activities of daily living, are subjective and more difficult to measure. Donabedian (1966) refers to the outcomes measures as the ultimate validators of the effectiveness and quality of healthcare, however, also refers to the need to consider other variables, as part of a patient 's management, before undertaking quality assessment (Donabedian, 1988). These variables include pre-existing conditions and the natural progression of disease (Donabedian, 2005).

The structure-process-outcome model has, consequently, been utilised to assist in the development of performance measures for healthcare facilities (Ayanian & Markel, 2016). Donabedian's model has been accepted and used within the literature to support the development of quality standards (Haj et al, 2013).

Donabedian continued to refine and further develop his framework over his career, to further describe how the quality of care impacts on patient outcomes (Ayanian & Markel, 2016). In 1990, Donabedian also described the quality aims that would be used to inform the core aims of the health care system into the 21st century. These core aims constituted the delivery of safe, effective, patient-centred, timely, efficient and equitable care to all patients. These aims have also informed the development of metrics, globally, to assist the measurement of quality of care delivery (Ayanian & Markel, 2016). The esteem in which Donabedian and his model is held is exemplified by Berwick and Fox who describe the work as a masterpiece and "to this day, his subheadings would compose an adequate framework for a course syllabus on measuring the performance of health care" (Berwick & Fox, 2016, p. 237). Against this background, there has been increased attention to patient safety due to the awareness that patients were being harmed whilst they were in hospital and that this harm was preventable.

2.2.1 Development of patient safety - an international perspective

In the late 1990s, patient safety in hospitals gained momentum. The literature presents a variety of definitions of patient safety, some of which have been provided earlier. These definitions can be summarised as "the avoidance of unintended or unexpected harm to people during the provision of healthcare. Patients should be treated in a safe environment and protected from avoidable harm" (NHS, 2019). It is expected that hospitalised patients will not be harmed, either actually or potentially, and will be free from accidental injuries (Kohn et al., 2000).

As a measure of quality care delivery, several studies have reported the contribution of adverse events and harm caused to patients receiving hospital care, through the review of medical records. Leape et al. (1991) published a study that described a retrospective review of 30,196 randomly selected medical records from 51 hospitals in the state of New York during 1984. This study found that 3.7% (1,133) of patients were injured and that almost 28% of these were due to negligent care, therefore, potentially preventable (Leape et al. (1991). This study has been replicated with some variations across the world, including Canada, United Kingdom and Denmark, with similar findings (Baker et al., 2004)

The continued impetus of the reference to patient safety was reflected in the publication of the ground-breaking paper, 'To Err is Human' by the Institute of Medicine (Kohn et al., 2000). The paper presented the necessity for a system to safeguard patients in healthcare facilities. Findings included the fact that there were up to 98,000 Americans who died annually as a result of medical errors, together with a multibillion dollar cost due to the loss of earnings and healthcare costs associated with medical errors (Kohn et al., 2000). Other factors that were identified in the paper as challenging to measure included a loss of trust in the system by patients and a loss of confidence in the system by healthcare professionals (Kohn et al., 2000). It was recognised there was a need to review all cases with adverse events which resulted in serious injury or death, in an effort to identify any system improvements that could be implemented. (Kohn et al., 2000). The finding by the IOM galvanised governments and healthcare facilities to recognise the importance of patient safety and this period saw the creation of patient safety as a discipline. There were a variety of recommendations that suggested a focus on leadership, learning from errors, and a standardised approach to a safety culture in healthcare organisations, would be beneficial (Kohn et al., 2000).

Over recent years, there have been several inquiries into patient safety, internationally, and, more locally, in Australia (Braithwaite et al, 2006). The Bristol Royal Infirmary and the Bristol Royal Hospital for Sick Children in the United Kingdom were the focus of one of the highest profile investigations in recent times (Braithwaite et al, 2006). In this review, in 1995, it was identified that the quality of paediatric cardiac surgery that was being delivered was poor, with suboptimal outcomes. Issues were raised within the organisation but there was no acknowledgement or actions to address what was occurring. Key findings following this investigation revealed a system with fundamental weaknesses, including cultural issues in the organisation, where there was no questioning of performance despite mortality data indicating that there were serious issues (Department of Health, 2001).

Between 2005 and 2008, the care that was being provided by the Mid Staffordshire General Hospital NHS Trust to their patients was noted to be dreadful (Francis, 2013). The mortality rate of the Trust was higher than other similar trusts. A public investigation revealed that poor care was being provided and issues existed with the management oversight of care delivery and also governance (Francis, 2013).

Over a nine-month period in 1994 at the Winnipeg Health Service in Canada, it was noted that there were 12 paediatric deaths post cardiac surgery (Braithwaite et al., 2006). Similar to the Bristol Infirmary, there had been concerns raised by the clinical staff and patients' relatives regarding the standard of care prior to the investigation being instigated. The findings of a coronial inquest by the Chief Examiner of the Province of Manitoba, in 1995, indicated that five of the 12 deaths were preventable, four of the 12 deaths were potentially preventable and one of the deaths was not preventable. There was insufficient information in two of the 12 cases to determine whether death was preventable or not. The coroner also identified systemic issues that resulted in poor care delivery. These issues included poor staffing, policies not in place, leadership issues, poor communication and a lack of quality assurance processes (Braithwaite et al., 2006).

There were commonalities identified in the recommendations across all of these investigations. These included that the organisational cultures were not transparent and did not allow for concerns to be raised and acknowledged, there was a general lack of procedures/policies in place, and there were deficits in team work, documentation and communication (Braithwaite et al., 2006). These examples of investigations and subsequent recommendations have all informed the development of patient safety, internationally, by identification of commonalities. The commonalities include organisation cultural issues and the lack of internal processes to identify and monitor patient safety issues as they arise.

2.2.2 Development of patient safety - the Australian perspective

Similarly, across Australia, there have also been several investigations into suboptimal healthcare delivery that have informed the development of safer patient care. In Western Australia, by 2001, there had been several inquiries into the practice that was occurring at the King Edward Memorial Hospital (KEMH) (Douglas et al., 2001). This tertiary hospital was the primary provider of obstetric and gynaecological care in the state. Concerns had been raised regarding the standards of care provided over several years, which had resulted in several informal and formal reviews, internally and externally. The report of an inquiry that was published in 2001 indicated that there had been multiple infrastructure changes, mergers between services and a changing executive staff which had impacted on the ability of the staff to deliver good care to their patients. It was also revealed that

there was under-reporting of clinical incidents and adverse events, with no real processes in place for review of these events indicating deficits in the clinical governance procedures (Douglas et al, 2001). There were also 605 deaths reviewed, within the boundaries of the inquiry, which revealed that there were eight deaths that should have been reported to the coroner, but in fact had failed to be reported

In 2017, Oakden Older Persons Mental Health service in South Australia, a facility that consisted of three wards, was closed amidst claims of poor care of the residents (Lander, 2018). There were claims of assaults against the consumers, including excessive seclusion, and other suspected misconduct by staff towards the consumers that was not reported to the Australian Health Practitioners Regulation Agency (AHPRA). Other issues included poor governance within the faculty and a failure of leadership. Complaints were made repeatedly by family members which eventually escalated to a review by the Chief Psychiatrist (Groves et al. 2017)

Another high-profile investigation involved Bundaberg Base Hospital in Queensland and a surgeon whose competence was questioned (Dunbar et al. 2007). There were 20 or more complaints raised by clinical staff, both nursing and medical, about the standard of delivery of care. There were also potentially 13 surgical deaths that met the coroner's reporting criteria that were not reported, and it was determined that the care that the patients received was unacceptable (Davies, 2005). The investigation identified substantial individual performance issues. There were also system-wide concerns, as follows:

- the recruiting and credentialing processes for medical staff was not thorough or robust;
- there were inadequate review of deaths within Bundaberg Hospital and also across Queensland Health at this time; which may have contributed to;
- under reporting of deaths that meet the coronial reportable criteria.

According to section 7 of the *Coroners Act 2003* (Queensland), "... a death certificate should not be issued unless a coroner advises the doctor that the death is not a reportable death".

Historically, adverse clinical outcomes were thought, globally, to be due to the contribution of clinical complications and, therefore, not able to be avoided (Australian Commission on Safety and Quality in Health Care [ACSQHC], 2019). This was disproven when the methodology utilised by (Leape et al. 1991) was replicated in an Australian study undertaken in 1992, under the auspices of the Australian Commonwealth Department of Human Services and Health. The Australian federal government department wanted to ascertain the number of patient admissions that were associated with adverse events. Of 14,179 admissions across 28 hospitals in the states of New South Wales and South Australia that were reviewed, there was an adverse event noted in 16.6% (n=2,353)

of admissions (Wilson et al. 1995). Again, in this study, there was recognition that 51% of the adverse events were potentially preventable and 4.9% (n=112) of these patients died. This research by (Tricco et al. 2018; Wilson et al. 1995)) in Australia also identified that one in 10 patients who are hospitalised will have a complication of care whilst they are in hospital. Usually, there is only a minor impact on the patient. There is a group of people, however, for whom these complications result in permanent disability or even death.

2.2.3 Development of patient safety - the Victorian perspective

More locally, in Victoria, there have been various investigations of sub-optimal care delivery within the health care sector. In 2002, there were allegations made to the Health Services Commissioner regarding the practice of nursing staff at Royal Melbourne Hospital (RMH). Issues identified centred on medication management, leadership, clinical incident reporting and operational management.

The allegations were referred for review to the Victoria Police and the Coroner (Health Complaints Commissioner, 2002). The investigation centred on one clinical area, with deaths being reviewed by the Victorian Coroner's office due to accusations made of inadequate care delivery and even escalation of deaths.

More recently, in 2015, the Minister for Health in Victoria commissioned a review of the clinical governance, including the management, of significant clinical incidents at the Djerriwarrh Health Service (Duckett et al. 2016). This health service consists of six facilities, including a 42-bed acute care hospital, a residential aged care centre and other community-based centres and services in the North-Western regional area of Melbourne, Victoria (Duckett et al. 2016).

The Djerriwarrh Health Service came to the attention of the state government following a dramatic series of events. The review, known as *Targeting Zero*, (Duckett et al. 2016) was requested because there were deficits noted in the processes that were being followed by the service. The inadequacies were revealed when there was delayed recognition and review of the deaths of seven infants who had died from preventable and potentially avoidable deficiencies in care delivery, reflecting the lack of monitoring of outcome measures. Issues were identified in the structure and processes of care delivery as also described by Donabedian (Donabedian, 1966). These system issues included the reporting framework for significant events within the organisation, were reviewed and recommendations were put in place, at a state level, in reference to leadership and ongoing governance at both the Board and at the Department of Health and Human Services levels (Duckett et al., 2016).

The establishment of Safer Care Victoria (SCV) as an entity was informed by the findings of the *Targeting Zero* report (Safer Care Victoria, 2018). One of the responsibilities of SCV was to not only monitor and improve quality and safety within organisations but also to provide support to health services, in order to identify and manage these areas. To facilitate this, 70 recommendations were formulated, to be implemented by the end of 2020. The Victorian Clinical Council (VCC) was formed at this time. The aim of this group of more than 70 people from a variety of disciplines was to review system-level issues (Safer Care Victoria 2017). The VCC, together with the clinical networks, was tasked with identification of processes that would decrease the number of high-impact but potentially preventable events and reduce variations in clinical practice. The areas included patient experience, hospital readmissions and mortality.

The process of monitoring, responding and acting upon the CCOV recommendations is another focus of SCV. The two-way information sharing between SCV and the CCOV was identified as beneficial for ensuring that recommendations are implemented and support is offered to health services, as required. The process is also a vehicle for the sharing of findings to health services and the CCOV, regarding work that may be undertaken (Safer Care Victoria 2017). At the time of writing, significant progress had been made to the implementation of these recommendations (Safer Care Victoria 2017).

A brief summary of a section of recent investigations of circumstances, which have impacted on the provision of patient care, is presented in Table 2.2.

Patient safety has developed due to the essential need to improve patient safety in healthcare facilities by putting in place measures to reduce harm occurring to patients. This has primarily come about due to an enhanced awareness of preventable adverse events, through monitoring and research (Duckett et al., 2016). Public reporting of measures that determine patient safety and quality-of-care delivery has been not as forthcoming or advanced in Australia as it has been internationally (ACSQHC 2019). Several high profile investigations, as described, with resultant concerns raised publicly regarding the safety of health systems were also the impetus for change within Australia (Duckett et al., 2016). The focus on system issues versus individual performance issues has also become more evident, as has the use of principles of human factors (Dekker, 2011). Along with this focus is also a focus on the role of governance and leadership within organisations, as oversight of adverse events and the associated systems may contribute to the preventability of these events (Duckett et al., 2016).

2.3 Adverse events in healthcare

The rate or frequency of adverse events is considered an indicator or measure that determines whether the delivery of safe, quality care to patients has occurred (Baker et al., 2004). As referred to by Donabedian when describing the evaluation of the outcomes of healthcare delivery, domains such as death and the frequency of adverse events are outcome measures of safe and effective healthcare delivery (Donabedian, 1988).

There are a variety of definitions used to describe the term 'adverse events'. They can be defined as "an unintended injury that is caused by medical management and that resulted in measurable disability" (Leape et al., 1991, p. 377). The definition by Baker et al., (2004, p. 1678), however, states adverse events are, "unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from healthcare management ". The Australian Institute of Health and Welfare (AIHW) defines adverse events as "incidents where harm resulted to a person receiving health care" and the number of these events is deemed as one measure of safe and quality care delivery to patients (Australian Institute of Health and Welfare 2018). In Victoria, SCV refers to an adverse event as occurring when there is harm to a person who is receiving healthcare. The concept of whether the event is preventable is one of the common factors of all the definitions that address where harm is caused to the patient.

Furthermore, there are defined categories of more serious adverse events which result in the death of a patient, and these are reported as sentinel events. Sentinel events are a cohort of significant adverse events with meet specific criteria that result in serious harm or even death to patients. In order to gain some consistency and clarity, in Australia, there is an agreed list of events which are deemed to be sentinel events. (ACHS 2019).

2.3.1 Sentinel events

There has been a recent review of the list of sentinel events nationally, with a strengthening of the categories. Although these events are numbered 1 to 10, this is not reflective of their severity. Victoria has maintained an extra category, category 11, which allows for the reporting of any other adverse patient safety events that result in serious harm or death. These are presented in Table 2.1.

Table 2.1 List of sentinel events –Australia (effective 1/7/2019)

Category	Descriptor
1	Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death
2.	Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death

Category	Descriptor
3.	Wrong surgical or other invasive procedure performed on a patient resulting in
	serious harm or death
4.	Unintended retention of a foreign object in a patient after surgery or other invasive
	procedure resulting in serious harm or death
5.	Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting
	in serious harm or death
6.	Suspected suicide of patient in an acute psychiatric unit or acute psychiatric ward
7.	Medication error resulting in serious harm or death
8.	Use of physical or mechanical restraint resulting in serious harm or death.
9.	Discharge or release of an infant or child to an unauthorised person
10.	Use of an incorrectly positioned oro-or naso-gastric tube resulting in serious harm
	or death
11.	All other adverse patient safety events resulting in serious harm or death (Victoria
	specific category) *

*In Victoria, additional work has been undertaken to further categorise the events to be notified in category 11. Events that occur under any of these sub-categories require notification if there has been serious harm or death to the patient. These include:

- Clinical process or procedure-refers to delay or non-performance of a diagnosis, assessment or intervention.
- Falls- serious harm or death as a result of a patient fall(s)
- Deteriorating patients- failure to identify, escalate or respond to a patient's clinical deterioration
- Self harm (behaviour)- intended self harm that result in serious harm or death (suicide). This includes suspected suicide of a person within a health care facility or whilst a patient is on approved or nonapproved leave as a compulsory patient.
- Communication of clinical information-incident due to issues with administration or documentation of clinical information or failure of an administrative process to be performed adequately, or in a timely manner
- Medical advice or equipment- errors related to medical advices or equipment
- Nutrition- variety of errors that are associated with provision of nutrition and food to patients
- Resource or organisational management- a lack of resources or deficiencies in organisational management, such as staffing, bed availability or management
- Healthcare associated infection this includes infections of the blood stream, surgical site, intravascular cannula or urinary drain infections that are acquired within a healthcare setting.

Patient accidents, such as thermal or chemical injury, poisoning, and bed entrapment occur whilst a patient is receiving healthcare (Safer Care Victoria, 2019). According to AIHW, 2018, from 2007 to 2008 and from 2015 to 2016, the rate of adverse events in hospitals increased from 4.8 to 5.4 per 100 separations (AIHW 2018). This increase in numbers may have been due to the changing acuity of patient profile or increased reporting within hospitals. The majority of adverse events that are notified for review do not always result in death. This cohort is important to be reviewed objectively to determine causation and potential prevention of the death to inform patient safety and quality care delivery.

Occasionally, following the review of a clinical incident that reported as a sentinel event, there may be factors identified that meet the criteria for reporting to the coroner. In 2017 to 2018, 92 of the

122 sentinel events reported in Victoria resulted in death of the patient. Figure 2.2 illustrates the breakdown of sentinel events in Victoria and the significant number of deaths that resulted.

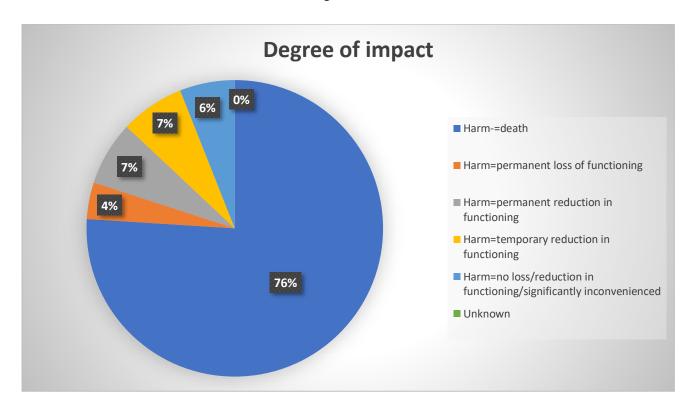


Figure 2.2 Breakdown of sentinel events reported in Victoria 2017-2018

State of Victoria, Australia, Safer Care Victoria, January 2019 (www.safercare.vic.gov.au)

2.4 Preventability of adverse events/deaths

The terms 'preventable deaths' and 'avoidable deaths' appear to be interchangeable within the literature. An avoidable death, as defined by Bourke & Vale, 2018, is one where "there was a greater than 50 % probability of avoidability in the event of trained medical review" (p 21). In Canada, it was noted, following the retrospective review of inpatient notes, that up to 51% of these adverse events may have been preventable (Baker et al., 2004). These factors reference a potentially avoidable or preventable death in the background of an adverse event. The level of causation or contribution to the potential avoidability of an adverse event or death is also a factor. Examples include a failure to recognise the deteriorating patient and inadequate escalation of care, and incorrect treatments, diagnoses or management of patients (Baker et al., 2004).

The AIHW describes potentially avoidable deaths from a broader, variable-based process, also referring to specific groups, such as indigenous people, heart disease and other chronic conditions (AIHW, 2018).

The notion of preventability is often raised within the patient safety literature. Bourke and Vale (2018) demonstrated a less than expected number of deaths that were deemed avoidable following review. They surmised that there may have been some subjectivity regarding the identification of these deaths. The vulnerability of clinicians to litigation or prosecution is an issue, as they are required to report to the family if there was an avoidable component to the death following review (i.e., open disclosure is required) (Bourke & Vale, 2018). Over time, there has been greater importance placed on health care organisational culture to allow clinicians to feel supported and comfortable in being transparent and open and to discuss when care has not occurred according to expectations.

A component of this transparency is the discussion with patients, their families or significant others that occurs when a patient has been harmed during health care delivery. To achieve this transparency, there needs to be the appropriate systems in place to support clinicians performing this task which, therefore, allow the opportunity to also determine if there are any lessons to be learned. Whilst acknowledging that there are existing legal requirements for reporting deaths to the coroner, an openness of review can also inform practice and or system changes to further assist in the delivery of safe patient care.

Baker et al. (2004) utilised a 6-point scale for the medical record reviewers to determine whether an adverse event may have been preventable. Wilson et al., 1995 assert that preventability of an adverse event is determined by the review of an error in management or judgement regarding the delivery of care to the patient, utilising the same 6 point scale (Figure 2.3).

- 1. Virtually no evidence of preventability
- 2. Slight to modest evidence of preventability
- 3. Preventability not quite likely (less than 50/50, but "close call")
- 4. Preventability more than likely (more than 50/50, but "close call")
- 5. Strong evidence of preventability
- **6.** Virtually certain evidence of preventability

Figure 2.3 Scale utilised to determine the preventability of an adverse event (Wilson et al., 1995, Baker et al., 2004)

2.5 Performance monitoring and patient safety.

Currently, in Australia, the safety of a hospital is assessed by monitoring multiple variables, with the development of national clinical indicators to measure care delivery (Gardner et al., 2013). These are not direct measures but rather indicate areas that require greater analysis. There are 20 clinical indicator sets; for example, those focussed on the emergency department, anaesthesia and

perioperative care and other clinical areas (ACHS, 2018). Hospital-wide indicators include monitoring of patient deaths and the number of deaths that occur in the low mortality diagnosis-related groups (DRGs). These deaths are unexpected, as the patient was admitted without a prominent risk of mortality. The analysis or further scrutiny of these measures of quality care follow Donabedian's structure-process-outcome formula (ACHS, 2018).

There has been further development, at a national level by the Australian Commission on Safety and Quality in Health Care (ACSQHC), of the performance indicators, under two dimensions. Dimension 1 includes safety and appropriateness to describe/measure safe care. In Dimension 2, patient outcome measures include mortality and avoidable hospital readmissions (ACSQHC, 2018).

2.5.1 Mortality monitoring and its role in patient safety

Within health care settings, numerous methods are used to monitor and review deaths to determine their potential preventability. The monitoring of mortality rates within hospitals has long been recognised as a valuable measure of quality and safety of care (Hogan et al., 2014).

Florence Nightingale was an early influencer in reference to measuring mortality numbers and identification of the contributory factors to inform the quality of care delivery (Karimi & Alavi, 2015). In 1854, she went to the British camps during the Crimean war with a group of nurses, where she described the soldiers being cared for in terrible conditions. Nightingale identified that 600 of every 1,000 soldiers were dying from infectious and communicable diseases due to the environment. She was one of the first individuals working in healthcare to measure the mortality rates as a method of informing the evaluation of the level of care provided to patients (Fee & Garofalo, 2010; Karimi & Alavi, 2015). Furthermore, she recognised the need for uniform hospital statistics related to deaths (Nightingale, 1863). Statistical review was developed and put into operation on her return to England, when she recognised how the statistics on mortality she had collected could be used as a tool to improve medical care for both members of the military as well as civilians (Fee & Garofalo, 2010). The data provided an organised way of learning from experience. Similarly, it is of note that it is essential that there is the opportunity for learning from mistakes as a measure to improve patient safety, when the opportunity is presented (Berwick, 2013).

In Victoria, mortality numbers are reported quarterly to Safer Care Victoria, with any identified outliers requiring further review and relevant findings also reported. Part of this clinical benchmarking process includes hospital standardised mortality ratios (HSMRs) (Department of Health and Humans Services, Victoria, 2019). The HSMR is described as indicators of trends of deaths within hospitals and allow for a comparison with other hospitals. They are commonly used as a tool

to determine or identify any areas of concern and one method to assess the quality of care delivery (ACSQHC, 2014).

The HSMR compares the actual number of deaths in particular clinical areas with the expected number of deaths amongst the selected groups (Figure 2.4).

HSMR = <u>actual number of in hospital deaths amongst selected diagnosis groups</u> expected number of in hospital deaths amongst selected diagnosis groups x 100

Figure 2.4 Hospital standardised mortality ratios (HSMR) (Scott et al., 2011)

This measure has been utilised as a tool to determine both the safety and effectiveness of a hospital (Hogan et al., 2015). An increased or high HSMR may indicate that there are deficiencies in the hospital care that requires further review. Whereas there are specific requirements for further review of outliers, there is increasing concerns about the usefulness of the data, its accuracy and the consistency of the parameters being measured (Doran et al., 2015).

Some researchers believe that an important link or opportunity to review the preventability of a death may be missed if deaths are under-reported or not or reported at all (Higginson et al, 2012). This is particularly evident where deaths occur in community settings or within healthcare organisations (Higginson et al 2012).

Hogan et al. (2014) describe the increase in the systematic review of hospital mortality and the role of mortality review to assist in the recognition of preventability of deaths (Hogan et al., 2014). Subsequently, the review can then be used to inform clinical practice, using examples such as the investigations into the Mid Staffordshire Foundation Trust and the Bristol Royal Infirmary (see Chapter 1). Whilst there is a body of literature that describes the process of death review within healthcare settings by means of morbidity and mortality meetings, the review processes vary, both across organizations and within organizations, with respect to the use of a variety of paper-based and electronic tools. However, there is a paucity of literature available as to whether deaths that should be reported to coroners are, in fact, reported, and, in particular, the relevant factors that may influence the reporting of deaths that meet the criteria for reporting to the Coroner.

In Victoria, Australia, the *Coroners Act 2008* (Vic.) (enacted in 2009) states that one component of the role of the coroner is to provide an independent investigation of the cause of death. This is to

ensure that the independent investigation of the circumstances surrounding the death are highlighted, to enable coroners to make recommendations. These recommendations aim to avoid the repetition of events, ultimately to potentially decrease deaths that are preventable, and this, in turn, informs public health and safety (Coroners Act 2008 (Vic).

Donabedian (2005) also refers to death of patients as one of the domains that may be used to evaluate the safety and quality of patient care. This is one of the more definitive measures and may also demonstrate how the coronial process of review can assist in the review and identification of adverse events.

Within the literature, there is reference to the impact of adverse events on mortality within healthcare facilities. In Norway, Flaaten et al. (2017) reviewed all hospital deaths which occurred over a year to describe the cause of death, according to Norwegian law. Flaaten et al. (2017) classified deaths into two groups, based on whether the death was sudden or unexpected. In the unexpected death group, there was further classification based on whether death was due to (1) natural causes or (2) unnatural causes. The review also identified any contribution of adverse event(s) to the death and if the death was preventable. Of 1,185 deaths reviewed, 16 deaths (1.4%) had an associated adverse event and were potentially preventable and 18 deaths (1.5%) may have been preventable; however, the data were unable to be unequivocally established. In total, there were 2.9% (34/1,185 deaths) that may have been preventable. Similarly, Hogan et al. (2014) reported on a retrospective review of 1,000 deaths in 10 hospitals in the United Kingdom, in 2012, which determined that 5.2% of the deaths were judged as preventable. Since 2016, it is a requirement that all NHS trusts in the United Kingdom determine the potential avoidability for all deaths that occur in their care. As a result of this process, one Trust identified that, following a review of over 1600 deaths, there were only 12 deaths that may have been avoidable (Hogan et al., 2014).

Multi-disciplinary mortality and morbidity (M & M) meetings provided the opportunity to review deaths other than the *expected* deaths (Bourke & Vale, 2018); for example, the deaths of patients on an end-of –life pathway, such as chronic, long term patients, and those patients who were being offered palliative care. It was discovered that, through this M & M process, clinicians were cautious when referring to a death as potentially avoidable. Factors, such as family distress and a sense of exposure regarding potential litigation or even criminal charges, contributed to the sense of vulnerability of clinicians about exposure. To achieve a level of consistency in the mortality reviews, guidelines were developed and published by the National Quality Board for use within the NHS trusts (Bourke & Vale, 2018).

Mortality meetings are one way to ensure that a systematic, organisational approach is implemented to assist in a more comprehensive understanding of patient safety. An organisational-level approach to this review is also replicated by the coronial services and the opportunity for broader lessons to be learned and subsequent information more widely disseminated (Hibbert P et al., 2016). Traditionally, any error made by a clinician demonstrates incompetence and, consequently, punitive measures must be put in place (Emanuel et al., 2017). This process has not encouraged reporting or review of the circumstances surrounding adverse events and may have actively encouraged concealment of the events and, therefore, no information to be shared about them (Emanuel et al., 2017). A culture of 'no blame' is preferable and needs to be developed within the healthcare setting, to allow for transparency and honesty to facilitate the open review process and allow for insights, without any stigma or fear (Emanuel et al., 2017). To be able to document the impact of preventable or avoidable adverse events or deaths, there needs to be an openness and transparency in the reporting. Open disclosure, as described earlier in the chapter, is one component of this review process.

Public reporting on identified areas that may compromise patient safety is one measure to ensure accountability for healthcare organisations (AIHW, 2018). Included in the process of reporting is the number of adverse events that occur in hospitals as a measure of the level of safety offered by the organisation (AIHW). Australia is not as progressive in the public reporting of patient safety and quality measures when compared with others internationally (ACSQHC, 2019). In Australia, the federal government has introduced costing for quality and safety into the funding model for public hospitals. Complications of care and re-admissions to hospitals that are avoidable, and all sentinel events, are to be reported and measured, including the impact on funding for hospitals. Duckett and Jorm (2018) estimated that the potential savings, should funding be linked to quality and safety for the state of Victoria, would amount up to \$398 million.

2.6 Summary

In this chapter, the evolution of patient safety has been presented, from an International, Australian, and then Victorian perspective. The numerous health service investigations highlighting system failures and suggested actions have also been discussed. Common themes identified as a result of these investigations include leadership issues and the lack of internal processes for incident management. Also highlighted has been the importance of the culture of organisations for allowing concerns about patient care delivery to be raised, heard and investigated without fear of retribution or being labelled as a troublemaker.

Donabedian's framework that was developed in the 1960s, and which underpins the delivery of safe and quality care to patients, is also presented. (Donabedian, 1966). Within this framework, the methods to evaluate the quality and, therefore, safety of health care delivery, and the structure-process-outcome concepts that have been influential in the development of the discipline of patient safety are described. The application of the model of structure-process-outcomes to the construct of patient safety is evident in terms of:

Structure: the setting of care delivery, staff qualifications, the presence of clinical governance procedure;

Process: the culture of the organisation, the processes of incident identification and subsequent management; and

Outcome: the management of incidents and mortality review, with lessons learned from the reviews.

It is understood that, despite the best efforts of health care professionals and established systems, patients will die whilst in acute care hospitals. The information, however, that can be obtained following the review of deaths is very useful for both organisational reflection and to inform the ongoing improvement in care. Both perspectives allow for the potential to make change to practice (Hogan et al., 2014).

One of the main objectives of patient safety is to achieve the eradication of preventable harm in healthcare. As well as the too often tragic ramifications of an adverse event that may be preventable, the human and financial costs cannot be underestimated. There also needs to be the acknowledgment of these events as being part of the complex system of healthcare delivery. Increased length of stay, ongoing procedures, and loss of productivity are just some of the factors that emerge from preventable complications and diminish the safe care for patients.

To examine the evidence available regarding clinicians' understanding of their role in deaths that meet the criteria for reporting to the coroner, a scoping review of the literature was performed. The results of this scoping review will be presented in chapter 3.

Table 2.2 Brief summary of a selection of recent investigations of circumstances that impacted on the provision of safe patient care.

Organisation	Context	Findings	Recommendations
Bristol Royal Infirmary and the Bristol Royal Hospital for Sick Children United Kingdom	Sub-optimal outcomes from paediatric cardiac surgery Report published 2001	 Systemic issues with concerns raised by families and staff not heard No questioning of clinical performance Staffing and funding issues Skill and expertise of staff to manage complex patients Inequitable treatment of staff Communication issues with patients and families Lack of clinical governance, in that data was collected regarding adverse events but no lessons were occurring as a result No mortality and morbidity meetings Punitive and destructive environment that discouraged 'speaking out' Board of management was not involved or did not provide oversight of the operations. 	 Review of the provision of paediatric services in the NHS Improved communication with patients and their families Safe care delivery is to be expected, and include elements of communication, physical environment, teamwork, and equipment The development of a safety culture and elimination of the culture of blame A centralised agency for the reporting, analysis and subsequent dissemination of information
Mid Staffordshire General Hospital NHS Trust United Kingdom	Report of investigation between 2005-2008	 A public investigation revealed: poor care being provided issues with management's oversight of care delivery and governance issues lack of a culture of openness, transparency and candour (i.e., there was no open disclosure process) issues in the value and standards of the organisation lack of leadership in healthcare fundamentals of behaviour missing poor monitoring of healthcare system regulatory functions 	There were 290 recommendations made and presented thematically. Broadly, suggested actions included: • Earlier detection and warning systems within the NHS of serious failures; • Leadership from the Department of Health in all aspects of care • Reporting, review and oversight of coroners including the Chief Coroner

Organisation	Context	Findings	Recommendations
		 the coronial process in health care-related deaths was not utilised 	
Winnipeg Health Service Canada	Increased number of paediatric deaths post surgery Report 1998	 Systemic issues that resulted in poor care delivery, such as poor staffing, lack of policies Issues with leadership Lack of quality assurance processes Concerns raised by clinical staff and relatives not heard Coronial inquest showed that care was deficient and that 5/12 of the paediatric deaths were preventable and 4/12 were potentially preventable Inadequate supervision of clinical staff Poor teamwork and communication. Inequitable treatment of staff 	 Recruitment policies be put in place Standard operating guidelines be implemented Leadership skill programs be developed and delivered An environment where all voices are heard, as required, be created
King Edward Memorial Hospital (KEMH). Western Australia	Report released in 2001 Several inquiries into practice had occurred, informally and formally	 Multiple changes in senior staff and infrastructure; mergers between services Under-reporting of clinical incidents and adverse events Deficits in clinical governance procedures, compliance monitoring, and procedure and policy development No hospital-wide quality improvement program Eight deaths that met the criteria for reporting to the coroner were not reported 	 Development of guidelines for planning of clinical care Supervision of junior staff Increased clinical accountability and clinical governance accountability
Oakden Older Persons Mental Health Service, South Australia	In 2017, the service was closed due to multiple complaints regarding the care the consumers were receiving.	 Claims of assault against the consumers, including excessive seclusion Other suspected misconduct by staff towards the consumers was not reported to AHPRA Poor governance within the facility Failure of leadership Complaints not heard by the management 	 Review of the clinical governance and management of mental health services by the Chief Executive of the Department of Health and Ageing Review of the management strategies in collaboration with the Chief Psychiatrist

Organisation	Context	Findings	Recommendations
			 Training and improved oversight of the staff of the facilities Ongoing inspections by the Chief Psychiatrist of services offering mental health care Review of the restrictive powers of staff Adequate and appropriate staffing of the mental health services to be overseen by the Chief Executive of the Department of Health and Ageing
Bundaberg Base Hospital Queensland	Complaints regarding the competence of a general surgeon to practise	 Several complaints raised by clinical staff, both nursing and medical, regarding the standard of care delivery, unheard Potentially 13 surgical deaths that met the coroner's reporting criteria were not reported and the level of care the patients received was unacceptable Substantial individual performance issues identified System-wide concerns, such as the recruiting and credentialing processes for medical staff, not very thorough or robust Inadequate review of deaths within Bundaberg Hospital and also across Queensland Health at this time The above may have contributed to the underreporting of deaths that meet the coronial reportable criteria 	 Review of the governance processes within Bundaberg Base Hospital and Queensland Health Implementation of robust recruiting and credentialing processes for medical staff
Royal Melbourne Hospital (RMH), Victoria	In 2002, allegations made to the Health Service Commissioner regarding the conduct of nursing staff	 The changes from an organisational and leadership perspective that had occurred across Victoria had impacted on RMH and the standards of care, with instability of leadership and lack of accountability 	 Maintenance of consistent and transparent management practices Leadership to be developed Processes to be implemented that allowed staff to learn from errors that

Organisation	Context	Findings	Recommendations
	•	 Medication management and control standards had declined Allegations against the nurses were subject to investigations by the Victorian Coroner, police and Nurses Board of Victoria, and suspended their registrations There was no value attached to any issues by the organisation that were raised by the staff 	had occurred and there be a hospital- wide program for reporting sentinel events • Patient medication storage systems to be reviewed and access to documented audit process be put in place
Djerriwarrh Health Service Victoria	Review commissioned by the Minister of Health in 2015 into the clinical governance of the health service, including the management of several significant events, including the potentially preventable deaths of seven infants.	 Delayed recognition and review of the deaths of seven infants who had died from preventable and potentially avoidable, deficiencies in care delivery Lack of governance for reporting and reviewing events Leadership issues at the health service Board level 	 72 recommendations made, which are still in the process of being actioned One recommendation was the establishment of Safer Care Victoria (SCV) to monitor and improve quality and safety within organisations SCV to provide support and leadership to health services in quality and safety areas A process has been implemented for SCV to monitor, respond and act upon recommendations made by the coroner

Chapter 3 Literature Review

3.1 Introduction

This chapter will present a scoping review of the available literature which examines clinicians' practices and understanding of reporting inpatient deaths to coronial services, and the impact of the medico-legal death investigation processes on patient safety.

This scoping review will examine current literature related to the aim of this study (Arskey and O'Malley 2005). The chapter will describe the rationale for the performance of a scoping review, and then outline the criteria for the selection of the studies within the review. A summary of the key findings will then be presented, with a description of ongoing implications for clinical practice.

3.1.1 Rationale

Improvements to the delivery of patient care can be enhanced by the lessons learned following an investigation or review of an inpatient death. Mortality investigations or reviews may be performed at a local level, within healthcare facilities, or by an independent body, such as a coroner or medical examiner. Modern mortality investigations of inpatient deaths have been conducted with, firstly, a view to determining whether the death may have been preventable and, secondly, as a vehicle for open and transparent discussions to assist in the identification of any potential lessons that can be learned (Higginson et al; 2012; Travaglia & Debono, 2009).

Much of the literature is concerned with the intersection between clinicians, inpatient deaths and the medico-legal death investigation system, which tends to focus largely on the utility of the autopsy findings to validate the accuracy of the clinician's diagnosis. While this is a valuable source of information, from an educational perspective, the literature does not describe the clinician's understanding of the legal requirements for reporting inpatient deaths for investigation and the role that the investigation can play in patient safety. The findings following review of deaths can also be used as a tool to inform ongoing patient safety in the healthcare setting, potentially influencing change in clinical practice (Gill et al.;2014). The literature that is available on the coronial processes is limited, therefore, the execution of a scoping review was appropriate.

There is a necessity to explore the area of coronial death reporting from a clinician's perspective, to determine their understanding of the legal requirements of their role. The impact that this independent review may have on informing patient safety is also not well understood and, therefore, is also an area that requires further exploration.

A sub-category of the systematic review is a scoping review, which is more exploratory and wide-reaching than a systematic review, providing a broad overview of a topic (Peterson et al., 2017).

Although a reasonably new method to review evidence pertaining to a particular subject, scoping

reviews are gaining momentum as a methodology (Munn et al., 2018). The aim of a scoping review is to review findings from a body of knowledge that may be diverse, to identify any gaps in knowledge, and to clarify any concepts within the literature (Munn et al., 2018; Tricco et al., 2018). Scoping reviews can be used if the available literature is varied or heterogeneous and, therefore, not lending itself to systematic review but, rather, a narrative review (Khalil et al., 2016; Peterson et al., 2017). Arskey and O'Malley (2005) have described a framework for conducting scoping reviews, which has been modified over the evolution of the process. This framework includes the:

- 1. identification of the research question;
- 2. identification of the relevant studies;
- 3. study selection;
- 4. charting of data (or the data extraction); and
- 5. collating, summarising and reporting of results.

There has been further modification and development of guidelines for the conduct, use, and rationale for scoping reviews, including the following, as described by Munn et al. (2018), to:

- 1. identify the types of available evidence in a given field;
- 2. clarify key concepts/definitions in the literature;
- 3. examine how research is conducted on a certain topic or field;
- 4. identify key characteristics or factors related to a concept;
- 5. act as a precursor to a systematic review; and
- 6. identify and analyse knowledge gaps.

To describe the findings of the scoping review in this study, a narrative synthesis was utilised. Campbell et al., (2018) describe narrative synthesis as a collation of the findings of studies into a textual narrative. It is also described by others as a form of "story telling" or a descriptive account which includes an overarching framework that brings together a variety of styles and methodologies (Arskey & O'Malley, 2005; Popay et al., 2006).

3.1.2 Objectives

The aim of this scoping review was to examine the available literature on clinicians' practices and understanding of the reporting requirements for inpatient deaths and the role of the medico-legal death investigation in patient safety.

3.2 Methods

3.2.1 Protocol and registration

The review was performed in accordance with the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-SCR).

3.2.2 Eligibility criteria

Inclusion criteria

Studies that met the following criteria were considered for inclusion in the scoping review if they were:

- i. full texts of original research in a peer-reviewed journal;
- ii. primary research studies;
- iii. published in the English language;
- iv. studies of human subjects;
- v. involved either qualitative or quantitative methods for data collection and analysis;
- vi. examined clinicians' practices or understanding of the reporting requirements of inpatient deaths to the medico-legal death investigation system; and
- vii. examined the role of medico-legal death investigation in patient safety.

The population comprised inpatients within hospitals and the exposure that needed to have occurred was death. The outcome measure was that the inpatient's death was subject to medicolegal death investigation. A medico-legal death investigation was defined as being reported to the office of the coroner/medical examiner, irrespective of whether an autopsy was performed. The secondary outcome measure was clinicians' understanding of deaths that meet the reporting requirements to the coroner.

Exclusion criteria

Studies were excluded from the scoping review where:

- the full text of the article was not available;
- ii. secondary research studies;
- iii. the full text of the article was not available in English;
- iv. the study did not examine clinicians' practices or understanding of the reporting requirements of inpatient deaths to the medico-legal death investigation system; and
- v. the study did not examine the role of medico-legal death investigation in patient safety.

3.2.3 Information sources and search

A search of electronic databases, in the fields of medicine, nursing and health sciences, was performed to locate studies from the first available year to December, 2018.

The databases searched were Ovid Medline, Ovid Embase, Ovid PsycINFO, the Cochrane library and CINAHL via EBSCOHost. Additional studies were located following a bibliographic review. A search strategy was generated from the following three key concepts: (1) inpatients; (2) patient safety and

(3) coroners or medical examiners (Table 3.1). Indexed (e.g. Medical Subject Headings) and key words were identified for each concept to develop a search strategy (Table 3.2).

Table 3.1 Concepts and search terms

CONCEPT	SEARCH TERMS UTILISED
1. Inpatients	inpatients
	patients
	clients
2. Patient Safety	patient safety
	patient care
	iatrogenic injury
	iatrogenic disease
	clinical complication
	clinical error
	medical error
3. Coroners or Medical Examiners	coroner
	medical examiner
	death investigation
	forensic medicine
	legal medicine
	medico-legal

Table 3.2: Search strategy

Search strategy terms

- 1. inpatient*.tw.
- 2. Patients/
- 3. Hospital patient/
- 4. patient*.tw.
- 5. client*.tw.
- 6. consumer*.tw.
- 7. Consumer/
- 8. 1 or 2 or 3 or 4 or 5 or 6 or 7
- 9. Patient Safety/
- 10. (patient* adj1 safety).tw.
- 11. exp Patient care/
- 12. (patient* adj1 care).tw.
- 13. Patient Harm/
- 14. (patient* adj1 harm*).tw.

- 15. IATROGENIC DISEASE/
- 16. (iatrogen* adj1 disease*).tw.
- 17. (iatrogen* adj1 injur*).tw.
- 18. (clinic* adj1 complication*).tw.
- 19. (clinic* adj1 error*).tw.
- 20. exp Medical Errors/
- 21. (medic* adj1 error*).tw.
- 22. (medic* adj1 adverse adj1 event*).tw.
- 23. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
- 24. Coroners and Medical Examiners/
- 25. coroner*.tw.
- 26. (medical adj1 examiner*).tw.
- 27. (death* adj1 investig*).tw.
- 28. exp Forensic Medicine/
- 29. (forensic adj1 medicine).tw.
- 30. (legal adj1 medicine).tw.
- 31. medico?legal.tw.
- 32. medico-legal.tw.
- 33. 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32
- 34. 8 and 23 and 33
- 35. limit 34 to humans
- 36. limit 35 to english language

3.2.4 Study Selection

Search results were exported into systematic review management software, Covidence, and duplicates were removed. The title and abstract of each article were screened by one author (AC), against the eligibility criteria. The full texts of included articles were independently screened by two authors (AC, WC) against the eligibility criteria and conflicts were adjudicated by a third author (LB). A bibliographic review of included articles was performed by one author (AC), to identify further articles of relevance.

3.2.5 Data collection process and data items

A data extraction protocol was developed by the student researcher and one supervisor (AC, LB) and comprised the following: authors, year of publication, study setting, study aim, study population (inpatients), reference to deceased, subject to medico-legal investigation, methodology, study design, evidence of clinician's understanding of inpatient death reporting requirements, evidence of medico-legal death investigation in patient safety. Data were extracted from each article by the student researcher (AC) into a table for analysis

3.2.6 Quality of evidence

One of the criticisms of scoping review methodology is the potential lack of attention to the quality of the included studies and the impact of this on what is subsequently reported. (Peterson, Pearce, Ferguson and Langford (2017).

3.3 Results

3.3.1 Study selection

From the searches conducted, 3,218 articles were identified, with 538 records removed as duplicates. Figure 3 1 shows a summary of the review process, from identification through to the inclusion of studies, utilising a PRISMA-SCR flowchart.

Title and abstract screening was performed on 2,680 articles against the eligibility criteria, of which 2,591 were excluded. This left 89 articles for full text review, of which 82 were excluded for the following reasons: 33 studies assessed the wrong outcome, 15 were based in the wrong setting, 13 studied the wrong patient population, 13 identified the wrong intervention, three articles were duplicated, three were pre-1990, one had an improper study design and one study described the wrong indication. There were seven remaining studies that met the inclusion criteria of the review, with one study identified through bibliographic review, resulting in a total of eight articles. A summary of the included studies is presented.

3.3.2 Study characteristics

Included studies were published between 2003 to 2016 and conducted in a variety of countries, including: Japan (n=3); Australia (n=1); South Africa (n=1); Taiwan (n=1); the United Kingdom (n=1); and and the United States of America (n=1). There were three quantitative papers, consisting of retrospective record reviews (medical records and/or autopsy data), four qualitative papers, (interview data, surveys and scenario completion) and one discussion paper. In five of the individual studies, the aims included determination of whether there was potential under-reporting, with the other three papers reviewing the lack of understanding or consistency of the deaths that met the reporting requirements.

The study populations also varied, including deceased inpatients (n=4) and clinical staff (n=4). Five studies identified under-reporting of deaths to the coroner that met the reportable criteria, and three studies reported a lack of consistency/understanding of deaths that were to be reported.

3.3.3 Risk of bias within studies

As this was a scoping review and, therefore, providing a mapping or an outline of the available evidence, there was no requirement to perform an assessment of the risk of bias within this evidence (Munn Z et al., 2018).

3.3.4 Results of studies

The clinician's understanding of deaths that are required to be reported to the coroner was the primary focus of this review. The findings were summarised and grouped according to the similarities of the concepts described (Ryan R, 2013).

Under-reporting of deaths to the Coroner

Five studies examined under-reporting of deaths to the coronial services (Charles et al., 2007; Drake et al, 2016; Lu et al., 2008, Maeda et al., 2003, Maeda et al, 2010). These studies referred to inpatients in healthcare facilities. Lu et al. (2008) reviewed mortality data from a Taiwanese health service to determine if there had been an under-reporting of deaths that met the unnatural death criteria and the potential impact on safe patient care delivery. The categories that this occurred in was in deaths that were related to complications in the provision of care. Within this study, medical record data linkage was used to determine that only 57% (2,346 / 4,086) of known or suspected deaths from unnatural causes, were referred to the coronial service. This is despite the law stating that deaths that are unnatural should be referred for coronial investigation (Lu, 2008). The study by Charles, et al. (2007) reviewed the number of deaths that met the criteria for reporting to the coroner, within two metropolitan hospitals in Victoria, Australia. Findings noted that there was significant under-reporting of deaths to the coronial services, which was demonstrated in the review of 229 medical records of deceased patients from the hospitals. There was acknowledgment that the coronial services rely on the reporting of deaths within the health sector by the clinicians to allow them (the coroners) to investigate the deaths. A secondary finding of this study was to report improvements in the understanding of doctors regarding hospital death reporting requirements to the coronial services (Charles et al; 2007).

The study by Maeda et al., 2010 examined the attitudes of medical personnel and risk managers regarding the reporting of deaths, and whether there were any medical errors that contributed to a death (Maeda et al., 2010). Scenarios that described different deaths were presented to the clinicians (medical staff) in the form of a questionnaire. They were then asked to respond as to whether there was a contribution of medical error/ care and identification of the causal relationship to the death. Risk managers were asked if they would advise the medical staff to report the deaths in the same scenarios. The findings demonstrated that most of the participants who completed the questionnaire would report the deaths to the police if the death had been caused by medical error., Although they would err on the side of caution, potentially, with respect to reporting any deaths that occurred.

A retrospective review of the data from forensic autopsies was performed on 856 deceased people in Osaka, Japan, between 1996-2001. The cohort of decedents had died in hospitals unexpectedly, unnaturally or, potentially, with medical negligence as a contributory factor. Of the 856 deaths reviewed, 28 deaths were related to clinical care. Of these 28 deaths, there were 14 deaths that were related to nursing care. The other 14 deaths were due to diagnostic or therapeutic procedures. A total of 14 of the 28 deaths identified were reported by clinicians and there were 6 of the 28 deaths notified to the police by family members. Once again, a tendency demonstrating a potential lack of understanding by clinical staff of the correct criteria for reporting a death.

There was also acknowledgement that within healthcare facilities there is a lack of understanding of the medico-legal death investigation (MLDI) process and how this review can inform both patient safety and quality improvement activities (Drake, Harper, & Wolf, 2016). The MLDI are performed by trained professionals who are not necessarily police/medical examiners in Texas, United States of America (USA). Approximately 32,000 deaths were reported between 2006 and 2014, with 186 cases in which the MLDI identified issues that had relevance to patient safety. These included diagnoses that were missed or inaccurate, and failure to report deaths that appeared to be unnatural, including falls related deaths.

Lack of consistency/understanding of reportable deaths

Three papers referred to a lack of consistency or understanding of deaths that met the criteria to be reported to the coroner (Gill et al., 2014; Madiba et al., 2011, Kamishiraki & Maeda, 2010).

In Ireland, it was reported that neonatal deaths were being reported to the coroner to aid in accessing postmortem examinations for unexplained deaths, as a method to review and, potentially, improve clinical practice. The use of postmortem examinations in neonatal deaths are seen as the optimal standard to determine the cause of death of infants (Gill et al., 2014). Telephone interviews were performed across several paediatric units, with the researchers identifying that there was a lack of consistency under which conditions neonatal deaths were reported to the coroner across these units. Madiba et al; reviewed deaths that occurred during or after a surgical procedure and potentially considered medico-legal deaths. There is also reference to the lack of clarity between countries and jurisdictions related to deaths that occur within the clinical area of anaesthesia, specifically, and the reporting requirements (Madiba et al; 2011).

This possible inappropriate reporting could be seen as defensive practice, as practitioners may face criminal charges in Japan if there is a causal relationship between the death of a patient and health care. Inpatients who died unexpectedly during their hospitalisation presented a challenge to the decision making by the physicians as to report the death or not (Kamishiraki & Maeda, 2010).

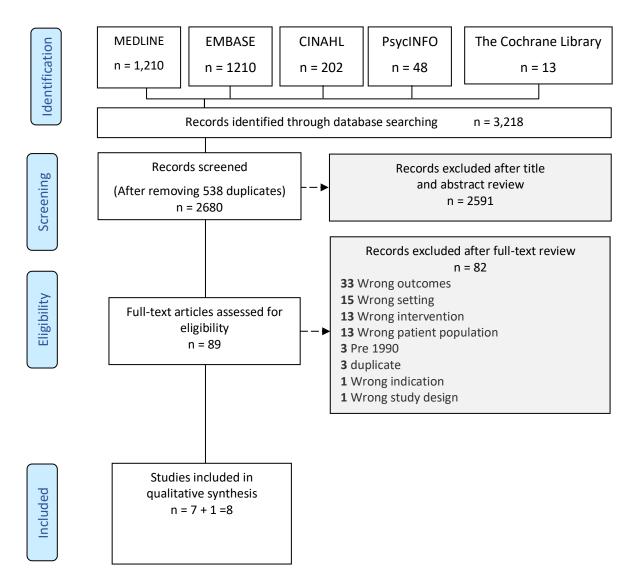


Figure 3.1: PRISMA-ScR guidance flow diagram of eligible studies identified, screened and included in the current study

3.4 Discussion

3.4.1 Summary of key findings

This scoping review examined eight studies, published between 2003 and 2016, that described the potential for under-reporting, or the inappropriate reporting of deaths which, in fact, met the criteria for reporting to the coronial services. There were three quantitative papers, four qualitative papers and one discussion paper identified as eligible for review.

The key findings of the review indicate that there is an under-reporting of reportable deaths. This is due to a lack of understanding or clarity regarding the legal requirements for reporting particular groups of deaths, namely those that meet the criteria for reporting to the coroner by clinicians.

The potential negligence in care delivery and any associated contribution to death was another of the key findings, with discussion about attitudes of the clinicians to reporting deaths that meet the reportable criteria. This demonstrates a lack of understanding of the legal requirements to report deaths, with clinicians merely thinking the reporting processes are optional (Drake et al., 2016; Kamishiraki & Maeda, 2010; Maeda et al., 2003; Maeda et al., 2010). The terminology of *unnatural cause of death* and *unexpected deaths* (during healthcare), which define the eligibility criteria for a reportable death, can also be ambiguous and confusing to clinicians and requires further definition (Gill et al., 2014; Madiba et al., 2011).

Of note, the key findings identified in the papers that were excluded during the scoping review are also presented. They are presented, as they also provide valuable insights and information into other areas of patient safety and medico legal investigation of deaths. Patient safety is a broad concept and is defined by the World Health Organization as, "efforts to minimise preventable harm to a patient during their interaction with health care service" (WHO, 2019). There is a great opportunity for the identification of potentially preventable events in healthcare delivery that may contribute to deaths of patients, and a review of these factors can inform patient safety.

There were six papers excluded, as they did not refer to a clinician's understanding of reporting requirements for inpatient deaths for medico-legal investigation. Bohensky et al. (2006) describe the development of the Clinical Liaison Service (CLS) to improve patient safety and increase links between medical and legal practitioners. The paper also refers to system error (medical error) as a cause of adverse events and preventable deaths. It is posited by Bohensky et al. (2006, p. 26) that the opportunity to augment the reciprocal exchanges between legal and clinical practitioners will enhance the respective groups' understanding of system reviews, "Coronial investigations offer a wealth of health information from which preventable deaths and systems failures can be identified".

Others also refer to the impact that CLS has had on the coronial review of healthcare related deaths (Ibrahim et al., 2009). Similarly, Cunningham (2018) refers to the enhancement of the preventative focus of the coroner by applying a different approach to the investigation process. Moreover, it has been highlighted that patient safety can be influenced by a changed investigation focus, given that deaths that are related to health care delivery are among the ten most common causes of death (Ibrahim et al., 2009). The value of the autopsy to determine cause of death and any missed diagnosis was the focus of another six of the papers identified but that were excluded from the review. This was also in the context of litigation and the occurrence of medical error. Swaro and Adhiyaman, (2010) described the use of either clinical or coronial autopsy to corroborate the antemortem diagnosis of older medical patients in Wales, in the United Kingdom. In their German study, Madea et al. (2009) concluded that the value of autopsy in determining potential medical malpractice due to misdiagnosis and its contribution to death is invaluable for informing patient safety. Sakai et al. (2010), in their retrospective review of 3,355 inpatient deaths in Japan, noted that there were 291 (8.7%) cases where the occurrence of medical adverse events at the time of death was identified on autopsy. There were more diagnostic errors (missed or misdiagnosis of patient conditions) recognised than performance errors following forensic autopsy. This group is also noted to make up to 30 % of medical injury claims. The legislation relating to medical staff in Japan states that unusual deaths are reported to the police and forensic autopsies are conducted (at the School of Medicine), except in five major cities who have medical examiners. Generally, in Japan, forensic autopsies are undertaken after being requested by the police (Sakai et al., 2010).

The coronial recommendations process and the use of coronial data as a resource to inform patient safety and a description of the investigation process within the coronial jurisdiction was noted within another seven of the papers. These papers focussed on the coronial recommendations that had been made following death investigations (Burrell, 2014). Pudney and Grech (2016) describe how inquest data could potentially be used to inform patient safety, with the identification of 11 recurrent themes within the factors that contributed to death in the 113 cases that were analysed from South Australia. Reference was also made, in this study, to the underuse of data that was generated from the coronial findings, in the form of recommendations as part of the preventative role of the coroner (Pudney & Grech, 2016).

Claridge et al. (2008), in their exploratory study, analysed the findings from 12 semi-structured interviews with senior managers who had operational responsibilities within the NHS in the UK. It was noted that there was a lack of clarity within the organisation as to the management of any coronial recommendations that were received. This included the identification of the lack of a safety culture within the organisations to ensure organisational level lessons could be learned, together

with ongoing communication of this perceived source of underutilised information to inform patient safety. There was also a lack of comprehension of the role of the coroner within the healthcare system and the potential contribution of the coroner to patient safety Claridge et al, (2008). Curran and Taylor (2012) described the use of coroners' recommendations, specifically within the Emergency Department (ED), and the usefulness of coroners utilising the NCIS database. The way in which the recommendations aim to prevent future deaths were identified and recommendations were made that they should be used more broadly, to look at system issues, not just changes to policies in response to individual cases (Curran and Taylor, 2012).

3.4.2 Strengths and limitations

Scoping reviews do not strive to evaluate the quality of evidence that has been generated, which can be seen as a limitation (Arskey & O'Malley, 2005). Limitations to this scoping review include the differences in terminology across the world when referring to medicolegal investigation, such as 'coroner' and 'medical examiner', as roles and expertise may differ across countries. Similarly, there are differences with respect to the use of autopsy to determine cause of deaths, from the clinical perspective, versus its use in the determination of the cause of death, from a legal viewpoint. The low number of studies that were included is another limitation of the scoping review. Strengths of the scoping review, however, include the identification of a gap in the contemporary literature regarding clinicians' understanding of reportable deaths.

3.4.3 Implications for clinical practice and research

Ongoing implications for clinical practice and future research include further exploration of clinicians' understanding of their requirements regarding deaths that meet the criteria for reporting to the coroner. This includes determining what factors may cause confusion to clinicians regarding their reporting responsibilities. It may also be the opportunity to further clarify the criteria for reportable deaths and the presence of any perceived or actual barriers to the reporting process. Further research into the usefulness of the reporting data to inform the delivery of safe patient care would be beneficial.

3.5 Conclusion

This chapter described the process undertaken to perform a scoping review to examine the available literature on clinicians' practices and understanding of the reporting requirements for inpatient deaths, and the role of the medicolegal death investigation in patient safety.

The key findings of the studies identified in this review indicated that there is under-reporting of inpatient deaths that meet the legal requirements of reporting to coroners and medical examiners. The possibility of medical negligence being detected is one reason. There have been several

published Australian studies that demonstrate how external review of deaths in health care, such as by the coronial services, has been informative to patient safety. With regards to deaths which meet the reportable criteria, there is a lack of consistency. This indicates a deficiency in the understanding of clinicians as to which deaths require reporting to the coroners, which can result in underreporting by this cohort.

Chapter 4 will describe the methodological approach and methods used to conduct a series of studies.

Chapter 4 Methods

4.1 Introduction

This chapter will comprise a description of the methodological approach selected and the methods applied to conduct a series of studies to address the following research objectives: to examine the frequency and characteristics of deaths at one health care facility during one calendar year; to examine factors that impact on clinicians' decisions to report a death to the Coroner, and, to determine clinicians' knowledge of the legal requirements on reporting a death in the health care facility to the Coroner.

To address these research objectives, the following studies were conducted:

- Study 1. Retrospective audit of clinical notes
- Study 2. Semi-structured key informant interviews and clinical scenarios
- Study 3. In-depth review of unreported deaths that meet the reportable death criteria as identified in Study 1.

This chapter will be divided into two parts: Part 1 describes the research methodology, and Part 2 describes the methods applied and the processes undertaken in each of the three studies conducted.

4.2 Part 1: Methodology

The methodology selected for this research was a mixed methods research strategy, using an explanatory sequential design (Creswell & Plano Clark, 2018). Mixed methods research, as a strategy, dates back to the 1950s and was further developed in the 1980s through to the present times, with ongoing evolution of its associated language and concepts. (Maxwell, 2016). Since the 1990s, there has been a further evolution, which has seen a shift from convergence to integration of qualitative and quantitative data (Maxwell, 2016).

The mixed methods approach is defined as the collection of both quantitative and qualitative data, in distinct phases, with the integration of these data to produce research findings. This allows for data integration of the same phenomenon using different methods, which is referred to as triangulation. There are several levels where data integration may occur in mixed methods research: at the design level; at the data collection level; at the data analysis level; or, at the reporting/interpretation level (Doyle et al, 2016).

The strength of mixed methods is that it allows for increased confidence in the findings since the data is corroborated from several sources (Creswell & Plano, 2018; Guetterman et al, 2015). This approach generates broad knowledge of the subject matter under examination (Tashakkori &

Teddlie, 2003b). Limitations to the research strategy include that it may be time consuming and require expertise in both qualitative and quantitative methods (Holloway & Galvin, 2017; Tashakkori & Teddlie, 2003a).

In the current research study, the quantitative analysis of data on deaths at the health care facility in Study 1 informed the sample for the qualitative analysis for Studies 2 and 3. Specifically, the results of the quantitative analysis of deaths informed the development of the questions for the interviews and the focus of clinical scenarios in Study 2. The results from Study 1 also informed the cases of unreported deaths identified for in-depth review in Study 3.

4.2.1 Explanatory Sequential Design

The explanatory sequential design describes how research is conducted in two phases (Creswell & Plano Clark 2018). In phase one, quantitative data is collected and, in phase two, qualitative data is collected. Phase two data is then integrated with phase one data to explain the results.

In step one, quantitative data were retrospectively collected from medical records. Data were extracted and entered as a series of categorical variables in the Statistical Package for Social Sciences (SPPS), to generate a unit record dataset. Data analysis occurred in step two, using bivariate descriptive statistical techniques and the chi-square test. In steps three and four, data from steps one and two were used to inform the development and conduct of the semi-structured interview and clinical scenarios. In step five, the responses to the semi structured interviews and clinical scenario were thematically analysed, using a content analysis. In step seven, data from steps one and two were used to identify and analyse the sub-set of deaths where a reporting error was made. Finally, in step eight, the integration of the results of both the quantitative and qualitative data occurred, with identification of discussion points and implications for practice. There was connection of the phases of data collection by utilising some of the findings from the quantitative data to inform the development of both the interview questions and the clinical scenarios, with integration of the outcomes within the discussion.

A visual representation of data collection and analysis is shown in Table 4.1.

Table 4.1 Visual model of Mixed Methods Explanatory Sequential Design applied to the current study

Steps	Procedure	Product
STUDY 1		
Step 1: Quantitative		
Data Collection	 Retrospective audit of clinical records for all deceased patients over 12 months. 	 Categorical data entered into a statistical program (SPSS).
Step 2: Quantitative	- Data summaries	- Bivariate descriptive
Data Analysis	- Chi-square	statistical analysis of deaths with and without a reporting error. - Chi-square analysis of
		deaths with and without a
STUDY 2		reporting error.
Step 3: Qualitative		
Interview protocol development	Development of semi structured interview questions informed by quantitative data	Interview instrument.Clinical scenarios.Recruitment strategy.
Clinical scenario development	 Recruitment of clinical staff by means of existing forums 	
Step 4: Qualitative	_	
- Data Collection	Conduct of key informant interviews.Conduct of clinical scenarios.	Interview audio files and transcripts.Scenario responses.
Step 5: Qualitative		
Data Analysis	Content analysis of interviews. Content analysis of clinical scenario responses.	 Identification of themes within recorded interview. Identification of consensus in decision making regarding the clinical scenarios and if they meet the reportable criteria. Analysis of any comments made in reference to the decision making to be themed for analysis.
STUDY 3		
Step 6: Quantitative	Cases identified from Study 1:	- Case information extracted
Data Collection	retrospective audit of clinical records.	from SPSS dataset.
Step 7: Quantitative Data Analysis	 In-depth review of deaths using content analysis. 	 Identification of characteristics and themes among deaths with a reporting error.
INTEGRATION Step 8: Integration of results	 Interpretation and explanation of quantitative and qualitative results. 	DiscussionImplicationsFuture research

Note. Adapted from Creswell and Plano Clark, 2018.

4.3 Part 2: Methods

4.3.1 Setting

The site selected for the study was a tertiary referral hospital in metropolitan Melbourne, Victoria Australia. Bed capacity consists of over 980 beds, across three separate sites, all offering a variety of acute and sub-acute services. The facility provides healthcare, health professional education, and research and is a long-established public health service. The services offered by the facility include a comprehensive range of acute, sub-acute, mental health, outreach and outpatient services to the local community. There are also several state-wide, specialist services offered. Maternity and neonatal services are not provided by the hospital. Annually, there are over 100,000 inpatient admissions and over 90,000 presentations to the Emergency Department (ED) (Austin Health, 2015). These figures reflect the information for 2015, which contextualises the same year that the data for the study were collected.

This site was selected as it was convenient to the researcher in relation to knowledge of policies, processes and health care records management. It was also convenient in relation to access to records and clinicians, which were key data sources for this study. This knowledge was acquired from the researcher's current employment at the site.

4.3.2 Ethics and Associated Approvals

To conduct this study, ethics approval was required from both the health care service and the relevant institutional human research ethics committee, constituted in accordance with the National Health and Medical Research Council (NHMRC). Ethics approval is required for any research involving humans, to identify and outline mitigation strategies for risks posed by the research. Risk is defined by the National Statement on Ethical Conduct in Human Research July 2018 as the potential for harm, discomfort or inconvenience and includes the assessment of the likelihood and severity of harm (NHMRC, 2018).

Following completion of the required documentation and submission to the health service low risk ethics committee, the committee identified an issue that required resolution before the research could commence, namely the management of significant underreporting by specific clinical unit or individual. An escalation /reporting process was implemented collaboratively with the Chief Medical Officer should the issue off performance be identified.

In addition, prior to approval by the health service, a letter of endorsement from the Coroners Court of Victoria was required. The letter outlined support for the researcher's study and any other support that may have been required (see Appendix 4.1).

The support of both the Chief Medical Officer (CMO) and the Chief Nursing Officer (CNO) was obtained to ensure that the researcher had an avenue of discussion when auditing the medical records or when performing the interviews, if any issues were identified.

If there had been the discovery by the researcher of individual sub-optimal clinical performance pertaining to review and subsequent reporting of deaths to the Coroner, this would have been raised in a de-identified manner, with the CMO and the CNO. Similarly, a discussion was held with the Corporate Counsel of the health service regarding a process should an incident of sub optimal performance become apparent. This met the requirements of the ethics committee

There was potential for an issue to have been identified in the retrospective audit of clinical notes of deceased patients (Study 1) or in the semi-structured interviews (Study 2). Ethics approval for all three studies was obtained from the health services low risk ethics committee in August of 2015 (LNR/15/XXX28) (see Appendix 4.2). Approval was also obtained from Monash University Human Research Ethics Committee in August of 2015 (see Appendix 4.3).

4.3.3 Data Storage

All hard copy data was stored in a locked filing cabinet in the secured office of the student researcher and was accessible only to the researchers named on this project. Electronic data was stored in a restricted folder on a password protected computer with the passwords known to the researcher. The data associated with, and generated for, the research will be stored for seven (7) years in accordance with the National Statement on Ethical Conduct in Research Involving Humans guidelines. Seven (7) years after the completion of the study, all paper records and electronic files will be destroyed and deleted.

4.3.4 Data Use

De-identified aggregated data has been used for publication in peer-reviewed journals and at conferences. However, individual level data was not used or shared. There were no safety risks identified in the study, with minimal likelihood of any form of psychological or physical distress to the participants.

4.4 Study One: Retrospective Audit of Clinical Notes

4.4.1 Additional Ethics Considerations

In addition to the ethics considerations outlined in *Section 4.3.2 Ethics and Other Approvals*, it was determined that Study 1, Retrospective Audit of Clinical Notes, was low risk, as the data being collected was from the scanned medical records of deceased patients. The primary considerations were the confidentiality and data storage concerns. No consent was required, as the data collected was audit in nature. Data were recorded in a de-identified manner directly into a Microsoft Excel

spreadsheet. All hard copy and electronic data were stored in a locked filing cabinet in a locked office. Electronic data were stored in a restricted folder on a password computer that was only accessible to the researchers named on the project.

4.4.2 Research Design

The research design was a retrospective case series study of the population of inpatient deaths at one heath care facility during one calendar year. A retrospective case series review is an objective and structured method of reviewing clinical notes that is widely used. (Hogan, 2015). The study population (inpatient deaths) was followed over time to determine whether or not the outcome of interest (inpatient death reported to the Coroner) occurred and whether the factors of interest (deceased demographics, death details, and reporting details) were associated with the outcome.

4.4.3 Data Sources

The data sources for this study comprised (i) the health care facility's electronic clinical information system and (ii) the deceased patient's medical record.

(i) Electronic clinical information system

The clinical information system is a data warehouse where each episode of information is collated from a variety of clinical information sources. The data can be filtered to determine variables, such as separation destination (for example, nursing home, home or death), admission and discharge clinical units providing care for the inpatients, date and time of admission and discharge /death, and other data, such as costing information. The warehouse data are updated each night and are used predominately for reporting data, not for monitoring, therefore are not regarded as "real-time" data.

(ii) Scanned medical records

Each individual clinical note of the patient is scanned, on the patient's discharge from the facility, by hospital information services staff. These are then able to be accessed by staff via the hospital's information technology platform, which is password protected and has its access able to be tracked. Filtering of the notes is available for each patient episode (or admission).

4.4.4 Definitions

Death

The definition of death, as per Section 41 of the Human Tissue Act 1982 (Vic) is as follows.

A person is deemed to have died when there is:

- (i) irreversible cessation of circulation of blood in the body of the person; or
- (ii) irreversible cessation of all function of the brain of the person.

For the purpose of this study, death was defined as an inpatient separation with documentation of discharge destination as death.

Inpatient

An inpatient admission is described by the clinical research data warehouse schema guide as an episode of care from admission to discharge (Austin Health, 2018).

Reportable Death

A reportable death was defined in accordance with the *Coroners Act 2008* (Vic). According to the Act, the death of a person is reportable if:

- 1. the body is in Victoria; or (b) the death occurred in Victoria; or (c) the cause of the death occurred in Victoria; or (d) the person ordinarily resided in Victoria at the time of death- and the death was a death specified in subsection (2).
- 2. For the purposes of subsection 1, the deaths are:
- (a) a death that appears to have been unexpected, unnatural or violent or to have resulted, directly or indirectly, from an accident or injury; or a death that occurs
- (b) (i) during a medical procedure or (ii) following a medical procedure where the death is or may be causally related to the medical procedure, and a registered medical practitioner would not, immediately before the procedure was undertaken, have reasonably expected the death; or
- (c) the death of a person who immediately before death was a person placed in custody or care; or
- (d) a death that occurs in Victoria if a notice under section 37 (1) of the Births, Deaths and Marriages Registration Act 1996 has not been signed and is not likely to be signed. (*Coroners Act*, 2008 (Vic).

4.4.5 Eligibility Criteria

The inclusion criteria for the study comprised:

- 1. a person admitted as an inpatient of the heath care facility at the time of their death; and
- 2. a death that occurred during the study period calendar year.

Cases were excluded from the study if it was established that a person was deceased prior to arriving at the health care facility or prior to being admitted to the health care facility.

4.4.6 Case Identification

Inpatient deaths that occurred at the health care facility during the study period were identified using the electronic clinical information system to determine which inpatients were deceased. The

system was accessed electronically and the inpatient separations where the destination was documented as death were copied into an excel spreadsheet for analysis.

The scanned medical records of the identified cases were then accessed and reviewed to ensure that the case met the inclusion criteria of an inpatient death.

4.4.7 Variables

The selection of independent variables was informed partially from the convenience of data accessibility, to illustrate the patient population of the healthcare facility. These variables, such as those contained in the demographic information, were used to illustrate the population of the healthcare facility. This also allowed the opportunity to examine the healthcare factors, as per clinical units caring for the patients, and to investigate whether these influenced the death reporting

The outcome was defined as whether or not there was an error in reporting an inpatient's death to the Coroner by the clinician in the health service.

This created two no-error categories and two categories where errors were identified:

- (i) reportable death and reported to the Coroner; or not reportable death and not reported to the Coroner, and,
- (ii) reportable death and not reported to the Coroner; or not reportable death and reported to the Coroner.

An error was determined by considering whether the cause of death met one of the criteria of a *reportable death* defined in the *Coroners Act 2008* (Vic); and whether the death was reported to the Coroner.

The dependent and independent variables are shown in Table 4.2.

Table 4.2 Study dependent and independent variables and categories

Variable	Category
ADMINISTRATION	
ID number	Digit unique identifier
DEPENDENT VARIABLE	
Reporting Error Code	1 = No reporting error
	2 = Reporting error
Reporting Error Categories	1 = Reportable Death AND Reported to CCOV
	2 = NOT Reportable Death AND NOT Reported to CCOV
	3 = Reportable Death AND NOT Reported to CCOV
	4 = NOT Reportable Death AND Reported to CCOV
INDEPENDENT VARIABLES	
Demographics	
Age group	1 = <30 years
	2 = 30-39 years
	3 = 40-49 years
	4 = 50-59 years
	5 = 60-69 years
	6 = 70-79 years
	7 = 80+ years
Gender	1 = Female
	2 = Male
Death Details	
Ward/Clinical Unit	1 = Cancer and Neurosciences
	2 = Surgery
	3 = Medicine
	4 = Continuing care
	5 = Other
Time of death	1 = 2400-06:00
	2 = 06:01-12:00
	3 = 12:01-18:00
	4 = 1801:2400
Day of death	1 = Weekday
	2 = Weekend
Length of stay (for last admission)	1 = 0-9 days
	2 = 10-19 days
	3 = 20+ days
Departing Dataila	
Reporting Details	4. Consultant
Level of experience of clinician	1 = Consultant
reporting death	2 = Hospital Medical Officer
	3 = Registrar 4 = Resident
	4 = Resident 5 = Intern
	J = 111(BIT)

Documentation of communication 1 = Yes

with CCOV

2 = No

Reportable criteria

1 = Not Reported

2 = Unexpected death

3 = Violent or unnatural

4 = Accident or injury

5 = Medical procedure

6 = In care

7 = No death certificate / cause of death

4.4.8 Data Collection

Deaths that met the inclusion criteria were systematically reviewed using a structured audit tool (see Appendix 4.4). This structure was applied to record information for each eligible case into a Microsoft Excel spreadsheet, to generate a unit record dataset. The dataset was exported to SPSS for data preparation and analysis.

4.4.9 Data Preparation

Univariate and bivariate preliminary analyses were conducted using SPSS to identify missing or miscoded data and identify the frequency of cases in each category. Where data were missing or appeared to be miscoded, the scanned medical record for the case was re-reviewed. Where categories had less than five observations, consideration was given to collapsing categories while ensuring the variable remained meaningful.

4.4.10 Data Analysis

The variables generated for the case series study were categorical and related to the deceased's demographics, the details of the death and the death certification. To test whether the variables in these factors were associated with an error in reporting the death to the Coroner, a combination of descriptive and analytic statistical tests were conducted.

Descriptive statistics, specifically cross-tabulations, were performed between all independent variables (e.g. age group, gender, ward, length of stay, etc.) and the dependent variable (reporting error). These cross-tabulations were conducted to examine the frequency and proportion for each category of the independent variable. A chi square test was then performed to determine whether there was a statistically significant difference between the error in reporting and no-error in the reporting groups (Schneider, Whitehead, LoBiondo-Wood, & Haber, 2014). Further cross-tabulations were conducted between each independent variable and the dependent variable (all categories) to identify reporting and non-reporting patterns.

4.5 Connection of the Qualitative and Quantitative phases

The information that was obtained from the data collection and early analysis informed the development of the clinical scenarios and semi-structured interview questions.

4.6 Study2A Key Informant Interviews

Study 2 was subdivided into two components: Study 2A key informant interviews with clinicians; and Study 2B clinical scenarios, completed by clinicians and practising coroners.

4.6.1 Additional Ethics Considerations

In addition to the ethics considerations outlined in *Section 4.3.2 Ethics and Other Approvals*, Study 2A included recorded interviews and completion of clinical scenarios (paper-based). This required consideration of additional ethical issues, specifically privacy, informed consent and data storage. Prior to commencement of the interviews, each participant was given an explanatory statement. The explanatory statement described the study, including the aims and the options for withdrawal from the study at any time during the data collection. No participants took up the option to withdraw. There was opportunity for any questions pertaining to the study to be raised at this time. Signed consent was then obtained for both the semi-structured interviews and the completion of the clinical scenarios. The interviews were conducted in a private office space.

All interviews were audio recorded onto the researcher's password protected laptop computer and saved as a coded identity. To maintain confidentiality, each of the participants were assigned a number and code to designate their profession and experience, for example: 1 RNY1, (Registered Nurse Year 1), 1 DRY2 (Doctor Year 2). The data were stored on a password-protected computer. There was no other identifying information attached to the data.

4.6.2 Research Design

The research design was a qualitative interview study. Interviews are a commonly used and popular tool for qualitative data collection, and there are a variety of types of interview processes that can be used. For this study, a semi-structured interview format was selected. This format is best used when the researcher has the knowledge of what they want to determine but is uncertain of the expected response (Morse, 2010). The researcher uses the broad topic that they are interested in to guide the interview. This broad focus allows for analysis and comparison of the participant's responses whilst still allowing for some flexibility in the information shared.

This type of interview also allows for participants to have the flexibility to tell a "story" to demonstrate key components of their answers, and adds depth, as well. Similarly, the use of open questioning techniques enhances the depth of the responses (Jirojwong & Welch, 2011, Schneider et al, 2014).

4.6.3 Participant Recruitment

A convenience sample of participants (clinicians) was accessed via a variety of clinical forums, including the weekly surgical audit review, unit mortality and morbidity meetings and grand rounds. Clinicians at other forums, such as clinical review panels where cases are reviewed by a multidisciplinary group, were also included. In hospitals, deaths are predominately reported to the coroner by the medical staff, but it is a requirement within the *Coroners Act, Vic (2009)* that any person who believes that a death meets the reportable criteria has a responsibility to report the death, hence the inclusion of nursing staff. Nursing staff can also influential in the recognition of reportable deaths and the subsequent reporting to the Coroner by medical staff. Following a description of the study outline, a verbal expression of interest was called for and then followed up with further information.

In this context, convenience sampling indicates non-probability sampling, in which the participants are sampled as they are "convenient" sources of data for the researchers, i.e., they are available and able to participate. Support was also given by the Chief Medical Officer and the Chief Nursing Officer to allow the researcher access to these forums. There were no exclusion criteria for participants.

There was also an opportunity for practising Victorian coroners to complete the clinical scenarios at a national conference. The researcher was discussing the study with one of the coroners who offered to complete the scenarios. This then snowballed to the other coroners in attendance, resulting in completion of the scenarios by the group.

4.6.4 Instrument Used for Interviews

The interview instrument was developed (see Appendix 4.5). The questions were designed to examine the clinicians' understanding of the criteria for reporting an inpatient death to the Coroners Court of Victoria (CCOV) and why death investigation is required. Questions were also included to identify barriers or enablers to the death-reporting process, whether internally or externally, to the health care facility. A pilot of the questions occurred with a clinician who was working within the clinical governance unit, to determine their face validity. There was no refinement of the questions required after this review.

4.6.5 Data Collection

Development of the interview questions

The interview questions were designed to probe and identify clinicians' understandings of deaths, in particular, those which met the criteria for reporting to the CCOV. The interviews also provided an opportunity to explore several aspects of reporting, including the reasons why participants believed reporting was required and if there were any identified enablers or barriers, internally or externally,

to this process. The semi-structured interview approach enabled the participants to make any further comments, prior to the interview being completed.

Procedure

Each interview was conducted face-to-face at a mutually convenient time and location for the participant, in a quiet and private area away from distractions. The researcher made general conversation prior to the interview commencing, to put the participant at ease. Moore, (2012) describes the challenge of research positionality whereby the researcher is seen as an "insider" to the group or "outsider" to the group and the ability to separate the roles. Although the participants were all known to the researcher, as they were employed in the same health care facility, the researcher had no line of authority over them, therefore establishment of rapport was not difficult

The explanatory statement was provided to each participant and time was allowed for the document to be completely read (see Appendix 4.6). Participants were reminded of the study aims and the option for withdrawal at any time. An opportunity for clarification of any details was also offered by the researcher prior to commencement of the interview. Further explanation was provided regarding the audio recording of the interview and how the data would be managed and stored.

The participants were each given a consent form to read, sign and date and return to the researcher. There was reinforcement that the interview would be transcribed at a later time for review by the researcher and supervisors, as required. When the participants were ready to begin the interview, the recording and questions were commenced.

Data Recording and Transcription

Each interview was audio recorded using the recording capability on the researcher's lap top computer. The recordings were saved in a password protected drive for transcription. Following the interviews, each recording was transcribed by a transcription service into a Word document, to allow for analysis. The researcher listened to each recording immediately after the interview, to ensure that it was audible and able to be understood easily. This also allows for immersion in the data, to ensure familiarity with the entire content (Braun & Clarke, 2006). The recordings were professionally transcribed, verbatim, into a Microsoft Word format. Each of the interviews was coded as N1, N2, D1, or D2 (Nurse 1, Nurse 2, Doctor 1, Doctor 2, etc.) depending upon their professional group, to maintain confidentiality.

Field notes were taken by the researcher after each interview, to summarise how the interview had progressed. These notes were reviewed whilst the researcher was listening to the transcripts, to assist in "setting the scene" and to support the identification of any nuances during the recording.

Once the recording had been transcribed, the transcript was again checked against the recording for accuracy.

4.6.6 Data Analysis

Data Preparation

The transcripts were reviewed and any gaps in the documentation were checked and completed by repeated listening to the recordings. To prepare for the analysis, each of the questions was entered into a table and numbered. The responses were recorded as D1, N1, etc., for the main theme of the response. Each of the interviews was conducted face-to-face and was audio recorded, and the content of each interview was transcribed. Each of the transcripts was then thematically analysed, following Braun and Clarkes' (2006) procedure as a guide. In this procedure there are six steps outlined to ensure a systematic method of analysis (Braun & Clarke, 2006). The six steps are outlined in Table 4.3

Analytic Procedure

Table 4.3 Braun and Clarke's (2006) thematic analyses guidelines

Steps in Guidelines	Descriptors
Step 1. Familiarisation with the data	In the first step the researcher became fully immersed in the data by reading and rereading the transcripts of the recording and listening to the audio recording multiple times to assist in becoming familiar and embedded in the data.
Step 2. Generating initial codes	Broad discussion points within the data were identified and these preliminary codes or words gave some prompts as to the information obtained.
Step 3.Searching for themes	In this step the data was split according to identified themes and subthemes and how they relate to each other, and there was some integration of the themes and the code words at this time by the researcher.
Step 4. Reviewing themes	Further review of the data to identify the ongoing appropriateness of the themes occurred by the researcher.
Step 5. Defining and naming themes	Further review of the themes and definition of any subthemes with ongoing analysis. For example the theme "Lack of awareness (of reporting requirements) with subthemes such as "accountability" and "blame"
Step 6. Producing the report	In the final stage, the themes as they were identified were described, grouped and

Steps in Guidelines	Descriptors
	analysed in full, supporting the requirements to
	provide evidence to answer the research
	questions.

Note. Adapted from Braun and Clarke (2006).

4.6.7 Reflection

Reflection was important during this research project, particularly within this interview phase. As already stated, after each of the interviews had occurred, the researcher wrote notes of any thoughts or impressions that were presented by the participants during the interview process. Listening to the recordings immediately after the interview also allowed the researcher the opportunity to modify the way questions were presented to the participants, and to review pauses for answers during the interview. There were no changes made to the actual questions being asked, but there was some modification to the technique in delivering the questions by the researcher. This included allowing more time for the participant to consider and respond to the questions and providing non verbal feedback.

4.7 Study 2B: Clinical Scenarios

4.7.1 Additional Ethics Considerations

In addition to the ethics considerations outlined in *Section 4.3.2 Ethics and Other Approvals*, Study 2B included completion of clinical scenarios (paper-based). As for the collection of data for the semi structured interviews, the primary considerations for the clinical scenarios were confidentiality and data storage. Informed consent was obtained prior to the interviews with the clinicians, for both the interviews and the completion of the clinical scenarios. The data collected from the scenarios were collected and entered onto an Excel spreadsheet. All hard copy and electronic data were stored in a locked filing cabinet in a locked office. The computer used for the study was password protected and accessible only to the researchers named on this project. As noted previously, if there were clinicians identified as performing at a sub-optimal level, this would have been raised with the CMO/CNO for their review and information.

4.7.2 Research Design

The clinical scenarios were "real life" situations that were used to evaluate the clinicians' understanding of deaths that met the reportable criteria. The scenarios were presented as a structured tool, with the opportunity for the participants to comment on their decision making.

4.7.3 Participant Recruitment

See Section 4.3.5.3 Participant Recruitment.

4.7.4 Clinical Scenario

Ten clinical scenarios were developed from a combination of information obtained during the retrospective audit of medical records, data from sentinel event reports and AIHW (Chapter 6) and the researcher's knowledge of commonly occurring deaths within the health care setting. To ensure that each of the scenarios was accurate in representing a cross section of the deaths in health care, and to confirm this face validity, an experienced Victorian Coroner reviewed each clinical scenario to determine "definitively" which deaths met the reportable criteria (Schneider et al, 2014).

4.7.5 Data collection

Each of the clinical scenarios were also completed by the 22 clinicians complementing the data that was collected during the semi-structured interviews.

Following the semi-structured interview, participants were given a hard copy of ten clinical scenarios. For each scenario, the participants were asked to record whether they believed that the death described met the criteria to be reported to the Coroner. If the death was thought to be reportable, the participants were given the opportunity to document any comments regarding their decision-making process. This included rationale as to why the clinician believed the death met the reportable criteria. Each of the participant's answer sheets were coded the same as for the interviews, as N1, N2, etc.

The clinical scenarios were also completed by seven of the practising Victorian Coroners as an expert panel, to obtain their opinions on whether the death was reportable and any other accompanying comments and the rationale for their decision making. The Coroners were designated as C1, C2, etc. and this information was reviewed in conjunction with the answers and comments offered by the 22 clinicians.

The participant's assessment of each of the ten scenarios and comments was recorded in a Microsoft Excel spreadsheet.

4.7.6 Data Analysis

The participants were asked to nominate if they believed that the death met the reportable criteria and, if so, their rationale for the decision. The data was collected as *yes* (reportable criteria) or *no* (not reportable criteria). Any comments made regarding the scenarios were thematically analysed, similar to the process for the interview data.

4.7.7 Sources and control of bias

At no time during either the performance of the interviews or during the completion of the scenarios did the researcher offer any opinion or feedback to the participants. The researcher had no direct line management over any of the participants who were involved in the study, although

they were all known to the researcher. Selection bias was avoided by the voluntary recruitment process for the participants.

4.8 Study 3: In-depth Review of Deaths where a reporting error was identified.

4.8.1 Additional Ethics Considerations

The ethical considerations of previous phases of the study, regarding confidentiality and data storage, were maintained for Study 3.

4.8.2 Research Design

A qualitative, in-depth case review was performed for the cohort of deaths identified for Study 3 from the data collected in Study 1 (i.e., retrospective audit of clinical records). In this group of deaths, a reporting error was identified and there was further thematic analysis of this group of deaths.

4.8.3 Data Collection

Within the group of inpatient deaths identified in Study 1, there was a sub-group of deaths where a reporting error was identified, and these deaths required further review.

4.8.4 Data Analysis

The analysis of the cases identified in Study 3 followed the same process as for Study 1. The data were categorised under the reportable criteria defined in the *Coroners Act 2008* (Vic.).

4.9 Chapter Summary

This chapter described the methodological approach and methods selected and applied to conduct the current study. A description of the mixed methods research strategy of explanatory sequential design was provided. This research strategy entails the collection and analysis of quantitative data followed by qualitative data collection and analysis.

This was followed by a description of the quantitative methods applied in Study 1 to conduct a retrospective case series study, using data collected from scanned medical records with an audit tool and then statistically analysed. The qualitative methods applied to collect and analyse data generated from semi-structured interviews and clinical scenarios with clinicians were also described in study two. These included the application of thematic analysis. Thematic analysis was also undertaken following an in-depth analysis of the cohort of deaths identified as having a reporting error, study three).

Chapters 5 and 6 will describe the results of both the quantitative and the qualitative data collection and analysis respectively. Specifically, Chapter 5 will comprise the results and discussion of study 1, the retrospective medical record audit, and Chapter 6 will report the results and discussion of the thematic analysis of the semi-structured interviews and clinical scenarios in study 2.

Chapter 7 will present an in- depth discussion of the findings and results of the cases determined in study 3 where there was a reporting error identified. The final chapter, Chapter 8 will describe the recommendations and implications for practice that have been identified as a result of this study.

Chapter 5. Results and Discussion – Study1 Retrospective Audit

Let whoever is in charge keep this simple question in her head (not how can I always do this right thing myself, but) how can I provide for this right thing to always be done? Florence Nightingale

(1859/1946)

5.1 Introduction

This chapter presents the results of Study 1, the retrospective audit of clinical notes, and the findings will be discussed. These results and discussion examine the frequency and characteristics of deaths at one health care facility during one calendar year. Study 1 data was collected from the retrospective audit of the medical records of inpatients who had died in the study healthcare facility. This chapter is arranged as follows. Firstly, the stratification of the data is described, according to whether the correct reporting process was followed or not. Secondly, the findings of the audit are presented by the demographic details, the details of the death and of the reporting processes. These findings are then discussed within the chapter.

The data were stratified into two groups: 1) *correct reporting process*; and 2) *incorrect reporting process*. If the *correct reporting process* was followed, this indicated that the death met the criteria for reporting (i.e., was reportable) to the CCOV and was reported or that the death did not meet the reportable criteria and was not reported. The *incorrect reporting process group* indicated that the death did not meet the reportable criteria (i.e., was not reportable) but was reported to the CCOV or the death did meet the reportable criteria but was not reported to the CCOV. A descriptive statistical overview of the deaths is presented by:

- 1. Demographic characteristics, including:
 - the sex of the deceased patients whose medical records were reviewed; and
 - the age group of the deceased patients, sub-categorised into seven groups.
- Death details, which include:
 - the ward in which the patient was recorded as having died;
 - the time of death, as documented in the medical records;
 - the day of the week that the death occurred;
 - the length of stay, sub-categorised into five groups; and
 - the level of experience of the clinician who documented the patient's death.
- 3. Reporting details, which include:
 - any documentation of any discussion with the CCOV; and
 - the criteria under which the death may have been reported.

These data were also utilised to assist in the development of the clinical scenarios and the questions for the semi-structured interviews (Study 2). The results of this analysis are presented in Chapter 6.

5.2 Overview of Results

The audit identified 1,262 deaths that occurred at the health service during the one-year study period. Among these 1,262 deaths, the correct reporting process was followed or there was no reporting error in 1,198 deaths (94.9%). In the remaining 64 deaths (5.1%), there were errors in reporting to the CCOV or incorrect reporting processes occurred (Table 5.1).

Further analysis of these groups, by the deceased patient's demographics (age group and sex), showed that both groups ranged in age from 18 to 103 years. In the correct reporting process group, the median age was 79 years (interquartile range, 68-87 years) and in the *incorrect reporting process* group the median age was 77.5 years (interquartile range, 66.7-89 years). A chi square analysis was not completed for each age group due to the expected count being less than five in the three youngest age categories (< 30 years, 30-39 years and 40-49 years). Sub-group analysis of the deceased patient's sex showed that there was a slightly greater proportion of males than females in both groups (54.4% in the *correct reporting process* group and 53.1% in the *incorrect reporting process* group). The results of a chi square analysis showed that this difference was not statistically significant.

For the details surrounding a death, further analysis was conducted on the clinical area overseeing the care of the deceased at the time of death, time and day of death, and the deceased patient's length of stay in the health care facility. For the analysis of the clinical area overseeing the care of the deceased, most of the deaths, both in the *correct reporting process* group and the *incorrect reporting process* group, occurred in the *Cancer and Neuroscience* (48.7% and 34.4%, respectively) and in the *Medicine* (38.9% and 54.7%, respectively) areas. A chi square analysis could not be performed, due to the expected count in the areas of *Surgery*, *Continuing Care* and *Other* being less than five.

Further analysis of time of death showed that the highest number of deaths occurred in the 1201 to 1800 hours timeframe, for both the *correct reporting process* group (45.7%) and the *incorrect reporting process* group (56.3%). The results of a chi square analysis showed that there was no statistically significant difference observed between groups for time of death. Further analysis of day-of-death data showed that approximately 75% of deaths in both groups occurred on weekdays (73.0% for the *correct reporting process* group and 78.1% for the *incorrect reporting process* group). Results of a chi square analysis showed that there was no statistically significant difference between groups for the day that death occurred. Further analysis of the deceased patient's length of stay in hospital showed that the majority of cases in both groups were in the 0 to 9 days category (67.4% for the *correct reporting process* group and 70.3% for the *incorrect reporting process* group). There

were no statistically significant differences observed between the two groups for a deceased patient's length of stay.

For the reporting details, further analysis was conducted on clinician level of experience, evidence of discussion with the CCOV regarding reportability, and the criteria under which the death was reported. For clinician level of experience, the majority of the cases in the *correct reporting process* group were reported by the registrar/resident level clinician (72.2%), which was also reflected in the *incorrect reporting process* group (60.9%). No chi square analysis could be performed for the clinician level of experience, due to the count being less than five for the categories of *Consultant*, *HMO* and *Intern*. Further analysis of evidence of discussion with the staff of the CCOV showed that, in the majority of deaths, there was no discussion for both the *correct reporting process* group (83.4%) and the *incorrect reporting process* group (65.6%). Results of a chi square analysis showed that there was a statistically significant difference between groups for evidence of discussion with the CCOV regarding the reportability of death ($\chi^2(1) = 13.272$, p = 0.000*). Further analysis of the criteria for which death was to be reported showed that the majority of deaths in the *correct reporting process* group were categorised as *Not Reportable* (84.6%). The majority of deaths in the *incorrect reporting process* group were in the criteria for reportable deaths, due to the expected count being less than five in the *In care, Medical procedure*, and the *Violent/unnatural* groups.

Table 5.1 Overview of cases

	No Error F	Reporting	Error Rep	orting	Total	Results of Statistical
	to Co	COV	to CCC	VC		Tests
	n	%	n	%	n	
DEMOGRAPHICS						
Age Group						NB 3 cells (21.4%) have
< 30 Years	9	0.8	1	1.6	10	expected count less than
					10	5.
30-39 Years	17	1.4	1	1.6	18	
40-49 Years	52	4.3	3	4.7	55	
50-59 Years	105	8.8	6	9.4	111	
60-69 Years	160	13.4	6	9.4	166	
70-79 Years	282	23.5	19	29.7	301	
80+ Years	573	47.8	28	43.8	601	
Total	1198	100.0	64	100.0	1262	

		Reporting COV	Error Rep to CC	_	Total	Results of Statistical Tests
	n	%	n	%	n	
Sex						$\chi^2(1) = 0.041$, p = 0.839
Female	546	45.6	30	46.9	576	
Male	652	54.4	34	53.1	686	
Total	1198	100.0	64	100.0	1262	
DEATH DETAILS						
Ward						NB 3 cells (30.0%) have
Cancer and Neuroscience	584	48.7	22	34.4	606	expected count less than 5.
Surgery	89	7.4	4	6.3	93	
Medicine	466	38.9	35	54.7	501	
Continuing Care	53	4.4	2	3.1	55	
Other	6	0.5	1	1.6	7	
Total	1198	100.0	64	100.0	1262	
Time of Death						$\chi^2(3) = 7.347$, p = 0.062
2400-0600	277	23.1	8	12.5	285	
0601-1200	298	24.9	19	29.7	317	
1201-1800	547	45.7	36	56.3	583	
1801-2400	76	6.3	1	1.6	77	
Total	1198	100.0	64	100.0	1262	
						$\chi^2(1) = 8.28$, p = 0.363
Weekday	874	73.0	50	78.1	924	
Weekend	324	27.0	14	21.9	338	
Total	1198	100.0	64	100.0	1262	
Length of Stay						$\chi^2(2) = 0.544$, p = 0.762
0-9 days	807	67.4	45	70.3	852	
10-19 days	200	16.7	11	17.2	211	
20+ days	191	15.9	8	12.5	199	

		Reporting COV	Error Rep	_	Total	Results of Statistical Tests
	n	%	n	%	n	
Total	1198	100.0	64	100.0	1262	
REPORTING DETAILS						
Level of Experience						NB 6 cells (60.0%) have
Consultant	2	0.2	1	1.6	3	expected count less than 5.
НМО	3	0.3	-	-	3	
Registrar	865	72.2	39	60.9	904	
Resident	327	27.3	22	34.4	349	
Intern	1	0.1	2	3.1	3	
Total	1198	100.0	64	100.0	1262	
CCOV Discussion						$\chi^2(1) = 13.272$, p = 0.000
Yes	199	16.6	22	34.4	221	
No	999	83.4	42	65.6	1041	
Total	1198	100.0	64	100.0	1262	
Criteria for Reportable Death	1					NB 6 cells (42.9%) have
Not Reportable	1014	84.6	6	9.4	1020	expected count less than 5.
Unexpected	8	0.7	5	7.8	13	
Violent or unnatural	11	0.9	-	-	11	
Accident or injury	87	7.3	39	60.9	126	
Medical procedure	15	1.3	3	4.7	18	
In care	3	0.3	1	1.6	4	
No death certificate / cause of death	60	5.0	10	15.6	70	
Total	1198	100.0	64	100.0	1262	

Note: Chi square analyses were not conducted due to small frequencies in some categories. * statistically significant at 0.05.

5.3 Detailed Results and discussion of findings

A sub-group analysis of these reporting groups was conducted, by further stratifying the *correct* reporting process and incorrect reporting process groups. The correct reporting process group was stratified into reportable and reported and not reportable and not reported. The incorrect reporting process group was stratified into not reportable and reported and reportable and not reported.

The results and findings are presented under the categories of:

- (i) demographic characteristics, including sex and age group;
- (ii) Death details which includes the ward area, the time and day of week of the death, the length of stay and the level of experience of the clinician reporting the death;
- (iii) Reporting details, including documentation of discussion with CCOV and a review of which reportable criteria was met by the death.

5.3.1 Demographic Details

5.3.1.1 Sex

Table 5.2 Demographic Details - Details by sex

		CORRECT REPORTING PROCESS							INCORRECT REPORTING PROCESS						
	Reportab Repo	NOT Reportable AND NOT Reported		Total Correct Reporting Process		NOT Reportable AND Reported		Reportable AND NOT Reported		Total Incorrect Reporting Process		Grand	Total		
Sex	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
Female	81	44.5	465	45.8	546	45.6	5	41.7	25	48.1	30	46.9	576	45.6	
Male	101	55.5	551	54.2	652	54.4	7	58.3	27	51.9	34	53.1	686	54.4	
Total	182	100.0	1016	100.0	1198	100.0	12	100.0	52	100.0	64	100.0	1262	100.0	

An analysis was conducted of reporting of death by the sex of the patient that died in hospital. In the *correct reporting process* group, 54.4% (n=652) were male and 45.6% (n=546) were female. Further analysis of the *correct reporting process* group showed minimal difference in the proportions by sex. In the *incorrect reporting process* group, there were 53.1% (n=34) males and 46.9% (n=30) females. Sub-group analysis showed that sex differences were greater in the *not reportable and reported* group (58.3% male) than the *reportable and not reported* group (51.9% male) (Table 5.2). The demographic data reflected contemporary Australian society with an even distribution between male and females. The population is living longer with the life expectancy of a male at birth in 2016-2018 was 80.7 years and for females, it was 84.9 years (Australian Bureau of Statistics (ABS), 2018). The Australian Institute of Health and Welfare (AIHW) reports that the median age of deaths in 2017 was 81.0 years nationally, and that 51 % of the population aged between 65-74 years were female, and 54% aged between 75-84 years (AIHW, 2018).

5.3.1.2 Age Group

Table 5.3 Demographic Details - Details by age group

		CORRI	ECT REPOR	TING PR	OCESS		INCORRECT REPORTING PROCESS							
	Reportable AND Reported		NOT Reportable AND NOT Reported		Total Correct Reporting Process		NOT Reportable AND Reported		Reportable AND NOT Reported		Total Incorrect Reporting Process		Grand	Total
Age Group	n	%	n	%	n	%	n	%	n	%	n	%	n	%
<30 Years	5	2.7	4	0.4	9	0.8	-	-	1	1.6	1	1.6	10	0.8
30-39 Years	5	2.7	12	1.2	17	1.4	-	-	1	1.6	1	1.6	18	1.4
40-49 Years	14	7.7	38	3.7	52	4.3	1	8.3	2	4.7	3	4.7	55	4.4
50-59 Years	15	8.2	90	8.9	105	8.8	4	33.3	2	9.4	6	9.4	111	8.8
60-69 Years	17	9.3	143	14.1	160	13.4	2	16.7	4	9.4	6	9.4	166	13.2
70-79 Years	30	16.5	252	24.8	282	23.5	2	16.7	17	29.7	19	29.7	301	23.9
80+ Years	96	52.7	477	46.9	573	47.8	3	25.0	25	43.8	28	43.8	601	47.6
Total	182	100.0	1016	100.0	1198	100.0	12	100.0	52	100.0	64	100.0	1262	100.0

To analyse the age of the deceased patient, the ages were sub categorised into seven groups.

In the *incorrect reporting process* group, 43.8% (n=28) of the deaths were in the 80+ years age group. Further sub-category analysis of this group, the *not reportable but reported* group, showed that 33.3% (n=4) of the deaths occurred in the age group of 50-59 years and, for the *reportable*, *but not reported* group, 43.8% (n=25) of the deaths occurred in the 80+years age group (Table 5.3).

The age range of the cases was 18-103 years. There is a small group of paediatric inpatients serviced at the healthcare facility which is grouped within the cases in the under 30 years age group. The 70+ years age group, by comparison, comprised 70% of the deaths (n=855) in the correct reporting process group. In the group where the incorrect reporting process was identified (n=47), 73.5% of this group were aged 70 years and older.

The national ageing population is also represented within these findings. The majority of deaths at the health care facility occurred in the 70 years and older age group. The Australian Bureau of Statistics (ABS) describes a steady increase in the number of older people (defined as aged 65 years and older) over the last century, equally for both males and females (ABS, 2018). The contribution of decreased death rates, higher healthcare standards and declining birth rate, are all acknowledged. Similarly, the Australian Institute of Health and Welfare (AIHW) describe approximately 15% (over 3.6 million people) as being aged 65 years or older in 2017 (AIHW, 2018).

The leading cause of death among older Australians is coronary heart disease (AIHW, 2018). The majority of patients with coronary heart disease at the study healthcare facility would be categorised as medical patients. This was one of the categories with the largest number of deaths identified in the data in both the correct reporting process group (n=466, 38.9%) and the incorrect reporting process groups (n=35, 54.7%). The other clinical units in the study hospital where there was a large volume of death rates was in the cancer and neuroscience clinical unit. In this unit, there were 584 deaths (48.7%) documented as occurring in the correct reporting process group, and 22 deaths, (34.4%) in the incorrect reporting process groups. Patients who are being cared for by the palliative care services are included in the cancer and neurosciences units, so it would be expected that the numbers in this service would be high.

Of note, the leading causes of death in older people are medical conditions (Table 5.4). Not surprisingly, at the study facility, patients may have been admitted under one unit initially, and then transferred to palliative care for their ongoing management. For example, a patient may be admitted under the stroke clinical unit and then be transferred to palliative care for the final part of their admission. For each of the deceased patients, the last admission records were reviewed which may also have influenced the cases within specific units, such as the cancer and neurosciences

clinical unit. This may be relevant in the cases where the incorrect reporting process groups was identified (n=64) as at times, events or clinical conditions earlier in the admission may not be identified by clinicians and this may impact on reporting of the deaths. A prolonged hospitalisation or difficulty in accessing the electronic clinical notes from during the admission may also be factors that influence the reporting process. This may be an opportunity to review the processes of documentation that occurs during a patient's admission to ensure that there are summaries of any relevant events are not omitted which may inform the communication and review process should the patient die during the admission.

Table 5.4 Five leading causes of death for all older Australians 2015-2017 (AIHW, 2018)

Leading causes of death (most frequent)	65-74 years	75-84 years	85 years and over
1	Cancer (Lung)	Coronary heart disease	Coronary heart disease
2	Coronary heart disease	Dementia and Alzheimer disease	Dementia and Alzheimer disease
3	Chronic obstructive pulmonary disease	Cerebrovascular disease	Cerebrovascular disease
4	Cancer (Colorectal)	Cancer (Lung)	Chronic obstructive pulmonary disease
5	Cerebrovascular disease	Chronic obstructive pulmonary disease	Heart failure and complications

Source: Modified from AIHW (www.aihw.gov.au)

5.3.2 Death Details

5.3.2.1 Ward

Table 5.5 Death Details - Details by ward area where death occurred

		cc	RRECT REPORT	ING PROCES	is		INCORRECT REPORTING PROCESS							
	Reportable Report		NOT Reporta		Total Co Reporting F		NOT Report		Reportable A		Total Inco		Grand T	otal
Ward	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Cancer and Neuroscience	48	26.4	536	52.8	584	48.7	3	25.0	19	36.5	22	34.4	606	48.0
Surgery	39	21.4	50	4.9	89	7.4	-	-	4	7.7	4	6.3	93	7.49
Medicine	81	44.6	385	37.9	466	38.9	9	75.0	26	50.0	35	54.7	501	39.7
Continuing Care	10	5.5	43	4.2	53	4.4	-	-	2	3.8	2	3.1	55	4.4
Other	4	2.2	2	0.2	6	0.5	-	-	1	1.9	1	1.6	7	0.6
Total	182	100.0	1016	100.0	1198	100.0	12	100.0	52	100.0	64	100.0	1262	100.0

To analyse where a death occurred, the ward locations were sub-categorised into five groups. The ward name, as described here, indicates the unit that was overseeing a patient's care at the time of their death.

In the *correct reporting process* group, 48.7% (n=584) of the deaths were in the Cancer and Neurosciences unit and 38.9% (n=466) of the deaths were in Medicine unit. Note that the Cancer and Neurosciences unit includes the palliative care unit under its auspices.

In the incorrect reporting process group, 54% (n=35) of the deaths were in the Medicine unit with 34.4% (n=22) in the Cancer and Neuroscience unit. Further sub-group analysis of the incorrect reporting process group indicated in the not reportable but reported group, 75% (n=9) of deaths occurred in the Medicine unit, and 25% (n=3) of deaths occurred in the Cancer and Neuroscience unit. In the group where the deaths were reportable, but not reported, 50% (n=26) of deaths were in the Medicine unit and 36.5% (n=19) in the Cancer and Neuroscience unit (Table 5.5).

5.3.2.2 Time of Death

Table 5.6 Death Details - Details of time of death as recorded

		CORF	RECT REPOR	TING PRO	CESS		INCORRECT REPORTING PROCESS							
Time of Death	Reportable AND Reported		NOT Reportable AND NOT Reported		Total Correct Reporting Process		NOT Reportable AND Reported		Reportable AND NOT Reported		Total Incorrect Reporting Process		Grand Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
2400-0600	33	18.1	244	24.0	277	23.1	2	16.7	6	11.5	8	12.5	285	22.6
0601-1200	35	19.2	263	25.9	298	24.9	2	16.7	17	32.7	19	29.7	317	25.1
1201-1800	114	62.6	433	42.6	547	45.7	7	58.3	29	55.8	36	56.3	583	46.2
1801-2400	-	-	76	7.5	76	6.3	1	8.3	-	-	1	1.6	77	6.1
Total	182	100.0	1016	100.0	1198	100.0	12	100.0	52	100.0	64	100.0	1262	100.0

The time of the death for each case were categorised into six hourly increments. In both the group where the correct reporting process occurred 45.7% (n=547) and the incorrect reporting process group, 56.3% (n=36), the majority of the deaths occurred between 1201-1800 hours (Table 5.6).

This is the time of the day when staffing is optimal and there is appropriate availability of resources, including senior staff. Other resources, such as medical administration, the Chief Medical Officer (CMO), relevant personnel in the Quality and Safety units/ Clinical Governance units are all also available for any consultation regarding the deaths and investigation.

This is particularly relevant in the incorrect reporting process group where there were seven deaths that did not meet the reportable criteria that were reported in this time frame of 1200-1800 hours. It was also in this time frame that the largest number of deaths where the incorrect reporting process was followed occurred (n=29). Similarly, the number of deaths in the incorrect reporting process group was proportionately highest on weekdays, compared with the weekend.

It could be assumed that, like the time of death, these deaths occurred during the *working week* when resources are readily available within the study hospital. The documentation in the medical notes did not indicate if there had been any consultation generally within or external to the clinical unit when a death occurred regarding the review that was required. That is not to say that the discussion did not occur, but there was a paucity of documentation to support the decision making. This is an area worthy of consideration from the perspectives of internal governance, oversight and documentation processes within the facility.

5.3.2.3 Day of Death

Table 5.7 Death Details - Day of death by weekday/weekend

		COF	RRECT REPOR	TING PROC	ESS		INCORRECT REPORTING PROCESS							
	Reportable AND Reported		NOT Reportable AND NOT Reported		Total Correct Reporting Process		NOT Reportable AND Reported		Reportable AND NOT Reported		Total Incorrect Reporting Process		Grand Total	
Day of Death	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Weekday	129	70.9	745	73.3	874	73.0	8	66.7	42	80.8	50	78.1	924	73.2
Weekend	53	29.1	271	26.7	324	27.0	4	33.3	10	19.2	14	21.9	338	26.8
Total	182	100.0	1016	100.0	1198	100.0	12	100.0	52	100.0	64	100.0	1262	100.0

An analysis was performed of the reporting of deaths by the day that death occurred. The day of death was separated into weekdays and weekends.

In the correct reporting process group, 73.0% (n=874) of the deaths occurred on a weekday.

In the *incorrect reporting process* group, 78.1% (n=50) of the deaths occurred on a weekday. Subgroup analysis showed that in the *not reportable, but reported* group, 66.7 % (n=8) of the deaths occurred on a weekday and, in the *reportable and not reported* group, 80.8% (n=42) of the deaths occurred on a weekday (Table 5.8).

Similarly, the number of deaths in the incorrect reporting process group was proportionately highest on weekdays, compared with the weekend. It could be assumed that, like the time of death, these deaths occurred during the *working week* when resources are readily available within the study hospital. The documentation in the medical notes did not indicate if there had been any consultation generally within or external to the clinical unit when a death occurred regarding the level of review that was required. This is an area worthy of consideration from the perspectives of internal governance, oversight and documentation processes within the facility.

5.3.2.4 Length of Stay

Table 5.8 Death Details – Length of stay as an inpatient prior to death

Length of Stay		CORRECT REPORTING PROCESS							INCORRECT REPORTING PROCESS						
	Reportable AND Reported		NOT Reportable AND NOT Reported		Total Correct Reporting Process		NOT Reportable AND Reported		Reportable AND NOT Reported		Total Incorrect Reporting Process		Grand Total		
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
0-9 days	127	69.8	680	66.9	807	67.4	9	75.0	36	69.2	45	70.3	852	67.5	
10-19 days	27	14.8	173	17.0	200	16.7	3	25.0	8	15.4	11	17.2	211	16.7	
20 + days	28	15.4	163	16.0	191	15.9	-	-	8	15.4	8	12.5	199	15.8	
Total	182	100.0	1016	100.0	1198	100.0	12	100.0	52	100.0	64	100.0	1262	100.0	

An analysis was performed of the reporting of death by the length of stay as an inpatient prior to death occurring. The length of stay was sub-categorised into three categories. In the *correct reporting process* group, 67.4% (n= 807) of the deaths occurred within 0 to 9 days of admission.

In the *incorrect reporting process* group, 70.3% (n=45) of the deaths occurred within 0 to 9 days of admission. Sub-group analysis showed that, in the *not reportable, but reported* group, 75% (n=36) of the deaths occurred within 0 to 9 days of admission and, in the *reportable and not reported* group, 69.2% (n=36) of the deaths occurred during 0 to 9 days of admission (Table 5.8).

The majority of deaths occurred within 0-9 days of an inpatient stay. This may reflect the policy of the study hospital to transfer the patients to the palliative care unit during their acute admission as demonstrated by the numbers of deaths within this unit. There is also an increased acuity of patients being administered to hospitals which may also be reflected in this finding. The last admission of the clinical notes was reviewed for the study. It was identified by Kobewka et al, 2017 in a retrospective review of deaths over a 3-month period in a Canadian hospital), that greatest volume of deaths occurred between 3-16 days of admission. The Canadian study reported similar time frames to the study hospital and also considers the increased acuity of admitted patients and the impact on the length of stay (Kobewka et al., 2017).

5.3.2.5 Level of Experience

Table 5.9 Death Details – Level of experience of clinician completing the report

Level of		COI	RRECT REPOR	TING PROC	ESS		INCORRECT REPORTING PROCESS							
	Reportable AND Reported		NOT Reportable AND NOT Reported		Total Correct Reporting Process		NOT Reportable AND Reported		Reportable AND NOT Reported		Total Incorrect Reporting Process		Grand Total	
Experience	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Consultant	1	0.5	1	0.1	2	0.2	-	-	1	1.9	1	1.6	3	0.2
НМО	2	1.1	1	0.1	3	0.3	-	-	-	-	-	-	3	0.2
Registrar	115	63.2	750	73.8	865	72.2	8	66.7	31	59.6	39	60.9	904	71.6
Resident	63	34.6	264	26.0	327	27.3	4	33.3	18	34.6	22	34.4	349	27.7
Intern	1	0.5	-	-	1	0.1	-	-	2	3.8	2	3.1	3	0.2
Total	182	100.0	1016	100.0	1198	100.0	12	100.0	52	100.0	64	100.0	1262	100.0

An analysis was performed of the level of experience of the clinician who certified/verified/reported the death. A clinician's experience was sub-categorised into five categories.

In the *correct reporting process* group, 72.2% (n=865) of the deaths were reviewed by the registrar-level of clinician.

In the *incorrect reporting process* group, 60.9% (n=39) of the deaths were reviewed by the registrar-level of clinician. Sub-group analysis showed that, in the *not reportable*, *but reported* group, 66.7% (n=8) and, in the *reportable and not reported* group, 34.6% (n=18) of the deaths were reviewed by clinicians practicing at the level of registrar (Table 5.9).

The majority of the deaths were documented by the registrar or resident level of medical staff in both the correct and incorrect reporting process groups. The more senior level of staff, that is Consultant level, were not recorded as being involved in the documentation regarding the deaths. This may be a lost opportunity for role modelling and education particularly in the incorrect reporting process group of deaths, for the more junior staff by the senior, more experienced staff. This would also provide an opportunity to facilitate open discussion regarding the circumstances around the deaths. As was indicated in the finding of the semi structured interviews and the clinical scenarios in Study 2, seniority of staff does not necessarily equate with expertise and knowledge regarding reportable deaths. The use of open discussion and review of the deaths could be beneficial for the education of all levels of experience.

5.3.3 Reporting Details

5.3.3.1 CCOV Discussion

Table 5.10 Reporting Details – Discussion with Coroners Court of Victoria (CCOV)

		RRECT REPOR	ESS		INCORRECT REPORTING PROCESS									
Documentation of discussion with CCOV	Reportable AND Reported		NOT Reportable AND NOT Reported		Total Correct Reporting Process		NOT Reportable AND Reported		Reportable AND NOT Reported		Total Incorrect Reporting Process		Grand '	Total
	N	%	n	%	n	%	n	%	n	%	n	%	n	%
												-		
Yes	171	94.0	28	2.8	199	16.6	6	50.0	16	30.8	22	34.4	221	17.5
No	11	6.0	988	97.2	999	83.4	6	50.0	36	69.2	42	65.6	1041	82.5
Total	182	100.0	1016	100.0	1198	100.0	12	100.0	52	100.0	64	100.0	1262	100.0

Note: $\chi^2(1)$ =13.272, p = 0.000* (statistically significant).

An analysis was performed of whether there was any documentation of any discussion between clinicians and the CCOV. For a death to be accepted as a reportable death, there is a requirement for clinicians to have had a discussion with the CCOV's office, the time of death.

In the *correct reporting process* group, for 83.4% (n=999) of deaths, there was no documentation of any discussion between clinicians and the CCOV. In the *incorrect reporting process* group, for 65.6% (n=42) of deaths, there was documentation of no discussion occurring with the CCOV regarding the reporting of death.

Sub-group analysis showed that in the *not reportable, but reported* group, for 50 % (n=6) of deaths and, in the *reportable and not reported* group, for 69.2% (n=36) of deaths, there was no documentation of any discussion between clinicians and the CCOV (Table 5.10).

The documentation within the medical notes of any discussion that had occurred with the CCOV was also reviewed. For a death to be considered reportable by the CCOV, telephone contact is made with the CCOV by the clinician (in the hospital setting). The circumstances surrounding the death are then described to the CCOV staff, and the decision then made as to whether the death is required to be reported. In the correct reporting process group (n=171), there was documentation of discussion with CCOV in 94% of the cases. This is also demonstrated by the presence of a CCOV case number and a copy of the coroner's electronic deposition document. In the remaining 6% of cases (n=11), there may have been a delay in reporting. This delay could be the result of a more detailed internal review of the death or referral from the Registry of Births, Deaths and Marriages (BDM) resulting in recognition that the deaths met the reportable criteria. A referral from BDM to the CCOV occurs when there is a prompt on the death certificate that indicates that the death meets the reportable criteria. For example, there may be a reference to a previous or recent trauma mentioned on the death certificate which may not have been deemed relevant to the cause of death according to the clinician's understanding. This may require clarification to meet the legislative requirements of BDM (see Chapter1).

5.3.3.2 Criteria for reportable death

Table 5.11 Reporting Details – Criteria for reportable death

		CC	RRECT REPO	RTING PRO	CESS		INCORRECT REPORTING PROCESS							
Case Type	Reportable AND Reported		NOT Reportable AND NOT Reported		Total Correct Reporting Process		NOT Reportable AND Reported		Reportable AND NOT Reported		Total Incorrect Reporting Process		Grand 1	Гotal
	N	%	n	%	n	%	n	%	n	%	n	%	n	%
Not reported	3	1.6	1011	99.5	1014	84.6	-	-	0	-	0	9.4	1014	80.3
Unexpected	8	4.4	-	-	8	0.7	1	8.3	6	11.5	7	10.9	15	1.2
Violent or unnatural	11	6.0	-	-	11	0.9	-	-	-	-	-	-	11	0.9
Accident or injury	83	45.6	4	0.4	87	7.3	6	50.0	33	63.5	39	60.9	126	10.0
Medical Procedures	14	7.7	1	0.1	15	1.3	2	16.7	1	1.9	3	4.7	18	1.4
In care	3	1.6	-	-	3	0.3	-	-	1	1.9	1	1.6	4	0.3
No death certificate/cause of death	60	33.0	-	-	60	5.0	3	25.0	11	21.2	14	21.9	74	5.9
Total	182	100.0	1016	100.0	1198	100.0	12	100.0	52	100.0	64	100.0	1262	100.0

An analysis was performed to determine the most relevant criteria under which a death may have been reported. A clinician's experience was sub-categorised into seven categories, which reflect the criteria within the *Coroners Act, 2008* (Vic).

In the *correct reporting process* group, there were a total of 84.6% (n=1014) deaths that were reportable and were reported. Sub-group analysis showed that 45.6% (n=83) of the deaths were reported under the category of accident or injury.

In the incorrect reporting process group, in 65.6% (n=42) of the deaths, there was documentation of no discussion occurring with the CCOV regarding the reporting of death.

Sub-group analysis showed that, in the *not reportable, but reported* group, 50% (n=6) and, in the *reportable and not reported* group, 63.5% (n=33) of deaths fell within the category of accident or injury (Table 5.11).

There are criteria under which deaths are required to be reported to the CCOV (*Coroners Act 2008* (Vic)). The majority of the deaths that were reportable and reported were under the *accident or injury category*, (n=87). This was also reflected in the group where there was an incorrect reporting process noted in 10% of the cases (n=39).

5.4 Chapter summary

This chapter presented the results of the quantitative data analysis of the frequency and characteristics of deaths that occurred in one calendar year at a metropolitan health care facility in Victoria. A descriptive statistical overview of the deaths was presented, according to whether the correct reporting process was followed. This analysis included the demographic characteristics, such as the age and sex, of each deceased patient. The analysis showed that there was a reasonably even spread of males and females in both the groups, where the correct reporting process was followed and where the incorrect reporting process was followed. The analysis also indicated that the largest number of deaths occurred in the age group of 80+ years where the correct reporting process was identified.

Other key findings include that the most common criteria for reporting of deaths were the accident or injury categories, for both cases in which the correct reporting process was followed and in which the incorrect reporting process was identified. The incorrect reporting process was also identified in 64 of the cases reviewed, the analysis of which will be discussed in Chapter 7. The findings of Study 1 informed the development of the questions for the semi structured interviews and the development of the clinical scenarios that are presented in Chapter 6.

Chapter 6. Results and Discussion – Study 2 Key Informant Interview and Scenarios

6.1 Introduction

This chapter presents the results and discusses the findings of Study 2, which examines factors that impact on a clinician's decisions to report a death to the Coroner and to determine a clinician's knowledge of the legal requirements of reporting a death. Findings from Study 1 revealed that not all deaths which occurred within a large tertiary health service and met the criteria for reporting to CCOV were actually reported.

Data for Study 2 were generated from interviews conducted with clinicians, namely registered medical practitioners and registered nurses. Study 2 comprised semi-structured interviews and the completion of clinical scenarios. The interview questions were informed by the data collected and analysed in Study 1. This is in keeping with the explanatory sequential design selected for this study, whereby separate qualitative data collection and analyses were undertaken.

This chapter is arranged as follows. Firstly, the participants are described, according to their respective roles and qualifications. Secondly, the findings of the interview data are presented. From the analysis of the interview data, six themes emerged. The themes were timing, lack of awareness/knowledge, fear/ blame/ stigma, education, accountability and practicalities. These themes and associated sub-themes are presented, to highlight an understanding of the clinicians' knowledge of the legal requirements of reportable deaths. Finally, the findings of the analysis of the responses to the clinical scenarios will be presented.

6.2 Description of participants

There were 22 clinicians recruited to participate in the study, comprising 13 registered medical practitioners and nine registered nurses who were all employed at the one metropolitan healthcare facility. The clinicians' experiences varied considerably, from the head of a unit to a graduate nurse completing their first rotation (Table 6.1). The clinicians were all employed at the health care facility where Study 1 was undertaken. The participants were all employed in active clinical roles, with direct patient contact, and were accessed via a variety of clinical forums. Support was also given for the study by the Chief Medical Officer and the Chief Nursing Officer.

Table 6.1 Profile of interview participants

Discipline	Medical Staff	N	Nursing Staff	N
	Consultant	7	Registered Nurse > 5 years' experience	3
	Registrar	4	Nurse Unit Manager	2
	Advanced trainee/fellow	2	Associate Nurse Unit Manager	2
			Nurse Practitioner	1
			Graduate Nurse	1
Total		13		9

The following provides a brief description of the core components of the roles of the clinicians who participated in the semi-structured interviews and who completed the clinical scenarios. The areas of clinical practice for the clinician group were quite varied, including areas such as palliative care, geriatrics, general medicine and surgery. Participants were also drawn from critical care areas, such as intensive care, cardiology and the emergency department.

The medical staff comprised registered medical practitioners with varying levels of experience and education. These roles will be briefly described. In this study, a consultant is a senior medical staff member who has a position with professional responsibilities, such as leadership and teaching, training and supervision of staff. Generally, these medical practitioners have greater than ten years' experience in their chosen area of clinical specialty. Medical practitioners who are practising at a registrar level are in the early stages of their specialist practice. The role of this level of medical staff is to be responsible for the direct day-to-day clinical care of patients, within the respective rotation. An advanced trainee/fellow is a medical practitioner who is undertaking further education in a specialist clinical field, for example, cardiology.

Similarly, the registered nurse appointed in charge of a ward or unit is the Nurse Unit Manager (NUM) who will have completed a three-year training program. The NUM is responsible for the day-to-day running of a ward or department, with oversight of all aspects of patient care and other administrative roles. To fulfil this role, the NUM will have gained variable levels of clinical experience prior to undertaking the role. The Associate Nurse Unit Manager (ANUM) is a registered nurse who deputises for the NUM and assists with the overall clinical and administrative management of the ward or unit, over a 24-hour period.

The experiences of the registered nurses involved in this study were variable. To be employed as a registered Division 1 (RN Div1) nurse, a three-year training program is completed. A graduate nurse is a RN Div 1 nurse who is in the first year of supervised clinical practice whereas RNs with greater than five years' experience will have been employed in the clinical areas, delivering direct patient care.

A recognised advanced practice nursing role is the nurse practitioner (NP). This nurse is endorsed by the Nursing and Midwifery Board of Australia to practice within their scope, under the title of Nurse Practitioner, which is protected by legislation. This group of practitioners has undertaken further tertiary study and clinical experience to be endorsed as a nurse practitioner (Australian Nursing and Midwifery Accreditation Council, 2017).

6.3 Emerging themes

The following six themes emerged from the analysis of the interviews: 1) timing; 2) lack of awareness/knowledge; 3) fear/blame and stigma; 4) education; 5) accountability; and 6) the practicalities of reporting. These themes are explained in detail below.

(1) Timing

Within this theme, a lack of understanding of the requirements regarding the timing to report a reportable death was evident. According to the *Coroners Act 2008* (Vic), a death must be reported without delay, if it is a reportable death. There is, however, no reference to actual time frames or to number of hours or days. This presents a challenge to clinicians in their determination of when the death should be reported. Within the interview data collected, there was reference to several clinical settings when the time frames influenced whether the clinician believed that the death met the criteria to be reported to the Coroner or not.

Deaths that occurred as a result of a clinical procedure or surgery represented an area that lacked clarity for clinicians, particularly relating to the timing of death and reporting. The temporal relationship between the death and a procedure or surgery was the source of some confusion. Further confusion occurs when Subsection 1 of the *Coroners Act 2008* (Vic.) is read, which refers to the relationship of the death to a medical procedure being performed. There are no concrete time frames, however, the emphasis of the subsection focuses on a causal relationship between the death and the requirement for the death to be reported. Other Acts, such as the *Coroners Act 2003* (South Australia), refer to a reportable death as being one that occurs during or as a result of or within 24 hours of a surgical or invasive medical diagnostic procedure. A death is also reportable if it occurs within 24 hours of the patient being discharged after being an inpatient or treated in the emergency department, as defined in the *Coroners Act 2003* (South Australia).

The equivalent legislation in the Australian Capital Territory and New South Wales both refer to a death being reportable if the person had not been cared for by a medical practitioner within six months of their death (*Coroners Act, 1997* [Australian Capital Territory]; *Coroners Act, 2009* [New South Wales]).

The participants provided varied responses. One participant indicated that reporting was necessary when death was "... subject to a procedure [occurring] in the past 28 days ..." (D1). Another believed that death was reportable if it occurred within "...24 hours post operatively ..." (N5). Yet another participant stated that a death was reportable when it occurred "within 28 days..." (D4). Another participant considered that the deaths of patients who "died within 24 hours of their admission" (D6) needed to be reported. Similarly, another participant stated that a death was reportable if it occurred "within a certain number of days of surgery" (N3), which also demonstrated a lack of knowledge of the reporting requirements. These responses highlight confusion that occurs possibly in part due to the differences between the Australian jurisdictions which can result in confusion and a lack of understanding of the precise requirements in any one state or territory. This misunderstanding may be particularly related to the causal relationship of the death and the event. This was also evident in the second theme identified as a lack of awareness or knowledge by clinicians of what type of death or circumstances of the death are reportable and the rationale for reporting at all.

(2) Lack of awareness/knowledge

The initial question, regarding what clinicians understand about the type of deaths that are reportable to the coroner, drew a variety of responses. Several clinicians stated that, if the cause of death was not apparent, the death should be reported. Similarly, if a death was unexpected, participants indicated that the death met the reportable criteria.

The lack of awareness or knowledge as to why a death that did meet the reportable criteria needed to be reported was highlighted in some of the responses. The legal requirement to report certain deaths was not acknowledged widely by the participants. It is quite clear within the *Coroners Act 2009* (Vic) that there is a statutory requirement to report a death that occurs in specified circumstances and that failure to do so may result in a significant fine. That said, there are also inconsistencies in the potential penalties across Australia, which lead to further confusion and fear for clinicians, which will be further discussed (Middleton & Buist, 2014)

The participant responses further highlighted a lack of awareness and knowledge of the reasons why deaths are reported to the CCOV. There was minimal formal acknowledgement from participants of the basic legislative requirement to report deaths that met the reportable death criteria. If this

obligation to report the reportable death is not met, the penalty includes 20 penalty units (and a significant fine of \$161.82 per point) being awarded to the individual (Coroners Court of Victoria, 2017). The data revealed that there were wide-ranging reasons provided for why deaths were required to be reported to the CCOV. Some participants stated that there was a focus on the quality assurance and audit role of the CCOV, with one participant indicating that reporting deaths was "to collect statistics" (D4); and, on the same theme, another participant thought it was to look at a "hospital, to [run] checks and balances" (N3). Others suggested that the reasons for reporting were to provide "an audit of health records" (D1) or to "determine the cause of death for data collection purposes, and to identify [if] any prevention, [or] traumatic or unnatural deaths" (D12).

The reporting of deaths was also seen as a way for some participants to identify any system errors or to identify "medical errors or omissions that may have contributed to the death" (N7). The reporting of deaths was also seen as a way to determine if there were "... complications from specific techniques or conditions undertaken" (N3).

The concept that the reporting of deaths to a centralised area, such as the CCOV, was to provide a more broad oversight and identify any clusters, was likened by one participant as a "...big recommendation, might be around speed limits or manufacturing structures, or systems in hospitals and other organisations that enable [staff] to keep people safe" (N4). Similarly, other participants commented that the CCOV, due to the state-wide focus, is an entity that will contribute to the "identification of systems issues to provide feedback and education" (D3), "clusters and trends across the community" (N4), "identification of cluster event types of deaths" (N3), "informing patient safety" (D1), and patterns of deaths (D5). This identification of clusters and/or trends in deaths allows for the development and dissemination, more widely, of information that may contribute to patient safety within the healthcare environments. Furthermore, one component of the coroner's role is to independently investigate deaths, with a view to contributing to the reduction of preventable deaths, and so this information gathering will enhance their findings (Coroners Act 2008, Vic).

The reasons provided for reporting deaths to the CCOV, under the *Coroners Act 2008* (Vic), were also varied and demonstrated some understanding of the coronial role. When the participants were asked to describe which deaths met the reportable criteria, an assortment of reasons were given. These reasons included that the death was "suspicious" (D1, N1), or if there was reference to criminal matters around the death. Other reasons were that the death was iatrogenic and that there was the requirement for the determination if something has happened related to care delivery, perhaps preventable; and may inform systems improvement (N2, N4) were all used.

There was an understanding demonstrated by clinicians that situations where there was an unexpected death or if the death certificate could not be signed were also criteria for reporting a death. There appeared to be a clearer understanding regarding deaths due to trauma or violence or those deaths that were deemed "unnatural", as deaths which met the reportable deaths criteria. With respect to satisfying the reportable criteria, one participant stated that deaths that were due to "violent or unnatural (causes) like drowning", and "suicides, workplace, misadventure" (D10) constituted criteria for reportable deaths.

In summary, within the interviews, clinicians indicated that they believed that the reporting of deaths was required to facilitate audit and collection of statistical data by CCOV. Whereas one component of the coroner's role is to independently investigate deaths and fires, primarily, the role is required to confirm the identity of the deceased, cause of death or fire and the circumstances around the death or fire. The understanding of this role appeared unclear to the clinicians interviewed indicating a lack of awareness of what constitutes the coroner's role. Awareness of the coroner's role may be improved by ongoing information sharing between the CCOV and the health care facilities. For example, via the mortality and morbidity committees and referring again to the impact that the reviews and subsequent findings and recommendations may have on informing patient safety. There is a missed opportunity for a system level review to assist in the identification of contributing factors that may be able to manage and work towards reducing the risk of any identified issues being repeated and causing further harm to the patients. There is information for health professionals readily available via the CCOV website (Coroners Court of Victoria, 2018). This information briefly outlines the role of the coroner and provides guidelines for which deaths are reportable. The role of the Coroners Prevention Unit (CPU) as a specialist service to assist coroners in their review of the deaths and the generation of recommendations that may contribute to patient safety is also available on the website. There are quarterly information sessions available for health professionals where the reporting of deaths, the investigation process, including information about inquests and recommendations is provided (Coroners Court of Victoria, 2019).

(3) Fear, blame and stigma

Among the clinicians' responses, there was an underlying concern expressed that the reporting of a death to the CCOV held a negative connotation and there was a sense of guilt or blame associated with those health professionals involved with the death. Comments, such as it was "arbitrary whether the death is reported or not" (D8) and "...humans make mistakes" (D9) were also made. One participant stated that a reason to report a death to the CCOV was "to protect the physician involved in the patient's care when it comes down to the cause of death" (D4).

One participant referred to the reporting of deaths as "contact with the Coroner meant that you were at fault" and that the process of reporting is "still stigmatised and uncomfortable for medical staff" (D8). Reference was also made that "there is always a natural anxiety about the need to report a death" (D3) and "trying to break down that sort of stigma; that is, you report to the coroner you might in some way be vulnerable" (D6). This theme was the subject of several responses - participants referring to their concerns that the process exposed a vulnerability or suggestion of fault on their part. This was clearly expressed in the following quotes regarding reporting of deaths, which participants saw as "opening yourself up to scrutiny" (D5) and expressed concern that the CCOV are "going to find fault with you" (N4). Another indicated that there may be a "chance of victimisation of the victim [meaning clinician] unless there is an open review by the team" (D2).

There was a sense of unease in reporting a death that had occurred during the treatment of a patient. Donabedian, in describing the six domains used to evaluate the delivery of health care and outcomes in framework, refers to deaths as one of these domains (Donabedian, 1988). He also advocates a system-based approach to patient safety, which is reflected by the independent role of the coroner in death review, and a "no blame" culture (Moore et al, 2015). The Coroners' systems in Australia are inquisitorial with a focus less on innocence or guilt but rather with an emphasis on investigating deaths and fires in specified circumstances, with the aim of reducing the number of preventable deaths through their findings and recommendations. This differentiates this court from an adversarial court where there are opposing parties attempting to argue the point at hand (Dillon & Hadley, 2015).

This difference may contribute to a common lack of understanding as to the role and function of the Coroners' death investigation process. Coroners are not bound by the rules of evidence and are able to gather information from a range of different sources. Their role is not to apportion blame but the legislation does provide the Coroner with the opportunity to refer the case to other authorities for further investigation. These authorities may include the Office of Public Prosecutions (OPP), for criminal matters, the Australian Health Practitioner Regulation Agency (AHPRA), for matters pertaining to professional issues, and WorkSafe, for matters relating to occupational health and safety. There are also inconsistencies across the Australian states and territories regarding the legal penalties for not reporting deaths which further challenges clinician's understanding of the expectation of them. (Middleton & Buist, 2014). The Coroner also has the power to make recommendations to any organisation that is connected to the death regarding matters of public health and safety or the administration of justice. This fear of reporting deaths is one area which may be alleviated by further education within the healthcare organisations particularly as to the role

of the coroner. Ideally, from a legal perspective but also as an influence on preventability of deaths and in turn enhanced patient safety.

(4) Education

Participants described where their education related to the coroner was largely attained, either as students (nursing or medical) or in their clinical roles. They indicated that:

- training was not formalised into university programs, commenting, "no formal training in med school, should be like a lecture" (D1);
- there were shortcomings in current university programs, commenting, "...undergraduate year re death certification, no definite education about the coroners" (D3) and;
- there was a perceived training deficit, stating, "...nothing ongoing" (D10).

The data highlights that, for a majority of the clinicians, their understanding and knowledge about reporting deaths was largely gained through workplace learning. Many stated that they "picked up [the need to report some deaths] through experience and osmosis from the system" and that actually "being involved in the process" (D2) is how they learned what was expected of them. This indicates, again, that there may be a perceived deficit in ongoing information regarding reportable death requirements.

There was acknowledgment among participants that there was a gap in education in this area and that there was still a "...fairly high level of ignorance about both the law and the application of it in the hospital setting" (D4).

The clinicians referred to the introduction of the electronic death certificate as the only recent education that they had received regarding management of the deceased patient. This change in process was accompanied by a demonstration of the completion of the form and an on-line module, as an educational adjunct. Similarly, the introduction of the electronic medical deposition form (coroner's report) was also accompanied by "education re on-line [of] the new e-deposition, nothing else, [there] should be some education" (D10).

The clinicians did feel that this was a gap in their learning and that ongoing education should be offered by the health care facility. Suggestions, such as the use of medical grand rounds as a source of education regarding the process, were raised. It was acknowledged that there were, at times, bulletins distributed from the Office of the Chief Medical Officer or the Medical Board as a form of communication but no further information was available nor did the clinicians recognise the importance of pursuing this knowledge. There was also an understanding that, despite the education and resources available, "at three o'clock in the morning that some of our registrars, not only here

but all over the hospital, who wouldn't be aware of what they need to do and what their rights and responsibilities are. So, I think that [ongoing education] would be a valuable thing to do." (D7).

From the data, participants did not appear to recognise their own responsibility for further and ongoing education and that there was a legal requirement for them to be aware of the reportable deaths process; nor was there any recognition of resources that may be available to assist them with the process. This was "something we probably should have more of an understanding about" (N8).

Education was described as either the formal education received during the clinicians' student time, or their "on the job" education. Deficits in information sharing about the processes pertaining to reportable deaths was identified as being present within the interview data. Medical staff at the consultant level made up over half of the medical staff that were interviewed (n=7), so it is evident that this group of clinicians' knowledge about reportable deaths was not very strong, (as presented in Chapter 5). A component of the senior staff role is to lead, teach and supervise junior staff which is difficult if the senior staff do not have the awareness of which deaths meet the reportable criteria and what is required in the reporting of deaths. It is acknowledged that there are a large volume of skills and tasks to be learned and then performed in day to day practice, however the legal requirements remain relevant and definite. The opportunity to utilise the reporting process and the subsequent investigation as a learning activity contributing to safer patient care also cannot be underestimated.

The opportunity to learn on the job by role modelling and supervision needs to be supported within the healthcare organisations case by case to assist in learning by reviewing the cases. Some clinical units will very rarely have deaths occur amongst their patients, so it is not unreasonable that the staff may not be exposed very often to the process and consideration of reporting of deaths.

Training in the real clinical setting has long been acknowledged as the ideal way for the junior staff to learn and gain experience in a supportive environment (Ash et al, 2012).

Ongoing education both in the clinical setting and in more formalised continuing education seminars could be delivered to ensure that clinicians are kept abreast of the coronial requirements.

Conversely, feedback from the coronial investigations is also required to be available in a timely and relevant manner to assist the clinical staff in learning from the cases and disseminated widely for broader opportunity to understand the Coroners' death reporting requirements.

(5) Accountability – transparency of any contributing factors to death

There is an expectation that there will be transparency in the review of patient care to determine whether the death may have had any preventable factors. The responsibility or accountability for the requirement of the reporting of reportable deaths is enhanced by the external, independent

review provided by the CCOV, which enhances the lessons that can be learned and also complements the internal review. One of the benefits of this review of the circumstances around deaths is the reassurance it provides to the community that there is a "mechanism for society to be accountable for the loss of a life" (D3). The external review contributes to the transparency and accountability of health professionals whilst assisting them with the identification of "something like foul play involved"(D9) and "to make sure that it [the death] wasn't through error in the hospital's part" (N9).

The protective role as motivation for reporting deaths was mentioned by several participants, particularly in relation to the more vulnerable members of society, such as those held in care. The coroner has a particular role to play in the investigation of the deaths of specific groups, such as those held in custody or care of the state. Other groups include those under mental health care and the coroner also investigates deaths that occur during, or as a result of, police operations (Dillon & Hadley, 2015). This protective role ensures that the voices of susceptible groups are heard and that there is transparency in the review of deaths by an independent group. Comments, such as, "[the] coroner takes an interest to ensure that all appropriate care was undertaken", (D8), further reinforces this understanding of the objectivity of the coroner's role.

This role of protection and transparency could also be expanded to the role of clinicians, as the external review of the circumstances of deaths by an independent entity, such as the coroner, complements the regular clinical audit processes within healthcare facilities.

The legal requirements or responsibility to report the health-care-related deaths also result in transparency for the clinicians. To ensure that these responsibilities are met by the clinicians, the philosophy or culture of the organisation needs to be supportive and the "no blame" way of thinking to be evident and overt in all areas. Contribution of any adverse event to a death needs to be acknowledged in a professional, objective and compassionate way, including the discussion or open disclosure of events to the family or significant others (ACSQHC, 2013).

(6) Practicalities of reporting

The participants were asked if there were any barriers, either internally or externally, to reporting deaths. The barriers that were raised referred to the logistics of the actual reporting of the death. Externally, barriers included the time taken to make telephone contact with the CCOV and the amount of paperwork that is required to make the report. There was reference to the significant length of time that it took to get through by phone to the reporting office at CCOV and that this delay impacted on workload issues (D11). The participants raised their concerns that it was time consuming to actually perform the report due to the telephone contact that was required with the

CCOV and the completion of the paperwork. From a clinician's point of view, ensuring that all of the required information to make the report is available may enhance the process. Resources within the CCOV may also be required to facilitate the process. Other comments were that the electronic submission of the report that occurs following the telephone contact has been made is not difficult, and the office has streamlined that component of the process (D5).

One factor that was seen as an impediment to the reporting process was that there appeared to be a lack of consistency of the acceptance of the report when attempts were made to report the deaths. For example, one participant highlighted that it "was a bit arbitrary as to what [which deaths] are deemed reportable or not reportable" (D7) and, for one participant, the process was considered random, "it still feels like a toss of a coin" (D7). Also expressed was uncertainty about which deaths should be accepted as reportable, "it's surprising that some things [deaths] don't get there, versus some that do" (N3). One reason for this may be that there is a lack of clarity by the clinicians as to which deaths meet the reportable criteria, and therefore the clinical history may not be presented as accurately as possible to the CCOV. Similarly, the CCOV may not appreciate the finer details of the clinical communication and therefore not accept the report.

Other, more personal concerns that were expressed related to "preconceived ideas and previous experience" (D5) of dealings with the CCOV. This refers also to the perceived stigma around deaths which need to be reported and the sense that they (the clinicians) are anxious about reporting, as "they think they are going to get into trouble" (D6).

There was also reference to the deceased patients' families and the perception that reporting a death to the CCOV would cause the families further distress. The concerns included that there may be a delay in the family being able to make the funeral arrangements, which may contribute to their anguish. Also raised was the potential for the families to think that there had been some *mismanagement* of the deceased or that care had been sub-optimal.

There was an understanding expressed by some of the participants of what was required prior to reporting a death to the CCOV, such as the demographics of the patient, brief clinical history, any family concerns that had been raised regarding the death. There was very little acknowledgement of the consideration that the death was reportable, or under which criteria a death may be required to be reported.

6.4 Clinical Scenarios

6.4.1 Development of the clinical scenarios

In study two, the clinical scenarios were developed utilising two main sources of information. The primary source was the retrospective audit of the medical records of deceased inpatients at the

health care facility over a 12-month period (study one). The second source was the researcher's knowledge of commonly occurring deaths that occur within healthcare facilities. This process demonstrated the corroboration of information from several sources and the mixed methods research strategy of explanatory sequential design.

6.4.2. Delivery of the clinical scenarios

Of the 22 clinicians that completed the scenarios, 13 were medical staff who had all personally reported patient deaths to CCOV during their clinical practice. Although the nursing staff had not directly been responsible for reporting deaths to the CCOV, they were all aware of cases within their own areas of clinical practice that had been potentially reportable. For each of the clinical scenarios, the "definitive" answer, regarding whether the death described in each of the scenarios was reportable or not, was determined by a senior Victorian Coroner, together with the rationale for the decision. There was inconsistency in the responses of the clinicians when comparing their answers with the definitive determination of whether the deaths within the scenarios met the reportable criteria. Similarly, there was no uniformity for the scenarios among the coroners.

The lack of clarity in the understanding of which deaths constitute a reportable death reinforces the data obtained from the semi-structured interviews, and the findings of the deaths with the incorrect reporting process identified (Chapter 5). This absence of consistency between the clinicians also has significant consequences for the "by the bedside teaching" that occurs. The development of clinical scenarios that reflect the patient population and contexts of the organisation may lead to a better understanding of where the areas of focus of clinical support and education is required. This approach makes it possible to be transferred to other health care organisations.

Noting that the coroners generally do not have any formal clinical backgrounds there may the opportunity for peer review between the coroners of healthcare related cases to obtain further consistency.

The ten clinical scenarios, as they were presented to the participants, are as follows.

Scenario 1

An 87-year-old female presents to the hospital after a fall at home where she sustained a fractured neck of femur. A dynamic hip screw is inserted, and the patient is assessed as ready for transfer to a rehabilitation facility, five days later. The night before the transfer occurs, she becomes confused and has a fall in the ward. She is diagnosed with a chest infection and her condition deteriorates despite treatment with antibiotics. Referral is made for palliative care and she dies three days later in the ward.

Q. Is the patient's death reportable to the office of the coroner?

A. Yes, indirectly from injury

Discipline	Agreement
Medical staff	7/13
Nursing staff	2/9
Coroners	7/7

In reference to this scenario, the clinicians gave varying reasons as to why they believed this death met the reportable criteria. They considered it reportable due to it being the outcome of a fall (meeting the accident or injury criteria) or related to the procedure to repair the fracture as a result of the initial fall. Several clinicians referred to the death as reportable because it occurred within a variable time frame of the procedure, "...death occurred within 2 weeks of an operation, chest infection a complication" (D10) and in a healthcare setting, "... fall in healthcare setting"(N9). The clinicians who did not think that the death, as described, was reportable commented, "not attributable to operation, as day 5, thus not surgery related" (D9) and "had fall in hospital but clinical deterioration can be explained by chest infection and hence palliation" (N3).

There was agreement between all of the coroners and the senior coroners on the reportable nature of the death described in the scenario, however, the rationale for the acceptance of the death as reportable varied: "Appears to be directly connected with fall/procedure" (C 1); "yes her decline in her health and ultimate death is directly related to her fall (arising from accident or injury" (C4); and, "unexpected, is death related to fall and /or medical procedure (also there is no cause of death thus reportable" (C3).

Scenario 2

A 46-year-old male, who has been paraplegic since a motor car accident four years ago, is admitted with recurrent sacral pressure injuries. Whist an inpatient, he develops sepsis and is treated with antibiotics. During this time, he also develops a chest infection, requiring non-invasive ventilation assistance. Over the next five days, his condition continues to deteriorate, and he dies.

Q. Is the patient's death reportable to the Coroner's office?

A. Yes, Indirectly from injury

Discipline	Agreement	
Medical staff	4/13	
Nursing staff	2/9	
Coroners	2/7	

The majority of participants (6/22) did not agree that this death met the reportable criteria. Those that did agree that the death was reportable commented that the death was an unexpected complication or due to "maybe the patient's age" (N 5). One comment was that the death was "unexpected, original injury was trauma – good case to seek advice from the coroner" (D3). Those that did not agree stated that "no trauma or medical procedure involved with this hospital admission" (N1); "clear cause of death" (4 N); "clear medical reason for death" (D11); and "it's likely that his most likely [cause of] COD is overwhelming sepsis" (D5). There was a lack of certainty within the coroners' group, with comments reflecting that they were in two minds as to whether this death was reportable:

"Y/N direct correlation between the accident and the development of pressure areas – sepsis and death. Therefore, easy to justify /accept as reportable. On the other hand, it is arguable that there is a break in the causal link b/w accident and development of chest infection which has been found to be the cause of death and death was also arguable expected and therefore not reportable (C4)"

Another commented that "death as a result of accident but may need an investigation of reportable incident to get to the point of saying this is unreportable" (C5).

Scenario 3

A 68-year-old woman has been recently diagnosed with adenocarcinoma and is admitted for extensive abdominal surgery. Immediately post-operatively, she is in the intensive care unit (ICU) and stable. She is extubated the next day and transferred to the surgical ward. She is mobilising by day 4 and is progressing well, when she is found collapsed by her bed. Resuscitation is attempted, unsuccessfully, and she dies of a presumed pulmonary embolus. It is then discovered that she had not received any VTE prophylaxis.

Q. Is the patient's death reportable to the Coroner's office?

A. Yes, unexpected death

Discipline	Agreement
Medical staff	11/13
Nursing staff	9/9
Coroners	6/7

In this scenario, there was a higher level of agreement, in line with the definitive answer, that the death was reportable to the CCOV. Within the comments made by the clinicians, there were a range of reasons given for the death to be reported. These included that there was an "unknown COD in hospital" (N1) or "unexpected death after a medical procedure. The issue about DVT prophylaxis will be of interest to both the coroner and the hospital clinical governance team" (D3) or that "she has had a surgical procedure in the preceding 28/7 prior to her death" (N6). The identification of care management issues and the potential preventability of the death were also suggested by several clinicians in their comments, "could have been a preventable death" (D6) and "failure in care that should have been standard" (N4).

Similarly, the coroners' group also had a high level of agreement among each other for this clinical scenario but for different reasons. "[The death] appears to be related to the procedure" (C1) or "the surgery may have caused her death" (C6). Coroner 4 referred to the death as being reportable, as it was unexpected, but not reportable, as it "doesn't satisfy the medical procedure limb of reportable death".

Scenario 4

A 27-year-old unemployed woman was admitted with jaundice for investigation. She confessed to taking an overdose of paracetamol, five days previously. Investigation revealed deranged liver function tests and abnormal clotting. Despite full treatment, she developed hepatic encephalopathy and renal failure in ICU. Her condition continued to deteriorate and she died four days later.

Q.Is the patient's death reportable to the Coroner's office?

A. Yes, unexpected and unnatural death

Discipline	Agreement
Medical staff	8/13
Nursing staff	4/9
Coroners	6/7

The reasons given for the death in this scenario being described as reportable referred to the overdose of medication as being "deliberate self-poisoning led to death, unnatural death" (D7) or "maybe a deliberate overdose or given by someone else- unnatural death" (D11).

One clinician expressed that they were uncertain as to whether the death was reportable as "not entirely unexpected, but? mental health service contact" (N6).

Clinicians that did not think that the death described in this scenario should be reported commented that "COD acute liver failure, I am not sure if suicide cases are reportable, would at least discuss with coroner's office" (D5) and "not unexpected and known causes" (N1). In this scenario, there was a high level of agreement, again, as the death was "unnatural" (C1), or "death unnatural, unexpected, drug related" (C7).

Scenario 5

A 56-year-old male, previously well, presents to the Emergency Department (ED) following an out-of-hospital cardiac arrest. Effective resuscitation was quickly instigated at the scene, with return of spontaneous circulation within four minutes. On arrival in ED, a 12-lead ECG showed a large anterior myocardial infarct (MI). The patient was transferred to the cardiac catheter lab where he suffered another cardiac arrest.

Q.Is the patient's death reportable to the office of the coroner?

A. Yes, unexpected death

Discipline	Agreement
Medical staff	5/13
Nursing staff	4/9
Coroners	2/7

The association with a procedure was one reason given by the clinicians (N2) for reporting this death, in agreeance with the Senior Coroner's opinion. Another reason was that the patient had died

following a significant event, "died within 24/24 of admission and following/during a procedure" (D6). Further comments included, "unexpected death in a previously well man. In my experience, this scenario may or may not be accepted by coroner for review so I would be inclined to discuss it with the coroner's office at the time" (D12).

Of the clinicians that did not agree that the death was reportable, the rationale given was that the "death from natural causes despite best medical care, COD [Cause of Death] well understood and no concerns re care" (D7) and "Natural disease process? Potentially all COD could be explained" (N3).

The majority of the coroners did not agree with the Senior Coroner's assertion that this death was reportable. The rationale given was that the death was not related to the procedure. Three of the coroners referred to the death as being due to "natural causes" (C1, C2, C4).

Scenario 6

An 18-year-old man, who was a pedestrian hit by a car, sustained a fracture at the base of his skull, frontal lobe contusions and a contrecoup injury. He was transferred to ICU and mechanically ventilated but, after a few hours, his condition improved and he was able to breathe spontaneously. He did not show any further improvement and despite supportive care, his condition deteriorated and he died six weeks after admission.

Q. Is the patient's death reportable to the Coroner's office?

A. Yes, unexpected death and maybe directly from injury

Discipline	Agreement
Medical staff	11/13
Nursing staff	7/9
Coroners	7/7

This scenario had the highest level of agreement among participants within all three groups. There was reference to reporting the death because the cause of death was unknown and may have been due to multiple factors and there was another reference to the age of the patient as potentially influencing the reporting of the death (N5). The majority of the comments referred to the patient's death having occurred as a result of traumatic injury. All of the coroners were in agreement with the definitive answer to the case presented in this scenario; i.e., there was a "direct causal link between injuries sustained from MVA and death" (C4).

Scenario 7

An 84-year-old male is admitted from a high-level care facility after a witnessed episode of him choking and vomiting. He has a history of Alzheimer's dementia and an acquired brain injury. His condition deteriorates and he dies two days later.

Q. Is the patient's death reportable to the Coroner's office?

A. Yes, unexpected and unnatural death

Discipline	Agreement
Medical staff	4/13
Nursing staff	3/9
Coroners	6/7

There was consideration of whether this patient was under the care of the Department of Human Services (DHS) and that the clinicians would seek advice. Of concern was one comment, "no value in investigating this death as end stage of a progressive neurodegenerative disorder" (D7). This demonstrated minimal understanding of the rationale for reporting deaths as a legal requirement. There was another high level of agreement within the coroner's group for this scenario. The death was deemed to be reportable as it was "unexpected, unnatural, result of injury-choking" (D7). Although it was stated that this was "borderline" and "arguably choking is a symptom of deteriorating illness – dependent on the doctor's preparedness to sign DC" (C1).

Scenario 8

An 84-year-old female is admitted to the ward for palliative care. She has a history of recurrent urinary tract infections on the background of a long-standing, non-traumatic paraplegia, and is wheelchair bound. She dies four days after her admission.

Q. Is the patient's death reportable to the Coroner's office?

A. No, natural cause death

Discipline	Agreement
Medical staff	9/13
Nursing staff	8/9
Coroners	7/7

The coroners were unanimous in their answer to this question, agreeing that the death described in this scenario was not a reportable death. The only comment made was, "because she was receiving palliative care and her death was expected" (C6).

In their agreement with the coroner's answer, comments confirmed that the patient was "admitted for palliation" (N1); "expected death, clear cause" (D4) and "natural death without any criteria for reporting, no value in investigating non preventable deaths" (D7). Conversely, those that did not agree with the coroner's opinion (i.e. believed that the death should be reported) commented, "unclear COD from what has been mentioned ?Sepsis" (D5) and "don't know COD but expected, therefore, cannot sign death certificate" (D9).

Scenario 9

A 70-year-old male with chronic renal failure becomes hypertensive and complains of abdominal pain whilst undergoing haemodialysis. He then becomes unresponsive and a Code Blue is called. His resuscitation status is checked and there is a "not for resuscitation" order in place. The patient dies soon after.

Q. Is the patient's death reportable to the Coroner's office?

A. No, natural cause death

Discipline	Agreement
Medical staff	6/13
Nursing staff	4/9
Coroners	2/7

Within the clinician group, there was a reasonably even distribution of agreement and disagreement for this scenario.

The clinicians that disagreed with the Senior Coroner (i.e., believed that the death was reportable) supported their decisions by stating "absences of a clearly certifiable COD, undergoing a procedure at the time of deterioration. Presence of NFR doesn't negate the need for referral" (N6) and "unsure, COD not clear so I wasn't clear if this is reportable" (D11). Those that agreed with the coroner stated, "died of ruptured AAA, well recognised associated with HT vascular disease and management appropriate" (D9) "no but should be discussed as unclear COD" (D13) and "has NFR" (D10). There was a low-level agreement with the coroner's group for this scenario. Comments made by the coroners for this scenario included that the death" occurred during a medical procedure, may be

casually related to procedure, and not expected by doctor" (C7) and was "following a medical procedure" (C5).

Scenario 10

A 69-year-old male is admitted with shortness of breath in the background of newly diagnosed non-small cell lung carcinoma. The next day he collapses and has a cardiac arrest. Resuscitation was attempted, unsuccessfully, and he dies with his family.

Q. Is the patient's death reportable to the Coroner's office?

A. No, natural cause death

Discipline	Agreement
Medical staff	6/13
Nursing staff	4/9
Coroners	4/7

Again, there was an even distribution of agreeance and disagreeance with the definitive answer among the clinicians. The clinicians who did not believe the death to be reportable (i.e., agreed with the coroner's opinion) gave reasons, such as "if COD attributed to lung cancer" (N2) "but would only be considered reportable if the duration between diagnosis and death is considered quite short" (N5) and "but would only be considered reportable once the serious diagnosis was confirmed major events, including cardiac arrest are not unexpected" (D3).

The clinicians who did not agree with the Senior Coroner gave reasons, such as "died within 24/24 of admission" (D6) "unknown cause" (N9) and "new diagnosis and not expected to die" (D10).

There was mixed agreement within the group of coroners. Of those that agreed with the definitive answer supplied by the Senior Coroner that the death was not reportable, there was only a single comment made. This coroner stated that "it is all explainable BUT have had deaths (reported) with a similar cases on basis they said the death was unexpected" (C4). The coroners believed that the death was reportable as it was "unexpected" (C2) or "unless a doctor thinks his death was not unexpected given his condition" (C7).

6.5. Chapter summary

In this chapter, the findings of study 2, the qualitative data analysis have been presented. The development of both the semi-structured interview questions and the clinical scenarios has been described, with the content being drawn from the quantitative data acquired from the retrospective audit of medical notes.

The six themes that were identified in the responses to the interviews included (1) timing, (2) a lack of awareness or knowledge of reportable deaths, (3) perceptions of fear/ blame/ stigma attached to the reporting of deaths, (4) education, (5) transparency /accountability and (6) the practicalities involved in reporting of the deaths.

The results of the clinical scenarios indicate that the participants' understandings of reportable deaths are quite variable and there is a need for ongoing educational support for the identification of reportable deaths.

A lack of clarity was also reflected in the coroners' responses, and this finding reinforces the data obtained from the semi-structured interviews.

In the previous chapters the results have been presented and discussed for both study 1 and study 2, (Chapters 5 and 6 respectively). The results indicate that several factors impact on the appropriate and accurate reporting of deaths to the CCOV.

In the next chapter, Chapter 7, the 64 cases that were identified in the analysis of the quantitative data in study 1 as having a reporting error will be presented. In these cases, the incorrect reporting process was followed in that the deaths were either reported inappropriately or were not reported, despite meeting the reportable criteria. The implications for clinical practice, health care organisations, the CCOV and broader community will also be discussed.

There have been two publications that describe the key findings of study 2 (see Appendix 6.1, 6.2):

Appendix 6.1 What do clinicians understand about deaths reportable to the coroner (interviews) Charles, A; Cross, W & Griffiths, D, (2017)

Appendix 6.2 What do clinicians understand about deaths reportable to the coroner – Use of clinical scenarios to enhance learning. Charles, A; Cross, W & Griffiths, D, (2018)

Chapter 7 Results and Discussion – Study 3 In depth review of cases where incorrect reporting was identified.

The first requirement in a hospital is that it should do the sick no harm." Florence Nightingale 1863

7.1 Introduction

In this chapter, the results of study 3, the in-depth review of the cases where a reporting error was identified, will be presented and the findings will be discussed. In the previous chapters, the results have been presented and discussed for both studies 1 and study 2 (Chapters 5 and 6 respectively). These results indicate that several factors impact on the appropriate and accurate reporting of deaths to the Coroners Court of Victoria (CCOV).

The results and discussion of the findings of study 3 address research objectives 2 and 3. These objectives were: to examine factors that impact on a clinician's decision to report a death to the coroner and to determine a clinician's knowledge of the legal requirements of reporting a death in the health care facility to the coroner.

The chapter is arranged as follows. The 64 cases identified, following analysis of the data in study 1 where the inappropriate reporting process was followed, are first described. Secondly, the criteria under which each of the 64 identified deaths is presented and discussed. Included in this discussion will be a separate presentation of the 12 cases where there was incorrect reporting. There will then be discussion of the findings.

For this study, there is a definition of incorrect reporting under two descriptions.

Incorrect reporting is defined as:

- (i) the death that was not reported (failure to report) when it met the reportable criteria, or
- (ii) a death that did not meet the reportable criteria but was reported (this includes inappropriate /over reporting)

These cases are then presented under the specific criteria for the circumstances of the death met, as defined within the *Coroners Act 2008* (Vic). Of the criteria, there were four specific areas where deaths were identified, with the majority of the deaths occurring as a result of an accident or injury.

7.2. Detailed results and discussion of findings

As stated earlier, the results of the in-depth review of the 64 cases that were recognised as having a reporting error are presented in this chapter. Figure 7.1 graphically presents the breakdown of the

reporting criteria, with the cases presented under the individual reportable criteria. This is the criteria within the *Coroners Act 2008* (Vic).

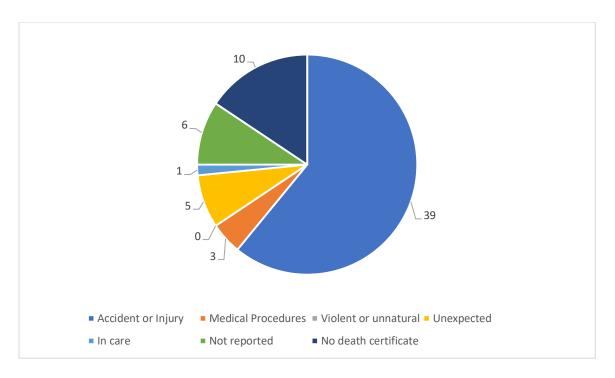


Figure 7.1 Criteria of deaths where the incorrect reporting process was identified

(i) Accident or injury -a death that appears to have resulted, directly or indirectly, from an accident or injury (Coroner's Act 2008 [Vic]). The reportable death criteria in the Coroners Act 2008 (Vic) gives the example of accidental deaths as "deaths resulting in complications such as fractured neck of femur or subdural haemorrhage" (Coroners Court of Victoria, 2018)

A common area that causes confusion is the interpretation of the criteria where the death occurs as a result of accident or injury. This was demonstrated in the results of both study 1 and study 2 and a criterion where there was a large volume of cases identified. Under this criterion, a causal link must be made between the injury and the death, although there are no time frames to guide decisions. Of the 64 cases where a reporting error was identified, there were 60.9% (n=33) that may have been reportable, according to the criteria of accident or injury. In the in-depth review, it was identified that these patients were reported to have suffered a fall, either immediately before or during their hospital admission, and, therefore, met the reporting criteria of death resulting directly or indirectly from an accident or injury. For example, in the death of a patient who previously sustained an injury in a motor vehicle accident and the accident contributed to the death, it must be reported, as per the criteria. From a healthcare facility perspective, for inpatients who sustain a fall during their

admission and, subsequently, die, it is often challenging to determine whether the death is reportable. If there is a causal link between the fall and the death, then this death is required to be reported. However, this link can be difficult to establish and, therefore, the contribution of the fall and injury to the death can be difficult to determine. Of the patients with a documented fall prior to their admission, there was documented harm, in the form of fractures or other injuries, that precipitated the hospital admission.

In this subset of deaths, there was documentation of discussion with the CCOV in eight cases, with seven cases documenting that there was discussion/consideration at the time of death. There was generally a reference to a more senior person (Consultant) who was asked for advice. The documented discussion between the clinicians and the CCOV, in the majority of cases, referred to the lack of contribution of the fall to the death (with or without documented injury) and, therefore, any causal link of the contribution of the fall could not be demonstrated.

For example, there was one case where a patient presented to hospital, following a fall at home, and died a week later. The CCOV response was documented as "despite fall at home, no SDH (subdural haematoma) or NOF (neck of femur fracture) so not reportable death". This is not a very constructive or educative focus for the clinicians who were commonly seeking advice regarding whether the death was reportable. Another example involved a patient who fell at home, sustaining a fractured pubic ramus, and was admitted with vomiting and hypotension and, subsequently, died two days later. The decision had been made, clinically, for conservative management of the fracture, however, there was discussion with the CCOV, who stated that fall did not contribute to the death. The cause of death was recorded as sepsis/end stage renal failure. This also demonstrates a lack of understanding of which deaths meet the reportable criteria.

Another patient, who was admitted for palliation, had a fall as an inpatient on the day prior to the death. The clinician was advised by the CCOV that "given no significant injury (was) sustained and the patient was admitted for palliation, this is not a coroner's" (case). The reasoning given by the CCOV as to why the death was not reportable was that the patient was "admitted for palliation", which does not assist the clinicians in their understanding of why the death is, or is not, reportable.

There were also examples of a lack of understanding of deaths that are reportable. In one case, a patient who suffered an inpatient fall with presumed head strike died two days after the fall. In the documentation, reference is made to the senior clinician who commented that it "was up to the family if they want to report the death". This demonstrated a lack of understanding that, according to the legislation, there is a legal obligation to report a death if it meets the reportable criteria

(*Coroners Act, 2008* [Vic]). Similarly, in another case, it was noted that if there were "no questions that the family had that they wanted the coroner to answer, the fall would be considered secondary to ischaemic stroke, and not a cause of deterioration. Therefore, not a coroner's case".

The area of patient falls (with resultant harm or death) is one of interest in many areas and a focus of patient safety studies. The Australian Patient Safety Foundation, in their recent research report that reviewed sentinel events in Victoria, also noted that falls with harm make up a significant number of reports to the Department of Health and Human Services and the sentinel event program (Hibbert, et al., 2016). A sentinel event is an event in health care that occurs as a result of deficiencies in processes and/or systems and usually results in harm, or even death, to the patient.

This report also noted clinicians' confusion when deaths associated with falls require further investigation. One recommendation to assist in the review of the circumstances around these falls was the development of a template, to ensure a consistent approach to the investigation (Hibbert, et al., 2016). There is also some lack of definition regarding what is described as a mechanical fall compared to a patient collapsing from a medical condition. This, potentially, further adds to confusion and the absence of documenting precise details. In New South Wales, there is an age restriction in place for accidental deaths. Section 38 (2) of the *Coroners Act 2009* (NSW) refers to someone aged over 72 years who dies from accidental injuries and whose age may have contributed to their death. These cases do not need to be reported to the coroner. The reasons for this change appear to be twofold. One is to minimise the angst and stress of the deceased's family regarding the process of the coronial investigation. The second is to reduce the case load of the coronial services (Cordner, 2013). Despite the intentions of these reasons, this approach may lead to a missed opportunity to assist in the identification and enacting of preventative measures.

A pilot study was conducted in 2017, regarding falls in hospitals and the required reporting process, collaboratively between CCOV and the Victorian Institute of Forensic Medicine (VIFM). In this proposal, it was stated there are over 1000 deaths of elderly people, annually, who die due to complications following a fall resulting in a femoral fracture. In the past, the deceased were transported to VIFM for medical examination. The bodies were to be held within the hospital mortuary facility for 48 hours to allow for the preliminary review to occur at CCOV and to determine if any further investigation was required. These deaths were still to be reported to the CCOV but would not necessarily have an autopsy or other medical or scientific examination (S. Hinchey, personal communication, 2017) (see appendix 7.1) Whilst this is a positive change for families of the deceased and, potentially, minimises any extra distress or delays for them and may result in enhanced utilisation of resources at VIFM, this approach may prove challenging for clinicians. There

is already some confusion among clinicians regarding the contribution of a fall to death and this may be intensified with these changes. This process has now been incorporated into usual practice at the CCOV (J. Leditschke, personal communication, 2019).

The majority of the deaths that required further review were patients who had suffered a fall, potentially associated with their deaths; however, there were other deaths recognised in this category. These were deaths that appear to have resulted, directly or indirectly, from an accident or injury but were not categorised as falls.

In one case, a patient who had previously sustained a cervical spine fracture (C5) and incomplete quadriplegia in a motor vehicle accident was admitted with pneumonia. He died during this admission and the clinician was advised that the death was not reportable, since the legal claim had been finalised. The death was reviewed by the Registry of Births, Deaths and Marriages (BDM) and referred to the CCOV for review, and the report was, then, accepted. This type of information makes it difficult for clinicians to understand which factors contribute to the deaths that meet the reportable criteria.

In another case, a patient was admitted with a fall. The documentation indicated that the consideration for reporting was due to a minor procedure that had occurred in close proximity to the death but had no contribution to the death, therefore, creating further confusion for the clinicians.

(ii) Unexpected death-, not reported and death certificates were written - a death that appears to have been unexpected, unnatural or violent (Coroners Act 2008 [Vic]).

An unexpected death is another criterion that requires further definition for clinicians to accurately report deaths. This is an ambiguous and subjective description and is challenging to define. There may be one criterion where the death may have been deemed preventable, as the death was not predicted or expected to occur during the admission. The definition of what is an "unexpected death" has been highlighted as problematic. Middleton & Buist (2014) point out the circumstances or perspectives that may be interpreted as contributing to death that was unexpected: during a procedure, on admission to hospital, whether clinicians shared the same understanding of whether the death was unexpected, and what the family members understood to be the circumstances. There is considerable scope for subjective interpretation (Middleton, 2015). There may also be a lack of clarity between the interpretations of unexpected deaths. from either a legal or medical perspective (Neate et al., 2013).

There were three deaths that were identified in this category as being an unexpected death. In only one of the three cases was there documentation of discussion with CCOV.

(iii) Unable to sign death certificate- a death that occurs in Victoria if a notice under section 37(1) of the Births, Deaths and Marriages Registration Act 1996 has not been signed and is not likely to be signed (Coroners Act 2008 [Vic]).

Of the 64 cases in this group, there were five cases identified as not able to have a death certificate signed. Two of these cases involved the deaths of patients who had suffered out-of-hospital cardiac arrest with an unclear cause of death. There was a cause of death opined as hypoxic brain injury secondary to cardiac arrest, however, the primary cause of the cardiac arrest was unclear.

In another case, a 71-year-old patient who had metastatic disease was admitted to hospital with generalised debility, including a fall before admission, with head strike. Radiological examination showed a new haemorrhage and the patient developed pneumonia soon after and died. A death certificate was written at the time, with documentation as "confident cause of death pneumonia in setting of cerebral bleed post fall with head strike on a background of metastatic RCC". The death was later discussed within the medical unit caring for the patient and also with the CCOV. The death was then reported, retrospectively. This case reflects the inconsistency in the interpretation of which deaths are reportable, which can result in under-reporting or inappropriate reporting of the deaths. The inconsistency also results in confusion and uncertainty for clinicians in considering the required review of patients and, subsequently, a potential lost opportunity for any learning as a result of these death.

(iv) Medical procedure- a death that occurs— (i) during a medical procedure; or (ii) following a medical procedure where the death is or may be causally related to the medical procedure— and a registered medical practitioner would not, immediately before the procedure was undertaken, have reasonably expected the death; (Coroners Act 2008 (Vic)).

There was only one death in this subset that fell within the criteria. In this case, an 82-year-old female was admitted with intracerebral bleeds, secondary to the new diagnosis of atrial fibrillation. She had suffered an intracerebral bleed in the past, which had been managed surgically at another hospital, although the time frame was unable to be clarified. This procedure was mentioned on the completed death certificate and the case was referred to the CCOV from the BDM, due to the reference to the craniectomy on the death certificate. There were no clear time frames documented, therefore, the relationship between the death and the surgery was unable to be established by clinicians. It would appear that a conversation with the CCOV was required to

determine whether the death met the reportable criteria. This is one area where there may be an inappropriate or under-reporting of deaths occurring.

Although this may be a small number of cases where there is inconsistency in reporting identified, the situation does reflect the potential lack of understanding and consistency in the reporting or acceptance of the report. There has been some research into the possible area of the underreporting of deaths to coronial services and how this information may impact on the delivery of safe patient care (Charles et al., 2007; Dwyer et al., 2012; Neate et al., 2013). Neate et al. (2013) found that the largest group of under-reported deaths in their review fell under the criteria of accident or injury, including deaths as a result of a fall. There were similar findings in the study by Dwyer et al. (2012), who audited deaths within the organisation that had coronial involvement, finding that, of the 82 deaths reported, 68 had been directly reported but the remaining 14 deaths had been referred by BDM (under the accident and injury criteria). This, again, indicated that there is a lack of understanding of the information required to report a death.

Within study 3, there were 12 deaths that were reported by the clinicians but were later deemed to not meet the reportable criteria, following further review by CCOV. Barnes et al. (2014) refer to the use of resources within the coronial services, as a result of deaths where there is a reporting error; i.e. the death is reported when it did not meet the criteria or require independent investigation.

Again, this is only a small number of the total of deaths for this particular health care organisation but these numbers may be reflected across the state and, potentially, across the nation. As well as these deaths utilising resources unnecessarily, as stated above, they offer another reflection on the comprehension of the clinical staff regarding which deaths are reportable. Of course, for a reported death to be accepted, the staff at the CCVOV are required to make that decision, however, yet again, are reliant on the information that is provided. Barnes et al. (2014) determined that there were three groups of deaths where the was inappropriate reporting.

These groups were:

- (i) following a fall,
- (ii) where a death certificate was not able to be signed, and
- (iii) health care related deaths.

This was reflected in the results of this study, with 50% (n=6) of deaths reported, although not actually reportable under the criteria of deaths as a result of accident or injury (i.e., falls that contributed to the death). In the category of the death certificate able to be signed, there were 25%

(n= 3) deaths and 16.7% healthcare-related deaths (n=2). The other death that was inappropriately reported (n=1) was under the category of an unexpected death.

Efforts have been made to simplify the classification of a death that occurs within a healthcare setting in the *Coroners Act 2008* (Vic), with attempts to make the definition clearer, however, this cohort of deaths may be one of significant under-reporting and is, therefore, an area of further study

7.3 Conclusion

This chapter has presented the results of study 3, which has further reinforced the important contribution that an independent review of deaths can make to the delivery of safe patient care. An in-depth review of the 64 deaths identified as having a reporting error in this healthcare facility over the period of one calendar year was performed. The findings demonstrated that the criteria of deaths that occurred as a result of accident or injury are one in which there is confusion and a lack of clarity for clinicians, which is also reflected in the findings within study 2. Donabedian refers to the measurement of adverse events or harm that occurs to a patient receiving healthcare as one of the measures of quality health care delivery (Donabedian, 1966). The identification and subsequent review of deaths can only be further enhanced if there is clarity as to which deaths meet the reportable criteria.

In Chapter 8, the results of the three studies and a discussion of the implications for clinical practice, health care organisations, the CCOV and the broader community will be presented.

Recommendations for further actions will also be presented in this final chapter.

Chapter 8 Overall discussion, recommendations and conclusion 8.1 Introduction

The primary aim of this study was to examine clinicians' understanding of which types of deaths meet the criteria to be reported to the Coroners Court of Victoria (CCOV). To address this aim, a mixed methods study was conducted, with three studies or components of the overall study undertaken. The three studies were comprised of:

- Study 1 Retrospective audit of clinical notes (Chapter 5)
- Study 2 Semi-structured key informant interviews and clinical scenarios (Chapter 6)
- Study 3 In-depth review of deaths, where incorrect reporting processes were identified
 (Chapter 7)

This study was underpinned by the concept of patient safety and how issues relating to reportable deaths and a clinician's understanding of this process might impact this concept. This is against the background of an evolution in the concept of patient safety and the understanding that there is preventable harm occurring during health care delivery. Internationally, since the 1990s, there has been an increased focus on harm, including death, that may occur during a patient's journey within healthcare and the potential for these adverse events to be monitored and, potentially, prevented. Identification of preventable deaths is also an element of the Coroners' mandate. The concept of monitoring and reviewing mortality figures was described by Donabedian in 1966 and, prior to this, by Florence Nightingale, who also demonstrated this as a measure of quality of care delivery in the 1860s.

In Chapters five, six and seven s the results have been presented and discussed for the three studies that were completed. The results indicate that several factors impact on the appropriate and accurate reporting of deaths to the CCOV. This chapter will present a summary of the key findings, the implications for clinical practice, health care organisations, the CCOV and the broader community. The findings will be discussed under the concept of a recognised failure in the reporting process. The cases will be described where there is either (i) failure to report the death or (ii) failure of appropriate reporting (inappropriate reporting).

Within Chapter 8 the integration of the results of the quantitative and qualitative components of the study are presented, together with possible explanations for these findings. The strengths and limitations that were identified during the conduct of the research will, similarly, be presented, together with recommendations for practice. To conclude, opportunities for future research will be proposed. The key findings of the three studies are summarised against the research objectives in Table 8.1.

Table 8.1 Summary of Key Findings

Research objectives and data type	Description	Key Findings
Research objective Research objective To examine the frequency and characteristics of deaths at one health service over one calendar year. • Quantitative data	Retrospective audit of clinical notes Structured review utilising an audit tool developed to determine: (i) Demographics (ii) Details of death (iii) Reporting details	 Data were categorised as correct reporting process/incorrect reporting process (i) Demographics Number of deaths reviewed in one calendar year in one healthcare facility (n=1,262). Ages ranged between 18-103 years. In 1,198, (94.9%), of deaths the correct reporting process was followed (i.e. no reporting error). There were 64 deaths, (5.1%), where an incorrect reporting process was identified.
		 Even distribution between male and female patients in both groups. (ii) Details of deaths Majority of deaths occurred in the following areas: Cancer, Neurosciences, or Medicine clinical units. Deaths most frequently occurred at 1201-1800 hours (both categories) (iii) Reporting details Majority of deaths met the accident or injury criteria of the Coroners Act 2008 (Vic)

Research objectives and data type	Description	Key Findings
Research objective To identify factors that impact clinician's decisions to report a death to CCOV, To examine clinicians' knowledge of the legal requirements of reporting a death. • Qualitative data	Semi-structured key informant interviews and clinical scenarios. These questions and clinical scenarios were developed following the audit of clinical notes. Thematic analysis of the data was performed.	Six themes identified. Timing Lack of awareness/knowledge Fear/blame/stigma Education Accountability Practicalities of reporting
Research objective To identify themes that present in the cohort of deaths where the incorrect reporting process occurred. • Quantitative data	In-depth review of unreported deaths that meet the reportable death criteria. Thematic analysis of this group of deaths performed.	 The incorrect reporting process was identified in 64 cases. 12 of the 64 cases were reported to CCOV but then determined not to meet the reportable criteria. The majority of cases where the incorrect reporting process occurred also fell under the criteria of accident or injury as per the <i>Coroners Act</i> 2008 (Vic).

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8.2 Failure to report or inappropriate reporting of deaths

8.2.1 Failure to report

As presented in Chapter 2, when describing the concept of patient safety, the role of mortality monitoring is an integral measure of the delivery of safe patient care. The mortality figures form a part of various clinical indicators and are reported both internally and externally to organisations in various forms, as a component of the clinical governance structure. This reporting process enables the review of deaths within organisations and assists in the determination of any preventable aspects to a death. There is a legal obligation in Victoria for a death that meets the reportable criteria to be reported to the CCOV. It is a requirement that "... a registered medical practitioner who is present at or after the death of a person must report the death without delay to a coroner or the Institute (Victorian Institute of Forensic Medicine) if the death is a reportable death" (Coroners Act 2008 (Vic) S.10(1) amended by No. 31/2013 s.12 (1)). Similarly, according to the *Coroners Act 2008* (Vic), any person who has reasonable grounds to think that a death is reportable and has observed that the death has not been reported, also has an obligation to report the death as soon as possible. It is within the description of reportable deaths that there were a cohort of deaths where it was acknowledged that there were reporting errors.

In this study, 64 deaths were determined to have failed to be reported or there was a failure to report the death appropriately. This indicates, primarily, that the legal requirements of death reporting have not been met, as per the *Coroners Act 2008* (Vic). The assumption is that this is not a result of criminal activity but, rather the result of a lack of understanding of the reportable criteria or inconsistency in the acceptance of the death report. Barnes et al. (2017) describe that, across Australia, only about 10 to 20% of deaths are investigated by the Coroner and this is the only independent scrutiny of deaths external to organisations, with the assumption that there are internal reviews of the means of mortality and morbidity processes (Barnes, Kirkegaard, & Carpenter, 2014). Again, the ability for this review to inform safe clinical practice cannot be underestimated.

Other Australian studies have previously recognised the issue of under-reporting of deaths to the Coroner (Charles et al., 2007; Freckelton & Ranson, 2006), particularly healthcare-related deaths that may be attributed to clinicians' lack of awareness or understanding of their roles. Neate et al. (2013) refer to under-reporting or non-reporting of deaths and issues as being related to the interpretation of terminology, such as unnatural and unexpected, and the lack of clarity of the causal relationship of trauma to death and whether a death is deemed "suspicious" and, therefore, needs to be reported (Neate et al., 2013). This study also examined the accuracy of death certificates, including the mode of death (e.g., cardiac arrest) rather than a pathological condition, the

contribution of other conditions and the contribution to the death. One of the issues identified from the inaccuracy of the death certificates is concerned with the aggregation of mortality data, which may be compromised due to this inaccuracy (Neate et al., 2013).

The inaccuracy of mortality data collection has also been recognised in a number of international jurisdictions, specifically Canada, the United Kingdom and Japan. Concerns have been raised in Canada about the quality of the medicolegal investigation of deaths and the accuracy of mortality statistics (Kelsall & Bowes, 2016). In six Canadian jurisdictions, it is the responsibility of the physician coroners or medical examiners to investigate any suspicious deaths. In the other Canadian provinces, these deaths are reviewed by a coroner, who is not a physician, and, thus, the reviewers have variable backgrounds. This leads to inconsistency in the level of investigation that occurs, including whether an autopsy is performed. In light of the findings of several reviews that have been conducted in the United Kingdom, in response to events such as the Dr Harold Shipman inquiry, the Office of the Chief Coroner has been put in place (Smith, 2003). One of the roles of the office, which was created in 2009 by the *Coroners and Justice Act, 2009* (United Kingdom), is to provide leadership and training for the coroners of England and Wales, together with the development and maintenance of national standards for review.

The Japanese Medical Care Act (Act No. 205 of July 30, 1948) was reviewed in 2014 and modified to enhance the reporting system of deaths that occur during or as a result of medical care. The aim of this "iryojiko chosa seido" (medical accidents investigation system) is to review medical accidents and, potentially, prevent them (Leflar, 2009) There is mandatory reporting of any "unexpected deaths" that occur and when there is a contribution of medical care to the death.

This lack of understanding by clinicians of reportable deaths is also present in the United Kingdom (Start et al., Similar to the findings of Neate et al. (2013) and Dwyer et al. (2012), deaths due to trauma or accident were commonly under-reported (Dwyer, Visser, & Russell, 2013; Neate et al., 2013). Deaths associated with medical treatment presented another area of confusion.

Several studies have identified criteria, within the reportable criteria to be problematic, for different reasons. Start et al. (1993), also refer to reasons for under-reporting of deaths as confusion in Coroners' practices, according to geographical location, in the United Kingdom (Start et al.,1995). There have been several studies that have reported areas of under-reporting of deaths, specifically in healthcare-related deaths. Charles et al. (2007) retrospectively audited the medical notes of 229 deceased patients from two hospitals. Of the 229 cases reviewed, 58 cases met the reportable criteria, with only 22 of the deaths having evidence of being reported to the Coroner's office. This

study found that the deaths of elderly people and those who died over night were less likely to be reported to the Coroner's office. The criteria for reporting were not reviewed, however, similarities were noted with under-reporting of deaths in the elderly patient group (Charles et al., 2007). This, again, represents the potential for a lost opportunity to determine if there were any preventable factors regarding the death and, hence, for clinicians to be able to learn from this.

Healthcare-related deaths is one criterium where there have been attempts to clarify the definition of death in this category, including in the revised *Coroners Act 2008* (Vic). These changes have not assisted clinicians' understanding (Middleton, 2015). In their study published in 2014, Middleton &Buist (2014) reviewed the Australian Coroners' Acts from the perspective of medically-related deaths and determined that there was no strong consistency in the definitions, which was also supported by Bird (2005). In Table 8.2, the differences in these definitions across Australia are described.

Table 8.2 Health care related deaths defined as per State or Territory of Australia

	Jurisdiction	Definition
Anaesthetic related death	Northern Territory (NT)	Death during or following as a result of an anaesthetic
	Tasmania (Tas)	Death during or as a result of an anaesthetic or sedation
	Western Australia (WA)	Death during or following as a result of an anaesthetic
Causal or temporal association with death Australian Capital Death due to an operation or hours		Death due to an operation or procedure, within 72 hours
	South Australia (SA)	Death due to procedure or anaesthetic or within 24 hours

		Death within 24 hours following inpatient discharge or presentation to emergency department.
Death not a reasonably expected outcome	New South Wales (NSW)	Death not reasonably expected as a result of health-related procedure
	Queensland (QLD)	Death not reasonably expected and occurs following and as a result of healthcare or the failure to provide healthcare.
	Western Australia (WA)	Death during or immediately following as a result of a medical procedure and not reasonably expected.

Note: In the causal relationship it must be quite clear, that is the death is, "as a result of". In Queensland it must be clear or likely, whereas, in Victoria, there needs to only be a "possible" casual connection with the death. Although these differences are subtle, they are differences nonetheless. This highlights the potential for subjective interpretation and error, in so far as the death may or may not be reported, omitting an opportunity for health professionals to be informed and learn from a particular patient's death.

The issue of healthcare-related deaths, specifically, was recognised, with a report commissioned to KPMG International Cooperative (KPMG) by the then Department of Justice and Regulation (now Department of Justice and Community Safety) on behalf of the Coronial Council of Victoria and was released in 2017. The purpose of this report was to review the underlying practices of inappropriate reporting of deaths and to improve the overall reporting of deaths (KPMG, 2017). Despite a review of the terminology and description of healthcare-related death by the Victorian Law Reform Committee in 2006, when the Victorian Coroners Act was reviewed, it was found that there was still confusion for clinicians (Victorian Law Reform Committee, 2006).

As with the findings of the qualitative and quantitative data in this study, the deaths related to accident or injury, particularly falls, was another area of misunderstanding for medical staff. The KPMG recommendations were for there to be a retrospective review of falls-related deaths, to determine if there are any benefits being achieved as a result of the reports and the impact on patient safety.

Unexpected deaths

Unexpected death is defined as one that occurs when a person, who appears to be healthy, dies unexpectedly (Department of Health & Human Services, 2019). KPMG reported that the definition of the term "unexpected" death was one which caused confusion to clinicians (KPMG, 2017). The

expectations of the definition of 'unexpected, when referring to death is not clear, from either a time frame or causal relationship. For example, it is not unexpected that a patient who is admitted to hospital with an aortic aneurysm that has ruptured may die prior to definitive management, however, the diagnosis of a ruptured aortic aneurysm may be an unexpected diagnosis, yet to be determined, at the time of death. Uncertainty about what constitutes an unexpected death may also be due to differences between the legal perspective compared to the clinical perspective of unexpected death (Middleton & Buist, 2014). What also needs to be determined is whether an objective or subjective assessment is made as to whether a death is unexpected, since the assessment of whether a death is unexpected may be either subjectively or objectively considered.

Unnatural and violent deaths

Harris (2017) describes the confusion of clinicians in the United Kingdom impacting their ability to differentiate between natural and unnatural causes of death and, consequently, whether a death needs to be reported. Recently, a Victorian Coronial finding, following an Inquest into the unnatural death of a patient that was not reported to CCOV, also identified several factors that may have impacted on whether a death was reported or not. These included a lack of recognition of prior trauma as a contributor to death by the clinicians and uncertainty regarding the reportability of deaths that are related to medical procedures (Neate et al., 2013; Spooner, 2012).

8.2.2. Failure to report deaths appropriately

Of the 64 cases identified, there were 12 cases that were deemed to have been reported inappropriately. This indicated that the deaths did not meet the reportable criteria but were reported to CCOV. There are several factors that influence whether the reporting of a death to CCOV is inappropriate or does not meet the reportable criteria. In Victoria, as stated earlier, for a death to be accepted as a reportable death by the CCOV, there is communication between the clinicians and staff at the CCOV.

Barnes et al. (2014) discuss a number of deaths that were reported to the Queensland Coroners Court due to a death certificate not being completed. Reasons included an inability to locate the treating doctor, reluctance to issue a death certificate or lack of access to relevant medical records. Conversely, a lack of familiarity of the clinicians with which deaths should be reported may also be problematic, as death is reported if the clinicians err on the side of caution. In Queensland, the category of 'natural cause of death' is an area where there is a perceived over-reporting of deaths, on which the focus of the paper was directed.

Recommendations have been made for ongoing support and education of clinicians by the coroners' office regarding the reporting requirements. Included in these recommendations is acknowledgment of the significant use of coronial resources for people who have died from natural causes, whose deaths require no further investigation (Barnes et al., 2014). As has been previously mentioned, there are information days offered to health professionals through the CCOV. These sessions provide information about the role of the coroner, the investigative process and the formulation of recommendations, which may lead to system improvement and, therefore, enhance the delivery of safe patient care.

This study demonstrated that there were three main groups of deaths which caused confusion regarding whether the death required reporting. The groups were healthcare-related deaths, deaths following a fall, and a death where there appeared to be a natural cause of death but the clinician was not prepared to sign certificate, therefore, the death needed to be reported (Barnes et al., 2014).

If there is under-reporting of deaths to the CCOV, there are lost opportunities for the systematic review of potentially preventable deaths and, therefore, missed opportunities to inform patient safety from a healthcare perspective.

8. 3 Strengths and Limitations of study

Strengths of the study

Creswell & Plano Clark (2018) describe explanatory sequential design as being one of the most straightforward of the mixed method designs. This design allowed for exploration of the research question utilising both quantitative and qualitative methods which also allowed for a deeper understanding of the question (Cresswell & Plano Clark, 2018). The quantitative data collection demonstrates what is occurring within the healthcare facility whereas the qualitative data collection, interviews and scenarios, describes what the clinicians believe is occurring regarding reportable deaths.

Although none of the participants availed themselves of the opportunity to review their interview transcripts, this was offered to them. The interviews, however, were professionally transcribed and the researcher listened to the recordings, checking the transcripts and the field notes several times to enhance the rigour and credibility of the study. Another strength of this study was the access of the researcher to the electronic clinical information systems and scanned medical records of the health care facility. This, coupled with the researcher's familiarity with the formatting and filing of the records, ensured a timely and accurate review of the data. The researcher's strong clinical

background, confidence when meeting with clinicians and familiarity with healthcare facilities were distinct advantages for this study.

Familiarity with the coronial practices that occur when deaths are reported, and access to coronial staff and the processes involved, was also advantageous for the researcher. The access to a senior coroner to determine the definitive answer for the clinical scenarios also proved to be an advantage

Limitations of the study

Mixed method research as a research design can be seem as time consuming for researchers (Creswell & Plano Clark, 2018). This study was based at only one healthcare facility and over a single calendar year, which may be seen as a limitation. However, the results of the study would be easily transferable to other healthcare facilities. The degree to which the conclusions can be applied to comparable settings and contexts, or the inference transferability of the study, is significant. There is the ability to replicate the study over other sites, with consideration of processes that may already pre-exist within the facility (Plano Clark & Ivankova, 2016).

There was a small sample size of the clinician group who were interviewed and completed the clinical scenarios, but there was a broad range of experience within the group.

8.4. Implications of the study and suggested ongoing actions.

As discussed earlier, under Part 9 of the *Coroners Act 2008* (Vic), there was the formation of an independent group, the Coronial Council. One of the primary functions of this group was to advise the Attorney-General regarding the role of the CCOV and their engagement with families, amongst other requirements. One piece of work that was commissioned by the Coronial Council was a review of inpatient death reporting to the coroner. This began after this study had commenced, and there were 22 recommendations made as a result of the review. (Coronial Council of Victoria, 2017; KPMG, 2017). The recommendations have not been made public at the time of writing. The progress of these recommendations was unable to be ascertained at the time of writing, despite several attempts to obtain the information from the Department of Justice and Community Safety.

The implications following this study and recommendations for ongoing actions have been considered, with reference to the findings of this study. The implications are presented under several sub-groups. These include implications for clinical practice; healthcare organisations; the CCOV; the broader community; education, policy; and future research.

8.4.1 Implications of the study for clinical practice

At an organisational level, the findings of this study described several areas of recommended actions. One of the issues raised by the clinicians was the feedback to them from the CCOV in a

timely manner about the deaths that were reported. Prompt feedback would enhance the opportunity for the clinical staff to learn from the independent review of the deaths by the Coroner and be able to act upon the information whilst the case was fresh in their memories. Information, such as the cause of death, would be useful to inform the clinical perspective on the coronial findings and any system-related improvements that may be recommended as a consequence. The complexity of the coronial review process may not be understood from the perspective of a clinician, who may be primarily focussed on the pathological cause of death of the deceased. The coronial process also includes the investigation of the circumstances around the death, to fulfil the expectations of the coroner's role. Information may need to be obtained via statements from relevant parties, which may include clinicians and organisations such as Safer Care Victoria. As Victoria Police members request the statement on behalf of the Coroner, with return of the completed document within a six-week period, this can also add significant times to the investigation and, subsequently, closure of the case.

Delays in the provision of this information from the CCOV may mean that there is a lost opportunity for timely lessons regarding the potential preventability of death and, therefore, to support safer patient care.

The lack of understanding by clinical staff as to which deaths are to be reported to the CCOV is another aspect of practice that requires consideration. This may be improved by focus of the clinicians at several critical points of inpatient care, particularly if the patient's condition is deteriorating; for example, if the death is anticipated when the patient is in a critical care area, such as an intensive care unit, and death is imminent. One suggestion would be to ensure there is a proactive discussion amongst the clinicians as to what the cause of death may be for the patient or whether there is a reason for the death to be reported and the factors to be considered. This could be both an educational and supportive process for the staff. Discussion at each clinical unit's mortality meetings could include reference to whether the death was reportable and why the death might be reported, by considering under which criteria the death met the reportable criteria. This may increase clinicians' understanding of the requirements as well as enhance clinicians' learning in a safe environment. The development of more robust guidelines outlining both the medical and the legal requirements would also be an adjunct to this process. Audit of the completed death certificates and circumstances would be part of the review process.

The principles of the study would be easily transferable to other healthcare facilities – scenarios could be modified to reflect the particular patient population, for example, paediatric, neonatal, and obstetric cases, as required.

8.4.2 Implications for healthcare organisations

The implications of the findings of this study for healthcare organisations have consequences for practice, policy and education. Organisations, such as healthcare facilities and training institutions, including universities and specialist medical colleges, need to acknowledge the comments made by clinicians regarding their training needs and areas of deficits. These needs occur at an undergraduate level and continue throughout their practice. As this study showed, it is across all levels of experience that there is some confusion and inconsistency regarding reportable deaths, so this ongoing education needs to be offered at all levels. The legislative requirements of reporting deaths would be included in this training along with further information regarding the role of the coroner in preventable deaths and informing public safety.

The opportunity for organisations to audit deaths that occur in a structured and formalised way is another method that could be employed to enhance the identification of reportable deaths. The documentation could be reviewed, and any discrepancies identified could be managed in a timely manner. This may be an important component of the mortality and morbidity meetings held at the healthcare organisational level, if the meetings occur within appropriate timeframes. These meetings are a valuable tool for identifying the potential preventability of the deaths and also for implementing a review process to determine if a death meets the criteria for reporting to the CCOV. It is also an opportunity to identify and implement practice changes which may enhance the safety of patients within healthcare organisations. There is also the need for an assurance of a "safe" environment without fear of retribution or blame for clinicians who identify that a death is reportable. It should be reiterated that if a death is reportable to the CCOV it does not equate with there having been some adverse event, wrong-doing or mistake made during the patient's care. There are requirements in the *Coroners Act 2008* (Vic) that need to be met.

In addition, there is an opportunity for organisations to review documentation practices, particularly for longer term patients; for example, those who have a fall at home but may die in rehabilitation some time afterwards. A regular summary of clinical events for patient would allow for ease of determination of any causal relationship between events and the patient's death.

8.4.3 Implications for Coroners Court of Victoria

There was identification of the need for continued communication with clinicians and organisations regarding their legal responsibilities regarding reporting deaths in this study. The CCOV's website is one avenue for this communication. Feedback, however, at the time of contact, as to why the report of death is being accepted or not, would also be beneficial, from an educational perspective.

Proactive feedback to the organisation and, therefore, the clinicians, regarding the progress of a coronial review will be required; for example, whether there is going to be an autopsy performed and the level of further review that will be required. For clinicians, early communication regarding the interim cause of death would assist in informing the local/organisational level review and enhance the opportunity for learning.

More timely and frequent information to the healthcare facilities regarding coronial findings from cases across organisations could also be educational for the clinicians. Safer Care Victoria (SCV) is now receiving and monitoring coronial recommendations and sharing information from the CCOV. Safer Care Victoria also supports information being offered to healthcare facilities to fulfil the suggested actions (Safer Care Victoria, 2018).

From the results following completion of the clinical scenarios, there was not strong agreement among clinicians regarding which deaths were reportable. There was reference to the varying criteria of the *Coroners Act 2008* (Vic) by which the deaths were reported, which again demonstrates the need for clarification of the criteria and reporting responsibilities. It may be beneficial for the CCOV to implement an audit of the deaths that are reported and determine which reporting criteria they meet. This audit may be similar to the suggested actions at an organisational level, where the findings could be shared between the CCOV and the healthcare facilities as an educational opportunity.

The lack of consistency in the Coroners Acts across Australia is also reflected internationally. There is the opportunity to develop some clear consistency across the jurisdictions, as has been implemented in the UK, in the form of the Office of the Chief Coroner to oversee the coroners of the UK. Recently, under the *Coroners and Justice Act, 2009*, the Office of the Chief Coroner has been provided additional roles. These responsibilities include the provision of leadership and education to the coroners of the UK and Wales. There is also a requirement to ensure that there are national standards for death investigations and that these are adhered to and supported.

Consistency across Australia regarding Coronial requirements would need collaboration and agreement in various circles, including the respective Attorney Generals, healthcare professionals and coronial services. The recent UK model of the implementation of the Office of the Chief Coroner could be considered.

Inconsistency regarding the criteria for reportable deaths and also subsequent investigation has been identified in several countries across the world. Provisions have been made to provide direction in some of these countries. In Canada, for example, within each jurisdiction there is a

requirement that physicians will report a death if they "reasonably believe" that the death meets specific circumstances (Ministry of the Solicitor General, 2019).

In the USA, although there is some variation across all the states regarding which deaths meet reportable criteria, there is still a requirement for reporting (Sedgewick, 2003) Typically, this includes deaths that occur in unusual or suspicious circumstances or occur in violent (accident, suicide, homicide) situations. Other criteria include natural disease processes when a death occurs suddenly and without warning, when the decedent was not being treated by physicians or the death was unattended. There is also some reference to time limits of when death is to be reported. More specifically is the reference to medical adverse events as the third leading cause of death in the US, which enhance the need for the preventative role of the independent review of deaths, together with the identification of any groups or clusters of circumstances (Sedgewick, 2003).

A mortality review is one tool that can be used to inform patient safety. There is also the opportunity to use these data to influence the development of quality improvement activities and areas of research which can, in turn, be used to inform and alter clinical practice.

8.4.4 Implications for society

The volume of cases in this study where incorrect reporting was noted, either inappropriate reporting or under reporting, was not large. However, there are implications for society, as there is an expectation that inpatients in healthcare facilities will receive the best, safest care possible. The safe care delivery from the perspective of this study is two-fold. There is the requirement for clinicians and the organisation to meet their legal obligations to report deaths and to have the appropriate practices in place to monitor this and to escalate, as required. Patients and their significant others generally have a higher level of health literacy than in the past. As such, there is an expectation that, if there is an adverse event that has contributed to the death or potential preventability of the death, this information must be shared through the open disclosure procedure, in a timely and transparent way.

8.4.5 Implications for research

There are several areas of ongoing interest, as a result of this study, that would benefit from further investigation and provide an opportunity to inform patient safety directions within health care organisations.

(i) It would be of interest to determine the frequency of adverse events that contributed to the death of a patient and whether there was any relationship between deaths that were reported or not. These events that cause harm or even death to patients may be

- unreported within clinical areas. This, coupled with the perceived stigma when reporting deaths to the CCOV, may demonstrate an area where a change in practice may be indicated.
- (ii) If a patient's care was focussed towards palliation, it would be useful to know whether there was any impact on the decision making, regarding whether the death was reportable or not. There is a large volume of deaths which occur in this area of palliative care where the outcome may be death. This does not mean that the death does not meet the reportable criteria and the casual relationships between any adverse event, for example, would need to be identified.

8.5 Recommendations

The recommendations are directed towards healthcare providers and the CCOV and highlight a need for consistency in reporting of deaths, from a clinician's perspective. This includes an enhanced understanding of which deaths require reporting to the CCOV and the rationale for these reports to be made. There is also a requirement for consistency in the expectations of the CCOV regarding which deaths are accepted as reportable. This consistency in understanding should result in an enhanced appropriate reporting of deaths and of the roles responsible for reporting these deaths. As already discussed within this study and the literature, the value of the review of deaths and the influence on patient safety cannot be under-estimated.

The opportunity to utilise this information gained from transparent and independent review will ultimately identify preventable aspects of deaths, adding another dimension to the delivery of safe patient care within healthcare facilities.

The recommendations for ongoing actions have been categorised under the following themes, noting that there are some aspects of the themes where there may be a degree of overlap between them:

- 1. Communication
- 2. Awareness
- 3. Accountability
- 4. Clarity and /or consistency
- 5. Education

8.5.1 Communication

Communication is one area where recommendations for action is recognised. Communication in this context refers to the understanding of clinicians and their subsequent documentation. In particular,

it was found that documentation of the clinical progress of patients whilst they are inpatients, particularly longer stay patients, could be improved.

Recommendation (1) The healthcare organisation reviews the expectations of documentation by clinicians relating to clinical progress of inpatients and ensures that this requirement is disseminated to clinicians.

Recommendation (2) Regular internal audits performed within the clinical units of the clinical documentation and both individual and aggregated feedback shared with the appropriate clinicians.

A review of the expectations of documentation at the organisational level will not only enhance communication more broadly but will also assist in the acknowledgement of any causal relation between the event and the death, for example, patients who suffer a fall and subsequently die. This will also assist in the appropriate and timely reporting of deaths, as required.

The documentation of any discussion by clinicians with the CCOV, regarding whether deaths met the reportable criteria, was an area identified as requiring improvement. This discussion is required prior to the death report being accepted by the CCOV and requires an understanding of the relevant information that is required prior to a consideration to report the death. Guidelines for clinicians, to ensure that the appropriate information to inform the report presented, should be developed. The CCOV has a checklist, called the Reportable Death checklist for hospitals or other medical facilities (Appendix 8.1), which provides some assistance, but there is still no guidelines for clinicians to determine why the death is reportable. Follow-up review of discussion points could be performed at both the organisational level and also at the CCOV, for consistency and improved understanding of the requirements. At times, the death of a patient is anticipated and there is the chance for a proactive discussion between the clinicians and /or the CCOV, to determine if the death is likely to meet the reportable criteria. This provides the opportunity for further consideration and determination of whether the death is reportable in a less time-pressured environment. This also allows the possibility for a timely learning situation to occur.

Recommendation (3) Development of standards or a checklist collaboratively between the CCOV and healthcare organisations to assist in the details required prior to communicating with the CCOV.

Recommendation (4) Documentation standards or checklist for information required prior to contact with the CCOV, to guide clinicians and ensure that the appropriate information is being communicated in regard to whether a death is reportable or not.

Recommendation (5) Documentation within the medical notes and /or inclusion of a checklist allows for audit of the discussions, which is beneficial for the organisation and clinicians and from the perspective of the CCOV.

Another aspect of communication that was identified by this study was the timeliness of feedback following the reporting of a death. Feedback included informing the clinical staff as to whether the death was going to be further investigated by the CCOV and the progress of the investigation, which would allow for two-way information sharing.

Recommendation (6) Development and implementation of an electronic database or portal by the CCOV, to allow clinicians and organisations to determine the progress of investigations and provide updated information

8.5.2 Awareness

There was a lack of awareness of the role and responsibility of the coroner in review of deaths and identification of potential preventability of a death, which could, in turn, inform safe patient care delivery. The clinician's awareness of their legal responsibly to report a death that meets the reportable criteria should also be considered.

Recommendation (7) Further face-to-face education and also the use of on-line resources, shared between the CCOV and organisation, to inform and reiterate the roles and responsibilities of both groups in reporting of deaths and to explain why this is important.

8.5.3 Accountability

The accountability for the decision making regarding the reporting of deaths to the CCOV, at the level of the organisation and the CCOV, was another area identified by this study where modifications could be made. This accountability may be recognised as further awareness of the role and responsibilities of the coroner and the clinicians in this area, which could be reinforced by communication and education.

Recommendation (8) Timely discussion as to whether a death is reportable with clear indications as to why death is to be reported from the perspective of the reportable deaths criteria being met.

8.5.4 Clarity and /or consistency

To ensure that there is a level of consistency of the deaths that are reported, further clarification of the reportable criteria needs to be undertaken. There is a lack of understanding of not only which deaths are reportable and require independent review by the CCOV but also why these deaths need to be reported. The lack of consistency between the Coroners Acts across Australia, in reference to reportable deaths, has also been identified as a source of potential confusion to clinicians. Again, this confusion may result in under-reporting or inappropriate reporting of deaths, which leads to missed opportunities to inform patient safety through the review process and the use of valuable resources.

Further education regarding the reportable criteria may be one method to assist in developing consistency in reporting, with the provision of on-line tools, such as drop-down boxes with guided questions, that could be used to assist in the definitions of reportable deaths. There may be an opportunity to review the *Coroners Act 2008* (Vic), however, this can be a time-consuming process, given the levels of consideration required to change an act or law through the governmental processes. This may be achieved by the formation of a working party or sub-committee, collaboratively working between CCOV and the speciality medical colleges, for example. This group may be able to develop clear definitions ad guidelines to further clarify the reportable criteria, such as "unexpected" death.

Recommendation (9) Review of the Coroners Act 2008 (Vic) by the CCOV, in collaboration with clinical staff, to assist in clarifying the reportable criteria and how they relate to Victorian health care.

Recommendation (10) Consider the appointment of an Office of the Chief Coroner, as per the model in the United Kingdom, to oversee the activities and the consistency of the Coroners Acts across Australia.

8.5.5 Education

There is a need for all levels of medical staff within healthcare facilities to be specifically aware as to what their role is in death reporting/review and, subsequently, their responsibility in referral to the CCOV and the coronial process.

An audit of deaths within healthcare organisations, to determine if all reportable deaths are reported, would be a useful measure of whether obligations and responsibilities were being met. Following on from this, feedback to clinicians, regarding whether the deaths that occurred were reportable or not and the factors influencing reporting in a timely manner, would be useful. This opportune discussion would be educative and allow for open and transparent discussion regarding deaths and the circumstances surrounding a death, to assist in determining if there were any preventable factors. This would also present an opportunity to review death certificate completion, for accuracy and consistency in documentation.

If the CCOV and healthcare organisations perform regular audits to determine which criteria the death was reported, this information should be fed back to both organisations. There could be the development of a template/algorithm guidelines to assist in this process, to ensure that there is a clear description of reportable criteria, to provide knowledge to both groups. This could be a regular, internal process undertaken by both the CCOV and the healthcare organisations and, potentially, by external, independent auditors, to ensure transparency.

Recommendation (11) Incorporation of the role of medical staff, at all levels, in death reporting/review and subsequent referral to the CCOV, into the continued education that occurs for ongoing registration of medical practitioners.

Recommendation (12) Audit of deaths within the CCOV and healthcare organisations, using a standardised tool, to determine if all reportable deaths are reported.

In summary, the aims of the actions described are to:

- ensure consistency in reporting of deaths;
- enhance appropriate reporting; and
- appreciate the roles in reportable death requirements and the value that can be realised by this process.

From the perspective of society, the ability to be reassured that there has been an independent and transparent process in place to review deaths that have occurred is extremely important. With the development of higher levels of health literacy, there are higher expectations of safe and informed care delivery.

8.6 Conclusion

The aim of this thesis was to determine clinician's understanding of deaths which meet the criteria for reporting to the Coroner's Court of Victoria, according to the study's objectives. In Chapter One, the evolution of the role of the coroner, from medieval times to the present day, and the influence of this on patient safety was described. The criteria for reportable deaths was also described, from an Australia-wide to Victorian perspective.

In Chapter Two, the concept of patient safety, including the evolution of the concept over recent times, was presented. Refence to the framework developed by Donabedian, specifically referring to outcome measures and mortality review processes and how they inform patient safety, was presented (Donabedian, 1966).

The scoping review of the literature, regarding clinicians' understandings of the coroner's role was presented in Chapter Three. A description of the methodological approach that was selected for this study, namely an explanatory sequential research design, was described in Chapter Four. Chapters Five and Six described the results and the findings of Study One and Study Two, respectively. Study One consisted of a retrospective audit of medical records of deceased patients, using a structured tool. Study Two presented the findings and discussion of the results of the semi-structured interviews and clinical scenarios, as the qualitative phase of the overall study. Chapter Seven

comprised the results and discussion of the findings of Study Three, the in-depth review of 64 cases which were identified in Study One as having a reporting error.

This chapter, Chapter Eight highlights the existing processes and legal framework by which deaths that meet the Victorian reportable criteria should be reported. This study has identified that there are a number of deaths which are either not reported or are reported inappropriately or incorrectly. The coroner is mandated to investigate certain deaths (and fires). The investigation is required to determine the identity of the deceased, the cause of the death and the circumstances surrounding the death. Another component of their role is to ascertain if there are any aspects of a death that may have been preventable, and the coroner may make recommendations following their investigation to help prevent similar deaths in the future. There is also evidence that there may be very different interpretations between clinicians and coroners regarding the legal requirements associated with the reporting of deaths.

If deaths are not reported, there are lost opportunities to inform patient safety principles and learning and, hence, prevent future similar deaths. Coroners may make recommendations after their investigation of deaths, and an absence of data provided by unclear or unsure clinicians may impact the ultimate findings of a particular case. The process of monitoring and self-governance, at all levels, is an important component of the delivery of safe patient care. In recent years, there has been an increase in the reporting of adverse events that have harmed patients receiving healthcare This may be due to an acknowledgment by clinical staff of the requirements to report such events and an awareness that the reporting and subsequent review of these events can improve patient safety. Similarly, the appropriate reporting of deaths to the CCOV also informs patient safety, by the review of the level of preventability of deaths. The notion of preventability has been documented within the patient safety literature and this is also reflected within the mandate of the coroners in determination of preventability. The link to preventable deaths is defeated if deaths are not reported appropriately. If deaths that meet the reportable criteria are not reported to the CCOV, the legislative and legal requirements are not satisfied and, therefore, the law has been breached. This has ramifications for the clinician who has not reported the death. It is also a missed opportunity for an objective and independent review of the circumstances of the death. Following this review, there may be recommendations made to change and improve aspects of practice or system issues identified. There is also the opportunity to use this data to influence the development of quality improvement activities and areas of research which can, in turn, be used to inform and alter clinical practice.

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Appendices

Appendix 4.1 Letter of support from senior Victorian coroner



Coroners Court of Victoria

65 Kavanagh Street Southbank 3006 T 1300 309 519

F 1300 546 989

W www.coronerscourt.vic.gov.au

6 July 2015

Austin Hospital Low or Negligible Risk Review Committee

To whom it may concern

I have spoken to Amanda Charles regarding her doctoral studies research into the reporting of deaths to the Coroner's Court of Victoria.

She has explained that part of the data collection is to include the review of approximately 1200 deaths that occur annually within the health service to determine if these deaths meet the reportable criteria and were reported under the Coroner's Act, 2008.

If there are deaths that have not been reported that meet the reportable criteria, these deaths will be reported and reviewed through an already established process within the Coroner's Court for review of deaths that have been identified through review of the Death Certificates at the Registry of Births, Deaths and Marriages.

I have agreed to be a liaison contact for Amanda with in the Coroner's Court of Victoria, as required during her study.

Yours sincerely

lain West

Deputy State Coroner

Appendix 4.2 Austin Health Low risk ethics committee approval



Austin Hospital

145 Studiey Road PO Box 5555 Heidelberg Victoria Australia 3084 Telephone 03 9496 5000 Facsimile 03 9458 4779 www.austin.org.au

Date: 10/08/2015

To: Ms Amanda Charles

Project: Reporting of deaths in the hospital setting to the Coroner's office

in Victoria

LNRR Ref No: LNR/15/Austin/228

Agenda Item No: 5.4

Approval Period: 10/08/2015 to 10/8/2018

Re: Low & Negligible Risk Research (LNRR) Application APPROVED				
Document(s) reviewed	Version	Date		
NEAF	1	03/06/2015		
Protocol	1	30/07/2015		
Audit Tool	1	29/05/2015		
Letter from Coroner		06/07/2015		

Further to my letter dated 25th of June 2015 concerning the above detailed project, I am writing to acknowledge that your response to the issues raised by the Austin Health Clinical Research Review Committee (CRRC) at their meeting on 23th of June is satisfactory.

This project now has full ethical approval for a period of three years from the date of this letter on the provision that the following conditions are met.

It is now your responsibility to ensure that all people (i.e. all investigators, sponsor and other relevant departments in the hospital) associated with this particular study is made aware of what has been approved.

1. Conditions

The Austin Health HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

The Principal Investigator will provide a progress report to the Office for Research annually, or more frequently as directed. Please note a final report must be submitted for all studies.

These are to be submitted electronically to: ethics@austin.org.au using templates provided at: http://health.vic.gov.au/clinicaltrials/application-instructions.htm.

Should you plan for your study to go beyond the 3 year ethics approval, please request in writing an extension of ethics approval prior to its lapsing.

If your study will not commence within 12 months, a request must be forwarded to the Office for Research justifying the delay beyond 12 months. Should such a request not be received, ethics approval will lapse and a resubmission of the application will then be necessary.

2. Adverse Events

The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including any unforeseen events that might affect continued ethical acceptability

Clinical research Review Committee (CRRC) Office for Research, Level 8 HSB. Phone: (03) 9496 4090

E-mail ethics@sestn.org.au

CRRC V2-34Y-2014 AS

of the project. Serious Adverse Events must be notified to the Committee within 24 hours of the event by the Principal Investigator. In addition the Principal Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Participant Information Sheet and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.

Amendments

If there is an event requiring amendments to be submitted you should follow the instructions found on the following website: http://www.austin.org.au/researchethics/

Should you have any queries about the Austin Health CRRC consideration of your project please contact the Office for Research. The Austin Health CRRC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Office for Research.

Yours sincerely,

Dr Sianna Panagiotopoulos, PhD Manager, Office for Research

This CRRC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC)
National Statement on Ethical Conduct in Human Research 2007 (Updated March 2014) NHMRC and Universities Australia
Australian Code for the Responsible Conduct of Research (2007) and the applicable laws and regulations; and the Health Privacy
Principles in The Health Record Act 2001.

Appendix 4.3 Monash University Human Research Ethics Committee approval



Monash University Human Research Ethics Committee (MUHREC) Research Office

Human Ethics Certificate of Approval

This is to certify that the project below was considered by the Chair of the Monash University Human Research Ethics Committee. The Chair was satisfied that the proposal meets the requirements of the National Statement on Ethical Conduct in Human Research and has granted approval.

Project Number: CF15/3077 - 2015001299

Project Title: Reporting of deaths in the hospital setting to the Coroner's office in Victoria

Chief Investigator: Prof Wendy Cross

Approved: From: 17 August 2015 To: 17 August 2020

Terms of approval - Failure to comply with the terms below is in breach of your approval and the Australian Code for the Responsible Conduct of Research.

- 1. Approval is only valid whilst you hold a position at Monash University and approval at the primary HREC is current.
- 2. Future correspondence: Please quote the project number and project title above in any further correspondence.
- Final report: A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
- Retention and storage of data: The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

Professor Nip Thomson Chair, MUHREC

cc: Assoc Prof Debra Griffiths, Ms Amanda Charles

Human Ethics Office

Monash University
Room 111, Chancellery Building E
24 Sports Walk, Clayton Campus, Wellington Rd, Clayton VIC 3800, Australia
Telephone +61 3 9905 5490 Faosimile +61 3 9905 3831

Email muhrec@monash.edu http://intranet.monash.edu.au/researchadmin/human/index.php

Audit Tool

001		
Age		
Sex		
Time of De	eath	
Day of dea	th	
Admission diagnosis		
Length of stay (in days)		
Where they died (ward/department)		
	leath on death	
Does the d reportable If yes,	leath meet the criteria?	Yes □ No □
ii.	Documentation of report – EDeposition /Other Under which criteria was death reported	Yes □ No □ Criteria for reportable death: 1. unexpectedly 2. in a violent or unnatural way 3. from an accident or injury 4. following a medical procedure where the death may be causally related to the procedure and where a medical practitioner would not have reasonably expected the death to occur as a result of the procedure 5. while held in care (for example, in prison, police custody or a psychiatric institution) 6. when the deceased's identity is not known 7. where a doctor has been unable to sign a death certificate
If No. doot	h not roported but	detailing the cause of death.
If No, death not reported but meets the reportable criteria is there documentation of consideration/discussion with CCoV		Yes □ No □ What form does the documentation take?
	eported, under	 Unexpected In a violent or unnatural way From an accident or injury following a medical procedure where the death may be causally related to the procedure and where a medical
wnich crite	eria does the	practitioner would not have reasonably expected the death to occur as a result of the procedure

death meet the reportable criteria.	 5. while held in care (for example, in prison, police custody or a psychiatric institution) 6. when the deceased's identity is not known 7. where a doctor has been unable to sign a death certificate detailing the cause of death
Was an adverse event documented during the care of the patient?	Yes □ No □ If yes, what was the adverse event?
Comments	

Document review

1.	Adverse event	-specific criteria (Riskman)
2.	Discharge summary	
3.	Medications	
4.	Progress notes	Referrals
		Pathology results
		MET call- Disposal
		Advanced care planning
5.	Death Certification	Level of experience
		Intern (first 12 months)
		JMO /Resident (12 months out, for 2 year period)
		Registrar
		Fellow
		Consultant

 $\underline{\text{http://www.courts.vic.gov.au/courts-tribunals/victorian-courts-and-tribunals/coroners-court-}\underline{\text{victoria}}$

Appendix 4.5 Semi structured interview questions

Semi structured Questions Examples

What do you understand about reportable deaths?

Do you know which deaths need to be reported to the Coroner?

Why do these deaths need to be reported?

Does anything worry you about reporting a death?

Have you reported deaths to the coroner yourself? Did you receive any feedback

What is the information that you need to consider before reporting the death?

Have you been involved in any ongoing investigation?

Have you been asked for further information, such as provide a statement?

Are there any time frames that you must meet to report a death?

What education have you received regarding death certification and reporting of deaths to the coroner?

In hospital education?

At university?

Anywhere else?

Are there any barriers either internally or externally to reporting deaths?

What are your major concerns/issues about reporting deaths?

Any other comments

EXPLANATORY STATEMENT

Project: An investigation into the reporting of deaths in a health care setting

Chief Investigator's name: Student's name

Professor Wendy Cross Amanda Charles

Department of Nursing Phone: 0417142871

email: ajcha17@student.monash.edu

Phone: 9905 4843

email: wendy.cross@monash.edu

You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

What does the research involve?

The aim of this study is to examine the issues around reportable deaths in a large tertiary hospital in Victoria, Australia.

The objectives of this study are to:

- 1. determine the level of under reporting of reportable deaths within this health service, and
- 2. to determine the factors that impact on the under reporting of these deaths.

You will be asked to be involved in a semi structured interview to discuss several factors relating to reportable deaths within a health service. As a health professional employed within the organisation, you will be asked questions around your understanding of what is a reportable death, education received around this process, any perceived barriers to reporting of deaths. Prior to this interview, you will be given you paper based scenarios that will be focussed on deaths which commonly occur within the health care setting.

Why were you chosen for this research?

You were chosen for this research as you are employed by the hospital in a clinical role and best placed to inform the researcher of the factors that may be involved in the under reporting of deaths. The researcher obtained your contact details from the Chief Medical Officer and Executive Director of Nursing

Consenting to participate in the project and withdrawing from the research

Signed consent will be obtained from each participant prior to the commencement of each interview, including the audio recording of the discussions. If you do consent to participate, you may

withdraw at any time. If you decide to withdraw from the project, please let the researcher know and be reassured that there will be no compromise to your position.

Possible benefits and risks to participants

There are no safety risks involved with this study and the likelihood of psychological distress is minimal.

This study is significant and the under reporting of deaths to the coroner's office and the subsequent review that occurs is a valuable source of information may not be recognised and utilised as effectively as it could. The importance of the prevention role is one factor that remains very valuable to society and indeed as catalyst for change to health and safety practices potentially with information to assist in the ongoing evolution of patient care with the lessons from this group of patients informing potential practice change for health professionals. This study will examine whether there is under reporting of deaths and whether there is a loss of this valuable information.

Confidentiality

Each of the participants will be assigned a number and code to designate their profession and experience, for example: 1RNY1, (Registered Nurse Year 1), 1DRY2 (Doctor Year 2). The information obtained from the data will be thematically analysed and stored on a password protected computer. There will be no individual identifying information attached to the data and all data will be reported as an aggregate.

Storage of data

All hard copy and electronic data will be stored in a locked filing cabinet in the locked office of the student researcher, and will be accessible only to the researchers named on this project. The electronic data will be password protected with the passwords known to the researcher and supervisors. The data associated with this research will be stored for 7 years in accordance with the National Statement on Ethical Conduct in Research Involving Humans, 12.11. Seven (7) years after the completion of the study, all electronic files will be deleted and paper records will be destroyed.

Use of data for other purposes

The data will be used for publication and will not be shared. Summary reports may be made available to the organisation, or for presentation at appropriate conferences, with all identifying information removed. The data collected will only be used for this project.

Results

The results of this study will be made available to the participants by distribution through the Medical and Nursing Education departments of the hospital and publications that will result from this study.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics (MUHREC):

Executive Officer

Monash University Human Research Ethics Committee (MUHREC)

Room 111, Building 3e

Research Office

Monash University VIC 3800

Tel: +61 3 9905 2052 Email: <u>muhrec@monash.edu</u> Fax: +61 3

9905 3831

Thank you,

(insert Chief Investigator's signature)

Professor Wendy Cross

Appendix 6.1 What do clinicians understand about deaths reportable to the Coroner? (Interview paper)

Journal of Forensic and Legal Medicine 5) (2017) 76-80



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What do clinicians understand about deaths reportable to the Coroner?



Amanda Charles', Wendy Cross, Debra Griffiths

Naming and Allied Health, Faculty of Medicine, Nursing and Health Sciences, Monash University, Clayers, Victoria 3800, Australia

ARTICLEINFO

Article featury: Received 11 May 2017 Accepted 24 July 2017 Available online 25 July 2017

Keywords: Coroner Death review Patient safety

ABSTRACT

Setting: The study setting is a tertiary referral hospital of over 980 beds, in Victoria, Australia. The hospital is a long established major academic public health service providing healthcare, health professional education and health research. The hospital has 103,756 in-patient admissions, 190,756 outpatient attendances and over 82,000 presentations to the Emergency Department annually.

Purticipants: 22 clinicians completed an in-depth, audio-recorded interview: 12 medical and 10 nursing staff, with a variety of clinical experience.

Intervention(s): Each audio recorded interview was transcribed verbatim for thematic analysis. The semi structured questions were designed to explore the clinician's understanding of deaths that meet the criteria to be reported to Corocers Court of Victoria (CCOV), and why such reporting was required. There was also the opportunity to identify any barriers or enablers to the reporting process, whether internal or external to the organisation.

Results: Two main themes emerged from the interviews: 1. lack of awareness of which deaths are

Results: Two main themes emerged from the interviews: 1. lack of awareness of which deaths are reportable to the coroner and 2, the need for educational support. Several subthemes were also identified such as accountability, the need for feedback and blame. Discussion: The understanding of clinicians as to which deaths meet the reportable criteria in healthcare.

Discussion: The understanding of clinicians as to which deaths meet the reportable criteria in healthcare is quite variable and this indicates that there might be a level of under reporting. Apart from the potential of not meeting legal obligations, there may also be the loss of a valuable opportunity for lessons to inform clinical gractice and enhance the delivery of safe patient care.

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Death review or investigation within the health care sector can be an extremely valuable tool in the provision of safe patient care. It is understood that people admitted to hospital may die whilst they are an inpatient and that at times, those deaths may be expected, These deaths are subject to regular review and the monitoring of mortality rates within hospitals has long been recognised as a valuable measure of quality and safety of care. There is a belief that an important link or opportunity to review the preventability of a death may be missed by the under or non-reporting of deaths which occur in settings such as the community or within healthcare organisations.1 These reviews occur in a variety of formats dependent upon the setting, for example the weekly Mortality and Morbidity meetings (M & M). These meetings are implemented in both public and private hospitals as a vehicle for open and transparent review of practice to identify areas of preventability and potential improvement. One aim of the meetings is to foster

discussion and learning from deaths that have occurred in healthcare settings in a rigorous, timely and systematic way.²

However, there is a cohort of deaths that are required by law, to be reported to the Coroners Court of Victoria (CCOV). The role of the Coroner is to ascertain the identity of the deceased person, the cause of death and the circumstances of the death (Coroners Act, Vic 2008). More broadly, the coronial investigation can contribute to the reduction of preventable deaths by the distribution of recommendation(s) made as a result of the investigation (Coroners Act, Vic 2008).

In November 2009, the Coroners Act Vic (2008) came into effect following an extensive review and reform of the jurisdiction. As part of this review the prevention function of the court by means of contribution to public health and safety was reinforced.

There is scant literature available as to whether deaths that meet the reportable criteria are actually reported (Appendix 1). The under reporting of deaths may be an indication of broader system based issues and the contribution of the information that is gained

E-mail address: Ajchal 7th tradent monathedu (A. Charles).

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Corresponding author.

following reviews of death cannot be underestimated. If these deaths are not reported to CCOV, then a valuable opportunity for review and potential recommendations to inform patient safety may be missed.

One study retrospectively audited the medical notes of 229 deceased patients from 2 hospitals within Victoria, Australia.³ Of these 229 cases reviewed, 58 cases met the reportable criteria, with only 22 of the deaths having evidence of being reported to the Coroner's office. Within Australia, there has been discussion of the under reporting of deaths with several papers recently published, ³⁻⁵ In Queensland, Australia, a recent paper has described the potential negative consequences of deaths being reported to the coroner unnecessarily with the resultant overuse of available resources.⁵

Start et al. highlights that the failure to report deaths to the Coroner may result in the lack of medicolegal investigation that is expected to occur. Other reasons for under reporting of deaths was also thought to be related to differences in Coroner's practices, according to geographical location. It was also evident that clinicians in the United Kingdom demonstrated a lack of understanding of the criteria for reportable deaths including deaths associated with medical treatment. The

In a recent Victorian Coronial finding following an Inquest into the unnatural death of a patient that was not reported to CCOV, the Coroner identified various factors that may have impacted on whether a death was reported or not. These included a lack of recognition of prior trauma as a contributor to death, and uncertainty regarding the reportability of deaths that are related to medical procedures.

In Victoria, according to the Coroner's Act, 2008 [s11 Coroners Act 2008], a medical practitioner has an obligation to report a reportable death, and a person has an obligation to report a reportable death if they have reasonable grounds to believe that it has not been reported. Practically, this means that other professional groups such as nursing also share this obligation. It is of interest that there are discrepancies within the reportable criteria across Australian jurisdictions, notably in the area of health related deaths. In response to events over the last 15–20 years, within Australia and internationally there have been attempts made for these differences to be clarified. These attempts by the coronial jurisdictions have included review of the Coroner's Acts, particularly in the area of health care related deaths however, there still appears to be some confusion in reference to the reportable deaths.

It is within this background that this research was developed. The aim was to determine practitioners' understanding of reportable deaths. It was also to ascertain the level of potential under reporting of deaths that meet the reportable criteria, and the factors that might impact on reporting. Gaining an understanding of the practices and the potential level of under reporting will assist in the review of information and the potential opportunity for beneficial lessons that may have been missed.

1. Methods

The study setting is a tertiary referral hospital of over 980 beds, in Victoria, Australia. The hospital is a long established major academic public health service providing healthcare, health professional education and health research. It offers a comprehensive range of acute, sub-acute, mental health, outpatient and outreach services to the local community. Maternity and neonatal services are not provided by the hospital. The hospital has 103,756 inpatient admissions, 190,756 outpatient attendances annually as well as over 82,000 presentations to the Emergency Department annually.

The study utilises a mixed methods research approach incorporating an integrative design whereby both qualitative and quantitative approaches are combined.¹³

There are three phases to the study:

Phase 1 Audit of clinical notes (Quantitative)

Phase 2 In-depth review of unreported deaths that meet the reportable criteria

Phase 3 Semi structured interviews and clinical scenarios (Qualitative)

This paper will describe the findings of the semi structured interviews.

There were 22 interviews completed by clinicians. ¹⁴ Participants consisted of 13 medical and 9 nursing staff, and their experience ranged from a graduate nurse completing a first rotation to a head of unit. A participant's information statement was provided for each of the participants to read and they were asked to sign a consent form prior to the commencement of the interviews. The participants were accessed via a convenience sample within a variety of forums, such as the weekly surgical audit review, unit mortality and morbidity meetings and clinical review panels where cases are reviewed by a multi-disciplinary group. The interviews varied in length with a median time of 17 min. Each interview was audio recorded verbatim and each transcript was thematically analysed using Braun and Clark's procedures. ¹⁵ This included immersion in the data to ensure familiarity with the entire content (see Table 1).

The semi structured questions were designed to determine what was the clinician's understanding of deaths that meet the criteria to be reported to Coroners Court of Victoria (CCOV), and why this reporting was required. There was also the opportunity to identify any barriers or enablers to this reporting process, whether internally or externally to the organisation.

2. Results

Two main themes emerged from the interviews: 1. a lack of awareness regarding which deaths need to be reported to CCOV; 2. The need for educational support. Sub-themes included accountability, blame and time frames (Table 2).

Not surprisingly, all of the medical staff interviewed (N = 12) had personally reported deaths to CCOV at least once. None of the nursing staff had formally made a report themselves, but were aware of the discussions or had been involved in conversations with their medical colleagues in reference to the reported deaths. To ensure confidentiality, participants are referred to as D1 (doctor 1), and N1 (nurse 1) throughout the manuscript.

2.1. Lack of awareness

Participants possessed varying degrees of knowledge and understanding of the criteria for reporting a death. Unexpected death was one of the better understood criteria by the clinicians. Another recognised criteria highlighted was if the death certificate was unable to be signed.

There was reference to deaths that occurred post procedure being reportable, with varying timeframes suggested by the participants, ranging from intra operatively or immediately, or within 28 days, or within 30 days.

Deaths that were due to prescribed circumstances or due to defined disease processes such as asbestosis, or fractured neck of femur were a group of deaths that was acknowledged by the participants. When asked to describe what reportable deaths meant to the participants a variety of terms such as "suspicious" (D1, N1),

Table 1 Phases of thematic analysis

Phase	Description of the process
1. Familiarising yourself with the data:	Transcribing the data (if necessary), reading and re-reading the data, noting down initial ideas
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme
4. Reviewing themes:	Checking in the themes work in relation to the orded extracts (level 1) and the entire data set (level 2), generating a thematic "map" of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells; generating clear definitions and names for each theme
6. Producing the report:	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back to the analysis to the research question and literature, producing a scholarly report of the analysis

Braun and Clarke, 2006.

Table 2 Identified themes from interview data.

Thene	Subtheme
Lack of anareness	Accountability Blame
The need for educational support	Time frames

"unable to be explained," (N3), "criminal" (D1, N7), "mistakes" (N7), to determine "trends or clusters of mistakes" (N7, D10) were used.

2.2. Accountability

There were an assortment of responses to the question as to why some deaths need to be reported. These included reference to CCOV as a repository for reviewed cases and as an agency to determine any clusters or patterns of deaths that may indicate systems issues within hospitals and health services, or as a quality improvement initiative (NR, D6).

The concept of the coroner's role regarding the review of practice "to potentially make changes to practice (N2) was also evident. Participants also indicated that the collection of data for statistical purposes and analysis is useful as evidence and "reassurances to the community of a review of the death" (D2) This review was also seen as being "population based to determine any systemic problems in the organisation" (D5).

The participants noted the value of the external review of deaths and circumstances surrounding these deaths as a significant value to society as a whole and to ensure that there was transparency and accountability of health professionals and services, reinforcing the governance process ¹⁰This would also identify if there was "something like four play involved" (D9).

Participants also saw this as reassurance to the community of a "mechanism for society, through the coroners, to be accountable for life" (D2).

The majority of the participants had no concerns regarding reporting deaths, perceiving that it was a transparent and fair process. Logistic issues such as the ability to understand and be aware of all the events and the sequencing of those during an extended patient admission was noted as a concern. For these cases, the clinician may not be aware of everything that might have occurred, especially early in the admission episode particularly at another site or health service.

The main concerns that were raised by the participants referred to the "acceptance" of the reportable death by the CCOV. Acceptance in this context indicates the death is assessed as meeting the reportable criteria and requires further review by the coroner's office. The concerns raised by the participants in relation to reporting was that it "was arbitrary whether a death is accepted or not, a toss of a coin" (D4). Of note were several comments that "medical staff don't want to be part of an unexpected death" (N6), "personal repercussions to assist" (D1), "reluctance to report and don't do it often enough" (D7), and "concerned about a Shipman affair-anxiety about reporting leading to trouble, and a lack of transparency of M and Ms" [Mortality and Morbidity] meetings) (D8).

No barriers appeared evident to the participants, regarding the actual reporting of the death to CCOV, although there were some references to the "paperwork and waiting for the police" (D3), and as being time consuming "barriers of anything that takes more time" (D3). Other more personal barriers to reporting included "preconceived ideas and previous experience" (D5), but that "the process was culturally, well accepted" (D7), and "generally a smooth process and not difficult" (N6).

2.3. Blame

Among the clinicians there was a sense of apportioning blame or potential perception of contribution to deaths that were reported. Comments included 'high level of ignorance about both the law and the application in hospital" (D7), "arbitrary whether the death is reported or not" (D8), "still stigmatised and uncomfortable for medical staff" (D8), "humans make mistakes" (D9) and "contact with the Coroner meant that you were at fault" (D3). There was also a sense that clinicians believed that there would be blame or a sense of no transparency in the review process and the potential for "hiding and collading like Bundaberg" (D8). Bundaberg here refers to an issue in Queensland, Australia where a surgeon was implicated in the deaths of several patients, and there had been no review process in place. [1]

Nevertheless, there was a sense that the process was generally done well within the hospital, and that staff want to make sure that they are doing the right thing. There was, however, still a lack of understanding of the scope of the role of the coroner by the medical staff. The concerns raised about it was that it was "haphazard in the investigation that takes place, which deaths get further investigation and which ones don's" (D9). There are a number of myths about what happens at the coroner and fears were expressed about "nurses losing their jobs" (N10), "more an investigation of me "(D1), "chance of victimisation unless there is a more open review" (D1) and other negativity. Concern for the family of the deceased was also raised in reference to the reporting of the death and the challenges for a nowice practitioner explaining the requirements and process to the family.

2.4. Educational support of the workforce

Education pertaining to deaths that meet the criteria for reporting to CCOV was reported by the medical staff as being very brief or limited, either during their university studies or through other post-employment continuing education. On occasion, updates were received from the Chief Medical Officer or the Medical Board. Education experiences were similar among the nursing participants, with reference made to the policies and procedures that are readily accessible to assist "and you can always make a phone call" (D4).

2.5. Time frames

Reference to time factors also emerged in the findings of the study. The loss of the opportunity for potential lessons learned following the death review by the CCOV was hampered by the delay in the return of information to the clinicians. Timing refers to 1. Time for feedback to the clinicians and 2. Time frames for reporting the death. Participants referred to feedback about the death that had been referred to the CCOV and the timeliness of these responses referring to "missed chance for learning" (D3), not timely, hard to follow up (D6). The information fed back could be viewed as valuable to inform the internal review during the mortality and morbidity meeting process. It was also noted that the participants were generally unaware (6/22) that deaths should be reported as soon as possible after they occur. There was also awareness that the death could be reported at a later time such as following a mortality and morbidity meeting and that there "was no extinction of the requirement to report" (D4).

3. Discussion

This study sought to investigate health professionals' understanding of reportable deaths. Whilst there is clear criteria for deaths that meet the obligations for reporting to the Coroner's Court of Victoria there remains a lack of clarity in the interpretation and the application of the reporting requirements. One of the main areas of confusion is the type of deaths related to health care that are reportable.11 This is similar to the findings by Start et al., who highlighted several areas of the coronial system that were not well understood by clinicians and was also demonstrated by the clinicians in this study, with the focus on health care related deaths.

The understanding of clinicians as to which deaths meet the reportable criteria was quite variable and there was a "lock of understanding of the scope of the coroner by medical staff" (D2). To illustrate, responses in this study included the use of the term "suspicious" to describe a death or the circumstances surrounding the death. It is noted that this term is not referred to in the Coroner's Act (2008) in any form and that this may be seen as outmoded terminology which has significant ramifications due to the potentially negative connotations11 The ambiguous and indistinct wording of the descriptors for reportable deaths in the health care setting increases the difficulty for clinicians to know their obligations and subsequently act upon them.1

Within the Act, no absolute time frames are referred to for deaths that meet the reportable criteria and are associated with contribution by a medical procedure. The clinicians interviewed referred to defined time frames ranging from during the procedure/ surgery to 28-30 days following the procedure, it is not clear whether there is any reason that timeframes around the death are even useful as a determinant of reportability to a coroner. Moreover, there is lack of consistency across Australia in relation to the time frame post procedure and this has been noted as another area of confusion for clinicians. This includes reference to the relationship of the death to anaesthetic, or whether the death was caused by or temporally related to a procedure.

In Victoria, the criterion is where the death occurs as an unexpected outcome of a health-related procedure, but there is no defined time period associated with the requirement to report the death.11 Whilst this study reflected predominantly health care related deaths in one tertiary organisation within Victoria, this may be indicative of other health care facilities in Australia.

In Victoria, in 2015, there were 73,568 deaths registered of which over 6000 deaths were reported to CCOV.15 From these reported deaths, approximately 60% occurred within health care settings of which there may have been important lessons in patient safety and preventability. The number of deaths that have not been reported for reasons such as the lack of clarity and understanding of the requirements of the Coroner's Act may reflect an untapped area of information to be gained, learned from and shared.

Appendix 1. Brief summary of deaths that are reportable to the Coroners Court of Victoria.

(1) In this Act, a death of a person is a "reportable death" if-

ection (1), the deaths are

(2) for the purposes of

(a) the body is in Victoria: or

(b)the death occurred in Victoria; or (c)the cause of the death occurred in Victoria; or

d) the person ordinarily resided in Victoria at the time of death—and the death was a death specified in subsection (2). a'a death that appears to have been unexpected, unmatural or violent or to have resulted, directly or indirectly, from an

(b'iz death that occurs-

(i)during a medical procedure; or

(ii)following a medical procedure where the death is or may be causally related to the medical procedureand a registered medical practitioner would not, immediately before the procedure was undertaken, have maximably expected the death; or

c) the death of a person who immediately before death was a person placed in custody or care; or

a death that occurs in Victoria if a notice under section 37 (1) of the Births, Deaths and Marriages Registration Act 1996.

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Appendix 6.2 What do clinicians understand about deaths reportable to the Coroner? Use of clinical scenarios to enhance learning

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What do clinicians understand about deaths reportable to the coroner – Use of clinical scenarios to enhance learning



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1. Introduction

The opportunity to review deaths that occur in hospitals is considered a valuable source of information to enhance patient safety. This can occur at a local level by means of the mortality and morbidity meetings that are held in both public and private hospitals. These meetings facilitate an open and transparent review of deaths that occur in health care. This is undertaken with a view to identify whether there was any level of preventability of the death and to encourage discussion and potential learning from these deaths. 1 Legally, there is a cohort of deaths that must be reported to the Coroner's Office according to the criteria outlined in the Coroners Act of Victoria (2008) (The Act).2 In November 2009, The Act, (2008) came into effect following an extensive review and reform of the role and the function of the Coroner within the jurisdiction. As part of this review the prevention function of the Coroner's court by means of contribution to public health and safety was reinforced. A component of the role of the Coroner is to perform an independent investigation of the dircumstances around the death and to determine the cause of death. For this investigation to occur deaths that meet the reportable criteria must be reported. There is a paucity within the available literature as to whether reportable deaths are actually reported. One study reported that there was an under reporting of deaths when a retrospective audit of medical records was performed.⁶ In 2015, of the 73,568 deaths that were registered through Births, Deaths and Marriages in Victoria, there were over 6000 deaths reported to the Coroner's Office.3,4 This investigation may also identify if there were any preventable factors that may have contributed to the death and the lessons that may be learned. These lessons may be formulated and disseminated in the form of Coroner's recommendations.5

There has been discussion within the Australian literature about the lack of understanding of which category of deaths should be reported and the potential for under reporting^{6–6}. It is not believed that any under reporting is done is with an intention to undermine the legal requirements, but rather as a result of ignorance and challenges across the country in relation to the wording of the Coroner's Acts 7.10.

This lack of understanding of the requirements of deaths which meet the reportable criteria may also indicate over reporting, therefore an inappropriate/inefficient use of resources.¹¹

The aim of this research is to review the understanding of a group of clinicians in reference to deaths that meet the criteria for reporting to the coroner's office by using simple clinical scenarios.

2. Method:

A large, tertiary referral hospital in Victoria, Australia was chosen for this study. The hospital offers acute, sub-acute, mental health and outpatient services The hospital has 103,756 in patient admissions, 190,756 outpatient attendances and over 83, 000 presentations to the Emergency Department annually. ¹² Several state wide services are provided and there are no maternity or neonatal services offered at this hospital. It is a public hospital that also produces health care related education and research.

A mixed methods research approach incorporating an integrative design whereby both qualitative and quantitative approaches are combined was utilised.¹³ Mixed methods allowed for increased confidence in the findings where the data is corroborated from several sources.¹⁴

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There are three phases to the study:

Phase 1 Audit of clinical notes (Quantitative)

Phase 2 In-depth review of unreported deaths that meet the reportable criteria

Phase 3 Semi structured interviews and clinical scenarios (Qualitative)

This paper will describe the findings of one component of phase 3 of the study which was the completion of clinical scenarios by 22 clinicians and complements the findings of interviews completed. ¹⁵ The participant group consisted of 13 medical and 9 nursing staff, with a variety of experience ranging from a graduate nurse completing a first rotation to a head of unit. Their area of practice was also quite broad, including critical care, oncology, general and specialist medicine and surgery. A participant's information statement was provided for each of the participants to read and they were asked to sign a consent form prior to the commencement of the scenarios. Prior to the scenario completion, the participants were also involved in a semi structured interview designed to determine what was the dinician's understanding of deaths that meet the criteria to be reported to Coroner's Court of Victoria (CCOV), and why this reporting was required.

This complete study received Ethics approval from both the healthcare facility and Monash University, Melbourne, Australia.

A convenience sample of participants was accessed within a variety of dinical forums. In this context, convenience sampling indicates non probability sampling in which the participants are sampled as they are "convenient" sources of data for researchers ie they are available and able to participate. ¹³ The scenarios were based partially on the findings of the retrospective review of medical records and commonly occurring denths within the healthcare setting. The participants were asked to determine if the death met the reportable criteria, and if so, why. There was also the opportunity for the participants to make a comment considering their decision making regarding the reportability of the death and these comments were thematically analysed.

To ensure face validity, the scenarios were reviewed by a senior Victorian Coroner to determine "definitively" which deaths described in the scenarios met the reportable criteria. The scenarios were also completed by seven Victorian Coroners, which represented the majority of the group who are all actively practicing in the role. The scenarios are provided in Appendix 2.

3. Results

Of the 22 clinicians who completed the scenarios all medical staff (N = 13), had personally reported deaths to CCOV at least once. There was a variety of experience and also specialities such as surgery, medicine and critical care areas in both clinician groups. Nursing staff may not have formally reported the deaths themselves but had been involved in the discussions and some decision making in reference to the reported deaths. Comments were encouraged in reference to the decision making by both the dinician and coroner groups when completing the scenarios.

In the Coroner's group, there was agreement with the senior Coroner's definitive answer in 3/10 the scenarios. This is compared with the nursing group, where there was consensus with only one scenario, scenario 3 which describes the potential omission of medication which may have been preventable. There was no consensus within the medical group. For example, scenario 6 had the highest level of agreement in the three groups (doctors 11/13, nurses 7/9, and 7/7 coroners agreed with the senior coroner decision). (See Table 1). This scenario described a death following a motor car accident. Scenarios 2, 5 and 9 all had low correlation by the clinicians with the senior Coroner. (Appendix 2). There were three scenarios (scenarios 6,7 and 10), where one individual nurse was uncertain whether the death was reportable. Similarly, one Coroner also determined that they were

undecided about the death meeting the reportable criteria in scenarios 2,3 and 7 (Appendix 2).

The comments made by the participants have been themed according to the section of The Act, (2008), that was described in the scenario.

Deaths resulting, whether directly or indirectly, from an accident or injury

There is a requirement that deaths due to car accidents or drownings are reported under this criteria. This is one area where there was some ambiguity according to some of the comments made by the clinician group. With patients who suffer a fall (s) prior to their deaths, it can be difficult to determine the contribution of the injury to the subsequent death, and this is an area of confusion for clinicians. Comments referred to "uncertain as due to MCA (motor car accident)" in the past (Nurse 2), and "original injury was trauma" (Doctor 2), demonstrates lack of darity for this criteria.

3.2 Death where a medical procedure was involved

Deaths which occur in a medical setting is another area that is confusing to clinicians. Reference was also made to medical procedures/surgery as an indication to report the death to the coroner, together with time frames post procedure. This is despite there being no reference to time frames within The Act, (2008).² This area of deaths within medical settings was an identified area of potential under reporting.⁹ There have been attempts made to review the definition of medical setting deaths, but there is no consistency across the Australian jurisdictions which has led to increased confusion of dinicians.⁹

3.3. Unexpected death

Similarly, the area of an unexpected death requires further definition. The understanding of when a death is expected or unexpected, for example, may be a contributor to inappropriate reporting, or reporting that does not necessarily occur for the correct reason, according to The Act, (2008). The term unexpected death is ambiguous and a subjective term as revealed by the Victorian Law Reform Committee during their review of the Coronial legislation in 2006. This term is also not used widely in other jurisdictions. Reference to unexpected deaths within the comments by the participants included "unexpected, unclear cause of death, may have been preventable" (Doctor 13) and "died during a procedure but could have been expected" (Doctor 13).

3.4. Inability to certify the cause of death

Another area was an inability to sign the death certificate due to unknown cause of death as a criteria to report the death commented on by the clinician group. There was also evidence that if the decision to report the death was not dear, that there was the opportunity to have a discussion with the Coroner.

4. Discussion

This paper is a part of a larger study and reveals another facet of the understanding of which deaths met the criteria for reporting to the Coroner. ¹⁶⁻¹⁰ The lack of understanding and clarity of the reportable deaths is demonstrated by the finding that there was no consensus in any of the scenarios across both groups of clinicians and coroners as to whether the death met the criteria for reporting to the coroner's office. ^{15,19}. There was a broad range of experience and specialty areas of practice within the clinician group who completed the scenarios. The lack of consensus and therefore the understanding of the reportable deaths within the clinician group has significant ramifications for the "on the job" training that occurs on a daily basis in the clinical area.

moment to clinical at market

Discipline	Agreement with definitive answer	Scenario	Somerio								
		1 (Y)	2 (Y)	3 (Y)	4 (Y)	5 (Y)	6 (Y)	7 (Y)	8 (N)	9 (N)	10 (N)
Medical staff Nursing Staff Commen		7/13 2/9 7/7	4/13 2/9 2/7	11/13 9/9 6/7	8/13 4/9 6/7	5/13 4/9 2/7	11/13 7/9 7/7	4/13 3/9 6/7	9/13 8/9 7/7	6/13 4/9 2/7	6/13 4/9 4/7

Table 2 Suggested engoing actions

Responsible body	Suggested action
Education facilities	 Important component of numing and medical education-reinforcement of the legal exponsibilities to report deaths, but also the opportunity for ongoing education.
Healthcare organizations	 Structured and engoing education of clinicians in reference to reportable deaths;
	 Structured "handower/referral" tool developed to assist in the determination of reportable deaths;
	 Appropriate level of experienced staff determining whether the death meets the exportable criteria with clear governance processes in
	place internally for this to occur,
	 Review within most slity and modeldity meetings to determine if each death meets the criteria for reporting, and under which criteria the death is reported by means of an audit process,
	 Timely feedback to reporting clinicians by amior staff
Commerts Court of Victoria (C CoV)	 Provision of clear definitions for terms such as unexpected, violent or unnatural to be available for clinicians to access easily;
	 Ongoing audits of death reported to CCOV

Clinician's education for both nursing and medicine in reference to the reportable deaths appears to be very brief or even nonexistent during their university studies. 10,15

Of concern was that there was no consensus within the coroners group either. This may indicate an ongoing lack of understanding of The Act (2008) and generally what the requirements are for reporting deaths, and the legal requirement for reporting deaths. 10-20 Within the standards of practice for both nursing and medical practitioners there is reference to compliance with legislative requirements, which includes the reporting of deaths to the Coroner. 21, 22 The Australian Medical Council refers to the expectations of the medical graduate as a profes-sional leader and the application of legal responsibilities. 221 These include the requirement for mandatory reporting and notifications. Similarly, the Australian Nursing and Midwifery Accreditation Council refer to the responsibility for alignment between the Nursing and Midwifery Standards of Practice and the Accreditation Standards.²⁴ The lack of emphasis on these areas within the undergraduate programs offers opportunity for further education, which has been acknowledged

A death may meet several of the reportable criteria, for example, unexpected, indirectly due to accident or injury, which was reflected in the comments made by the participants. The information that can be obtained from the coronial investigation and findings may be under utilised. 19,

The review of deaths which occurs in healthcare settings has benefits for numerous groups. The benefits include reassurance to the community that deaths are being reported and investigated in a robust and timely manner. Clinicians are also afforded the opportunity to learn from deaths that occur in healthcare settings with a view to identify any systems issues that may assist in the prevention of deaths occurring in similar circumstances.

A sample of ongoing opportunities for improvement to enhance the reporting of the deaths that meet the reportable criteria can be seen below in Table 2.

5. Conclusion

In 2015, there were over 6000 deaths reported to the Coroners Court of Victoria. The findings of this study illustrated that there remains a significant lack of understanding of which deaths meet the criteria to be reported to the coroner. The findings of the clinical scenarios presented indicates that the clinicians' understanding of reportable death criteria is quite variable and these findings will assist in considering the practices that impact on the level of reporting. The variable interpretation of The Act (2008) by the group of coroners that were involved in completing the scenarios also indicated the lack of clarity. There is scope for further development of educational support for the clinicians from the coroner's court and also, internally within organisations. This study involved one hospital but may be representative of other health care institutions.

The review of these deaths, as well as being a legal requirement, is the opportunity for significant lessons for health care professionals, as well as a valuable opportunity for appraisal and for potential recommendations to inform patient safety.

Appendix 1. Brief Summary of deaths that meet the criteria for reporting to the Coroner's Court of Victoria

- 1.In this Act, a death of a person is a
- (a) The body is in Victoria; or
- (b) The death occurred in Victoria; or (c) The cause of the death occurred in Victoria; or
- (d) The person ordinarily resided in Victoria at the time of death- and the death was a death specified in subsection two (2).
- deaths are:
- 2. For the purposes of subsection (1), the (a) a death that appears to have been unexpected, unnatural or violent or to have resulted, directly or indirectly, from an accident or injury; or
 - (b) a death that occurs- (i) during a medical procedure; or (ii) following a medical procedure where the death is or may be causally related to the medical procedure- and a registered medical procedure

- practitioner would not, immediately before the procedure was undertaken, have reasonable expected the death; or
- (c) the death of a person who immediately before death was a person placed in custody or care; or a death that occurs in Victoria if a notice under section 37 (1) of the Births, Deaths and Marriages Registration Act 1996 has not been signed and is not likely to be signed.

Appendix 2. Clinical Scenarios

For each of the ten clinical scenarios, the participants were asked to determine if they believed that the death met the criteria for reporting to the Coroner's Office of Victoria. If the participant's answer was yes, there was the opportunity to state why they believed the death should be reported. An area to make any further comments accompanied each of the clinical scenarios. For each of the scenarios, the definitive answer in reference to meeting the reportable criteria as per the senior Coroner, is indicated.

For example:

Scenario 1: Yes, Indirectly from injury

An 87 year old female presents to the hospital after a fall at home where she sustained a fractured neck of femur. A dynamic hip screw is inserted and the patient is assessed as ready for transfer to a rehabilitation facility 5 days later. The night before the transfer occurs, she becomes confused and has a fall in the ward. She is diagnosed with a chest infection and her condition deteriorates despite treatment with antibiotics. Referral is made for palliative care and she died 3 days later in the ward.

Is the patient's death reportable to the Coroner's office?

If yes, why does the death meet the reportable criteria?

Comments:

Scenario 2: Yes, Indirectly from injury

A 46 year old male who has been paraplegic since a motor car accident 4 years ago is admitted with recurrent sacral pressure injuries. Whist an impatient, he develops sepsis and is treated with antibiotics. During this time, he also develops a chest infection requiring non invasive ventilation assistance. Over the next 5 days, his condition continues to deteriorate and he dies.

Scenario 3: Yes, Unexpected death

A 68 year old woman has been recently diagnosed with adenocarcinoma and is admitted for extensive abdominal surgery. Immediately post operatively, she is in ICU and stable. She is extubated the next day and transferred to the surgical ward. She is mobilising by day 4 and is progressing well, when she is found collapsed by her bed. Resuscitation is attempted unsuccessfully and she dies of a presumed pulmonary embolus. It is then discovered that she had not received any VTE prophylaxis.

Scenario 4: Yes, Unexpected and unnatural death

A 27 year old unemployed woman was admitted with joundice for investigation. She then admitted to taking an overdose of paracetamol 5 days previously. Investigations revealed deranged liver function tests and abnormal clotting. Despite full treatment she developed hepatic encephalopathy and renal failure in ICU. Her condition continued to deteriorate and she died 4 days later.

Scenario 5: Yes, Unexpected death

A 56 year old male, previously well, presents to the ED following an out of hospital cardiac arrest. Effective resuscitation was quickly instigated at the scene, with return of spontaneous circulation within 4 minutes. On arrival in ED, a 12 lead ECG showed a large anterior ML. The patient was transferred to the cardiac catheter lab where he suffered another cardiac arrest.

Scenario 6: Yes, Unexpected death and maybe directly from injury

An 18 year old man was a pedestrian hit by a car and sustained a # base of skull, frontal lobe contusions and a contrecoup injury. He was transferred to ICU mechanically ventilated, but after a few hours, his condition improved and he was able to breathe spontaneously. He did not show any further improvement and despite supportive care, his condition deteriorated and he died 6 weeks after admission.

Scenario 7: Yes, Unexpected and unnatural death

An 84 year old male is admitted from high level care after a witnessed episode of choking and vomiting. He had a past history of Alzheimer's dementia and an acquired brain injury. His condition deteriorates and he dies 2 days later.

Scenario & No, Natural cause death

An 84 year old female admitted to ward for palliative care. She has a history of recurrent urinary tract infections in the background of a long standing non traumatic paraplegia, wheel chair bound. She dies 4 days after her admission.

Scenario 9: No, Natural cause death.

A 70 year old male with chronic renal failure becomes hypertensive and complains of abdominal pain whilst undergoing haemodialysis. He then becomes

um esponsive and a code blue is called. His resuscitation status is checked and there was a "not for resuscitation" order in place and the patient dies soon after.

Scenario 10: No, Natural cause death

A 69 year old male is admitted with shortness of breath in the background of newly diagnosed non-small cell lung carcinoma. The next day he collapses and has a cardiac arrest. Resuscitation was attempted unsuccessfully and he died with his family present.

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Appendix 7.1 Communication. S Hinchey

LETTER TO HOSPITALS

Dear [name]

Investigation process for femoral fracture deaths

I write to invite your feedback on a proposed pilot for investigating deaths related to age-related fractures, specifically femoral fractures.

The Coroners Court of Victoria and the Victorian Institute of Forensic Medicine (VIFM) have determined that certain cases no longer require the deceased person to be transported to the coronial services centre for medical examination.

Importantly, this process aims to bring significant relief to Victorian families who are often frustrated by the process, intrusion and delays caused by what they see as unnecessary medical examinations.

Please take the time to review the attached information sheet, which outlines the proposed investigation method for femoral fracture deaths. Please share this with the head of your anatomical pathology department and your in-house legal counsel.

If you have any procedural questions about the attached, please email jodie.leditschke@vifm.org.

Otherwise, please send your feedback to registry@coronerscourt.vic.gov.au by COB 31 August 2017.

Yours Sincerely

Judge Sara Hinchey

State Coroner

REPORTABLE DEATH CHECKLIST FOR HOSPITALS OR OTHER MEDICAL FACILITIES

The following checklist will assist you to complete all required paperwork for a reportable death to the coroner.

Call Coronial Admissions & Enquiries (CAE) on 1300 309 519 (24/7) to determine if case is reportable.

	Description	Rationale / Information	√
1.	Go to www.vifm.org/meddep Secure code No:	Enter secure code provided by CAE. Complete this form as soon as possible. This will facilitate timely transfer of the deceased person to the Coroners Court of Victoria.	
		Print a completed copy for the patient medical record.	
2.	Complete a Statement of Identification Court Ref No:	Complete the identification form with a family member or someone who has known the person for more than 6 months while they are with the deceased person.	
3.	Fax the completed Statement of Identification to CAE as soon as possible	Fax to 9682 1206	
4.		Police are requested to attend by CAE	

	Police will attend to obtain details about the deceased		
	and NOK.	Have police attended?	
5.	Transfer the deceased person to your hospital/facility mortuary	Transfer the deceased person to the mortuary once family and police have left.	
		If your facility does not have a mortuary, please contact CAE on 1300 309 519 to arrange transfer	
6.	Notify your hospital co-ordinator (or similar) that the deceased person has been transferred to the	CAE contact the hospital co-ordinators to arrange appropriate transfer time.	
	mortuary	Time critical for Tissue Donor cases	