Getting the foundations right for the measurement of medication safety: the need for a meaningful conceptual frame

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ABSTRACT

A number of initiatives aimed at improving medication safety in and across New Zealand public hospitals have been introduced over recent years. Clinicians, policymakers and patients now want to know whether patients are safer today from medicine use than they have been in the past. The challenge has been determining exactly what should be measured. In this viewpoint, we critically examine the suitability of adverse drug events (ADE) as a primary metric for assessing the progress of medication safety improvement. We provide an overview of contemporary dialogue on medication safety measurement and highlight the emergent challenges. Finally, we reflect on how New Zealand has approached medication safety measurement so far and argue the need for a multi-stakeholder informed conceptual framework with a view to further enhancing meaningful assessment of medication safety.

Research shows that patients admitted into New Zealand public hospitals are harmed by the medical care intended to help them.[1–7] Since the publication of the *New Zealand Quality in Healthcare Study* (NZQHS) a number of initiatives aimed at improving patient safety, in particular safety associated with medication use, have been introduced.[8,9] Clinicians, policymakers and patients now want to know whether patients are safer today than they have been in the past, and whether medication safety across hospitals has improved.[10–13] To track progress and inform improvement, the assessment of medication safety has mainly focused on detecting and measuring medication error and more recently, harm.[14,15]

In this article, we discuss important but commonly missed limitations of using medication-related harm as the primary metric for assessing progress around medication safety. We explore contemporary dialogue on medication safety measurement and the challenges involved with operationalising this construct. Finally, we outline our observations on local medication safety measurement activity and argue that a key practice and research gap has been the lack of a common understanding of medication safety by stakeholders and the absence of a framework for measurement. We propose that the way forward is to develop a locally agreed multi-stakeholder derived conceptual framework which can be used to guide and inform the meaningful measurement of medication safety across New Zealand public hospitals.

Preventable harm as a primary metric for assessing medication safety progress

A large proportion of iatrogenic harm (up to 38%) relates to medications.[16] Such injuries are known as adverse drug events (ADE). Most ADEs are expected to occur despite appropriate and error-free care because the use of medicines to derive benefit carries with it an intrinsic risk of injury.[17] Up to 47% of ADEs, however, could be prevented through the implementation

of safer medication practices, and it is this type of harm that national improvement programmes have tended to target.[16,18–21] A number of measurement techniques and indicators have been developed to assess the progress of medication safety, focusing on total ADEs or subsets thereof as the primary safety metric.[14,16,19,21–35]

If medication-related harm is the primary metric used to determine progress then has medication safety across hospitals improved? In New Zealand and countries such as the UK and the US, the answer is unknown. No national longitudinal studies have been conducted and no ADE reporting rate appears to exist.[36–38] Where large scale longitudinal studies have been conducted, for example in the Netherlands, preventable harm rates have remained relatively stable.[39,40] One possible interpretation is that national medication safety improvement programmes have been ineffective. Other interpretations, which are more likely in our view, are that ADEs as a primary metric are neither sensitive nor reliably measured enough to demonstrate progress, even if programmes are successful at making medication use safer for patients.

There are pragmatic, methodological and conceptual reasons why ADEs may not be suitable as a single primary metric for monitoring medication safety and progress over time. From a pragmatic perspective, because different types of ADEs are detected by different tools, the resource required to reliably and accurately measure changes over time is challenging to undertake in practice, on a regular basis.[25,27,28,41] From a methodological perspective, the relative rarity and heterogeneity in types of ADEs means that any single intervention may not affect the total harm rate in a significant enough manner for a change to be detected.[42–44] Advances in medical knowledge and technology can change how harm and the degree of preventability are classified, so rates may appear to be unchanged.[38,42–50] As the sensitivity of ADE detection techniques and surveillance systems improve, the rate of harm may appear to increase, which misrepresents the true state of affairs.

From a conceptual perspective, ADEs only represent the visible consequences of unsafe medicines use. In most instances, medication use can be erroneous and unsafe with no visible or consequential injury.[16,51] An acute and unexpected drug shortage which necessitates the use of alternative medications and strengths, for example, may mean that the potential for error and harm is higher today compared to yesterday.[52] The resulting change in the state of safety from moment to moment, however, will not be indicated by ADEs as a metric. If ADEs are solely used for monitoring, the apparent lack of safety present in a system may be invisible and go undetected. Furthermore, ADEs can only be measured after the fact so it can only provide an indication of how safe the medication system has been in the past but does not inform whether it is safe in the present, or likely to be in the future.

The measurement of ADEs is still an important facet of medication safety assessment because ADEs highlight the types and relative frequency of some safety problems that may occur. The major limitation of ADEs as a primary safety metric is that they only provide part of the overall picture in determining whether patients are safer now than they have historically been.[12,43,44,50,53,54]

Contemporary views on medication safety measurement and its challenges

There is a shift to widening how medication safety measurement should be thought about. In parallel with increasing knowledge on the factors associated with unsafe medication systems, and the characteristics which contribute to making them safer;[16,20,23,55–63] the scope of medication safety measurement has broadened (see Table 1 for an overview of existing medication safety measures and their foci).[55,64]

As can be seen from Table 1, assessment now includes, for example, determining whether safe practices are in place and working as expected. If they are, then one could assume that the likelihood of adverse outcomes would be reduced.[12,13,55,64] Reliable clinical systems and organisations which learn from, and respond to, safety incidents are other examples of the key characteristics thought to influence and contribute to safer hospitals.[75] And so, when such facets of medication safety are concurrently

Table 1: Existing medication safety assessment measures, tools and their foci.

Category of measure types	Description and focus of assessment (example)	Metric sets and tools examples
Structure based	Assess the attributes of the settings in which medicines use occurs. Can be related to:[65] **Material resources** (eg necessary equipment available? Adequate lighting in drug preparation room?); **Human resources** (eg adequate staffing?) and; **Organisational structures** (eg medicines governance group and systems in place and its robustness?)	Assessment frames (eg Medication safety-self assessment (MSSA) tool)[66,67] Hospital certification standards[68,69] Quality Safety marker[70]
Process based	Assesses the actions or steps of medicines use (eg % of patients initiated on warfarin who are counselled before discharge, administration error rates).	Indicator sets[24,32,71] Observation[72]
Outcome based	Determines the effects of medicine use on the health status of patients (eg harm, patient experience): focus has been on undesired consequences (ie ADEs) rather than effectiveness.	ADE detection (eg trigger tools, record review and others)[25,28,29]
Characteristics and principles based	Assesses medicines use related organisational traits, attitudes, mind-sets and behaviours of organisations and its members (eg safety culture, learning environment, reliability, resiliency, mindfulness).	Safety culture[73,74] May include other measures from above

measured and monitored over time, they provide a more holistic and balanced view of medication safety than harm rates alone could ever provide.

The increase in the number of assessment frames, measure sets and tools has not, however, been without its own challenges. It is now unclear exactly which assessment frame or set of metrics should be used to measure medication safety in its entirety. Even though some overlap exists between assessment frames and metrics, there are differences between them, and research has not been undertaken to determine whether one is superior to another, and if so, on what grounds.

A single conceptual frame which synthesises the breadth of scientific knowledge on what constitutes a safe medication system is needed in order to provide a coherent, balanced and cohesive structure for organising and informing subsequent medication safety measurement.[12,13,76–80] The process of canvassing stakeholders' preferences then incorporating them within the developed framework increases the likelihood of the data obtained being meaningful[81–83] and used.[87,84–89] Standardised and longitudinal measurement and monitoring based on the elements incorporated within the framework can then be used to ascertain whether medication safety has improved or not, across a broad range of facets.

Observations on the New Zealand approach to assessment and a way forward

A review of New Zealand research and practice suggests that, similar to the international literature, ADEs have been focused upon as the primary metric for monitoring medication safety.[1–7] Reports commissioned by the Health Quality and Safety Commission (HQSC) to measure and evaluate the national medication safety programme, for example, have focused on tools designed to measure harm.[38,90,91] These efforts should be congratulated and continued because enhanced detection of ADEs and standardised national taxonomies to classify identified harm can help New Zealand better understand the types of medication related problems that occur in hospitals.

In this viewpoint we have argued that to more holistically measure and monitor medication safety, there is a need to expand beyond ADEs as the primary metric. This change in thinking appears to have been reflected in recent measurement related activity in New Zealand. The HQSC, for example, have proposed a quality safety marker (QSM) relating to whether electronic medicines reconciliation (eMR) has been implemented.[70] Because eMR is a process which may help reduce the risk of harm from errors resulting from unintended medication discrepancies, its implementation may suggest safer hospital practices.[92,93] More comprehensive assessment, which includes medicines reconciliation but importantly extends to other medication safety considerations, have also recently been trialled at a district health board (DHB).[22]

The acknowledgement for the need to broaden the scope of medication safety measurement and monitoring in New Zealand and the beginning of efforts is heartening. The absence of a single conceptual framework for measurement which establishes a common understanding of medication safety among its stakeholders, however, is sub-optimal. There is certainly no shortage of measures and tools which can be used to help assess medication safety, but until there is a locally agreed conceptual framework to guide medication safety measurement and monitoring, New Zealand faces the possibility of piecemeal, *ad hoc*, inconsistent and unreliable medication safety measurement, which can mean that results cannot easily be summated into anything useful.

Proposed approach to developing a conceptual framework

A multi-stakeholder informed conceptual framework for measurement is the most appropriate route to take when making sense of what is important to include.[94] We propose the development of a locally agreed multi-stakeholder derived conceptual framework which can be used to guide and inform the meaningful measurement of medication safety across New Zealand public hospitals. This needs to be founded on what key stakeholders value and find meaningful.

The relevant stakeholders for medication safety measurement include three key groups. Firstly, government and local management bodies who make policy and funding decisions. Secondly, clinicians, researchers and managers who have expert knowledge of the medication process and are likely to be involved in advocating for and implementing the framework as well as subsequent changes to practice. Thirdly are the consumers, patients and family members who are the service end-users and the ones most impacted by system change. Engagement of relevant stakeholders at the outset would not only increase the face validity of the conceptual framework but would also increase the likelihood of its use in practice settings.[95]

Final thoughts

Contemporary research suggests that in order to comprehensively and holistically assess whether medication safety has improved, it is no longer enough to measure the occurrence of harm. We believe the development of a conceptual framework for medication safety measurement informed by input from multiple stakeholder groupings provides a platform to begin developing the right metrics in order to conduct longitudinal studies and determine whether systems are safer over time. Until there is a clear understanding of what it means to be "safe" in this context it will not be possible to measure it. The development of a multi-stakeholder informed conceptual framework is expected to provide a meaningful, clear and comprehensive approach to progressing the sound measurement of medication safety.

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