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Development of a conceptual framework for medication safety measurement

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Abstract

Many patients are harmed by medications intended to help them. Significant efforts have been directed toward the improvement of medication safety. Policymakers, clinicians, researchers and consumers are interested in knowing the progress of medication safety but it is unclear whether it is safer than before. Part of the challenge has been the achievement of a common understanding of what medication safety means to multi-stakeholders, and then developing a measurement framework. Existing approaches to measurement have been narrow and piecemeal, failing to encompass diverse stakeholder beliefs and preferences. A multi-stakeholder derived conceptual framework for medication safety measurement was required.

The interview method was used to elicit and explore stakeholder views in-depth. Stakeholders were selected by purposive sampling on the basis of their job role or expertise in the area of medication safety in the New Zealand public hospital setting. Snowball sampling was also used and data collection was continued until data saturation which occurred after interviewing 30 people. Transcripts were thematically analysed and interpreted with the aid of NVivo and mind maps using a general inductive approach.

The developed multi-stakeholder derived conceptual framework for medication safety measurement consists of seven key dimensions meaningful to multi-stakeholders in the New Zealand public hospital setting. These are: 1) Outcome goals of medication safety; 2) Financial costs and effectiveness; 3) Medications available for and their use; 4) Safety culture; 5) Technical components of the medication use system; 6) Factors affecting medication use by patients; and 7) Staff competency.

The contribution to knowledge has been the development of a multi-stakeholder derived conceptual framework for medication safety measurement. As a consequence of this research, the measurement of medication safety should change from one which has been narrow and fragmented, to one which is multi-dimensional and holistic. The developed framework incorporates diverse multi-stakeholder views and preferences increasing its relevance in the local context and is important for engagement and buy-in. It draws together all meaningful dimensions and facets providing a necessary and robust single theoretical frame to measure medication safety. Understanding stakeholders' priorities and beliefs for medication safety can also be used to facilitate improvement programmes.

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Chapter 1: Introduction and literature review

A) Aim

To develop a multi-stakeholder derived conceptual framework for medication safety measurement meaningful for the New Zealand (NZ) public hospital setting.

B) Context

Medicines are the most common medical interventions used to treat disease. They are effective but not without risk. Even though the exact size of the problem remains unclear, studies have consistently shown that many patients are harmed by medications intended to help them (1-3). The lack of medication safety in hospitals is an important healthcare problem (1, 4, 5). Medication safety has been prioritised for improvement by the New Zealand Government and other countries (1, 6-11). The research setting focuses on medication safety within and between NZ public hospitals.

Despite extensive research into how medication safety can be improved (1, 9-13) and efforts in practice (14-16), it is unclear whether patients and medication systems are safer today than they were before (17-21). Policymaking organisations such as the Health Quality and Safety Commission (HQSC) and the National Health Board (NHB) are interested in evaluating the impact of medication safety initiatives (22-24). Consumers, researchers and healthcare staff across a range of sectors want to measure medication safety for improvement purposes and to provide evidence for the effectiveness of improvement initiatives (17, 19, 21, 25-31).

The need for data obtained from measuring medication safety has led to the development of a large number of tools and measurement frameworks such as the Adverse Drug Event (ADE) trigger tool and the Medication Safety Self-Assessment (MSSA) tool as examples (1, 12, 21, 25, 29, 30, 32-38). Different researchers and organisations advocate for specific measurement approaches, with each approach placing varying degrees of emphasis on certain dimensions of medication safety. Measurements typically use quantitative approaches, although qualitative approaches can also be used (39).

Despite the number of measurement tools it is still unclear whether improvement has been made. The measurement of medication safety faces several challenges and these are:

- Challenge 1: Measurement has been too narrowly focused

- Challenge 2: The expansion of knowledge and not knowing what to measure
- Challenge 3: The failure to incorporate multi-stakeholder views

These challenges provide the rationale for why a single framework (and one specifically for medication safety) is required. These challenges will be discussed later in this chapter over the next few pages.

C) Rationale

The need for a conceptual framework for measurement

Borrowing from the literature, conceptual frameworks have been regarded as being important for measuring healthcare concepts such as quality care (40-42). A widely accepted definition of quality care has been “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (43). The concept of quality in healthcare has generally been considered a multi-dimensional construct. Quality healthcare is one that is safe, timely, effective, equitable, efficient and patient-centred (STEEEP) (40, 41). The Institute of Medicine National Roundtable on Healthcare Quality states that quality healthcare can be defined and measured based on the STEEEP dimensions (44). Frameworks such as STEEEP can help non-experts better understand the meaning and relevance of complex concepts and measures (42). The development of STEEEP has provided a fundamental framework by which to guide and inform measurement initiatives (40, 45-49).

A single conceptual framework for measuring the concept of patient safety has also been deemed important (18). Highlighting the importance of framework development research, a group headed by Professor Charles Vincent from Imperial College London was commissioned and funded by the Health Foundation to develop a framework for patient safety measurement (18). To better understand why a single framework was needed, it is worthwhile exploring the challenges associated with measuring the patient safety concept and examine the parallels with medication safety.

Challenge 1: Measurement has been too narrowly focused

Patient safety

Patient safety has been defined as “freedom from accidental or preventable injuries produced by medical care. Thus, practices or interventions that improve patient safety are those that

reduce the occurrence of preventable adverse events” (50). A patient who has the wrong foot amputated is a clear example of medical care which was unsafe. This is because unnecessary harm had occurred which was the result of an error and could have been prevented (51, 52). Patient falls and central intravenous line infections are other examples of unnecessary and preventable adverse events where harm has occurred (52-55).

Errors and preventable harm have been the predominant focus of patient safety measurement (52, 54-58). If errors and preventable adverse events can be measured and reduced over time, this could suggest that patient safety is improving. The challenge to measuring patient safety in this manner has been the difficulty in identifying, let alone, measuring errors and preventable harm in an accurate, reliable and robust manner.

Many errors are subjective and their measurement can be negatively affected by poor intra- and inter-rater reliability (59-61). For example, many patients identified as dying from the consequence of an error would have died anyway due to their pre-existing disease—making the determination of error difficult (59). The boundary of what is defined as an error changes as healthcare knowledge grows. Diseases thought to be previously non-preventable are becoming preventable, so the failure to treat these conditions can now be argued to be an error of healthcare (61). Error being subjective means that the validity of the data is questionable and the ability to compare year on year in a reliable manner is compromised. Even if errors can be reliably and consistently identified and measured, many errors are inconsequential (61). A preoccupation with the reduction of error may overwhelm improvement efforts with negligible beneficial effects on patient outcomes.

A sole focus on measuring preventable harm to measure patient safety is also problematic. While the total number of preventable injuries from medical care is high, the rate at which it occurs is relatively low (51). The rarity of such adverse events means that changes in rates can be difficult to compare and interpret reliably (62). A sole focus on preventable harm when measuring patient safety also means that harm which is not the result of an error may be ignored—presenting a missed opportunity for improving safety (61). Determining what exactly constitutes preventable harm is also subject to debate, and this makes determining what should be measured unclear. For example, if a patient contracts measles because they were not vaccinated, is this an incident of preventable harm? Or is this an issue of quality because healthcare was not necessarily unsafe but rather not effective at delivering care? (51, 52) Further adding to this confusion is that if the patient declines vaccination, then it is neither a safety nor quality issue, because it was avoidable but not preventable by healthcare. Understanding where the conceptual boundaries lie is important because they impact what is

being measured. Variation and inconsistency in what is measured will mean comparison within and between settings and time periods cannot be reliable and accurate. Further research is required to ensure more accurate, standardised and reliable identification of errors and preventable harm.

The limitations of measuring errors and preventable harm mean that they cannot be relied upon as a sole measure for patient safety. Errors and harm measurement remains an important part of how patient safety can be measured but they are only a starting point of inquiry. Even if somehow, errors and preventable harm can be measured in a reliable and valid manner they are narrow in scope focusing only on visible consequences of unsafe healthcare (18). In the literature, there is increasing recognition that in order to measure patient safety in a holistic manner other facets need to be included because safety does not just mean avoiding injury or error (18).

Through constant monitoring, compensation, and adjustments a system is kept safe and these safety actions are often invisible (18). Safety is therefore a ‘non-event’ and being intangible makes it challenging to measure (18). Moreover, poor safety that has occurred in the past does not inform how safe it is now or likely to be in the future (18). Thus, there has been a call in the literature for an expansion in focus for patient safety measurement. Measurement should not just measure adverse consequences such as error and harm, but also toward broader ‘presence of safety’ characteristics in order to actively manage hazards (63). A single framework which brings together the various characteristics and dimensions of patient safety for measurement was required and this was the output of the report by Vincent et al (18). Because many of these characteristics and dimensions align with those identified in this research, the discussion of the Vincent et al patient safety measurement framework will be reserved until the latter parts of this thesis in Chapter 4C: Implications.

Medication safety

Medication safety has been defined in the literature as “freedom from accidental injury during the course of medication use; activities to avoid, prevent, or correct adverse drug events which may result from the use of medications” (1, 9). This mirrors the patient safety definition, but differs by specifically focusing on incidents related to medication use. Medication safety measurement has also focused on measuring errors and preventable harm (26).

In order to identify a universally acceptable system for measuring medication safety, an invitation-only conference comprising of thought leaders was held in Tucson, Arizona in 2002 (29, 30). Five medication safety specific approaches which focused on the measurement of

error and harm were discussed. These were the observation method (64), computerised monitoring method (65, 66), practitioner intervention method (67), chart review method (68) and the voluntary reporting method (69). The ADE trigger tool (37, 38) was not discussed, but has been recommended in other literature to measure medication safety (1, 27). Medication safety specific indicators focusing on instances of error and harm in the hospital settings have also been developed in countries such as Canada (25, 35) and Germany (33). See Appendix 1: Most common methods to identify medication errors and ADEs.

The focus on measuring medication errors and preventable harm to assess medication safety faces many of the same challenges to those encountered in patient safety measurement. For example, medication errors are also subjective with the degree of preventability changing over time (61). There is also a poor causal relationship between error and harm (70) which means many errors are inconsequential. These challenges appear more pronounced in medication safety because the causal relationship between error and harm is even less clear. Many errors are described as “near misses”, where the patient is not harmed because the error was identified prior to reaching the patient or, even if the error reached the patient, no harm occurred because of good fortune or the resilient nature of human physiology. For example, even if gross overdosing or under-dosing occurs there may be no observable adverse consequences (44, 70).

Determining exactly what constitutes as a preventable ADE is difficult and can also complicate the accurate measurement of medication safety. For example, if a patient fails to receive an anti-hypertensive agent and a patient suffers from a heart attack, is this scenario an issue of safety because the patient did not receive the benefit of the medication? Or is this an issue of quality because medication use would have been optimal but it was not necessarily unsafe care. If such issues are not resolved, this may mean that measurement can be inconsistent which makes data unreliable for comparison over time. The concept of quality use of medicines (QUM) can be regarded as being similar to the concept of quality healthcare, but relates specifically to medication use. The blurring of conceptual boundaries between (QUM) (71) and medication safety has affected measurement in a reliable and accurate manner.

The identification and measurement of error and harm is important. Their limitations, however, mean that they cannot solely be used to measure medication safety. Even if errors and harm can somehow be reliably and accurately measured, a sole focus on the measurement of error and harm to assess medication safety is narrow in scope. This is because errors and harm only focus on visible instances of unsafe medication use. In the literature, attention has shifted to include measuring the presence of safety. For example, the ISMP has identified 10

key dimensions which are prone to risks and hazards and 20 characteristics thought to increase the likelihood of safety in a hospital (13, 32). The MSSA tool allows a hospital to assess itself against these key dimensions and characteristics identifying areas for further improvement (32). Even though the MSSA has been widely advocated for, it is not a comprehensive measure of medication safety and there are several unresolved research gaps which form the basis for this research. The MSSA will be revisited and such issues discussed as they relate to the research (see Chapter 1C: Challenge 2 and Chapter 3: Emergent Finding 5B: importance of measuring the technical components) .

The measurement of patient safety and medication safety has traditionally focused on measuring errors and preventable harm. It is challenging to identify and measure instances of unsafe care in a consistent, reliable and valid manner. Even if errors and preventable harm can somehow be measured in a robust manner, they are too narrow in focus. The literature has recognised the need to expand the scope of measurement to include the various dimensions and facets if safety is to be measured in comprehensive and holistic manner.

Challenge 2: The expansion of knowledge and not knowing what to measure

Patient safety

The shift in measurement focus from the visible consequences of poor safety to the presence of safety has its own challenges and these are discussed in this section. The knowledge on patient safety and how it can be improved has grown over the years. More is now known about the contributory factors, influences and hazards that give rise to error and harm. More is also known about the characteristics and approaches that can improve patient safety. Various models of patient safety have been developed. Each model places varying degrees of emphasis on different dimensions and facets but all have the underlying aim of improving patient safety. Measurement based on these models would focus on their respective characteristics to assess safety.

One of the most widely used models of safety is the Swiss Cheese model proposed by Reason (72). Root cause analysis (RCA) is a technique which investigates the underlying causes and contributing factors which may have led to the adverse event. Contributing factors such as the lack of staff resulting in increased workload is one example of a latent condition which predisposes errors (or active failure) to occur (72). In order to improve safety, improvement strategies need to be multi-factorial focusing on not just the person who caused the error but also the underlying factors and weaknesses in the system. Layers of defence in the system such as double-checking to make sure the correct leg is amputated add to safety, because they

prevent or correct errors before harm is caused (72). Measuring patient safety based on the Reason model would focus on the adequacy of these defences (18). Vincent et al expanded on Reason's model and identified a range of contributory factors, of which institutional context is an example, which influence clinical practice and the occurrence of adverse outcomes (73, 74). Both models are linear and causal in nature and are based on analysis of past mishaps to identify causes and influencing factors (34). If Reason's or Vincent's models were used to improve patient safety, effort and measurement would be directed toward the factors and influences thought to contribute to outcomes and optimising them (18).

Adding further to the preceding models of safety is high reliability theory. This theory emphasises the importance of organisational characteristics of highly reliably operations and organisations (75). The capability to react to unexpected sequence of events and training to promote the understanding of the complex technologies operated are examples of characteristics identified in highly reliable organisations (75). Improvement initiatives based on the high reliability theory focus on measuring and enhancing these characteristics (18). Another model that has been described in the literature focuses on safety as collective mindfulness (76). This model emphasises the improvement of processes which produce mindfulness, such as a preoccupation with failure, a reluctance to simplify interpretations, and a commitment to resilience (76). Measurement in this instance would also focus on the presence and quality of these processes (18).

A model of safety by Amalberti takes the view that safety is a dynamic concept which can change from moment to moment, causing staff to violate standard instructions migrating the system to less safe situations (77, 78). For example, if a staff member unexpectedly calls in sick, other staff members may knowingly cut corners to increase speed and therefore place the system at risk. Continued violations may lead to normalised behaviours. Improvement based on the Amalberti based model focuses on addressing the environment and behavioural drivers underlying such violations (18). A model by Hollnagel proposes a similar model, and emphasises the importance of the ability of individuals and systems to proactively recognise and adapt to disruptions and disturbances to safety (79). Improvement based on the Hollnagel model focuses on what can go wrong and how to prevent such incidents from occurring. It also focuses on what goes right and the resilience of the organisation to correct unexpected changes. An example of a characteristic of a resilient organisation is collaborative cross-checking because it represents a team's ability to react before an incident occurs (18). Measurement of safety based on both models would focus more on the factors which influence violation and system resilience respectively (18).

The various models of safety illustrate the complexity of factors and dimensions thought to most significantly influence safety by different researchers. They also demonstrate the growth in knowledge on how safety can be improved. Each model of safety has advantages and limitations. For example, some researchers have expressed that although the models proposed by Reason and Vincent et al make sense and are easy to operationalise for measurement (18), they are also too linear and causal, and thus do not adequately address the complexity and diversity inherent in healthcare delivery (34). Conversely, models such as those by Amalberti and Hollnagel may more adequately address the complexity inherent in healthcare, but may be harder to operationalise as they focus on peoples' behaviours which may be hard to change (18, 80).

The dilemma associated with the increase in knowledge is determining exactly what to focus on to measure patient safety (18). A framework is needed which synthesises the breadth of knowledge to guide and inform measurement initiatives. Without a single comprehensive framework, measurement may be piecemeal and not holistic. A comprehensive model is needed which brings together the various models of safety.

Medication safety

Similar to patient safety, the knowledge on medication safety and its improvement has also increased. More is known about the factors and influences which give rise to risk and harm. More is also known about how errors and harm can be avoided or minimised. Some of the models of patient safety, such as those by Reason (72) and Vincent (73, 74), relate to medication safety (34). Other models specific to medication safety also exist (13, 32, 34).

The previously discussed ISMP developed MSSA tool (in Chapter 1C: challenge 1) provides a framework of medication safety similar to the Reason (72) and Vincent et al (73) models. These models focus on improving the adequacy of defences and reducing risk from contributory factors to enhance safety. Measurement based on the MSSA tool would focus on ensuring the 20 core characteristics of medication safety were present and working well (13, 32, 81). Some of the characteristics have been shown to reduce error and harm (82, 83), while others have been informed based on experiences and lessons learnt from the critical analysis of error and harm incidents (84).

Another model of medication safety, proposed by Mackinnon, suggests eight key dimensions (12). Mackinnon emphasises dimensions, of which timeliness and documentation are examples, that if improved have been thought to enhance safe and effective medication use. This is similar to the 10 key dimensions within the MSSA tool but differs in the dimensions

focused upon and how they can be measured. Mackinnon suggests the use of measures developed by the Joint Commission for the Accreditation of Healthcare Organisations (JCAHO) and the American Society of Health-System Pharmacists to assess these dimensions of safety (12). For example, one of the indicators recommended was median time from arrival at the hospital to administration of the first dose of antibiotic. This measure would assess the dimensions emphasised by Mackinnon such as timely recognition, appropriate prescribing and accessible medicines. Even though many measures have been developed by JCAHO (85), it is unclear exactly which ones should be used or whether they are necessarily applicable to other settings outside of the United States.

Conceptual models relating to the communication dimension of medication safety have been researched by Liu et al (34). Communication has generally been viewed to be central to medication safety, and has been a dimension that has been extensively researched (34). It is worthwhile examining the conceptual models identified by Liu et al because they illustrate that even in one dimension of medication safety which has been extensively studied, there is a lack of agreement on how to describe it, let alone measure it.

Liu et al identified six conceptual models, two of which (Reason's and Vincent's models of safety) have already been discussed. Another identified model was the Shared Decision Making Model (34, 86, 87). This model places the emphasis on the need to involve both patients and doctors in developing a consensus about the treatment, and how it is implemented to increase the likelihood of safe medication use (86, 87). The Medication Decision Making Model also emphasises the importance of consensus, but outlines the importance of the patient's role in actively monitoring medication use (88). The Australian Pharmaceutical Advisory Council's Partnership Model places the emphasis on collaboration and communication between all sectors of care, because any miscommunication is thought to result in error (89). The Medication Communication Model (90) takes a much broader approach to medication safety and emphasises three dimensions in communication. These are antecedents such as sociocultural and environmental factors, attributes and actual communication encounters such as who speaks and what is said, and outcomes such as whether patients and family were engaged and whether harm occurred (90). Measurement based on the various models examined would focus on the different dimensions of communication being emphasised depending on which model was used.

Models such as those by the ISMP within the MSSA tool, Mackinnon and those identified by Liu et al are some examples which illustrate that a substantial amount of research has gone into how medication safety can be improved. Other frameworks on how medication safety can

be improved have been developed (1, 9-11). There are many models of medication safety available in the literature which has been advocated for by different researchers and organisations. Each model gives emphasis to different facets and concepts, which mean measurement can be quite varied based on the model used.

Each of the discussed models has added to the body of knowledge on how medication safety could be improved. The expansion in knowledge however, means that it is unclear exactly what should be focused upon if medication safety is to be measured. A single framework for measuring medication safety could have been developed which simply synthesised the knowledge in existing literature. However, an important but commonly missed research gap has been the lack of exploration into how stakeholders conceptualise medication safety and what they find meaningful for measurement. Thus, existing approaches to measurement and what is measured may not align with how medication safety is conceptualised by multi-stakeholders or what is required. There is no known conceptual framework for the measurement of medication safety in the NZ hospital setting, let alone, one which incorporates multi-stakeholders views. The need for such a framework and why this is important is discussed in the following section.

Challenge 3: The failure to incorporate multi-stakeholder views

Patient safety

There has been a proliferation of measurement frameworks and measures for patient safety which have been advocated for by different researchers and organisations. Despite this, the data measured and presented to the intended target audience does not always match what it is the audience wants or needs. The consequence of this mismatch means that intended target audiences such as consumers do not always find the presented data meaningful leading to a lack of engagement and non-use (42, 91-94). Purchasers of healthcare such as policymakers and clinicians were sceptical of the data obtained from measurement and did not find it useful and therefore did not use it frequently (93). The lack of relevance in the data obtained also limited managers' responses to and use of the information (95). These studies suggest that data obtained from measurement needs to be meaningful to its intended target audience before the data is used.

Different stakeholders will have different preferences and different purposes for the data obtained from measurement (39, 96-98). These preferences and purposes need to be identified to help guide measurement efforts which are meaningful to its targeted end users. Conceptualisation refers to “inventing or contriving an idea or explanation and formulating it

mentally” (99). Different stakeholders conceptualise in different ways. For example, a study into how consumer stakeholders conceptualise medical errors showed that they regarded a lack of attentiveness as an issue of error, which is not typically included under the definition of medical error (100). Understanding how patients conceptualised medical errors was important if their engagement and use of the data obtained is desired (100). For example, if consumer stakeholder groups are the intended target audience of the data obtained, then measurement should include inattentiveness within a patient safety metric to make it more meaningful for them. Conversely, if inattentiveness should not be included then stakeholders need to be given an explicit definition of what medical errors mean and why inattentiveness should not be measured.

This research posits the importance of eliciting the views and preferences of the intended target audience of data obtained from measurement. A better understanding of stakeholder views and what they prefer can inform the development of a conceptual framework which is more meaningful to its stakeholders. Understanding how stakeholders conceptualise patient safety is also important because it exposes divergences between stakeholder views and views held by the literature. This understanding can help the development of more holistic conceptual frameworks. Since the conceptual framework developed can be used to inform measurement initiatives, obtaining the views of intended target audience of the data was an important step to increasing its relevance in the local context.

Beyond obtaining the views of stakeholders who are the likely end-users of the data, it is also important to elicit the views of people who measure and compile the data (101). The measurement process is as much a social practice as it is a technical one (101). Views and beliefs of people who conduct the measuring are important because it affects how data is compiled and measured (101). A recent ethnographic study of infection data rates suggests that people collecting data on possible infections were not counting the same things or in the same way (101). Some people deliberately adjusted definitions so that evaluations appeared better. However, many did so in a non-wilful manner to account for time, or in an attempt to provide results which reflected what they perceived as true—such as reporting a higher rate of infection in an organisation (101).

Regardless of how explicit measurement criteria were, local interpretation and adaptation was inevitable because of different priorities, lack of utility of measures and other social and contextual factors (101). The researchers concluded by saying that measurement “requires the development of metrics and data collection systems that clinicians and organizations believe to provide fair and true comparison” (101). If people do not buy into the measures used, then

they may not engage or do so in an inappropriate manner. The observations from this ethnographic study have important implications for the measurement of medication safety. They highlight the importance of eliciting and including local organisational members' views and beliefs when developing a conceptual framework for safety measurement.

Language expressed in conversation has been thought to convey underlying beliefs and values that determine shared behaviour (102) and are demonstrated through action (103). Thus, by speaking to stakeholders, the way patient safety has been conceptualised can be elicited. Understanding stakeholders views and preferences can help determine the dimensions of safety that are more meaningful for measurement and improvement (102). An exploration into stakeholder views can help the development of a conceptual framework for patient safety measurement which is meaningful to its intended target audience which are policymakers, experts and consumers. Even though obtaining stakeholder views are important, this appears to be an under-researched area. Yet, research of this kind is important in order to develop measurement frameworks which are meaningful to its user, and thus are more likely to be used.

Medication safety

The literature on medication safety measurement suggests stakeholder views have also largely been ignored. For example, a group in Canada which aimed to develop medication safety indicators intended for public reporting did not include consumer stakeholder views at all (25). Instead, a group of 17 medication safety experts chose the measures. One of the recommended measures was: Proportion of patients with acute myocardial infarction who were discharged with appropriate medications (defined as acetylsalicylic acid, beta-blocker, angiotensin converting enzyme inhibitor or angiotensin receptor blocker anti-hypertensive, and statin) (25). It is not clear whether the recommended measure was actually meaningful to the general public. Previously described research suggests patient stakeholders instead value facets such as perceived standard of care from friends and family (93, 94). Without taking into account stakeholder views and preferences, data obtained from measurement may not be meaningful, and thus not used by its intended target audience.

The research method employed by the Canadian group in the preceding paragraph has been commonly used to elicit stakeholder preferences. For example, the use of questionnaires to obtain stakeholder views has also been used to derive performance indicators in the field of clinical pharmacy (104) and emergency care performance (105). However, even if the Canadian study had included consumers, the research method used does not lend itself to eliciting a deep and rich exploration of stakeholder views and beliefs. For example, consumer

involvement would have been limited to choosing from a pre-selected list of measures. This approach is deductive in manner (106) because a priori ideas have already been imposed by the researcher. The method used in these studies does obtain stakeholder preferences to some extent, but other methods such as in-depth interviews (107) can be used to elicit a deeper and richer understanding (106).

Despite the importance of the intended target audiences' views and beliefs, it is not known what stakeholders actual preferences are in relation to medication safety and measurement. There has been no research identified which has explored stakeholders' preferences and views on what should be measured for medication safety in a holistic manner. Despite the concept of medication safety having been defined in the literature (1, 9), and many people instinctively knowing what the concept is about, no published study has been identified which has explored how stakeholders conceptualise medication safety. An in-depth interview can be used to elicit these views and beliefs (107).

Reflections on existing knowledge and justification of this research

This research posits that the measurement of medication safety has been challenging. The primary challenges have been problems associated with: 1) a narrow focus on measurement; 2) an expansion of knowledge on safety; and 3) the failure to incorporate multi-stakeholder views. The first two challenges can largely be solved by the development of scientifically sound, robust and feasible measurement tools and approaches (108-113). As the knowledge base expands on the factors and characteristics that cause error and harm, and the knowledge of how such risks and hazards can be minimised, measurement can focus on these various facets to produce robust, reliable and valid measurement tools and approaches.

Safety is complex and the paradox of increasing knowledge is that it becomes unclear what exactly should be measured. As the preceding discussions have identified, an important but rarely identified problem is that the developed measurement tools and approaches must also be meaningful to the intended targeted audience (114). This research postulates that if data obtained from measurement is not meaningful to its targeted audience then it may not be used (42, 91-95). Also shown is that if data obtained from measurement is not meaningful to the people measuring and compiling the data, then it may be measured in an inconsistent manner because measurement is as much a social practice as it is a technical one (101). This is not to detract away from the importance of the development of scientifically sound and robust measures, but rather, that both are required. The gap in knowledge being specifically addressed in this research is the lack of insight into stakeholder views and preferences. The

literature on existing measurement tools and approaches will also be examined to determine how the dimensions identified as being meaningful to NZ public hospital stakeholders can be measured.

Vincent et al developed a conceptual framework for patient safety measurement with multi-stakeholder input (18). The need to develop a measurement framework for patient safety mirrors the importance of a framework for medication safety. Patient safety encompasses all preventable injuries including those which occur as a consequence of medication use (50). The challenges facing measurement appears similar to those faced in medication safety (18). A reasonable question that arises is why not simply adopt the Vincent et al developed conceptual framework?

Firstly, the framework developed by Vincent et al was not published until mid-2013, two and a half years after the inception of this research. Thus, there was initially no conceptual framework available for use. Though not formally studied or reported, several guesses can be made about why it took so long for a framework for patient safety measurement to be developed, despite extensive research in the area. One reason is because the development of an overarching framework is difficult and complex. Even though great bounds in knowledge have occurred in patient safety, it is still a relatively immature field (115). Only now has there been an ability, and need, to synthesis the expansive and fragmented evidence base and consolidate this under a common framework. The development of a framework which synthesises the various conceptual dimensions and stakeholder views of patient safety measurement is innovative. The fact that Vincent et al was commissioned to undertake this report highlights the importance and requirement for this type of research.

Secondly, the conceptual framework developed by Vincent et al cannot simply be adopted for medication safety because it is not clear where patient safety ends and where medication safety begins. In the literature, medication safety appears to exist as an important concept in its own right. Many researchers specifically use the term ‘medication safety’ (1, 9, 21, 26, 116, 117), but do so while recognising there are also quality healthcare and patient safety concepts. This research has shown that there are similarities, but also differences between the two concepts. Different and specific models of safety exist for both concepts, and these affect the dimensions emphasised upon and measured.

Though one could speculate that many of the dimensions may be similar and overlap (see Figure 1), there may also be areas which do not. There needs to be research that specifically explores the medication safety concept and its measurement. Understanding this first step will

provide the platform for robust discussion into differences that may exist between patient safety and quality healthcare concepts. Exposing dissonance between the concepts also has practical applications, such as determining whether patient safety specific measurement tools and approaches are applicable to medication safety, and determining whether improvement strategies and models used in patient safety are relevant to medication safety. Specific research into the medication safety concept is important and required. The findings from the Vincent et al report and findings derived from this research will be contrasted against and discussed at the end of this thesis in Chapter 4C: Implications.

Figure 1: Potential conceptual differences and similarities between quality healthcare, patient safety and medication safety.



Research question

The current approach to measurement has been narrow. The knowledge on medication safety has been fragmented. There has been a lack of research into how stakeholders conceptualise medication safety and what they find meaningful. In light of this context, the research question arises as:

- What do stakeholders find meaningful for medication safety measurement?

It is difficult to improve or measure medication safety until there is a clear understanding of what it means to be safe. The development of an inductively built framework which assimilates multi-stakeholder views and preferences increases its relevance in the local context which is important for engagement, buy-in and use of the data obtained. The research output, which is the development of a conceptual framework for measurement, is fundamental to understand what medication safety means to its stakeholders and how it can be measured.

Chapter 2: Methodology and method

Ethics approval: approved by the Northern Region Y ethics committee on the 11 October 2010. Reference no. NTY/10/EXP/064

The aim of this research was to develop a multi-stakeholder derived conceptual framework for medication safety measurement meaningful for the NZ public hospital setting. In order to achieve the research aim, certain methods were used and the rationale for their use will first be discussed under the heading of methodology. The method used in this research will then be outlined.

A) Methodology

The respective parts of the method and their rationale will be outlined under the following headings:

- Eliciting stakeholder views: In-depth semi-structured interviews
- Multi-stakeholder views: Purposive and snowball sampling methods
- General inductive approach: Data management, analysis, interpretation and framework development

Eliciting stakeholder views: In-depth semi-structured interviews

This research previously posited that stakeholder values and beliefs influence behaviours which are demonstrated through actions (102, 103). Stakeholder values and beliefs also affect the measurement process (101) and whether the data obtained from measurement will be used (92, 93, 97). It was not enough to simply develop a conceptual framework which was derived from the literature. If stakeholder views were not explored in-depth then incorporated, the framework may not be meaningful to them. It was important to study stakeholders' views, then synthesise this information with existing knowledge on medication safety measurement to develop a robust and meaningful conceptual framework. Values and beliefs can be conveyed through language thus stakeholder views can be elicited through discussions and conversation (102). A one-to-one, in-depth semi-structured interview technique was chosen to explore stakeholder views and elicit the dimensions meaningful for measurement (107).

By using a one-to-one interview technique, the range of viewpoints could be canvassed without pressure and influence by other stakeholders that can occur if other techniques, such

as a focus group, are used (118). Views and opinions expressed and new knowledge generated during the interaction between the stakeholder and interviewer (119) can be more deeply explored during the interview process, compared to other techniques such as the use of a questionnaire or survey. Interviews that are conducted face-to-face can help the stakeholder feel more at ease, thus providing insight that they may not otherwise have given (107). A semi-structured interview utilises a fixed set of topics to anchor points of discussion, but is flexible enough to allow the researcher to explore other topics, views or initial concepts in greater detail where relevant (107, 120). An interview guide was applied more or less consistently in each interview in order to be able to compare different points-of-view (119). Continuous design refers to the adaptation and iterative improvement of the interview design throughout the research process where relevant (119). For example, if new insight emerges which warrants further exploration, interview questions could be adapted so the new insight could be further explored in subsequent interviews.

Dimensions refer to top level categories (121) that represent underlying conceptual themes which relate to the measurement of medication safety (122). Ryan and Bernard describe themes as “abstract and often fuzzy constructs that link expressions” (106). They use the example that if someone throws a book across a room, this is an expression of being angry but the underlying theme is about anger. A dimension is a common underlying thread of concern expressed by stakeholders explicitly or inferred through what was said (121, 122). Each dimension may itself be comprised of sub-dimensions. A sub-dimension represents a more specific conceptual theme, but is still aligned with the dimension’s overall underlying conceptual theme. Meaningful is defined in this research as having a relevant, important or useful quality or purpose to the stakeholder in relation to the measurement of medication safety (123, 124). Dimensions emerging from the interview data were deemed to be meaningful if the stakeholder explicitly stated it to be meaningful or was inferred by the researcher based on what was said (125).

The interview schema consisted of four main questions which were used to elicit the dimensions meaningful to stakeholders for medication safety measurement. The questions and the rationale for asking them were:

1. What is medication safety?
 - This question explored stakeholders’ views on what it means to be safe for them and how they conceptualise medication safety. Differences in the conceptualisation of medication safety between stakeholders could indicate variations in the perceptions of, and priorities for, medication safety (102).

Understanding these priorities can help inform the dimensions stakeholders find meaningful for measurement.

2. Has medication safety improved over the past 10 years and why?
 - Even though it was interesting to elicit stakeholders' views on whether medication safety had improved over the past 10 years, the underlying purpose of the question was to understand which dimensions were used by stakeholders to base such a decision on. This question aids the understanding of the facets considered by the stakeholder to decide whether medication safety has improved. This question provides insight into the dimensions that are meaningful for measurement because they were used by the stakeholder to make a decision about whether safety had improved.
3. If one wishes to measure medication safety, what are the key dimensions to include?
 - This question specifically asks what stakeholders believe are the most important and meaningful dimensions to measure.
4. What are the key dimensions to improving medication safety?
 - This question aids the understanding of the dimensions thought by stakeholders to most significantly influence and contribute to improving medication safety. Understanding these views provides insight into the dimensions stakeholders would prioritise if medication safety was to be measured and monitored.

Multi-stakeholder views: Purposive and snowball sampling methods

A purposive sampling technique was used (119). This technique involved choosing people most likely to use the data obtained from measuring medication safety, and the people most likely to implement the measurement of medication safety. The views of three key stakeholder groups were important to elicit. These groups were consumers, policymakers and experts (96). The stakeholders were chosen by the researcher in consultation with his supervisors, based on the stakeholder's suitability in terms of their job roles and/or expertise in medication safety and medication management.

Stakeholders from the consumer category are the people who suffer the consequences of harm from medical injury. There is an increasing trend in the literature for consumers to receive safety and performance data obtained from measurement (25). Many researchers argue that the provision of safety data to consumers is required to demonstrate improved efforts for transparency and accountability purposes (25). Consumer views were obtained in this research to help inform the development of a conceptual framework which was more meaningful to this group (93). Two of the 30 stakeholders involved in this research study were consumers.

An underlying assumption in obtaining stakeholder views from the consumer group was that they know what information they want. However, it has been shown that when people are faced with a situation that is complex and unfamiliar, they may actually construct preferences at the moment it was posed (42). Thus, these answers may not be stable and may change depending on how the question was asked and what information was discussed prior to the question being asked (42, 126). Instead, the authors of this paper recommend educating consumers and using a framework (of which STEEEP is an example) to inform discussions (42). No such single framework exists for medication safety measurement. Nonetheless, stakeholders were provided some background information about medication safety such as the incidences of medication error and harm in the participant information sheet to set the scene and inform the discussion. Stakeholders were also sent a copy of the interview schema prior to the interview which contained some definitions of terms commonly used in the medication safety measurement literature.

Views of stakeholders from the policymaker category were also important to elicit. Stakeholders involved in this study held job roles in various medication safety related organisations (see Appendix 2 for a full listing). These organisations are directly responsible for monitoring and ensuring the safety of medication use, or the decisions they make directly influence it. Some of the stakeholders also hold key medication safety related portfolios within the government arena such as the HQSC and the Ministry of Health (MOH). These stakeholders are the people that are most likely to decide on healthcare policy and allocate resources based on the data obtained from medication safety measurement. Thus, it was important to elicit this stakeholder group's views on what is deemed meaningful if medication safety was measured. Twelve of the 30 stakeholders involved in this study were categorised in the policymaker category.

A large proportion of stakeholders (16 out of 30) were clinicians and medication safety experts. Medication safety experts refer to stakeholders who have been involved in, or have led, medication safety projects at a local or national level, or have conducted research in areas related to medication safety. Clinicians such as doctors, pharmacists and nurses were also considered experts, because they are involved in, and are aware of, the safety issues associated with the medication use process. Many of these stakeholders hold key advisory roles within some of the influential medication safety related organisations, and can therefore also be categorised as policymakers. However, the primary reason these stakeholders were chosen was due to their expertise rather than their policymaking job role. Expert stakeholders were also chosen because they would be the ones most likely to implement and monitor medication safety activities at the frontline, thus, it was important to explore their knowledge and views.

The snowball sampling technique was also used. This method utilises already chosen stakeholders to identify other relevant people that may have been suitable to be sampled (127). Because of this, there was an increased ability to adapt to the conditions in the field and ensure the views of key experts were canvassed (127). Multi-stakeholders from across the NZ public hospital setting were included in this research. With such a high calibre and informed group of stakeholders, it was thought that the study had included a broad range of expertise and views from various parts of the healthcare sector representing stakeholders at multiple levels.

Stakeholders were asked to answer the questions in the interview based upon their own personal opinions rather than on behalf of the organisation where they were employed or represented. In this way, it was hoped that stakeholders would discuss their personal thoughts and opinions more freely. Despite this, given these selected representatives were often also experts who would advise their respective organisations on medication safety related matters it was assumed these stakeholders would inherently and indirectly reflect, within their answers, some of their organisation's views and beliefs. Because many of these stakeholders were also active researchers and experts on medication safety, it was also assumed that their views would reflect recent and evidence-based knowledge on medication safety and its measurement.

General inductive approach: Data management, analysis, interpretation and framework development

Digital audio recordings obtained from the interviews were sent to a transcription company. Intelligent verbatim transcribing (128) was chosen and this is a full representation of what was said, without filler words. There are proponents who suggest that transcribing can help the initial interpretative process and immerse the researcher in the research data (129). Even though the transcription was not performed by the researcher, there was still a robust interpretative and immersion process as the recordings were listened to multiple times by the researcher while reading the transcripts. This process also helped provide quality control of the transcripts. Stakeholders were sent copies of the transcripts and they had up to three weeks to edit, comment, verify and ensure any sensitive information was removed. Stakeholders were informed that if no feedback was received within this time, it was assumed that no further changes were required. After this period, personal identifiers were removed from the data.

A general inductive approach was utilised which refers to the use of detailed readings of interview data to derive concepts through the researcher's interpretations (121). A general inductive approach analyses and groups data into dimensions or questions posed in the

research, with findings emerging from the analysis of the raw data and not from a priori expectations or models which are more deductive in approach (121). Despite the predominant use of the general inductive approach to analyse and interpret data, it is important to acknowledge that it is difficult to analyse data based solely in an inductive manner. Both inductive and deductive techniques are often used (119, 121) because findings which emerge from the analysis of the data mix and integrate with the researcher's prior theoretical understanding (106, 130, 131).

Ryan and Bernard suggest that a theme has been found when the following question can be answered: *What is this expression an example of?* (106). This question was used as a form of mantra to help uncover the underlying theme of what was said in relation to answering the question at hand. Dimensions emerged from the interview data through a process of data cleaning, familiarisation, categorisation and refinement in a general inductive manner (121, 122, 130). Excerpts of interview data were used to illustrate the underlying conceptual theme of the dimension (121). Mind maps were also used to help reduce data and increase sense-making. Mind maps focus on one central concept, such as medication safety, with ideas and themes branching from this (132). In relation to this research, these ideas and themes were the dimensions and sub-dimensions of medication safety meaningful to stakeholders. Emergent associations appearing between the dimensions and sub-dimensions represent potential associations. Mind maps were useful because they helped to structure the topics discussed (133, 134).

At this point, it is important to acknowledge that the interpretation of the data and how the data emerged from the interview data may be different had another researcher conducted the analysis. Gibbs suggests "the qualitative researcher, like all other researchers, cannot claim to be an objective, authoritative, politically neutral observer standing outside and above the text of their research reports" (130). Different techniques can generate different sets of themes (106, 135). There was no one 'true' single set of themes waiting to be discovered (136). Truth or meaning is constructed in and out of interaction from the human mind (137). The themes and interpretation that have emerged from the data have been formed from the interaction between the data, stakeholder views, knowledge from the literature and the researcher's mind (106).

Reflexivity is the "recognition that the product of research inevitably reflects some of the background, milieu and predilections of the researcher" (130). This research is predominantly of an exploratory nature. This research adopts the view that "meaningful reality is constructed in and out of an interaction between human beings and their world" (137). Emergent findings

from the data were synthesised with literature and personal insight to inductively construct meaning. This research does not go as far as subjectivism where “...meaning does not come out of interplay between subject and object but is imposed on the object by the subject” (137). To a certain degree, there is a need to be objective enough to not just impose the researcher’s thoughts on the data to attain findings. This research recognises that some degree of bias may exist based upon an objectivist point-of-view. However, in-line with the epistemological view of the world which views interpretation as part of meaning construction, the concept of bias is part of the construction and interaction between interviewer and interviewee.

Some might argue that given the background of the researcher and supervisors, this may have influenced how the data was analysed and interpreted. This was viewed as an advantage for this study because the researcher, as a consequence of previous job roles, was already part of the world in which the research was conducted. This means that the researcher had in-depth ‘behind-the-scenes’ insights which take into account nuances inherent within the NZ environment. The researcher’s prior experience and knowledge may have also aided the understanding of the context, taking into account historical or political influences (107). The researcher’s knowledge and expertise in medication safety was also beneficial because it could help improve the quality of the interview data. For example, for people of high social status or experience, termed *elites* (107), Kvale suggests that interviewers with good knowledge of the field can challenge existing views which may lead to new insights (107).

B) Method

The method used in this research will be outlined under the following headings:

- Interview schema and process refinement
- Interview process
- Data management, analysis, interpretation and conceptual framework development

Interview schema and process refinement

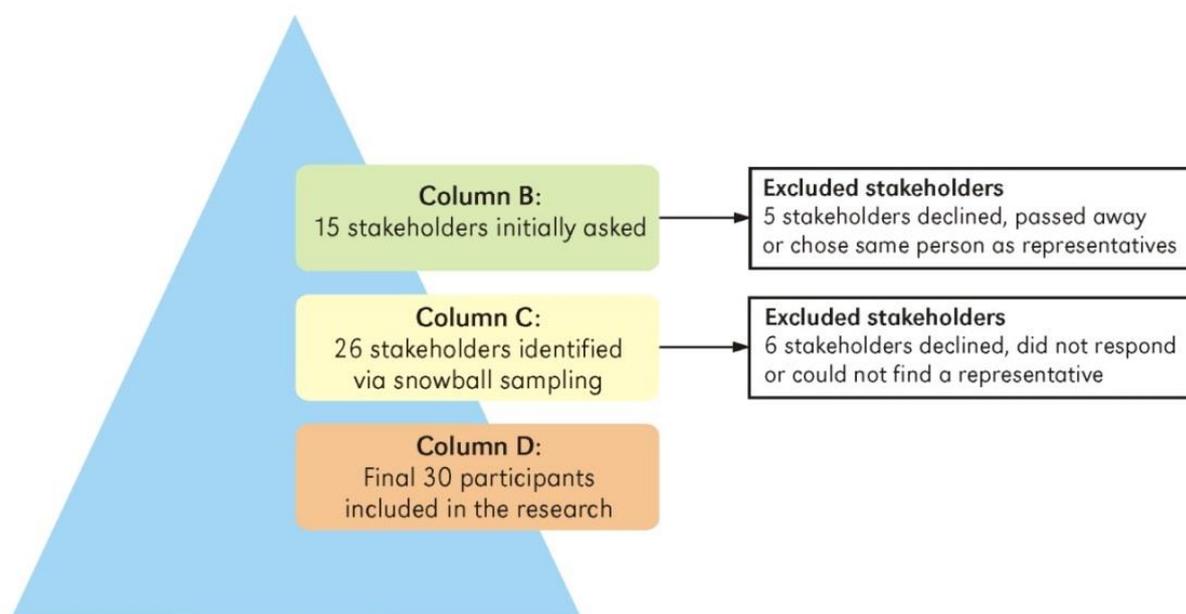
The interview schema, based on the four broad questions previously discussed, was developed by the researcher with advice from a supervisory team. The interview schema and the interview process were piloted on stakeholders who held similar job roles and expertise as that of the purposively chosen stakeholders used in this research. Stakeholders involved in the pilot comprised of a Chairperson of a local medicines advisory committee and also a physician, a hospital pharmacist, a hospital pharmacy manager, two pharmacy-based academics, a hospital

based neonate nurse, an anaesthetist, a former CEO of a local DHB, and a health systems researcher with expertise in qualitative research. A total of nine stakeholders took part. Stakeholders were asked to comment on overall structure, flow, length and the interview technique and questions. Feedback was used to enhance the interviewer’s technique and questions. Comments suggested that no major changes needed to be made. Pilot interview recordings were also replayed in an attempt to learn about weaknesses in the interview technique. For example, during the pilot phase an insufficient amount of time elapsed before asking the next question. By being cognisant of this, adjustment was made to allow stakeholders to completely answer the question before moving to the next question.

Interview process

Following the pilot study and refinement of both the interview schema and interview technique, a total of 30 stakeholders were interviewed individually. The complete list of stakeholders interviewed can be found in Appendix 2.

Figure 2: Stakeholder selection process.



As can be seen in Figure 2, a total of 15 stakeholders were initially chosen. Of these, two people declined because they were undergoing restructuring changes in their organisations, and one person had initially been selected but unfortunately passed away prior to the interview and no subsequent representative was available. Two stakeholders selected the same person as their representative. This reduced the group to a total of 10 stakeholders. A further 26 stakeholders were then identified using the snowballing sampling method. Of these, 6 people declined, did not respond or could not find a representative. A total of 20 stakeholders added

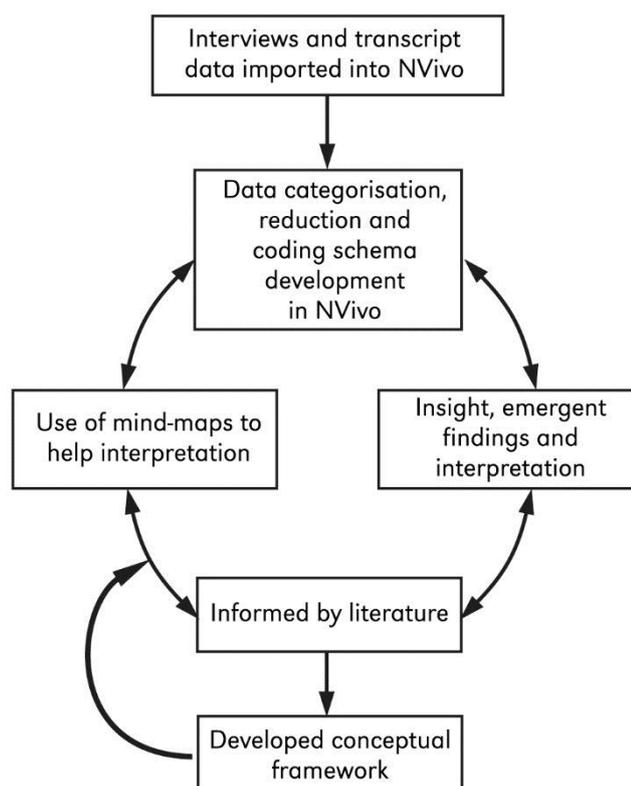
to the original 10 gave a total of 30 stakeholders who participated in this study. Sampling continued until saturation point when no new information was obtained (138, 139).

All stakeholders were sent the interview questions prior to the interview along with a participation information sheet. Interviews were digitally recorded and stored on secure password protected drives. Field notes were also taken during the interview which served as mental reminders for questions that needed further exploration or clarification (130). During the analysis phase, field notes were checked against what was contained within the transcripts as a reminder of the context of the transcript.

Data management, analysis, interpretation and conceptual framework development

The overall process used to develop the conceptual framework is outlined in Figure 3.

Figure 3: Outline of conceptual framework development.



Transcripts were imported into NVivo for data management and analysis. NVivo was used as a tool to help categorise and sort data into codes and themes, which formed the subsequent dimensions and sub-dimensions. Data analysis was performed by the researcher with advice and discussion on emergent findings taking place with supervisors at 3–4 week intervals.

The first phase of data analysis was data familiarisation. This refers to immersion in the raw data to become familiar with it (131). This was done by listening to the recordings and reading the transcripts and field notes twice. In the first round, the transcript was briefly read whilst listening to the interview. In the second round, each transcript was read in more depth. The transcripts and recordings were then revisited as required. Even though formal analysis did not begin until all the transcripts were returned by the stakeholders, implicit data analysis and interpretation had already begun. After each interview, critical reflection occurred and relevant mental and written notes such as any insight, key factors, ideas, mind maps, thoughts, and themes were collected in a notebook. At this stage the analysis method was broad, ad hoc and of a bricolage manner (130), which meant that no structured format was used to analyse the data. Literature about the emerging dimensions was explored. For example, if safety culture appeared to be one of the emerging dimensions, literature surrounding this area such as what had been defined as safety culture, or how it could be measured, was read by the researcher.

The second phase of data analysis was the categorisation phase. This stage explored the underlying themes hidden behind what was said. The question: “*What was this an expression of?*” (106) was continuously asked of the passage read to consider the underlying theme hidden behind what was said. Concepts that emerged were categorised and labelled according to nodes. Nodes refer to a collection of interview excerpts about a specific theme (140). At this point, no explicit definition had yet been given to each of the nodes and coding schema. In this way, the coding scheme could be left organic and flexible, allowing for new ideas and developments to iteratively form, which is in-line with a general inductive approach (121). A variety of other generic analysis techniques such as constant comparison (119, 131), repetitions (106), missing data (106) and other techniques (106, 107, 120, 131, 141, 142) were used during this phase.

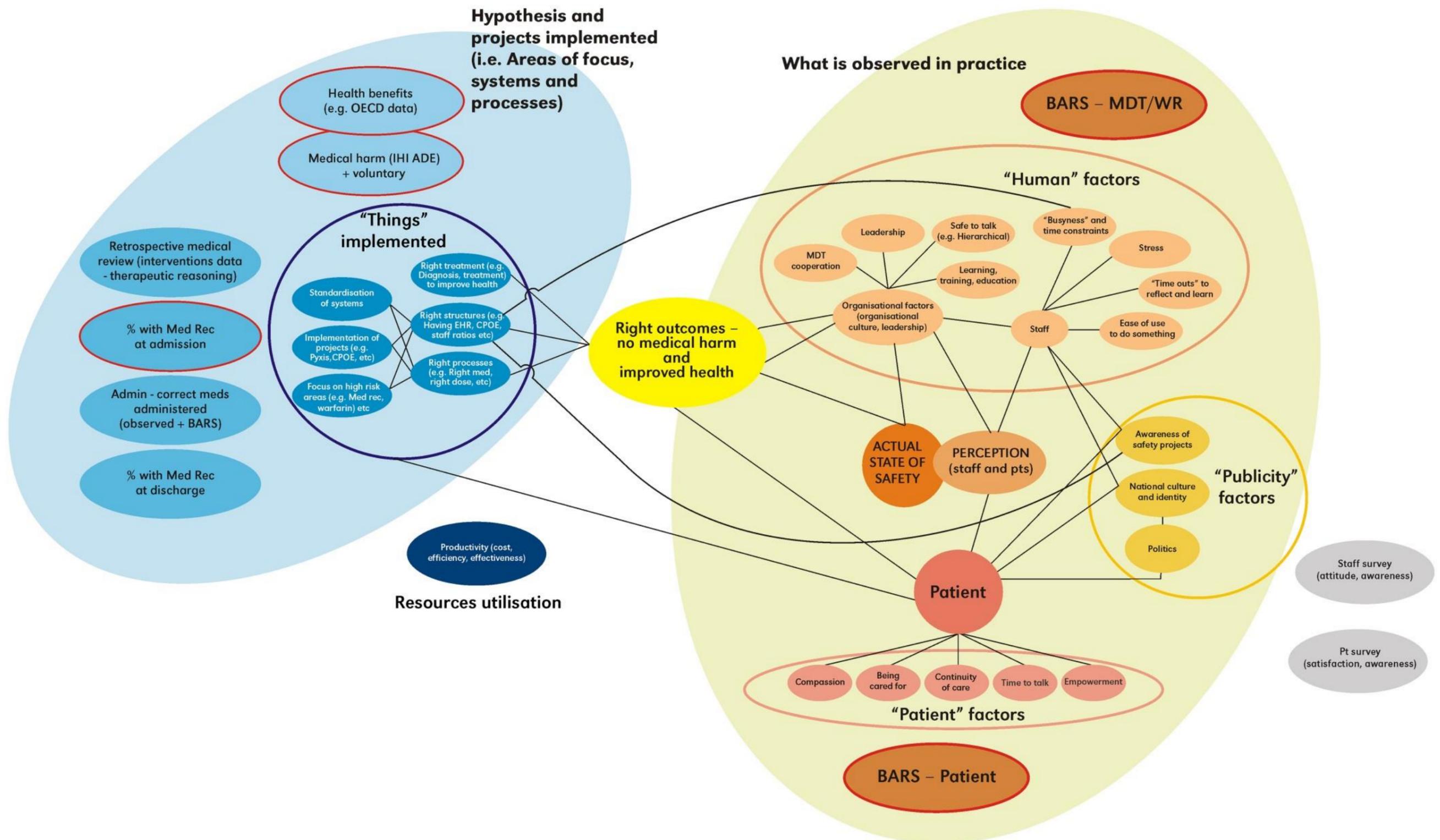
The coding or indexing phase involved combing the data for themes, ideas and categories which were then labelled for easy retrieval and exploration (143). It is important to note that the data acquisition and data analysis phase were not a segregated or linear process, but rather both phases often occurred concurrently (129). For example, the analytical process started during the data collection phase since data was already being analysed unknowingly or unconsciously by the researcher to shape ongoing data collection. Such continuous analysis has been deemed to be almost inevitable in qualitative research, because the researcher is “in the field” collecting the data and it is impossible not to start thinking (130).

Meaning condensation is a term used to describe the process of looking for conceptual themes with similar meanings. Segments of text containing similar themes were grouped together for

further analysis and interpretation (107). Each of these segments of text was given a category label and represented a particular concept. Each identified concept was given a category label. A category label was a word or short phrase used to refer to the category (121). The label carried inherent meanings that represented a specific feature of the concept. For example, each question in the interview schema was initially utilised as a category label known as a parent node. Through a general inductive approach, certain themes begin to emerge from stakeholders views on each of the questions answered. When consolidated and grouped, concepts from the stakeholders' answers were given a category label which was sub-grouped below the parent node. These sub-category labels were known as child nodes. Each child node could also have its own category label (121).

Once the data was coded they were given category descriptions. Category descriptions describe the meaning of the category, such as key characteristics, scope and limitations (121). Each category label and its description was iteratively refined when the data did not fit the definition, or where there needed to be more specific detail within a broader category. Conversely, categories were grouped together to represent a similar theme and reduce data. Each category label and description would then be linked with an example of text coded to help illustrate meanings and perspectives associated with the category (121). The coded data and its categories were represented in a hierarchical manner and provided an initial framework to make the data more manageable for further analysis (131). The raw interview data was condensed and mind maps were used during the data analysis phase to help reduce data and increase sense-making of the various nodes. A series of mind maps were developed and used by the researcher to help organise and reduce data for coding. Figure 4 is one example which has been included to illustrate this process.

Figure 4: An illustrative example of a mind map used for sense-making, data reduction and uncovering potential associations.



To find emerging patterns and trends, mind maps such as those in Figure 4 and manual manipulation using Microsoft Word, pen and paper were used. The various concepts emerging from the data were consolidated, printed, cut then physically arranged to give a better visual representation of the data and groupings. Some passages were re-coded and moved, whilst some were consolidated to better fit the data to the coding schema. The data was then systematically indexed and rearranged to the appropriate part of the developed framework (131). Codes and list of codes were refined during analysis as new ideas and new ways of categorising were detected (130, 144, 145). If definitions changed, each coded passage of text was re-examined to determine whether it could still fit in the same code or whether it needed to be re-coded. In this way, the coded material was constantly updated, renewed and improved to mould the coding schema into its final form.

Using this final coding schema, the transcripts were once again re-categorised but this time with the use of NVivo. The purpose of repeated categorisation served to ensure that no important theme was missed out, along with ensuring that the final coding schema used was robust. Utilising NVivo to categorise this information also meant that the data was more granular allowing the specific example of text to be accessed if required. The development of the coding schema was iterative, improving to better fit the data as the analysis took place (136). This was not considered a disadvantage because the process allowed the researcher to refine questions, develop hypotheses and pursue emerging avenues of inquiry in further depth (131). Several iterative cycles of data reduction and categorisation were undertaken to refine the dimensions and sub-dimensions that emerged from the interview data. The eventual result of the refinement process was the development of an initial conceptual framework which encapsulated the conceptual dimensions of medication safety measurement meaningful to stakeholders.

Once the transcript data had been fully coded, interpretation of the data along with how the various dimensions fitted together was explored. Emergent underlying themes were manually collated and categorised under each question on a separate piece of paper to provide an initial overall impression on what the range of themes were. Insight was gained into how the underlying themes could be categorised under a broader theme. Using pen and paper, some of these were sketched to give a better conceptual idea in a pictorial sense, and mind maps such as Figure 4 were once again used to consider how the various conceptual themes fitted and whether associations existed between them (134). Every 3–4 weeks, discussions on insights and findings that were relative to the data were discussed with the researcher's supervisors. Specific discussions on the interpretation of the data and whether these findings reflected

current understanding and how to refine the coded data was conducted to help to ensure data analysis and findings were robust.

Chapter 3: Findings and Interpretations

Emergent finding 1: Outcome goals of medication safety

A substantial part of the dialogue on the measurement of medication safety has focused on its desired outcome goals. The outcome goals of medication safety could be categorised as:

- The freedom from medication errors and harm; or
- Optimising health outcomes which are beneficial

In this section, excerpts will be used to illustrate how the sub-dimensions and the overall dimension emerged from the interview data and what they are about. The importance of the dimension to the measurement of medication safety will then be discussed. This dimension and how it can be measured will be discussed later in this section (see Chapter 3: Emergent finding 1B).

A) Emergence from the interview data

Freedom from medication errors and harm

There were subtle but important differences in exactly which types of medication related harm should be encompassed and focused upon within this sub-dimension. Exposing dissonance in views aid the understanding of what medication safety means to stakeholders, and this has important implications on how the concept should be measured.

At this point it is worthwhile clarifying some of the terms used in this research to ensure shared understanding with the reader. Clarifying these terms will also help the understanding of the subtle but important differences between stakeholder views. Adverse drug events (ADEs) are any harm related to medication use (1). Medication errors are any preventable event, based on currently available means and knowledge that may cause or lead to inappropriate medication use or patient harm (1, 146). A medication error of commission is where the wrong and preventable incident was done—a wrong medication inadvertently administered to a patient is an example of such an error (147). Not administering medications at the appropriate time is an example of a medication error where there has been a failure to do the right thing which is termed an error of omission (147). Some medication errors can lead to harm, and when these occur they are known as preventable ADEs (1, 148). Not all medication errors result in harm, and these are known as potential ADEs which are preventable (1, 148).

Stakeholders predominantly conceptualised medication safety as the avoidance of medication errors and their consequences—which are preventable ADEs. It is important to note that ADEs can also occur which are not the result of error. ADEs that occur which could not have been avoided by any means currently available are known as non-preventable ADEs (1). Some non-preventable ADEs are the result of patient choice. There is no fault in the healthcare system if a patient deliberately makes a fully informed choice to inappropriately or not use medications resulting in harm (149). Most other non-preventable ADEs are adverse drug reactions (ADRs) which occur as a result of the inherent pharmacological effect of a drug (148, 150). Some ADRs can be preventable. A patient who was administered penicillin despite a documented allergic reaction then suffering from anaphylaxis is an example of a preventable ADR. However, a patient who previously has had no allergic reaction to penicillin suddenly suffering from anaphylaxis despite appropriate use and monitoring is an example where a patient has suffered harm as a result of an ADR that was non-preventable.

Many stakeholders conceptualised medication safety as being about freedom from medication errors and medication related harm. For example, stakeholders expressed:

When I see the words medication safety that's always meant to do with medication errors specifically... medication safety to me would be medication safety centres and their work it's to do with med errors and prevention or preventing harm to patients. (S15, Expert)

Preventing unnecessary harm to a patient and I guess that relates to preventable ADEs or med errors that maybe result in near misses... To first do no harm, it's making the patient safe. (S18, Expert)

Making sure you get the right thing at the right time in the right dose. (S13, Consumer)

These excerpts were typical examples of most stakeholder views from across all stakeholder groups. They highlight the importance of medication errors and preventable events in the conceptualisation of medication safety. Stakeholder 15 and 18 specifically spoke about medication safety as meaning the avoidance of medication errors and their consequences. Stakeholder 13 spoke about the five rights of correct medication use, recently expanded to six (151), and that the right medication should be given to the right patient, at the right dose, by the right route, at the right time and recorded correctly. But underlying this discussion was still a focus on the process of medication use which was correct and, importantly, error and harm free.

Despite the best possible and appropriate medication use and medical care, some patients will suffer from non-preventable ADEs because of the idiosyncrasies in patient physiology and because medications and their use are intrinsically risky:

Generally speaking I think of medication safety as preventing error. If people have reactions to drugs and that's a big part of it [safety concerns], but I think as a practitioner that's something that you live with. Just like you live with accidents on the road. But it's what you can do, as a practitioner, is make sure that you don't err on the side of the wrong dose or drug. (S20, Expert)

Studies have shown that of all ADEs that occur, non-preventable ADEs make up a large proportion of all harm that occurs (1, 152-155). There is some literature which estimates that non-preventable harm may in fact have a greater adverse impact on morbidity and mortality than preventable ADEs (156, 157). Stakeholder 20 acknowledged the significance of non-preventable ADEs, recognising them as a major safety concern. However, as can be clearly observed, non-preventable ADEs did not form part of how medication safety was conceptualised by this stakeholder. Non-preventable ADRs and ADEs were regarded simply as part of the risks associated with medications and their use.

Stakeholder 20 and many other stakeholders believed the focus of medication safety should instead be directed toward medication errors and preventable ADEs which are actually amenable to improvement (5). Directing resource and effort toward non-amenable events may not provide much utility. Moreover, errors and preventable harm that occur as a result of medical care strongly resonate with the general public and in need for improvement (20). Regardless of the eventual consequence, medication errors represent undesirable failures in the medication use process and these have the potential to harm patients (26, 158).

Similar to stakeholder views, the literature has also predominantly conceptualised medication safety in terms of medication errors and their avoidance. For example, literature on medication safety tends to target medication errors and their consequences as a basis for improvement (1, 10, 11) and measurement (21, 26, 27, 29, 30). Medication errors are common in the hospital inpatient setting (1, 10, 11, 159). Medication errors occur at various stages of the medication use process such as prescribing, dispensing and administering (154). One study found that at least one medication error was discovered for each patient during their admission into hospital (70). Studies around the world suggest 0.4–7.3% of all patients hospitalised are harmed by ADEs which could have been prevented (1), and they add unnecessary financial costs to the healthcare system (160, 161). Medication errors and their consequences are significant healthcare issues that have many adverse implications (1, 159, 162).

The excerpts provided above were typical of views held by many other stakeholders and the literature. The conceptualisation of medication safety as being about the avoidance of medication errors and their consequences was understandable. However, it is important to note that not all stakeholders conceptualised medication safety in this manner. Some stakeholders

recognised that even though many medication errors occur and represent failures in the medication use process (26), only approximately 1% of all medication errors actually result in harm (70). It is recognised that health systems should be aiming for zero defect and even 1% of medication errors resulting in harm can be considered too high (70). However, the predominant focus of medication safety on the avoidance of medication errors may potentially provide little utility for the degree of effort. As stakeholders expressed:

Certainly in the area of [name of institution/area etc. removed to maintain confidentiality] we seem to be able to make quite a lot of mistakes without any noticeable impact on outcome... I'm quite in favour of this concept of error management rather than error prevention. I mean the difference being that the focus on error management is the mitigation of harm, the objective is to reduce harm [i.e., ADEs]. It's not really to reduce errors. And so monitoring the effect of drugs might allow you to intervene and reduce harm even when mistakes occur, so I think that's quite an important element. (S3, Policymaker)

You can often find very high rates of errors with prescribing but a lot of them have been incredibly minor and non-consequential to the patient... You have some sort of outcome measures and we find differences or whatever it happens to be but yet you don't really know what that change [to medication error rates] means to patient outcomes and that's really ultimately what matters. What does that mean in terms of overall health benefits to the health system to people or whatever? (S26, Policymaker)

The causal relationship between error and harm is loosely coupled (70, 163). Most errors are intercepted before they reach the patient (70). But even when they do reach the patient they do not cause damage because of the resiliency of humans and good fortune (70). The complete elimination of error is difficult and probably not achievable (72). As Stakeholder 3 pointed out, instead of focusing on the complete avoidance of errors (many of which may be inconsequential), there should be a shift in focus to the avoidance of ADEs. Alternatively, instead of avoiding all errors, one should instead aim to minimise the effects of errors and ADEs—a concept known as error management (72). Indeed, some literature states that the focus of medication safety should be shifted from error prevention to ADE avoidance and minimisation (26). Conversely, some literature also points out that a sole focus on ADEs may miss potentially risky and unsafe situations which need to be addressed before they cause harm (26). The fact that no harm has yet occurred, for the same reasons why errors don't always lead to harm, does not mean that the medication use is safe. Seemingly, instead of a situation which is either error or harm, the goal of medication safety should focus on both avoidance of medication errors and harm.

Many stakeholders believed medication safety should focus on both medication errors and preventable harm, but importantly also highlighted the need to include non-preventable ADEs. For example, stakeholders expressed:

[I see] *medication safety as containing both the preventable and non-preventable.* (S10, Expert)

It's any of the parameters that have an impact on the individual that produces some untoward experience. On that kind of clinical dimension [i.e., non-preventable events] as well as the safety issues around the actual administration, the use and the sort of logistics and procedural sort of elements around that [i.e., wrong medication administered]... it's really a catch all phrase or term that picks up anything to do with untoward events relating to medication and within that you get a whole bunch of sub-sets of things. (S14, Policymaker)

Medication safety for me is the use of appropriate medicine in an appropriate [manner] or the correct patient, and really that means the use of the correct medicine dose form and route. [Medication safety should also include] being able to monitor adverse reactions or emerging safety signals for medicines that are being used and taking action to either restrict their use or keep patients informed about risks, discover interactions, so that's part of it. (S6, Policymaker)

Medication safety to these stakeholders means the avoidance of both medication errors and all types of medication related harm, including those that are non-preventable. As had been previously recognised by Stakeholder 20, medications inherently have risks and harm that will occur despite the best possible and appropriate care. Clinical dimension, spoken about by Stakeholder 14, referred to the recognition of these inherent risks and harm, many of which are non-preventable, and the need to balance these in relation to the benefits gained from using the medication(s). Unlike Stakeholder 20 however, Stakeholder 14 was of the view that medication safety should include both clinical considerations of inherent risks and harm and erroneous facets. Stakeholder 6 had similar views to Stakeholder 14, and this was illustrated through the discussion of the six rights which are error focused and the monitoring of ADRs, emerging safety signals and discovery of interactions.

The discussion of non-preventable ADEs, ADR monitoring, emerging safety signals and discovery of interactions has traditionally been conceptualised more in-line with the concept of pharmacovigilance (164, 165). Pharmacovigilance is concerned with post-marketing surveillance of ADRs in an effort to discover previously unknown adverse consequences of medications (1, 164, 166). Pharmacovigilance organisations such as the World Health Organization (WHO) International Drug Monitoring Programme and the New Zealand Pharmacovigilance Centre (NZPhVC), focus on capturing ADEs that occur as a result of the medication itself (i.e., pharmacological effects) rather than errors associated with their use (1, 164). Even though such pharmacovigilance programmes have long recognised and do capture some medication errors, this has traditionally not been their focus (164, 165).

Despite non-preventable ADEs not being traditionally conceptualised as part of medication safety, its inclusion is nevertheless important and understandable. For example, one stakeholder expressed:

At the end of the day all harm is preventable, we just may not have the technology to date to, or the processes, refined processes to prevent that harm, you know, a patient's harmed by a drug we might not have made that causal link yet but in the future we may. So all harm is, by definition, preventable to some capacity. When I mentioned preventable harm that those that are known to us now that are preventable either by alternate therapies, or alternate process, or checking procedures or whatever it may be, that's something for us to target our interventions, or medication, patient safety campaigns, to prevent that harm, or that error that may lead to harm. So I guess that's where I was going with preventability more around, less about the definition but more around what you would do if that harm was known, if you could prevent it, that's more of a focus of patient safety is identifying the harm and preventing unnecessary harm. (S18, Expert)

As Stakeholder 18 recognised, the degree of preventability is relative and changes over time (59). One example which illustrates the characteristics of preventability is the increased knowledge base gained from pharmacovigilance. Pharmacovigilance is important to medication safety because it provides the evidence of harm by certain medications and helps identify the sub-groups of patients at risk for ADRs. The thalidomide tragedy, for example, found that the medication caused congenital abnormalities in pregnant women (164). The understanding of this ADR now means that if thalidomide is prescribed today for patients with nausea and vomiting in pregnancy, this would be regarded as a prescribing medication error. Understanding how often, and to whom ADRs happens to, makes such events preventable. Moreover, advances in pharmacogenetics in predicting ADRs (167) and other technologies may change what was previously considered a non-preventable event to a preventable event.

The relative and changing nature of preventability makes deciding whether an event was preventable difficult. Medical knowledge, being incomplete and with much still to be learnt, adds further challenges. There are still gaps in medical knowledge where determining what the right thing to do remains unclear. As explained by one stakeholder:

I think the decision about what drug to give somebody is an art form to some degree as well as a science, so quite difficult. And you can get into quite heated debates where two people might have different views as to what drug a person should be on. And so that is more subject to variation, you would expect variation around individual patients, but currently I think there would be variation between practitioners. That is somewhat legitimate because I think it's not always clear. I mean, to give you an example, I'm on primary statin and a lot of people would think that that's, you know, primary prevention statin is not really a, that's very controversial. Many people would say it was the wrong thing to do, I obviously think it's the correct thing to do and I think that there are areas like that where we don't really know. (S3, Policymaker)

In the example provided by Stakeholder 3, if an ADE such as muscle aches does occur as a result of statin use in primary prevention for cardiovascular disease (168), then debates could be held on whether this was a preventable event or not. On the one hand, if statins for primary prevention use was deemed appropriate and was used in an appropriate manner, then muscle aches that occur can be interpreted as an inherent adverse effect of the medication that is outweighed by the benefits of preventing cardiovascular events. On the other hand, if statin use was deemed inappropriate for primary prevention and muscle aches occurred, then this ADR could be deemed preventable because no efficacy was expected in the first place and has been erroneously prescribed. Without knowing what the exact right course of treatment is, it can be difficult to determine whether a particular course of treatment or any adverse consequence was wrong, or whether it was preventable.

Interestingly, the stakeholders who strongly believed there was a clear medication safety conceptual boundary between non-preventable and preventable events actually provided contradictory excerpts which illustrated the overlap. For example:

I tend to tie in, with what I've read internationally, is what we're focusing on is the preventable stuff. Within the realms of medication safety, yeah, say within the realms of my role [medication safety pharmacist], certainly adverse drug reaction reporting, sound-a-like reporting, and things like that, that doesn't come up on my radar at the moment. And I guess I would try and argue that that shouldn't be on my radar either. (S11, Expert)

As can be seen from this excerpt, Stakeholder 11 was of the view that non-preventable ADEs should not be part of medication safety. This excerpt was interesting because Stakeholder 11 provided the example of 'sound-a-like reporting', where the wrong medication was used due to similarities in medication names, being a non-preventable scenario. Yet, the literature strongly suggests ADEs associated with sound-a-like medications as being preventable events (169, 170). One possible interpretation of Stakeholder 11's view was that it was simply an error in classification. Another possible interpretation for Stakeholder 11's view which is in contrast with the literature is that a blurry boundary exists between non-preventable and preventable events. Determining preventability is subjective, context dependent and difficult (59, 171-175). Indeed, studies have shown poor intra- and inter-rater reliability when determining the degree of preventability (59, 171-175). Not all stakeholders shared the same view as that of Stakeholder 11, and many stakeholders recognised the difficulties associated with determining preventability. For example:

There's this grey area in between, of ADRs on one side and medication, outright medication errors on the other, with some muddled grey area in the middle that it's hard to sometimes determine if it's preventable or not preventable. (S15, Expert)

The discussions so far suggest that determining preventability is difficult. Instead of trying to determine whether an event was preventable or not, it may be better to simply reframe medication safety in terms of avoidance of medication errors and all types of medication related harm. For example, pharmacovigilance centres have recently expanded their attention to also focus on medication errors and preventable ADEs (165, 176). The framing of medication safety to include non-preventable ADEs may help one to remain vigilant and open to ideas and approaches, striving to reduce all types of harm associated with medication use (21, 26). In fact, reframing medication safety to include non-preventable ADEs has been thought to have spurred the development of newer medications with less adverse consequences (156). The conceptualisation of medication safety should include both facets.

Emerging from stakeholder views and clear from the literature, medication safety, at the very least, means the avoidance of medication errors and their consequences. There were differences in views as to whether errors or harm should be focused upon, but these have been resolved with this research showing that both need to be considered. There were also differences in views on whether non-preventable ADEs should be included. Some stakeholders suggested that non-preventable ADEs should not be included because they are not amenable to change. However, as can be seen from this research, the degree of preventability is relative, subjective and changes over time. A better knowledge of non-preventable events can help make them preventable in the future. Exploring, recognising and understanding how medication safety has been conceptualised by different people is important. These discussions and how the dimension can be measured will be discussed later in this section (see Chapter 3: Emergent finding 1B). For now, it is important to acknowledge that for most stakeholders, medication safety means the avoidance of medications errors and harm.

Optimising health outcomes which are beneficial

An important and novel finding which contrasts with previous research was medication safety meaning the optimisation of health outcomes which are beneficial for a patient or population as a result of medication use. Emerging from the interview data was the notion that efficacy is related to medication safety, and therefore significantly reframes the conceptualisation of medication safety. For example, stakeholders expressed:

It's a case of no harm. And I think the other end is the best possible outcome for the patient. (S13, Consumer)

We are actually in the business of trying to treat people. The reason we're doing this is to treat disease and so our primary goal is successful treatment of disease and safety, successful and safe treatment of disease... if you increased the average

life of the population by one month that would be a lot of life years. If you killed a few people by errors in the process you might still be well ahead. So unless you're managing both sides of the equation and I do think one of the problems with the safety movement is it tends to focus on eliminating the negative rather than looking at the positive. And I think you need to look at both. (S3, Policymaker)

The excerpt by Stakeholder 3 was interesting because some might argue that even 1% of medication errors resulting in ADEs are not acceptable (70). A sole focus on efficacious medication use which may be beneficial for the general public may neglect individuals who may be affected by medication errors and harm. A patient who is harmed by the medical care intended to help them should not be merely ignored, just because everyone else receives beneficial effects. Some patients will have good outcomes despite poor or unsafe care due to the resilience of humans or good fortune, but this cannot be regarded as safe. The sole focus on beneficial outcomes will not necessarily consider care which has not been appropriate or harm free. There is a need to consider both parts of the overall equation.

However, the point of Stakeholder 3 and others was not to detract importance away from adverse or negative consequences such as medication errors and harm. Instead, Stakeholder 3 and others insightfully recognised that positive and beneficial outcomes need to also be considered to provide a more balanced view of what medication safety means. Stakeholder 10 went on to explain:

If you give a drug to a patient who's not going to get any benefit from that drug, 'cause it's not in their genetics as such that the drug's not going to be activated to its active form, you're wasting a huge amount of money from the drug and you can't expect any benefit from it. So there is a safety concern there because a person will die earlier say with breast cancer, they'll die earlier than they should because the drug's not working. Yet they're getting the drug, it's costing a lot of money and it's not working, that's a huge safety issue. Because irrespective of the toxicology of the drug, that's just purely on efficacy. So if you're going to give a drug and it's not going to work it's not particularly useful. (S10, Expert)

This excerpt supports the notion that beneficial consequences are related to adverse consequences. Stakeholders recognised that there is no point to medication use, no matter how safely they are used if no benefits are expected. Using medications with no benefit means that patients are unnecessarily placed at risk of error and harm and waste occurs. Seemingly, the use of medications with no benefits may negatively influence medication safety by increasing the risk of medication errors and harm, including preventable harm, such as dying earlier than they should which may result from the failure to do the right thing, which is an omission error. It is important however, to note that the relationship is not unilateral. There is also a need to minimise adverse consequences in order to optimise health outcomes which are beneficial, such as increased life-span or improved quality of life. Clearly, adverse and beneficial

consequences are related and both need to be considered to provide a more rounded view of medication safety.

Some stakeholders recognised that if medication errors and harm were the sole focus of medication safety improvement, stringent measures to reduce harm and injury from medication use could result in the unintended effect of fewer patients receiving essential medications and thus their benefits. For example, one stakeholder expressed:

Come back to the real thing which is, the objective is to treat patients, so you could make it entirely safe by not having any medications, get rid of medications we won't have any medication harm. But that's not the outcome you're interested in, and that's really why I'm sort of balking a little bit at outcomes being, you know [focused on medication errors and harm], I'm interested in, the purpose of the medication is to treat disease, so if you are not looking at the positive outcomes, you're only looking at the negative outcomes, [i.e., adverse consequences of medication use such as medication errors and ADEs] is only part of the picture. (S3, Policymaker)

As can be seen from the excerpt, Stakeholder 3 has strongly and consistently emphasised the need to include the consideration of both beneficial and adverse health outcomes in medication safety.

Interestingly, in the example provided, the strategy to not use any medications as the best way to avoid medication harm is not entirely valid, if medication related harm is interpreted in its broadest sense. To a degree, Stakeholder 3's view was correct in that not using medications will help to avoid errors and harm associated with unnecessary medication use. For example, prescribing antibiotics for a viral infection where antibiotics have no benefit may cause harm such as diarrhoea, and could have easily been prevented by not using the medication at all. Not using medications can also help the avoidance of errors and harm associated when using medication. A patient suffering from anaphylaxis because penicillin was inadvertently administered, despite having a documented penicillin allergy, could have also been prevented by not using medication. However, not using medication as a strategy to prevent error and harm, neglects harm that may occur as a consequence of non-use. Not choosing to treat with an alternative antibiotic resulting in sepsis is also an error because there has been a failure to do the right thing which is an omission error (147). In this case, non-use has led to an ADE which could have prevented by using an appropriate antibiotic.

Despite the inconsistency and not entirely valid example, importantly, the focus of Stakeholder 3's excerpt should be directed towards the need to conceptualise medication safety as both optimising health outcomes which are beneficial and avoidance of adverse

consequences. To help make sense of what Stakeholder 3 was trying to express, consider the following vignette.

Warfarin is a medication recommended to treat atrial fibrillation because of its effectiveness (177). However, there are many interactions and the dosage schedule needs to be precise. Warfarin has commonly been implicated in harm such as excessive bleeding (178). Given that many patients are harmed by warfarin use, a goal might be to reduce the degree of harm associated with its use. Indeed, the Agency for Healthcare Research and Quality tracks the number of patients hospitalised as a result of warfarin use to help indicate the overall safety of medication use (179). Yet, paradoxically, one approach to reduce the number of patients harmed from warfarin use is to not use warfarin at all. This approach will reduce ADEs associated with the use of warfarin. However, this approach neglects the safety concerns associated with the non-use of medications. The narrow focus on reducing harm as a result of medication use has the potential to lead to the unintended effect of fewer patients receiving the benefit of warfarin use with a net negative impact on the overall health of the population.

The conceptualisation of medication safety so far in the literature, as the avoidance of medication errors and harm, has focused predominantly and negatively on the adverse consequences of healthcare. This focuses on determining how bad medication use has been, what has been done incorrectly, and the bad things that have occurred such as ADEs. Conversely, one could take a positive view and ask how good medication use has been and what has been done correctly. As can be seen from previous discussions, most stakeholders conceptualise medication safety as the six rights of medication use. Regardless of whether a negative or positive perspective is taken, underlying the focus on errors is the attempt to determine whether healthcare was appropriate and delivered in an appropriate manner. However, just because healthcare was appropriate and error free does not necessarily mean that ADEs will not occur. For example, previously it was noted that some patients will suffer from harm regardless of the best possible and appropriate care such as the occurrence of non-preventable ADRs.

Neither the focus on error nor harm actually answers the specific question of whether medication use has actually achieved what it was meant to—which is to optimise health outcomes. The excerpt by Stakeholder 3, which focuses on conceptualising medication safety as optimising health outcomes which are beneficial, addresses this gap and specifically asks the question of whether beneficial health outcomes have been optimised. The change in framing of medication safety from solely focusing on adverse consequences, to also considering beneficial consequences is subtle, but important, and has significant implications.

For example, if medication safety means the avoidance of medication errors and harm, which is how it has traditionally been conceptualised, then the medication system is safe as long as there are no medication errors and no medication related harm. Determining whether medications and their use were actually effective at doing what they were meant to do is not necessarily required. Thus, medication use may not actually be effective, but because there was no error or harm, was deemed safe.

Reframing the conceptualisation of medication safety to the optimisation of health outcomes means that the system may be unsafe even when there are no medication errors or medication related harm. It is still important to avoid medication errors and harm because they contribute to beneficial health outcomes not being achieved. But more importantly, it also considers whether medications and their use were actually effective at doing what they were meant to do—treat and prevent disease. Framing medication safety as optimising health outcomes which are beneficial may also proactively push for ways to continually optimise health outcomes. The inclusion of both adverse consequences and beneficial consequences expands the current conceptual boundary of medication safety and increases the expectation of what is deemed to be safe.

The concept of quality healthcare was introduced by stakeholders when discussing the expanded conceptual boundary of medication safety to include beneficial health outcomes. For example:

I guess it's, apart from safety it's quality for a start. And that the efficacy is greater than the potential harm. (S25, Policymaker)

Well there's a number of things I think that, the absence of side effects and adverse events and harm, okay, I suppose is one way to look at it, so we don't cause harm. That's one way of doing it. And then the other side of it is looking at efficacy of the treatment, I suppose. That's more a quality measure I suppose. But they sort of go together. And that would be the way that I would sort of just frame it up, along those sorts of lines. (S21, Expert)

Quality, as a concept, includes medication error and harm but expands to include other considerations (44, 71, 180). Quality healthcare has been defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and that are consistent with current professional knowledge (44). The QUM concept also aims to achieve these goals, but focuses on those related to medication use (71). Quality healthcare not only considers safety, but also timeliness, effectiveness, efficiency, equitability and patient-centeredness (40). Importantly, both the quality healthcare and QUM concepts focus on the optimisation of health outcomes as the goal (44, 71, 180, 181).

Stakeholders' conceptualisation of medication safety to include the achievement of beneficial health outcomes is arguably more closely aligned to the concept of quality. The expansion of the conceptual boundary of medication safety goes against how medication safety has been typically conceptualised in the literature and stakeholder views so far. For example, an excerpt which illustrates how medication safety has been traditionally conceptualised is:

I'm purely concentrating on medication safety; I'm not looking at quality, at all? For medication safety, it's just preventing harm to the patient... to me medication safety is an aspect of quality. In my mind there's a bit of a boundary 'cause to me qualities in medicines could be making sure that every patient who's had a heart attack is on the correct medication, post-cardiac arrest, so that's the quality in medicine, and I'm not sure that's a medication safety issue. (S22, Policymaker)

Similar to the literature, medication safety was deemed a dimension of quality but a distinctly different concept. Some incidents appear to resonate as safety issues, while some incidents resonate more as quality issues. Borrowing from the literature, two factors that appear to influence how strongly an incident resonates as a quality or safety issue are immediacy and causality (51). Some incidents, such as the inadvertent administration of vincristine intrathecally causing harm or death, easily resonate as a safety issue (51). This is because harm occurs almost immediately after the error, and there is no doubt that the adverse consequence of death was caused by the error.

As outlined by both the stakeholder and the literature, the failure to use certain preventative cardiovascular medications resulting in myocardial infarction resonates less clearly as a safety issue and more of a quality issue (51). This example is less clear, because if myocardial infarction is considered an ADE as a consequence of the non-use of medication, it does not occur immediately to non-use. Typically, a myocardial infarction may not occur until many years later. Complicating the issue, patients who do not take the preventative cardiovascular medications may not suffer from myocardial infarction, while patients who do take the preventative cardiovascular medication may still suffer from myocardial infarction. Myocardial infarction may not necessarily be an ADE at all resulting from non-use of the medication, due to other confounding factors which may contribute to a larger extent such as poor diet, lack of exercise and so forth. The causal relationship between taking the medication and harm is less clear, and the occurrence of myocardial infarction cannot solely or easily be attributable to the non-use of preventable cardiovascular medications. These reasons may explain why it less clearly resonates as a medication safety issue.

Stakeholder 21 spoke about underuse, overuse and misuse problems, and despite these being healthcare quality problems, are also major safety issues:

I think it's people being on medications that they really need to be on. So it's actually about the appropriateness of the medications for effective treatment of real conditions. And those medications, there's the administration, prescribing administration aspect of all of that, to ensure that people are getting the right medications at the right time by the right route, for the right person. So, I mean it's, there are aspects about whether they should be on certain amounts of medications, over use, misuse, and underuse of medications, okay. And then there's the business of the safety of those medications, with regards to I suppose allergy, and then the right dose, right time, right route, right person. (S21, Policymaker)

Problems of underuse refer to the failure to provide a healthcare service where it would have produced a favourable outcome for a patient (44). Even though the causal relationship between preventable cardiovascular medications and mortality from myocardial infarction is not always certain, studies have shown the benefits in reduction of mortality as a consequence of the use of preventative cardiovascular medications (182, 183). If patients were dying from myocardial infarction unnecessarily, and medications were not being optimally prescribed, then this is a problem of underuse. Not prescribing preventative medications to patients who should have them can also be considered a prescribing omission error and harm that occurs, such as cardiovascular deaths and hospitalisations, could be regarded as preventable (184). Even though underuse is deemed a healthcare quality problem, it can be clearly seen that safety and quality are related.

Misuse problems occur when an appropriate service has been selected but a preventable complication occurs and the patient does not receive the full potential benefit (44). A patient who is administered an incorrect medication and suffers from harm as a result, is a problem of misuse. In this case, the decision to treat was appropriate, but a preventable complication has occurred and the patient does not receive the full benefit. Overuse problems occurs when a healthcare service is provided under circumstances in which its potential for harm exceeds the potential benefits (44). An example of an overuse problem is the prescribing of antibiotics for a viral infection where antibiotics have no effect and cause harm such as diarrhoea. Both misuse and overuse were caused by medical care and medication use, and can also be categorised as commission medication errors which are preventable. These scenarios illustrate the conflation between quality and safety concepts. Even though some incidents resonate more easily as one concept than the other, when one delves into the incident more deeply it is often difficult to make the distinction between what is a safety incident and what is a quality incident.

Some stakeholders spoke of medication safety and quality overlapping so much that it is difficult to distinguish one concept from the other. For example:

[In relation to the difference between a safety event and a quality event] *false debate we have between safety and quality... You know if you haven't got effective care then it's probably not safe, if you haven't got efficient care then you're probably not safe. If it's not timely it's probably not safe, so I'd be interested in where you think that's going but I think we can tie ourselves in semantics.* (S17, Policymaker)

Ensuring that patients get the optimal benefit from medicines that they're prescribed or ordered with the minimum amount of risk... I think quality and safety are so inextricably linked that it is an artificial device to try and separate. (S16, Expert)

As has been previously mentioned, timeliness, effectiveness and efficiency are dimensions of quality healthcare separate from safety (40) (see Chapter 1C: Rationale). Even though these are dimensions of quality, these dimensions also relate to safety. Stakeholder 17 believed that when one dimension of healthcare is missing it may not necessarily be safe. For example, if a crucial medication was not administered in a timely fashion, and a patient suffered as a consequence of not receiving the medication in time, then this presents as an unsafe situation (185). Ensuring healthcare is effective and efficient was spoken about as also contributing to safety. Indeed, researchers in the literature have suggested that at no point is there a distinction where safety topples into quality, but rather, that there is a continuum between the concepts (51). Taking a continuum view may be the best approach to describing overlaps which exist between the medication safety and quality concepts.

Conceptualising medication safety in a similar manner to quality raises several questions and has important implications. For example, should the concept of medication safety be made obsolete and absorbed within the QUM concept, or should it be a related but standalone concept? Even though the outcome goals of the two concepts seem similar, are they similar conceptually? What might the differences or similarities be? There appears to have been a lack of in-depth research into exploring specific differences between the medication safety and quality use of medicine concepts.

In the literature, the patient safety concept has been studied in-depth more extensively and has been specifically compared against the concept of quality healthcare (51, 52, 186). Such studies suggest that, though related, patient safety exists as an important concept in its own right, but is typically conceptualised as a dimension of quality focusing more predominantly on freedom from error and harm (40, 52). Patient safety has typically been viewed to encompass all aspects of medical related injury, including those related to medications (52). However, there has not been specific research which has actually explored whether differences exist between medication safety and patient safety, or whether there are any dimensions only specific to the concept in question. Similarly, there has been little research that articulates the

similarities and differences between medication safety and QUM. Emerging from stakeholder views and inferring from the literature, medication safety is an important concept in its own right, but does resemble QUM. Research findings suggest that the medication safety concept is different from the patient safety concept although there is overlap. These discussions will take place at the end of this thesis in Chapter 4C: Implications.

Underlying the discussion on both the avoidance of medication errors and harm and beneficial health outcomes, has fundamentally been a focus on what the outcome goal of medication safety should be. An outcome denotes the end effect of care on the health status of patients and populations (187). It is recognised that medication error may contrast with how outcome has been defined in the literature. However, as can be seen from stakeholder excerpts so far, the avoidance of medication errors are one of the clear outcome goals of medication safety. Indeed, there are some researchers who support the notion that medication errors be regarded as an outcome in the literature (26). In the context of this research, medication errors were categorised as an outcome goal because they can be regarded as the outcome of a particular process of medication use. For example, a dispensing error where the wrong medication was dispensed can be considered an undesirable outcome of the dispensing process.

Medication safety was conceptualised as having the goal of avoiding adverse consequences such as medication errors and harm. Fundamentally, this view of medication safety focuses on whether medication use was appropriate and delivered in an appropriate manner, and whether medication use did what it shouldn't have. Alternatively, medication safety was conceptualised as having the goal of optimising health outcomes which were beneficial. Fundamentally, this view of medication safety focuses on whether medication use and healthcare achieved what it was meant to do—improve patient health. Both adverse consequences such as medication error and harm and beneficial consequences such as optimal health outcomes have been encapsulated and labelled the outcome goals of the medication safety dimension. This dimension contributes to the overall conceptual framework to measure medication safety. The manner in which this dimension contributes will be discussed in later chapters of this research (in Chapters 4A & B).

The exploration of stakeholder views and the recognition of the differences on what medication safety means to people was important. The traditional conceptualisation of medication safety has been expanded as a consequence of findings from this research. For a healthcare system to be safe, it needs to not just avoid medication errors and harm, but also achieve what it set out to do which is to improve health outcomes. The implications of the subtle but important reframing are significant—affecting both the targets for measurement but

also improvement of medication safety. The discussions thus far on the optimisation of health outcomes which are beneficial do not detract importance away from adverse consequences, such as medication errors and harm when medication safety is conceptualised. Instead, the consideration of benefits gained from medication use adds to the traditional conceptualisation of medication safety. Reframing medication safety in terms of both adverse consequences and beneficial outcomes provides a more rounded and balanced view of medication safety.

B) Importance of measuring the outcome goals of medication safety and how it could be measured

The measurement of medication safety outcome goals to measure medication safety is important for several reasons. Emergent from the interview data, the outcome goal of medication safety dimension is clearly meaningful to stakeholders in a measurement context. The understanding of the differences in preferences of exactly which outcome goals are preferred, in prior discussions, means that measures can be better customised for its intended target audience.

Measuring the outcome goals to measure medication safety is important because such measures can be used to fulfil multiple purposes such as improvement (188), clinical governance (189), inform resource allocation (190) and performance management which is increasingly tied with financial considerations (191, 192). The measurement of medication errors is important because it indicates how appropriate or inappropriate medication use has been and, as defined in this research, represents the outcomes of certain stages of medication use. However, as has been previously discussed in the earlier part of this chapter, poor care does not necessarily lead to poor patient health outcomes, while appropriate care does not always lead to good patient health outcomes. Importantly, there is also a need to measure the end effect of overall medication use on the patient or population. Ultimately, people want to know whether medication use did what it was meant to do, and not do what it shouldn't.

As can be seen from the excerpts so far, medication safety meant different things to different people. There were significant variations between stakeholders in what exactly was emphasised within the concept of medication safety. The fact that some people find particular conceptualisations of medication safety more meaningful than others reveals different priorities and ways in which they view the world. This research explores in-depth, medication safety and its meaningful facets. It is recognised that particular facets will not be meaningful to particular stakeholders. Thus, even though it is important to recognise the breadth and scope of medication safety as a concept, it is also important to recognise that different individuals

will find different facets particularly meaningful. Importantly, their view is not necessarily more or less valid than another person's view. Because certain stakeholders may prefer the measurement of medication errors and harm, while others may prefer the measurement of beneficial health outcomes to measure medication safety, it is important to consider how each of the sub-dimensions can be measured.

Emerging from the interview data, stakeholders explicitly noted the importance of measuring medication errors and harm to measure medication safety. For example:

I think measuring one of those hard points like the number of medication errors.
(S19, Expert)

Try and reduce the number of errors, to reduce the number of preventable hospitalisations through either drug treatment injuries, or to well to try and prevent prolonged hospitalisation due to adverse effects, or errors, or preventable events. That's what I see medication safety is primarily if you're wanting something to measure and you want to see how much of it is actually occurring in the New Zealand health system. (S6, Policymaker)

Many researchers in the literature have also advocated, or have measured medication errors and harm to measure medication safety (21, 26, 27, 29, 30, 38). If medication errors and harm were to reduce over time, one possible interpretation is that medication use was becoming safer (26). It may also indicate that interventions implemented to improve medication safety were effective.

Despite the benefits that can be gained from the measurement of medication errors and harm, clear from the discussions from the start of this thesis were the challenges which affect their measurement in a robust and reliable manner. The identification of events which are preventable faces a major challenge which has been poor intra- and inter-rater reliability (59, 171-175). The consequences of such reliability issues can mean that any changes to the rate of error or preventable ADEs over time may be due to methodological limitations, unless they were robustly and consistently measured in a standardised manner.

Despite the challenges associated with measurement, it is still important. The challenge is instead to make best use of imprecise measures (193). Measurement of errors and harm is required to track the progress of safety (193), which may be required for regulation purposes, and may help highlight deficiencies in medication use for improvement purposes (188, 193). Most importantly, because errors and harm resonate with people as clear safety issues and problems associated with poor healthcare (20, 51), they serve to bring attention to the general public. With this in mind, a number of methods and approaches to measure medication errors

and harm were spoken about. For example, some stakeholders spoke about retrospective medical record review:

[In relation to whether medication safety had improved] I do not know and what's more I don't think we have the data and all I could come up with was Peter Davis' study. (S12, Policymaker)

The New Zealand Quality in Healthcare study (NZQHS) referred to by Stakeholder 12 was conducted by Davis et al (194). This study, and most of the landmark studies such as the Harvard Medical Practice Study (HMPS) (195), measured adverse consequences of medical care, such as ADEs, to determine the adverse outcomes resulting from medical care. The approach used to identify and measure harm in these studies was the retrospective medical record review. This approach has generally been considered the gold standard because it tends to identify the most incidences of harm as compared to other approaches (27, 68, 196, 197). Other stakeholders spoke about using the trigger tool approach to measure medication safety:

Trigger tool. (S8, Policymaker)

The trigger tool, it's probably more focused on outcome. (S15, Expert)

A number of other approaches, such as direct observation, computerised approaches and spontaneous voluntary reporting methods were spoken about by stakeholders to identify and measure medication errors and harm. Many of these approaches have been described in the literature to measure medication safety. For example, the most common methods in the literature appear to be ADE trigger tools which can be electronic or manual (38, 197), medical record review (155, 196), practitioner intervention database (67, 198), voluntary spontaneous reporting such as MedMarx[®] and RiskMonitorPro[®] (193, 199-202), observation methods (64) and computer based methods such as data mining and Bayesian-based methods (65, 203). A selection of the most commonly used approaches to identify and measure medication errors and harm have been summarised along with a synopsis of some of their advantages and disadvantages in Appendix 1.

It is important to note that stakeholders, when determining medication safety changes, do not just consider the change in occurrence or rates of error and harm, but also whether the characteristics of medication related harm have changed. For example, stakeholders expressed:

Every month there's at least 30 events and that hasn't really changed. And it tends to be, this is a reflection on our poor performance really, but it tends to be the same sort of things time after time. (S1, Expert)

Gee this looks like the same kind of report, have I seen this, or have they given me a duplicate of this report. And in fact it was the same patient, same hospital, two months later different doctor, same drug, same problem... gentamicin ototoxicity, why is that happening today, still? (S14, Policymaker)

Measuring the number of errors and harm is important, but only part of the process. There is also a need to classify and categorise adverse consequences according to their characteristics such as where the incident occurred, the severity of the consequence, the type of medication involved, the degree of preventability, who was involved and other such considerations (148, 154, 155, 204, 205). Understanding the characteristics of errors and harm may help identify and target high risk areas (206) for improvement and focus. Indeed, classification criteria and algorithms have been developed to help the understanding of the characteristics of medication errors and harm, such as the use of National Coordinating Centre for Medication Error Reporting Program (NCCMERP taxonomy to classify errors (207) and the Naranjo scale to determine the probability of ADRs (208). As can be seen from these excerpts, stakeholders had consistently observed not just similar numbers, but also characteristics of ADEs, and used these considerations to base their decision on whether medication safety had improved.

Interestingly, despite the many approaches described by the stakeholders and the amount of research into identifying and measuring medication errors and harm to measure medication safety, many stakeholders still did not know whether medication safety had improved. An excerpt which eloquently illustrates many of the stakeholder's views was:

I don't really have any evidence either way, I really don't know. (S30, Expert)

It remains unclear whether medication use is safer today than it was before (17, 20, 209). The continual lack of clarity could be due to many reasons. One possible reason is that the process of identifying then measuring medication errors and harm is difficult and expensive, thus prohibiting measurement. For example, it is recognised that certain approaches such as medical record review are notoriously expensive and time consuming, so are unlikely to be useful outside of a research setting (30, 68). There may simply have been insufficient will to carry out further such studies to identify any possible changes to medication safety. Another simple reason may be that improvement has been slow (19, 20, 209). Previously, it has also been pointed out that methodological challenges, such as subjectivity, add inconsistency to measurement and this may make any measured results not necessarily reliable and negatively impact its interpretation. Although not entirely obvious, it is likely that a combination of reasons contribute to why medication safety improvement remains unclear.

Perhaps, in recognising the limitations of measuring medication errors and harm, some stakeholders spoke about the use of generic safety indicators as a way to measure medication safety instead. For example, stakeholders suggested:

At the end of the day as individuals we're just concerned about the harm aspect. But it could be that you want to measure re-admission rates so there's indirect measures of problems. (S15, Expert)

Length of stay due to medication injury. Death, maybe to, but length of, additional length of stay caused by drug reactions... hospital days, hospital time extended due to medication error, serious medication error, might be quite a good one. (S24, Expert)

Mortality rates, general perceptions of safety in hospital, we're doing okay. (S28, Policymaker)

Standardised mortality rates so that's an outcome, so those are what I'd call definite outcome measures. (S3, Policymaker)

Instead of specifically trying to measure medication errors and ADEs, the approach suggested by these stakeholders was to focus on outcomes which were more definitive. For example, even though medication errors can be subjective, death is not. Notwithstanding, debates about what it means to be clinically dead such as heart stoppage or lack of brain activity, generally, a person is either dead or alive. Focusing on identifying and measuring the number of deaths is thus relatively easy and non-subjective. Other indicators suggested by stakeholders such as length of stay and falls are also relatively easier to identify and measure. For example, such measures commonly feature in overall patient safety and quality measurement and monitoring programmes and can be automated due to electronic records (56, 210).

It is important to note that although many of the aforementioned indicators such as mortality, falls, and length of stay measures do not specifically feature medication related facets (33, 211, 212), they are generally assumed to encompass medication safety facets. For example, Stakeholder 8 expressed:

[Four indicators that should be used to measure medication safety should be] patient falls, bed sores, hospital caught infection, etcetera, sort of stuff. They are all symptoms of a dysfunctional service... On the patient stuff I mean if you want a ward that's got issues around those four things I've talked about, sort of stuff, yeah, medication plays a big part in that, right. If you do independent medication and those four metrics don't move something's wrong, right, 'cause remember medication is part of a suite of intervention that you do to improve the patient health outcomes, right. So if you're doing something in medication and it doesn't move those four indicators, something is wrong with the way it's being done. So those things that you're saying, it's very difficult to have a direct causal link, but intuitively we know that if we are fixing our problem with prescribing the right things, we're fixing the problem by making sure we dispense the right thing, we're fixing the problem by administering the medications that sort of stuff, it must have an impact on those four basic indicators, right. (S8, Policymaker)

If a patient dies from a haemorrhagic event as a result of medication use, such events should theoretically be captured in measures of mortality. If, as a result of poor prescribing of

sedatives a patient falls, such events should also theoretically be captured in measures of patient falls. Thus, Stakeholder 8's views to use broad generic safety measures to measure medication safety were understandable. However, as Stakeholder 8 and others also recognised, establishing association between the medication and the adverse event can be difficult which makes the use of generic safety measures imprecise:

Morbidity and mortality in hospitals are complex events. And it's almost never the, a single event that can pinpoint it. And even with, if there were a single event it's incredibly difficult in a complex system to tease that out as a primary event, unless the person has a very clear anaphylactic reaction to a certain drug. (S20, Expert)

If a patient falls, medications are rarely the only contributory factor. Other factors such as the patient being frail, has postural hypotension, poor nursing care or a slippery floor also contribute and may have played a more significant role in the patient falling. Thus, associating the fall to medication use is difficult. Generally, the physiological resilience of humans to medications makes causality between medication errors and adverse consequence difficult to establish. For example, even if a patient is inadvertently administered a 10 times overdose of a medication, harm may not have occurred. Even if harm does occur, they generally resolve without causing death. Measures which focus on overall mortality may not be sensitive enough to detect instances of poor medication use and medication harm, thereby significantly underestimating true figures of poor medication use and harm caused. On the other hand, the measurement of certain indicators such as patient falls, can conceivably overestimate true figures of medication related harm if contributory factors other than medication play a larger role in a patient falling.

At best, generic patient safety indicators are blunt measures which may provide an indication of overall trends in medication use, but cannot be used to measure medication safety in a precise manner. Yet, the need to measure medication safety in a precise and accurate manner is important especially if there are financial implications tied to performance management. There appears to be room for further research into how medication errors and harm can be more reliably, robustly, precisely and accurately measured. An important, but not yet discussed challenge to measuring medication related harm in a reliable and robust manner is the fact that ADEs occur relatively rarely (51, 62). For example:

When you think about it, the trouble is that quite often with drugs your medication harm might only be 2% and it's significant. I mean, I saw some figures, where did I see it, I couldn't really believe them, that yeah lactic acidosis with metformin. I mean it's bloody rare, it really is and the diabetologists would say that practically it never occurs. And so to measure that is actually not necessarily that easy. It's much easier to say well all diabetics should be on metformin so you can actually figure out what percentage of them are on metformin. To find out how many of them got harmed by the metformin is not quite as easy as it looks... instead of

measuring say the harm of sulfonyureas and all of that sort of stuff that we actually look at HbA1c as a proxy for how well diabetes is being controlled. (S25, Policymaker)

Between 1977 and 2012, 12 reports of lactic acidosis have been reported to the Centre of Adverse Drug Reaction Monitoring (CARM) (213). Approximately 50% of patients who suffer from lactic acidosis as a result of metformin use will die and it is a significant and serious ADE (214). Even though some cases of lactic acidosis can be prevented, for example, by not prescribing medications such as metformin in patients with severe renal impairment, some can also occur as a result of non-preventable ADRs. Regardless of preventability issues however, the incidence of this ADE is very rare occurring only 0.03 cases per 1,000 patient years (214). Lactic acidosis occurs so rarely that it can be difficult to draw conclusions when they are reported. For example, if it occurs one year and not the next, one cannot reliably make the conclusion that safety has improved. As a consequence, Stakeholder 25 believed that to measure and monitor safety it may be easier to measure the beneficial patient health outcomes such as improvements in HbA1c (glycated haemoglobin) which is used to monitor diabetes control. If the physiological measure of HbA1c for the population improves over time, this implies that medications are being used in an appropriate manner since there has been an improvement in health outcomes.

As has been highlighted at the start of this chapter, medication safety also means the optimisation of health outcomes which are beneficial. The excerpt by Stakeholder 25 moves the discussion on to measuring patient health outcomes which are beneficial, such as the use of HbA1c as a proxy indicator to indicate health outcomes. The reframing of medication safety significantly changes the need to measure beyond medication error and harm to measure medication safety. Measuring beneficial consequences will need to be included as part of medication safety measurement. The measurement of health outcomes which were beneficial might help indicate the appropriateness of healthcare, since the avoidance of medication error and harm contributes to overall health outcomes. But importantly, it will also help the determination of whether medication use had actually achieved what it was supposed to— which was to optimise health outcomes.

Some stakeholders specifically recommended that measures used to indicate overall health outcomes should also be used to measure medication safety with some providing specific examples. For example:

Inter-country comparisons, like the top 20 OECD (Organisation for Economic Co-operation and Development) countries and things like comparing them on neonatal mortality and compare them on overall life expectancy, comparing them

on teenage suicides, teenage pregnancies, hypertension control anything you can think of. (S10, Expert)

I think you could choose a few outcomes and I would be interested not only in the harm outcomes but also in some indicators of success. (S3, Policymaker)

Clinical, economic and humanistic measures that are associated with the great majority of outcome studies and the clinical measures are improvement in asthma control, diabetic control, HbA1C improving, less hospitalisations over a given period all of those sorts of things. (S16, Expert)

Measures like overall life expectancy or neonatal mortality are part of the measures used to indicate the overall state of health of a population (215). For example, such indicators are included in the *Health at a Glance* report published by the OECD and the WHO (215). Such reports aim to provide a concise and quantitative overview of health status, determinants of health, healthcare resources and utilisation and health expenditure and financing of various countries (215). Mortality data such as the NZ mortality statistics (216) do more than just show adverse consequences of medication use. Mortality data can also show what people are not dying from, and can be used to monitor trends of how effective medical care have been for a certain disease. For example, there has been a steady decline in the percentage of deaths as a result of cardiovascular disease over the past two decades (216). Although there are many potential confounders such as better diets and more exercise, changes in such trends are likely also influenced by more effective medications and their use and better management of patients with cardiovascular disease.

As has been previously noted, the measurement of beneficial health outcomes implies that medication use has been relatively appropriate and error and harm free. As explained by Stakeholder 14:

There are any number of measures that there are and in the end a lot of countries settle on infant mortality rate, or maternal mortality rate as indicators that that's a good proxy measure of the whole system. If that's low well then the rest of the system must be working quite well. (S14, Policymaker)

The excerpt by Stakeholder 14 implies that because mortality rates are low, one could assume that medication use could not necessarily have been that unsafe. Another assumption in Stakeholder 14's excerpt is that if mortality rates were generally good, the degree of error and harm was relatively inconsequential because if they were significant then they would have been identified through a higher mortality rate.

Despite the assumptions associated with the measurement of beneficial health outcomes, and similar to generic patient safety measures, mortality rates may not be precise or accurate enough to identify changes to medication errors and harm. For example, even though the

measurement of beneficial health outcomes such as deaths from cardiovascular events may show a trend which is improving, emerging safety concerns from medications and their use may not necessarily be highlighted. For example, incidences of bleeding as a result of the introduction of dabigatran which is a new anti-coagulant medication have occurred (217). Even though 78 episodes of bleeding were reported, no one died (217) and so will not feature in cardiovascular mortality data. A sole focus on measuring health benefits may potentially miss significant and important safety issues relating to medications. As has been highlighted at the start of this thesis, patients should not be harmed by the medical care intended to help them. Even 1% of errors leading to harm can be, and should be, deemed unacceptable (154). The measurement of only beneficial outcomes may under recognise the significance of adverse consequences.

Moreover, as has been previously shown, medication errors occur frequently in hospitals. Even though many are inconsequential and do not lead to harm, administering wrong medications or in the wrong way are undesirable instances which demonstrate failures in the medication use process. The sole measurement of beneficial health outcomes may not detect such failures, because harm does not occur or benefits obtained overshadow rare events. Health outcomes may have also become progressively better as a consequence of initiatives not necessarily related to traditional domains of healthcare or medication use, such as clean water or better warmer houses. Thus, improvements to patient health outcomes do not necessarily indicate that medication use has become better or safer either. There has also been a lack of research into the use of beneficial health outcomes to measure medication safety, which makes determining exactly which measures to use or their utility to medication safety unclear. Even though beneficial outcomes are important, these reasons suggest that much more research is required.

It is important to note that the measurement of beneficial health outcomes is not more or less important than the measurement of medication errors and harm to measure medication safety. Throughout this chapter, and again emphasised here, is that both facets need to be measured to ensure a more balanced view of medication safety. In the literature, and for the majority of stakeholders, it was clear that there has been a traditional focus on measuring medication errors and harm to measure medication safety. Such views are understandable, because the imperative to not harm patients by the medical care intended to help them is strong. Even if no harm occurs, medication errors are undesirable. Harm that occurs, regardless of whether it was due to an error or not, is also undesirable and should be targeted for measurement then further improvement.

Importantly, the benefits associated with medication use should also not be neglected. Conceptualising medication safety as including the optimisation of health outcomes which are beneficial is important, because there is no point in using a medication if no benefits are expected, regardless of whether its use was error or harm free. Using a medication with no benefit places the patient at risk of unnecessary error, harm and waste for no apparent benefit. This subtle but important reframing of medication safety to include both adverse and beneficial consequences significantly impacts the target of both improvement and measurement of medication safety.

The measurement of adverse consequences such as medication errors and harm is difficult and faces many challenges. Subjectivity, causality and costs are just some examples of such challenges. Despite these challenges, the measurement of adverse consequences is important because they serve to highlight issues of poor safety and they highlight areas in need for improvement. The measurement of error and harm brings attention to the general public about poor healthcare and provides a compelling reason for improvement. The measurement of beneficial outcomes is useful and will help to measure medication safety in a more comprehensive manner, and will fit with how the concept has been conceptualised by stakeholders. Furthermore, the measurement of beneficial health outcomes to measure medication safety will help determine whether medication use has done what it was intended to do.

The excerpts by stakeholders which have been complemented by the literature show that the health outcome goals of medication safety are important to the measurement of medication safety. Both adverse and beneficial consequences of medication use need to be measured to provide a more comprehensive view of medication safety. It is important to note that the sole measurement of outcome goals of medication safety to measure medication safety is not enough. As this thesis will show over the next few chapters, other dimensions also need to be considered to measure medication safety in a holistic manner. However, at this point it is important to recognise that the dimension of outcome goals of medications should be measured.

Emergent finding 2: Financial costs and effectiveness

An important part of the dialogue on medication safety measurement was on financial costs and effectiveness. In this chapter, excerpts will be used to illustrate how this dimension emerged from the interview data. The importance of this dimension and how it can be measured will be discussed later in this section (see Chapter 4: Emergent finding 2B).

A) Emergence from the interview data

An interesting finding was that medication safety meant the need to consider financial costs and choosing the most cost effective treatments and interventions. For example:

We all live in a resource constrained world and if you're committing resource it's limited. Let's say ensuring that we never ever make any kind of medication mistake but yet the health benefit of that is negligible. Then actually we've done a disservice to patients in general because actually you haven't been able to use that resource to deliver some other kind of care or whatever. (S26, Policymaker)

From a government's perspective it's a cost effectiveness issue, that the funding that we're advancing is meeting, broadly, the needs of the population... if you say it's [medications are] going to work these wonders for this group of patients, well let's see some demonstration ... from where I sit it will be a bit of all of the above [avoidance of medication error and harm and other facets] plus from a value for money perspective. (S28, Policymaker)

These excerpts were important because they highlight the important yet commonly missed consideration of financial costs and cost effectiveness in discussions on medication safety. The inclusion of financial costs and effectiveness facets in the conceptualisation of medication safety has significant implications. It reframes what medication safety means. In existing literature, a safe medication system has traditionally been regarded as one which avoids medication errors and harm (1, 9). In the previous chapter, the outcome goals of medication safety dimension (clear from stakeholder views) was that medication safety meant more than the avoidance of error and harm. Instead, there needs to also be a consideration of whether beneficial health outcomes were achieved.

Emergent from the excerpts above, the conceptual boundary of medication safety is expanded even further. A medication system is now only safe when it avoids medication errors and harm, has optimised patient health outcomes and has done so in a cost effective manner. To better illustrate how financial costs and effectiveness have implications on medication safety outcome goals, and why if these facets are not considered then the medication use system may be unsafe or less safe, consider vignette one:

A hospital receives a grant of \$10,000 to spend on improving medication safety in terms of the reduction of ADEs. It is up to the hospital to choose how it plans to spend this money. After extensive discussion, two interventions were chosen for implementation consideration. One is intervention A and one is intervention B. After an extensive literature review, it appears both interventions are equally effective at preventing ADEs. The point of difference is cost. Intervention A costs \$1,000 per ADE prevented per 100 admissions. Intervention B cost \$2,000 per ADE prevented per 100 admissions. This would mean that for \$10,000, intervention A could reduce 10 ADEs per 100 admissions while intervention B could reduce 5 ADEs per 100 admissions. Even though the vignette was discussed in the context of medication safety improvement interventions at a system level, the vignette can also be applied to the context of medications such as medication A and medication B.

The rarity of ADEs and ADE prevention being speculative are examples of issues which make the above vignette oversimplified. However, the important point of the vignette is to illustrate that if financial costs and effectiveness were not taken into consideration, there can be undesirable implications on medication safety. For example, choosing intervention B over intervention A would have resulted in a medication use environment which was arguably less safe. This is because five more ADEs were occurring in the system which could have been prevented by Intervention A given the same amount of money.

Even if given the rarity of ADEs it was not possible to reduce ADEs more than 5 per 100 admissions, the same level of benefit or safety could have been achieved using only \$5,000. This would mean that the remaining money could be better spent on other interventions which may provide other forms of utility. For example, this money could be directed to other interventions, such as new technology which decreases the turnaround time for blood tests. As Stakeholder 26 noted in the previous excerpt, the consideration of financial costs and effectiveness is important because resources used for one thing cannot be used for another—this is termed the opportunity cost (218). The consideration of financial costs and effectiveness requires a broader level of consideration, but clearly has implications on influencing medication safety and the avoidance of adverse consequences.

Conceivably, if all resources were directed to reducing adverse consequences and somehow all adverse consequences were completely eliminated, but came at the expense of the inability to afford medications to treat modifiable disease, then the environment is also not safe because net positive consequences are not being optimised. There is a need to not just solely focus on reducing adverse consequences, but rather there is a need to consider the broader net beneficial outcomes to provide a more balanced view. To illustrate this point consider vignette two:

A hospital receives a grant of \$10,000 from an anonymous benefactor without specifying the condition in which it is spent. Group A wants to spend the \$10,000 on implementing a new intervention thought to be able to prevent one person out of every 50,000 patients treated from dying unnecessarily from an ADE caused by the administration of a wrong medication. Group B wants to spend the money on buying essential medications which could benefit patient health outcomes by preventing one person from every two patients treated from dying unnecessarily from a modifiable disease.

Vignette one differs from vignette two because vignette two considers a broader net benefit than the avoidance of adverse consequences alone. For example, if the figures were applied to 100,000 patients treated each year, the benefit gained from resources allocated to group A would be 2 deaths prevented per year. Whereas, if resources were allocated to group B, the benefit would have been 50,000 deaths prevented per year as a consequence of the disease. If group A was allocated the resource, then the occurrence of 49,998 deaths could have been prevented—a scenario which also appears unsafe. The discussions and vignettes so far have been important because firstly they support the notion outlined in the previous dimension that net beneficial health outcomes should be considered as part of the outcome goal of medication safety, but also, that these financial costs and effectiveness considerations have significant implications on medication safety and its outcomes. There is a need to think more broadly about medication safety than just the avoidance of medication errors and harm, as has been traditionally thought of in the literature.

Stakeholders' focus on the need to consider financial costs and effectiveness when medication safety and its improvement were discussed was understandable. A significant proportion of a nation's annual gross domestic product (GDP) is spent each year on healthcare and the proportion spent is continually rising (219-221). The New Zealand Treasury estimates that health expenditure as a proportion of GDP is estimated to double from 6% in 2000 to 12% in 2050 and has stated that this is not sustainable (222). Instead of spending more money, there is a need to ensure that resources available for use are more effectively spent and in a manner which offers the greatest utility and value for the least amount of money (223). Applied to a medication safety context, Stakeholder 27 eloquently expressed:

There's a level at which you basically have to say enough's enough. Where we can't reduce our error rate any more. Or we have to wait until technology is cheaper so that we can afford it [medication safety improvement initiatives]. You can't divorce the pursuit of safety from all opportunity costs. There's a balance. (S27, Policymaker)

Stakeholders recognised the importance of considering financial costs and effectiveness in medication safety discussions, because there may be no additional or only minimal utility associated with further increases in investment toward its improvement—this is termed diminishing marginal utility (218). Even though the avoidance of adverse consequences should be a priority and needs to be improved upon, it is important to also recognise that this cannot be achieved at all costs.

The excerpts so far have been interesting because the inclusion of considering financial costs and effectiveness in the conceptualisation of medication safety expands how the concept has traditionally been considered. Even though financial costs and effectiveness considerations do feature for some medication safety interventions such as medication reconciliation (224), they are relatively rare (9, 225). Financial costs and effectiveness facets have seldom been considered during discussions on medication safety (226). For example, the literature defines medication safety as “freedom from accidental injury during the course of medication use; activities to avoid, prevent, or correct ADEs which may result from the use of medications” (1, 9). At no point does financial cost or effectiveness feature in this definition.

Literature on medication safety has typically focused more on what the intervention is about, the problem being addressed, the various interventions that can help and the effectiveness of the intervention at reducing medication error or harm (1, 82, 83, 227). An observation of the literature suggests that determining whether the intervention was effective in improving medication safety, in terms of medication errors and harm, is generally more highly prioritised than determining whether they were financially cost effective.

The discussions in this research so far do not detract importance away from the goals of avoiding errors and harm and optimising beneficial health outcomes. Instead, research findings suggest there is a need to also consider financial costs and effectiveness in medication safety dialogue. Emerging from the interview data, medication safety meant the need to consider financial costs and choosing the most cost effective treatments and interventions—this has been labelled as the financial costs and effectiveness dimension. This dimension is important to be considered when medication safety is discussed because it impacts medication safety and the achievement of its outcomes. A sole focus on improving medication errors and harm without the consideration of financial costs may create unintended and net negative consequences or a situation where net positive consequences are not being optimised. Beneficial outcomes gained and financial costs and effectiveness need to be considered to provide a more balanced view of medication safety.

In the literature there has been a predominant focus on the avoidance of adverse consequences, and a lack of focus on the beneficial effects of medication use and financial costs and effectiveness. This needs to change. The findings from this research significantly reframe how medication safety should be conceptualised. The impact of this reframing means that the improvement of medication safety now needs to not just improve outcome goals, such as the reduction of adverse consequences or the optimisation of health outcomes, but they must be done so in a cost effective manner. This means that the measurement of medication safety will also need to take such findings into account and expand what needs to be included in measurement. These will be discussed in the next few pages.

B) Importance of measuring the financial costs and effectiveness dimension and how it could be measured

Financial costs and effectiveness clearly emerged from the interview data as a dimension important to stakeholders when medication safety was discussed. If medication safety was to be measured, it was likely that stakeholders were also interested in measuring financial costs and effectiveness. In fact, some stakeholders explicitly and specifically spoke about the importance of quantifying the financial costs of adverse consequences of medication use, such as those relating from medication errors and ADEs.

I mean one of them [medication safety measures] has got to do about cost of the system. He [in relation to the researchers of the NZQHS (161, 194, 228)] said the average medication, the average error, prolonged the hospital stay by seven or eight days or whatever it was. What that translates into is cost. (S14, Policymaker)

If they had to be ventilated [as a result of an ADE], let's say, you might want to put a cost, a dollar cost on that. Surplus dollars cost, so it might be time. Surplus dollars cost due to things, would be of interest. (S24, Expert)

Some stakeholders specifically spoke about the need to have information relating to cost effectiveness so that informed decisions could be made about which intervention to fund and allocate resources toward:

There has to be some sort of economic evaluation, or of the cost of the service, what are the potential cost savings, what's the cost of the alternatives... So when X DHB wanted an evaluation of Y services what they had in mind was, is this something worth us investing in the future? Is it going to give us some real health returns? Is it going to save us some money? Which is probably the question that politicians and funders would ask about any new service. (S16, Expert)

Clearly, stakeholders were of the view that the measurement of financial costs and effectiveness information should be included as part of medication safety measurement. Before discussing how financial costs and effectiveness can be measured, the reasons for why it was important to measure financial costs and effectiveness to measure medication safety will

be discussed. One reason which emerged from the interview data was because financial based measures are simple to understand and resonate with experts and the general public alike. For example:

So you need to have that [financial measures of medication safety] because people don't understand the subtleties of these complex metrics. (S14, Policymaker)

Measures relating to financial costs and effectiveness were thought to be more intuitive to understand. The use of financial cost measures can translate potentially complex measures of medication safety into a single understandable common denominator. For example, the general public may not easily understand measures, such as percentage of patients at high risk of venous thromboembolism that receive appropriate prophylaxis (229). This measure is useful for indicating whether medications such as enoxaparin were appropriately used at the right time and in the right way. But to better appreciate the value of this measure, one needs to first be aware that venous thromboembolism is a potentially fatal complication of hospital admission (230). One also needs to know that there is widespread underuse of prophylaxis medication use and thus a major safety problem (230). This is not to suggest that such a measure cannot be understood by the general public, but rather that more explanation may be required. Instead, measures such as 'the underuse of venous thromboembolism cost an additional X million dollars to the healthcare system' may more easily resonate with and be understood by the general public.

Indeed in the literature, mortality and financial costs data have commonly been used to headline and bring attention of medication safety issues to the general public. For example, 44,000–98,000 patient deaths each year from medical related injuries and the analogy of a jumbo jet crashing each day have provided the tipping point for quality improvement in healthcare (231). Based on landmark studies such as the NZQHS (228, 232) and the HMPS (195), the financial costs of these adverse consequences have been calculated and have been shown to be costly. For example, in the US the average additional hospital cost associated with an ADE ranges between US\$1,939–\$2,595 per case (1, 160, 233). Extrapolating these figures to all hospitalised patients in the US, the additional hospital costs were estimated to be approximately US\$1–4 billion dollars (1).

In NZ, where the incidence of medical related injury is similar to those identified in studies around the world (1), the cost of preventable adverse events has been estimated to cost an additional NZ\$590 million, representing 30% of public hospital expenditure (161). The discussion on how these costs were calculated along with their challenges will be discussed later in this chapter. For now, it is important to note that these landmark studies have been

credited with bringing the problems of healthcare to the attention of the general public (19, 26, 234). It is difficult to ignore the adverse consequences of medical care and medication use when there are such significant implications on both morbidity and financial costs.

A better appreciation and understanding of the significance of medication safety problems was thought to be able to influence mind-sets, attitudes and behaviours which prioritise medication safety for action and improvement. For example:

'Cause I mean what you want to do is get the managers interested in this sort of stuff and the only thing they're going to be interested in is the cost, so if you say, "Well actually medication errors are important 'cause it costs you money", then they're going to say, "Okay, let's put a few resources into that"'. (S24, Expert)

Stakeholders believed financial costs information has the ability to help positively influence peoples' behaviours, especially managers and funders, to one which was committed to improving medication safety. Such measures could help prioritise medication safety for improvement by providing an impetus for resource allocation. The initiation of increased effort towards the improvement of medication safety may then result in actual reductions in adverse consequences and improvements in beneficial outcomes.

Importantly, as had been previously noted by Stakeholder 16, stakeholders also spoke about the importance of measuring financial cost information relating to cost effectiveness so they can make evidence-based decisions about which medication safety improvement interventions to allocate resources to. Generally, the total costs saved from implementing the intervention can be compared against the costs spent in implementing and using the intervention to give an indication of the cost effectiveness. Such calculations can be used to assess different types of interventions or medications in order to provide comparisons between interventions.

Financially related information on different interventions is important because as has been previously discussed at the start of this chapter, there are limited resources available for use. There is need for information which can inform the choice of intervention which provides the best value for money (223). Even though the consequences of poor medication safety are costly, interventions to improve medication safety like computerised physician order entry (CPOE), are also often costly and forms one of the barriers to their implementation (235-237). Those with fiscal responsibilities are likely to require financial justification of proposed interventions to improve safety, and whether financial returns would accrue before allocating funds towards its implementation (226, 238). The ideal intervention would be one which improved safety at a lower cost as compared to other interventions or usual standard of care (225).

Even once interventions have been implemented, the measurement of financial costs and effectiveness information was also thought to be useful for governance and accountability purposes where there is a need to justify healthcare interventions implemented and demonstrate their value (189, 239). For example:

Pyxis® technology, automated drug distribution technology should be used, it saves money. In the first year post implementation at Hospital A, we saved 1.2 million dollars in drugs costs [from wasted and expired medications]. If you take off 440,000 dollar leasing costs that it cost us at the time, it's still [700 and] 60,000 dollars. You can't argue with that. (S23, Expert)

I guess you're showing the tax payer that they're getting value for the technological input [medication safety interventions such as CPOE]. (S6, Policymaker)

Pyxis® is one brand of automated dispensing cabinets which is commonly recommended to reduce medication errors associated with picking the wrong medication (83). Such systems may also help ensure medications are appropriately stored and allows electronic dispensing of medications in a controlled fashion and tracks medication use thereby potentially reducing waste (83). Stakeholder 23 claimed that at their hospital there was a net saving of NZ\$760,000 from the reduction of wasted or expired medications as a consequence of implementing the intervention. Such figures are impressive, and notwithstanding discussions about whether there were actually any implications on safety, how such savings were calculated, costs of unintended consequences or what other costs were not included it serves to highlight and justify medication safety interventions that have been implemented.

The measurement of financial costs and effectiveness information can also be used to further positively reinforce attitudes, mind-sets and behaviours committed to improving medication safety once improvement efforts have been initiated. For example, stakeholders expressed:

Look here! All the initiatives and the money that we put into this electronic prescribing have had this effect, it was so much and now it's so little. (S14, Policymaker)

If you can say to staff here "Hooray we prevented that error therefore that has saved us five million for this next year", that's quite an incentive. (S13, Consumer)

Clear from the excerpts and discussion so far, measuring financial costs and effectiveness is important to the measurement of medication safety. The measurement of this dimension was thought to serve the purpose of quantifying the financial costs of adverse consequences to help bring attention and improvement to the medication safety issue. They can be used to shift attitudes, mind-sets and behaviours toward improving medication safety. They can also be used to help choose the most cost effective intervention, justifying interventions that have been funded for and reinforcing positive behaviours and efforts towards medication safety.

Despite all the espoused benefits of measuring financial costs and effectiveness facets, interestingly, these facets do not often feature in medication safety measurement literature. For example, financial costs and effectiveness measures do not commonly feature in existing medication safety measures such as the MSSA tool (32), the Patient Safety Indicators for Medication Safety (AMTS-PI) (33) or other commonly used tools which specifically measure medication safety (21, 25, 29, 30, 229). Additionally, despite an extensive amount of literature on medication safety and its improvement, comparative economic evaluations of various improvement strategies are relatively rare (226). Many highly promoted improvement strategies have not been subjected to comparative economic analysis and evaluation (225). When they are performed, researchers in the literature suggest that there are gaps in costing methodology (238), have low data quality, a lack of transparency and often narrow economic perspectives (225). There is uncertainty about which improvement strategies offer the best value (225, 240).

The lack of focus on financial costs and effectiveness facets in the literature on medication safety and its measurement was explained by one stakeholder:

We're driven by the theory that as quality goes up costs come down. (S17, Policymaker)

As can be seen from this excerpt and through observations of the literature, there appears to be an implicit assumption that the improvement of safety would reduce costs. Such assumptions as expressed by Stakeholder 17 are based on the fact that ADEs and errors are costly (160, 241-243), and thus by improving this facet, there would be cost saving implications (244). Thus, if medication safety measurement showed an improvement in trends then unnecessary additional costs should be reduced anyway (245). Interestingly, even though a reduction of error and harm has commonly been thought to be associated with a reduction in costs, there appears to be little evidence in the literature to support this assumption (245).

There may be other reasons why existing literature on medication safety measurement has not focused on financial costs and effectiveness facets; however, this is an area that requires further research. Nonetheless, there are limited resources and growing healthcare needs and wants. As has been discussed previously, there is a need to measure financial costs and effectiveness because such facets have implications on medication safety and its improvement. Stakeholders clearly regard such facets as important for medication safety measurement and frequently spoke of the need for their inclusion. Given that financial costs and effectiveness is an important dimension for measurement when measuring medication safety, there is a need to

better understand how this dimension can be measured. Along the way, some of the challenges to measuring financial costs and effectiveness will be discussed.

To calculate financial costs of adverse consequences, studies typically first identify the incidence and occurrence rate of ADEs in a representative sample population using retrospective medical record review. Once ADEs have been identified, they are further classified into categories such as those which are preventable. The general approach to estimating costs typically identifies the additional resources used as a consequence of the ADE, then applies a cost to those resources and is known as direct costs (161). For example, as spoken about by Stakeholder 14 and 24 at the start of this chapter, studies may identify the number of additional bed days attributable to the ADE, the type of ward the additional bed days were attributed to because certain wards cost more to stay in than others, and any additional procedures the patient may have received as a consequence of the ADE such as additional tests or treatment such as mechanical ventilation as noted by Stakeholder 24 (161).

Depending on the study and ability to track specific consumable resources, these may or may not be included. Some studies may include indirect costs such as lost wages or productivity losses (218), though not all do (161). In studies where indirect costs have been included, they can make up a substantial proportion of costs calculated. For example, in a US based study, of the total costs that were estimated as a result of an adverse consequence, 48% of were attributed to indirect costs (246). Such variations can make direct comparisons challenging so there is a need to make sure similar costs are being compared. It is important to note that those stakeholders who identified economic costs as an important measure of medication safety talked (almost) exclusively about direct costs to the health system. The impact of error or harm on indirect costs was not well articulated by stakeholders, but remains an important consideration in any mechanism to measure the financial effect of the impacts of medication safety.

Understanding how financial costs of adverse consequences have been calculated is also important because it forms the basis for determining whether one intervention was more cost effective—information which was also thought to be important if medication safety was to be measured. Because many medication safety interventions are attempting to avoid or minimise ADEs (1, 82, 83), the approach to calculating financial costs and effectiveness is to calculate the resultant costs which would have occurred if the intervention was not present. Of course, there is also a financial cost associated with implementing the intervention itself, so these need to be taken into account to determine cost effectiveness (218). For example, direct costs such as the purchase of equipment which are known as capital costs and the direct cost of resources

used to provide and use the intervention such as labour which are known as health services cost (218). There is also a need to measure the indirect costs but some studies do not (161). The total cost of implementing the intervention can be compared against the benefits obtained from the intervention to determine cost effectiveness information.

Despite the seemingly straightforward task of calculating financial costs and effectiveness information, it is actually quite hard to do and subject to debate and assumptions. For example, if the goal of the medication safety intervention was to prevent medication errors and harm, this first requires a good baseline data from which to compare against. However, as has been noted in Chapter 1: emergent finding 1B, the measurement of error and harm is subject to challenges such as poor reliability and subjectivity. Without a robust and reliable baseline measure, changes to rates of error and harm may be due to methodological differences rather than reflect actual improvements. If financial costs were applied to such data, this may give unreliable figures. Different contexts, different approaches to costing, adjustment required for inflation or less expensive technology, timescales used and other challenges further complicate direct comparison between interventions (245), and means that one needs to be careful when interpreting and comparing between interventions to determine which is more cost effective.

Measuring the financial costs and effectiveness dimension to measure medication safety can be challenging. They have not been encompassed in the majority of existing literature on medication safety measurement. However, information on such facets is crucial. Measuring the financial costs and effectiveness dimension can be used to illustrate the significance of the medication safety issue in a manner which is simple to understand and resonates with people. They can be used to shift attitudes, mind-sets and behaviours toward improving medication safety. Financial costs and effectiveness information is also needed for comparing between interventions to determine which provide maximal benefit at the lowest cost. Such data is needed because healthcare resources are limited and choosing non-cost effective interventions has implications on medication safety. Once the intervention has been chosen, financial costs and effectiveness information is still useful because it can help reinforce positive medication safety behaviours and help justify the continued funding of the intervention.

The findings so far suggest that in order to measure medication safety in a holistic manner, measurement will now also need to consider financial costs and effectiveness facets. The measurement of financial costs and effectiveness to measure medication safety is indirect and by its very nature, complex, but is intuitive to understand. Measuring financial costs and effectiveness to measure medication safety is important because it provides a simple to understand common measure for both experts and the general public. It is also important

because medication safety means more than just the achievement of outcome goals, but whether these were achieved in a cost effective manner.

Emergent finding 3: Medications and their use

An important part of the dialogue on the measurement of medication safety focused on the intrinsic pharmacological nature of medications available for use and the manner in which medications are used. In this chapter, excerpts will be used to illustrate how this dimension emerged from the interview data. The importance of the dimension and how it can be measured will be discussed in Chapter 3: emergent finding 3B).

A) Emergence from the interview data

Stakeholders believed that technological advancements have meant that ‘cleaner, better, safer’ medications, as noted in the excerpts below have become available, and this meant that medication safety had improved over the past 10 years. For example, stakeholders expressed:

Yes... we're using actually intrinsically safer medications in many instances, some of the more dangerous medicines have gone... the drugs we use today are way cleaner, safer and better than the ones I started out on. (S3, Policymaker)

It's a lot better than it was 10 years ago, I mean it's a lot better than it was 10 years before that... every new pharmacological agent introduced clearly has to be an advance of what was there previously, otherwise no point in introducing it. (S16, Expert)

Stakeholder 3 explained why a change to the intrinsic pharmacological profile of medications available for use would influence medication safety:

I mean take halothane, dangerous drug, causes halothane hepatitis... post anaesthetic hepatitis you'd have to call it 'cause it wouldn't be due to halothane now, it's virtually unknown, whereas it was actually quite a common problem. So you look at propofol versus thiopentone it's a way better drug, much safer in every respect... [a person had] swallowed a whole bunch of amitriptyline. Ended up three days in intensive care being monitored with tachycardia. A genuine risk of disaster. You could probably get away with swallowing a whole lot of SSRIs [Selective Serotonin Reuptake Inhibitors] without the same risk. (S3, Policymaker)

“Cleaner” was discussed in the context of target specificity. For example, SSRIs specifically target the pathways thought to be involved in depression, whereas tricyclic anti-depressants (TCA) tend to also affect other pathways not involved in depression resulting in adverse effects (247). “Better” was discussed in the context of a medication having more desirable pharmacological properties for a particular condition. For example, relative to thiopentone, propofol has more advantageous pharmacological properties like rapid onset and shorter duration of effect (248). These effects are more beneficial in neuroanesthesia where rapid rousing is required (248). Stakeholder 3 and 16 believed the intrinsic pharmacological profiles

of medications available today are generally ‘cleaner’ and ‘better’ than before and the consequence of this has been improvement of medication safety.

Improved medication safety as discussed by Stakeholder 3, referred to a reduction in ADEs. Halothane is a medication used in anaesthesia. Even though appropriate use may minimise halothane’s toxic effects on the liver, ADEs can still occur as a result of its intrinsically risky pharmacological profile (249, 250). The availability of newer and more technologically advanced anaesthetic medications have largely reduced such ADEs when they have been used appropriately (249, 250). The replacement of thiopentone with propofol was another example provided by Stakeholder 3. Thiopentone is a barbiturate medication with sedative and anti-epileptic effects (248). Propofol has largely replaced the use of thiopentone and the benefits of this change include fewer adverse effects such as nausea, vomiting and improved haemodynamic stability (248). If one assumes that medication use was appropriate with both older and newer medications, then indeed, the availability of these newer medications appear to have reduced ADEs and thus the improvement of medication safety over time.

Stakeholder 3 also mentioned that even when medications are used inappropriately, newer medications available for use may still reduce the number and severity of ADEs. Stakeholder 3 gave the example of SSRIs. In the treatment of depression, SSRIs such as citalopram have largely replaced TCA as the first-line treatment of choice (251). Even when SSRIs are inappropriately used, such as during suicide attempts where a large amount of the medication may have been ingested, ADEs that occur are less detrimental than if TCAs were inappropriately used (251).

Interestingly, when discussing whether medications and their use were safe, the pharmaceutical quality of the medication in terms of manufacturing was not specifically discussed by stakeholders. Cases of counterfeit medications (252) and contaminated injectable methylprednisolone acetate resulting in meningitis outbreaks in the US (253) are clear illustrations of the importance of pharmaceutical quality of medications on morbidity and mortality. When stakeholders were explicitly asked about why the pharmaceutical quality of the medication was not spoken of when conceptualising medication safety, stakeholders explained:

I had assumed that we were starting from a quality control production point... the manufacture of them, you assume that there’s good manufacturing process controls there. (S2, Consumer)

Obviously if something goes wrong in the manufacturing process, clearly you want that feedback to the manufacturer. But those processes are so mind-blowingly well

documented and checked and double checked, the error rate is going to be pretty damn low. (S27, Policymaker)

These excerpts are important because they show stakeholders' conceptual boundaries of the medication safety concept. The manufacturing process and the pharmaceutical quality of medications are regularly and strictly scrutinised by pharmaceutical companies themselves and organisations such as Medsafe—an organisation responsible for the regulation of medicines in New Zealand (254). Even though stakeholders recognised the importance of good manufacturing processes and the medications available for use being of high quality, stakeholders did not necessarily or explicitly consider these points because it was assumed that medicines were of a safe pharmaceutical standard. Despite these assumptions, it is clear how the poor pharmaceutical quality of medications can significantly impact health outcomes in patients, and should thus be an important consideration of medications available for use.

For the many reasons described above, it is understandable why some stakeholders believed that the availability of newer medications with better pharmacological profiles have reduced the risks, severity and occurrence of ADEs, thus contributing to medication safety and its improvement. However, it is important to note that not all stakeholders believed the changes to the intrinsic pharmacological nature of medications available for use had necessarily improved medication safety. A valid point raised by stakeholders was that the availability of new medications simply means new risks and threats to medication safety. For example, stakeholders expressed:

It's a difficult one, because some of the drugs have got more potent so the potential risks are greater. (S1, Expert)

It's about the same... I guess we've got a lot more effective drugs, and I guess if a drug's effective then it's potentially harmful. (S24, Expert)

Introducing a whole lot of new risks associated with those new medicines... And as we move into a sort of cancer treatment and immune modulation and so on the risks with these drugs are pretty high. (S16, Expert)

Several immune modulating medications such as monoclonal antibodies have been developed in recent times (255). Their development has advanced the treatment of conditions like cancer and rheumatoid arthritis (255). Providing a counter-point to the beneficial effects of new medications has been the discovery of various long term risks and harm (255). Some examples include the onset of particular type of cancers or the reactivation of hepatitis B causing potentially fatal hepatitis (255, 256). Safety, in terms of the incidence of harm caused by medications as previously discussed may not necessarily have improved. There may simply have been a reduction of one type of harm while other types of harm have increased.

Changes to the pharmacological profile of medications available for use were also thought to have become more complex, and this was perceived to have increased the likelihood of error and harm during their use. For example, in relation to determining whether medication safety has improved, stakeholders expressed:

Medications are becoming more complex. So whether overall it's safer in that context I don't know, but it's getting more complex. (S10, Expert)

Yes and no... new uses of old medicines, new medicines and it's all become a lot more complex. (S15, Expert)

As medical knowledge grows there are now more considerations for clinicians to take into account which can make medication use seemingly more complex. Using the previously discussed monoclonal antibodies as an example, baseline liver function testing, hepatitis screening and other factors need to be considered before they are used (256). Add to these dosing, duration of therapy, pharmacoeconomic (257), pharmacogenomics (167) and other considerations it is understandable why some stakeholders believe that medications available and their use have become more complex. Adding to the complexity has been the proliferation of the number and types of medications available for use. Diseases that were previously untreatable can now be prevented or treated with new medications, which means clinicians need to additionally consider and keep abreast of these new developments to provide optimal care to patients. For example, stakeholders expressed:

[Whether medication safety has improved]It's about the same... there are more drugs we give people. I mean take for example myocardial infarctions, 30 years ago a patient was put in bed, now they're given anti-coagulants, they're given beta blockers, they're given ACEI [Angiotensin Converting Enzyme Inhibitors], they're just given a whole, they're given three or four drugs as part of an acute admission, so the treatments have got much more sort of complicated. (S24, Expert)

I don't know that we have [improved], we don't have that information to say that... I think the medication use has got more complex, there's a lot more medicines being used than 10 years ago. (S22, Policymaker)

Increasing complexity, additional medications becoming available for use, and additional steps during the medication use process was thought to negatively influence medication safety because patients are more frequently exposed to the risks and adverse effects of medications. Risks and harm can arise from the medication itself such as allergic adverse drug reactions to a certain medication, or errors during the medication use process such as the wrong medication being given. As described by Stakeholder 24, the advancement in medical knowledge on disease and treatment has meant that treatment has changed from one that was predominantly conservative and simple, such as bed rest, to one involving multiple parts and is complicated. Medications such as anti-coagulants, beta blockers and other drugs are now being used when

they weren't before. Despite the benefits associated with increased knowledge and therapies, paradoxically, the advancement of medicine has been perceived by some stakeholders to be associated with poorer safety because patients are more frequently exposed to risks associated with medication use.

The excerpts so far suggest that even though the intrinsic pharmacological profile of medications is important, it is not the sole influence of medication safety. In the previous chapter, "Outcome goals of medication safety" for example, many stakeholders conceptualised medication safety as the six rights of medication use. Despite the six rights being categorised within the outcome goal of medication safety dimension, fundamentally, the six rights focus on the correct use of medications. An assumption held by stakeholders is that if medications are used correctly in an appropriate manner then the likelihood of harm is low. As can be observed from the discussions in this chapter, additional medications and complexity involved in medication use can also affect how medications are used and thus safety.

One example which highlights the importance of the manner in which medications are used despite a reputedly better intrinsic pharmacological profile, was the introduction of dabigatran into the NZ healthcare environment. Warfarin has long been the anti-coagulant treatment of choice for patients with atrial fibrillation. Even though effective, warfarin has multiple medication and food interactions (258). Bleeding associated with warfarin is one of the most common types of ADEs that occur (258). The consequence of such problems with warfarin has made it a medication commonly deemed a high safety risk (206). Such problems have led to the development of alternative anti-coagulants which are reputedly better.

One such anti-coagulant is dabigatran, which was introduced on the premise that it had fewer interactions with food and medicines, was more convenient to use and had more reliable anti-coagulation effects and was therefore potentially better than warfarin (258). Indeed, in the clinical trial setting where the use of the medication was monitored closely, dabigatran at a certain dose showed lower incidences of major haemorrhage while maintaining similar efficacy in patients with atrial fibrillation (259). However, when dabigatran became available in the NZ healthcare setting, the perceived benefits created an under-appreciation of the risks involved which resulted in a number of haemorrhagic incidents (217). Conceivably, a perceived 'safer' medication unintentionally led to complacency in vigilance and awareness characteristics in healthcare professionals resulting in poor use of dabigatran. Dabigatran is a good example which illustrates the importance of using medications in an appropriate manner, regardless of the intrinsic pharmacological profile and the effects it can have on medication safety.

The example of dabigatran also illustrates the importance of regulatory bodies, such as Medsafe and PHARMAC (Pharmaceutical Management Agency), at influencing the medications available for use in a particular setting. Dabigatran was deemed to be intrinsically and pharmacologically safe enough for it to be approved for use in NZ by Medsafe (260). PHARMAC, an organisation whose remit is to determine which medications are funded for use in a manner which maximises health outcomes from the money spent by the government on medicines (261), made dabigatran fully funded without restrictions in 2011 (260, 262). The decision to fully fund dabigatran without restriction appears to have significantly influenced the use of dabigatran with approximately 7,000 patients being started on the medication in the first two months (217). Even though other factors such as lack of prescriber knowledge in how to use the medication in an appropriate manner confound the exact reason for why there had been over 78 incidences of haemorrhage over a 2 month period (217), the decision to freely fund dabigatran without restriction may have played a part. In this case, making a medication with a better intrinsic pharmacological profile too freely available for use, and without appropriate management in how it should be used, had potentially led to adverse consequences on medication safety.

Conversely, medication shortages or the lack of availability of medications for use is also important to medication safety. For example, in relation to what should be measured, stakeholders spoke about:

How do you measure things like stock outs because there's an international shortage and the fact that you've got to use a product that the clinicians aren't familiar with and the risk of that? (S1, Expert)

Medication shortages occur when all interchangeable versions of a regulated medication is unable to meet current or projected demands at the patient level (263). The frequency of medication shortages appears to be increasing both nationally and internationally involving important medications such as adrenaline, antibiotics, electrolyte and nutrition and oncology medications (263, 264). Such shortages have important implications and ADEs have been reported as a consequence (265). Reasons for an increase in ADEs were thought to be due to the prescriber's lack of familiarity with the alternative medication being prescribed as a consequence of the shortage (265). These scenarios highlight the need for education and training and the risk of critical medications not being available (264, 266). The availability of medications for use significantly influences and contributes to medication safety (266).

Discussions so far suggest that the intrinsic pharmacological profile of medications available for use, and the manner in which they are used significantly influence medication safety. Medicines and their use was a dimension meaningful to stakeholders. There is a lack of clarity

on the exact causal link between the intrinsic pharmacological profiles of medications available for use and medication safety. Some stakeholders spoke of the changes to pharmacological profiles of medications in having positive effects on medication safety, while some stakeholders believed there were minimal or even negative effects. Stakeholders spoke of complexity, additional medications and additional steps complicating the manner in which medications are used, and these need to also be considered because they influence medication safety.

B) Importance of measuring the medicines and their use dimension and how it could be measured

Given that medicines and their use was an important dimension to stakeholders, the measurement of medication safety should include this dimension. The measurement of this dimension may help predict the likelihood of ADEs and thus medication safety.

Many stakeholders based the decision of whether medication safety had improved on changes to the pharmacological profile of medications. Interestingly, however, stakeholders did not recommend or specify how changes to the pharmacological profile of medications could be measured. The pharmacological profiles of medications have largely been neglected by both stakeholders and literature on medication safety measurement. It is not entirely clear why but one potential reason may be because it has been measured and monitored elsewhere. Clinical trials for example, compare medications to determine whether one medication is superior to another in terms of efficacy and safety. As Stakeholder 16 noted at the start of this chapter, new medications are only released into the market for use when they have demonstrated improved, or at least no worse, efficacy or safety compared to existing treatments. In a way, the measurement of whether medications available for use today have more desirable pharmacological profiles than those of its predecessors are conducted one clinical drug trial at a time.

The need to prove the benefits of newer medications through clinical drug trials before a medication is approved for use, implicitly measures then changes the pool of medications available for use. Previously, for example, dabigatran was approved for use in the NZ healthcare environment only after it had proven benefits over warfarin (259, 260). Thus, even though no published index or measure which indicated the overall ‘intrinsic pharmacological profile of medications available for use’ was identified in the literature, existing regulatory processes for medicine approval and clinical drug trials may already implicitly measure changes to safety. Moreover, such regulatory processes help to ensure the medications

available for use are of high pharmaceutical quality. The current gap in the literature is that the intrinsic pharmacological profile of medications available for use does not explicitly feature as a dimension for medication safety measurement.

As noted at the start of this chapter, even if somehow the intrinsic pharmacological profile of medications available for use could be measured, it does not necessarily indicate medication safety. Dabigatran is a good example where even though the medication may be pharmacologically safer, poor and inappropriate use may have a greater impact on medication related harm. It was thus understandable why instead of measuring the pharmacological profile of medications available for use, many stakeholders spoke about assessing the manner in which medications are used as a means to measure medication safety. For example, stakeholders expressed:

Total number of medicines is a risk factor... your interaction and your total burden on the personal system is always going up... total medication complexity load. (S4, Expert)

Medication harm index or something like that which, it was fairly crude but it was quite useful, I've seen in the context of residential care where you just look at the patient's medication and you ascribe a number to the potential harm so a benzodiazepine or a tricyclic or something you ascribe the number and then you add them all up and you can work out a sort of potential index of how [unsafe a patient's medication list is]. (S16, Expert)

Current approaches to measuring medication safety frequently evaluate the appropriateness of medication use. One example, as noted by Stakeholder 4, uses the total number of medications a patient is on as a proxy for indicating the safety of a patient's medication regimen. The number of concomitant medications a patient is on is thought to be correlated with increased risk of errors and ADEs (267-269). The number of medications a patient is on has been positively correlated with an increase in medication regimen complexity (270-272). Implied was that as the complexity increases, the likelihood of risk, error and ADEs increase. Thus, if the average number of medications are measured and they fall over time, it may indicate more rational medication use. Specific approaches to measure the level of complexity in medications, such as the medication regimen complexity index tool have also been developed (270-272). They typically use an expert panel to ascribe a "level of complexity" score based on the number of medications, frequency, dosage forms and other items (270-272). The higher the score is, the greater the risk of medication errors and harm. If the level of regimen complexity is measured and it falls over time, it could indicate a lower degree of risk and adverse consequences, thus providing a surrogate measure for medication safety.

Tools such as Beers' criteria or STOPP (Screening Tool of Older Persons' potentially inappropriate Prescriptions)/START ('Screening Tool to Alert doctors to Right Treatment') criteria can also be used to evaluate the appropriateness of medications prescribed (33, 273-275). These criteria have a list of "unsafe" medications which have been shown to, or thought to be, implicated in ADEs. While the START part of the criteria, and other tools such as the Assessment of Underutilisation (AOU) index can also be used to evaluate those medications a patient should be on but isn't (276). To illustrate how STOPP/START can be used to measure medication safety, consider the following example. Given that anti-inflammatory medications such as diclofenac are commonly implicated with gastric bleeding, one of the criteria might be whether a person prescribed anti-inflammatory medications had gastro-protection to prevent such bleeding occurrences (274). Applied to the measurement of medication safety, a measure could be proportion of patients with peptic ulcer disease or in patients aged 75 or over prescribed an anti-inflammatory without gastro-protection (275). If gastro-protection trends improve this may suggest overall medication safety has also improved because medications are more appropriately used.

Tools like the medication appropriate index (MAI) have also been developed (276-278). MAI utilises a more implicit criteria than those employed in Beers or STOPP/START, where experts judge and assign a score for the degree of appropriateness of a medication (276-278). The MAI can be used to estimate the degree of appropriateness of a patient's list of medications, but may be quite labour intensive making it unsuitable outside research settings. Audits using the various tools described such as the Beer's and STOPP/START criteria can be applied over time to indicate changes to the appropriateness of medication use.

Stakeholders and the literature on medication safety measurement have tended to focus on measuring medication use and its appropriateness. Many tools and approaches have been developed and described in the literature. Medication use can also be evaluated in other ways, and these will be further discussed over the next few chapters. Despite the importance placed on the intrinsic pharmacological profile of medications available for use by stakeholders, they did not specify or suggest how this facet can be measured. Likewise, the researcher is not aware of any indexes or measures which specifically focus on the intrinsic pharmacological profile of medications available for use. Potential reasons for the lack of focus on this facet may be because it has been implicitly measured elsewhere such as within clinical trials and regulatory processes. Nonetheless, this research has demonstrated that the dimension of medications and their use was meaningful to stakeholders and forms part of how they conceptualise medication safety. The dimension of medications and their use should be part of medication safety measurement.

Emergent finding 4: Safety culture

A substantial part of the dialogue on medication safety measurement was on safety culture. At this point it is important to clarify the terms used in this research to ensure shared understanding with the reader. Emerging from stakeholder views, terms such as safety culture, safety climate or culture of safety were often used interchangeably. In the literature, these terms are also often used interchangeably and ongoing debate remains about whether such differences are significant (279, 280). Safety culture was used in the context of this research to encompass the various terms.

Underlying and emergent from interview discussions; safety culture was viewed as the collective attitudes, mind-sets and behaviours that determine an organisation's commitment to medication safety. Importantly, this dimension focuses on people and their cognitive aspects, such as how they think which is demonstrated through the way they speak and behave. Specifically, a positive safety culture was one which showed:

1. Awareness of medication safety
2. Leadership
3. Teamwork and communication
4. Learning and a non-punitive environment; and
5. A caring environment

The presence of these characteristics at the person and collective level represents a culture which is committed to medication safety and its improvement. Understanding the importance of safety culture to medication safety significantly impacts how medication safety should be measured. In this chapter, excerpts will be used to illustrate how the sub-dimensions and the overall dimension emerged from the interview data. The importance of this dimension to the measurement of medication safety and how it can be measured will be discussed (in Chapter 3: emergent finding 4B).

A) Emergence from the interview data

Awareness of medication safety

Awareness featured prominently during discussions on medication safety. For example, one stakeholder conceptualised medication safety as being a culture of awareness:

Medication safety is about a culture of awareness and doing the most that we can to, I guess, reduce harm to patients that could be done through the use of medicines. (S11, Expert)

As can be seen from this excerpt, the goal of medication safety was viewed to be the reduction of harm from medication use. Awareness and a commitment to improvement were desirable attitudes, mind-sets, and behaviours of safety culture thought to contribute to a reduction of ADEs.

Awareness frequently emerged from the data when stakeholders were asked whether medication safety had improved over the past 10 years. For example, stakeholders expressed:

I think definitely. I think hospitals have always tried to improve their use of medicines or improve safety. The culture, the awareness, it's, like it's expanded like a hundred fold... There is definitely a more conscious effort on part of all health professionals and definitely a lot more awareness of what they're doing in regards to medicines. So yes absolutely. (S5, Expert)

People are much more conscious about medication errors these days the research has shown a huge amount of errors that we kind of knew informally were happening. But now they're there before us in black and white, the statistics, and they're quite frightening and I think we're all aware that it's been a wake up. (S2, Consumer)

I think it's improved a lot. I think there's definitely a far, there's a lot more awareness, I think, especially amongst clinicians... I think there's more and more understanding and awareness that we're not infallible. (S20, Expert)

Stakeholders were of the view that because the collective awareness of medication safety issues had spread, this has had positive influences on medication safety and the effect of improved medication safety. In the literature, landmark reports such as *To Err is Human* (3) and *An Organisation with a Memory* (2) which lead with headlines such as 98,000 people dying each year from preventable healthcare related injuries, have been commonly credited with bringing healthcare safety and quality issues into the consciousness of the general public (19, 26, 234). The publication of such reports is thought to have spurred a significant amount of research and effort dedicated toward the improvement of healthcare in general (19, 26). Such research and efforts have been extended to the area of medication use because medication related harm make up a large proportion of all medical related injuries (1).

Seemingly, awareness is a desirable attribute which can influence medication safety improvement efforts.

Emerging from the interview data, awareness was thought to be able to improve medication safety by making medication safety a priority for improvement. For example:

I guess we were not worried about medication safety 10 years ago, now that's not the case, I think certainly pharmacists ultimately safe use of medicines and all those sort of things are what we strive for. I think maybe what has been the issue is to try and convince others outside of pharmacy quite how important that is and that's been half the battle. And I think that battle is now, certainly in our organisation, something somewhat resolved because we do have the support of adult services and paediatric services with our committees and so on and so forth and then nationally through SQUM [Safe Quality Use of Medicines] and SMMP [Safe Medication Management Programme] and all those sort of things. There is a voice and it's making itself heard so I think the support for medication safety has changed. (S11, Expert)

Pharmacists, and pharmacy as a profession, has traditionally focused on all aspects of medication use, from the preparation and dispensing of medicines to cognitive services which aim to optimise medication related outcomes throughout the medication management process (281, 282). Not surprisingly, the significance of problems associated with medication use, such as medication errors and harm, has long been recognised by pharmacists. In fact, many of the cognitive based services such as pharmaceutical care planning were developed in an attempt to reduce risks associated with medication use and optimise patient health outcomes (104, 281). Stakeholder 11 suggested that the significance of medication safety issues have been under recognised by people outside of the pharmacy profession. However, the collective awareness of such problems has now spread. People are now increasingly aware. Medication safety as a healthcare issue has now been made a priority in the general public, and people are becoming increasingly engaged in its improvement. The increase in engagement has meant people approach medication safety with positive attitudes, mind-sets and behaviours. The commitment towards medication safety and its improvement has increased. The net consequence of such changes was thought to have led to increased effort and initiatives, such as those by organisations such as SQUM (283) and SMMP (284), and has had positive flow on effects on medication safety and its improvement.

The view that awareness has the ability to influence peoples' attitudes, mind-sets and behaviours was shared by many stakeholders.

Let's be very clear about that, once you get money and you've got a budget, you then can do things that you can't do if you don't have one. So the fact that (a) we've got a medicines policy, (b) that's it's identified safety within that, then you had the quality improvement committee which had that as a major part of its brief.

So you have suddenly a culture of, at ministerial level there was this awareness of safety in a way that it hadn't been before, so we're talking safety and we're talking medication events. And then there was the publication of sentinel events that occurred that actually happened across the hospitals about three years ago. So suddenly we have X number of patients have suffered and died from events, so that's all part of the, you know, let's benchmark, put it out there, no blame culture type concept. So it's the stuff that we as pharmacists were trying to do years ago. SQUM held a workshop back in, I think it was 2004, yeah 2004 or 5, so there has been quite a lot of activity in the last 10 years within this environment. (S23, Expert)

Many factors such as leadership and a no blame environment also contribute to changes to medication safety. These facets are important and warrant further discussion, and these will be discussed in the next few sections. At this stage, the attention should be focused on the spread of awareness to the Minister of Health level by publications such as the annually published *Serious and Sentinel Reports* (199-201, 285) which outline major adverse events related to healthcare. Stakeholder 23 was of the view that because medication safety issues and their significance have spread, this has resulted in increased support, resources and effort toward medication safety and its improvement. For example, people were more willing to work together toward improving medication safety. Initiation of groups like SQUM and SMMP and the implementation of the medicine policy were used by stakeholders to illustrate changes that occurred as a result of an increase in support toward medication safety.

Awareness was an important and desirable characteristic of safety culture, which seemingly spurs effort and engagement to improve medication safety. But what exactly does awareness mean and what does it comprise of? Emergent from the interview data so far, awareness could be simply interpreted as meaning the consciousness of medication safety issues by people. However, clear from the interview data, awareness meant more than knowing that medication safety issues exist. Awareness also meant a belief in the importance of medication safety and its improvement. As can be inferred from Stakeholder 11 and 23's excerpts, people only became engaged with medication safety improvement when they believed in its importance. The allocation of resources and effort towards its improvement were the observable effects of the increased engagement.

Indeed, in the literature, both awareness and belief in the importance of medication safety appear to be needed to influence behaviours (103, 286, 287). For example, consider the following vignette (adapted from (103)):

Treatment A has been the usual standard of practice. A new robust and rigorous study has been published which shows that treatment B is more effective and has less adverse effects than treatment A. If clinicians are not aware of the existence of

treatment B then clinicians will continue to use treatment A. A team member alerts the healthcare team about the new study espousing the benefits of treatment B but clinicians continue using treatment A because they have not yet, or do not necessarily believe in treatment B. After some reading, reflection and thought, some clinicians begin to believe in the utility of treatment B and start to use it.

The vignette is an oversimplification and many factors potentially influence why treatment B was not used initially. But the point of the vignette was that it illustrates that both awareness and belief was required to modify behaviour. There was a need to be aware of the existence of treatment B in the first place before treatment B could be used. But just because clinicians became aware of treatment B, did not necessarily equate with it being used either. Only when clinicians believed in the utility of treatment B did they start using treatment B. For example, people have long been aware of injuries associated with medical care (288). However, only until recently has there been an increased belief in the importance of medication related adverse events and significant action directed towards its improvement (1, 5, 26, 62). In this study, awareness encompasses belief and refers to a collective mind-set and attitude which is conscious, accepts and understands the significance of medication safety.

Awareness as defined in this research has also been shown to be important in the literature because it influences people to behave in a manner which is safe (286). For example, awareness forms one of the significant steps required for the adoption and diffusion of innovations in service organisations (287), many of which have been advocated to help improve safety (82). If stakeholders are aware of medication safety issues and believe in the importance of improving medication safety and its initiatives, they are more likely to engage and participate (287). One such example is the adherence to clinical guidelines by clinicians. Even though specific patient characteristics and contexts may require healthcare staff to deviate from clinical guides, guidelines typically outline the appropriate course of action for the majority of cases and people (289). Clinical guidelines have been developed in certain conditions, such as myocardial infarction (183), to guide medication treatment in an evidence-based and appropriate manner. Notwithstanding debates about the appropriateness of the guideline itself, if practice consistently deviates from guideline based treatment then this may indicate inappropriate and unsafe clinician practices (289). Awareness of the availability of the clinical guideline is thought to positively influence people to behave in a manner which is safe, such as adherence to clinical guides (286, 289). Conversely, a lack of awareness is thought to influence people to behave in a manner which can be deemed unsafe such as the non-adherence to clinical guides (289).

The following excerpt further illustrates the importance of awareness and belief in being able to influence peoples' attitudes, mind-sets and behaviours toward medication safety and its improvement.

I am struck by the carelessness of a lot of the doctors in that they don't take the trouble to use safe practices. There are still anaesthetists giving drugs without naming their syringes and I don't think that's right. And I mean systematically, to be clear, within a year's practice I would undoubtedly give a few drugs without naming a syringe for a variety of reasons, one of which is pressure of time and one of which is just clear absentmindedness on a particular day, but not systematically. Systematically I make a conscientious effort and try and label everything. I see people who systematically never label their drugs and that's just bad practice. I don't think you could find a credible authority in the field who would say that was acceptable practice. They say, "Well where's the evidence?" It's certainly, that's I think disingenuous. I think there is evidence but it's not randomised controlled trials there's so many case reports of problems, very few case reports are problems where the proper processes have all been followed... what I said about their bad attitudes, if you really explore them, they're not going out there to harm patients. They're just not convinced that these things matter. And so the right thing to do is to try to convince them. And, or indeed listen to them about what they're saying and see whether they've got a point. (S3, Policymaker)

Stakeholder 3 believed the reason why some healthcare professionals have been displaying unsafe attitudes and behaviours, such as not labelling their syringes, was not because they were cynical or apathetic. Instead people were sceptical of the importance of medication safety and the interventions promoted to improve it, and thus do not necessarily engage in safe behaviours. For example, Stakeholder 3 was of the view that some clinicians simply did not believe or buy-into the benefits of labelling their syringes. Without this belief in the importance of labelling syringes, which can be deemed as safe practice, clinicians did not alter their behaviour accordingly. As can be seen from this excerpt, it appears that belief and awareness are linked and both are required to influence safety behaviour such as the appropriate use of the technical components in its entirety—rather than trying to cut corners to increase speed.

Awareness also emerged from the interview data as a mind-set which prioritises medication safety, actively considering potential risks and problems before they occur. Stakeholders were of the view that this vigilant mind-set would help medication safety, because risk, error and harm can be pre-emptively avoided. For example, stakeholders expressed:

That whole concept of awareness is a fundamental challenge that we face, it's not out there in the way it should be, and that goes right back to the dumbing down of the whole undergraduate curriculum in pharmacology... I think what it does is it fails to generate an awareness of the risk, and of the need for a personal understanding and awareness around medicine safety. (S9, Expert)

[In relation to how to improve medication safety] *giving medicines a greater importance 'cause quite often a medication event will happen and one of the contributing factors is busy. But they've been rushing like mad to get the bed baths and the showering done, but really that is probably a lesser priority. So things need to be turned on and the importance of medicines needs to be emphasised for all disciplines.* (S1, Expert)

Seduced with the urgent as opposed to the important and this stuff's [medication safety is] important... train all these people to become addicted to the urgent and they can't settle down and do the important. (S24, Expert)

Prioritising showers instead of medications was an example of a mind-set which did not give medications and their use the importance they deserve. The dumbing down of the undergraduate curriculum in pharmacology was attributed with a mind-set which was not actively vigilant in considering potential risks and harm such as those relating to dosing, interactions, adverse reactions and others. Stakeholder 9 expressed that many young prescribers lack the knowledge of the risks they should be vigilant for, which suggests a notion that awareness may be related to knowledge and competency. In the literature, and as will be discussed in latter parts of this thesis (Chapter 3: emergent finding 7), lack of knowledge and competency has been identified as a common cause of many medication errors and mistakes (290-293). Importantly, the excerpt by Stakeholder 9 recognises the role of knowledge being able to affect vigilance and awareness characteristics in young prescribers.

Interestingly, even though awareness has been identified as a foundational facet for diffusion of innovations which is related to organisational culture (287), awareness was not specifically identified as a dimension of safety culture in the literature (280). Awareness was also not identified specifically as a dimension of safety culture relating to medication use (294). Awareness, as has been defined in this research, includes the belief in the importance of medication safety, but does however appear similar to the sub-dimension of “shared belief in the importance of safety” dimension of safety culture (280). It is not entirely clear why awareness was not identified as a specific dimension because it clearly emerged from stakeholder views. However, the similarity between the awareness sub-dimension identified in this research and the shared belief dimension identified in the literature, suggests that the concept of safety culture as defined in the literature may be applicable in a medication safety specific context. In the literature, there has been a lack of articulation and research around exploring whether specific differences exist between concepts.

Awareness, which encompasses a belief in the importance of medication safety, is clearly important to stakeholders. Awareness is an important facet of safety culture. In this study, awareness includes belief and refers to a collective mind-set and attitude which is conscious

and accepts and understands the significance of medication safety. Awareness also refers to situational awareness which vigilantly and actively considers safety risks and issues during medication use. There was a strong view by stakeholders that awareness of medication safety issues plays an important role in being able to positively influence peoples' attitudes, mind-sets and behaviours toward medication safety and its improvement. As a consequence of the findings so far, awareness should be part of safety culture measurement. Safety culture is important to be measured as part of medication safety measurement. The importance of these findings and why they should be included when medication safety is measured is discussed at the end of this section (see Chapter 3: emergent finding 4B).

Leadership

Leadership emerged from the interview data as an important facet of safety culture. Leaders and leadership was deemed important to safety culture and medication safety, because it was perceived to be able to influence people's attitude, mind-set and behaviour to one which was committed to medication safety. For example, stakeholders expressed:

Someone like Person A who's got a huge amount of integrity and good reputation it's a bit of window of opportunity I think to get this [medication safety] on to a national profile. (S16, Expert)

I think there's a lot more awareness because there's been a lot more attention by champions, people are interested in it. (S14, Policymaker)

Yeah he's the one who put it [initiatives to improve medication safety] in place so is the passionate advocate about it, or isn't the "in word" is champion. (S13, Consumer)

As can be seen from these excerpts, leadership meant an ability to, and action of, individuals or groups to lead other people and organisations toward positive behaviours focused on medication safety and its improvement such as medication safety improvement initiatives. As has been previously discussed, awareness of medication safety issues can also in itself help influence attitudes, mind-sets and behaviours of people to one that is committed to improving medication safety. Both leadership and awareness appear to be able to influence people, and it appears that both dimensions are related. For example, leadership was thought to drive and increase awareness of medication safety issues. Conversely, some leaders may emerge as a result of the spread in awareness of medication safety issues in people (295).

It is important to note that it is not only individual people that can be leaders or show leadership. Stakeholders explained that leaders and leadership by organisations also play a role in affecting peoples' attitudes, mind-sets and behaviours. For example:

Having set up the commission, the commission will be that focus for strong leadership. And it has identified medication management, medication safety as one of its sort of key priorities. I mean it's a very powerful signal. It's going to take a little while for that to sort of filter down but there has to be a very strong signal from that commission to the Ministry of Health and then through the Ministry through the DHBs that medication safety is a priority. (S16, Expert)

Leadership at a national level, in terms of the MOH and the HQSC, was believed to be important to medication safety. Organisations such as these were thought by stakeholders to formalise, promote awareness and highlight the importance of medication safety to people and organisations such as DHBs and hospitals. Consequently, stakeholders believed that leadership by certain individuals and organisations have increased the commitment of people toward the improvement of medication safety resulting in actual change. For example:

I think it comes to organisational awareness of issues. And once you have buy in from higher level management that certain safety issues should be followed, like hand washing which was something that was adopted by certain DHBs, and the central line care bundle, once this is adopted and start, and is promoted from a high administrative level there is a better chance, if there is a cost involved, for them to have buy in, rather than clinicians to come and say, "We suspect this is a good thing". (S20, Expert)

The reason for why leadership was thought to affect the attitudes, mind-sets and behaviours of people was explained by stakeholders. For example, one stakeholder expressed:

Much more powerful of course if you can get peers to talk to peers. I mean bringing Person Y up to talk to the doctors he did a presentation and they wanted electronic prescribing [a commonly recommended medication safety improvement intervention] tomorrow. If I'd done the same presentation it would have been very ho-hum. It was just magic watching the way they [other doctors] responded to him and engaged with him so if he'd told them the same story and he did have a couple of medication event stories, they were far more engaged and listening to that event story because it was peer talking to a peer. (S23, Expert)

As has been previously shown, a belief in the importance of medication safety is required in people before they necessarily commit to medication safety improvement. Because Person Y was also a doctor, Stakeholder 23 believed Person Y was able to exert peer influence thereby increasing the belief in the importance of medication safety in others. Such findings are similar to those in the literature. Leaders and leadership has also been thought to be able to increase awareness and belief in the importance of an issue because of the leader's peer representativeness and credibility (287). Leadership also appears to be able to shift attitudes, mind-sets and behaviours toward improving medication safety and is demonstrated through action such as wanting to use electronic prescribing.

Another reason for why leaders and leadership was thought to increase awareness was because of their attitude, mind-set and behaviour, but also their status and authority:

I don't know how it is now to be honest, but a while back Hospital X was way ahead of the other boards up in Auckland and most in New Zealand in terms of addressing these issues. They got electronic prescribing early using the Ascribe® system [electronic medication management system], they were one of the first to introduce medicines reconciliation, they were good on drug information. And the reason for that was their CEO at the time was different from the other, the CEO actually wanted things to go well, whereas other CEOs like the one in Hospital Y at that time was only interested in saving money and satisfying bureaucratic criteria that was in the 90s. (S10, Expert)

In the literature, a leader's authority and status has been identified to be associated with improving awareness but also directly influences improvement effort (287). The CEO with a positive attitude, mind-set and behaviour committed to medication safety was thought to also influence other people in the same way. Moreover, because of the CEO's ability to allocate resources, the CEO was able to facilitate and influence the implementation of such interventions directly. Seemingly, leadership appears to be able to influence whether certain components of the medication use system, such as electronic prescribing, are implemented and whether they are used in an appropriate manner. Leadership appears to make medication safety a priority for intervention and change in other people.

Leadership was also believed to have the ability to shift attitudes, mind-sets and behaviours toward willingness to work as a team and communicate in an open manner. For example:

I think senior leadership, so if I work in a team where the consultant and the pharmacist [leaders] are happy to meet with me over an issue or a risk, and then [I can] take the evidence and then to adjust it safely to the setting. (S7, Expert)

Because leaders were perceived to openly communicate and there was a positive team environment, Stakeholder 7 felt more comfortable in being able to discuss new evidence and propose changes for improvement. Stakeholder 7's excerpts highlight the importance of leaders being open and receptive to suggestion having a potential beneficial effect on practice.

Leadership was also viewed to be a key driver in influencing how people communicate:

And it's [communication in an open manner] got to actually come from the top down because you can get, yeah it has to come from the top down. You have to have it, walk the talk, the top people have to put it into practice and make everyone in the organisation feel confident about being open about issues. (S12, Policymaker)

There was a perception that if leaders were communicating in an open manner then their staff would feel more comfortable to discuss potential issues and risks. Implied is that by being able to discuss identified potential issues and risk, improvement can occur. Stakeholder 7 and 12's excerpts show that teamwork and communication are important characteristics of a positive safety culture, and these characteristics will be discussed in greater detail later in this chapter.

For now, it can be seen from the excerpts that leaders and leadership was thought to be able to influence whether people work as a team and communicate in an open manner.

So far, leaders and leadership appears to be able to significantly influence people's attitude, mind-set and behaviour to one which is committed to improving medication safety. In the literature, leadership has been extensively studied and has consistently been identified as playing a significant role in affecting the diffusion and dissemination of health innovations (287), many of which are related to improving safety of systems. The adoption of an innovation such as electronic prescribing which has been designed to improve medication safety, is more likely if key individuals in a social network support an innovation (287).

In the literature, leadership has been identified as a key dimension of safety culture (280). Leadership has also been identified as a dimension of safety culture specific to medication safety (294). Given a leader's ability to influence people's attitudes, mind-sets and behaviour, it is understandable why leadership has commonly been encompassed as a safety culture dimension. Leadership formed a substantial part of the dialogue on safety culture because of such influences. Emerging from the interview data, leaders and their commitment to safety appeared to be a key driver for increasing awareness of medication safety. Consequently, medication safety is made a priority for improvement, intervention and change. Moreover, leadership is viewed by stakeholders as also being a key driver for other aspects of safety culture like teamwork and communication. Leadership is deemed a beneficial characteristic by both stakeholders and the literature of safety culture and medication safety. The implications of these findings mean that leadership should form part of medication safety measurement. These discussions and how safety culture can be measured will be discussed at the end of this chapter (see Chapter 3: emergent finding 4B).

Teamwork and communication

During discussions on medication safety, teamwork and communication emerged as a key sub-dimension of safety culture. Stakeholders often spoke about the importance of team members being able to work together in a collaborative and open manner. Stakeholders believed teamwork was an important dimension to focus upon if medication safety was to be improved. For example, stakeholders expressed:

The biggest factor is being able to sit round with the senior team and create a policy or guideline that works for your setting and that you're all supporting each other to make it a safe outcome for the person. (S7, Expert)

Practising safe medicine is a collegial multidisciplinary approach... If we want to do quality stuff it is not about the thing, it's about the people, we really have to

understand whether the individuals and the team that they work with and stuff, what's their buy-in, what's their understanding, how well do they support each other, how well are they supported? (S8, Policymaker)

In the literature, teamwork between healthcare professionals has commonly been identified as being important to improving safety (296, 297). However, just because people are arranged in a team structure does not automatically create an effective team (296). Instead, effective team performance requires team members to willingly work towards shared goals and this can help improve safety because of the knowledge, expertise, skills and attitudes brought in by various members (296). Conversely, many stakeholders have observed a practice environment where there has been a lack of teamwork and implied that medication use was not safe. For example, many stakeholders had observed hierarchical environments in their practice and this was thought to hinder effective collaboration between staff. For example, stakeholders expressed:

There's hierarchical things going on that someone isn't prepared to discuss it with somebody else because they're senior. Or in the case of some clinicians I've even heard they'll stop speaking to you. And there's really disrespectful treatment... because there was the whole patriarchal model, the whole I'm the boss and I'm not going to listen to anybody trying to check me. (S12, Policymaker)

It has taken longer in hospitals where the consultants have this god-like-view still. That's changed much more slowly than with the general doctors. You know, it's kind of been indoctrinated into the system that that's where they are and you don't challenge that and I think that has changed quite dramatically and that adds to the, if something's going wrong you can challenge it. (S13, Consumer)

Feelings of superiority and authority were thought to lead to disrespectful behaviour towards colleagues and patients, thus preventing a collaborative environment (298). Even though such behaviours permeated across the health system, stakeholders seemed to focus on doctors. The literature suggests that the physician ethos favours individual privilege and autonomy rather than teamwork (298, 299). If a person questions a particular decision or makes a recommendation to alter the course of action, this may be seen as a threat to their competency and reputation (298). Such views are perhaps an over simplification, and in fact, other factors have been identified as to why such disrespectful behaviours exist. For example, endogenous factors identified in the literature include insecurity and anxiety, depression, narcissism, aggressiveness and prior victimisation (298). Exogenous factors like characteristics of the workplace, societal acceptance and stressful environment also contribute to why such disrespectful behaviours exist (298). However, underlying these discussions, hierarchical environments negatively influence the ability of staff to work in a collaborative manner.

In both the literature (298) and findings from this study, negative attitudes and behaviour towards teamwork was thought to negatively impact safety efforts:

Nurses for example, who know they should ring a consultant because they think there's something the matter but they know that they will get a really bad response. And even if they take it to a registrar, the registrar might be really reluctant to discuss it with the consultant as well... organisational culture around safety and openness and that's crucial actually it's probably the overarching thing really. (S12, Policymaker)

Previously, Stakeholder 12 expressed that some clinicians will stop talking to another healthcare professional if they want to clarify or recommend a particular course of action. The consequences of such negative behaviours may lead the recipient to avoid the person inflicting the behaviour (298). In such environments, there is a lack of open communication because the nurse cannot trust that they will receive a positive response if they speak up. An implication for medication safety is the omission of potentially important information or a failure to clarify. When such communication breakdowns occur, there may be detrimental consequences to the patient being treated. But even when no error or harm occurs, team environments which do not encourage open communication represent situations of high risk. Hierarchical behaviour may also impact negatively on staff morale with healthcare professionals questioning their own competence (300). Conversely, an environment which is open and collaborative may encourage staff to speak up on unsafe situations to which they may have become aware of, and positively reinforces vigilance and situational awareness characteristics of staff since they will not be reprimanded.

Closed and non-collaborative environments also represent risky situations which affect the patient, leading to patients feeling unable to react or provide relevant information. For example, one stakeholder expressed avoiding doctors altogether:

People talk to the local pharmacist. They don't see it as threatening in the same way as going to the local doctor, or they think that the local doctor's time is so precious that they won't take up their time talking to them. (S2, Consumer)

Even when consumers do interact with the doctor and challenge their recommendation they are met with negative attitudes and reactions which do not facilitate a collaborative environment, and one which cannot be regarded as safe. For example, one stakeholder expressed:

Made observations about having a discharge script that was inappropriate for me and I did comment about it, it caused disruption and I had to weigh up whether I wanted to get home and get out, or would I be branded for being a disruptive person. I did have a change of script and I had a letter saying change of discharge plan and it had on it, "patient refused medication", nothing about it being inappropriately prescribed in the first place... what incentive does that give to me to go back freely and say "Well I observed these gaps and really things could have been improved", not in a critical way but I really believe that something could be usefully done differently. But I had no incentive to do that when I'm the one who's

blamed, in fact, for being difficult... you should be able to freely make a comment without being branded as the difficult patient. (S2, Consumer)

As can be seen from these excerpts, the inability for consumers to speak up in an open manner was perceived as an unsafe situation, because they felt uncomfortable and unable to discuss medication errors and harm that occurred. The clinician's attitude, mind-set and behaviour were one that did not encourage consumers to speak up. Conversely, attitudes, mind-sets and behaviours which value teamwork and open communication between healthcare professionals and patients has been identified in the literature to improve health outcomes (301, 302). Stakeholder 2's excerpt suggests that to ensure the safe use of medicines, more work needs to be done to facilitate teamwork and concordance between patient and healthcare professional to ensure medication safety.

Interestingly, consumers themselves have had a change in attitudes, mind-sets and behaviour to one that is more engaged and assertive in how their care is delivered. Consumer stakeholders want to work as a team with healthcare professionals to improve their own health. For example, in relation to whether medication safety had improved, consumer stakeholders expressed:

I've been married 40 years. If you look back when I was first married you'd never challenge the doctor and you would certainly never challenge the consultant. What I would do now is say, if someone says this is what you should have I'd say to whoever, "Justify, give me the evidence before I'm going to do whatever you say". Now that's a huge culture change but you then have the collaboration between the patient and the doctor so you're actually on the same side. (S13, Consumer)

I think there's a little more freedom to discuss taking them and what's happening around taking them and if a patient doesn't like them, or can't swallow them because the pill's too big, which is often what happens, I think there's an opportunity to discuss it and find another way. (S2, Consumer)

Changes to consumer attitudes, mind-sets and behaviours have brought about a more assertive attitude in consumers where they want to be able to make informed decisions about the healthcare services they receive. Patients should be involved in not just their own healthcare, but also how health services should be designed (303). The concepts of concordance (1) and care which is patient focused (304, 305) aim for collaboration between healthcare professionals and patients. Stakeholder 13 believed healthcare professionals have also changed in their attitudes to allow greater collaboration, valuing the patient's involvement in their own health.

Expert and policymaker stakeholders also expressed the importance of involving patients in their own care. Instead of being a passive recipient of healthcare, there was a belief that

consumers should become more engaged in their own health (1). Having an environment where open communication was encouraged was thought to help facilitate increased patient involvement. For example, in relation to how to improve medication safety, stakeholders expressed:

We need to put work in to empower the patient, in medication safety. Just becoming more involved in that whole medication cycle. So, empowering them to ask questions of all the health professionals... one way you build patient involvement, is that you're actually open about, more open about what's happening. (S22, Policymaker)

We need to actually empower the patients in the first instance, to actually be aware of what's happening, or what's about to happen to them. And if at any point they feel that, "Look I'm not sure about this", they should be able to say, "Well I want this to stop and I want some clarification". (S8, Policymaker)

Notion of concordance of the idea of the patient knowing, understanding, being on board with what's going on and the doctor similarly appreciating where the patient's coming from. (S4, Expert)

Emergent from stakeholder views, attitudes, mind-sets and behaviours committed to teamwork and communication was deemed to be beneficial. Inferred from stakeholder views, teamwork referred to people from various disciplines and backgrounds working in a collaborative manner for the pursuit of improved safety and outcomes for patients. Teamwork also referred to a collaborative environment between healthcare professionals and patients. Communication referred to an environment which was thought to be safe for people to be involved in and discuss without fear or criticism. Teamwork and communication appear linked. An environment of open communication was thought to promote teamwork because staff can trust that they will receive a positive response if they speak up. An environment which promotes teamwork and open communication was thought to be an important aspect of a positive safety culture.

Attitudes, mind-sets and behaviours which are positive toward teamwork and open communication were thought to be important toward medication safety improvement. In the literature, teamwork and open communication has been identified as a dimension of safety culture (280). Interestingly, teamwork and open communication was not identified as a dimension of safety culture specific to medication safety (294). It is not entirely clear why, because clear from the stakeholder views so far, teamwork and communication seemed important. Underlying the excerpts so far was that teamwork and communication was important to medication safety. Conversely, hierarchical and closed communication environments were not beneficial. Consumer stakeholders believed there had been disrespectful treatment preventing collaboration, but this was improving. There appears to be a

change to mind-sets and attitudes that permits openness in dialogue and teamwork between healthcare professionals themselves and between healthcare professionals and patients.

The importance of understanding how safety culture was conceptualised helps to determine which dimensions and sub-dimensions are particularly meaningful to stakeholders. Teamwork and communication was a sub-dimension viewed to be beneficial. The implication of these findings is that teamwork and communication characteristics are also likely to be important to the measurement of safety culture and medication safety. These discussions will take place later in this chapter along with how safety culture can be measured (see Chapter 3: emergent finding 4B).

Learning and a non-punitive environment

Stakeholders spoke of the need to have environments which support and help staff learn. There was a general perception among stakeholders that there has been a lack of learning support for junior prescribers. For example, stakeholders spoke of:

We don't give our young doctors enough learning support or oversight to avoid near-misses or harmful events. (S2, Consumer)

Doctor education, support for them, specifically if they are new in an area or junior. (S7, Expert)

...don't think junior doctors should actually be able to prescribe they should go through an apprenticeship which is guided by a pharmacist in the hospitals. (S16, Expert)

Importantly, these excerpts illustrate the importance of providing an environment of support and learning to help junior staff when they first start. Because medication errors have been associated with poor knowledge (290), providing adequate support to junior staff may potentially help reduce such undesirable events. In the context of the excerpts above, a learning environment means an environment of support and education.

A learning environment was also discussed in the context of collective learning. Learning meant collective attitudes, mind-sets and behaviours which focus on gaining knowledge and experience from past mishaps in an effort to continuously improve medication safety. Non-punitive meant not assigning unnecessary blame to people or organisations. Stakeholders frequently spoke about the need to have both a learning and non-punitive environment:

[United Kingdom] seem to be more forward, further down the track as far as identifying errors and near misses. Doing, it [measuring medication errors and harm] being open and transparent, no blame culture, all health professions being involved and being keen to be involved. Whether, because it was solely directed at improving practice and reducing the numbers of problems, so there was just, yeah

the process of identifying, doing proper root cause analysis and actually taking action. And then I was at a hospital where they were actually starting to do studies of sort of before and after where a student would come in and actually observe nursing staff and administration errors which was quite difficult to do. And then seeing if they could find trends and see common occurrences and then put practice in place, whether it be education or other processes in place and doing an after and seeing if there was a reduction. I haven't seen anything like that in New Zealand. (S6, Policymaker)

Policy reasons may play a role in the difference between the UK and NZ health systems. However, the focus from this excerpt should be directed towards Stakeholder 6's views on why there was a belief that UK systems were better than NZ systems. Stakeholder 6 spoke of characteristics such as a no blame culture and having processes which identify and analyse incidents as being beneficial. Stakeholder 6 believed UK systems were safer because they possessed such beneficial characteristics, whereas NZ did not.

Conversely, organisations which had attitudes, mind-sets and behaviours which blamed individuals for committing errors were perceived to not be a safe environment. For example, one stakeholder expressed:

Early on in my nursing career when I was a nurse at the bedside taking care of patients, a medication error was always about my error and I was to blame. And well it was my duty and I did report those errors it was very challenging at times to report those errors and I think the shift to, you know, it's yes it's an individual, it's not relieving the individual responsibility, but it's saying what other systems do we need to have in place to prevent this error occurring? Those sorts of changes in the last few years in the States I think have been really helpful. Just in creating, making it to understand that this is about an environment of safety rather than individual blame. (S19, Expert)

The perverse consequence of blaming was highlighted by Stakeholder 19 as being challenging to report. People became cautious in wanting to report errors because of the fear of repercussion. As a consequence, learning from such mishaps is less likely to occur. The focus on the individual healthcare professional being more careful, known as the person approach, and thus preventing errors and adverse events, has been a longstanding and widespread tradition (72). In the past, unsafe acts were thought to arise as a result of aberrant mental processes such as carelessness, negligence and recklessness (72). Traditional countermeasures such as litigation, blame and disciplinary measures use fear to make the individual healthcare professional more careful (72). These actions would be effective in cases where people have maliciously attempted to hurt people or violated recommended practices. However, the majority of people who make errors do so unknowingly and unintentionally, so disciplinary measures are seldom effective (62, 72). Errors more often occur as a result of poor latent and environmental conditions which predispose the person to make the error (72). Thus, it is more

important to explore and examine what some of these latent conditions are so that the same types of errors can be avoided. Being able to report potential issues, medication errors and ADEs in an open and non-blame manner allows better organisational learning, understanding and prevention efforts (72, 306, 307).

From the excerpts so far, stakeholders viewed attitudes, mind-sets and behaviours that learnt and were non-punitive as being important to medication safety. Having such characteristics meant that junior prescribers were supported and that the organisations could learn from past mishaps to improve in the future. Having attitudes, mind-sets and behaviours which were non-punitive encourages people to speak up on occasions of error so such events can be mitigated in the future. One way to determine whether such an environment exists is through the existence of surveillance systems which can be used to capture incidences of errors and adverse events, thus allowing analysis and learning. Surveillance systems are thought to be useful for improving medication safety because they allowed for learning at multiple levels. As one stakeholder expressed:

It's around information and around reporting I think, so I think the link up really is, well from a reporting perspective you've got your healthcare professions who can report either problems, adverse reactions. They can report complaints direct to the place, like if you get precipitation of particular medicines that you're not used to, or discolouration or whatever. But then there's also adverse reaction reporting and from a regulatory point of view [Medsafe] actually contract CARM [Centre of Adverse Reactions Monitoring] to collect and analyse that information and quite often those spontaneous reports can either, can actually bring up safety signals that need further investigation. They can actually show [Medsafe] that there's a batch problem with the medicine which means [Medsafe] can then communicate. So [Medsafe] can either go out and either communicate with the manufacturer and get a recall and get safe, well quality medicines into hospitals. [Medsafe] can, if [Medsafe] investigate a safety signal from adverse reaction reports and see that there is something previously unknown then [Medsafe] can add that to data sheets and [Medsafe] can put out information to help care professions to publications through direct letters. And that's one of the links I see with what a regulator can do and I guess what the regulator can do is withdraw medicine from the market if need be. (S6, Policymaker)

Stakeholder 6 spoke about medication safety in the context of poor medication quality and ADRs. A surveillance system was thought to be important because it can be used to detect manufacturing defects which may pose a safety risk to patients, such as precipitation and discolouration in the medication. Once such risks are identified, efforts can be taken to recall such medications to minimise and avoid harm to patients. Surveillance systems can also be used to detect and identify new ADRs occurring from medications, known as safety signals, which may be previously unknown. Information about these new ADRs can then be communicated to health professionals, so that additional precaution and monitoring can be

undertaken, thereby improving safety of medication use. Surveillance systems in the US (193) and NZ (165) also utilise voluntary reporting systems to collate information about medication errors and adverse drug events. Underlying these discussions, the subsequent analysis and learning from such events can be used to avoid and prevent such errors from occurring again.

In this study, surveillance systems referred to electronic based systems which could be used to collate reports and incidences of errors or ADEs for analysis and learning. Lessons learnt can be used to prevent future mishaps from happening. Surveillance systems provide the infrastructure to facilitate learning, but an organisation could have surveillance systems without having a safety culture which was learning and non-punitive. For example, stakeholders expressed:

Yeah, it's all well and good being able to report but if you're trying to get reporting in you need to be able to do something with it. (S6, Policymaker)

...not only recording or reporting but actually analysing and attempting to do something about it. (S11, Expert)

Surveillance systems were not just about the actual database itself, but implied was the importance of a learning and non-punitive environment.

There was a perception that policy frameworks in place in NZ play a part in influencing attitudes, mind-sets and behaviours which is learning and non-punitive. For example, one stakeholder expressed:

I think we're fairly firmly wedded to the sense of having a no fault system [i.e., Accident Compensation Corporation (ACC) scheme] because of the benefits that brings... But people do from time to time say, well and people from overseas will ask the question, well does that mean that healthcare in New Zealand is less safe? Because if practitioners are not bearing the cost of things going wrong, where's the incentive for them to practice safe medicine. To counter that I would say any evidence I've ever seen doesn't support at all that New Zealand is a less safe place to have healthcare delivered. I mean delivery of healthcare in New Zealand seems to be as safe as anywhere in the world, so the argument that you need to have that direct link to make sure people follow safe practices just doesn't seem to follow through at all. But yeah people do ask perhaps in the cases of error type cases and as I say we don't actually look at that issue any longer, you should be putting that back to the individual. There are other parts of the system in New Zealand where, I mean doctors aren't, all health practitioners, they're not completely free so the HDC [Health Disability Commissioner] is one and so there are other ways in which people can get redress. (S29, Policymaker)

The NZ health environment is unique in that there is comprehensive no fault injuries cover for all residents and visitors to New Zealand (308). This can include injury as a result of medical care. This means that consumers injured by medical care forgo their right to sue as the damages are covered by ACC (308). This is in stark contrast to different health systems in

other countries, where there may be litigation implications when errors occur in order to receive financial aid to treat the injury. The dominant paradigm to systems based on litigation is silence (309). It is thought that such systems do not foster a culture of open communication. Yet, a culture of open communication is required to learn from errors and mistakes and prevent these undesirable events from occurring again (309). Stakeholder 29 suggested that some people have asked about whether the fact that the inability to sue means that healthcare staff have no incentive to practice in a safe manner. Stakeholder 29 suggests that there are other avenues, such as via the HDC (310) and professional bodies such as the Pharmacy Council (311), to address negligent or malicious practice, so there are still procedures for redress. Interestingly, one might question why there needs to be external incentives or disincentives for safe practice to occur. It would seem unusual that someone would deliberately practice unsafely because they would not be sued.

A learning environment was one which supported its junior staff and learns from past mishap. Stakeholders believed an environment which is ‘no-blame’ is required for a learning environment to occur. Attitudes, mind-sets and behaviours that learnt and were non-punitive were thought to be beneficial characteristics required for medication safety. Therefore these findings were classified into the learning and non-punitive sub-dimension of safety culture. Given the importance of this sub-dimension to stakeholders and the frequency in which it is mentioned, it is perhaps understandable why the literature on safety culture also typically encompasses such facets (280). A study into medication safety culture has also identified a learning culture as one of the safety culture dimensions specific to medication use (294). Clear from stakeholder views and the literature, learning and a non-punitive environment was important. Given its importance to safety culture and medication safety, it is also likely important to measure this facet. The importance of measuring safety culture to measure medication safety is discussed at the end of this chapter (see Chapter 3: emergent finding 4B).

Caring environment

Emerging from the interview data, a caring environment meant attitudes, mind-sets and behaviours of healthcare staff which showed a genuine concern and interest towards patients. Many stakeholders believed that they had not observed a caring environment in practice and this was perceived as an unsafe environment. For example, in relation to whether medication safety had improved, stakeholders expressed:

My experience of going into hospital probably about 10 years ago was what drugs are you on, I don't really want to know, but tell us anyway and it wasn't right. And the nurse that interviewed me really wasn't interested and I knew it wasn't right.
(S13, Consumer)

They don't have time to talk to people anymore. (S2, Consumer)

In the excerpts above, consumers felt that healthcare professionals had an apathetic attitude and did not spare the time to show concern to them. At a systems level, stakeholders also spoke about the need to feel cared for through the actions of organisations. For example, in relation to what should be measured, Stakeholder 13 expressed:

It's about that trust thing is that seeing as an outsider that you as, in your professional role, that's what we expect, we expect the professionalism. That you're going to do the necessary to make sure that my safety is in my best interests, but whether there's 27 errors, or 47 errors I don't want to know that... So I don't really want to know that you're likely to get it wrong, I would like to think that I'm reasonably safe when I go into a hospital. The kind of reassurance stuff as there's a huge amount of research going into safety and systems are being improved and, you know, the nice warm fuzzy stuff that comes out sometimes. But at the end of the day there has to be that trust in this that you're working on it builds the trust letting that stuff come out. (S13, Consumer)

A significant amount of research and effort has gone into the development of measurement and monitoring resources which have been focused specifically for the public (25, 312-321). This excerpt is important because it shows that consumer stakeholders were not interested in the quantification of the number of medication errors or ADEs. Instead, they were more interested in whether organisations and healthcare professionals cared for them, and this subjective perception was used to determine trust and feelings of safety. An organisation which shows commitment to improving safety, demonstrated through action such as undertaking research and system improvements and professionalism, were more meaningful to consumer stakeholders. Underlying this view was that because organisations showed attitudes, mind-sets and behaviours of a caring nature, and were committed towards improvement, this indicated to stakeholders that there was a genuine concern and interest in patient health outcomes and thus could be trusted. The feeling of being cared for, professionalism and commitment to improving safety were characteristics of a safe environment to consumer stakeholders.

Interestingly, the caring environment sub-dimension was not identified as a dimension of safety culture in the literature (280). This is an important finding because it appears meaningful to stakeholders when medication safety was discussed. A potential reason may be because in the literature, the concept of a caring culture is one that appears more closely linked to the concept of patient centred care (322). The concept of caring is thought to overlap with patient centeredness, as it relates to healthcare professionals and organisations being compassionate and empathic (322). As can be seen from the findings, an environment that was caring was meaningful to consumer stakeholders. It was classified in this research as part of

safety culture, because underlying the views on a caring environment is fundamentally a focus on an attitude, mind-set and behaviour which is caring and focused on the patient. The implication of this finding on the measurement of medication safety is discussed in the next section (see Chapter 3: emergent finding 4B).

As can be seen from the excerpts so far, many sub-dimensions comprise the overall safety culture dimension. Underlying interview discussions, safety culture was viewed as being the collective attitudes, mind-sets and behaviours that determine the commitment to medication safety. Specifically, attitudes, mind-sets and behaviours reflecting the following sub-dimensions were thought to have a positive safety culture which was committed to medication safety:

- Awareness
- Leadership
- Teamwork and communication
- A learning and a non-punitive environment
- A caring nature

In the following section, a discussion on the similarities and differences between research findings and those of the literature will take place. A literature review by Halligan and Zecevic summarising the definitions and conceptualisation of safety culture as it relates to healthcare has been conducted (280). Of the 139 studies reviewed in the systematic review, the majority of studies ($n=82$ studies) did not define safety culture or variants of the term (280). Of the few studies which defined safety culture, the most commonly used ($n=17$ studies) was the one proposed in *Organising for Safety: Third Report of the ACSNI (Advisory Committee on the Safety of Nuclear Installations) Study Group on Human Factors* (279). The ASCNI definition of safety culture is:

The product of individual and group values, attitudes, competencies and patterns of behaviour that determine the commitment to and the style and proficiency of, an organisation's health and safety programmes. Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared safety culture perceptions of the importance of safety, and by confidence in the efficacy of preventive measure. (279)

There are several important points within the definition which mirror and contrast against findings from this study and these need to be given attention. Similar to findings from this research, stakeholders also spoke about safety culture as meaning individual and group attitudes, mind-sets and behaviours. Competencies appeared to play a role when deficiencies

in undergraduate curriculum influencing awareness were discussed. But in this research, competency emerged strongly as a separate dimension in its own right. The dimension of competency is discussed later in this thesis (Chapter 3: Emergent finding 7, staff competency). Similar to the ASCNI definition, this research found that stakeholders spoke about safety culture as being about commitment to medication safety. Inferred from stakeholders' views was that if the attitudes, mind-sets and behaviours were one that was aware, had leadership, teamwork, open communication and an environment that was learning and non-punitive and caring, that these were characteristics suggestive of a collective committed to medication safety and its improvement.

Another study into the conceptualisation of safety culture, but one specific to medication safety in the ambulatory setting was conducted by Stock and Mahoney in the US (294). This study identified similar sub-dimensions as those previously identified by the ASCNI and others, but also included physician responsibility and quality improvement as specific sub-dimensions. The quality improvement sub-dimension assesses the environment and whether staff perceive there to be continuous improvement. This appears similar to the learning sub-dimension identified in this research. Even though the study by Stock and Mahoney also includes a learning culture, they do not make a clear distinction between the two sub-dimensions and they appear the same. Physician responsibility was also identified as a sub-dimension by these researchers and referred to the creation of a safe environment rather than attributing blame (294). This sub-dimension again appeared similar to the learning and non-punitive environment identified in this research.

In order to compare the sub-dimensions between those listed within the definition by ASCNI, the dimensions identified by Halligan and Zecevic, Stock and Mahoney and the ones identified by this research see Table 1.

Table 1: Comparison of the sub-dimensions of safety culture identified from the literature with those from research findings.

ASCNI definition (279)	Halligan & Zecevic (280)	Stock & Mahoney (294)	Research findings
Positive safety culture is one that is characterised by:			
shared safety culture perceptions of the importance of safety	shared belief in the importance of safety	Safety as a priority	Awareness of medication safety which includes the belief in the importance of safety and its interventions
confidence in the efficacy of preventive measure	–	–	
–	leadership commitment to safety	Leadership	Leadership
and communications founded on mutual trust.	Teamwork	–	Teamwork and communication
	open communication founded on trust	–	
–	organisational learning	Learning culture	Learning and a non-punitive environment
–	and a non-punitive approach to adverse event reporting and analysis.	Quality improvement and physician responsibility.	
–	–	–	Caring nature.

As can be seen in Table 1, the dimensions in the ASCNI definition and the ones identified in the literature review by Halligan and Zecevic were similar, but the latter identified other sub-dimensions such as leadership commitment, organisational learning and a non-punitive approach (280). Stock and Mahoney identified similar safety culture sub-dimensions for medication safety in the ambulatory setting to those identified by Halligan and Zecevic. This research also identified similar dimensions to those in the literature, but additionally, identified awareness and caring nature as sub-dimensions of safety culture for the hospital setting. This research previously posited that both awareness and caring nature were spoken about by stakeholders to be characteristics of a positive safety culture.

In this research, safety culture emerged as also being about the collective attitudes, mind-sets and behaviours that determine the commitment to medication safety. Given the similarities between general safety culture and safety culture as identified within this research, one may be able to borrow from the literature to discuss some of the research findings. For example, stakeholders spoke of a positive safety culture significantly influencing the likelihood of whether medication errors or harm are likely to occur. This aligns with parts of the literature which have indeed shown that organisational characteristics associated with a positive safety culture correlate with better patient health outcomes (323, 324). Measuring safety culture may thus serve as a proxy for predicting the likelihood of medication safety and beneficial health outcomes.

In contrast, some stakeholders believed medication safety meant a positive safety culture. For example, an environment where the collective attitudes, mind-sets and behaviours that determine the commitment to medication safety were positive was deemed to be safe. Interestingly, some stakeholders found such attributes as being more important to indicating the medication safety of an organisation than information about medication errors or harm. Determining whether such characteristics were present was deemed to be necessary to determine whether medication systems were safe regardless of whether outcomes were beneficial or not.

Regardless of the view of whether safety culture influences, or is, medication safety, stakeholders spoke of similar attributes related to a positive safety culture. For example, environments which were aware, showed leadership, had teamwork and communication, were continuously learning and non-punitive and caring were deemed to influence medication safety in a positive manner. It is important to note that each of these attributes cannot be used in isolation to measure safety culture, and medication safety, but rather they need to be considered holistically. For example, just because people have good awareness of medication safety issues may not necessarily mean they will display a caring attitude or work well with others.

Safety culture appears to be a fundamental aspect of medication safety because ultimately it is about people. Safety culture seemingly influences other factors such as positive safety behaviours or whether certain components of the medication use system will be implemented or whether people will behave in a safe and appropriate manner.

Many stakeholders believed that for a medication use environment to be safe there must be a positive safety culture. This view implies that improving safety culture may influence the likelihood of reducing medication error and harm. The presence of safety culture also indicates medication safety regardless of the consequences. For example, if people were not talking to each other, had poor awareness, had no leadership, and even if no medication errors or ADEs occurred, stakeholders did not necessarily consider the medication environment to be safe. The safety culture dimension was an important facet of medication safety and should be part of the measurement.

B) Importance of measuring the safety culture dimension and how it could be measured

Many stakeholders clearly and strongly spoke of the importance of measuring safety culture. For example:

Some of the measurements will be about the tools, the technology sort of stuff. Some of the measurement will need to be about the team work, the human factor. But some of the measurements will go much more fundamental than that which is actually about the culture of medication safety in a particular ward, department, hospital sort of stuff ... we are in the early stages of thinking about how do we actually measure what we call the DNA or the culture of the institution of the hospital, of the department. Now that's a more meaningful thing to do. That's much more sustainable. It gives much more insurance that regardless of what the next new thing will be. If you have the right culture and the right DNA of the department, the organisation, they will actually recognise that they need to change ahead of the curve before it becomes a problem. (S8, Policymaker)

The use of DNA as a metaphor to describe safety culture outlines its importance. Safety culture was viewed as a fundamental and underlying characteristic. It threads through various levels, such as the ward or organisational level, and types of projects being implemented. A positive safety culture was thought to positively affect medication safety. The measurement of safety culture may serve as a proxy to measuring medication safety since it influences the likelihood of error and harm. If safety culture showed improvement as a consequence of measurement, this may indicate a reduction in the likelihood of error and harm.

At this point, it is important to note that there does not appear to be a clear linear causal relationship which exists between safety culture and health outcomes in the literature. Some studies suggest that there is no relationship existing between safety culture and outcomes. For example, in one study, changes to safety culture was not correlated with changes to risk-adjusted morbidity and mortality outcomes (325). Improved safety attitudes following training showed no correlation with complication rates and safety outcomes (326). There was no association between organisational culture and the prevalence of pressure ulcers which has been used as a marker for poor safety (327).

Conversely, other studies suggest that there is some evidence which shows safety culture being associated with safety outcomes. For example, poor safety culture was found to be associated with higher rates of re-admissions for heart attack and heart failure (328). In another study, for every 10% decrease in safety climate, the length of stay increased by 15% (329). A poor safety climate was thought to predict medication errors especially when patients with complex conditions were involved (330). A positive safety climate also appeared to impact on patient safety behaviour and initiative on medication errors in a beneficial manner (331).

The exact relationship between safety culture and outcomes appears unclear. But it was clear that stakeholders value the measurement of safety culture. Several important points about how

safety culture could be measured emerged from the interview data. Stakeholders were of the view that the measurement of medication safety need not be complicated:

You do get a feel for it or not. I'm just trying to think where I went, recently I went into a place and their emphasis on safety was quite remarkable. 'Cause you just knew that these people were, it was just so clearly part of the culture, it was impressive... some of these measures are soft, that's fine. I mean I would've thought that, you have a lot of on call kind of specialities in hospitals, that move around hospitals over time, I'd imagine every one of them would be able to tell you which hospital had a better culture of safety and which didn't. (S27, Policymaker)

Um, I suppose you talk to, I suppose it's all around talking to people and getting some sense of how those things are handled. Maybe having a hypothetical conversation in a DHB, now if this happened here what would happen, how would this be handled, what would you be doing, how would you be responding if that's on the provider side? The other side of course is on the consumer side, if something goes wrong with the patient having a conversation about how is it for you, how open were people to dealing with your issues, did they tell you what went wrong, how did you feel about that, what did they do to fix it up? Did you get the sense that there was any reluctance around the discussion of safety? (S12, Policymaker)

Measuring safety culture was viewed as a formative process which can be done by speaking to people. Understanding how people felt and what people thought provided important insights into an organisation's safety culture. Understanding such views may highlight areas in need of improvement or areas which are doing well (324). Stakeholder 27 and 12 were of the view that safety culture can be easily detected or perceived, and this formative process is sufficient to indicate the safety culture of an organisation. Other stakeholders also suggested that measurement of safety culture need not be formal. For example, the measurement of the caring environment sub-dimension of safety culture could be done by:

The subjective feel of patients and family that it's safe. (S4, Expert)

Visual analogue and you go to someone, "How safe's your hospital?" You know, we're looking, I don't actually know that we need something fancy, if people can tell you they're in pain from that, surely that's all we're looking for. (S5, Expert)

A visual analogue scale is a straight line with end anchors which are labelled as the extremes of the view or response being measured, and has been used widely to measure subjective phenomena (332). Applied to measurement, the subjective feeling of safety by the patient can be elicited through a straight line with labels such as 'Feel safe' and 'Do not feel safe' being used as end anchors. Such excerpts are important because they illustrate that stakeholders found formative and informal approaches to measuring safety culture useful. These findings provide insight into how safety culture can be measured in a manner meaningful to stakeholders.

Other more formal and summative methods have also been recommended to measure the caring sub-dimension of medication safety. The literature has recognised the importance of patient views (333, 334) and indeed, many approaches have been developed to measure patient views. For example, tools such as patient satisfaction questionnaires which can help identify whether care was perceived to be appropriate have been developed (18, 335). Other tools like the ‘Friends and Family Test’ have also been developed which ascertains whether services were of a high enough quality that they would recommend this to other family members and friends (315). Patient views on safety are important because they could indicate areas of poor safety, error or harm that had occurred in the delivery of care (336). Patient views on safety are also important because they could reflect actual conditions or environments which may not be safe. For example:

Patient experience. Are people satisfied? If people have gone on a misadventure they're probably going to tend to be unhappy about it. If they, again, you know, they're in the dark, stressed, over stretched, staff are trying to take care of them. There's a lot of reasons to think that that could be an indicator as well. (S5, Expert)

Other safety culture measurement tools and approaches have been written about in the literature and measure facets of safety culture other than the caring environment sub-dimension. Some examples include the Safety Attitudes Questionnaire (SAQ) (337), Hospital Survey on Patient Safety (338), Manchester Patient Safety Framework (MaPSaF) (339) and others (1, 18, 324). Each has their own strengths and weaknesses. For example, the MaPSaF measures safety culture across 10 dimensions such as continuous improvement, priority given to safety, recording incidents, evaluating incidents and with participants rating each dimension as pathological, reactive, bureaucratic, proactive and generative (339). Because the MaPSaF is completed by participants from across different professional backgrounds, it can be used to help teams reflect on safety culture and reveal any differences in views and perceptions. Exposing dissonance in views may help the understanding of what a safe culture might look like and identify areas in need for further improvement (340). However, because the MaPSaF has been predominantly used in the UK, it is unclear how transferable the tool might be in other settings (340).

The SAQ is another tool that has been advocated for to measure medication safety. The SAQ focuses on the perception of staff and their attitudes across six dimensions such as teamwork climate, stress recognition, perceptions of management, working conditions and others (326). Participants are asked to rate each of the dimensions using a Likert scale. The SAQ appears to show an association between high scores and positive patient and staff outcome data (341). The SAQ has been used in the US, and it is unclear whether it is transferable to other

healthcare settings. The use of Likert scales and a quantitative approach also means that even though differences are identified between participants, the reasons underlying the differences may remain underexplored (340).

As can be seen, even from only the comparison between the MaPSaF and SAQ, different tools measure different facets of safety culture. Even though some tools such as the SAQ appear to have been more widely tested than others (340), there does not appear to be one approach that is superior to another and tools may not be easily transferable from one setting to another (324). In some scenarios, the measurement of safety culture as rates, such as in the SAQ, may be more appropriate, while in others, descriptive measures may be more appropriate, such as the MaPSaF (324). Regardless of which tool is used, safety culture has been deemed important to be measured as part of patient safety and quality measurements (280).

Safety culture has also been measured as part of medication safety measurement and monitoring (1, 32). For example, of the medication safety measures, the MSSA tool, suggests that practitioners should be anonymously surveyed at least annually to assess the organisation's safety culture though it does not specify which tool to use (32). Safety culture is not a dimension explicitly measured in other medication safety measurement literature (25, 29, 30, 33). More research around whether safety culture measurement approaches can be applied to medication safety or how they correlate with health outcomes need to be conducted. However, it is clear that measuring safety culture is important to measuring medication safety.

An interesting point which emerged from stakeholder views was that despite the number of available tools to measure safety culture, many of the stakeholders were actually sceptical about their benefits. Many stakeholders were sceptical of whether simply asking people alone would provide an accurate view of safety culture. For example:

I've always been a little bit sceptical about just asking because people's responses to surveys may or may not be entirely true. Most people kind of know what the right answers are, so you, you know, "right answers", so you may or may not get, the way to know what peoples' attitudes are is to watch what they do. So if you can have an observer watch people and then identify behaviours... you can get quite quick answers from that sort of work, behavioural, looking at behaviours. And I think that's probably better than asking people, because you can, it's what, peoples' attitudes are manifest in the way they behave. So they're called BARS, B-A-R-S, Behavioural Anchored Rating Scales. (S3, Policymaker)

Instead of simply asking people, Stakeholder 3 was of the view that peoples' behaviours may provide a better view of people's attitudes and mind-sets towards medication safety which is demonstrated through their actions. Specifically, Stakeholder 3 recommended the use of the

Behavioural Anchored Rating Scales (BARS) to monitor culture. Stakeholder 3 explains how this tool works:

So typically they have like a type scale, 5-point scales but they're anchored with descriptors. So if you were to think, I haven't thought of one in a great deal around drugs because I'm thinking more around the [data removed to maintain stakeholder confidentiality] at the moment. But the, but if you would think about, oh a good behaviour could be always labels syringes, always takes time to read the labels, always has good sterile technique. And bad behaviours could be never labels syringes and, you know, you could think of several others. Now the point about them is that they're not binary so that you make a, the observer makes a judgement so that if he watches for half an hour and the person's labelling most of his syringes they can adjust in scale. But it's basically looking at the behaviours. (S3, Policymaker)

As noted by Stakeholder 3, BARS utilises a scale where behaviours of participants are noted and rated against whether they demonstrated safe behaviours such as the labelling of syringes. Indeed, such tools have been developed and have been used in the literature to assess safety culture (18). Underlying these types of tools is an assumption that safety culture manifests and is demonstrated through peoples' behaviours. If participants behave in a safe manner, then it could be assumed that they are aware and believe in the importance of medication safety, thus illustrating a positive safety culture.

Other stakeholders were also sceptical about the utility of questionnaires or surveys. Instead of using ethnographic type approaches, such as the BARS to observe safety culture, some stakeholders suggested that one could simply observe whether efforts were being implemented to improve medication safety. Medication safety improvement efforts and initiatives were believed to be a manifestation of an organisation's and individual's positive safety culture. For example, stakeholders expressed:

I think that the culture stuff is really important, I'm just not that convinced about how useful the tools are to measure that... I think that would need to be put into a broader context of other safety monitoring issues around hard data. And you may well look at a whole range of different interventions. I mean I know in this organisation that we have aim for zero harm campaign that looks at six different of aspects of patient safety... So that's hand hygiene, healthcare acquired infection, VTE [venous thromboembolism] prophylaxis, risk assessment, pressure ulcer care and the prevention of, falls, patient identification, and the last one is prevention of centralised associated bacteraemia. So there are six of those patient safety initiatives. All of them have got baseline measures, all of them have got, there's a bundle of intervention and ongoing measurement, and education programmes and promotion. And I think that's probably as good a measure of safety culture as a survey. (S21, Expert)

Some stakeholders believed that no one single approach to safety culture measurement would suffice and a combination of approaches is required. As one stakeholder explained:

I think they're [safety culture surveys and tools are] good tools, so all those surveys you've got to remember are snapshot of a point-in-time. What I think needs to happen is that in between the surveys there needs to be other evidence. So surveys are as good as the person who tick the boxes, right, sort of stuff. So in between the surveys you actually want to have another process that takes, it looks at the results of survey and do another process which is looking at the reality of the answers, right, when they're practising in between the surveys, right. And in fact you want that to be done by them as opposed to someone else coming to do a credential and accreditation audit sort of stuff. So, and if they, this comes back to the question around the DNA and the culture of the organisation, if they look at those things as a pain in the butt, there's something wrong here, right. So they're comfortable to tick the boxes once every year sort of stuff, but checking the reality of the answers with what they do every day, if they see it as a pain in the butt that actually says that something's not quite right with the answers sort of stuff. (S8, Policymaker)

Using multiple approaches to measure safety culture was thought to help in ensuring safety culture was more accurately measured.

An important point that has yet to be discussed but must be noted due to its relevance in the NZ public hospital setting, is that the act of measurement may, in fact, be useful regardless of which tool is used. For example, stakeholders expressed:

So the whole point of collecting the [medication safety] data is to learn from the mistakes and improve processes and systems so there's not as much value in terms of the effort to collect the data is quite onerous at times and you want to channel it back in and localise it. I think that that's where the learning and the value is, it's not necessarily on having a report at the end of the year that summarises the performance of the interventions in the hospital what do you do with that? They'll say, okay what now? And I think that's where it's got to be grass roots we've got to encourage our frontline nursing staff to self-report the errors they make and their colleagues make in a just sort of culture and knowing that the information will be collated and presented back and supported from various channels to improve safety. (S18, Expert)

Stakeholder 18's view was typical of many of the stakeholders. Regardless of the approach used to measure safety culture, the process and act of measurement may provide more utility because it allows people to reflect and have conversations about safety and identify areas in need of further improvement (324). As Stakeholder 8 previously noted, the act of not measuring safety culture may itself indicate the presence of poor safety culture, which may not necessarily be committed to medication safety and its improvement. As can be seen from these excerpts, stakeholders were not concerned with what exactly was measured or how it was measured. Instead, the process of measurement itself was important because it increases the awareness of medication safety issues and priorities medication safety for improvement.

Understanding the dissonance in views on what safety culture measurement should encompass, and how it could be measured in a manner which is meaningful to stakeholders

was important. These findings are important because they contrast with those of the literature. Even though many tools and approaches to measuring safety culture exist in the literature, the findings of this research have shown that stakeholders are actually sceptical of their benefits. Stakeholders believed that the observation of behaviours and a combination of multiple tools may be more useful in measuring safety culture in an accurate manner. However, even more importantly, the act of measuring safety culture itself is significant because it helps to reveal areas in need of further improvement and provides the opportunity for discussion.

Medication safety culture can be viewed as a variable of medication safety, which if improved may also improve medication safety—if medication safety is viewed as the avoidance of medication errors and harm. However, it was also evident from stakeholder views that the presence of medication safety culture indicated medication safety. The measurement of medication safety culture was important regardless of its eventual outcome on health outcomes. For example, if healthcare workers did not work as a team or showed poor communication, regardless of the outcomes, these characteristics were inherently risky and stakeholders deemed these to be undesirable. The presence of medication safety culture characteristics, such as the sub-dimensions identified in the literature, indicate the presence of medication safety and what it means to have a safe medication use environment.

Even though safety culture has been extensively studied in the literature, the same cannot be said about medication safety culture. Borrowing and contrasting from safety culture literature suggests that there are some similarities, but there are also important differences. This research has added to existing knowledge by identifying that sub-dimensions such as awareness and caring environments are important facets of medication safety culture. A better understanding of what medication safety culture means has implications on how safety culture is measured. The measurement of medication safety culture needs to encompass sub-dimensions such as awareness, leadership, teamwork and open communication, learning and a non-punitive environment and caring environment. Safety culture was clearly viewed in both the literature and stakeholder views as being important for measuring medication safety.

Emergent finding 5: Technical components of the medication use system

Underlying a substantial part of the dialogue on medication safety measurement was a focus on the technical components of the medication use system. This dimension emerged from the interview data and meant the physical procedural steps and environment involved in, and support for medication use during the delivery of healthcare to patients. The technical components of the medication use system most meaningful to stakeholders were:

- Technology
- Pharmacy based services
- Standardised medication charts and systems
- Labelling and packaging
- Information transfer
- Staffing, workload and workplace environment; and
- High risk medications and diseases

These sub-dimensions represent the technical components thought by stakeholders to most significantly influence medication safety and its outcome goals. This chapter starts by discussing how the sub-dimensions and dimension emerged from the interview data and what they are about. The importance of these findings and how the overall dimension can be measured will be discussed (in Chapter 3: Emergent finding 5B).

A) Emergence from the interview data

Technology

Technology emerged strongly as a key technical component of the medication use system important to medication safety. For example, stakeholders spoke of:

The prescribing should be electronic really, because you can support prescribing quite well with electronic prescribing type stuff on, at the point of prescribing and you can put in formulary type stuff. (S3, Policymaker)

Technology was viewed as being able to improve medication safety. For example:

I think in pockets there's been quite big advances and I mean, I think, the use of barcoding technology in the operating room for our own system as you know about, but also the use of Pyxis® type stuff, point of care type things... That's all

in the right direction, although it adds cost, it's in the right direction. So I think it's safer now than it was. (S3, Policymaker)

Even though only Stakeholder 3's views have been used so far to illustrate the importance of technology to medication safety, they were typical of many stakeholders' views.

Technology was the broad label used to encompass stakeholders' discussions on the various types of electronic equipment and software involved in, and to support, medication use. The excerpts above are important because they highlight the variety and breadth of technology thought to be useful for improving medication safety. Even though many different types of technology to help improve medication safety have been described in the literature (82, 83, 211, 342), only the examples in the excerpts above such as electronic prescribing, barcoding and Pyxis® will be discussed.

Electronic prescribing, also known as computerised physician order entry (CPOE) with Clinical Decision Support Systems (CDSS) has been developed to improve medication safety and can help in several ways. CPOE with CDSS requires the prescriber to key in their medication prescription which reduces errors associated with illegibility (155, 342-344). Electronic prompts, such as noting significant interactions or excessive doses, facilitate appropriate prescribing decisions helping reduce errors associated with inappropriate prescribing (155, 342-344). CPOE with CDSS systems can be integrated with other information systems so patient specific information such as laboratory test results and patient medicines lists are readily available to aid treatment decisions (345, 346). As noted by Stakeholder 3, medicines related information such as dose adjustment in renal impairment advice and medications available in the formulary, may also be made more easily accessible at the point of care to guide appropriate treatment (347). CPOE with CDSS has been shown in the literature to be an effective intervention in reducing medication errors at the prescribing stage of medication use in certain hospitals (83, 342, 348).

Barcoding technology has been developed as one approach to ensure the right medications have been used and force the correct action (10, 31). For example, barcodes attached to medications and patients are optically scanned to ensure that the correct medication is being picked and is being administered to the right patient (83, 349). If an error has been made, the user is warned proactively to take action or the medication may not be released and available for use. The implementation of barcoding systems is one type of intervention that has the potential to reduce errors at the dispensing (350) and administration (158, 351) stages of medication use.

Pyxis® is one brand of automated medication dispensing devices (83). Pyxis® can help reduce incorrect medication type errors by ensuring only the correct medication is released and available for use (83). In conjunction with unit dose packing, where medications are dispensed specifically to each individual patient, they are thought to reduce medication errors at the dispensing and administration stages of medication use (83).

Underlying discussions on CPOE with CDSS, barcoding, and Pyxis®, was a focus on the use of technologically based interventions to improve medication safety. Many stakeholders believed that technology can improve medication safety. In the literature, technology has also been commonly recommended to address many medication safety problems (342, 352). Given the general belief in its importance to influence medication safety in a beneficial manner, many organisations charged with medication safety improvement have prioritised the implementation of technologically based interventions (32, 82, 83, 342). In fact, organisations purely dedicated to the implementation of health technologies such as National Health Information Technology Board in New Zealand (353, 354) have been established as part of medication safety improvement efforts. Clear from both stakeholder interview data and the literature, technology emerged as an important technical component of the medication use system and was thought to be able to significantly influence medication safety outcomes. Technology was thought to be able to reduce and minimise adverse consequences of medication use.

At this point, it is important to highlight the implicit assumptions taken by stakeholders and the literature so far. Underlying discussions on technology, there has been an assumption that the implementation of certain technologies will contribute to the achievement of desirable medication safety outcomes. Not all stakeholders shared the view that the implementation of technology was beneficial. Some stakeholders believed medication safety can actually worsen as a consequence of implementing technically based solutions. For example, stakeholders suggested:

We're putting in the likes of the electronic systems where we can create more errors. (S15, Expert)

Some stakeholders believed that the implementation of technology does not improve medication safety because it may not be used appropriately. For example:

So, many organisations might have barcoding systems in place, but if the process is that the nurses have found a workaround that says that rather than scanning the patients wrist band, they actually have the patient's sticker on, or multiple patient stickers on the nurses lapel because it makes it easier for her to do her drug rounds. ...just having barcoding or, yeah barcode beside verification in place doesn't guarantee safety if the process is completely wrong. (S11, Expert)

The literature has shown that the implementation of technology has not always been successful at reducing undesirable consequences of medication use. For example, technology such as barcoding and CPOE with CDSS can in fact increase the number, or simply change the type of medication errors that occur (83, 355-358). For example, the published evidence of automated dispensing devices such as Pyxis® have failed to demonstrate the effectiveness of the intervention on reducing medication errors (83). Systematic reviews of studies around CPOE and CDSS show the evidence of benefit is only moderately strong (82). CPOE and CDSS may reduce errors, but they do not necessarily reduce harm associated with medication use (82). Methodological challenges complicate the interpretation of such findings, and are possible reasons why some commonly advocated technologically based interventions have not been shown to be effective. However, it is also conceivable that technology cannot, in itself, solve a problem which is complex, has multiple causes and is influenced by many factors. For example, this research has already identified that dimensions such as medications available for use, safety culture and others play a role in influencing medication safety outcomes. A multi-faceted approach is needed to improve medication safety.

As highlighted by Stakeholder 11, another reason for why some technology has not necessarily improved medication safety was because it was not used or inappropriately used by people. For example, if the technology was not user-friendly or practical, people may develop workarounds which actually increases risk. As Stakeholder 11 pointed out, nurses may affix patient identification barcodes to computer carts instead of on the patient to make the administrative workflow easier, and these pose significant threats to medication safety (359). Such problems reflect a lack of technology customisation to its users in the local context, but also suggest potential underlying problems such as being understaffed which necessitates such actions.

Technology may also not be used appropriately because staff are not necessarily aware of the technology or do not believe in the importance of the technology. Noted previously in the safety culture dimension chapter, awareness and belief was shown to significantly influence attitudes, mind-sets and behaviours committed to improving medication safety. Examples were provided where certain healthcare staff were sceptical of interventions or practices to improve medication safety, and as a consequence did not use technical components in their entirety and tried to cut corners to increase speed. Other facets such as leadership play a role because it was shown in the previous chapter to drive awareness and belief in the importance of improving medication safety. The relationship between safety culture and technology is not unilateral. For example, the implementation of technology provides broad aspirational goals

for healthcare staff to encourage awareness and belief in the importance of medication safety.

For example, one stakeholder noted:

I actually think in the absence of having an appropriate measure they're [technology as a proxy for medication safety measurement] the best tool. I think they're even better than audits, because it keeps the culture and the awareness right up there and also identifies for the organisation things that they can do to improve their systems from there. (S5, Expert)

This excerpt supports the notion that safety culture and technology is related. A positive safety culture appears to be needed for technology to be used and in an appropriate manner. Conversely, technology may provide an impetus to generate awareness and a positive safety culture. When stakeholders espoused the benefits of technology, they typically assumed that implementation would be successful and people would have attitudes, mind-sets and behaviours which facilitated the appropriate use of the technology. At this point, it is worth noting that this assumption was not isolated to just technology, but was also applied to other technical components of the medication use system.

In this research there is a distinction between the safety culture dimension and the technical components of the medication use system dimension. Safety culture specifically focuses on attitudes, mind-sets and behaviours. The technical components of the medication use system specifically focus on the physical procedural aspects like tools, infrastructures and practices associated with medication use and safety. Both facets are required, because if people are committed to improving medication safety but do not have the necessary technical components in place, then the environment may not be safe. Conversely, if the technical components are in place, but people are not necessarily committed to using them in an appropriate manner, then it is also not safe. The associations existing between dimensions are important and are discussed in further depth in the latter parts of this thesis (in Chapter 4A). For now, the focus is on the technical components of the medication use system.

So far, discussions have focused on how the technology sub-dimension emerged from the interview data. Stakeholders spoke of the importance of technology and how it has the ability to positively influence medication safety outcomes. However, some stakeholders also recognised that technology cannot solve all medication safety problems. Some technologies may cause unintended adverse consequences. Despite the espoused benefits of technology, evidence of their effectiveness is not necessarily strong. Technology may not be effective because it is not necessarily used in an appropriate manner. Technology may be poorly customised leading to workarounds, or end-users may be sceptical—leading to non-use or inappropriate use. These findings mean that even though the improvement of the technology

itself may help, further attention and effort should be instead directed towards how the technology is implemented and used. Clearly, technology cannot solely and completely solve medication safety problems.

Despite the limitations of technologically based interventions and for all their shortcomings, technology is important to medication safety and its improvement. Technologically based interventions can play an important role in improving medication safety. Technology is a meaningful sub-dimension of medication safety and is likely to be important to measurement. The importance of technology as part of medication safety measurement and how it can be measured is discussed later in this section (in Chapter 3: Emergent finding 5B).

Clinical pharmacy based services

A substantial proportion of the dialogue on medication safety measurement focused on clinical pharmacy based services. It is worth making the distinction that there is a difference between clinical pharmacy services and retail pharmacy services. Some stakeholders recognised this distinction, and in fact, were quite disparaging about the benefits of pharmacy services that were solely focused on the distribution of medications and retail. For example, some stakeholders expressed:

Community pharmacy is really shop keeping. And they don't sort of see the medication review side as their core business so, there almost needs to be a new group of people who are, whose medication review is their business. (S24, Expert)

Pharmacies are commercial. The community pharmacies have a very commercial focus on retail. And I don't hear very much about community pharmacy development of quality processes. I hear about issues with dispensing fees and them being really, really hard pressed to make their businesses work because I guess the Ministry's trying to clamp down on expenditure in that area. They don't focus on safety, they focus on other parts of their business. (S30, Expert)

Clinical pharmacy is a specialty field of pharmacy which has moved away from the traditional tasks of compounding and distributing medicines, to more cognitive clinical aspects focusing on optimising medication related outcomes for patients (104). This process is known as medication management (360). In this role, clinical pharmacists may conduct medication reviews. Medication reviews refer to the assessment of the patient and evaluating their medicine therapy and management (360). This may include the interpretation of laboratory tests, evaluation of patient signs and symptoms then providing medication related recommendations in order to optimise patient health outcomes (360). Stakeholders, in this chapter, refer to pharmacy service in terms of clinical pharmacy services which conduct medication reviews. There was an overwhelming recognition by stakeholders that having

clinical pharmacists perform medication reviews and attending ward rounds was beneficial to medication safety. For example, stakeholders expressed:

I think the pharmacy, the number of pharmacists involved is an interesting thing, I don't know what the numbers are but the more pharmacists there are the better. I think that particularly with reconciliation and checking [healthcare services typically conducted by clinical pharmacists—discussed later in the chapter], I think having people whose job it is to do just that is really good. So I would invest in more pharmacists. In fact it's probably the single most effective thing you could do really. (S3, Policymaker)

We have a clinical pharmacist on our ward rounds. And as shown in 1995 [1999], paper in JAMA [Journal of American Medical Association] around the, having a clinical pharmacist on ward rounds reduces medication errors by 50%. And so, around, and that's particularly around side effects or drug interactions and stuff like that, and appropriateness of treatments. So that kind of, having that kind of a structure on a ward round can be incredibly helpful for us, and we have one on our ward rounds every day, clinical pharmacist, we do a multidisciplinary round every Monday and a speciality round in the evenings. But that's an incredibly helpful thing for us. (S21, Expert)

Even though the excerpt by Stakeholder 21 also outlines the importance of an environment which encourages open dialogue, communication and teamwork the focus in this section should be on clinical pharmacy services being an important technical component of the medication use system. The sub-dimension of clinical pharmacy services denote healthcare services provided by clinical pharmacists with the goal of optimising medication use and patient health outcomes.

The JAMA paper referred to by Stakeholder 21 was a study which investigated the effect of having a clinical pharmacist attend intensive care unit ward rounds (361). In this study, the pharmacist attended the ward round and offered recommendations and advice around medication use and therapies prescribed in order to optimise patient health outcomes. Medication errors, situations of risk and instances of medication related harm were identified for intervention. Clinical pharmacy interventions referred to the recommendations and advice provided when errors, deficiencies, discrepancies or opportunities for improvement in patient care were detected (67). Clinical pharmacy interventions typically focus on preventing or mitigating errors, such as the wrong drug or wrong dose prescribed before they reach the patient.

The JAMA study found that the rate of preventable ADEs that occurred during the prescribing stage of medication use decreased from 10.4 per 1,000 patient days to 3.5 per 1,000 patient days, while the rate in the control unit remained unchanged during this time (361). Several studies and systematic reviews in the literature have now confirmed the benefits of clinical pharmacy services on reducing medication errors and preventable ADEs (83, 362-365).

Consequently, the implementation of clinical pharmacy services is an intervention commonly recommended to improve medication safety (1, 31). It was thus understandable why many stakeholders also spoke about the benefits of clinical pharmacy services.

Even though the excerpts so far imply that having clinical pharmacists conduct medication reviews was generally beneficial, some stakeholders recognised that there were limitations. For example, one stakeholder recognised that just because clinical pharmacists were available, or that they completed medication reviews, did not necessarily mean that medication use was safer. For example, Stakeholder 11 noted:

The fact that someone looked at 20 out of 25 charts on a ward doesn't mean they did it [medication review] properly, or they actually had any influence, or they actually picked up any of the errors. (S11, Expert)

As mentioned by Stakeholder 11, variation in the competency, expertise or experience of the clinical pharmacist doing the review may play a part in determining which pharmaceutical problems are detected and acted upon. In the literature, there is also a suggestion that doctors have become over-reliant on clinical pharmacists, thus potentially decreasing their vigilance and may increase the likelihood of undesirable consequences (366).

Despite the concerns expressed by Stakeholder 11, clinical pharmacy services and pharmacists were thought to positively contribute to achieving medication safety outcome goals. Clinical pharmacy services clearly emerged from the interview data, with many stakeholders espousing their benefits. Clinical pharmacy services also clearly emerged from the literature as an intervention that can help reduce undesirable consequences of medication use. The clinical pharmacy services sub-dimension is an important technical component of the medication use system and medication safety. Given the contributory effects of clinical pharmacy services to medication safety outcomes, it is important if medication safety is to be measured. The importance of this sub-dimension and how it can be measured is discussed later in this section (in Chapter 3: Emergent finding 5B).

Standardised medication charts and systems

An important part of the dialogue on medication safety measurement was on standardised medication charts and systems. For example:

I think standardisation of process is a really helpful thing too actually, that you actually find a way that works for you and you standardise as much of it as you possibly can, reduce as much variation as possible. (S21, Expert)

I believe standardisation is good generally. (S3, Policymaker)

Some stakeholders considered whether standardisation had occurred in order to make a decision about whether medication safety had improved over the past 10 years. For example, one stakeholder expressed:

No probably not actually, because the processes that we're using are very much the same, we've still got different systems in different hospitals. We have not managed to standardise and that happens even within some hospitals, across the board. (S1, Expert)

Standardisation as a concept was generally seen to be beneficial and thought to be one approach useful in improving medication safety. Stakeholder 1 believed medication safety had not improved because there was a perceived lack of standardisation in medication use systems across different hospitals. But what exactly is standardisation and what is its significance to medication safety measurement? Emergent from stakeholder views, standardisation referred to components of the medication use system being of the same type and having the same basic features. Specifically, stakeholders spoke about the benefits of standardisation when applied to medication charts, clinical procedures and processes.

A commonly spoken about approach to improving medication safety was the implementation of standardised medication charts. For example:

I think that the one thing about the standardised chart that's going to come out is that it should promote uniform methods of prescribing which must be good. It must be a good thing. (S3, Policymaker)

We should move to a national medicines chart that just makes absolute sense to me. (S16, Expert)

A standardised medication chart refers to a standard paper document for the purpose of medication ordering or prescribing for use in and across NZ public hospitals. The development of a standardised medication chart has been a key priority of the New Zealand HQSC Medication Safety Stream (8). As noted in the excerpts above, there was a general belief that having a standardised medication chart would be beneficial to improving medication safety.

The reasons why a standardised medication chart was beneficial to improving medication safety was outlined by some stakeholders. Standardised medication charts were thought to help reduce medication errors associated with unfamiliarity with the medication chart format, and facilitate more effective and more efficient training for staff between sites (367):

It would just make it a lot easier if you were transferring to another workplace if you can use the same system. I know that makes a lot of sense that if I start working in a new area I don't have to learn a new system again. (S7, Expert)

Studies into the effect of standardised medication charts have found a significant reduction in medication errors (367, 368). These studies found that the documentation of adverse drug reactions and potential risks associated with warfarin management, areas which are prone to medication errors, were improved as a consequence of using a standardised medication chart (367).

Standardising clinical processes and practices were also thought to be beneficial in improving medication safety. For example:

When I think about prescribing [and how to improve it] I think about guidelines, there's a whole lot of guidelines around various treatments, medical conditions that, and guidelines associated with evidence for good outcomes that involve certain medications. Myocardial infarction is a classic case, the role of aspirin, beta blockers, ACE-inhibitors, all that kind of stuff. So there are guidelines around that sort of stuff. (S2, Expert)

Clinical guidelines provide evidence-based information to guide treatment, practice and processes in a standardised and consistent manner (369). Standardised clinical guidelines can be used to help reduce inappropriate prescribing and improve efficiency in the treatment of patients with particular conditions, improving both the process and outcomes of care (369, 370). Clinical guidelines and protocols can be modified into checklists which are typically lists of action items or criteria, allowing the user to record the presence/absence of the individual items listed to ensure that all are considered or completed (371). Stakeholders believed that checklists offer one potential approach to ensure that critical aspects of medication use are not accidentally missed during times of stress and fatigue when cognitive function may be compromised (371). For example, one stakeholder explained:

The idea of simple protocols. So to try to fill in for the fact that the person's tired, distracted, very human and so they're going to lapse on things they should know anyway. (S4, Expert)

As can be seen from the excerpts and discussions so far, the concept of standardisation can be applied to many different facets of medication use to help improve medication safety. For example, stakeholders also spoke about standardising medication names:

Having the standardised name I think is quite crucial. (S13, Consumer)

Coordinated by the WHO, there has been a global attempt to minimise confusion and variation of medication names by using the recommended International Non-proprietary Names (rINNs) nomenclature (372, 373). This move was started because prior to rINN, medication names were inconsistent across countries with each using different nomenclature. For example, the medication paracetamol was known as such in the UK under the British Approved Name (BAN) nomenclature. However, in the US where the US Adopted Name Council (USAN)

nomenclature was used, the same medication was known as acetaminophen. Salbutamol (BAN) and albuterol (USAN) is another example. Inconsistencies between medication names were thought to have been a source of confusion with the potential to contribute to medication errors (373).

Interestingly, the standardisation of medication names from BAN to rINN nomenclature led to unintended medication errors. For example, as a result of the change to rINN, the medication cysteamine (BAN) was changed to mercaptamine (rINN). However, as a consequence of the change to standardise medication names, several incident reports were received involving the confusion between mercaptamine which is used to treat nephropathic cystinosis and mercaptopurine which is used to treat immunosuppression (373). Such unintended effects may have actually worsened medication safety. Thus, if medication safety in a nation was measured based solely on auditing against whether standardised medication names had been implemented, practice may have been implemented but does not mean medication safety had improved.

Another unintended consequence of standardising clinical processes and services was noted by Stakeholder 2. For example:

You almost get pre-formatted scripts for example for discharge. Well that may or may not be appropriate. I mean I had a pre-formatted script and if I was the normal sort of patient it might not have been too bad, but it just happened that my personal history didn't align with that pre-formatted script. And when they're pre-formatted I don't think you do the same kind of checking that you do when you're reading and writing and thinking about what you're reading and writing about. (S2, Consumer)

The implementation of pre-formatted prescriptions was thought to improve medication safety by using preferred medications and potentially reducing prescribing errors such as the omission of patient details (374). However, Stakeholder 2 believed that this had the potential to lead to complacency and less vigilance by healthcare staff and increase the likelihood of error. Even though standardisation of systems in general was considered beneficial, the individual, context and situation also need to be taken into account. Some stakeholders also believed standardisation in general tends to stem innovative practices, and thus potential solutions to improve medication safety may potentially be inhibited. For example, one stakeholder expressed:

Choose the best approach that we are aware of now, and we implement it everywhere, kind of, to me, suggests that ultimately we stagnate. And we stop inventing, and we stop getting better. Right? So, and this is the reason, this, the fundamental reason that the public sector fractionated, or disaggregated to have basically single purpose organisations was so that they could be effective, and

quick, and fast, and fleet-of-foot. And that's, and have a great deal of diversity, because ultimately that leads to an improvement in dynamic efficiency compared with this static efficient kind of, so, yeah, what we'll see is everybody in, this you getting my philosophy and I'm public sector, every, we've made all the arguments around how important dynamic efficiency is, we've created a whole pile of crown entities, we've disaggregated functions, we've got efficient at doing all of these things, we've had diversity, we've had, to get that we've had a degree of double up of background services etcetera, and now everybody thinks that there's some benefit to be had in re-aggregating. We'll do that, and then we'll get to the point and we'll say, "Actually, disaggregating is really important because we get a whole pile of dynamic efficiency effects", and we'll just continue on this cycle. At the moment we're in the, it's fashionable to talk about standard efficiency and going back to re-aggregating services. Personally I think it's a flawed approach.
(S27, Policymaker)

Changes to the NZ government from centre-right to centre-left in 1999 replaced a single purchaser with 21 national district health boards each with their own CEO and support staff (221). By 2008, the NZ government had changed again from centre-left to centre-right and questions were raised about why a small country with only 4.3 million people required 21 DHBs (221). The number of DHBs was thought to have resulted in unnecessary duplication and high transaction costs (221). Consequently, there have been efforts to increase centralisation and standardisation of healthcare services (221). Stakeholder 27 was of the view that standardisation as a concept was not necessarily beneficial, because this meant that this may impose unnecessary systems which are not required. Applied to a medication safety context, implementing standardised systems was thought to stifle innovative ways to improve medication safety and impose particular medication safety practices on hospitals which they may not require.

Standardisation as a concept appears to be subject to debate, and illustrates philosophical differences in peoples' ideas in how healthcare can be improved. It is important to have recognised both sides of the argument. The discussions so far have illustrated the potential for adverse unintended consequences and limitations of standardisation. This means that standardisation cannot solely be used to improve medication safety. There will be instances where standardisation would be inappropriate. However, despite these limitations, standardisation can also help improve medication safety such as the use of standardised medication charts. Standardisation was meaningful to many stakeholders.

Labelling and packaging

An important sub-dimension was the labelling and packaging component of the medication use system. For example, stakeholders expressed:

It's a typical, look-a-like products, sound-a-like names, those sort of things keep coming up time and time again [in incidents of harm]. (S1, Expert)

Some stakeholders spoke about changes to the labelling and packaging of medications resulting in improved medication safety:

Colour of the needle on the syringe, to eventually writing on the syringe, to having clear labels, and then barcoded labels on syringes, and pre-filled syringes. That's all things that have changed [leading to improved medication safety]. (S20, Expert)

We've also got much better dosing support, like people's, the things that people have to help them in the community. I think blister packaging, child safety locks on containers, better presentation, generally that's all improved. (S3, Policymaker)

Analyses of medication errors and adverse events have shown that medication errors can result from medications which look-a-like and sound-a-like (169, 375). For example, Lamictal® which is an anti-convulsant medication was inadvertently interpreted as Lamisil® which is an anti-fungal agent when a patient was transferred from one health setting to another (375). Poor documentation, poor handwriting and an increased number of therapeutic agents add to the confusion resulting in the wrong medication being used (170). In a voluntary medication error reporting programme, it was reported that labelling and packaging issues, like look-a-like and sound-a-like, made up 15% of all reports (170). Another report puts the figure around 30% (169). The exact figure has been difficult to establish, because the reports are voluntary and thus can depend on reporting rates rather than actual change. However, errors associated with labelling and packaging are a significant area of high risk which warrants attention for further improvement. Indeed, intervention programmes such as bulletins and warning programmes have been implemented to try and reduce medication errors (169, 170, 375). Tall man lettering has been another error prevention strategy (e.g., fluvoxa**MINE** and flavox**ATE**) by emphasising the differences between similarly named medications (376). Such interventions, focused on labelling and packaging, often form a substantial part of medication safety improvement programmes.

An interesting approach when considering the risks associated with labelling and packaging, and importantly considers the concept of future medication safety was discussed by Stakeholder 15 using a technique called Failure Mode Effect Analysis (FMEA):

There's a failure mode and effects analysis that I didn't mention, but again that might be something that could be used within hospitals and applied to certain processes and certainly it could be applied to the packaging too just to assess any new product. What I like about it is that it's prospective, so rather than everything much we've talked about so far has been looking at retrospective data, this is a way of trying to look at things to find how where errors might arise sort of in

advance of them happening. So it's a more proactive way and you end up with calculating a risk priority score for certain events. (S15, Expert)

FMEA is a structured method of prospective risk assessment (377). This approach uses a multidisciplinary panel to assess the degree of risk a new product, a new presentation such as altered medication label, or a new service may pose to existing medication systems (377). New products or services are evaluated against criteria such as the probability of occurrence of error or adverse event, the severity of effects if error occurred and ease of identification of the error (377). Using a 10-point scale, each new product can be assessed using the criteria to calculate a risk priority score and allows the panel to fully consider the risks and implication so harm can be mitigated or minimised (377).

Using FMEA in the context of medication safety measurement is interesting because it introduces the concept of safety in the future. As noted by Stakeholder 15, discussions so far in the research have focused predominantly on how safe it *has* been (18). For example, the identification and measurement of ADEs requires the event to have happened before it can be measured. Even though not explicitly noted, the medication safety measurement literature has focused predominantly on the measurement of past error and harm. In contrast, by considering the potential risks and calculating the degree of risk, FMEA can help predict the likelihood of how safe it is likely to be in the future. Even though this particular finding was only evident through Stakeholder 15's excerpt, this finding has important implications because it potentially expands what should be considered when measuring medication safety.

The excerpts so far show that stakeholders found the labelling and packaging sub-dimension meaningful. Labelling and packaging issues have been reported as substantial issues and make up a large proportion of medication errors. In the literature, sub-analysis of medication errors and ADEs associated with labelling and packaging has been conducted (169, 170, 375). Labelling and packaging is an important dimension of medication safety. The importance of measuring the labelling and packaging sub-dimension and how it can be measured will be discussed later in this section (in Chapter 3: Emergent finding 5B)..

Information transfer

A substantial part of the dialogue on medication safety measurement was on information transfer between sectors of healthcare. For example, stakeholders expressed:

A lot of stuff [information sources] was there but it was not tied together or coordinated, and I've talked to medical practitioners in hospitals, to hospital pharmacists, to others, they've all got their bit [i.e., respective information sources] but making sure that it's interrelated and that the information travels with the patient is the challenge. (S28, Policymaker)

I think the greatest errors come from every time people take information from one place to another place. Every time you have to re-transcribe it the chances of errors are very high. (S13, Consumer)

It's a very dangerous act, leaving hospital. It's a very dangerous act to go to hospital. That moat between the castle and the population, the drawbridge, crossing that drawbridge is a very dangerous act. And all sorts of harms go both ways. Communication is pitiful. Pitiful. (S24, Expert)

Health information such as patient personal medication lists or patient medical records was perceived to be poorly transferred in and between hospital and community healthcare settings. This was identified by stakeholders as an area of high risk and was thought to be in need of further improvement. Arguably, the focus on the information transfer between the healthcare sectors falls outside the remit of this research which focuses on medication safety in public hospitals. However, as noted by Stakeholder 16, poor information transfer to and from the community may have downstream effects on medication safety in the hospital setting:

The point of biggest breakdown is the transfer of patients through from one sector to the other. I know residential care isn't part of your brief but clearly in terms of medication safety practices that's a huge area to be looked at. (S16, Expert)

In the literature, the consequence of poor information transfer between healthcare settings was thought to lead to inadvertent discrepancies and medication errors in patients' medication lists. The most common type of medication errors identified in the literature were the omission of medications a patient is usually on, and the inadvertent reinstatement of medications a prescriber had deliberately discontinued (378). Several studies have confirmed that the risk of ADEs increase when patients transfer between wards or when they transfer from hospital to home (224, 379-385). Rates of clinically important unintended medication discrepancies range between 0.25–0.97 per patient (379). Problems with information transfer pose a significant risk to medication safety and should be prioritised for improvement.

Many stakeholders spoke about the need to improve the information transfer component of the medication use system in order to improve medication safety. Stakeholders believed there was a need for seamless and smooth information transfer between different sectors of care. A large portion of the dialogue focused on the various tools, infrastructures and processes thought to facilitate the transfer of health information in an accurate and reliable manner. One stakeholder spoke about having clinical liaison pharmacists to help ensure information about the patient's medications is transferred between sectors of care in a safe and accurate manner. For example:

Well I think the whole issue of liaison between the tertiary, you know, the hospital sector and the community sector is probably where the biggest gain will be made, but nobody knows how to do it, or at least nobody knows how to do it well. I

personally believe that the only way that you're actually going to affect change in that regard is to have liaison pharmacists working between the sectors. (S16, Expert)

Arguably, clinical liaison pharmacists could fit into the pharmacy services sub-dimension mentioned previously because they appear to be related. However, it has been categorised here because it specifically addresses the underlying problem which is poor information transfer. Clinical liaison pharmacists have been trialled in New South Wales, Australia (31). Clinical liaison pharmacists communicate with a patient's community pharmacy to obtain an accurate medication history and document this electronically (31). On discharge from the hospital, the clinical liaison pharmacist communicates with the patient's community pharmacy and GP to ensure any medication changes are communicated and are provided with additional information around patient monitoring (31). The clinical liaison pharmacist also arranges regular follow-ups with the patient to optimise medication use (31). Such services were thought to improve the information link between hospital and the community ensuring a seamless and continuity of care (31).

Shared electronic health records (EHR) were also viewed by stakeholders as another approach to improve information transfers between different healthcare sectors. For example:

I think that we should move now, over the next decade or quicker, to substantial electronic record keeping. We've got big penetration in general practice of electronic records, but not in the hospitals. And in particular we don't have a, the things that are missing are a common patient record which has got, amongst other things, the allergies, contraindications and drugs, and up to date, and reliable manner. And I think that we should do, we should be able to, if you came to see me as a GP or turned up at A&E or even at the ambulance, somebody should be able to go online and just get your record, and that should be straightforward to do. (S3, Policymaker)

EHR are information records which can contain patient information such as the medications they are on and the medical problems they may have (346). This sub-dimension could have also been categorised in the technology sub-dimension which shows the degree of overlap between sub-dimensions. However, it has been located here because it specifically addresses the underlying problem which is information transfer. As noted by Stakeholder 3, the ideal situation would be to have a common EHR spanning across multiple healthcare settings so that the patient information record is available when required. Several studies have found that the use of EHRs was more conducive to more complete and accurate information (346).

Another approach to improving information transfer which stood out was the implementation of a medication reconciliation process. Implied was that the implementation of medication

reconciliation would lead to the improvement of medication safety. For example, stakeholders expressed:

Medicines reconciliation should simply be a standard service... I think we should move to statutory implementation of medicines reconciliation services. (S16, Expert)

The two most significant interventions around medication safety are having a pharmacist on the round with the docs and implementing medicines reconciliation. So I guess the evidence is pretty strong for those two interventions if you like and that's been a big focus for us obviously. (S18, Expert)

I think medicines reconciliation. Ultimately, if your organisation isn't doing medicines reconciliation then I think you can safely argue that you're missing out on an opportunity to impact medication safety. (S11, Expert)

Medication reconciliation is a process which attempts to obtain the most accurate and current list of patient medicines and compares this against currently prescribed medicines (382). Any discrepancies are then reconciled by way of altering the prescription or providing a rationale for why the discrepancy exists (386). The medication reconciliation process is typically carried out by clinical pharmacists though the process is not profession specific (379). Medication reconciliation is about improving the accuracy of a patient's medication list when they transfer in and across different healthcare settings. Stakeholders, and a substantial proportion of the literature (1) suggest that the implementation of medication reconciliation processes is generally beneficial and if implemented would help improve medication safety.

Various approaches such as liaison clinical pharmacists, EHR and medication reconciliation were thought by stakeholders to improve information transfer. Implied was that this also has beneficial effects on medication safety. Information transfer is a component of the medication use system spoken about by stakeholders as warranting further improvement. Inferred from stakeholder data was that the improvement of information transfer would also lead to the improvement of medication safety. Several approaches to improving information transfer were spoken about by stakeholders. Specifically, they relate to clinical liaison pharmacist services, EHRs and medication reconciliation. The importance of including information transfer as part of medication safety measurement is highlighted at the end of this section along with how this dimension can be measured (in Chapter 3: Emergent finding 5B).

Staffing, workload and workplace environment

An important part of the dialogue on medication safety measurement was on staffing, workload and workplace environment. This dimension referred to the availability of staff to deliver healthcare, the amount of work done by healthcare staff and the conditions in which

staff work. There was a general belief that this component of the medication use system was important, and if improved would lead to the improvement of medication safety.

The importance of this sub-dimension was illustrated when stakeholders used it to determine if medication safety had improved. For example, some stakeholders believed medication safety had not improved over the past 10 years because there was less time than before for healthcare staff to do their duties:

Don't have the same time to check their work, when things are passed on to the next one in the chain. I think there's potential there for errors to come in. (S2, Consumer)

Don't have the downtime that we used to have, you know, in pharmacy for example you had time to, at the end of the day, to sort things out, to put things in order. Now it's just constant, and I assume it's the same for nurses and doctors as well, so you don't have that downtime to perhaps reflect on what you're doing, you're just at it full tilt. (S1, Expert)

Stakeholders spoke about the lack of time and its influences on the ability of healthcare staff to make the necessary checks to prevent errors occurring. The consequence of an inability to check and mitigate errors was thought to have resulted in poorer medication safety. A perceived cause of the lack of healthcare professionals' time was due to inadequate staffing and workforce issues.

Don't know [whether medication safety had improved]... the health workforce issues are very acute here in New Zealand and somewhat generally, so I'd also be a little bit surprised if it was getting better. I'd say it's quite a triumph if it is getting better 'cause there's certainly a lot of pressure on staff. (S4, Expert)

Inadequate staffing and healthcare workforce issues are prominent in various countries including New Zealand (387-389). Healthcare professionals like doctors, nurses, pharmacists and others are on the long-term skills shortage list issued by Immigration New Zealand (389). Health Workforce NZ is a government organisation set up specifically to plan and develop a workforce to address staffing issues (390). Feminisation of the health workforce, increasing patient and community demands for healthcare and globalisation of the healthcare workforce are three key factors thought to be associated with workforce shortages (387). Because there were fewer staff available, stakeholders believed there were increased demands on healthcare professionals' time and this could potentially lead to an increased likelihood of error.

The reason for why there was inadequate staffing and increased workload was explained by Stakeholder 13. Stakeholder 13 spoke about the shifts in staffing budgets from frontline workers to administration staff as one potential cause. Interestingly, Stakeholder 13 believed

the increase in workload was also due to the unintended consequence of upskilling nurses. For example, Stakeholder 13 expressed:

It concerns me sometimes about the allocation of budgets, it concerns, in terms of structure, about the amount of administration, that somehow we've got the structure wrong, that the value should be in the people who supply the service, not the administration. And I, that seems to have got out of kilter... In my mind, the swing should go to, for example, the nursing staff and increasing that funding and level there... We've also upskilled the nurses, which on one hand is really good, and on the other hand you almost need another layer doing core stuff. (S13, Consumer)

Stakeholder 13's view on the shift in the allocation of budget from clinical to administration staff referred to policy effects as a result of a change in government in NZ. As has been previously mentioned, a centre-left government was elected in 1999 which focused on the improvement of public health (221). There were high transaction costs, duplication of planning, purchasing and administrative activities, with clinical staff becoming increasingly alienated from management (221). The centre-right opposition promised, if elected, to increase the number of frontline healthcare workers (391, 392). Such findings suggest that health policy has influences on medication safety through the allocation of resources and staffing.

The upskilling of nurses for expanded roles, such as nurse prescribers in diabetes or aged care, is generally seen as a positive step toward helping reduce workload pressures in other professions such as GPs (393). However, Stakeholder 13 believed that the unintended consequence of upskilling nurses was the resultant shortage of workforce for core nursing duties. The implications of such changes on medication safety were explained by Stakeholder 13:

They're [nurses] spending time with patients and when you're administering to a patient, you're not just washing their face, you're actually observing their colour and their demeanour and their something. If you spend less and less time with patients 'cause you're doing the other stuff, then that human interaction thing which is what, in my mind medical care is about, is lessened. (S13, Consumer)

As previously discussed in the caring nature sub-dimension of safety culture, consumer stakeholders spoke about feelings of being cared for and the ability to be able to trust in the healthcare delivered as being important characteristics of a safe medication environment. Thus, if consumers feel that healthcare staff were constantly rushing and did not have sufficient time to show care for them, then medication safety was perceived to be poor. Stakeholder 13 highlighted that inadequate staffing also had important pragmatic implications. Because healthcare staff had less time available, they may not be able to observe clinically significant signs and symptoms of deterioration. Overall, the effects of increased workload and

workforce issues were thought to be detrimental to medication safety and thus should be prioritised for improvement.

Another perceived cause for the lack of healthcare professionals' time was because of increased workload pressures. For example, stakeholders expressed:

I think the pressures within the healthcare system are greater than 10 years ago. So, I think some things we've probably improved, but they've been compensated for by others probably. (S22, Policymaker)

High workload, long work day, interruption is going to downgrade the human performance and lead to errors with whatever kinds of tools you've got. So I mean there's always that problem that, you know, where's the problem in the system? Well it's somewhere between the chair and the keyboard. So if you make the environment hard on the human that's always going to be a problem. (S4, Expert)

Frequency of human error in stressful situations moves it to about 0.25–25% in extremely stressful situation. (S17, Policymaker)

There are many workload pressures that can affect the healthcare worker and these have been extensively studied. Fatigue (394, 395) and interruptions (396-398) have been recognised in the literature as having the potential to increase medical errors. Stress in the workplace can come from many sources such as lack of resources, job control and conflict (399-401). Stress has been shown to increase the occurrences of patient incidents such as medication errors and patient falls (401). Administrative hassles, emotional workload and complexity in tasks are some of the other factors contributing to workload pressures (400-404). The presence of such factors has been found to be positively correlated with burnout of healthcare staff (402). Workload pressures and burnout, in turn, was thought to negatively affect patient health outcomes (405-411). As recognised by these stakeholders, workload pressures were thought to increase the risk of error and implied that medication safety was worse.

As a consequence and recognition of the significance of workforce and workload pressures on medication error and safety, stakeholders spoke about the importance of improving these components of the medication use system as means to improve medication safety. Specifically, stakeholders spoke about the need to increase frontline healthcare workers to reduce workplace pressures. Such views were aligned with those in the literature, and many studies have shown the correlation between staff numbers and the rate of medication errors (407-409, 411). For example:

Well it's having enough staff on a specific shift to deal with the acuity, which is always challenging isn't it? So within a DHB setting I think that's a real issue for staff if they feel overwhelmed and pressurised and fatigued to be able to think straight about complex medication and their assessment around the patient on that. (S7, Expert)

I think often the nurses are so far extended that it's really perhaps not in the best interest of the hospital... I think sometimes we put so many demands, particularly on the nursing staff, with fewer and fewer that it makes that balance very difficult. (S13, Consumer)

The findings from stakeholder views imply that if workload, staffing and workplace environment was improved then medication safety may also improve. Conversely, if staffing and workplace were poor, then what was previously deemed as safe such as prescribing and dispensing, may become highly risky and unsafe because people are rushed. This highlights the transient nature of medication safety which changes from moment to moment. Staffing, workload and workplace environment were technical components of the medication use system which appeared to be important in influencing medication safety. Stakeholders spoke of the need to prioritise this sub-dimension for improvement. Implied in these views was that if staffing, workload and workplace environment was improved, medication safety would also be improved. Staffing and workload should be part of the measurement of medication safety and this is discussed later in this section along with how this sub-dimension can be measured (in Chapter 3: Emergent finding 5B)..

High risk medication areas and diseases

This sub-dimension directly emerged from stakeholders' discussions on determining what should be measured for medication safety. For example:

I think they need to concentrate on high risk medications. I think it would be good to do anti-coagulation, and to do clinical indicators looking at the INRs [International Normalised Ratios]. There's obviously narcotics so there's morphine. I mean for all the high risk medicines, there's insulin as well. I could go on for, but yeah, no, I would, just, I think there's a lot more that could be done on the high risk medicines. (S22, Policymaker)

The use of high risk medication to measure medication safety is well established in the literature. The measurement of warfarin use, for example, has been recommended as a medication safety indicator (33). High risk medications and related measures are included in the MSSA tool (32). High risk medications like anti-coagulants are used as a proxy to indicate overall medication safety by organisations like the Agency of Healthcare Research and Quality (179).

To better understand how these high risk medications can be used to measure medication safety, consider the following example provided by Stakeholder 11:

[The way to measure medication safety is the] *number of patients who are on heparin who get their aPTTs* [partial thromboplastin time which is used to measure

the extent of anti-coagulation of heparin] *monitored according to appropriate guideline.* (S11, Expert)

The measure spoken about by Stakeholder 11 can be used to measure the appropriateness of medical care when using the anti-coagulant medication heparin. Patients on heparin have the potential to bleed, and to use heparin safely, measurement of aPTT is recommended to monitor the degree of anti-coagulation and prevent under- or over- anti-coagulation (412). Thus, the measure of patients who have aPTT appropriately measured provides an indication that heparin was being used safely.

The use of high risk medications like anti-coagulants, narcotics and insulin to indicate the state of medication safety is understandable because they are commonly implicated with many errors and ADEs (206, 413). Thus, if these areas improved then an assumption was that medication safety overall would also improve. Many stakeholders held such views and also believed that to measure medication safety one should focus on high risk medications. Many high risk medications and diseases were spoken about, but the following were particularly prominent in stakeholders' views:

- Anti-coagulation
- Anti-infectives
- Opioids
- Insulin

Even though these specific medication classes were discussed, stakeholders did not seem too concerned about which exact high risk medications were selected for measurement and monitoring. For example, stakeholders expressed:

[To measure medication safety] So one or two monitoring parameters, the degree to which you get, I don't know, these are useful things but in the amiodarone lung or whatever, any of those sort of things where you should really be watching out for something that, the degree to which co-morbid, this is aminoglycoside, heparin things and whatever, the extent to which those heavyweight type issues are occurring. Maybe a parameter in terms of prescribing errors along the way and you'd have a sort of a snapshot and they'd all be incident figures of what's happening. And you'd say, this is my, this is not everything, but there's enough in here pick up on different elements of the safety system. (S14, Policymaker)

The important focus in this excerpt and other stakeholders' views wasn't necessarily on the specific medication used, but rather a focus on the underlying measurement of high risk medications. Stakeholder 14 had the view that even though not all aspects of poor medication safety would be identified, the selection of a few high risk medications to measure and

monitor medication safety would provide a good overview of the medication use system and its safety.

In the outcome goals of medication safety chapter, this research posited that measuring beneficial health outcomes may help overcome problems associated with measurement related to error and harm. Previously, it was suggested that harm such as lactic acidosis from metformin use occurred too rarely for it to be compared between different time periods so it would be difficult to know if safety has improved. Thus, instead of measuring harm to monitor safety of medication use, it may be better to monitor diabetes related health outcomes to provide a proxy for medication use. The assumption was that if diabetes related morbidity and mortality were generally trending in a positive manner, then this may suggest overall medication use was effective and safe. Many stakeholders held such assumptions and specified the conditions that could be used to monitor medication safety. For example:

Hypertension, cardiovascular disease, thyroid disease, diabetes we've said [to measure medication safety], I mean I think there's a whole lot of them that you could pick. I mean diabetes is so topical at the present time, I mean I guess that's number one. Ischemic heart disease in its various forms is number two. What would be number three, asthma, respiratory disease, a classic example there of where you're getting injured by not using the medication. (S25, Policymaker)

A common medication used in the prevention of asthma symptoms is inhaled corticosteroids. Stakeholder 25 noted that an underuse of medications such as corticosteroids can potentially lead to medication related harm such as the exacerbation of asthma. If asthma disease was generally improving, then implied is that patients were being managed appropriately with medications and medication related harm was reduced. Again, as with the high risk medications, stakeholders were not concerned about which exact medical conditions were used as a basis for medication safety measurement. Many other diseases and conditions can be used. However, emergent from stakeholders' views was the focus on:

- Elderly patients
- Cardiovascular disease
- Diabetes
- Thyroid disease

In the literature, medication use in patients that are elderly, have renal impairment, diabetes, cardiovascular conditions and other conditions are commonly implicated with ADEs (414). Because medications form a substantial part of the treatments used to treat these diseases, the assumption of stakeholders was that if the overall disease was improving then medication use

was appropriate and safe. This is because relative to the benefits gained, risks and harm were relatively minor. Understandably, the measurement of certain medical conditions as a proxy for the overall health of a nation has been well established in the literature. For example, global measures of health that are regularly published by organisations like the WHO or the OECD use changes to certain diseases to provide an overview of the health of a nation (215, 415). Indeed, certain medical conditions form the framework for certain medication safety measures recommended in the literature (416).

Stakeholders directly spoke of the importance of measuring high risk medications and diseases to measure medication safety. In the literature, this facet of the medication use system has commonly been used to measure medication safety.

Summary

As can be observed from the discussions so far, the technical components of the medication use system thought to be able to most significantly influence medication safety are:

- Technology
- Pharmacy based services
- Standardised medication charts and systems
- Labelling and packaging
- Information transfer
- Staffing, workload and workplace environment
- High risk medications and diseases

Each of these sub-dimensions was facets, which if implemented and worked well, were thought to reduce adverse consequences of medication use and optimise beneficial health outcomes. Alternatively, they represent areas of high risk which if improved can improve medication safety.

Regardless of how each of the sub-dimensions contribute and influence the outcome goal of medication safety, underlying these facets was a focus on the physical procedural steps and environment involved in, and support of, medication use during the delivery of healthcare to patients. Some stakeholders specifically spoke of the need to improve the overall medication use system in order to improve medication safety. For example:

Well it [the improvement of medication safety] takes the whole, it goes the whole range really doesn't it? From prescribing to ensuring dispensing accuracy, administration is extremely important. (S6, Policymaker)

Given the importance placed on this dimension, understandably, many stakeholders based their decision on whether medication safety had improved over the past 10 years on this facet.

For example:

If you look at the quality assurance work that Person Y's group's been involved in, and you look at the various other activities that have been around there... All of the signs are lining up the right way to give you the sense that we're doing much better than we were in terms of supplying the right medicines to the right people at the right time. (S28, Policymaker)

Discussions which relate to these physical components were labelled as technical components of the medication use system and these emerged as important dimensions of medication safety. The various technical components of the medication use system were one of the most commonly discussed facets of medication safety.

The views so far support the notion that there is a causal chain which links medication safety to beneficial outcomes. For example, the use of technology was thought to help the reduction of medication errors and harm (51). The notion that interventions, such as the technical components of the medication use system, are related to outcomes draws heavily on the work of Donabedian and Reason (51). Donabedian wrote about structures, processes and outcomes (187). Structure denotes the attributes such as equipment, technology, personnel or organisational structure of the setting in which healthcare is delivered (187). Process denotes what is actually done in giving and receiving healthcare (187) such as prescribing, dispensing, administration and using technology. Outcomes denote the effects of healthcare on the health status of patients and populations (187). ADEs are one example of an adverse outcome of medication use. Donabedian wrote about good structures increasing the likelihood of good process, and good process increasing the likelihood of good outcomes (187). Applied to a medication safety context, the implementation of technology like CPOE with CDSS, barcoding and Pyxis® were examples of the structures and processes implemented which were thought to have led to an improvement in medication safety outcomes over the past 10 years.

As has been outlined at the start of this thesis, Reason wrote of active failures and latent conditions (72). Active failures are the unsafe acts committed by people (72). Medication errors that occur during prescribing such as slips, lapses, violations or mistakes (290) which will be described in the staff competency dimension, are examples of active failures which occur at the proximal end of unsafe acts which may have resulted in harm (72). Latent conditions are the inevitable 'resident pathogens' within a system (72). Understaffing or

inadequate equipment are examples of latent conditions which predispose for an error to occur (72). Technology which is too laborious to be practically useful leading staff to ignore them are examples of latent conditions which create weaknesses in the systems designed to mitigate error and harm (72). Increasing the level of staffing was an example of efforts which aim to improve latent conditions and minimise the likelihood of adverse consequences. Additional defences, such as having clinical pharmacists conduct medication reviews to identify potential medication related problems, aim to prevent errors from reaching the patient and adverse consequences from occurring.

In the past, the approach to reducing or managing adverse consequences of healthcare focused on individuals and groups which is termed a person approach (417). Errors were thought to occur because of aberrant mental processes such as forgetfulness, recklessness or inattention which treats errors as bad things occurring to bad people (417). Countermeasures thus focused on reminders or disciplinary measures to avoid such errors from occurring (417). However, errors tend to occur in the best people and mishaps tend to recur in different people, which suggest the same set of circumstances can provoke similar errors (417). These findings suggest that it was more probable that latent conditions play a role in predisposing active failures from occurring (417). Reframing how error is viewed has significantly changed improvement efforts to one which focuses on system improvement rather than the person approach (417). There is now a widespread belief that in order to improve medication safety and make it more resilient to errors and harm, there is a need to focus on improving multiple components of the overall system (1, 9, 10, 13, 21, 34).

Understanding the assumptions of interventions being linked to outcomes was important, because it informs how the technical components of the medication use system have been predominantly viewed by stakeholders. Many stakeholders were of the view that if the appropriate medication safety intervention had been chosen, was successfully implemented, and used in an appropriate manner then the likelihood of the outcome goal of medication safety would be achieved. Similarly, many stakeholders were of the view that if the most significant and commonly occurring latent conditions and active failures were addressed and focused upon for improvement, then medication safety outcome goals would be achieved.

Clearly emerging from the interview data, however, was that the linear causal relationship of linking interventions to beneficial outcomes or poor conditions leading to undesirable consequences was perhaps an oversimplification. Stakeholders frequently provided compelling arguments on why focusing on the technical components may not necessarily lead to desirable consequences of medication use. Medication errors and adverse consequences appear to be

complex problems with multiple causes and are influenced by multiple factors. For example, even when technology was available, implemented and used appropriately, undesirable unintended consequences could still occur (355-358). Findings from stakeholder views and the literature suggest that in order to address problems associated with medication use there is a need for a multi-faceted approach.

Safety culture and competency of healthcare staff are just two examples that emerged from stakeholder views which also probably need to be addressed. However, this does not detract importance away from the technical components of the medication use system dimension. Even if the safety culture was positive and staff competency was excellent, without having the adequate or appropriate technical components in place and working well, undesirable consequences could still occur because the physical environment is not necessarily safe. Thus there is a need to focus on multiple dimensions to provide a more balanced and rounded approach.

The technical components of the medication use system specifically focus on the physical procedural steps and environment involved in, and support of, medication use. In the literature on medication safety and its improvement, this is the dimension that has been most frequently focused on. The literature has focused on the improvement of the technical facets of medication use in order to improve medication safety. For example, the ISMP focuses on ensuring there are adequate structures in place and appropriate processes relating to certain stages of the medication use system, such as having the adequate systems in place to ensure patient information is readily available (13, 21, 32). Literature on improving medication safety focuses on developing new tools such as CPOE with CDSS (211, 342, 352) or processes such as medication reconciliation (379, 382, 418). Comprehensive reports on medication safety improvement and organisations dedicated to improving medication safety also focus on the implementation of technologically based tools and implementing certain processes (1, 9-11, 31, 162, 419).

The discussion so far has shown how the sub-dimensions and dimension emerged from the interview data. The technical components of the medication use system encompass many different facets which are thought to be able to significantly influence medication safety. This dimension focuses on the technical facets which relate to the physical procedural aspects and environment involved in, and support of, medication use. Specifically, the key technical components relate to technology, pharmacy based services, standardised medication chart and systems, labelling and packaging, information transfer and staffing, workload and workplace

environment and high risk medications and diseases. Of the various technical components, these are the ones which emerged as being most meaningful to stakeholders.

As can be observed from the research so far, being safe means excellence in technical components of the medication use system. The technical components of the medication use system dimension were one of the most frequently talked about facets of medication safety. To stakeholders, being safe meant having appropriate technology and using them in an appropriate manner; having adequate clinical pharmacy services; having standardised medication charts and systems; appropriate labelling and packaging; optimal health information transfer; optimal staffing, workload and workplace environment; and focusing on and having systems in place to manage and improve high risk medications and diseases. However, being safe also means that other facets such as safety culture and staff competency also need to be addressed. Despite this, the technical component of the medication use system is a fundamental and important facet of medication safety. Given its importance, this dimension should be part of medication safety measurement. The importance of measuring this dimension along with how it can be measured is discussed in the next section.

B) Importance of measuring the technical components of the medication use system dimension and how it could be measured

Emerging from the interview data, many stakeholders spoke of the importance of including this dimension to measure medication safety. For example:

[In relation to what should be measured to measure medication safety] *Good medication management systems within the organisation.* (S22, Policymaker)

In the literature, several reports have been published which show that certain practices correlate with decreased error or ADEs (82, 83, 420). If medication safety measurement focused on assessing whether these practices were implemented and working well, it may help indicate the likelihood of achieving the desirable outcome goals of medication safety. Moreover, given that many of the technical components represent the physical procedural steps and environments thought to reflect the best practices associated with medication use, measuring a hospital against these may help to indicate gaps in practice and areas in need of further improvement.

The improvement of medication safety has tended to focus on the technical components of the medication use system. Understandably, many tools and approaches have also been developed and spoken about by stakeholders, which focus on measuring these various individual components. A significant proportion of the medication safety measurement literature has

focused on measuring whether these components are in place and how well they are being used in order to measure medication safety. Some examples are the MSSA tool (32), medication safety measures (25, 33) and so forth (1, 21). Because of the breadth and scope of measures, tools and approaches, this research will predominantly focus on those spoken about by stakeholders. These measurement tools will be briefly explored before a discussion on how the overall dimension can be measured.

One approach to measuring medication safety commonly discussed by stakeholders relates to clinical pharmacy based services. For example:

The actual total number of pharmacists in the [ward and hospital], and the staff ratios, I think that's probably very legitimate [as a measure of medication safety]. The WHO's taken the number of surgeons and the number of anaesthesia providers as indicative of the infrastructure of a country in terms of surgical safety. So I think that's the same idea. So you could say how many doctors per head of population does a country have, how many nurses and how many pharmacists, and I guess most people don't look at how many pharmacists [there are]. (S3, Policymaker)

[Medication safety measures can be] Very simple markers such as the number of pharmacists, etcetera and what their roles are within the organisation. (S17, Expert)

As has been previously discussed, clinical pharmacy based services and clinical pharmacists were thought to be generally beneficial during medication use. Having clinical pharmacy services were thought to be able to help achieve desirable outcome goals of medication safety. This means that if pharmacist to patient ratios were measured and results were positive, this may indicate a more optimal medication use environment which is potentially more conducive to achieving the desired outcome goals of medication safety outcomes. Alternatively, one could measure the number and rate of patients who have had their medications reviewed by a pharmacist. For example, stakeholders spoke of:

[In relation to what should be measured to measure medication safety] I mean other measures we have at Hospital Y around pharmacists go into the ward and looking at the number of charts they see and the number of patients they see and the number of charts they see. (S11, Expert)

Notwithstanding, arguments such as 'just because a clinical pharmacist reviews a medication chart for pharmaceutical problems does not necessarily mean that medication errors and adverse consequences will be reduced', the use of clinical pharmacist numbers or percentage of patients who have had their medications reviewed by a clinical pharmacist may serve as a useful proxy for measuring medication safety. Indeed in the literature, such measures do exist and are often recommended as part of other measures to help determine whether medication use was safe and optimal (229, 360).

Previously, excessive workload and poor workplace environments were identified from stakeholder views as having the ability to increase the likelihood of medication errors. Using staff ratios to measure medication safety may also be useful to provide an indication of whether the workplace environment and staffing workload, and thus the environment for medication use, was optimal. Indeed, some professional organisations, like the Society of Hospital Pharmacists Association, have recommended clinical pharmacist staff to bed ratios ranging from 15 critical care beds to a pharmacist to 90 long-term psychiatric beds to a pharmacist (360). Coupled with other measurement approaches such as qualitative reporting, they can be used to indicate workplace conditions. For example:

The reason for error is often process, which may include pressure to work, or understaffing, or, not the best environment, and I think on those, you'll pick up on those only on qualitative reporting. (S20, Expert)

If people are feeling stressed and thinking this is a difficult environment, then they probably are, you know, they probably are stressed and making errors. (S4, Expert)

As can be seen from these excerpts, it was perceived that workplaces being stressful or under-resourced may increase the likelihood of medication errors. By using qualitative measures to determine people's perception of current working conditions, this may indicate the level of risk and the likelihood of harm that exists in the healthcare system. In fact, recent studies suggest healthcare staff views may be correlated with undesirable safety outcomes (421). If healthcare staff perceived that workload pressures were high, there seemed to be a weak correlation with increased hospital standardised mortality ratios (421). This finding indicated that the views of healthcare staff on the workplace environment may provide an indication of the safety of an organisation (422), and so may be useful as part of medication safety measurement.

At this point it is important to note that even though staff to patient ratios and qualitative reporting may be useful in ascertaining the general sense of staffing, workload and workplace environment, their use only represents one point in time. As one stakeholder insightfully pointed out:

I think it's [determining whether medication safety had improved is] hard to generalise and even having been a nurse working within a service it can vary according to what is happening on a specific shift. So if I'm on a night shift and say two regular staff have called in sick, there's a risk there that I'm going to be pressurised that evening with a lot more interruptions, etcetera, when I'm say perhaps preparing a patient for thrombolysis. And I know myself that if I'm getting a lot of interruptions then my ability to focus on a medication can waver, so I think it does vary. When I was talking to my colleagues we don't generally think it's worse. Safety is quite, it's almost on a day-by-day, minute-to-minute sort of change. (S7, Expert)

This is an important excerpt, because it illustrates the transient and dynamic nature associated with medication safety. The likelihood of risk and harm changes from moment to moment. Even though the workload or staffing may be adequate generally, this can change quite suddenly. What was safe before may not be safe now or in the future. Measuring staff–patient ratios may help indicate general trends, but may not be sensitive enough to indicate current conditions. The qualitative approach previously discussed by stakeholders may provide a real-time indication of current levels of safety. Although, arguably less quantitative than traditional medication safety measures, organic qualitative measures of medication safety such as simply asking staff how safe it currently is, may be useful in knowing present medication safety.

Another measure related to clinical pharmacy services was the measurement of clinical interventions made by clinical pharmacists. For example:

I guess the prescribing aspects you can look at intervention rates, I guess that's the tried and tested way of doing it [measuring medication safety]. (S6, Policymaker)

It [measuring medication safety] probably needs to be something like the intervention type stuff. As part of that basket of tools [to measure medication safety] would be to look at interventions. (S1, Expert)

Clinical pharmacists conduct medication reviews to identify areas of risk, error and where improvements can be made (360). In the literature, these interventions by clinical pharmacists have been recommended as a way to measure medication safety (67). Interventions are usually captured in a database, graded for severity then analysed for trends and improvement (67). Despite interventions being challenging to capture in a consistent and accurate manner or in a time efficient way (67), clinical pharmacist interventions are a rich source of detailed information about the types of medication errors that commonly occur in hospitals (67). Capturing these interventions and recommendations may thus provide an idea of the commonly occurring errors, inappropriate prescribing or areas in need for improvement in a hospital and so should be considered when measuring medication safety.

Previously, this research has shown that standardisation, such as standardised medication charts and clinical guidelines were generally deemed to be a beneficial practice for medication safety. Having standardised systems in place could help reduce variation and errors that occur as a result of such differences. As a consequence, some stakeholders spoke of the importance of measuring whether standardised systems were in place or auditing against those standardised practices. For example:

You might have auditing activities of a medication chart and standardisation for whether that's an electronic or a hand written chart, whether you're meeting those standards [to measure medication safety]. (S7, Expert)

[To measure medication safety you could compare] *an individual practice to an aggregated everybody else, you could develop a standard and say we think this is appropriate amount of this medication. Or you could do it by condition.* (S30, Expert)

The development of standardised practices, clinical guidelines and processes such as those related to prescribing, means that a healthcare professional or service can be audited against them—a process known as clinical auditing (423). Having such standards may help organisations improve medication safety because they provide aspirational goals for organisations to work towards. For example:

Setting standards and goals for hospitals, and then trying to get them to achieve it, I think is essential for good standards of practice. And those sort of measures, although often not entirely accurate, at least, I think, move organisations, as a whole, towards a safer place. (S20, Expert)

Measuring current practice against recommended practices can help indicate gaps in practice and identify areas of significant variation. For example, one approach to measuring inappropriate prescribing of prescribers is to compare their practice against existing evidence-based guidelines. Standardised prescribing criteria like STOPP/START (274) and Beers (424, 425) have both been used to determine the level of inappropriate prescribing in the elderly population. Even though some variation is expected because of differences in individual physiology and context, a significant amount of variation at the population level may be indicative of poor prescribing practice which may have undesirable consequences. Being able to determine such variations allows for interventions which attempt to improve prescribing practice.

One of the most commonly discussed measures to measure medication safety related to medication reconciliation. For example:

Just for simplicity and do-ability it [measuring medication safety should] would be med rec [reconciliation] because it's there and we're doing it and we have to do it. (S1, Expert)

I mean medicines reconciliation is a big one at the moment [to measure medication safety] in terms of I guess the number of patients that you're seeing to reconcile the number of medications that need to be reconciled, how long is it taking to reconcile and those sorts of things. That's our main two KPIs at Hospital C [to measure medication safety], around medicines reconciliation. (S11, Expert)

We should all be doing [measuring] med rec discrepancy rate, average discrepancy rate. (S23, Expert)

Medication reconciliation (MR) has been commonly thought to, and shown to, help reduce medication errors associated with patients being transferred from one healthcare setting to another. A commonly used measure relating to MR is percentage of patients who have had

their medications reconciled within 24 hours of admission (418). If rates are high, it is implied that patients' medication lists are accurate and any discrepancies that occurred during the transfer between settings are accounted for because the process of MR has been conducted. Another measure related to MR is the measure of un-reconciled medication rates, such as the number of medication discrepancies per 100 admissions (382). This measure helps to indicate the occurrence of unresolved discrepancies which increase the likelihood of medication errors.

Stakeholder 1 indicated that measures relating to reconciliation are now a mandatory measure for hospitals, and Stakeholder 11 noted that this measure is already in use as part of measuring medication safety. Indeed, many researchers advocate for the measures relating to MR as part of their recommended measures for medication safety (33, 229). Given that many medication errors occur when patients are transferred from one healthcare setting to another, measures relating to MR provide a good proxy for ensuring defences are in place to prevent medication errors from occurring. Moreover, because the process of MR is often bundled with medication reviews (379), for example when conducted by clinical pharmacists, it means that measures relating to MR may indicate any significant medication issues are identified for intervention, thereby reducing the likelihood of undesirable consequences.

Labelling and packaging also emerged from stakeholders' views as an important sub-dimension to measure. For example:

One thing that I think is a key area [of medication safety measurement] is the labelling and packaging of medication... In the US about 30 or 40% of the medication errors arise due to labelling and packaging issues and I don't know if that's going to, that could easily be measured somehow. The products that we use for a start that would be something quite easy to measure. We have the standards of what needs to be on the product label against legislation, but I don't know specifically of any way of looking at safety, that we apply here. (S15, Expert)

Because many undesirable consequences of medication use occur as a result of look-a-like or sound-a-like medication errors (169, 170, 375), stakeholders were of the view that this facet should be somehow measured. Interestingly, beyond analysing medication errors and harm that have occurred as a consequence of look-a-like and sound-a-like medication errors, stakeholders were unclear how this dimension could be measured despite its importance. For example, Stakeholder 15 acknowledged that even though medication labels can be measured against recommended standards, this does not necessarily mean that they are safe. Conceivably, such an approach may actually create more look-a-like medication labels. Since they are all standardised, they may actually appear more similar in appearance and so the wrong medication may be used.

Conversely, by not standardising the appearance of all medications, a potential consequence may be that the user is forced to pay extra attention to make sure the actual intended medication is used instead. Previously, the use of FMEA was thought to be able to prospectively assess for risk associated with the introduction of a new medication. Potential problems associated with labelling and packaging may be proactively identified. This reframes how measurement has traditionally been viewed. Measurement has typically focused on capturing past events such as errors and ADEs which occur after the fact, or present facets of medication safety which determine whether current medication systems are working well. The inclusion of considering future safety such as predicting risk using tools such as the FMEA expands measurement requirements and may be a useful way to determine likely medication safety in the future.

As can be seen from the excerpts so far, stakeholders have spoken about a variety of approaches to measure the technical components of the medication use system. Because many of these facets contribute and influence the outcome goal of medication safety, they may also be useful to measure medication safety. In the literature, there is one tool which has consolidated the various different and significant components of the medication use system for assessment. The seemingly comprehensive tool that has been used to assess the state of safe medication practices in hospitals is the MSSA tool (32, 426). This tool has been used to determine whether the appropriate technical components of the medication use system are in place and assesses whether they are working well. For example, the MSSA tool evaluates an organisation based on whether certain technologies such as CPOE with CDSS, barcoding and automated dispensing cabinets have been implemented and to what extent (32, 427).

The MSSA is a tool developed by the ISMP in conjunction with the American Hospital Association and the Health Education Research Trust (32, 426). Since its inception in 2000, the MSSA tool has been updated and it reflects the most up-to-date best practices associated with medication use (426). The MSSA tool is comprised of 270 items organised into 10 key elements containing 20 core characteristics representative of safe medication use (32). A hospital would assess itself against the various items and rate itself against five responses ranging from no activity to being fully implemented (32).

Although not formally tested for its effectiveness or its ability to predict the likelihood of adverse consequence(s), the MSSA tool appears relatively robust with the 10 key elements and its items and characteristics being developed from the literature, what has been learnt from the collection of reports and incidents, and expertise and experience from certain experts (84). The 10 key elements relate to various components of the medication use system and many are

inherent in the sub-dimensions and dimensions identified in this research. Table 2 has been developed to contrast the dimensions identified by the ISMP with the findings identified in this research. Some of the dimensions, such as staff competency dimension will be discussed in greater detail later in this thesis (in Chapter 3: emergent finding 7, staff competency) because it is one of the emergent findings.

Table 2: Comparison of dimensions within the MSSA tool and research findings.

ISMP MSSA – 10 key elements (32)	Core characteristics representative of safe medication use	Sub-dimensions and dimensions identified from stakeholder views
Patient information	1. Essential patient information is obtained, readily available in useful form, and considered when prescribing, dispensing, and administering medications, and when monitoring the effects of medications.	Inherent in the technology and information transfer sub-dimensions
Drug information	2. Essential drug information is readily available in useful form and considered when prescribing, dispensing, and administering medications, and when monitoring the effects of medications. 3. A controlled drug formulary system is established to limit choice to essential drugs, minimise the number of drugs with which practitioners must be familiar, and provide adequate time for designing safe processes for the use of new drugs added to the formulary.	Characteristic 2 inherent in the technology sub-dimension Characteristic 3 inherent in the medications and their use dimension
Communication of drug orders and other drug information	4. Methods of communicating drug orders and other drug information are streamlined, standardised, and automated to minimise the risk for error.	Inherent in the technology and information transfer sub-dimensions
Drug labelling packaging and nomenclature	5. Strategies are undertaken to minimise the possibility of errors with drug products that have similar or confusing manufacturer labelling/packaging and/or drug names that look and/or sound alike. 6. Readable labels that clearly identify drugs are on all drug containers, and drugs remain labelled up to the point of actual drug administration.	Inherent in the labelling and packaging sub-dimensions
Drug standardisation, storage and distribution	7. IV solutions, drug concentrations, doses, and administration times are standardised whenever possible. 8. Medications are provided to patient care units in a safe and secure manner and available for administration within a timeframe that meets essential patient needs. 9. Unit stock is restricted. 10. Hazardous chemicals are safely sequestered from patients and not accessible in drug preparation areas.	Inherent in the high risk medications and diseases sub-dimension for characteristic 7. Interestingly, stakeholders did not speak of characteristics 8–10
Medication device acquisition, use and monitoring	11. The potential for human error is mitigated through careful procurement, maintenance, use, and standardisation of devices used to prepare and deliver medications.	Inherent in the technology sub-dimension
Environmental factors workflow and staffing patterns	12. Medications are prescribed, transcribed, prepared, dispensed, and administered within an efficient and safe workflow and in a physical environment that offers adequate space and lighting, and allows practitioners to remain focused on medication use without distractions. 13. The complement of qualified, well-rested practitioners matches the clinical workload without compromising patient safety.	Inherent in staffing, workload and workplace environment
Staff competency and education	14. Practitioners receive sufficient orientation to medication use and undergo baseline and annual competency evaluation of knowledge and skills related to safe medication practices. 15. Practitioners involved in medication use are provided with ongoing education about medication error prevention and the safe use of drugs that have the greatest potential to cause harm if misused.	Inherent in the staff competency dimension and the learning and non-punitive sub dimension as part of safety culture

ISMP MSSA – 10 key elements (32)	Core characteristics representative of safe medication use	Sub-dimensions and dimensions identified from stakeholder views
Patient education	16. Patients are included as active partners in their care through education about their medications and ways to avert errors.	Inherent in the factors affecting medication use by patients dimension and the caring environment sub-dimension of safety culture
Quality processes and risk management	17. A safety-supportive just culture and model of shared accountability for safe system design and making safe behavioural choices is in place and supported by management, senior administration, and the Board of Trustees/Directors. 18. Practitioners are stimulated to detect and report adverse events, errors (including close calls), hazards, and observed at risk behaviours, and interdisciplinary teams regularly analyse these reports as well as reports of errors that have occurred in other organisations to mitigate future risks. 19. Redundancies that support a system of independent double checks or an automated verification process are used for vulnerable parts of the medication system to detect and correct serious errors before they reach patients. 20. Proven infection control practices are followed when storing, preparing, and administering medications.	Characteristic 17 and 18 inherent in the safety culture dimension Parts of characteristic 19 inherent in the technology sub-dimensions Interestingly, stakeholders did not speak of characteristic 20
		Missing dimensions not inherent in MSSA are consideration of financial costs and effectiveness dimension. Another point of difference is the outcome goals of medication safety are significantly different

As can be seen from Table 2, many of the dimensions and sub-dimensions identified in this research were also incorporated in the MSSA tool. Some differences were simply due to the way in which they were labelled. For example, many of the characteristics identified under the quality process and risk management element of the MSSA are similar to those identified in the safety culture dimension previously discussed. However, there were certain sub-dimensions which appear to be directly similar. Dug labelling, packaging and nomenclature appeared similar to the labelling and packaging sub-dimension in this research.

Despite the similarities between the MSSA and research findings in Table 2, there were also some interesting differences. For example, characteristics 8–10 of the drug standardisation, storage and distribution element in the MSSA which includes the storage of medications in a safe and secure manner, the restriction of unit stock and the appropriate storage of hazardous chemicals were not directly discussed by stakeholders during the dialogue on medication safety and its measurement but they did indirectly refer to this in the automated dispensing cabinet (Pyxis®) discussions. The safe storage of medications to prevent the wrong medication being picked would be an instrumental part of ensuring adverse consequences of medication use would be avoided. Characteristic 20 of key element 10 relating to proven infection control practices relating to medication use was also not discussed by stakeholders.

It is not entirely clear why stakeholders did not necessarily speak about characteristics identified within the 10 key elements of the MSSA. Perhaps stakeholders had just failed to mention these characteristics in the midst of all the other facets discussed. It may also be because NZ public hospital stakeholders were not aware of these issues. Regardless of the reason, it can be observed that during interviews with NZ public hospital stakeholders, these characteristics were not meaningful enough or of significant priority to be spoken about as key issues of medication safety. Interestingly, stakeholders of this research instead spoke about financial costs and effectiveness which was less focused on in the MSSA. This was partly inherent in the drug information element, characteristic 3, when a drug formulary was discussed, however this was in relation to safe medications available for use rather than an explicit focus on the financial component.

Another interesting point of difference between the elements of the MSSA with the findings of this research is the outcome goal of medication safety being focused on. For example, in characteristic 18 of element 10 in the MSSA, the focus was on the identification and measurement of ADEs and errors. However, as outlined in the outcome goals of the medication safety dimension, stakeholders spoke of the outcome goals of medication safety as

expanding beyond the avoidance of adverse consequences and into the optimisation of beneficial health outcomes. This reframing of what medication safety means is significant and the implications of this will be discussed later in Chapter 4A: Summary of Findings.

This research has been unique because it explored the measurement of medication safety from the stakeholders' views of what they find particularly meaningful, and in an inductive manner. Despite differences in how the findings have been obtained there were many similarities. This means that NZ public stakeholders' view of medication safety and how it can be measured may be similar to those that were discussed in the literature. This would mean that the MSSA may be a potentially suitable tool that can be used to evaluate several facets of medication safety. The MSSA would provide a good snapshot in time of a hospital's current safe medication use practices against what is deemed best practice. This would provide an idea of what areas are in need for continual improvement. However, the differences also outline that for NZ public hospital stakeholders, medication safety meant more than how the concept has been framed in the literature. Understanding these differences, and what medication safety meant to stakeholders meant that medication safety can be measured in a manner which is much more meaningful for local use.

Despite the MSSA tool potentially being a useful measure, it is still incomplete to measure medication safety in its entirety. The fact that it only assesses the organisation's current practices at one point in time means that it does not necessarily capture the dynamic nature of medication safety and risks. For example, item 150 in the MSSA assesses a hospital against workspaces where medications are prepared to be orderly and free of clutter (32). However, just because it was free of clutter on one day does not necessarily mean it will be free of clutter the next. The MSSA is not necessarily sensitive enough to monitor moment-to-moment changes in medication safety. Another limitation of the static nature of the MSSA may conceivably give a false sense of security, which reduces vigilance behaviours in staff if the recommended practices were supposedly 'fully implemented'. The cost in implementing all the best practices may be unnecessary in organisations which may have particularly good or compensatory systems and the opportunity cost associated with this may lead to net negative outcomes.

It is clear that the MSSA is not a panacea for measuring medication safety. The intention to do good by implementing certain technical components of the medication use system may in fact lead to unintended adverse consequences. For example, there have been several case reports where different types of medication errors have been generated as a result of the implementation of CPOE with CDSS technology (355-357). However, what it does do is

provide a good snapshot of current medication practices in an organisation to help identify areas in need of improvement. Measuring the technical components of the medication use system has been, and will continue to be, an important part of measuring medication safety.

The discussions so far have covered a wide breadth and scope. The dimension of technical components of the medication use system was diverse and broad. This dimension emerged clearly from stakeholders' views through their discussions on technology, pharmacy based services, standardised medication charts and systems, high risk medications and diseases, labelling and packaging, information transfer, staffing, and workload and workplace environment. This dimension should be included as part of medication safety measurement.

A diverse number of tools, approaches and measures have been developed in the literature and many were discussed by stakeholders as being particularly meaningful. Clear from these discussions, was that no one tool was able to capture the entirety of the technical components of the medication use system. A multi-faceted approach to measurement is required in order to measure the technical components of the medication use system in a holistic manner. The MSSA tool helps hospitals to assess their medication use system across 10 key elements and 20 characteristics of a safe medication use system. However, the MSSA tool only provides a snapshot of the state of the hospital medication use system at one point in time, and may not be sensitive enough to measure minute-to-minute changes. Other measures such as qualitative approaches may be useful in complementing tools such as the MSSA to give a more rounded approach.

Emergent finding 6: Factors affecting medication use by patients

An important part of the dialogue on the measurement of medication safety focused on factors affecting medication use by patients. Specifically, stakeholders spoke about factors such as:

- Affordable access to medicines; and
- Patients' understanding of medications and compliance

Both factors were thought to contribute to how medications were used and medication safety. At this point it is important to acknowledge that other terms beyond compliance, such as adherence and concordance have been used in the literature (428). Trends in the literature suggest that the preferred term has moved away from compliance, which has a negative connotation associated with submission, to concordance and adherence which focuses on a collaboration between healthcare staff and patients (428). Recognising there are significant conceptual differences inherent with the different terms and the notion of adherence is preferred, compliance has been used in this research because it is the more prevalent term that has been used in the literature (428). Compliance, in this research, refers to the extent to which a person's behaviour in terms of taking medication coincides with medical or health advice with an assumption that medical and medication advice was generally appropriate and correct. In this chapter, excerpts are used to illustrate how the sub-dimensions and dimension emerged from the interview data. The importance of the dimension to the measurement of medication safety and how it can be measured will be discussed later in this chapter (in Chapter 3: emergent finding 6B).

A) Emergence from the interview data

Affordable access to medicines

A factor thought to significantly affect medication use by patients was affordable access. A patient's ability to afford medicines emerged strongly as being able to influence medication safety and its desired outcome goals. For example:

With the high needs community it [medication safety or lack thereof] might be about a lack of access, right, and it might be about not being able to afford medication, right. So in other words they're taking medication but they don't continue with it 'cause they can't afford it and this sort of stuff. So that's something you would need to do [to improve medication safety]. (S8, Policymaker)

Even though some complications can occur as a natural progression of disease, many of these can be considered preventable, such as diabetes retinopathy or nephropathy, because harm could have been minimised or modified through better diet, exercise, medical treatment and medication use (428, 429). In the literature there is strong evidence which has shown that non-compliance to medication use is one of the causes of preventable medication related morbidity and mortality (PDRM) (428, 430). Specifically, the consequence of non-compliance to medications by patients as a result of the inability to afford medications has been associated with undesirable consequences such as increased hospitalisation, heavy disease burden and shortened lives (44, 431-433).

In previous chapters, patients not receiving healthcare services when it would have provided a favourable outcome were known as an underuse healthcare problem (44). The inability to obtain medications because of cost appears to be able to adversely influence patient health outcomes and results in patients not receiving the full therapeutic benefits (44, 431, 432, 434, 435). Conceivably, if medications are made more affordable and patients have greater access to medicines that they need, this may lessen the burden of disease because it may facilitate medication use (436). Conversely, the lack of funding and inability to afford medications may lead to poor health outcomes. For example:

I mean there are heaps of examples of how safety has potentially been compromised by a funding decision, so they [PHARMAC] are not a good body to do this. I was involved early on in an evaluation of their decision to introduce quinapril in place of enalapril, and they put a part charge on enalapril and this caused all sorts of strife with people stopping their drugs and all that kind of thing... if you're going to talk about medicine safety you really need to include the whole issue around PHARMAC. (S9, Expert)

The Pharmaceutical Management Agency (PHARMAC) is an organisation responsible for managing the list of government subsidised medicines ensuring New Zealanders have access to effective medications (437). Importantly, the remit of PHARMAC predominantly focuses on determining which medications should be funded and which shouldn't, and is based on trying to optimise the greatest benefit for New Zealanders from medications at the lowest cost (261).

Stakeholder 9 was of the view that PHARMAC's funding decisions have had safety implications. Stakeholder 9 provided the example of an enalapril subsidy decision. The change in funding of enalapril from being fully subsidised by the government, which means there was only a small part charge when patients picked up their medications from their community pharmacy, was changed to one which was only partially subsidised and meant patients had to pay more. The effect of this change caused patients to stop taking their medicine, presumably

because of an inability or unwillingness to pay more, leading to patients not taking their usual medication with resultant potential safety implications such as uncontrolled hypertension. Stakeholder views and the literature so far suggest the affordability of medications have the ability to affect patient health outcomes and thus medication safety.

It is important to recognise, however, that making medications affordable for use by patients does not necessarily provide a panacea for solving PDRM. For example, making medications too easily accessible may conceivably create unintended consequences such as overuse since there are no disincentives, such as costs, to use medications when they should not have been used. For example, the intention to do good by funding the anti-coagulant medication dabigatran so it is freely accessible created the unintended consequence of people being unnecessarily switched from warfarin to dabigatran and undesirable consequences such as bleeding (217). In addition, even if medications are made affordable for use, patients may misuse these medicines in an inappropriate manner. Patient use of the medicine will be further discussed in the section which relates to patients' understanding of medications and compliance.

As can be seen from the discussions so far, a patient being able to afford medication plays an important role in influencing the achievement of desirable health outcomes and is an important facet of medication safety. Even though affordable access to medications has been a long recognised and researched healthcare problem and has significant safety implications associated with underuse (428, 432), it resonates less as a medication safety issue. For example, as has been described in previous sections, medication safety has more typically focused on undesirable incidents such as the wrong patient receiving the wrong medication in the wrong dose and their avoidance. Affordable access has not commonly been identified as a factor of medication safety incidents (1, 10). Many of the medication safety improvement strategies and initiatives do not address affordable access, and instead focus on ensuring hospital systems deliver medication use in an error free manner (1, 10).

The reason for why literature on medication safety has traditionally not focused on affordable access of medications is not entirely clear. One reason may be because access to medications has been more commonly regarded as a healthcare quality problem rather than a safety problem. As has been previously mentioned, immediacy and causality determine how much an incident resonates as a quality or safety issue (51). Harm that occurs as a result of the inability to pay for medicines may not occur immediately, and the relationship with adverse consequences such as poor health outcomes are not directly causal (51). People that don't take medications do not necessarily suffer from harm. Thus, such incidents do not resonate as a

medication safety issue as easily as say a person dying from the inadvertent administration of intrathecal vincristine.

Importantly, this research has so far shown that affordable access has important implications on safety and it appears that there has been a gradual recognition of the link—at least in New Zealand practice. Recently developed policy documents such as the *Medicines New Zealand and Actioning Medicines New Zealand*, which focus on improving the quality and safe use of medicines in NZ, now explicitly and specifically includes access to medicines as a key focus in order to deliver better health outcomes as a consequence of medication use (438, 439). Given the importance of affordable access of medications in affecting patient use of medicines, and thus medication safety, it is important to include this facet in medication safety measurement. The importance of this sub-dimension, how it expands current conceptual boundaries of medication safety, and how it can be measured is discussed later in this section (in Chapter 3: emergent finding 6B).

Patients' understanding of medications and compliance

As had been mentioned in the above section, even if medications are made affordable, health outcomes can also be influenced by patients' understanding of medication and compliance. Understandably, many stakeholders spoke about the importance of patients' understanding and compliance in affecting medication safety and suggested that this should be an area of focus in order to improve medication safety. For example:

Important issue [of medication safety] is whether they [patients] ever actually take them [medications]. (S3, Policymaker)

20% of our patients couldn't understand those [medication] instructions you'd sent them out with, and surprise, surprise they came in very quickly afterwards. (S17, Policymaker)

[In relation to how to improve medication safety] we try and improve the prescribing and there are three things probably. Patient information leaflets is one, yellow card is another one, which is useful for medicine reconciliation and the third one is unit dose packaging and all of those have the potential, we hope, of improving compliance, having the correct drugs taken at the correct times, all those sorts of things... patient information leaflets, yellow card and the unit dose packaging are all designed to improve compliance. (S10, Expert)

As had been noted previously, cost plays a part in affecting whether patients are able to afford and take their medications, and thus, health outcomes. However, studies into why patients are readmitted shortly after discharge reveal that some of these are due to poor medication use (440). A lack of understanding and poor health literacy contribute to patient re-admissions (441). Health literacy has been defined in the literature as the degree to which individuals can

obtain, process and understand health information and services they need to make appropriate health decisions (442). Patients do not always know why they need to take the medications or how to use them in an appropriate manner resulting in poor use. This means patients may not receive the full benefits of the medicines, but also may potentially overuse or misuse medications resulting in medication related harm.

Evident from stakeholder views and the literature, a patient understanding how to use their medications is important because it influences and contributes to beneficial patient health outcomes and the avoidance of adverse consequences. Understanding medications may help to improve compliance so that medications are used by patients in an appropriate manner (428). Perhaps for these reasons, medication safety improvement initiatives have focused on improving this facet (1, 442). For example, patient information leaflets on how to take their medications and unit dose packaging such as individual patient blister packaged medications are interventions commonly promoted to improve medication safety (442, 443).

Healthcare can aid compliance, for example, by better education of patients and better provision of health information or development of new technology to help improve compliance, such as depot injections (444) and electronic systems (445). However, there is no fault in the healthcare system if patients are harmed unnecessarily due to patient idiosyncrasies or if patients make an informed choice to deliberately overuse, underuse or misuse medications. Patients are also responsible for their own health and not all harm and undesirable outcomes are amenable by the healthcare system (446). Certainly, healthcare systems can help by making it as easy as possible to help patients do the appropriate thing (446). But patient responsibility is also required to optimise health outcomes.

So far, the excerpts and discussion show that both affordable access to medications and patients' understanding of medication use can affect patient health outcomes associated with medication use. Other determinants of health such as housing, energy, food and other factors such as provider behaviours, health system factors and patient attributes were not specifically spoken about but are likely to also influence medication use by patients (447, 448). For example, it is conceivable that if a patient does not have adequate housing or food supply, medications and their use may be less of a priority and this has the effect on affecting whether medications are used or in an appropriate manner. However, despite their likely influences, it was not evident from stakeholders that such determinants were recognised as major factors affecting medication use. It is not entirely clear why this is, however stakeholders may have implicitly assumed that factors such as housing and food were present. So even though important, it is not necessarily meaningful to stakeholders in a medication safety context.

The views held by stakeholders were interesting because even though the scope of this research was based in the hospital context, the discussions on affordability of medications and compliance is arguably more related to medication use in the community setting. However, evident from the discussions is that there appears to be an overlap that exists between the hospital and the community setting. Patients suffering from disease in the community would have flow-on effects to the hospital (449, 450). Conversely, poor medication management in the hospital prior to discharge may have flow on effects to harm that occurs in the community setting (451, 452). The community and hospital settings appear related.

The focus of the discussions so far has fallen heavily on affordable access of medications and patients' understanding of medications and compliance. It was evident from the data that affordability affects compliance, which may be amenable through funding and policy decisions. Even though other factors such as patient understanding and compliance can also be optimised through better healthcare provision such as patient information leaflets, education or improvements in technology, it is also important to recognise that some factors are not amenable. But more importantly, these multiple factors affecting medication use by patients are important and significantly contribute to, and influence, medication safety outcome goals. As has been previously mentioned, some facets such as compliance do form part of the medication safety discussion. However, an observation of the literature into medication safety reveals that medication safety more typically resonates with cases of medication error such as wrong drug or wrong dose. The findings of this research suggest that equal recognition and value should also be given to factors affecting medication use by patients such as affordable access and patients' understanding of medications and compliance. Overall, factors affecting medication use by patient appears to be an important facet of medication safety.

B) Importance of measuring the factors affecting medication use by patients dimension and how it could be measured

An important dimension to include when measuring medication safety was factors affecting medication use by patients. Given the importance of the factors affecting the medication use by patients dimension and its association with health outcomes, it was understandable why many stakeholders believed that these facets should be measured. For example, stakeholders expressed:

[In relation to how medication safety should be measured] for me the key would be that, and I'm looking purely at the patient here, that the patient's experience was one that they had the medicines they needed at the time that they needed.... One of my yardsticks is we get less complaints now about this medicine not being funded,

or that medicine not being funded, that used to be pretty common three or four years ago. (S28, Policymaker)

From a health professional perspective it [measuring medication safety] is about auditing records, whether you've given discharge information, what type of discharge information there is. (Stakeholder 7, Expert)

[In relation to how medication safety should be measured] do surveys about how they take [medicines], the number [of yellow cards] that take up on those, who's using them, we've even tried to do surveys of whether the patients find them useful or not....studies can be done on compliance by, very simply by pill count, not very reliable but can be done, but you can actually have electronic unit dose packaging so that the, it's measured every time it actually happens and they can go back and look at that on a computer and see what happens. So there are ways of actually measuring compliance as an end point of trying to improve compliance. (S10, Expert)

The factors affecting medication use by patients dimension can be used as a surrogate measure for determining beneficial or adverse consequences (428). This is because there is strong evidence which suggests poor compliance is linked with adverse consequences such as increased hospitalisations (428, 449, 450). Measuring whether patients were compliant may indicate whether healthcare services were effective at providing patient education about their medicines (428). As can be seen from the excerpts above, stakeholders spoke of the importance of measuring patients' understanding of medications and compliance to measure medication safety. Their rationale was that if patients did not understand how to use the medicines, they may use the medication in an inappropriate manner or overuse or underuse their medications. The excerpts above also illustrate some of the approaches that can be used to measure the factors affecting medication use by patients.

For example, Stakeholder 7 believed that one could measure compliance by assessing whether healthcare services provide the appropriate educational material and advice (428). Stakeholder 10 spoke of surveying patients about the quality of the educational resources such as patient information leaflets and that compliance can be directly measured using electronic systems (428, 453). Self reported questionnaires can be a practical way to measure compliance and may predict compliance behaviours (447). Compliance is an important facet of medication safety and should be measured as part of medication safety. Despite its importance and suggestions provided by the stakeholders, the measurement of compliance is difficult (428). For example, as recognised by Stakeholder 10, pill counts are not often reliable because patients may simply discard medications. Electronic methods are not always easily available (428). Even the measurement of medication concentration in body fluids, which may help indicate whether medications are being used, is difficult because blood tests to test for medications are not always available and invasive in nature (428). Other approaches such as

direct observed therapy can be costly and practically applicable only in single dose medication regimens (21). Prescription filling dates to ascertain compliance are relatively easy to obtain, but do not guarantee that patient will take the medication after obtaining the medications (1). No one approach appears to be comprehensive and a combination of approaches may be required (447).

The excerpts and discussions have focused predominantly on factors affecting medication use by patients related to compliance and patient understanding of medications. It is important to also measure whether there is an environment where medications are affordable. As has been previously discussed, an environment which had affordable access to medicines was thought to have increased levels of medication safety, because harm which results from the inability to access medications due to financial reasons may be reduced (432, 449). For example, certain diseases such as diabetes and hypertension can be successfully managed using certain medications. These medications may help reduce morbidity associated with these diseases and prolong life. However, if patients cannot afford to access the medications, these patients may be unnecessarily harmed when they did not need to be (435).

Measuring the level of affordable access to medicines by patients may serve as a proxy measure to help predict the likelihood of beneficial health outcomes which has been previously discussed as a goal of medication safety. Indeed, studies exist which measure whether medications in the community setting are being used when they should be (454, 455), and there are also studies which specifically evaluate such use as a result of financial reasons (432, 435). There are also approaches to measuring whether medications are affordable by calculating the average cost of essential courses of medication treatments in relation to average wages (456). For example, one month of combination therapy for coronary heart disease treatment cost 18.4 day's average wages in Malawi compared to 6.1 day's wages in Nepal and 5.1 day's wages in Brazil (456). A similar approach can be taken with other disease treatment regimens such as those used to treat asthma or diabetes.

As can be observed from the excerpts and discussions, affordable access to medicines and patients' understanding of medications and compliance were meaningful to stakeholders when medication safety measurement was discussed. Interestingly, even though there are safety implications associated with the various facets of factors affecting medication use by patients, affordable access does not typically feature in medication safety measurement literature (21, 25, 33, 212). Previous discussions revolving around how medication safety has traditionally been conceptualised meant that affordability issues fall outside the conceptual boundary of the medication safety concept. As has been previously discussed, medication safety in hospitals

has been more typically conceptualised in terms of medication errors and ADEs that occur in the hospital.

Sub-dimensions such as affordable access, patient understanding and compliance may also be thought about as more of a community setting issue, so this may also have contributed to why affordable access has not been included in traditional medication safety measures. This is a research area that needs further attention, because affordable access of medications plays a key role in influencing medication safety outcomes. Research on what should be used to measure affordability and their relevance to the medication safety context should be studied in-depth. Understanding whether stakeholders find specific measures in this area meaningful is also required.

The sole measurement of affordable access to measure medication safety may lead to unintended increased harm as a result of unnecessary use. If compliance alone is used to measure medication safety, patients who make a deliberate and conscious decision to not comply may falsely indicate that poor healthcare service was provided. Measurement of factors affecting medication use by patients across both of its sub-dimensions are required to ensure a more balanced and rounded view. As can be observed so far, factors affecting medication use by patients is important to medication safety. This means that this dimension should be included to measure medication safety. A better understanding of why and how factors affecting medication use by patients can be measured expands the conceptual boundary of traditional medication safety measurement.

Emergent finding 7: Staff competency dimension

Another important part of the dialogue on the measurement of medication safety focused on the healthcare professional's ability to use medications to achieve optimal health outcomes. In this section, excerpts will be used to illustrate how this dimension emerged from the interview data and what it is about. The importance of the dimension to the measurement of medication safety and how it can be measured will be discussed (in Chapter 4: emergent finding 7B).

A) Emergence from the interview data

Staff competency, as spoken about by stakeholders, does not simply mean acquiring facts or understanding information, but also an ability to apply the information in an appropriate manner. For example, stakeholders expressed:

It's [medication safety] about people who are prescribing medication understanding the adverse effects and adverse effects between medications, and factoring that into their prescribing. So that's probably what I'm thinking about when I'm thinking about safety in terms of medicines. (S29, Policymaker)

As indicated by Stakeholder 29, there was a need to be able to apply information acquired in a patient specific context. An interesting point was that stakeholders who spoke of staff competency as being meaningful, focused their discussions on prescriber competency. For example, stakeholders expressed:

[In relation to conceptualising medication safety] my interest is prescribing and it's in the way in which people prescribe, how they learn to prescribe, what prescribing means to them and how do they become safe prescribers. (S9, Expert)

[In relation to conceptualising medication safety] you go back to the prescriber then you need prescribers who know what they're doing and are reasonably confident and competent around the prescribing they're doing. (S12, Policymaker)

Stakeholders were specific and focused on prescriber competency and prescriber education. Even though nurses, pharmacists and other healthcare professionals have now also been legislated to prescribe, they typically make up only a small proportion of all prescribers (457). It has been said that in the UK, which may be also true in the NZ setting, that nurses and pharmacist prescribers typically undergo robust and rigorous assessment and training in pharmacology and pharmacotherapy relative to junior doctors and may arguably be less of a concern (458). In the context of these excerpts, the term 'prescriber' refers predominantly to junior medical doctors, though it is recognised that just because a junior doctor is implicated with an error does not necessarily mean the junior doctor had a poor level of knowledge. For

example, in practice, junior doctors often only prescribe in accordance to what their senior colleagues have asked them to do. It is therefore conceivable that the errors actually reflect the lack of knowledge in their senior colleagues despite the junior doctor actually implementing the error. Another scenario which may have caused the error might have been poor communication issues or the lack of time to look up the correct drug dose leading to error (290).

A sole focus on prescriber competency was interesting because prescribing forms only one part of the overall medication use process (282). Yet, medication safety issues can also occur at other stages of medication use such as dispensing and administration (10, 155). When stakeholders were asked why they had only focused on the prescribing stage, Stakeholder 29 expressed:

You assume that a medication that's available for prescription has already been through a whole raft of stuff which means it's safe to come to the market so the big risks are sort of taken out of the equation. But there's no medication that doesn't have adverse effects sometimes, so it's about prescribers understanding what those are and how they apply to the individual in front of them when they go to prescribe. It's that context, that would be my main focus, I guess there are some other aspects of it which relate to issues like medicines should be used by only those that they are prescribed for and the issues around medicines being passed on to other people, or having access by children, or other parties and things. So there's some of those things are to do with medicine safety as well, storage and but for me probably where I see it first and foremost is around prescribers and their use of medicines. (S29, Policymaker)

This excerpt provides insight into how medication safety was viewed by this stakeholder. This excerpt also provides conceptual parameters on medication safety for this stakeholder. There was recognition and acknowledgment that other aspects such as the pharmaceutical manufacturing of the drug and storage of the medicine relate to medication safety. Indeed, as discussed in previous sections, significant medication safety issues have arisen as a result of unsafe medications being available for use. But for this stakeholder, medication safety was conceptualised predominantly within the context of staff competency in the prescribing stage of medication use, and highlights that medication safety can mean different things to different people.

Views such as those held by Stakeholder 29 were understandable, because research into medication errors and ADEs has consistently identified prescribing as a common source of error (155, 459, 460). For example, in one study, 56% of all preventable ADEs occurred at the medication ordering or prescribing stage (155). Other literature reviews have found prescribing error rates between 0.3–39.1% of all medication orders written (461). The prescribing stage of medication use is where most medication errors occur (459). There are

many causes of prescribing errors. For example, errors can be caused by slips where a particular dose was meant to be written but due to distraction another dose was prescribed. Lapses such as meaning to cross off a prescribed medication but hadn't may also occur. Knowing the dose should be checked but the prescriber doesn't (because they assumed the pharmacist will check) is a violation which increases safety risks. Mistakes such as not knowing what dose had to be reduced in certain situations can also occur and present as an unsafe situation (290).

The context in which stakeholders discussed staff competency was on prescribing errors associated with mistakes. Mistakes occur because an inadequate or wrong plan was chosen and often as a result of inadequate knowledge (290). Pharmacology is the science that deals with the mechanism of action, uses and adverse effects of drugs (462). Pharmacotherapy refers to the ability and application of that drug knowledge to a particular context, patient or disease to achieve optimal outcomes (257). Inadequate knowledge in pharmacology and pharmacotherapy has been thought to be a causative factor in many prescribing errors (290, 458, 459, 463-465). Thus, Stakeholder 29's and other stakeholders' focus on the prescribing stage of medication use was understandable.

Other stakeholders held similar views to Stakeholder 29, and also spoke of the need to improve knowledge in pharmacology and pharmacotherapy in order to improve medication safety. Specifically, the competencies in need for further improvement related to the areas of:

People not knowing about interactions like the itraconazole, statin, rhabdomyolysis situation. Just not knowing necessarily, I just saw a thing the other day about erythromycin and calcium channel blockers causing hypotension, little things like that. (S24, Expert)

Equipping medical practitioners with the right prescriptive skills, "This is what you actually need to deal with this particular condition". (S28, Policymaker)

Interestingly, one stakeholder also highlighted the importance of diagnostic competency and how this contributes to medication safety:

Well I see it as the whole, as see it as related to the whole gamut of diagnosis, through prescribing, through actually taking them, through interactions, through the whole range of things to do with medications... if you haven't got the diagnosis correct then you've giving the wrong medication. (S30, Expert)

Delayed, missed or incorrect diagnoses are common, but underrepresented as a significant safety issue (466, 467). Yet, as illustrated by Stakeholder 30, competency in diagnosis is important because this has downstream implications on the appropriateness of treatment and medication related outcomes. As can be seen in these excerpts, competencies were discussed in terms of the understanding of adverse effects, interactions and therapeutic indications and

diagnosis. These competencies align with the Medical School Council's, based in the UK, core prescriber competency skills for safe prescribing (468). The proposed competencies include areas such as relating to planning appropriate therapy and writing a safe and legal prescription (468). Knowledge and competency in these areas are thought to be required to be able to prescribe safely (468).

A potential reason for why prescriber competency was lacking in junior medical doctors was perceived by Stakeholder 9 as being the result of deficiencies in the university curriculum:

[There has been a] dumbing down of the whole undergraduate curriculum in pharmacology. We're not new in this respect; UK is identifying exactly the same problem at the undergraduate curricular level, major concern in a report put out by the Council of Medical Schools around training in pharmacology in particular... I've actually seen maps, [university] curriculum maps [of pharmacology and pharmacotherapy] showing where people are supposed to do this sort of thing, but you actually discover they haven't done it at all... It's the old view that somehow biochemistry and physiology would combine and give you the base to understand drug action. ... So if you start teaching it [pharmacology and pharmacotherapy] in the third year that's just bloody ridiculous to put it mildly. It's very short sighted and it's a long standing traditional approach, it's wrong, fundamentally wrong. (S9, Expert)

Stakeholder 9 perceived that there has been a lack of, and poor approach to teaching, pharmacology and pharmacotherapy facets in the university curriculum. The focus on biochemistry and physiology rather than specifically pharmacology and pharmacotherapy was thought to be fundamentally misguided. The overall consequence of the “dumbing down” of the curriculum in relation to pharmacology and pharmacotherapy, was thought to have led to junior doctors having inadequate skills and expertise to prescribe safely. Indeed, several researchers in the literature agree with the viewpoint of Stakeholder 9, and there has been a call for a significant restructuring of medical education so that prescribing inadequacies can be addressed (293, 458, 463-465, 469-473).

A lack of staff competency in prescribing has been identified as a major contributor to medication errors (290). However, stakeholders also recognised that the lack of focus on pharmacology and pharmacotherapy during undergraduate studies may also deemphasise medication safety as an important issue to be aware of. For example, Stakeholder 9 expressed:

I think what it [not focusing on pharmacology and pharmacotherapy in the undergraduate curriculum] does is it fails to generate an awareness of the risk, and of the need for a personal understanding and awareness around medicine safety... And I'm quite convinced that 20 years ago there was still an awareness [sic] about prescribing which doesn't exist now. I mean the junior staff do not have the same feeling of responsibility for prescribing a medicine. (S9, Expert)

Excerpts such as those provided by Stakeholder 9, suggest that potential deficiencies in teaching curriculum have implications greater than just the lack of prescriber competency. Deficiencies in the curriculum may also unintentionally result in people under-appreciating the risks associated with medication use and a lack of belief in the importance of medication safety issues. Conversely, if staff attitudes were one which was aware and committed to medication safety, they may recognise their deficiencies and work towards upskilling and improving their competency (473, 474). The implications of such scenarios suggest a potential association existing between staff competency and education and mind-set, attitudes and behaviours of people.

The excerpts relating to this dimension present a clear picture. Some stakeholders conceptualised medication safety in terms of prescriber competency. There was a perception that junior doctors do not necessarily have the adequate skills and knowledge to be able to prescribe safely. Specifically, competencies required to prescribe safely are thought to require the understanding of aspects such as diagnosis, interactions and adverse effects of medicines. Underlying these views was a focus on competency, specifically prescriber competency. The sole focus on prescriber competency was understandable given most of the medication safety related incidents are thought to be due to prescribing errors. Moreover, given that prescribing errors are often caused by inadequate knowledge of pharmacology and pharmacotherapy, these provide a potential reason why prescriber competency was predominantly focused upon.

It is important to recognise, however, that not all stakeholders focused on prescriber competency. Some stakeholders also recognised the importance of nursing competencies. For example, stakeholders expressed:

[In relation to how to improve medication safety] ward based calculations by nurses showing 10 to 15% error rates and that's very scary when you're preparing an insulin pump for a diamorphine infusion or something on a regular basis. (S17, Policymaker)

To have the knowledge and resources I think, just being properly trained about what is involved and this is something, particularly with the undergrads, checking the name band to make sure you're giving it to the right patient is a really key part... what constitutes an unsafe event and then where might you report that and then how would you get fed back that information...Yeah it does require some system knowledge on the part of the nurse. (S19, Expert)

What maybe would help with medication safety is improving nurses' confidence to know where to find the standards for doctors. And that's easy to know once I tell them, like the Medical Council, it's very clear, or the piece of legislation that shows what the form for a prescription is. So I think that certainly could be improved because if I think about that that helps with their confidence to challenge what they perceive is poor practice. (S7, Expert)

Calculation of medication doses, knowing where resources are, and the process of administering medications were examples of competencies thought to be particularly important to nurses and their practice. Like a focus on prescriber competency, the focus on nurse competency by stakeholders was also understandable. While the majority of preventable ADEs occurred at the prescribing stage of medication use (56%) they also often occur at the administration stage of medication use (34%) (155). More experienced nurses have been identified as characteristics attributed with less medication errors (475), and this could be interpreted also as less experienced nurses being attributed with greater number of medication errors. Having a greater level of competency may, as highlighted by Stakeholder 7, help facilitate and influence positive safety behaviours such as challenging poor practice but also in ensuring staff are able to do what they are meant to do (476).

Discussions on staff competency have focused predominantly on whether each profession is competent in performing their role. In contrast, as highlighted in the excerpt by Stakeholder 19, having system knowledge competencies is also important. System knowledge, spoken about by Stakeholder 19 refers to knowledge in patient safety and quality improvement competencies. Recent literature has advocated for healthcare staff and students to be competent in these areas. For example, the WHO has specifically developed a patient safety curriculum guide (477). The Institute of Healthcare Improvement (IHI) have initiated the IHI Open School which aims to advance healthcare improvement and patient safety competencies in the next generation of health professionals worldwide (478). The IHI Open School has developed specific competencies, online courses and qualifications which have now been adopted into university curriculums such as Harvard and Cardiff Universities (478). Tools such as QIKAT (Quality Improvement Knowledge Application Tool) have been developed to assess a student's knowledge on how to implement a quality improvement project (479).

Content in the WHO and IHI curriculums typically highlight safety risks in healthcare, the principles and concepts of safety, how to recognise and manage hazards and adverse events, the importance of teamwork, communication and engagement (477, 478). Improving competencies in these areas are thought to be important and have been advocated for by several key healthcare organisations as a means to improve safety in the healthcare setting (477, 480). The discussions so far have been important because they highlight the need to consider both profession specific competency and patient safety competencies when considering staff competency.

It is important to note that despite the focus on prescriber and nurse competency, stakeholders also spoke of improving competency generally in other healthcare professionals as a means to

improve medication safety. The predominant focus on prescriber and nursing competency was understandable due to a large proportion of medication errors occurring at the prescribing and administration stages of medication use. This is in contrast to only 6% and 4% of preventable adverse drug events occurring at the transcription and dispensing stages of medication use respectively (155). However, despite the focus on only nursing and prescribing competency, staff competency in general is also important to medication safety. Staff that are competent in their roles may help to increase the likelihood that the tasks they are supposed to do are done and in an appropriate manner (476). Staff that are competent in patient safety curriculum may better understand and appreciate the hazards in healthcare and how to mitigate adverse events. Staff competency was an important dimension of medication safety.

B) Importance of measuring the staff competency dimension and how it could be measured

Given that staff competency was an important dimension to stakeholders and influences medication safety in terms of medication errors and ADEs, the measurement of this dimension was important. In the literature, assessing staff competency can help the understanding of whether staff are doing their job right and also whether they are applying these competencies to their practice when measured periodically (476). Measuring staff competency may also help organisations ensure staff perform to a certain standard and can be used as formal assessment for career progression (476). The measurement of staff competency may help predict the performance of the organisations (476), thereby indicating the likelihood of ADEs and thus medication safety (290, 458, 459, 463-465). An increased level of experience and expertise in other healthcare professionals has also been linked with less medication errors (475), which gives further weight to the staff competency dimension influencing medication safety in terms of patient health outcomes.

This research has shown that staff competency was thought to contribute to the occurrence and likelihood of medication errors and ADEs. Understandably, stakeholders spoke of the need for staff competency accreditation to be included as part of medication safety measurement though they do not necessarily specify how:

It's [measuring medication safety should include] accreditation with the, of the prescriber, and their ability to do their job correctly. (S27, Policymaker)

[Should have] certification processes for nurses so that you've passed competencies in relation to paediatric medication or intravenous. (S7, Expert)

[There should be a] national scheme to ensure a certain standard or awareness of safe prescribing requirements for junior staff. And this goes much more widely than just filling out a medicines chart, it talks about individual responsibility, it

deals with high risk medicines, a whole host of factors... [these requirements] should be done before you are entitled to practice in this country. (S9, Expert)

[In relation to what should be included in medication safety measurement] you can measure people's competency at different calculations, or simulation labs to see how they manage in certain areas. (S15, Expert)

In the literature, staff competency has been measured in a number of ways such as written or computer tests, performance records, job simulation and job samples (476). Each approach has its own advantages and limitations and the choice of which approach(s) to use will be determined by factors such as resources available for assessment or availability of appropriate assessors (476). Staff competency has been assessed by professional licensure organisations such as the General Medical Council in UK (481), Medical Council of New Zealand (482) or the Pharmacy Council of NZ (311) and these organisations also use a variety of approaches. For example, assessing competency for intern pharmacists to obtain registration requires a written examination, demonstration of knowledge by way of a portfolio and an oral examination simulating job scenarios (311). Ensuring staff are competent is an important aspect of maintaining healthcare quality and safety and governed under legislation such as the Health Practitioners' Competency Assurance Act in NZ (483). These competencies relate specifically to those skills required for the particular healthcare discipline. Specific patient safety competencies, and how they can be measured, have also been developed by organisations such as the WHO (477) and IHI (478).

Staff competencies which specifically address medication safety such as the MSSA tool have also been developed and staff competency is assessed under the element of staff competency and education (32). Staff competency has also been implicitly measured in other medication safety measurement tools found in the literature. For example, key performance indicators like *percentage of patients at high risk of venous thromboembolism that receive appropriate prophylaxis* (229) implicitly considers the education of prescribers, and whether they make an appropriate choice during assessment and treatment.

The measurement of staff competency has long been, and will continue to be, important to measuring medication safety. Even though the measurement of staff competency is important, it only indicates the likelihood of how staff might perform and may help predict the likelihood of error and harm in the future. But medication errors are complex and multi-factorial. Despite significant efforts toward the improvement of prescribers' knowledge in pharmacology and pharmacotherapy (292, 468, 473, 481, 484), the same degree of improvement has not been reflected in decreases in prescribing errors (484). One interpretation of this finding is that interventions for improving prescribing errors were not particularly effective. Another

interpretation is that other contributory factors, such as environmental, team, individual or task factors (290), also play significant roles in error generation.

Organisational circumstances, such as increased workload or the unavailability of certain components may also contribute to medication error and affect whether staff can perform in the appropriate manner (476). It is also important to recognise role changes and being competent at these is likely to change over time. For example, pharmacists' competencies have changed from one which was focused predominantly on manufacturing and dispensing based, to one that was more cognitive and pharmacotherapy based (281, 362, 363). Recognising changes to what is deemed competent is important in what is measured when staff competency is being measured.

The discussions so far clearly show that staff competency was a dimension meaningful to stakeholders when medication safety measurement was considered. Staff competency has been a dimension that has been recognised and extensively researched for measurement in the literature. The staff competency dimension should be included as part of medication safety measurement.

Chapter 4: Development of a conceptual framework for medication safety measurement

A) Summary of findings

Seven medication safety dimensions and their sub-dimensions emerged from the research and these contribute to the development of the conceptual framework. The seven dimensions and their sub-dimensions were:

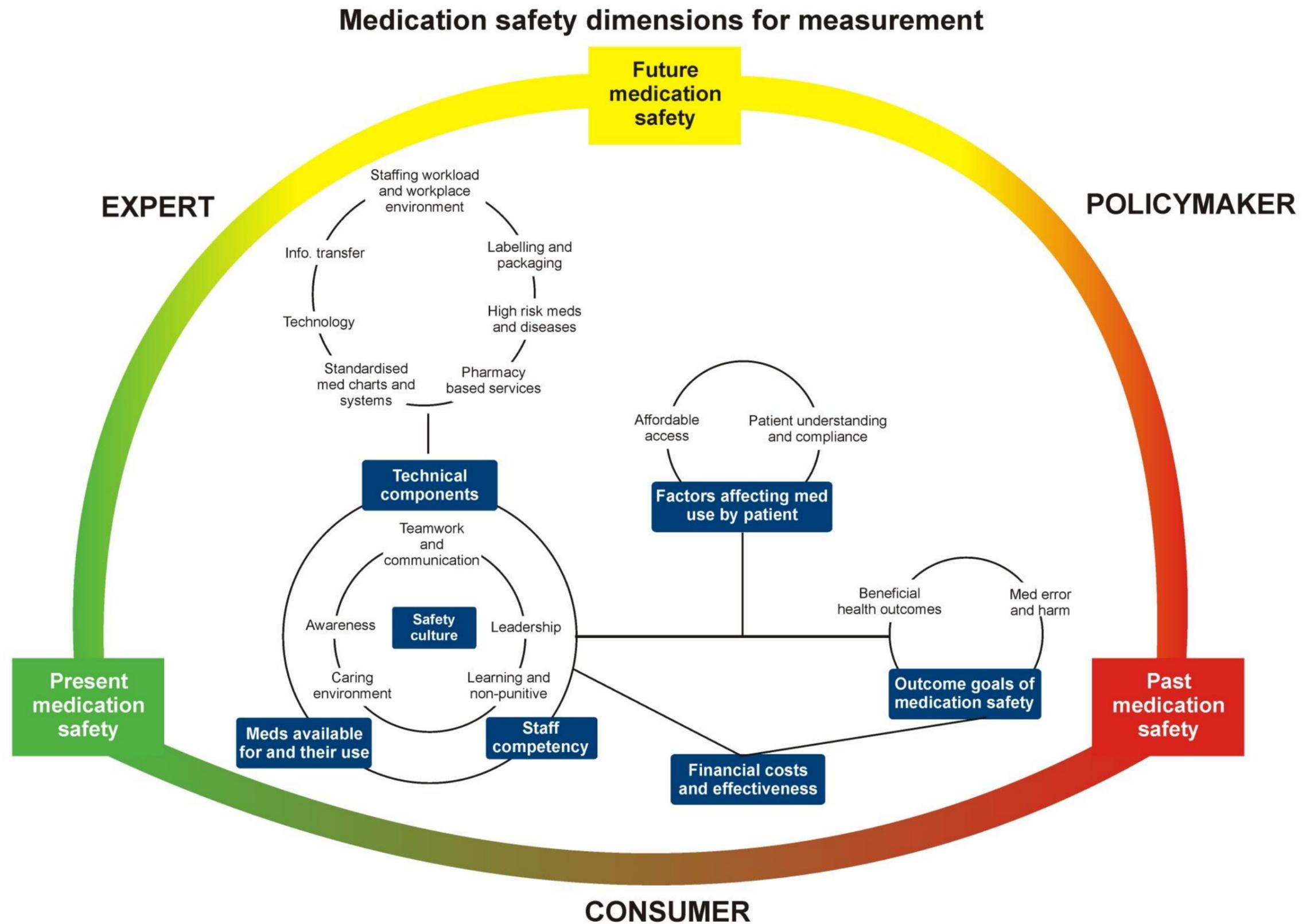
1. Outcome goals of medication safety, both:
 - a. Freedom from medication errors and harm, and
 - b. Beneficial health outcomes from medication use
2. Financial costs and effectiveness
3. Medications and their use
4. Safety culture, which includes characteristics related to:
 - a. Awareness of medication safety
 - b. Leadership
 - c. Teamwork and communication
 - d. A learning and a non-punitive environment
 - e. A caring environment
5. Technical components of the medication use system which includes:
 - a. Technology
 - b. Pharmacy based services
 - c. Standardised medication charts and systems
 - d. High risk medications and diseases
 - e. Labelling and packaging
 - f. Information transfer
 - g. Staffing, workload and workplace environment
6. Factors affecting medication use by patients such as:
 - a. Affordable access to medicines
 - b. Patients' understanding of medications and compliance
7. Staff competency

Each of the seven individual dimensions, how they emerged from the interview data, why they are important to measuring medication safety and how they could be measured has been discussed in detail in previous chapters. Up to now, discussions have shown that each individual dimension is important to the measurement of medication safety. However, it is also

clear that in order to measure medication safety in a holistic manner, the measurement of multiple dimensions is required. The original contribution to knowledge of this research has been the development of a multi-stakeholder derived conceptual framework for medication safety measurement (see Figure 5).

As can be seen from Figure 5, even though the research question did not specifically set out to explore relationships within or between dimensions, associations emerged from the data. These associations informed how the various dimensions and sub-dimensions interact. Overall observations of research findings are also considered. Both these discussions contribute to the development of the conceptual framework. This chapter starts by briefly describing and outlining how the conceptual framework was organised according to the research findings. The dimensions, their emergent relationships and general observations of the data will be discussed in a stepwise manner in relation to how they contribute to the development of Figure 5. The conceptual framework, its implications for research, policy and practice will be addressed later in this chapter (see Chapter 4C).

Figure 5: Conceptual framework for measuring medication safety including all meaningful dimensions and facets.



B) Description of the conceptual framework

The seven key dimensions which emerged from the research are highlighted in blue in Figure 5 to emphasise their importance. Associations between the sub-dimensions and the dimensions are illustrated with the use of connecting lines. No arrows have been used because the relationships need to be further researched and substantiated to establish causal effects. However, lines have been used to show the associations which emerged from the research findings. Sub-dimensions can be related to other sub-dimensions not immediately located next to each other in the figure, and this is illustrated through their arrangement in a cyclical manner. For example, for the safety culture dimension, stakeholders spoke of leadership being a key driver of awareness despite these sub-dimensions not being located next to each other in Figure 5. The cyclical arrangement illustrates that no one sub-dimension has a greater level of importance than another. Collectively, each sub-dimension contributes to, and was characteristic of, a positive safety culture. These are represented in the figure by sub-dimensions surrounding the safety culture dimension.

Other dimensions with sub-dimensions are represented in the same way as safety culture. For example, the sub-dimensions of the technical components of the medication use dimension are also represented in a cyclical manner. However, unlike the safety culture dimension, the sub-dimensions of the technical components dimension are linked via a line. The main reason for this was to make Figure 5 visually clearer and to avoid diverting attention away from dimensions such as medications available and their use and staff competency. Other dimensions which showed emergent associations between the sub-dimensions are outcome goals of medication safety and factors affecting medication use by patients.

Associations existing between dimensions also emerged from the interview data and these are represented with connecting lines. For example, despite a hospital having the best barcoding technologies available, if safety culture was poor and non-committed to improving medication safety then the technology may not be used in an inappropriate manner. Conversely, if safety culture was positive and committed to improving medication safety, but the physical environment was not conducive to safety then medication use may not be safe.

Relationships also emerged between the safety culture dimension and the medications available and their use and staff competency dimensions. For example, deficiencies in the educational curriculum were thought to have resulted in the lack of awareness being generated. Conversely, if staff attitudes were one which was aware and committed to

medication safety, they may recognise their deficiencies and work towards upskilling and improving their competency (473, 474). Safety culture may also influence, and be influenced by the medications available and their use. For example, stakeholders spoke of staff that were aware and vigilantly used complex medicines in a more careful manner. Conversely, new medications such as dabigatran which became available for use, and marketed as being better or more convenient (260), may cause healthcare staff to under appreciate safety risks and be less vigilant during their use, resulting in ADEs (217). These emergent associations reflect the influences of one dimension over another and are represented in Figure 5 through safety culture being located centrally within the other three dimensions.

The technical components of the medication use system, staff competency and medications available for and their use dimensions also appeared to be related and these have been represented using connecting lines. For example, the implementation of certain technical components of the medication use system, such as CPOE with CDSS which has been categorised in the technology sub-dimension, can help reduce errors associated with intrinsically risky medications and staff competency issues by providing prescribing guidance (82, 83, 342, 364). Prescriber competency influences how technical components of the medication use system and how safely medications are used (459). Conversely, medications with complex intrinsic pharmacological profiles may require staff to upskill and ensure competency or changes to the medication system, such as the addition of cautionary labels, to increase the likelihood of safe use.

The contribution of the various dimensions such as the technical components, medications and their use, staff competency and safety culture dimensions to the outcome goals dimension is represented by the use of a connecting line in Figure 5. It is important to recognise that the relationship between the dimensions of the medication use system and the outcome goals of medication safety dimension was not unilateral. Root cause analysis of medication errors may reveal deficiencies in the technical components of the medication use system which need to be changed and improved upon (485).

The factors affecting medication use by patients dimension exist as separate, but related dimensions in Figure 5. This was because factors such as patients' understanding of medicines and compliance play a role in the eventual patient health outcome which was not necessarily amenable by the healthcare delivered. The inter-relationship between factors affecting medication use by patients dimension and the other dimensions are represented through the use of connecting lines. Another dimension which exists as a separate but indirectly related dimension in Figure 5 was the consideration of financial costs and effectiveness dimension.

Resources need to be considered when deciding whether to implement a certain technical component of the medication use system. Medications available for use need to be considered for both their efficacy but also their cost effectiveness.

The association existing between the dimensions was represented via connecting lines in Figure 5. Of the various associations, safety culture appeared to be especially significant and this was represented through its placement on the centre-left side of Figure 5. Emerging clearly from the research, associations existed within and between dimensions. It is important to elaborate on these associations, because they illustrate the complexity inherent in measuring medication safety and how each of the dimensions influences, and is influenced by other dimensions. The dimensions represented in blue in Figure 5 represent a foundation of what should be included as part of medication safety measurement in a holistic manner.

Beyond the dimensions and sub-dimensions, several observations can be inferred from the interview data and these also contribute to the development of Figure 5. Medication safety meant different things to different people. The consumer, policymaker and expert stakeholder groups have been positioned in accordance to their preferences for particular dimensions. Stakeholder groups have also been included in the framework because they represent the inductive development of the conceptual framework based on multi-stakeholder views. They are positioned on the outside looking toward the dimensions to represent their contribution.

The consumer stakeholder group has been positioned on the bottom of the framework in close proximity to the safety culture sub-dimension to represent their preference of measures associated with a caring environment. For example, consumer stakeholder groups more frequently spoke of medication safety as being about safety culture and whether there was a caring environment. Medication safety to these stakeholders meant being able to trust in staff and for the hospital to provide safe care. Safe care was perceived as one where staff showed caring attitudes and positive behaviours, such as collaboration and openness towards them and towards other staff, rather than necessarily the display of technical excellence. Consumer stakeholders went as far as saying they were neither interested nor understood measures related to technical excellence or outcomes. Indeed, these observations align with recent findings in the literature which have also found that patients look for similar characteristics in order to determine patient safety (333).

The policymaker stakeholder group has been positioned on the right side of the figure to represent their preference for measures associated with outcome goals and financial considerations. Policymakers, who were from a pharmacy or medical background, had similar

views to colleagues in the expert stakeholder group and also focused on technical components and outcome dimensions to measure medication safety. Policymakers not from a medical related background typically spoke of the need to consider financial costs and effectiveness. Other studies exploring stakeholder group preferences, but not specifically for medication safety have observed similar findings (97).

Expert stakeholder groups have been positioned on the left side of Figure 5 to represent their preference for dimensions thought to most significantly contribute to outcomes of medication safety. For example, many of the expert stakeholders recommended medication safety measures which focus on determining whether certain components had been implemented and whether they were being used appropriately. Experts who were from the pharmacy profession appeared to more commonly speak of the use of measures relating to ADEs and information transfer to measure medication safety. Experts from the medical profession more commonly spoke about measures relating to high risk medication and disease areas. Experts with a nursing professional background appeared to speak more frequently of the measurement of staff competency to measure medication safety. The expert stakeholder group consists primarily of frontline clinicians and the technical components dimensions may represent the issues and problems they most commonly encounter. Given that many of the researchers working on medication safety measurement are often also active clinicians, this may be one reason why existing medication safety measures also typically focus on these areas (21, 29, 30, 33, 65-67, 69). Based on these findings and what consumers prefer, this may need to change in order to satisfy stakeholders from different groups.

The observation that certain concepts meant different things to different people is not new. Research into diverse differences between healthcare professions has been conducted and are well known (97, 102, 104, 299, 486-488). However, such differences applied to a medication safety measurement context have not previously been well explored. This research has identified that stakeholder groups also have particular preferences in the context of medication safety measurement. Stakeholders were purposively chosen because they represent the most likely end-users of the data obtained from measurement or the people who will most likely implement measurement. It is recognised that certain dimensions may have been over- or under- represented simply because of the constitution of stakeholder groups which were predominantly stakeholders from the policymaker and expert group. Further research is required to better understand the difference in preferences between stakeholder groups. An in-depth understanding of differences between stakeholder groups may help better identify and customise medication safety measures to its targeted audience.

The labels past, present and future are included in Figure 5 to represent that certain dimensions may better serve to measure different facets of medication safety in terms of the time period being considered. For example, the measurement of medication error or ADE captures incidents which have occurred in the past. Thus, past medication safety has been positioned in close proximity to the outcome goal dimension in Figure 5. Though observations need to be further substantiated, the measurement of whether staff are competent may be able to indicate the likelihood of safety in the future. This is because if they are competent, it may mean that they are able to perform their tasks appropriately and without error. Thus, they are positioned close to the staff competency dimension. Connecting lines have been used between past, present and future to indicate their inter-relatedness, because past safety and experiences will enable the improvement of medication safety in the present and future.

The past, present and future labels have also been included in the conceptual framework to represent the dynamic nature of medication safety which changes over time. Evident from the interview data, medication safety is a dynamic concept which changes from moment to moment. For example, stakeholders spoke of medication safety changing rapidly if there is a change in circumstances such as staff being absent due to sickness. The situation can suddenly go from being safe to being highly risky due to increased workload pressures. Traditional metrics and measures which are predominantly quantitative in focus and are typically audited on a weekly, monthly or yearly basis may not be sensitive enough to capture such minute fluctuations and may only capture particular moments in time. The research findings suggest there is a need to employ more intuitive, organic and qualitative measures such as discussion with staff to help provide a more rounded approach to measurement.

Safe practice in the past may no longer be safe today with the expansion of knowledge. The definition of medication safety has become, and will further become, more sophisticated. For example, this research has already identified a need to change the way medication safety is conceptualised. As a consequence of research findings, the conceptualisation of medication safety should expand from the avoidance of medication error and harm to the achievement of beneficial health outcomes. The continuous circle, with the labels of past, present and future surrounding the dimensions and sub-dimensions of medication safety represent a framework which needs continuous iterative refinement in accordance with changing views, knowledge and experience.

C) Implications

The development of a multi-stakeholder derived conceptual framework for medication safety measurement has been a significant contribution to knowledge. Research findings significantly impact theory, practice and policy.

Implications for theory

The findings of this research have significantly reframed how medication safety should be conceptualised and measured. The exploration of what medication safety means and the dimensions meaningful to multi-stakeholder groups and the development of a conceptual framework to measuring medication safety mean that several knowledge gaps have been addressed.

In the literature, medication safety and its measurement has focussed on errors, ADEs and their avoidance (1, 9). This has been narrow in approach. This research has shown that medication safety means more to people than just the avoidance of medication errors and harm. Medication safety also means the achievement of beneficial outcomes from medication use. There is no point in using medications, in an error or harm free manner, if no benefits to health are expected. Expanding the conceptual boundary means that medication safety improvement needs to consider facets beyond the avoidance of error and harm. The measurement of medication safety will now also need to change. As a consequence of this research, measurement of medication safety should determine whether medications are achieving what they were intended to do and whether it was done in a cost effective manner—facets which have not previously or specifically been targeted for improvement or measurement. These changes mean that existing measures for medication safety measurement would be insufficient. Measures used for measuring other aspects, such as patient health outcomes, require further study to determine their utility for measuring medication safety.

Another implication of expanding the conceptual boundary of medication safety is that the utility of medication safety as a concept comes into question. It is unclear whether the medication safety concept should stand alone or be absorbed within a broader construct. For example, the QUM concept goes beyond the avoidance of medication errors and harm and into optimising health benefits in a cost effective manner for the patient and the population (71). Research findings suggest the medication safety concept and the dimensions it is comprised of may be better encapsulated under a QUM concept. But importantly, the research findings also suggest that many stakeholders believe there is a distinct conceptual boundary. More research

which specifically explores in-depth the difference between the concept of medication safety and QUM is required.

There also appears to be a lack of research exploring whether distinctions exist between the medication safety and patient safety concept. It was unclear whether differences exist between the two concepts, or whether there were any dimensions specific to medication safety. As noted at the start of this thesis, a Health Foundation report (18) into the measurement and monitoring of patient safety was published. It is interesting that dimensions identified by this group for patient safety were similar to dimensions as those identified within this research. Specifically, the dimensions identified by these researchers for measuring and monitoring patient safety were:

1. Past harm: Psychological and physical measures of incidents with poor safety such as ADEs
2. Reliability: Of systems delivering healthcare
3. Sensitivity to operations: Information and capacity to monitor safety on an hourly or daily basis
4. Anticipation and preparedness: Ability to anticipate, and be prepared for problems
5. Integration and learning: The ability to respond to and improve from, safety information

Many of these dimensions are similar to those as identified in this research but there are also important differences. For example, the dimension of past harm aligns with the outcome goals of medication safety dimension in Figure 5 because it is associated with the measurement of incidents such as ADEs and error. The reliability dimension aligns with the technical components of the medication use system and staff competency, because both are about whether technical components are in place and whether they are being used appropriately to provide healthcare reliably. The sensitivity to operation dimension is similar to that in sub-dimension of awareness and learning and non-punitive environment encapsulated within the safety culture dimension. The dimension relating to anticipation and preparedness is similar to the consideration of past, present and future components of Figure 5. The integration and learning dimension is similar to the learning and non-punitive sub-dimension.

The conceptual framework in Figure 5 is unique, however, because other dimensions that appear specific to medication safety, such as factors affecting medication use by patients, medications available and their use and consideration of financial costs and effectiveness were not present. Again, there has been a lack of research which has specifically articulated or

explored whether differences exist. This research has offered an in-depth exploration into the medication safety concept. The research findings suggest that the medication safety concept is different from the patient safety concept, and each requires their distinct conceptual framework although there is overlap.

Borrowing from the quality and patient safety literature, researchers have suggested that at no point is there a distinction where patient safety topples into quality, but rather there is a continuum between the concepts (51). Some scenarios, such as the wrong medication being administered more easily resonate as a safety issue while other scenarios which may also have safety implications, such as non-vaccination of the flu vaccine with the patient contracting the flu, may resonate as more of a quality issue (51). Taking a continuum view may be the best approach to describing overlaps existing between the medication safety, QUM and patient safety concepts. So far, there has been a lack of research which has specifically articulated whether such differences exist, and this research contributes to knowledge by providing a rich conceptual exploration.

Findings from this research suggest that some stakeholders spoke of a clear distinction existing between the concepts of medication safety and QUM. Medication safety, QUM and patient safety concepts appear to overlap, and there is a need to make clear exactly what is desired to be measured and specify exactly which dimensions are to be measured. Recognising these differences and exploring stakeholder views on what medication safety means to people was important. The conceptual framework in Figure 5 specifies exactly what the concept of medication safety and its measurement is comprised of according to multi-stakeholders in the NZ public hospital setting. The development of a framework which synthesises the meaningful conceptual dimensions of medication safety measurement provides the necessary platform which is required to inform measurement initiatives.

A better understanding of what medication safety means to people can help the development of metrics which are more meaningful to its users. An observation of existing medication safety measures and the process by which they have been developed has been the lack of true stakeholder input and involvement. Previously, an example was given where medication safety indicators intended for public reporting (25) was developed without input by consumer representatives. Moreover, the level of involvement by the intended target audience of the data obtained from measurement has typically been limited to choosing from a pre-selected list of measures which are deductive in manner (106) because they were chosen by a researcher selected panel (33). The consequence of current approaches to developing measures has meant

that the existing measures of medication safety may not actually be what the likely end-users want.

As the research findings have demonstrated, there are significant differences between the dimensions recommended in the literature for public reporting (25) and the dimensions identified. This means that the measures identified in the literature may not be useful to the general public, at least in the NZ setting. Alternative measures are required. An inductive approach to explore medication safety measurement was useful because it allowed stakeholders to openly express their views, allowing for a deeper and richer exploration without a priori assumptions of the topic (106). The inductive approach has helped identify the meaningful dimensions for medication safety measurement. Atypical dimensions beyond those traditionally used for measurement such as technical components and outcome goals of medication safety were identified. This is not to say that an inductive approach was better than a deductive approach. Actually, they address different research questions. An inductive approach is hypothesis generating, while a deductive approach tests hypothesis. There has been a lack of inductive based research into stakeholder views of medication safety measurement and this research has contributed to knowledge by addressing this gap.

Exploring how multi-stakeholders conceptualised medication safety and determining what was meaningful to them for measurement exposed gaps between how medication safety had been recommended to be measured in the literature and what stakeholders preferred. Understanding such differences allows this gap to be bridged and the findings of this research can be used to develop more robust and meaningful medication safety measures. With the expanding knowledge on medication safety and its improvement, this research has synthesised the various conceptual dimensions and multi-stakeholder views to develop a single framework for medication safety measurement meaningful in the NZ public hospital setting.

The lack of true stakeholder input and involvement up to now may help explain why despite many measures having been developed, many have not been used. Even though time and resources play a role, a major reason for the lack of use of measures in healthcare organisations has been attributed to measures not being relevant to the local context or its users (91, 320). There was a need to explore what conceptual dimensions of medication safety measurement were meaningful to its end-users. Without a clear understanding of stakeholders' views and a conceptual framework which embraces these views, any subsequent developed metrics may not be meaningful and thus not used. It is difficult to measure medication safety in a holistic manner until there is a clear understanding of what medication safety means. This research has specifically explored what medication safety means to multi-stakeholders and

what dimensions of medication safety they would prefer if medication safety was to be measured using an inductive approach. Figure 5 provides a robust conceptual framework upon which measurement can be operationalised. A thorough understanding of how stakeholders conceptualise medication safety provides a platform for the subsequent development, and research, of measurement initiatives.

A better understanding of what medication safety means that multi-stakeholders in the NZ public hospital setting also have important implications of how medication safety can be improved. Participants of this study have been purposively chosen for their job role and expertise. Many of the participants from the policymaker stakeholder group have been charged with improving medication safety, such as the Chair of SQUM or their representative. Many of the participants from the expert stakeholder group were clinicians who work in the frontline and are the ones who actually implement improvement initiatives. As previously noted, people from the policymaker group tend to be more concerned with the consideration of financial costs and effectiveness. While for the expert group, the technical components were of a higher priority. In order to engage people from the policymaker stakeholder category in medication safety improvement, it may be more appropriate to use financial based incentives. However, using financially based incentives as an approach may not be particularly useful for people from the expert stakeholder group. Exploring views from multiple stakeholders from diverse backgrounds reveals the differences in priorities of different people and this may facilitate improvement initiatives.

It is difficult to measure or improve medication safety without having a single framework which synthesises the conceptual dimensions of medication safety meaningful to multi-stakeholders in the NZ public hospital setting. The conceptual framework in Figure 5 provides a blueprint of what medication safety looks like to stakeholders. This framework is useful because it provides aspirational goals for medication safety for multi-stakeholders. Organisations may be able to assess themselves against these dimensions in order to monitor and improve their progress. As noted at the start of this thesis, many conceptual frameworks, such as those by the ISMP–MSSA have been reported. Each of these emphasise different dimensions in order to improve medication safety. For example, ISMP–MSSA emphasises 10 key elements and 20 characteristics (32). Mackinnon suggests there are eight essential dimensions to an optimal medication use system (12). The dimensions contained in these two frameworks and the dimensions identified in this study have been included for the purpose of comparison have been summarised in Table 3.

Table 3: Comparison of some conceptual frameworks of medication safety.

Conceptual frameworks of medication safety and its dimensions		
ISMP (32)	Mackinnon (12)	Dimensions identified in this study
<ol style="list-style-type: none"> 1. Patient information 2. Drug information 3. Communication of drug information 4. Drug labelling, packaging and nomenclature 5. Drug storage, stock, standardisation and distribution 6. Drug device acquisition, use and monitoring 7. Environmental factors (e.g., poor lighting, noise, etc.) 8. Staff competency and education 9. Patient education 10. Quality processes and risk management (e.g., systems to detect and correct errors) 	<ol style="list-style-type: none"> 1. Timely recognition and diagnosis 2. Documentation and communication 3. Appropriate prescribing 4. Safe, accessible, cost-effective medications 5. Monitoring 6. Distribution and tailored patient advice 7. Patient participation and intelligent adherence 8. System evaluation, measurement and improvement 	<ol style="list-style-type: none"> 1. Outcome goals of medication safety, both: <ul style="list-style-type: none"> • Freedom from medication errors and harm; and • Beneficial health outcomes from medication use 2. Financial costs and effectiveness 3. Medications available for and their use 4. Safety culture, which includes characteristics related to: <ul style="list-style-type: none"> • Awareness of medication safety • Leadership • Teamwork and communication • Learning and a non-punitive environment • Caring environment 5. Technical components of the medication use system which includes: <ul style="list-style-type: none"> • Technology • Pharmacy based services • Standardised medication charts and systems • High risk medications and diseases • Labelling and packaging • Information transfer • Staffing, workload and workplace environment 6. Factors affecting medication use by patients such as: <ul style="list-style-type: none"> • Affordable access to medicines • Patients' understanding of medications and compliance 7. Staff competency

As can be observed in Table 3, there are similarities between the different conceptual frameworks. To illustrate their similarities, consider dimension nine of the ISMP framework which is about patient education (32). This dimension assesses a hospital on whether it provides the opportunities to include patients as active partners (32). For example, the ISMP framework emphasises the importance of whether patients are provided with written information about their medications (32) which helps patients understand their medications better. This dimension is also captured in Mackinnon's framework under dimension seven, patient participant and intelligent adherence (12). Using the dimensions identified in this research, it would best fit under dimension six, factors affecting medication use by patients, and dimension four, safety culture under the sub-dimension of a caring environment in terms of empowering the patient to engage in their own health. To an extent, there are similarities observed across the various conceptual frameworks.

However, several observations which illustrate the differences between the conceptual frameworks can also be made. Many of the dimensions have different labels and there are differences in exactly what is comprised within the dimensions used. This indicates that no one universally accepted conceptual framework for medication safety or its measurement are known. The conceptual framework of this research is unique for several reasons. Firstly, it was developed inductively based on multi-stakeholders views from the NZ public hospital setting. The conceptual framework developed represents what medication means to these stakeholders as interpreted via the researcher. As has been previously discussed, medication safety means different things to different people, and thus the conceptual framework developed elsewhere may not be relevant to local stakeholders. This research is the first known study that has explored medication safety as a concept meaningful for a NZ hospital specific context.

Secondly, the conceptual framework developed in this research has specifically explored stakeholder views and elicited their preferences. This means that the dimensions contained within the conceptual framework in Figure 5 represent stakeholder preferences. This is in contrast with ISMP's framework, which was developed based on analysis of medication error reports the organisation had received (84). This approach was predominantly technical in nature and focused on the contributory factors. Previously, this research has discussed the gap that can exist between what stakeholders want for measurement and what they should have. The findings of this research have led to the creation of a conceptual framework which has synthesised the dimensions present in the literature, but importantly captured those that were meaningful to stakeholders.

Figure 5 is the first known inductively built framework which has synthesised the conceptual dimensions of medication safety measurement and views meaningful to multi-stakeholders in the NZ public hospital setting. The discussions so far have shown that the development of the conceptual framework in Figure 5 has several important implications on theory. It has contrasted with current conceptualisations of medication safety, and changes the way the concept should be measured and what should be improved in order to improve medication safety. Knowing what medication safety means to key stakeholders provides the framework by which to direct and operationalise improvement efforts and measurement initiatives.

Implications for practice

The measurement of medication safety is required in order to know whether interventions implemented have been effective (25, 26, 189). Despite the importance of measurement and the effort already directed towards it, there has been a lack of clarity around whether medication safety has improved (17). The measurement of medication safety has typically focused on measuring certain technical components of the medication use system, or medication errors and ADEs. Due to methodological limitations, the measurement and comparison of error and ADE rates to determine if medication safety has improved is not always reliable or valid. But even if somehow, errors and ADE rates can be reliably and validly measured, they only form part of the overall picture of medication safety. The measurement of medication safety has been too narrow in focus. Part of the challenge has been the lack of a shared common understanding of what the concept of medication safety means among multi-stakeholders. Findings from this research have shown that medication safety means more than just the avoidance of error and harm to key stakeholders. The mismatch between what has traditionally been measured and how the concept has been conceptualised by stakeholders means that medication safety has not been measured in its entirety, thereby preventing comprehensive comparison. Without knowing what medication safety means to multi-stakeholders, it is difficult to measure the concept in a holistic manner.

The conceptual framework developed in this study means that there is now an understanding of how medication safety has been conceptualised by multi-stakeholders and what dimensions are preferred. This means that medication safety can now be measured in a more comprehensive manner. This research recognises that future research is needed to better operationalise and identify which measures would provide the greatest utility. However, the conceptual framework developed provides a fundamental step for medication safety measurement. It provides an understanding of what dimensions of medication safety are desired by stakeholders to be measured and the facets required for consideration. If certain

stakeholder groups are targeted as an audience, the framework can be used to guide the development of measures most meaningful. If certain dimensions or facets of medication safety are being targeted for measurement, the framework provides guidance on what should be measured and considered. The understanding of these facets will help the development of measures which are more meaningful to stakeholders.

Currently, the way medication safety has been measured across different nations is different. For example, safety indicators for medication use developed in Canada (35) are quite different from the ones used in Australia (229) and Germany (33). New Zealand currently does not have a measurement framework for medication safety. The development of the conceptual framework in Figure 5 synthesises the various dimensions of medication safety meaningful to NZ public hospital stakeholders. It offers a foundational framework by which to base measurement initiatives and the measuring of medication safety which is required in practice (17, 19, 21-31).

An important point which has not been discussed so far is the implications of the developed conceptual framework on improvement. Because the research has explored the priorities for medication safety by multi-stakeholders, it shows stakeholders' views on what dimensions they deem as important. If certain initiatives are missing, it means that stakeholders do not necessarily prioritise such dimensions and more education may be required to address such knowledge deficiencies if the initiative is important. Conversely, understanding what dimensions were important means that it can be used to further encourage and extend medication safety improvement. Because the developed conceptual framework has synthesised the most important dimensions of medication safety in the literature, it also identifies dimensions which may not have been, but should be, addressed for the NZ public hospital setting.

Implications for policy

The conceptual framework developed can be used to inform and guide measurement initiatives and can help to inform policy decisions around monitoring and clinical governance in the context of NZ hospitals. The conceptual framework may also be used to guide resource allocation. For example, knowing which dimensions are particularly meaningful will mean that funders can better decide and specify which facets of medication safety they would like to focus on.

As outlined at the start of this research, policymaking organisations such as the MOH, NHB and the HQSC are interested in evaluating the impact of medication safety initiatives (22-24).

There has been a call for expressions of interest to develop this framework. This research importantly outlines what should be measured, what is meaningful to multi-stakeholders in the NZ public hospital setting and has offered potential measures by which the dimensions can be measured. This research has potentially saved these organisations both resources and effort to better understand these issues. The findings of this research can be used by these organisations to operationalise measurement initiatives which are meaningful to its intended target audience. Furthermore, because the research findings highlight the priorities for medication safety by stakeholders, policymaking organisations can use this to understand why some improvement initiatives have not been implemented successfully. Research findings may indicate deficiencies in knowledge so that targeted stakeholders understand and recognise the importance of certain medication safety initiatives.

Chapter 5: Limitations of this study

The focus on only obtaining multi-stakeholder views from the NZ public hospital setting means that the framework may not be generalisable to another setting in another country. Further research is required to determine whether the conceptual framework is generalisable and relevant outside of the context of this study. However, evident from stakeholders' views was that the process of developing medication safety measures itself may increase awareness, commitment to, and shared belief in the importance of, medication safety. In fact, measures which are imposed and are mandatory may add to the degree of unsafeness, because staff are faced with increased workload. Thus, the process of developing a measurement framework may be better done by involving stakeholders in the relevant settings.

More research will be needed to operationalise the developed framework to add further value to practice and policy. This research has posited a robust conceptual framework upon which to build and operationalise both medication safety systems and the measurement thereof. The conceptual framework can be used to develop specific measures and metrics in collaboration with stakeholders which are customised to their local setting, purpose and context (18, 124).

Some researchers suggest the use of a second coder to increase the reliability of data coded. Such an approach is needed in research of a more deductive nature since categories and their definitions need to be established before coding can proceed (130). This research was more inductive with coding categories emerging from the data and is in line with within the epistemology framework of this research. Thus the use of a second coder was deemed unnecessary and inconsistent with the methodology of this research. It is recognised that the use of a general inductive approach to elicit findings means that another researcher using the same approach may interpret the data differently and develop a different framework depending on their experience, knowledge and expertise (137). However, the fact that the researchers' previous knowledge and preconceptions will inevitably influence this analysis is not necessarily a disadvantage because the researcher may be seen as a valid expert participant themselves thus providing greater insight and relevance for New Zealand settings that may otherwise have been missed (106, 107, 130).

The research involved two consumers and could be interpreted as under-representing the views of this stakeholder group. This was not considered to be an issue because this research is founded on theoretical sampling strategies (including purposive and snowball sampling) which mean that stakeholders who were able to understand the question, respond to them and are

likely to benefit from the research as end users were identified and included (see Chapter 2A: Methodology). Generalisation across an individual stakeholder group is limited in this type of research, but collectively the developed conceptual framework provides a foundation for understanding the issues across a range of stakeholders. Future research can be undertaken to test the generalizability within stakeholder groups and seek agreement with regards to the framework.

The appeal of identifying a sole measure for medication safety is understandable, but challenging to develop. No one measure is able to capture the entirety of the multiple dimensions and multi-stakeholder views of medication safety. Moreover, the concept of medication safety identified in this research has proven to be elusive and context dependent, which makes it challenging to measure. For example, as has been previously discussed in the medications and their use dimension, the advancement of medical knowledge has led to more medications being used. Paradoxically, this may mean that patients are exposed more frequently to risks associated with medication use, and thus may actually mean that medication safety is compromised because of increased risks. Thus, in one context, the administration of medications means that the patient is exposed to the risks associated with medications and their use and so may not be safe. In another context, the non-administration of medications means that the patient may not receive the benefits associated with the medications used which can also be deemed as unsafe. A conundrum exists where there may be no safe situation. The consequence of the conundrum is that medication safety is difficult to measure.

Medication safety and what it means to be safe depends on the context in which it is discussed. There will always be proponents who will suggest that what is measured does not measure medication safety, and their rationale and argument will focus on the contexts and situations this applies to. It is recognised that the conceptual framework in Figure 5 will be vulnerable to criticism by such proponents because the framework does not, and cannot, encompass every possible context or take into account every single situation. These arguments are valid and important. However, there is also a need for a certain degree of pragmatism. Instead, Figure 5 represents the majority of what medication safety means to stakeholders and what is meaningful most of the time. It is recognised there is a need to consider, then describe, the specific context the framework is being applied to.

Multiple measures across multiple dimensions are required in order to measure medication safety in a holistic manner that is meaningful across multi-stakeholders. Medication safety measures must be developed by, and customised to, the local context and the requirements of

people expected to use the information. The developed conceptual framework provides the foundation required to inform measurement initiatives. It is recognised that more research is needed to develop and operationalise the framework. Customisation is required to ensure the measures used take into account stakeholder requirements. However, the framework was required to provide a common platform for such discussions to take place. The framework maintains the ability to be used year on year, or institution to institution, to base discussions upon. The framework is generalisable to the New Zealand setting, but further research will need to be undertaken to test its relevance in other settings.

Chapter 6: Summary

Existing approaches to medication safety measurement have been too piecemeal and narrow in focus. The bulk of the literature has focused on individual dimension(s), such as technical components of the medication use system or medication error and ADEs to measure medication safety. This research has shown that a significant gap exists between what has typically been measured and stakeholders' conceptualisation of medication safety.

The aim of this research was to develop a multi-stakeholder derived conceptual framework for medication safety measurement meaningful for the NZ public hospital setting. The original contribution of this research to knowledge has been the development of a multi-stakeholder derived conceptual framework for medication safety measurement meaningful for the NZ public hospital setting. The findings of this research mark a significant reframing of how medication safety should be measured. It changes from one which is narrow and in isolation, to one which is multi-dimensional and holistic. The proposed conceptual framework helps to simplify the understanding associated with the complexities of measuring medication safety. The research output provides a robust theoretical frame by which medication safety measurement can be undertaken. The conceptual framework informs what dimensions need to be considered and has added value by discussing how the dimensions can be measured. This research has explored how different stakeholders conceptualise medication safety and the dimensions deemed most meaningful. These findings can be used to customise measurement initiatives to its intended target audience. The conceptual framework developed can be used to guide and inform medication safety measurement initiatives.

The medication safety concept appears dynamic and abstract. These characteristics have meant that the measurement of medication safety has been challenging and elusive. This does not mean that the measurement of medication safety cannot be undertaken or that it shouldn't be done. In fact, it can and it must. The measurement of medication safety is required for improvement and accountability purposes in NZ and abroad. There has been no known framework for medication safety measurement in NZ, let alone, one that is inductively built and synthesises the conceptual dimensions meaningful to multi-stakeholders. This research has addressed this knowledge gap by developing a multi-stakeholder derived conceptual framework for medication safety measurement.

Appendices

Appendix 1: Most common methods to identify medication errors and ADEs

Method	Brief description	Some advantages	Some disadvantages
<p>Computerised monitoring methods Some examples (65, 489)</p>	<p>Utilises computer algorithms and “triggers” based rules to detect potential and actual ADEs and medication errors (e.g., the use of an opioid antagonist, naloxone, may suggest that an opioid overdose incident had occurred, if an antihistamine was used this may have been in response to an allergic reaction to a drug, etc.). These triggered alerts can then be further investigated for whether an ADE had occurred either retrospectively or as part of real-time surveillance. Data mining methods—a form of the computerised monitoring method, this method instead relies on automated screening methods and computer algorithms to scan electronic information, medical records and administrative data for potential adverse incidents.</p>	<ul style="list-style-type: none"> • Thought to be relatively resource effective and easy to use • Ability to focus on the measurement of specific ADEs • Ability to produce a rate which can then be used to compare results over time 	<ul style="list-style-type: none"> • The sensitivity of the tool to capture ADEs depends on the robustness of the triggers and algorithms chosen • Trigger tools presuppose that particular errors and ADEs are known and cannot be used to identify errors and ADEs not previously seen
<p>Trigger tools Some examples (38, 490)</p>	<p>Similar to the computerised monitoring method this tool also utilises particular events (e.g., use of naloxone or use of an antihistamine) to indicate where an ADE may have occurred and further investigation can be undertaken but instead utilises a manual method. Typically, pharmacists or research nurses scan through medical records using the explicit criteria. If a particular “trigger” is activated this would then be investigated further to detect whether an ADE had occurred.</p>	<ul style="list-style-type: none"> • Thought to be relatively resource effective and easy to use • Ability to focus on the measurement of specific ADEs • Ability to produce a rate which can then be used to compare results over time 	<ul style="list-style-type: none"> • The sensitivity of the tool to capture ADEs depends on the robustness of the triggers and algorithms chosen • Trigger tools presuppose that particular errors and ADEs are known and cannot be used to identify errors and ADEs not previously seen

Method	Brief description	Some advantages	Some disadvantages
Medical record review Some examples (68)	Utilises trained staff to review medical records to detect medical incidents or where an ADE may have occurred. Many of the landmark studies which had quantified the problem of iatrogenic harm had utilised this method. Chart review can be explicit (similar to the ADE trigger tool where an explicit set of criteria are used to detect events) or implicit (relies on judgement, usually by an expert panel). Chart reviews can be done retrospectively or as part of real-time surveillance (196). Usually a panel of clinicians then review these incidents to determine whether an adverse event had occurred, the degree of preventability and other further classification.	<ul style="list-style-type: none"> • Tends to capture the most numbers of ADEs compared to the other methods • Method used by most landmark studies to quantify harm 	<ul style="list-style-type: none"> • Too highly resource intensive to be used practically outside of a research setting • Inter- and intra-rater reliability is variable reflecting a high level of subjectivity in the evaluation of records
Incident reporting Some examples (69)	Incident reporting involves staff reporting on any potential or actual events where an error or incident has occurred. These can be voluntary, solicited or facilitated.	<ul style="list-style-type: none"> • Tends to capture a wide range of events and typically only the most serious events • Relatively easy and inexpensive to set up 	<ul style="list-style-type: none"> • Least sensitive of the tools capturing only a small proportion of incidents • Rates produced not accurate since reporting is variable
Direct observation Some examples (64)	Utilises trained observers to monitor for medication errors or incidents during the administration and dispensing stages. Errors can then be further classified and analysed.	<ul style="list-style-type: none"> • Measures errors during dispensing or administration • With sampling, ability to produce a rate for comparison 	<ul style="list-style-type: none"> • Does not measure errors or near misses at the prescribing or monitoring steps
Intervention database Some examples (67)	Utilises clinicians to capture interventions as a result of the correction of a medication error or a medical incident (e.g., wrong dose charted on a prescription which was intervened and corrected by a pharmacist. The intervention would then be captured via a database).	<ul style="list-style-type: none"> • Potentially rich source of information on medication errors relevant to day-to-day practice 	<ul style="list-style-type: none"> • Only a small proportion of the total interventions are collected due to the collection of data being retrospective

Adapted from the following references (1, 27, 30))

Appendix 2: List and rationale for purposively selected stakeholders and those identified from snowball sampling

Column A: Stakeholder category used in this research	Column B: Purposively chosen stakeholders	Column C: Snowball sampling chosen stakeholders	Column D: People actually interviewed	Comments and rationale for choice of stakeholder
Consumer	Consumer group representative		Consumer group representative	Leveraging from the membership selection process conducted by the SMM programme the same consumer group stakeholders were used. There is an increasing trend of reporting hospital performance and safety information to the general public (25) so it was important to elicit insight into what information these stakeholders find meaningful.
Policymaker	HQSC chair or representative		HQSC chair or representative	The HQSC is charged with accelerating safety and quality improvement across the health sector and to reduce the effects of medical error (491). Information obtained from measurement would be relevant to this group since it can help monitor the progress and effectiveness of their initiatives. It was important to gain insight into what this stakeholder would find meaningful if medication safety was measured.
Expert	NZHPA president or representative		NZHPA president or representative	The NZ Hospital Pharmacists Association (NZHPA) is a voluntary organisation comprising of hospital pharmacists in NZ. This organisation has regularly contributed to medication safety efforts and is regularly consulted on such matters. Since hospital pharmacists are involved in almost all aspects of the medication management process (360), they are well placed to determine where errors may occur and provide insight into what should be measured.
Expert	Medication safety expert		Medication safety expert	This medication safety expert is a clinical pharmacist and has been involved with several national medication safety projects.
Policymaker		Medsafe representative but also served to represent the Minister of Health and Director General of Health	Medsafe representative but also served to represent: Minister of Health or representative Ministry of Health, Director General of Health or representative	This stakeholder served as the representative from the Minister of Health and the Director General of Health. Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand (492). They are responsible for administering the Medicines Act 1981 and Regulations 1984. Given their role it was important to gain their perspective in medication safety and medicines use.

Column A: Stakeholder category used in this research	Column B: Purposively chosen stakeholders	Column C: Snowball sampling chosen stakeholders	Column D: People actually interviewed	Comments and rationale for choice of stakeholder
Policy maker	Minister of Health or representative		See above	The Minister of Health is charged with all aspects of health (493), data obtained from measuring medication safety should be meaningful to them so their opinion was sought. A representative for the Minister was the same person as the Medsafe representative.
Policy maker	Ministry of Health, Director General of Health or representative		See above	The Director General (DG) of Health is the government's principal advisor on health and disability matters and is charged with leading the development and performance of the NZ health system (494). Data obtained from measuring medication safety is likely to be used by them to monitor safety initiatives and required to ensure medication use systems are safe. The DG of Health's views on what is deemed meaningful if medication safety was measured was sought. The selected representative was the same person as the Medsafe representative.
Expert	HINZ chair or representative		HINZ chair or representative	Health Informatics NZ (HINZ) is the national not-for-profit organisation aiming to facilitate patient care improvements and business process in the health sector through the use of information technologies (495). Information technologies are increasingly being used to improve medication safety such as medication barcoding, electronic prescribing, electronic health records and so forth. (1, 342) This stakeholder group's views were important because they provide insight into how these improvement initiatives can be measured.
Policy maker	NHB chair or representative		NHB chair or representative	The NHB business unit is charged with improving quality and safety, high service performance, improved regional and national decisions and reduction of administrative waste and costs (494). Understanding what the NHB would find meaningful for measuring medication safety was required because such information is likely to be used for allocating resource.
Expert		Clinical pharmacologist expert	Clinical pharmacologist expert	Clinical pharmacologists are general physicians who specialise in the management of complex toxicology, therapeutic drug monitoring and drug information service (496). They also often take up leadership roles such as chairing medicines and therapeutic advisory committees. They are also often involved with medication safety and quality use of medicines initiatives and thus are likely to be users of the data obtained from medication safety measurement.
Expert		Clinical pharmacologist expert	Clinical pharmacologist expert	See above.

Column A: Stakeholder category used in this research	Column B: Purposively chosen stakeholders	Column C: Snowball sampling chosen stakeholders	Column D: People actually interviewed	Comments and rationale for choice of stakeholder
Expert		Medication safety expert	Medication safety expert	This medication safety expert was selected because they have been involved in several national medication safety initiatives.
Policymaker	Health and Disability Commissioner or representative		Health and Disability Commissioner or representative	The HDC is charged with promoting and protecting the rights of consumers (310). This organisation also deals with complaints by health consumers on health services. Their experience provides valuable insight into what consumers might want if medication safety is measured. Moreover, because the HDC often recommend ways for a hospital to improve and ensure safe and effective treatment, they may hold valuable knowledge on what should be measured for medication safety.
Consumer		Consumer group representative	Consumer group representative	Leveraging from the membership selection process conducted by the SMM programme the same consumer group stakeholders were used. There is an increasing trend of reporting hospital performance and safety information to the general public (25) so it was important to elicit insight into what information these stakeholders find meaningful.
Policymaker	NZPhVC Director or representative		NZPhVC Director or representative	The NZPhVC and the CARM are responsible for the voluntary reporting of ADR, medication errors and medication related harm (164, 165). They have been actively promoting a central national reporting system and their expertise on reported events may provide insight into what should be measured for medication safety.
Expert	NZNO president or representative		NZNO president or representative	The NZ Nursing Organisation (NZNO) is the professional organisation who represents nurses aiming to promote the profession and participates in health and social policy to improve the health status of all people in NZ (497). Because nurses are often at the proximal and distal end of the medication management process, nurses are well placed to determine where and what errors have occurred. Their knowledge and practical experience in medication administration and their unique interaction with the patient and other health professionals gives them a thorough understanding of clinical practice. Their insight and experience is vital to help identify what should be measured.
Expert		Medication safety expert	Medication safety expert	This stakeholder was chosen because of their expertise in medication safety. This person has published in the area of medication safety and its evaluation.
Expert		Pharmacy expert	Pharmacy expert	This stakeholder was chosen because of their expertise in Pharmacy practice. Pharmacy is the only profession which is solely dedicated to medications and their use (360). This stakeholder is regarded as an expert on most aspects of pharmacy practice and may provide valuable insight into what should be measured for medication safety.

Column A: Stakeholder category used in this research	Column B: Purposively chosen stakeholders	Column C: Snowball sampling chosen stakeholders	Column D: People actually interviewed	Comments and rationale for choice of stakeholder
Expert		Quality Improvement and patient safety expert	Quality Improvement and patient safety expert	This stakeholder was recognised internationally as a quality improvement and patient safety expert and may provide insight into what should be measured for medication safety.
Expert		Medication safety expert	Medication safety expert	A senior medication safety manager at a large NZ hospital. They have had extensive experience in medication safety, implementing systems such as Pyxis® which is an automated medication dispensing system, electronic medication reconciliation and other various medications safety projects. They also bring a health informatics perspective having done several projects which attempt to evaluate aspects and outcomes of medication safety.
Expert		Nurse expert/nurse prescriber	Nurse expert/nurse prescriber	This stakeholder was chosen because of their nurse prescribing expertise. Their clinician knowledge could provide insight into what data obtained from measurement may be meaningful.
Expert		ANZ College of Anaesthetists selected representative	ANZ College of Anaesthetists selected representative	Anaesthetists have often been involved in improving healthcare quality and patient safety and often employ measurement systems to monitor anaesthesia safety (158). Their insight into how medication safety could be measured was valuable.
Expert		Quality Improvement and Patient Safety expert	Quality Improvement and patient safety expert	A member on the HQSC board and an internationally recognised quality improvement and patient safety expert. This stakeholder has been regularly involved with quality improvement projects and their insight into how medication safety could be measured was valuable.
Policymaker	SQUM chair or representative		SQUM chair or representative	The SQUM group was established by the District Health Board of NZ and reports to the DHB CEO (498). This group is charged with providing independent advice to the DHB's CEOs on any aspect to promote the safe and quality use of medicines (498). They are both the likely user of the data obtained from measurement but also the ones most likely to implement the measurement of medication safety. Their expertise and views on what is meaningful to be measured was important to elicit.
Expert		General practitioner expert	General practitioner expert	Studies suggest that many medication safety issues arise in the community (499) and many admissions into hospitals are due to medication issues (228). Getting a perspective on what a general practitioner would find meaningful if medication safety was measured was valuable.

Column A: Stakeholder category used in this research	Column B: Purposively chosen stakeholders	Column C: Snowball sampling chosen stakeholders	Column D: People actually interviewed	Comments and rationale for choice of stakeholder
Policymaker		Politician	Associate Minister of Health	Portfolio involvement with medication related policy and implementation. This particular member of parliament has been involved with several medication safety projects. They are likely to be a user of the data obtained from measurement so it was important to elicit this stakeholder's view on what was meaningful.
Policymaker		PHARMAC Medical Director or representative	PHARMAC Medical Director or representative	PHARMAC is charged with ensuring that the NZ public gain the best health outcomes with the resources available (261). It was important to elicit their views on how the monitor safety associated with medication use and what they would find meaningful for measurement.
Policymaker		PHARMAC expert or representative	PHARMAC expert or representative	See above.
Policymaker		PHARMAC CEO or representative	PHARMAC CEO or representative	See above.
Policymaker		ACC Minister or representative	ACC Minister or representative	ACC provides comprehensive, no-fault personal injury cover for all New Zealand residents and visitors to New Zealand (308). As such, they also provide injury cover related to harm associated with medication use. Eliciting their views on how they measure and monitor the significance of medication related harm and what they find meaningful was important.
Expert		Geriatric and general practice expert	Geriatric and general practice expert	The geriatric population group are at higher risk from medication errors and medication related harm and is an area of focus in many initiatives to improve medication safety (414, 500). Understanding geriatricians' views on what should be measured and what is meaningful for measuring medication safety was important.
Expert		Medication safety expert	Medication safety expert	Pharmacist by profession, this stakeholder has been involved in several national medication safety projects.
Policymaker	DHBNZ Chair or representative			Declined due to change of DHB NZ chair The CEO of each DHB is charged with the responsibility of their DHB. Each CEO is likely to be a user of the data obtained from medication safety measurement and the ones implementing measurement, their view on what they deem meaningful was important.

Column A: Stakeholder category used in this research	Column B: Purposively chosen stakeholders	Column C: Snowball sampling chosen stakeholders	Column D: People actually interviewed	Comments and rationale for choice of stakeholder
Policymaker	SMM Programme Lead or representative			Declined due to Safe Medication Management (SMM) programme undergoing restructuring. The SMM group is charged with overseeing the programme of selected medication safety interventions, aiming to reduce the number of New Zealanders harmed each year by medication errors across the health and disability sector (284). Their views on what should be measured and what they find meaningful was important.
Expert	NZ Medical Association chairman or representative			The stakeholder had passed away and no other stakeholder was available. The NZ Medical Association (NZMA) is the largest medical organisation in NZ aiming to provide leadership for the medical profession and promote the health of New Zealanders (501). Since, prescribers are mostly medical practitioners they may provide insight into what should be measured to monitor patient safety but also because they are the likely end-users of the data obtained from measurement but also the ones implementing the measurement of medication safety.
Expert		Medication safety expert		Declined due to time constraints, non-response or could not find an alternative representative. This stakeholder is a physician and is recognised as a medication safety expert having been involved with several medications safety initiatives and has published proficiently in this area.
Expert		Clinical pharmacologist expert		Declined due to time constraints, non-response or could not find an alternative representative. Please see clinical pharmacologist for reasons as to why selected.
Expert		Royal Australasian College of Physicians – Paediatric chair or representative		Declined due to time constraints, non-response or could not find an alternative representative. Children are at increased risk of medication related harm and so a stakeholder was initially selected to take part in our study.
Expert		Royal Australasian College of Physicians		Declined due to time constraints, non-response or could not find an alternative representative. Prescribers are mostly medical practitioners their involvement is vital to determine aspects of the medication management process which should be measured and how best to do this.

Column A: Stakeholder category used in this research	Column B: Purposively chosen stakeholders	Column C: Snowball sampling chosen stakeholders	Column D: People actually interviewed	Comments and rationale for choice of stakeholder
Expert		Psychiatry and mental health expert		Declined due to time constraints, non-response or could not find an alternative representative. Mental health and the medications used are often at high risk of medication related injury and so their advice and views were sought.
Expert		Psychiatrist expert		Declined due to time constraints, non-response or could not find an alternative representative.

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