

Online Research @ Cardiff

This is an Open Access document downloaded from ORCA, Cardiff University's institutional repository: <https://orca.cardiff.ac.uk/id/eprint/124976/>

This is the author's version of a work that was submitted to / accepted for publication.

Citation for final published version:

Mitchell, Rebecca, Faris, Mona, Lystad, Reidar, Pulido, Diana Fajardo, Norton, Grace, Baysari, Melissa, Clay-Williams, Robyn, Hibbert, Peter, Carson-Stevens, Andrew ORCID: <https://orcid.org/0000-0002-7580-7699> and Hughes, Cliff 2020. Using the WHO international classification of patient safety framework to identify incident characteristics and contributing factors for medical or surgical complication deaths. *Applied Ergonomics* 82 , 102920. 10.1016/j.apergo.2019.102920 file

Publishers page: <http://dx.doi.org/10.1016/j.apergo.2019.102920>
<<http://dx.doi.org/10.1016/j.apergo.2019.102920>>

Please note:

Changes made as a result of publishing processes such as copy-editing, formatting and page numbers may not be reflected in this version. For the definitive version of this publication, please refer to the published source. You are advised to consult the publisher's version if you wish to cite this paper.

This version is being made available in accordance with publisher policies.

See

<http://orca.cf.ac.uk/policies.html> for usage policies. Copyright and moral rights for publications made available in ORCA are retained by the copyright holders.



Using the WHO International Classification of Patient Safety Framework to identify incident characteristics and contributing factors for medical or surgical complication deaths

Rebecca Mitchell¹, Mona Faris¹, Reidar Lystad¹, Diana Fajardo Pulido¹, Grace Norton¹, Melissa Baysari², Robyn Clay-Williams¹, Peter Hibbert¹, Andrew Carson-Stevens³, and Cliff Hughes¹

¹ Australian Institute of Health Innovation, Macquarie University, Sydney, Australia.

² Faculty of Health Sciences, The University of Sydney, Sydney, Australia.

³ Division of Population Medicine, School of Medicine, Cardiff University, Cardiff, Wales, UK.

Corresponding author:

Rebecca Mitchell, Australian Institute of Health Innovation, Macquarie University, Level 6, 75 Talavera Road, Macquarie University NSW 2109, Australia

Email: r.mitchell@mq.edu.au Tel: +61 2 9850 2321 Fax: +61 2 9850 2499

Word count: 3864

Highlights

- The modified-ICPS operationalises the ICPS for use as a human factors taxonomy.
- The mICPS can identify sequences of incidents and contributing factors leading to adverse events.
- The mICPS can be used to highlight where preventive approaches should be targeted.

Using the WHO International Classification of Patient Safety Framework to identify incident characteristics and contributing factors for medical or surgical complication deaths

Abstract

This study aimed to operationalise and use the World Health Organization's International Classification for Patient Safety (ICPS) to identify incident characteristics and contributing factors of deaths involving complications of medical or surgical care in Australia. A sample of 500 coronial findings related to patient deaths following complications of surgical or medical care in Australia were reviewed using a modified-ICPS (mICPS). Over two-thirds (69.0%) of incidents occurred during treatment and 27.4% occurred in the operating theatre. Clinical process and procedures (55.9%), medication/IV fluids (11.2%) and healthcare-associated infection/complications (10.4%) were the most common incident types. Coroners made recommendations in 44.0% of deaths and organisations undertook preventive actions in 40.0% of deaths. This study demonstrated that the ICPS was able to be modified for practical use as a human factors taxonomy to identify sequences of incident types and contributing factors for patient deaths. Further testing of the mICPS is warranted.

Keywords: patient safety, taxonomy, error

1. Introduction

Investigating the factors that contributed to an event resulting in an unexpected patient death in hospital can aid in preventing and improving the quality of healthcare (Gill et al. 2006, Ibrahim et al. 2009). Prevention of adverse events (i.e. incidents which result in harm to patients (Runciman et al. 2009)) requires good quality information on how and why these events occur. Examining factors that contributed to an adverse event can involve a review through healthcare governance systems, such as root cause analyses (Percarpio et al. 2008, Nicolini et al. 2011) or morbidity and mortality meetings .

In Australia, if the death of a patient occurred as a result of a complication during a health-related procedure, it should be reported to a Coroner. Each Australian state and territory has its own Coronial Act and, in general, a death is legislated to be reportable to a Coroner if the death was not a reasonably expected outcome of a health-related procedure (i.e. medical, surgical or dental procedures, including the administration of an anaesthetic, sedative or other drug) (NSW Government 1980). Coroners are judicial magistrates whose main role is to establish the deceased's identity, cause of death, how the death occurred, and whether it could have been prevented (NSW Coroner's Court 2018). Coronial findings can provide an event narrative and a rich source of information to examine the circumstances of death (Hanzlick and Parrish 1996, Pudney and Grech 2016). Narrative text has previously been used to classify factors contributing to patient deaths using a human factors taxonomy (Mitchell et al. 2016). Identifying the human factors contribution to adverse patient safety events involves examining the interrelationships between healthcare providers, patients, the health organisation, the type of, and use of, technology, equipment and tools, the organisation of work, and the workplace, including both the physical and social environment (Holden et al. 2013, Carayon et al. 2014).

Human factors taxonomies have been used in healthcare to aid in identifying the factors contributing to adverse events and to identify priorities for preventive activities (Chang et al. 2005, Woloshynowych et al. 2005, ElBardissi et al. 2007, World Health Organization 2009, Mitchell et al. 2014, Carson-Stevens et al. 2016, Mitchell et al. 2016). A human factors taxonomy should include a formal structure for the classification of concepts, with each

concept or factor clearly defined. A data dictionary usually accompanies a taxonomy to provide coding frames for each concept that includes example application of the definitions. The human factors taxonomies that have been used in healthcare have largely been developed by independent teams and each has defined concepts differently and collected information on different types of concepts contributing to adverse patient safety events (Mitchell et al. 2014). Existing taxonomies have been lacking, as some taxonomies only include task and organisational factors and do not consider cognitive errors (Chang 2007, Itoh et al. 2007), while some taxonomies only considered cognitive errors (Henneman et al. 2010). Other taxonomies do not include patient-related factors (Hicks et al. 2008, Kantelhardt et al. 2011), only one has considered the sequence of causal factors leading to the adverse event (Mitchell et al. 2016), and for some taxonomies inter-rater reliability was not assessed during development (Chang 2007, Benavidez et al. 2008, Cagliano et al. 2011). Internationally, there are heartening efforts to develop taxonomies for care contexts with a paucity of research and development such as primary care dentistry (Ensaldo-Carrasco et al. in-press, 2019).

The World Health Organization (WHO) Conceptual Framework for the International Classification for Patient Safety (ICPS) was developed to work towards a common understanding of patient safety concepts and terminology (World Health Organization 2009). While the ICPS provides an informational framework, the framework needs adaptation and the concepts defined to make it suitable for use as a human factors taxonomy (Runciman et al. 2009, Schulz et al. 2009, World Alliance For Patient Safety Drafting Group et al. 2009). The relationships and links between the ICPS sub-categories are not clearly defined (Schulz et al. 2009) and some categories are not mutually exclusive. McElroy and colleagues (McElroy et al. 2016) adapted the ICPS to identify contributing factors (CFs) to adverse events involving adult liver and kidney transplant surgeries, but the ICPS has not yet been operationalised to identify factors contributing to patient deaths following medical or surgical complications. This study aims to operationalise and use the ICPS to identify incident characteristics and CFs of deaths involving complications of medical or surgical care.

2. Material and methods

A retrospective examination of a random sample of 500 coronial findings related to patient deaths following complications of surgical or medical care from the Australian National Coronial Information System (NCIS) was conducted. Ethical approval was obtained from the Macquarie University Human Research Ethics Committee (reference no: 5201500660), the Victorian State Government Justice Human Research Ethics Committee (CF/15/16426), and the Western Australia Coronial Ethics Committee (EC16/2015).

2.1 Data collection

The NCIS is a national internet-based data storage and retrieval system for deaths reported to a Coroner. The NCIS contains information regarding the cause and circumstances of death, as well as demographic information on the deceased. Accompanying their coronial findings, a Coroner may make recommendations aimed at improving safety and these determinations are also available, and where facilities have already implemented preventive actions prior to the coronial inquest, these activities may also be recorded in the coronial finding.

2.2 Identification of medical or surgical care deaths

All deaths resulting from complications of surgical or medical care for individuals of any age from 1 January 2001 to 31 December 2013 were identified using the NCIS intent at case completion classification of 'complications of medical or surgical care' (NCIS: 6) AND/OR via the intent at notification of 'complications of medical or surgical care' (NCIS: 6) AND/OR via mechanism of injury 'complications of health care' (NCIS: 20 to 20.99) AND/OR through ICD-10: Y40-Y84, complications of surgical and medical care and the death occurred in a hospital.

Of the 3,227 deaths identified following complications of surgical or medical care, 2,137 (66.2%) had a coronial finding and summary of events leading to the death attached to the mortality record in the NCIS. There were no significant differences by sex ($\chi^2= 1.1$ (df=1), $p=0.3$) for deaths that had a coronial finding present or not. However, there was a significant difference by age group ($\chi^2= 34.9$ (df=9), $p<0.0001$), with all children <1 year of age having a coronial finding present. Of the 2,137, a random sample of 500 coronial findings that had a

coronial finding attached in the NCIS were identified for review. A simple random sample was selected using PROC SURVEYSELECT in SAS. Patient demographic information was obtained from the NCIS coronial record.

2.3 Adaption of the WHO International Classification for Patient Safety

The ICPS was developed using a two-round modified-Delphi study with international patient safety experts (World Health Organization 2009). It contains ten high-level conceptual areas, of which six areas (i.e. patient characteristics, incident type, incident characteristics, CFs, actions to reduce risk, and ameliorating actions) were adapted for this study. Three of the remaining four areas of the ICPS (i.e. detection, organisational outcomes, and patient outcomes) were either not able to be identified or not relevant for this study. Information for the last area of the ICPS (i.e. patient characteristics) was collected through data recorded in the NCIS.

Both the incident types and CFs sections from the original ICPS were re-configured into three-level hierarchical classification frameworks. Each main incident type category was converted to represent Level 1 of the hierarchy, the process categories for each incident type were used to indicate Level 2, and the problem categories Level 3 of the incident type hierarchy. Likewise, for the CFs section each main category represented Level 1, the sub-categories were used to indicate Level 2, and the sub-sub categories used to indicate Level 3 of the CFs hierarchy. Each incident type and CF in the ICPS was defined and, where relevant, an example added (Mitchell and Faris 2018). Where the incident type or the CFs were not mutually exclusive, they were either revised or removed.

The ICPS phase of care categories were modified to indicate the patient's care phase at the time of the event. The location of the event within the healthcare setting was recorded using classifications adapted from Chang et al (Chang et al. 2005) and Webb et al (Webb et al. 1993). Any coronial recommendations or any organisational preventive actions made by the hospital since the death were classified based on a modified version of the ICPS of 'ameliorating actions' and 'actions to reduce risk' categories.

Two authors (RM and MF) reorganised the sub-categories to classify the patient deaths and refined the ICPS taxonomy for practical use (Mitchell and Faris 2018). The taxonomy was pilot-tested by two authors (MF and RM) using ten publicly available Australian coronial findings of patient deaths following complications of surgical or medical care. Pilot testing involved reading each coronial finding and then using the draft modified-ICPS (mICPS) to classify the incident types and the CFs. Average percent agreement between the two coders (MF and RM) for incident types at Level 1 was 48%, at Level 2 was 38% and Level 3 was 30%. Percent agreement for CFs at Level 1 was 78%, at Level 2 was 60%, and Level 3 was 58%. Three medical science students were also involved in reviewing and providing feedback on the draft ICPS taxonomy to classify patient deaths. Following pilot testing and review, further modifications were made to the taxonomy. This included removal of confusing terminology, such as 'not performed when indicated' to simply 'not performed', and including additional Level 3 categories for some factors to incorporate additional issues, such as delays/failure to respond.

2.4 Data collection and coder training

Data were recorded in a Microsoft Access database by coders, one with human factors training (RM). Three coders were trained by MF and were given an overview of the mICPS, were provided with a data dictionary that included the taxonomy and definitions of each concept, and conducted two example classifications of patient deaths using the mICPS. Debriefing was conducted and where there were discrepancies between the coders during the training exercise and the trainer, the rationale for classifications for each event was discussed and consensus achieved.

2.5 Inter-rater reliability

Following training, inter-rater reliability was assessed between four coders (MF, RL, GN, DF) using the mICPS using coronial findings of ten patient deaths. Pair-wise percent agreement was calculated for each pair of coders for each incident type and contributing factor level and then the average agreement for each incident type and contributing factor level was calculated. Average percent agreement between the coders for incident types at Level 1 was 83% (range 71-92%), at Level 2 was 81% (range 75-88%) and Level 3 was 78% (range 71-

83%). Percent agreement for CFs at Level 1 was 69% (range 46-83%), at Level 2 was 62% (range 46-75%) and Level 3 was 58% (range 33-75%).

2.6 Classification of coronial findings using the modified-ICPS

The patient's phase of care, location within the hospital/health setting at the time of the event, up to four incident types, up to four CFs, up to five preventive actions as a result of the death made by the organisation, and up to five targets for coronial recommendations were classified. An incident type was considered to be *"an event or circumstance which...led to unintended and/or unnecessary harm to a person..."* (Committee of Experts on Management of Safety and Quality in Health Care 2005). Each incident type must have played a role in causing the death to occur and was recorded sequentially as the incident(s) occurred. For example, incident type 1 occurred closest to the death preceded by incident type 2, preceded by incident types 3 and 4, respectively. The temporal sequence of incident types is based on Reason's Swiss Cheese Model of causation (Reason 1997) and the Human Factors Classification Framework for Patient Safety (Mitchell et al. 2016). This structured approach for sensemaking following an adverse event, known as the Recursive Model for Incident Analysis (Carson-Stevens et al. 2016), has been widely used to characterise adverse events (Cooper et al. 2017, Rees et al. 2017).

Each incident type was classified leading up to the patient death in a temporal sequential order. CFs could have occurred at any stage in the temporal sequence (Figure 1). A CF was considered to be *"a circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident"* (World Health Organization 2007). CFs could involve a staff member's behaviour or actions, the patient, the organisation (such as policies or guidelines, supervision), or the work environment (such as noise, remoteness). The CFs were considered to be factors that pre-existed before the sequence of incident types began (Mitchell et al. 2016).

2.7 Data management and analysis

Information regarding patient deaths from the NCIS were combined with the mICPS data from the Access database. All descriptive statistics and 95% confidence intervals were calculated using SAS version 9.4 (SAS Institute 2014).

3. Results

Just over half the deaths were of females (53.8%) and the mean age was 54.3 years (SD 28.0). Over two-thirds (69.0%) of adverse events occurred during treatment, 9.6% during assessment and 6.6% during pre-admission. The most common location of the event was the operating theatre (27.4%), ward/patient's room (20.0%) or the emergency department (10.8%) (Table 1).

All events had at least one incident type identified, 54.4% had at least two, 25.0% had three and 8.0% had four incident types identified. Clinical process and procedures (55.9%), medication/IV fluids (11.2%) and healthcare-associated infection/complications (10.4%) were the most common incident types identified across the sequence of events (Table 2). In the majority of events (82.0%) a least one CF could be identified, with 203 (40.6%) events having two, 96 (19.2%) events three, and 38 (7.6%) events four CFs identified. There were 756 CFs identified in total. CFs relating to healthcare staff (39.7%), the organisation/service (30.3%) or the patient (25.8%) were the most common (Table 3).

Within clinical process and procedures, the most common type of events were those relating to procedures/treatment/interventions (29.0%). Common sequences of incident types for patients that experienced an adverse event during a procedure/treatment/intervention involved (i) *diagnostic issues* (12.2%) involving either a delay/failure to recognise a deteriorating patient (57.9% of the diagnostic issues), a complication (26.3%) or an incomplete diagnosis (15.8%) and (ii) *treatment issues* (12.2%) involving either a delay/failure to recognise a deteriorating patient (47.4% of the treatment issues), a complication (42.1%) or an incomplete/wrong process (10.5%) (Figure 2). The most common CFs for adverse events involving procedures/treatment/interventions were staff factors (44.0%) (such as human error, miscommunication or inexperience), organisational/service factors (26.9%) (including guidelines not being followed, inconsistent

or no guidelines), patient factors (25.5%) (such as physical impairments or physical characteristics) and work environment factors (2.3%) (including remote/long distance).

Sepsis (6.5%) was the most common outcome of healthcare-associated infection. The most common sequences of incident types for patients that developed sepsis involved (i) *treatment issues* (31.5%) where there was a complication (58.8% of treatment issues), or there was a delay/failure to recognise a deteriorating patient (29.4%) or an 'other' type of incident (17.6%), (ii) *diagnostic issues* (20.4%) following a delay/failure to recognise a deteriorating patient (63.6% of diagnostic issues), or that were incomplete or not performed (27.3%) or involved the wrong process (9.1%), and (iii) *medication issues* (11.1%) that involved inappropriate medications (50.0% of medication issues), adverse patient reactions (33.3%) or omitted doses (16.7%) (Figure 3). The most common types of CFs for sepsis were staff factors (33.8%) (such as human error, bias/anchoring or inadequate communication between staff), organisational/service factors (32.3%) (including guidelines not being followed, inconsistent or no guidelines, work pressure) and patient factors (29.2%) (such as physical impairments or physical characteristics).

Coroners made recommendations in 220 (44.0%) deaths, with the most common involving changes to organisational policies/protocols/guidelines (33.2%), staff training/education (20.2%) and organisational record keeping (15.4%). Preventive actions undertaken by the organisation were reported in 1 in 5 (40.0%) coronial findings and the most common were changes to organisational policies/protocols/guidelines (38.9%), staff education/training (20.4%), equipment changes (10.2%), and improvements in record keeping (9.2%) (Table 4).

4. Discussion

Human factors classification taxonomies can assist in identifying factors that contributed to adverse events and in identifying areas for preventive efforts (Simsekler et al. 2015). This study trialed a method of examining coronial findings using a mICPS that went beyond establishing a patient's cause of death. Coronial investigations can provide an opportunity to identify factors contributing to fatal events and by identifying sequences of incident types and CFs, this study has shown that the mICPS could be used to supplement the coronial investigative process.

This study identified similar causal sequences for patient deaths that were immediately preceded by an incident that either involved a procedure/treatment/intervention or resulted in sepsis. During the diagnosis or treatment phase of care there were commonalities in the circumstances surrounding the fatal incidents where either healthcare staff did not recognise the patient was deteriorating and treatment was, therefore, delayed or there was a complication, such as a perforation during surgery, that was not immediately identified. Delays in recognising deteriorating patients and delayed identification of complications have been found to be associated with adverse events (Beaumont et al. 2008, Donaldson et al. 2014). Rapid response prevention programs, such as *Between the Flags* (Hughes et al. 2014), have been adopted by hospitals in an effort to trigger when patients are deteriorating and to escalate urgent patient review and rapid response.

Complications following treatment were common sequences in the incident pathway for sepsis cases and for incidents involving a procedure/treatment/intervention, particularly during surgery which comprised over one-quarter of adverse events in the current study. Further examinations of incident type sequences and CFs for patient deaths by type of surgery could be instrumental in identifying where reductions in patient mortality could be made. Gyomber et al (2006) analysed patient deaths associated with urological surgery and found that the majority of deaths were due to known surgical complications. The authors were able to identify patient characteristics, such as coronary artery disease, and increased monitoring and response activities, including the need for closer cardiovascular monitoring, and the ability to transfer patients rapidly to a coronial care unit, as further steps that could be undertaken to reduce the incidence of known surgical complications and potentially patient deaths. This level of analysis was not often demonstrated in the coronial findings reviewed for the current study.

Around one in ten sepsis cases had a medication issue identified in the temporal sequence of incident types, primarily involving the appropriateness of the medication prescribed, adverse reactions/contraindications or omitted doses. Delayed identification that the patient had sepsis is likely to have contributed to patients being administered inappropriate medication (Carrigan et al. 2004, McNab et al. 2018). Prior studies of adverse events have

also identified medication issues involving the prescription of the wrong drug or incorrect dose (Amato et al. 2017), particularly for older adults (Cooper et al. 2017).

While incident types and CFs could be identified for the majority of patient deaths in the current study, in some cases there was not enough detail available in the coronial findings to record the sequences of incident types leading to the death. It is possible that, for some deaths, particularly those involving known procedural/surgical complications, there was a limited investigation surrounding the circumstances of the event. In some cases, having an expert medical clinical team to provide assistance during the coronial process would be of benefit. For example, in Victoria, Australia a clinical liaison service including physicians and nurses experienced in the public health prevention approach are available to provide advice to police assisting the Coroner (Ibrahim et al. 2009).

Many of the investigations of adverse events result in recommendations being made to develop and/or improve guidelines, policies and procedures (Pudney and Grech 2016, Hibbert et al. 2018). In the current study, around one-third of coronial recommendations involved changing organisational policies/protocols/guidelines and for one in five patient deaths the organisation had already made changes to policies/protocols/guidelines that were documented in the coronial finding. The ongoing cycle of the development of policies and rules following adverse events attempts to ensure a reliable standard of patient care, but can create a more complex and brittle healthcare system (Cook and Woods 1994) and may not result in changes that lead to improvements in practice. Future research should consider the effectiveness of simply developing or modifying hospital-based policies and guidelines, in conjunction with efforts to enhance organisation factors, such as workplace culture, to prevent adverse events for patients.

There are several limitations of the current study. The use of the mICPS for this study only examined patient deaths, so it is possible that further refinement of the mICPS could be required to examine other patient outcomes across a range of settings, including primary care (Cooper et al. 2018). In terms of using coronial findings from the NCIS to examine the mICPS, for some deaths only limited information was available, limiting the ability to identify potential contributing factors. As there was a significant difference in the presence of a

coronial finding by age group, there was a greater likelihood that children <1 year of age were selected and included within this study. However, children <1 year only accounted for 10% of the random sample. The inclusion of a measure of the level of confidence by coders for their classifications could have provided a guide as to the certainty of the coder in their classification of incident types and contributing factors. In addition, there is known underreporting of patient deaths to a Coroner (Charles et al. 2007, Lu et al. 2008). Therefore, representativeness of the sample is unknown. Nonetheless, structured reviews of reports describing unsafe care present opportunity to identify opportunities for future care improvement, as demonstrated in the United Kingdom for older adults and children in primary care (Cooper et al. 2017, Rees et al. 2017).

Coronial investigations involve the most serious adverse events and, as they can provide in-depth evidence on the circumstances surrounding the event, they allow insights into prevention not necessarily available from other sources. This study was largely explorative in nature to determine if the mICPS could be used to describe adverse events, nevertheless, it was able to indicate a range of incident types and CFs for a sample of patient deaths. This study also showed how different causal patterns identified using the mICPS play a role in different types of adverse events. If applied internationally, mICPS could support temporal and geographical comparisons of the identified causes of adverse events and could catalyse efforts to target and design solutions for improved safety in healthcare systems.

5. Conclusion

This study operationalised the ICPS for practical use and field tested the mICPS as a human factors taxonomy. While potential variability in coder classifications needs to be monitored, the mICPS enabled non-human factors trained coders to identify sequences of incident types and CFs for a sample of patient deaths. The mICPS identified patterns of causation for patient deaths and highlights where preventive approaches should be targeted to tackling adverse events. The mICPS should be tested further to enable inferences regarding the nature of adverse events to be made.

Acknowledgements: The authors wish to thank the National Coroners Information System for providing access to mortality data, along with the three PACE undergraduate students, Clare McNamara, Taylor Monk and Shubham Anand, for assisting in the refining of the incident type and contributing factors for the mICPS.

Funding: RM was supported by a career fellowship from the NSW Ministry of Health under the NSW Health Early-Mid Career Fellowships Scheme.

Competing interests: Nil.

References

- Amato, M. G., Salazar, A., Hickman, T.-T. T., Quist, A. J., Volk, L. A., Wright, A., McEvoy, D., Galanter, W. L., Koppel, R. and Loudin, B. (2017). Computerized prescriber order entry–related patient safety reports: analysis of 2522 medication errors. *Journal of the American Medical Informatics Association* 24(2): 316-322.
- Beaumont, K., Luettel, D. and Thomson, R. (2008). Deterioration in hospital patients: early signs and appropriate actions. *Nursing Standard* 23(1): 43.
- Benavidez, O. J., Gauvreau, K., Jenkins, K. J. and Geva, T. (2008). Diagnostic errors in pediatric echocardiography: development of taxonomy and identification of risk factors. *Circulation* 117(23): 2995-3001.
- Cagliano, A. C., Grimaldi, S. and Rafele, C. (2011). A systemic methodology for risk management in healthcare sector. *Safety Science* 49(5): 695-708.
- Carayon, P., Wetterneck, T. B., Rivera-Rodriguez, A. J., Hundt, A. S., Hoonakker, P., Holden, R. and Gurses, A. P. (2014). Human factors systems approach to healthcare quality and patient safety. *Applied Ergonomics* 45(1): 14-25.
- Carrigan, S. D., Scott, G. and Tabrizian, M. (2004). Toward resolving the challenges of sepsis diagnosis. *Clinical Chemistry* 50(8): 1301-1314.
- Carson-Stevens, A., Hibbert, P., Williams, H., Evans, H., Cooper, A., Rees, P., Deakin, A., Shiels, E., Gibson, R. and Butlin, A. (2016). Characterising the nature of primary care patient safety incident reports in the England and Wales National Reporting and Learning System: a mixed-methods agenda-setting study for general practice. *Health Service and Delivery Research* 4: 27.
- Chang, A., Schyve, P., Croteau, R., O'Leary, D. and Loeb, J. (2005). The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. *International Journal for Quality in Health Care* 17(2): 95-105.
- Chang, A., Schyve, P. M., Croteau, R. J., O'Leary, D. S. and Loeb, J. M. (2005). The JCAHO patient safety event taxonomy: A standardized terminology and classification schema for near misses and adverse events. *International Journal for Quality in Health Care* 17(2): 95-105.
- Chang, Y. (2007). Testing a theoretical model for severe medication errors Ph.D., University of North Carolina at Chapel Hill.
- Charles, A., Ranson, D., Bohensky, M. and Ibrahim, J. (2007). Under-reporting of deaths to the coroner by doctors: a retrospective review of deaths in two hospitals in Melbourne, Australia. *International Journal for Quality in Health Care* 19(4): 232-236.
- Committee of Experts on Management of Safety and Quality in Health Care (2005). Glossary of terms related to patient and medication safety - approved terms.
- Cook, R. and Woods, D. (1994). Operating at the sharp end: the complexity of human error. *Human Error in Medicine*. Bogner, M. Hillsdale, Lawrence Erlbaum Associates: 255-310.
- Cooper, A., Edwards, A., Williams, H., Evans, H., Avery, A., Hibbert, P., Makeham, M., Sheikh, A., J. Donaldson, L. and Carson-Stevens, A. (2017). Sources of unsafe primary care for older adults: a mixed-methods analysis of patient safety incident reports. *Age and ageing* 46(5): 833-839.
- Cooper, J., Williams, H., Hibbert, P., Edwards, A., Butt, A., Wood, F., Parry, G., Smith, P., Sheikh, A. and Donaldson, L. (2018). Classification of patient-safety incidents in primary care. *Bulletin of the World Health Organization* 96(7): 498.
- Donaldson, L., Panesar, S. and Darzi, A. (2014). Patient-safety-related hospital deaths in England: thematic analysis of incidents reported to a national database, 2010-2012. *PLoS medicine* 11(6): e1001667.
- ElBardissi, A. W., Wiegmann, D. A., Dearani, J. A., Daly, R. C. and Sundt, T. M., 3rd (2007). Application of the human factors analysis and classification system methodology to the cardiovascular surgery operating room. *Annals of Thoracic Surgery* 83(4): 1412-1418; discussion 1418-1419.
- Ensaldo-Carrasco, E., Sheikh, A., Cresswell, K., Bedi, R., Carson-Stevens, A. and Sheikh, A. (in-press, 2019). Patient Safety Incidents in Primary Care Dentistry in England and Wales: A Mixed-Methods Study. *Journal of Patient Safety*.

- Gill, J. R., Goldfeder, L. B. and Hirsch, C. S. (2006). Use of “therapeutic complication” as a manner of death. *Journal of Forensic Sciences* 51(5): 1127-1133.
- Gyomber, D., Lawrentschuk, N., Ranson, D. L. and Bolton, D. M. (2006). An analysis of deaths related to urological surgery, reviewed by the State Coroner: a case for cardiac vigilance before transurethral prostatectomy. *BJU International* 97(4): 758-761.
- Hanzlick, R. and Parrish, R. G. (1996). The role of medical examiners and coroners in public health surveillance and epidemiologic research. *Annual Review of Public Health* 17: 383-409.
- Henneman, E. A., Roche, J. P., Fisher, D. L., Cunningham, H., Reilly, C. A., Nathanson, B. H. and Henneman, P. L. (2010). Error identification and recovery by student nurses using human patient simulation: Opportunity to improve patient safety. *Applied Nursing Research* 23(1): 11-21.
- Hibbert, P., Thomas, M., Deakin, A., Runciman, W., Braithwaite, J., Lomax, S., Prescott, J., Gorrie, G., Szczygielski, A., Surwald, T. and Fraser, C. (2018). Are root cause analyses recommendations effective and sustainable? An observational study. *Int J Qual Health Care* 30(2): 124-131.
- Hicks, R. W., Becker, S. C. and Jackson, D. G. (2008). Understanding medication errors: discussion of a case involving a urinary catheter implicated in a wrong route error. *Urologic Nursing* 28(6): 454-459.
- Higginson, J., Walters, R. and Fulop, N. (2012). Mortality and morbidity meetings: an untapped resource for improving the governance of patient safety? *BMJ Quality and Safety* 21(7): 576-585.
- Holden, R. J., Carayon, P., Gurses, A. P., Hoonakker, P., Hundt, A. S., Ozok, A. A. and Rivera-Rodriguez, A. J. (2013). SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients. *Ergonomics* 56(11): 1669-1686.
- Hughes, C., Pain, C., Braithwaite, J. and Hillman, K. (2014). ‘Between the flags’: implementing a rapid response system at scale. *BMJ Qual Saf* 23: 714-717.
- Ibrahim, J. E., Ranson, D. L., O'Brien, A., Charles, A. and Young, C. (2009). Forensic investigation of medical treatment related deaths. *Legal Medicine* 11(Supplement 1): S71-S75.
- Itoh, K., Omata, N. and Andersen, H. B. (2007). A human error taxonomy for analysing healthcare reporting culture and its effects on safety performance. *European Safety and Reliability Conference (ESREL 2007), Stavanger, NORWAY, Taylor & Francis Ltd.*
- Kantelhardt, P., Müller, M., Giese, A., Rohde, V. and Kantelhardt, S. (2011). Implementation of a critical incident reporting system in a neurosurgical department. *Central European Neurosurgery* 72(01): 15-21.
- Lu, T.-H., Shaw, K.-P., Hsu, P.-Y., Chen, L.-H. and Huang, S.-M. (2008). Non-referral of unnatural deaths to coroners and non-reporting of unnatural deaths on death certificates in Taiwan: Implications of using mortality data to monitor quality and safety in healthcare. *International Journal for Quality in Health Care* 20(3): 200-205.
- McElroy, L., Woods, D., Yanes, A., Skaro, A., Daud, A., Curtis, T., Wymore, E., Holl, J., Abecassis, M. and Ladner, D. (2016). Applying the WHO conceptual framework for the International Classification for Patient Safety to a surgical population. *International Journal for Quality in Health Care* 28(2): 166-174.
- McNab, D., Freestone, J., Black, C., Carson-Stevens, A. and Bowie, P. (2018). Participatory design of an improvement intervention for the primary care management of possible sepsis using the Functional Resonance Analysis Method. *BMC Medicine* 16(1): 174.
- Mitchell, R. and Faris, M. (2018). Operationalising the World Health Organization’s International Classification for Patient Safety Data Dictionary version 2. North Ryde, Australian Institute for Health Innovation, Macquarie University.
- Mitchell, R., Williamson, A. and Molesworth, B. (2016). Application of a human factors classification framework for patient safety to identify precursor and contributing factors to adverse clinical incidents in hospital. *Applied Ergonomics* 52: 185-195.

- Mitchell, R., Williamson, A., Molesworth, B. and Chung, A. (2014). A review of the use of human factors classification frameworks that identify causal factors for adverse events in the hospital setting. *Ergonomics* 57(10): 1443-1472.
- Mitchell, R., Williamson, A., Molesworth, B. and Chung, A. Z. (2014). A review of the use of human factors classification frameworks that identify causal factors for adverse events in the hospital setting. *Ergonomics* 57(10): 1443-1472.
- Nicolini, D., Waring, J. and Mengis, J. (2011). Policy and practice in the use of root cause analysis to investigate clinical adverse events: Mind the gap. *Social Science & Medicine* 73(2): 217-225.
- NSW Coroner's Court. (2018). The Coroner's role. Retrieved 30/5/2018, 2018, from http://www.coroners.justice.nsw.gov.au/Pages/coroner_role/coroner_role.aspx.
- NSW Government (1980). Coroners Act, NSW Government.
- Percarpio, K., Watts, B. and Weeks, W. (2008). The effectiveness of root cause analysis: what does the literature tell us? *Joint Commission Journal on Quality and Patient Safety* 34(7): 391-398.
- Pudney, V. and Grech, C. (2016). Benefit of hindsight: systematic analysis of coronial inquest data to inform patient safety in hospitals. *Australian Health Review* 40(4): 371-377.
- Reason, J. (1997). Hazards, defences and losses - the 'Swiss cheese' model of defences. *Managing the risks of organizational accidents*. Reason, J. Aldershot, Ashgate Publishing Ltd: 1-20.
- Rees, P., Edwards, A., Powell, C., Hibbert, P., Williams, H., Makeham, M., Carter, B., Luff, D., Parry, G. and Avery, A. (2017). Patient safety incidents involving sick children in primary care in England and Wales: a mixed methods analysis. *PLoS medicine* 14(1): e1002217.
- Runciman, W., Hibbert, P., Thomson, R., Van Der Schaaf, T., Sherman, H. and Lewalle, P. (2009). Towards an International Classification for Patient Safety: key concepts and terms. *Int J Qual Health Care* 21: 18-26.
- SAS Institute (2014). SAS: statistical software, version 9.4. Cary, North Carolina, SAS Institute.
- Schulz, S., Karlsson, D., Daniel, C., Cools, H. and Lovis, C. (2009). Is the "International Classification for Patient Safety" a classification? *Proceedings of MIE 2009*. Adlassnig, K. Amsterdam, IOS Press BV. 150: 502-506.
- Simsekler, M. E., Card, A. J., Ruggeri, K., Ward, J. R. and Clarkson, P. J. (2015). A comparison of the methods used to support risk identification for patient safety in one UK NHS foundation trust. *Clinical Risk* 21(2-3): 37-46.
- Webb, R., Currie, M., Morgan, C., Williamson, J., Mackay, P., Russell, W. and Runciman, W. (1993). The Australian Incident Monitoring Study: an analysis of 2000 incident reports. *Anaesthesia and intensive care* 21: 520-520.
- Woloshynowych, M., Rogers, S., Taylor-Adams, S. and Vincent, C. (2005). The investigation and analysis of critical incidents and adverse events in healthcare. *Health Technology Assessment* 9(19): 1-158.
- World Alliance For Patient Safety Drafting Group, Sherman, H., Castro, G., Fletcher, M., Hatlie, M., Hibbert, P., Jakob, R., Koss, R., Lewalle, P., Loeb, J., Perneger, T., Runciman, W., Thomson, R., Van Der Schaaf, T. and Virtanen, M. (2009). Towards an International Classification for Patient Safety: the conceptual framework. *Int J Qual Health Care* 21(1): 2-8.
- World Health Organization (2007). Report on the web-based modified-Delphi survey of the International Classification for Patient Safety. Geneva, World Health Organization.
- World Health Organization (2009). The Conceptual Framework for the International Classification for Patient Safety. Geneva, World Health Organization.

Figure 1: Conceptual model of the classification of mICPS incident types and contributing factors

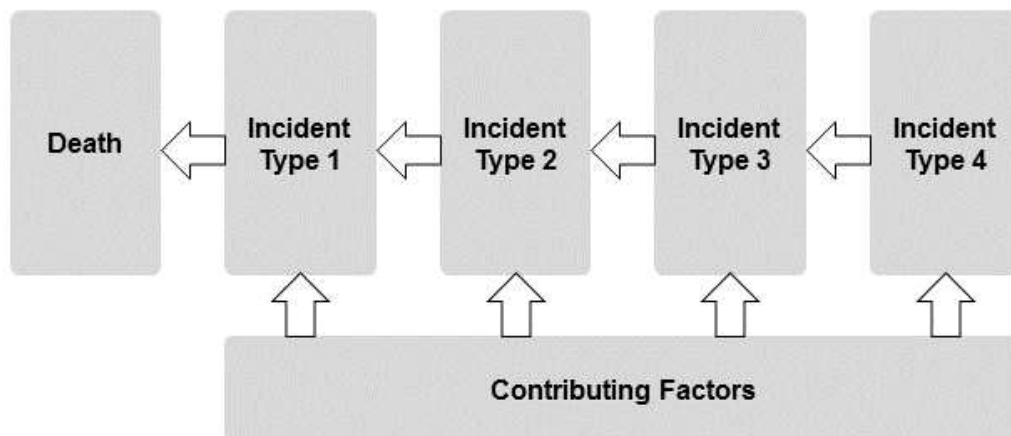


Figure 2: Sequences of incident types for patients who had a procedure/ treatment/ intervention incident type immediately prior to death (n=156)

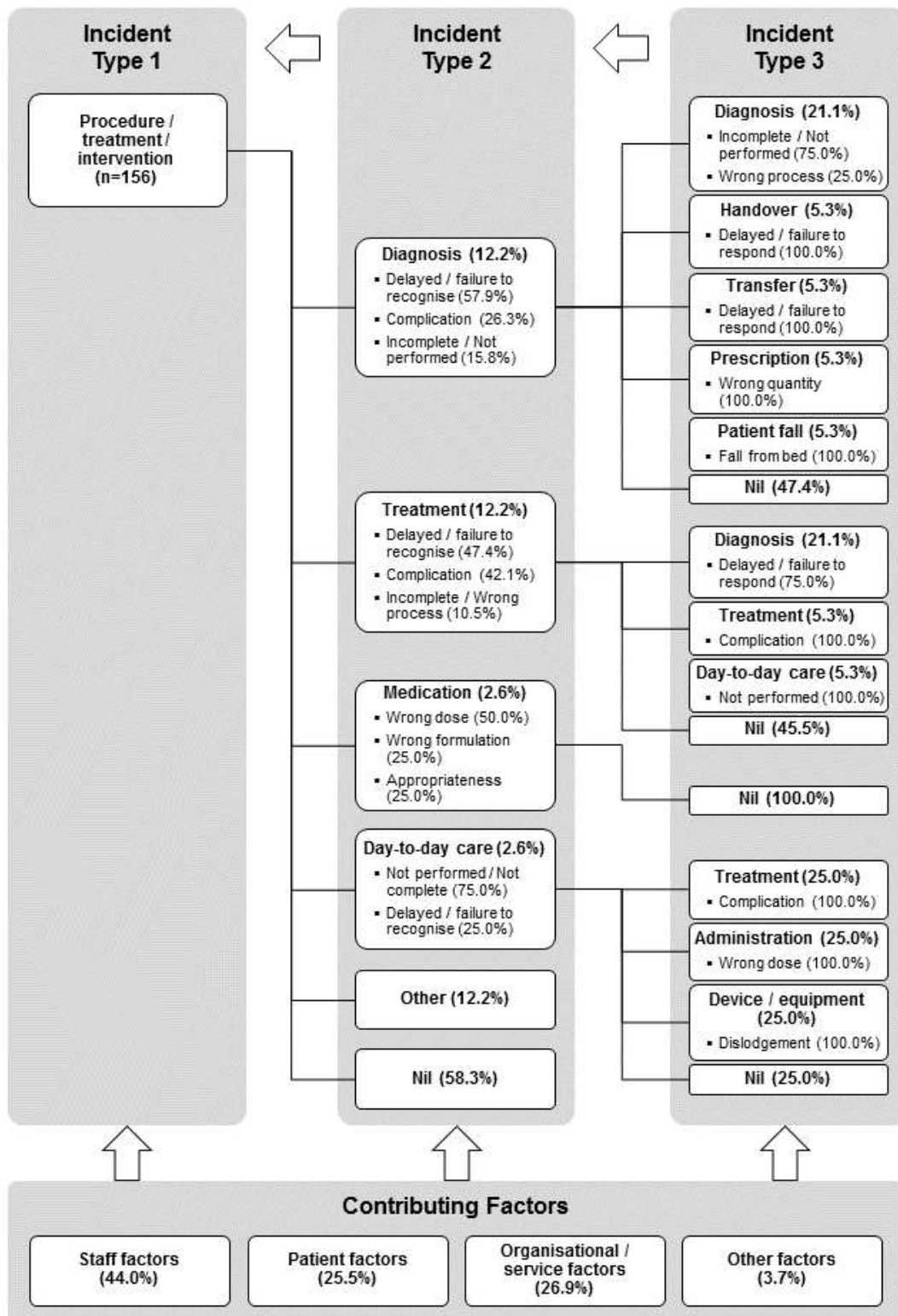


Figure 3: Sequences of incident types for patients who had contracted sepsis immediately prior to death (n=60)

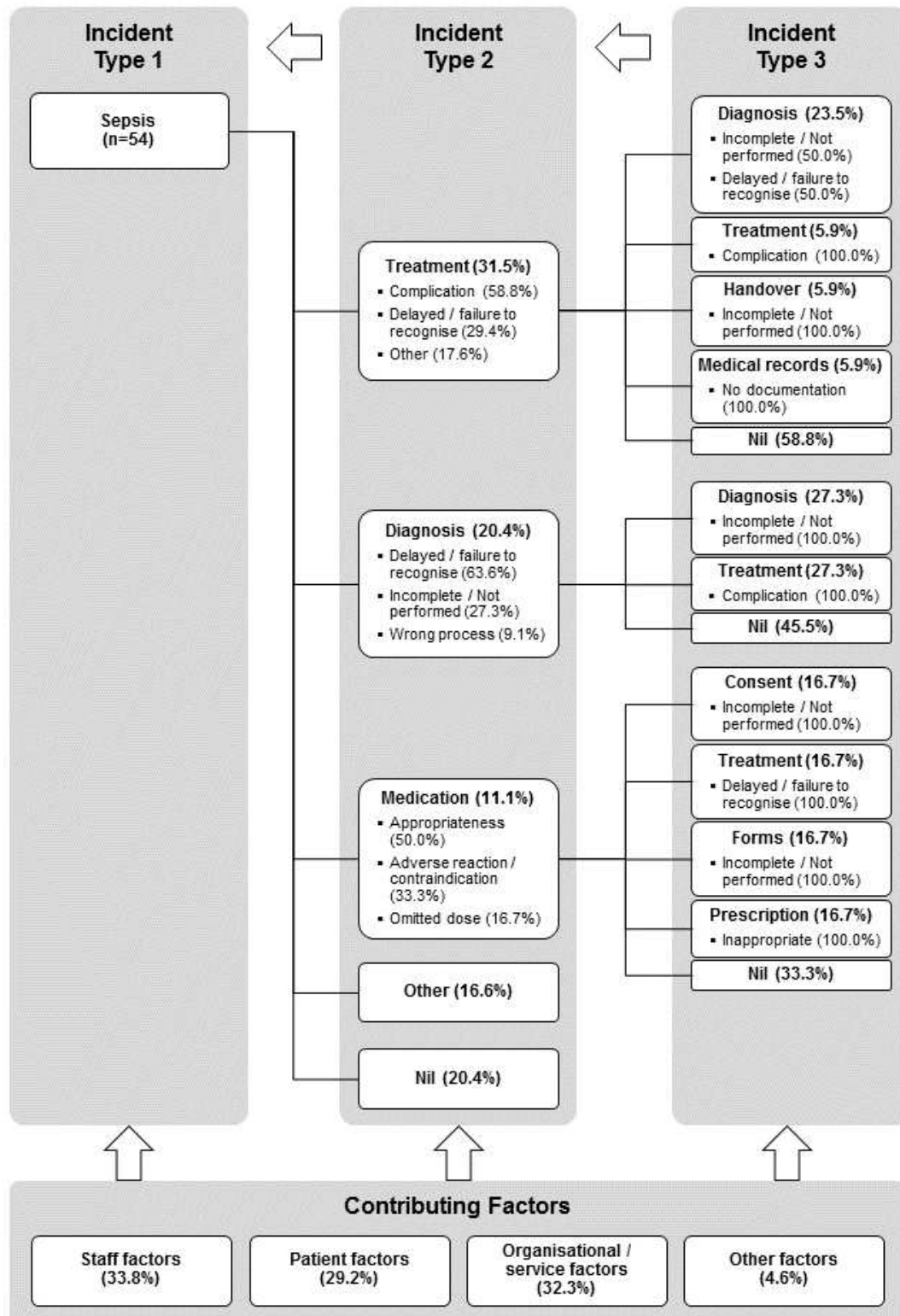


Table 1: Demographic, care phase and incident location characteristics for patient deaths in Australia

	Patient deaths (n=500)		95% confidence interval
	n	%	
Gender			
Male	231	46.2	41.8-50.7
Female	269	53.8	49.4-58.2
Age group			
<1 years	50	10.0	7.5-13.0
1-9 years	12	2.4	1.3-4.2
10-19 years	19	3.8	2.3-5.9
20-29 years	23	4.6	2.9-6.8
30-39 years	40	8.0	5.8-10.7
40-49 years	36	7.2	5.1-9.8
50-59 years	50	10.0	7.5-13.0
60-69 years	75	15.0	12.0-18.4
70-79 years	94	18.8	15.5-22.5
80+ years	101	20.2	16.8-24.0
Care phase			
Pre-admission	33	6.6	4.6-8.8
Care on admission	15	3.0	1.7-4.9
Assessment	48	9.6	7.2-12.5
Treatment	345	69.0	64.7-73.0
Discharge	7	1.4	0.6-2.9
Post-discharge	3	0.6	0.1-1.7
Transfer of care	8	1.6	0.7-3.1
In-patient resident	19	3.8	2.3-5.9
Other	22	4.4	2.8-6.6
Incident location			
Operating theatre	138	27.6	23.7-31.5
General ward/ patient's room	100	20.0	16.6-23.8
Emergency department	54	10.8	8.2-13.9
Intensive Care Unit	38	7.6	5.4-10.3
Birth suite, labour room	31	6.2	4.3-8.7
Diagnostic procedures (e.g. CT or MRI scan, X-ray, imaging)	12	2.4	1.3-4.2
Day procedure, treatment room	10	2.0	0.1-3.7
Mental health, psychiatric unit	8	1.6	0.7-3.1
Transfer between hospitals or units	8	1.6	0.7-3.1
Outpatient clinic	7	1.4	0.6-2.9
Neonatal or paediatric ICU	6	1.2	0.5-2.6
High Dependence Unit	6	1.2	0.5-2.6
Long-term acute care, hospice	4	0.8	0.2-2.0
Coronary care or acute care unit	2	0.4	0.05-1.4
Nursery	2	0.4	0.05-1.4
Other	54	10.8	8.2-13.5
Multiple	5	1.0	0.3-2.3
Not known	15	3.0	1.7-4.9

Table 2: Level 1 and common Level 2 incident types 1 to 4 involved in the patient death

Incident type	Incident type1 (n=500)		Incident type2 (n=272)		Incident type3 (n=125)		Incident type4 (n=40)		Total n
	n	%	n	%	n	%	n	%	
Clinical administration	25	5.0	30	11.0	15	12.0	7	17.5	77
Clinical process/procedure	251	50.2	165	60.7	77	61.6	22	55.0	515
<i>Diagnosis/assessment¹</i>	48	9.6	61	12.2	39	7.8	14	2.6	162
<i>Procedure/treatment/intervention</i>	156	31.2	75	15.0	28	5.6	8	1.6	267
<i>Day-to-day general patient¹ healthcare and observations¹</i>	39	7.8	22	4.4	8	1.6	0	-	69
Documentation	5	1.0	15	5.5	12	9.6	5	12.5	37
Healthcare-associated infection or complication	83	16.6	10	3.7	2	1.6	1	2.5	96
<i>Sepsis¹</i>	54	10.8	5	1.0	0	-	1	0.2	60
Medication/IV fluids	66	13.2	22	8.1	13	10.4	2	5.0	103
<i>Prescription¹</i>	18	3.6	9	1.8	9	1.8	1	0.2	37
<i>Administration¹</i>	39	7.8	9	1.8	4	0.8	0	-	52
Blood/blood products	3	0.6	3	1.1	0	-	0	-	6
Medical device/equipment	30	6.0	1	0.4	0	-	0	-	31
Patient incidents	22	4.4	15	5.5	5	4.0	2	5.0	44
Infrastructure/building/fixtures	1	0.2	8	2.9	1	0.8	1	2.5	11
Other	1	0.2	1	0.4	0	-	0	-	2
Not known	13	2.6	2	0.7	0	-	0	-	15

¹Only the most common Level 2 incident types are shown.

Table 3: Type of Level 1 and 2 contributing factors identified as involved in the patient death (n=756)

Contributing factor	n	%
Staff factors – behavioural/human action/ individual	300	39.7
<i>Clinical process or procedure – error or violation</i>	150	20.3
<i>Communication/miscommunication</i>	83	11.2
<i>Training</i>	22	3.0
<i>Experience</i>	36	4.9
<i>Fatigue/ exhaustion</i>	4	0.5
<i>Stress</i>	2	0.3
<i>Individual factors not elsewhere classified</i>	3	0.4
Patients factors	194	25.7
<i>Physical and psychological health or impairment (pre-existing)</i>	180	24.4
<i>Communication issues</i>	9	1.2
<i>Patient not elsewhere classified</i>	6	0.8
Organisational/service factors	229	30.3
<i>Work practices, protocols, policies or guidelines</i>	137	18.5
<i>Supervision</i>	11	1.5
<i>Organisational decisions/ culture</i>	10	1.4
<i>Workforce and teamwork</i>	35	4.7
<i>Workload, work pressure or workflow</i>	27	3.7
<i>Organisational factors not elsewhere classified</i>	9	1.2
Work environment factors	15	2.0
<i>Light</i>	1	0.1
<i>Security</i>	1	0.1
<i>Physical layout</i>	2	0.3
<i>Remote/long distance</i>	7	0.9
<i>Work environment not elsewhere classified</i>	4	0.5
Other factors	17	2.3
Not known¹	90	11.9

¹ Not known excluded from total count of 756 contributing factors identified.

Table 4: Coronial recommendations and organisational preventive actions undertaken

	Patient deaths (n=500)	
	n	%
Coronial recommendations¹		
<i>No recommendations</i>	190	-
<i>No recommendations as hospital already made changes</i>	90	-
Recommendations made regarding:		
<i>Organisational policies/ protocols/ guidelines</i>	138	33.2
<i>Organisational checklists</i>	12	2.9
<i>Organisational record keeping, medical or electronic records</i>	64	15.4
<i>Organisational culture</i>	8	1.9
<i>Organisational supervision</i>	23	5.5
<i>Equipment changes and/or design</i>	21	5.0
<i>Staff training or education</i>	84	20.2
<i>Recommendations not elsewhere classified</i>	66	15.9
<i>Organisational preventive actions</i>		
Organisational preventive actions¹		
<i>No preventive actions reported in the coronial findings</i>	300	-
Preventive actions made regarding:		
<i>Organisational policies/ protocols/ guidelines</i>	156	38.9
<i>Organisational checklists</i>	21	5.2
<i>Organisational record keeping, medical or electronic records</i>	37	9.2
<i>Organisational culture</i>	8	2.0
<i>Organisational supervision</i>	18	4.5
<i>Equipment changes and/or design</i>	41	10.2
<i>Staff training or education</i>	82	20.4
<i>Preventive actions not elsewhere classified</i>	30	7.5
<i>Preventive actions not specified</i>	8	2.0

¹ Up to five coronial recommendations and up to five organisational preventive actions could be indicated for each death.