Prepared for the Health Quality and Safety Commission

Medication safety programme: measurement and evaluation

Report A: A framework for the measurement of medication-related harm

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sapere research group

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1. Purpose of this report

This project has been undertaken by Sapere Research Group, the National Institute for Health Innovation (NIHI) and the Centre for Health Systems in the Department of Preventative and Social Medicine at the University of Otago.

This report is one of a suite of papers that comprise our deliverables in relation to the measurement of medication-related harm and the evaluation of the electronic medication management (eMM) Programme. This report:

- Presents a framework for the measurement of medication-related harm
- Explains the approach we took to testing the application of this framework, using data from existing data collection systems, and provides the results of this analysis,
- Sets out the practical implications of implementing this framework.

The content of the other reports is set out in Table 1, below.

Table 1 Project deliverables

Report title	Content
Summary report	• Overview of the project approach – Project process • Key findings and recommendations
Report A: A framework for measuring medication-related harm (this report)	• A framework for the measurement of medication-related harm • Testing the framework – Methodology – Results from data analysis in 4 DHB sites • Implications for implementing the framework
Report B: Evaluating eMM	• Defining the eMM Programme • Exploring eMM system design and implementation – Findings from two rounds of site visits • Measuring systems design – Evaluating eMM

2. Our approach

We have based our framework on a review of the literature, including an examination of measurement approaches in other jurisdictions. We tested our conceptual framework with a selection of experts, and refined it to incorporate their feedback. The resulting framework is set out in section 4.

We then sought to trial the application of this framework. We developed an approach for data collection and analysis that uses existing systems for capturing medication-related data. The methodology we employed to do this, and the results we generated, are explained in section 5.

3. What we know about medication-related harm

A number of studies have shown that adverse drug events (ADEs) in hospitals are a common cause of harm to hospitalised patients.[1] This is because drugs are the single most common medical intervention[2]. Similarly, the largest source of errors involves medications, but the significant majority of these errors do not result in harm to the patient (Resar et al, 2003).

Medication errors can occur throughout the medication process. Data from the National Patient Safety Agency's Reporting and Learning System in the UK shows that nearly half of medication incidents (across all care settings including primary) occur with the administration or supply of medicine to a patient.[3]

Some studies have shown that many potential ADEs are due to errors taking a medication history.[4,5,6] Studies report that 10-67 per cent of patients have at least one prescription medication history error. When information regarding drug allergies or prior adverse drug reactions was added the frequency was 34-95 per cent of patients with at least 1 error (Tam et al, 2006, p.511).

Points of patient transition between providers (transfer from primary to secondary care, between services or wards, or discharge to the community) are areas at particular risk of miscommunication of unintended changes to medication.[7]

The focus of the international literature tends to be on hospitalised patients.[8] However, hospital patients represent only a fraction of the total population at risk of experiencing a

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1 For example David W. Bates et al (1995) 'Incidence of adverse drug events and potential adverse drug events: implications for prevention', *JAMA*, Jul5 5 1995, Vol.274, No. 1; LL Leape et al (1991) 'The nature of adverse events in hospitalized patients: results from the Harvard Medical Practice Study II, *N. Engl. J Med*, 1991: 324; Ugochi Nwulu et al (2012) 'Improvement in the detection of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools', *Eur J Clin Pharmacol* (2013) 69:255 .

2 R. K. Resar et al (2003) 'Methodology and rationale for the measurement of harm with trigger tools', *Qual Saf Health Care* 2003:12 (39-45), p.40.

3 National Patient Safety Agency (2007) *Safety in doses: improving the use of medicines in the NHS*. Lessons from national reporting 2007 (NHS), p.12.

4 J Pippins *et al.* (2008) Classifying and predicting errors of inpatient medication reconciliation, *Journal of General Internal Medicine,* vol.23, no.9, p.1414-1422.

5 P Cornish *et al* (2005) Unintended medication discrepancies at the time of hospital admission, *Archives of Internal Medicine,* vol.165, p.424-429.

6 J Schnipper *et al* (2009) Effect of an electronic medication reconciliation application and process redesign on potential adverse drug events: A cluster-randomised trial, *Archives of Internal Medicine,* vol.169, no.8, p.771-780.

7 *DHB hospital electronic medication management*. Business case considered by the Medication Safety Governance Group and the HQSC Board in December 2011.

8 Kohn, l., Corrigan, J., Donaldson, M (eds.) (2000) *To err is human: Building a safer health system,* National Academy Press, Washington D.C.

medication error. Numerous primary care studies document errors in prescribing medications[9,10] and dispensing by pharmacists.[11]

Estimates of the rate of ADEs vary widely. One review of overseas studies found estimates ranging of 1.5% to 35% for hospitalised patients, depending on the methodology used in each study (Bates et al, 1995).

A 2001 New Zealand study involved a two stage retrospective review of 6,579 medical records and determined that adverse events were associated with 12.9% of public hospital admissions. Taking into account those events originating outside the hospital setting (in an ambulatory or community setting), and preventability, then the rate of preventable, in-hospital adverse events would be around 6.3%.[12] (Davis et al, 2001, p.60). Adverse drug reactions comprised 13.3% of total adverse events and 4.2% of total preventable in-hospital adverse events recorded (Davis *et al*, p.41).

According to an extrapolation of these results, around 2% of hospital admissions in New Zealand each year (12,500 people) are subject to medication error.[13] Of those subject to a medication error, about 390 result in death, over 1,000 in permanent disabilities, and about 10,500 in short-term disabilities. Approximately 35% of adverse events were classified as highly preventable. Patient age was an important risk factor for an adverse event. Nearly a fifth of events originated from outside public hospitals, only a quarter of which arose in another institutional context. There were distinct patterns according to clinical and administrative context.

The 2011eMM business case[14] stated that around 4.8% of admissions experience an ADE, of which 27% are preventable and 39% of which can be attributed to prescribing error. This figure was based on New Zealand and overseas literature. A 2011 NZIER cost benefit analysis used a central estimate of 0.5% preventable ADEs per admission, based on research by ScHARR (2007).[15]

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9 Hallas, J., Haghfelt, T., Gram, L., et al (1990) Drug related admissions to a cardiology department: Frequency and avoidability, *Journal of International Medicine,* vol.228, p.379-384.

10 Willcox, S., Himmelstein, D., Woolhandler, S (1994) Inappropriate drug prescribing for the community dwelling elderly, *Journal of the American Medical Association,* vol.272, p.292.

11 Murray, M., Ritchey, M., Wu, J and Tu, W (2009) Effect of a pharmacist on adverse drug events and medication errors in outpatients with cardiovascular disease, *Archives of International Medicine,* vol. 169, no.8, p.757-763.

12 P Davis *et al* (2001) *Adverse events in New Zealand public hospitals: Principal findings from a national survey*, Ministry of Health, Wellington, p.60.

13 B Anderson (2012) *Improving medication safety: Bedside verification,* p.10.

14 *DHB hospital electronic medication management*. Business case as a complement to the Cost Benefit Analysis report by NZIER December 2011.

15 The University of Sheffield, Health and Related Research (ScHARR) (2007) *A systematic review of the effectiveness and cost-effectiveness of interventions aimed at preventing medication error (medicines reconciliation) at hospital admission*. National Institute for Health and Clinical Excellence.

A more recent New Zealand study using the ADE Trigger Tool found an average rate of ADEs of 28.9% of admissions and 38/1,000 bed days. 94.5% of identified ADEs were in the lower severity scales with temporary harm.[16]

Kuna et al (2009) examined the incidence, preventability and seriousness of ADEs and potential ADEs in the paediatric inpatient setting in Dunedin hospital. They found an overall rate of 12.9 ADEs per 100 admissions and 22.1 per 1,000 patient-days. At a higher risk were those patients in the neonatal intensive care unit and surgical ward. 46% of the ADEs had serious consequences for the patient and of these 15% were life threatening or deemed to result in persistent disability.[17]

There are other academic articles that consider narrower components of the medication process. In a survey of anaesthesiologists in New Zealand, 89% of the 66 respondents reported at least one error of drug administration and 12.5% had actually harmed patients.[18] Another study found an overall incidence of drug administration error of 0.75%, based upon self-reporting.[19]

16 Mary E. Seddon et al (2013) 'The adverse drug event collaborative: a joint venture to measure medication-related harm', *NZMJ* 25 January 2013, Vol.126, No.1368.

17 DL Kunac et al (2009) 'Incidence, preventability, and impact of Adverse Drug Events (ADEs) and potential ADEs in hospitalized children in New Zealand: a prospective observational cohort study', *Paediatr Drugs* 2009: 11 (2).

18 Merry, A and Peck, D (1995) Anaesthetists, errors in drug administration and the law, *New Zealand Medical Journal*, vol.24, p.185-187.

19 Webster, C., Merry, A., Larsson, L et al (2001) The frequency and nature of drug administration error during anaesthesia, *Anaesthesia and Intensive Care*, vol.29, p.494-500.

4. A framework for measuring medication-related harm

4.1 Defining medication-related harm

There is a variety of terms and definitions relating to harm from medicines available in the literature.

The traditional stages of the medication management cycle are: prescribing, dispensing, administration and monitoring. We have adapted this traditional cycle to separate out medication history-taking – this is usually considered part of the prescribing stage but we have included it separately given that medication history-taking is part of medicines reconciliation (a focus of the eMM programme).

We have also included a separate stage for supply and delivery. Supply refers to the purchasing and supply of a medicine (e.g. by the hospital or community pharmacy). Delivery relates to the steps of delivering the medicine to the patient – e.g. to the correct hospital ward or department, or the patient's home address in the community.

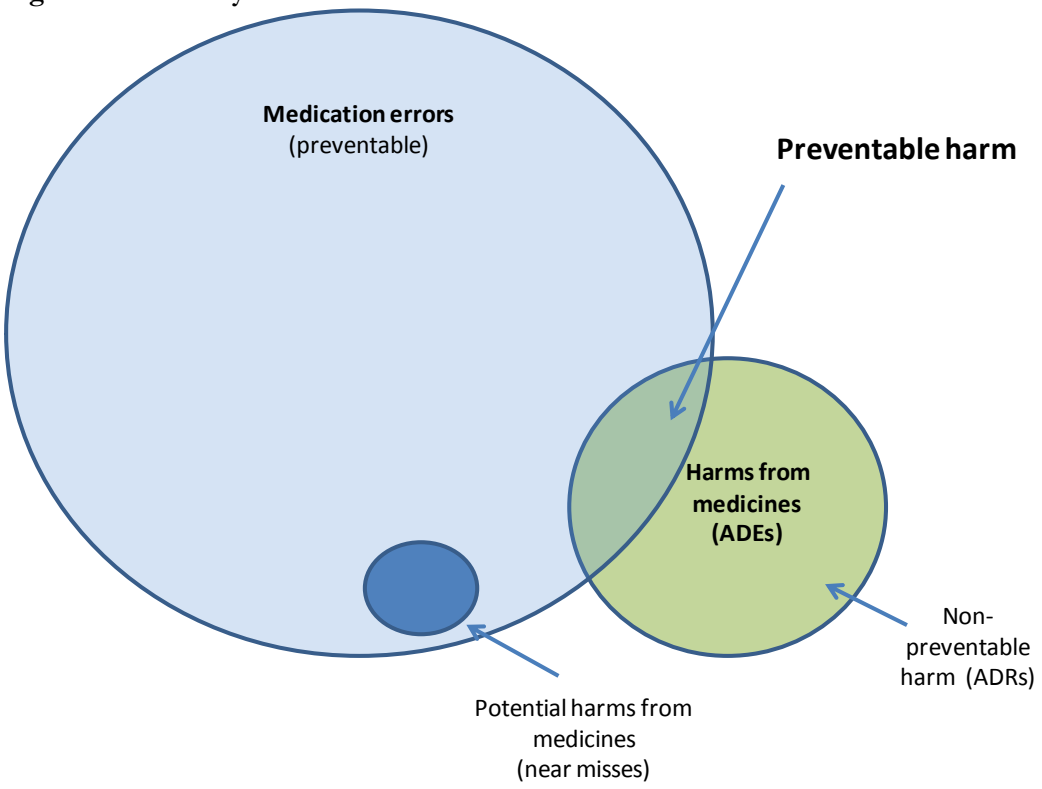
These adaptations give us the following stages of medication management:

1. Medication history-taking
2. Prescribing/ordering (includes documenting)
3. Dispensing
4. Supply and delivery
5. Administering (to the patient), and
6. Monitoring of medicines.

Underpinning all of these stages is communication of the medicines information, whether this is written or verbal.

The following taxonomy diagram is taken from the UK National Health Service's National Patient Safety Agency, which is based on definitions by Bates *et al* (1995).

Figure 1 Taxonomy of medication-related harm



Source: National Patient Safety Agency, National Reporting and Learning Service (2007) *Safety in doses: improving the use of medicines in the NHS* (NHS: UK).

Medication error

Medication error is defined as:

> *…any incident where there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing medicines advice, regardless of whether any harm occurred or was possible. This is a broad definition and most errors results in no or low harm.*[20]

Harm from medicines

Adverse Drug Events

Bates *et al* use the term Adverse Drug Event (ADE) to refer to 'an injury resulting from medical intervention relating to a drug'. By this definition, ADEs can be preventable or non-

[20] National Patient Safety Agency, National Reporting and Learning Service (2009) *Safety in doses: improving the use of medicines in the NHS* (NHS: UK), p.6; David W. Bates *et al* (1995) 'Incidence of adverse drug events and potential adverse drug events: implications for prevention' *JAMA*, July 5 1995, vol.274 No. 1 (pp.29-34).

preventable, distinguished by whether or not an error took place. *This is represented by the green circle in the above diagram 'harm from medicines'.*

Preventable harms from medicines

When harm arises due to an error, these are preventable ADEs i.e. the harm they caused can be minimised or eliminated. For example, when a medicine is prescribed to a patient who has a known allergy to that medicine (NHS: 2007, p.6). *This is shown by the overlap between errors and harm in the diagram.*

Adverse Drug Reactions

This is distinguished from harms that have arisen despite the patient being given the correct care. This is known as an Adverse Drug Reaction (ADR), which is a response to a drug that is 'noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function. [21] *This is the area of the green circle that does not overlap with errors.*

Events that may be classified as ADRs today may become preventable in the future, e.g. through more sophisticated dosing or monitoring methods. Vincent *et al* (2013) refer to the 'expanding perimeter of safety', as over time more types of incidents and harm (which were previously considered to be inevitable consequences of medical intervention) come to be regarded as unacceptable and potentially preventable.[22]

Potential harm from medicines

A potential harm is defined as a medication error that has the potential for causing patient injury or harm. These are often referred to as 'near misses'. An example of a potential harm is the administration of a medicine to a patient who has a known allergy in which the patient does not experience an allergic reaction.[23] It also includes potential harms arising from errors that are intercepted before they reached the patient. *This is illustrated by the dark blue circle within the errors circle.*

4.2 Measuring medication-related harm

4.2.1 Errors and harm

Much of the international literature focuses on measuring errors rather than harm. This is partly because of the difficulties of robustly measuring harm. But from a quality improvement perspective, we advocate a focus on seeking to measure harm. This focus is supported by Resar et al (2003) who suggest that the advantages of this approach are that:

- It is patient-centered.

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21 WHO (1972) 'International drug monitoring: the role of national centres'. *Tech Rep Ser WHO* 1972, No.498.

22 Charles Vincent et al (2013) *The measurement and monitoring of safety* (The Health Foundation: London, UK), p.3.

23 Bates, D., Boyle, D., Vander Vliet, M., et al (1995) Relationship between medication errors and adverse drug events, *Journal of General Internal Medicine*, vol.10, pp.199–205

- It can target the system rather than the individual, with the aim of enhancing clinical outcomes.
- It reduces punitive concerns associated with the reporting methodology and thereby fosters greater (reporting) compliance. This is consistent with a patient-centered approach, focusing on an environment of continuous improvement rather than the punishment of individuals.
- It allows analysis of unintended results (that occur despite operational compliance) and encourages learning from events to continually improve the process.

The measurement of harm should be supplemented with the measurement of contributing factors, to enable the identification of areas where there may be systemic problems, and where root cause analysis may inform quality improvement efforts. Our framework therefore focuses on harm, but also seeks to link errors with harm. The following chapter describes how we trialled this approach with data from four DHBs sites.

4.2.2 A focus on preventable harm

We recognise there is opinion that the distinction between preventable and non-preventable harm is not necessary, as from the patient's perspective it is only the fact that they have been harmed that is important. We also note that preventability is a subjective assessment, and in practice is limited by the quality of data (both by what is available from current reporting systems, and variations in how information is entered and coded – recognising that assessing preventability is not a feature at present).

However, from a quality improvement perspective, we believe it is important to know whether the harm could have been prevented or minimised (and what were the contributing factors), in order to guide the focus and design of quality improvement investment. We are therefore of the view that the measurement of preventable harm is the ideal. In section 5 we discuss the features of the current data sets in terms of what they can and can't tell us about medication-related harm, and in section 6 we outline the changes that would need to occur in order to work towards this ideal.

4.2.3 The framework

With respect to the classification of medication-related harm, we recommend measurement of the following dimensions:

- Severity of harm
- Stage in the medication process
- Classifying harm according to the 5 rights, and
- Medicine name.

These dimensions are set out in Table 2, below. This is broadly consistent with that used by the National Patient Safety Agency in the UK (NHS: 2007). Some important distinctions can be made between their report and ours:

- The UK's National Reporting and Learning Service reporting framework spans all health care settings (including community and ambulance) so at this stage results are not comparable with those from our analysis.

- The UK approach relies on a voluntary reporting system, which has been nationally standardised. The data analysis we have done to trial our framework has used retrospective data from a range of existing data sources, and linked these together. Our methodology for undertaking this analysis is explained in chapter 5.
- The UK reports in whole numbers, rather than using a denominator (such as rates per admission or per bed day), and as such is more of a thematic analysis (it does not present baselines or change). They also have a large sample size and in this regard their results may be considered more robust.

Table 2 A framework for measuring medication-related harm

System-level indicator (harm)		
Preventable ADEs		
Contributing factors and patient outcomes		
Severity of harm	Stage in the medication process	Error type (5 rights)
Death Severe harm Moderate harm Mild harm No harm 3 No harm 2 No harm 1 No specific patient involved Unspecified	Delivery Supply Medication history-taking Prescribing/ordering Dispensing Administration Monitoring Unspecified	Dose (includes strength, commission and omission) Medicine Patient Route Time Unspecified
Medicine name		

Notes: We have included categories for 'unspecified' to account for instances where there is insufficient information to code an entry.

Classifying the severity of harm

We have considered two options for classifying the severity of harm: the World Health Organisation's International Classification for Patient Safety system for categorising patient outcomes (WHO ICPS) and the National Coordination Council for Medication Error Reporting and Prevention (NCC MERP) system.

There are arguments in favour of either system. Using the WHO system would enable international comparison and can be applied to all patient safety events (not just medication-related). However the WHO definitions have not yet been finalised and may yet change. The two systems can be mapped against each other, which means that results can be converted to enable international comparisons.

The New Zealand Pharmacovigilance Centre uses a modified version of the WHO ICPS, which can also be mapped to NCC MERP. The mapping of these systems is set out in the following table.

Table 3 Mapping the WHO ICPS to the MERP index categories

Patient outcome description	NZPhvC MERP	WHO ICPS	NCC MERP
An unsafe situation that has the potential for error	N/A	No specific patient involved	A
Error was intercepted and did not reach the patient	No harm	No harm 1	B
Error reached the patient but did not cause harm		No harm 2	C
Error reached the patient and resulted in the need for additional monitoring or tests but no harm		No harm 3	D
Symptoms were mild, temporary and short-term; no treatment or minor treatment was required	Mild harm	Mild harm	E
Symptoms required additional treatment or operation; event caused hospital admission or prolonged hospital stay	Moderate harm	Moderate harm	F
Symptoms required major treatment to save patient's life or caused major permanent or long-term harm	Severe harm	Severe harm	G, H
There is reason to believe that the event caused the patient's death or hastened the patient's death	Death	Death	I

Source: New Zealand Pharmacovigilance Centre (2012).

Classifying by the 5 rights

There are a variety of more granular classification systems for type of error than the one presented in Table 2. For example, the NCC MERP coding system includes:

- Incorrect dose
  - Resulting in overdosage
  - Resulting in underdosage
- Incorrect strength/concentration
- Incorrect drug
- Incorrect dosage form
- Incorrect medication administration technique
- Incorrect patient
- Drug therapy monitoring problem

  - Drug-drug interaction
  - Documented allergy
  - Drug-disease interaction
  - Clinical (e.g. blood pressure)
- Deteriorated drug

And the classification system used in the UK (referred to above) includes omitted medicine/ingredient, wrong medicine, wrong formulation and wrong method of preparation/supply.

We think that it could be useful to collect more detailed information for the purposes of root cause analysis and quality improvement – i.e. to code to more granular categories if possible, and then potentially aggregate up for reporting/general communication purposes. But to us, there appears to be some overlap between some of these error types and the medication stage components of our framework (e.g. some appear to relate to medication history-taking). We have opted for a framework that separates out the information components.

4.2.4 How to measure?

There is no accepted 'gold standard' for measuring harm. Traditional methods include retrospective or concurrent review of charts or records, incident reporting, and observational data. Trigger Tools involve review of a random selection of charts using a predetermined list of specified 'triggers' that are associated with ADEs. The Trigger Tool methodology is discussed in more detail in Appendix 1

The following table summarises the range of potential methodologies for measuring medication-related harm, and their relative advantages and limitations. We note that a number of these systems are not specifically designed to measure harm.

Table 4 A range of potential methodologies for measuring medication-related harm in the hospital setting

Method	Advantages and features	Limitations
Systematic record review		
Record review	Can capture harm as well as errors	More resource intensive than chart reviews Can suffer from variability between reviewers, and lack of consistency in identifying events and classifying harm Hampered by incomplete or poor entries Would need to develop bespoke methodology
Chart review/audit	Detects more events than incident report reviews Good at detecting moderate drug-related problems (cf severe) compared to other methods NZ methodology available, as well as guidance and support	More labour intensive and expensive than incident report review and trigger tools Can suffer from variability between reviewers Hampered by incomplete or poor entries Detects errors cf harm
Trigger Tools	Generally more time efficient and effective than other methods The ADE Trigger Tool is specific to medication-related events and less time intensive than the Global Trigger Tool Provides a standardised measure, useful for longitudinal study NZ methodology available, as well as guidance and support	Not strictly a measurement tool, but identifies triggers for further investigation Capture a smaller range of events than retrospective records review Is used on random samples of charts, so is not expected to capture all ADEs and may miss some major harms Likely to have high start-up costs Usefulness dependent on design Lack of control ward/s would limit robustness of findings Does not detail the harm to the patient – this must still be collected manually from patient notes; and does not distinguish between preventable and non-preventable harm

Method	Advantages and features	Limitations
Reporting systems		
Incident report reviews • Voluntary incident reporting • Sentinel event reporting	Commonly used method Cited as best method for identifying high severity drug-related problems and is most specific (fewer false positives) Can be used to identify unintended effects of new system e.g. introduction of new errors, which are then followed up by evaluators to determine root cause Comparatively less resource intensive	Biased by voluntary reporting and significantly underestimates events
Safety indicators from existing data sources		
Pharmacy intervention database	Electronic system by which pharmacists report any interaction they have with the medication process in the hospital, including the observation of medication incidents, corrections to prescribing and administration, and training of staff or patients Includes recording of medication errors and harms where individuals deem it appropriate	Dependent on individual pharmacists, and hospital processes and policy
ICD-10 coding of hospital discharge data • Code subset Y40-Y59 codes for 'Drugs, medicaments and biological substances causing adverse effects in therapeutic use'	Electronic record of diagnosis, procedure and external cause narratives of discharge data is routinely coded to the ICD-10 coding system (International Classification of Diseases – version 10) Is submitted to the Ministry of Health for their National Minimum Dataset Uses an international coding system Undertaken on all patients admitted to hospital, in all public hospitals	Only captures events linked with morbidity, and where there is a positive connection documented between medication and the morbidity Dependent on clinician and hospital coder recording and coding an adverse reaction Does not detail the harm to the patient – this must be collected manually from patient notes

Method	Advantages and features	Limitations
	Captures every ADE that has been clearly described in a patient's notes, so is suitable for pre- and post- comparison	
Prospective analysis		
Direct observation	Detects up to 400 times more drug-related problems compared to incident report review, trigger tools or chart reviews, but may be ineffective in identifying or quantifying harm	Resource intensive
Qualitative analysis		
Semi-structured interviews	Can elicit more in-depth/richer information than from a survey	More time consuming than a survey, both to undertake interviews/focus groups and then to transcribe, code and interpret information
Staff survey	Can achieve larger sample size/wider reach Can be undertaken at relatively low cost via tool such as SurveyMonkey, and quicker to record and code results Easy to reproduce/repeat	Lacks richness of information Need to consider participation rate

Source: Taxonomy adapted from Charles Vincent *et al* (2013) *The measurement and monitoring of safety* (The Health Foundation: London, UK).

5. Testing our measurement framework

5.1 Introduction

5.1.1 A change in approach

Our initial methodology, that was agreed with HQSC, envisaged data collection/extraction being undertaken by the DHBs, and was expected to involve manual auditing of patient charts, as well as extraction of administrative data.

We prepared a draft evaluation framework and indicator set based on previous evaluations, on which we received feedback from the governance group, EAG, DHB sites and HQSC Board and staff.

General concerns were expressed regarding the practical ability to measure a number of these indicators, and the resource implications for DHBs to collect and extract the data. Questions were also raised as to the number and relevance of some the eMM process and outcomes measures. In addition, we identified practical issues with robustly measuring the safety improvements (reduction in harm) delivered by the eMM initiatives (lack of a robust baseline, and the problem of robustly measuring change with small numbers).

In response to these concerns, we developed a revised framework (as presented above) and an approach for data collection and analysis that uses existing systems for capturing medication-related data.

This exercise has involved trialing our proposed framework by using the types of data that can readily be extracted from existing data sources. We did this by seeking to:

- Establish the level/rate of medication-related harm, in particular preventable harm, that can be determined from existing data sources (i.e. how much harm do these systems detect).
- Estimate the completeness of the level of harm that these existing systems detected (i.e. how much harm is not captured by these data systems).
- Analyse the pattern/type of errors associated with the harms detected. To the extent that post-intervention data were captured in our analysis, we sought to explore whether the introduction of eMM initiatives changed the pattern of errors or the pattern of harm, including whether new errors were introduced.

5.1.2 Challenges obtaining data

We encountered challenges in obtaining information on what exits in terms of data sources at the sites, and then in obtaining data from these systems. Altogether, the process of obtaining the data that are reported on here took us around nine months and around 120-240 hours of consultant time.

5.2 Methodology

5.2.1 Data collected from the 4 sites

We sought to cast a wide net across the existing hospital data collections, in order to identify the full range of systems that may capture information on medication-related harm.

We made initial contact with a representative at each of the four sites implementing eMM initiatives: Southern, Taranaki, Counties Manukau and Waitemata. We requested descriptions of any available systems or studies that record medication incident data (including medication error and ADEs) collected in their hospital. This initial general request included the descriptions of the collections, fields and additional documentation about collection processes and data quality. From there, we were able to liaise with specialist staff (with responsibility for particular data collections) and issue more specific data requests.

A number of similar systems that included information on either medication error and/or ADEs were identified:

1. Pharmacy intervention reporting
2. Hospital incident reporting (voluntary reporting/serious and sentinel events reporting systems)
3. ICD-10 Y40-Y59 coded hospital discharge data
4. ADE Trigger Tool or Global Trigger Tool case reviews.

In the following discussion, we collectively refer to the first three data sources as 'administrative data'. There is also eMR reporting (incorporated into pharmacy intervention reporting in some DHBs).

Our data requests to these DHBs sought the extracts from these data sources/systems with raw NHI for the period 1 January 2010 to 31 December 2012, and any fields that describe:

- Date of event
- Hospital ward
- Patient age
- Patient sex
- Medicine
- Dose
- Stage of medication process
- Type of error (5 rights - route, dose, time, drug, person)
- Description of error
- Indication of error/harm
- Indication of near miss of error/harm
- Indication of severity of harm.

The data we received are summarised in the following table.

Table 5 Hospital throughput and data received, by collection and time period

System	Counties Manukau (Middlemore)	Waitemata (North Shore/Waitakere)	Southern (Dunedin)	Taranaki (Taranaki Base)
Public hospital discharges	275,572	286,003	111,982	54,339
Bed days	805,984	723,428	350,126	153,353
Incident reporting	3 years	3 years	3 years	2 years 4 months
Pharmacy intervention reporting	2 years	3 years	3 years	2 years 4 months
ICD-10 coded discharge data	3 years	3 years	3 years 3 months	2 years 4 months
ADE TT / Global TT reviews	No data provided	336 admissions / 52 weeks GTT study undertaken by Waitemata DHB for other purpose	175 admissions / 35 weeks Study undertaken by Southern DHB pharmacists for project and funded by HQSC	203 admissions / 41 weeks Study undertaken by Taranaki DHB pharmacists for their own evaluation

Source: As provided by the four DHB sites and obtained from the Ministry of Health's National Minimum Dataset

5.2.2 Data storage protocols implemented

Ethical and privacy concerns were raised by three of the sites from whom we requested data. In response to this, we reviewed the current Health and Disability Ethics Committee (HDEC) guidelines, which suggested that the privacy concerns were an issue to be resolved at the individual site level, rather than the province of HDEC. We consulted with a regional ethics committee representative – while this discussion was not conclusive, it supported our interpretation that referral of the matter to the HDEC for review and approval was not appropriate.

In these three sites, we agreed a protocol for the collection and storage of data. In one of these cases, the discussion was facilitated by a representative of the Privacy Commissioner, who modified the protocol to their and the DHB's legal representative's requirements. Both protocols were very similar and followed the outline below:

- The data will be stored on a secure, encrypted, password-protected drive and will only be accessible to Sapere analysts.

- NHI numbers on data will be deleted and replaced with an internal identifier once duplicates have been resolved and data is ready for analysis
- Any staff member accessing this data has signed the Sapere Research Group confidentiality agreement as well as being bound by the HQSC contract overseeing this project. A list of personnel and/or roles with access to the information is below.
- The data, either identifying or otherwise, will not be disclosed to a third party except in aggregate form in dissemination of themes and trends across the suite of data sources reviewed. The ultimate aim being to profile medication related errors, assess any duplication across datasets and attempt to identify levels of identified harm.
- The results of this work will be presented in such a way that individuals cannot be identified nor can information be identified as belonging to any individual.
- All copies of the data held by Sapere will be deleted following acceptance of the final project deliverable by HQSC.

We also arranged for data to be able to be transmitted without email, via a direct connection and download onto a secure server.

5.2.3 Step 1: Linking the data sets

In order to avoid double counting, and to identify in which systems events are detected, we undertook the following process to match up events across the first three data sets that related to the same patient:

1. Using an Excel spreadsheet, line up all the data supplied by NHI, date of event, ward and drug by columns.
2. Sort the data by NHI and date of event so that all events for the same patient are grouped together in date order.
3. Work through the file line by line checking whether one data source has provided an error or harm that is also present in another data source.
4. If there are duplicate events, we flagged in an additional field the row that should be excluded from analysis.

Table 6, below, which provides a hypothetical illustrative of this process across seven events and three patients. It shows that some of the events involve the same patient, on the same day and ward, but were due to separate errors. The circled events were linked together as capturing the same event, so were assigned the same identifier (5). The preceding four events were not linked together as they represented separate events.

Table 6 Illustration of data linking
For illustrative purposes only – not real data

NHI	Source	Date	Ward	Description	ID
XXX1234	Pharmacy Intervention	3 Dec 2011	1	Incorrect dose charted and corrected	1
XXX1234	Incident Reporting	3 Dec 2011	1	3 hour delay in patient receiving dose	2
XXX1234	ICD10 Y coded	5 Dec 2011	1	Allergic reaction to therapeutic analgesics	3
YYY8888	Incident Reporting	27 Dec 2011	4	Charted but omitted dose with monitoring of patient	4
ZZZ9999	Pharmacy Intervention	1 Jan 2012	8	Drug charted to wrong patient	5
ZZZ9999	ADE TT	1 Jan 2012	8	Medication related allergic reaction	5
ZZZ9999	ICD10 Y coded	1 Jan 2012	8	Allergic reaction to therapeutic opioids	5

Source: Sapere analysis

5.2.4 Step 2: Coding the data

Once the data had been linked in this way, we sought to code the data by:

- Stage in the medication process
- 5 rights
- Severity of harm
- Near-miss
- Preventability, and
- Whether there was an intervention in operation at the time of the event (eMR or ePA).

This was a manual process, in many cases requiring interpretation of the information provided in free text fields.

Table 7, below illustrates this coding process across six events where only simple partial data were available. It shows the difficulty involved in coding the stage, right and severity for events with incomplete or partial data. The first column presents a description of the event and the last three columns describe the outcome of the coding process. What is presented here assumes no other information is available but in some cases one or other of the variables is coded on the data system already.

An important point to note in the coding of this type of descriptive data is that without expert knowledge, in many cases coding even simple descriptions of medication error events accurately and consistently is time consuming at best and in really complex cases impossible for someone with rudimentary knowledge.

Table 7 Illustration of data coding
For illustrative purposes only – not real data

Available Description	Coded Stage	Coded Right	Coded Severity
Cylosporin causing rash	Unknown	Unknown	Harm but severity unknown
Misread medication chart and administered patient 3 times dose for two days	Administration	Dose	Unknown
Patient charted IV drug / change to IP	Prescribing	Route	Unknown
Patient charted drug 750mg IV tds only give twice yesterday	Administration	Dose	Unknown
Medication error with allergic reaction	Unknown	Unknown	Harm but severity unknown
Patient getting 600mcg salbutamol up to 15 times daily. Dose changed to 200mcg.	Unknown	Dose	Unknown

Source: Sapere analysis

5.2.5 Step 3: Linking to the trigger tool data

We then undertook a further linking exercise, matching the ADEs from the three data sources to the trigger tool data, for the three sites for which this was provided. We did this in order to estimate the proportion of ADEs detected by the trigger tool that were also identified by the administrative data. As a by-product this allowed us to indirectly estimate the proportion of ADEs that were only detected by the administrative data. This linkage process was very similar to the within site data source linkage but much faster due to small number of admissions reviewed (between 175 and 336 admissions).

This linking involved two stages:

- Firstly, we reduced the administrative data for each site down to only those NHIs that had reviews in the trigger tool data *and* were recorded has having an ADE. Then the dates of the events were compared to the dates of the trigger tool admission event to exclude ADEs not occurring during the trigger tool admission. We then checked that the drug that caused the harm matched between the administrative data and the trigger tool data.
- We then flagged the resulting linked items to indicate when the ADE was identified in the administrative data and matched to an ADE detected by the trigger tool data. With this we calculated the proportion of ADEs detected by both the trigger tool and administrative data; and by only the trigger tool.

5.2.6 Denominator

There is a range of denominators we could use, including admissions, bed days and doses. The advice we received from experts was to use bed days as the denominator. This has

conceptual appeal, as one of the aims of medication safety programmes is to reduce the number of (additional) bed days arising as a result of medication-related harm.

We have presented results using both bed days and admissions, to enable comparison with other analysis.

We acknowledge that there are concerns with presenting the results of this work as a rate, given the under-reporting inherent in the various systems. However, we note that the same issue also relates to the presentation of whole numbers – in that both can be mis-leading if interpreted as a 'baseline' burden of harm.

5.2.7 Issues arising

Existing systems not designed to measure harm

We note that each of these existing data collections has been designed for a particular purpose, which is not specifically the measurement of harm. Unsurprisingly, this created challenges in coding and categorising data, as described below.

Inconsistent classification systems across data systems

Each data system uses a different coding system for the variables of medication stage, the 5 rights, and severity, and some do not code particular categories at all (because, as we discuss below, they are not designed or required to do so). The exception is the ICD-10 Y-coded discharge data which consistently codes to the ICD-10 classification system. The coding systems used in each of the collections we received are set out in Appendix 2 .

Much information is 'unspecified'

For much of the administrative ADE data we could not code severity, rights, stage and specific medication name, and for few of the ADEs could we code to the framework exactly. There are two reasons for this:

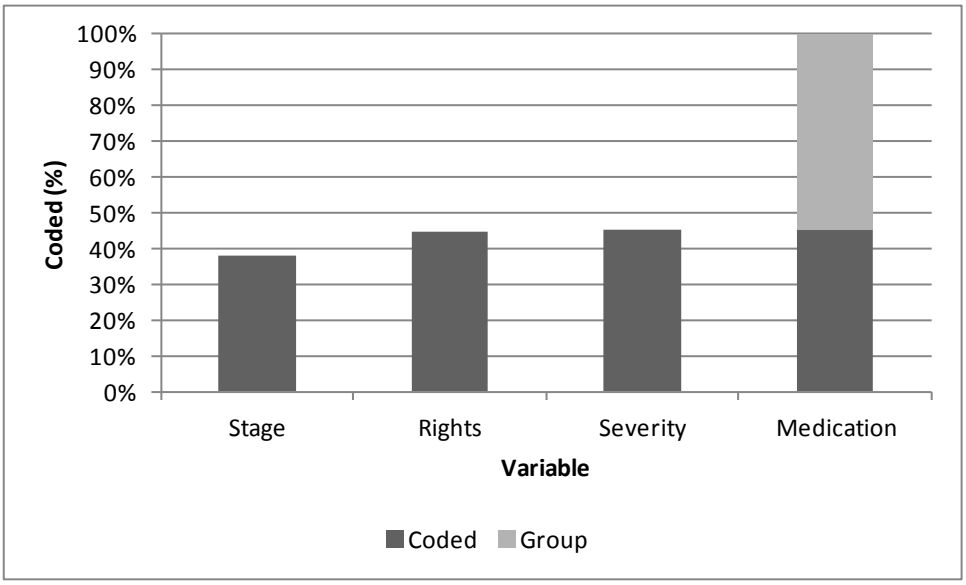
- Firstly there was frequently no information collected relating to one or more of the three variables. An example of this was ICD-10 Y-coded data where no additional data is recorded but the broad drug group.
- Secondly, information is often recorded as a free text description of the ADE. The effort to read through and code the text to the framework is prohibitive in terms of time, and would likely produce incomplete and inconsistent results. For example, where the medication name is available on any of the four sites' data systems it is as free text with the associated typographical errors and misspellings, as opposed to formal coding (e.g. according to the New Zealand Universal List of Medicines or the Pharmacy Society's Pharmacodes). The inclusion of a medicine coding system and/or a process of standardisation would therefore need to occur before the medication names could be readily used.

The following figures present the proportion of ADEs for each site that could readily be coded to some version of severity, 5 rights, stage and medication. The rate of ADEs detected by the ICD-10 Y-coding varies across sites, and because of the large proportion of 'unspecified' records in this collection, these proportions are partly what drives the differences in rates of ADEs between sites.

Figure 2 shows that of the ADEs recorded in Counties Manukau data for 2012, approximately 35% could be coded to stage, 45% to rights and severity, and 45% to the specific medicine name. The light grey section of the stacked medication bar labelled 'Group' denotes the other 55% of ADEs for which only the broad medication group could be coded from ICD-10 Y-coded data. Where the actual medication name is entered as free text in the description field for each Y-code, rather than the default ICD-10 code description, this would afford much greater detail around the medication. These fields were not provided, so the level of detail could not be determined. ICD-10 Y-coded ADEs make up a relatively large part of Counties Manukau ADE events so all of the first three variables have a relatively low coding percentage.

Figure 2 ADEs for which stage, rights, severity and medication name are coded – Counties Manukau

2012 data

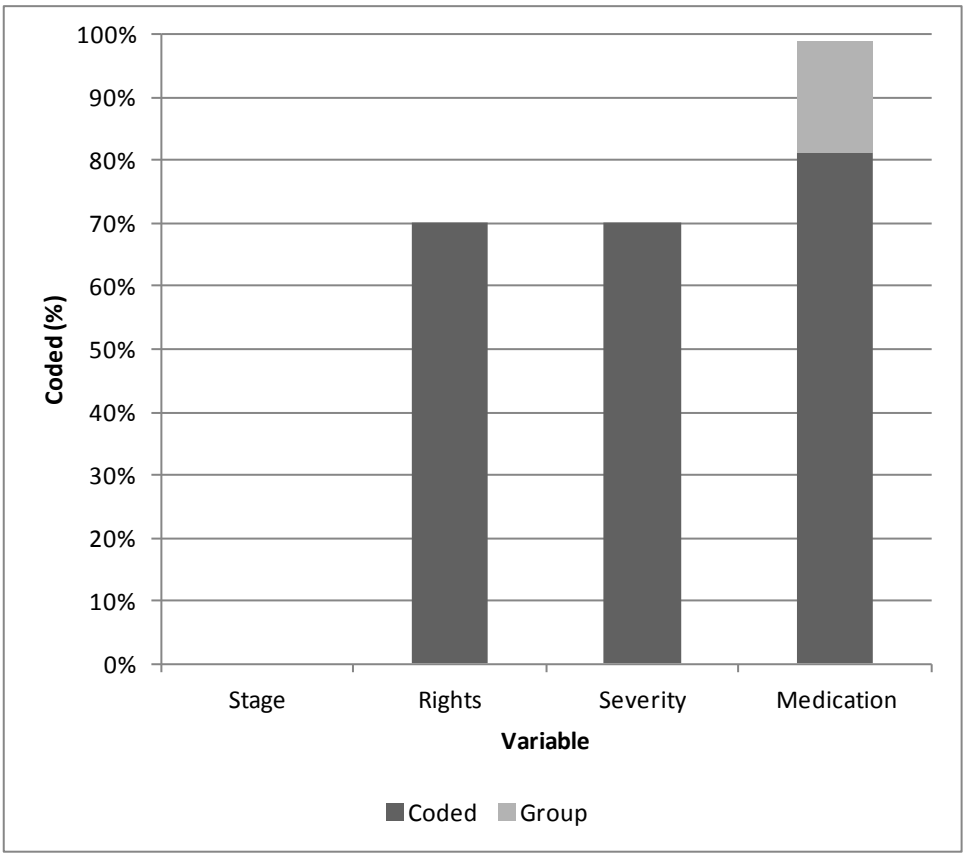


Source: Sapere analysis

Figure 3 shows that of the ADEs recorded in Waitemata data for 2012: none can be readily coded to stage; approximately 70% could be coded to rights and severity; and 81% to the specific medication name. The light grey section of the stacked medication bar labelled 'Group' denotes the other 18% of ADEs for which only the broad medication group could be coded from ICD-10 Y-coded data. As the actual medicine name is entered as free text in some of the description fields for Y-codes and this data was provided, the level of percentage of ADEs for which specific medication could be determined was high. ICD-10 Y-coded ADEs make up a relatively small part of Waitemata ADE events so the rights and severity have a high coding percentage. None of the collections code stage.

Figure 3 ADEs for which stage, rights, severity and medication are coded – Waitemata

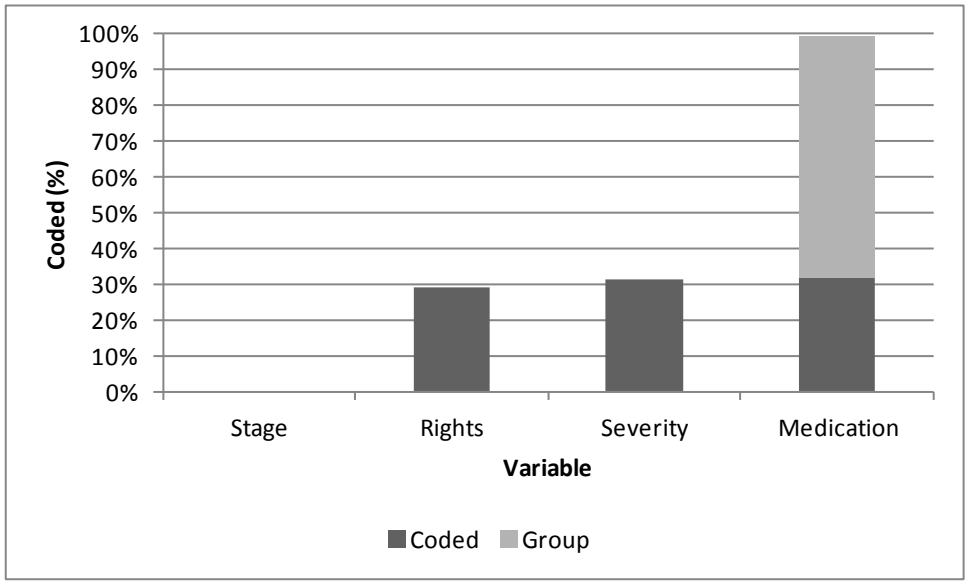
2012 data



Source: Sapere analysis

Figure 4 shows that of the ADEs recorded in Southern data for 2012, none can be readily coded to stage, approximately 30% could be coded to rights and severity, and 31% to the specific medication name. The light grey section of the stacked medication bar labelled 'Group' denotes the other 68% of ADEs for which only the broad medication group could be coded from the ICD-10 Y-coded ADE data. As the free text descriptions for the ICD-10 Y-coded ADEs were provided we could determine that almost all free text descriptions are default coded, with little opportunity for identification of the specific medication name. ICD-10 Y-coded ADE events make up a relatively large part of Southern ADE events so the rights and severity have a low coding percentage. None of the collections code stage.

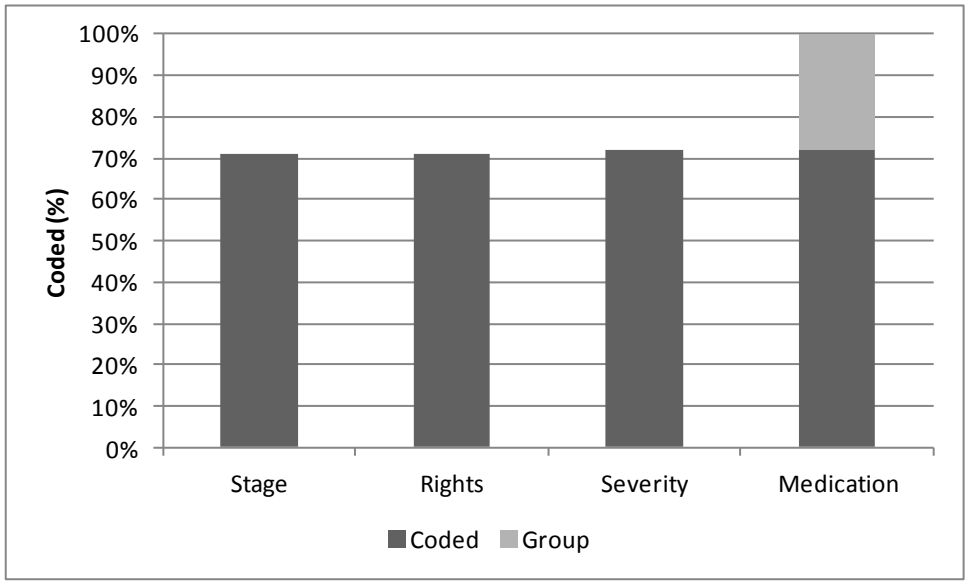
Figure 4 ADEs for which stage, rights, severity and medication are coded – Southern 2012 data



Source: Sapere analysis

Figure 5 shows that of the ADEs recorded in Taranaki data for 2012, approximately 70% could be coded to stage, rights, severity and specific medication name. ICD-10 Y-coded ADEs make up a relatively small part of Taranaki ADEs. The light grey section of the stacked medication bar labelled Group denotes the other 28% of ADEs for which only the broad medication group could be coded from ICD-10 Y-coded data. Where the actual medication name is entered as free text in the description field for each Y-code, rather than the default ICD-10 code description, this would afford much greater detail around the medication. These fields were not provided, so the level of detail could not be determined. As with the other three sites, the ICD-10 Y-coded discharge data is the only one of the three Taranaki collections that doesn't code any of the first three variables. Because ICD-10 Y-coded ADEs make up a small part of Taranaki ADEs the percentages of stage, rights and severity coded are high.

Figure 5 ADEs for which stage, rights, severity and medication are coded – Taranaki 2012 data



Source: Sapere analysis

Judgement required in coding

Step 2 in the linking process involved judgement on our part to reconcile the IDC-10 Y-coded data with the pharmacy intervention data. This is because the ICD-10 coding system uses broad groups of medicines such as 'opioids', while the pharmacy intervention data lists the actual drug. We looked up specific medicines online to find out which group they would fall into.

Table 8 illustrates the type of coding difficulty that arises when trying to link events where the ICD-coded data refers to a drug group and the Pharmacy Intervention narration refers to a specific drug.

Table 8 Examples of non-specific coding of ICD-10 Y-coded discharges

ICD-10 Y-code	ICD-10 Y-coded default description	Pharmacy intervention narration
Y400	Penicillins causing adverse effects in therapeutic use	Piperacillin causing adverse effects in therapeutic use
Y400	Penicillins causing adverse effects in therapeutic use	Augmentin causing diarrhoea in therapeutic use
Y401	Cephalosporins and other -lactam antibiotics causing adverse effects in therapeutic use	Cefuroxime
Y401	Cephalosporins and other -lactam antibiotics causing adverse effects in therapeutic use	Cefuroxime causing adverse effects in therapeutic use
Y413	Other antiprotozoal drugs causing adverse effects in therapeutic use	Ornidazole
Y420	Glucocorticoids and synthetic analogues causing adverse effects in therapeutic use	Prednisone causing adverse effects in therapeutic use
Y442	Anticoagulants causing adverse effects in therapeutic use	Warfarin causing adverse effects in therapeutic use
Y520	Cardiac-stimulant glycosides and drugs of similar action causing adverse effects in therapeutic use	Digoxin toxicity

Source: Sapere analysis

Unable to code preventability

Based on our framework, our analysis sought to focus on preventable harms. However, we found it close to impossible to code preventability from any of the data collections provided, including the trigger tool. The two main reasons for this were:

- These collections are not designed to record preventability, so there are no fields available with information on preventability or that make provision for coding preventability, and
- Where detailed free text descriptions of events are available, the writer's focus is not on preventability (as they are not required to record this information) and hence this information is not determined or provided. This makes coding preventability from this data very difficult.

We were therefore were unable to distinguish preventable from non-preventable harms, and unable to estimate the large blue 'medication errors' circle in our taxonomy diagram.

As a work around, we modelled all ADEs, both those associated with medication errors where harm occurred and ICD-10 Y-coded discharges where an ADR was coded. This is the full green circle in our taxonomy diagram (Figure 1).

Variations in approach to trigger tool record reviews

We found that the trigger tool case reviews had been undertaken at some stage in all four DHBS, but for different reasons and in different ways and numbers. For example, in two hospitals the standard ADE Trigger Tool was used across 20 records per month for two different periods, in the third hospital it was undertaken at 40 records per month for the first year and then 20 records a month for the following year, and in the fourth hospital a 'blanket' review (i.e. all charts) was undertaken for a shorter period (note that the trigger tool data were not provided from this site). One of these latter sites (Waitamata) used the Global trigger tool rather than the ADE version. Given that the Global trigger tool's medication triggers are of a more general nature than the ADE trigger tool triggers, one would expect it to capture different types of errors and its overlap with the hospital data systems to be distributed differently.

Resource implications

Altogether we identified 202,000 line items from the four sites that required linking and coding. The process of linking the data sets took us around one hour per thousand line items. The coding process took around one hour per 250 line items, if we attempted to interpret as much information as possible from all available fields. Based on expert advice, we changed our approach to coding items only where information is readily available. This took about one hour per 2,000-3,000 line items and accordingly resulted in a higher proportion of items coded as 'unspecified'.

5.3 Results

What the data can detect?

The following figures and tables present our results by site. They show:

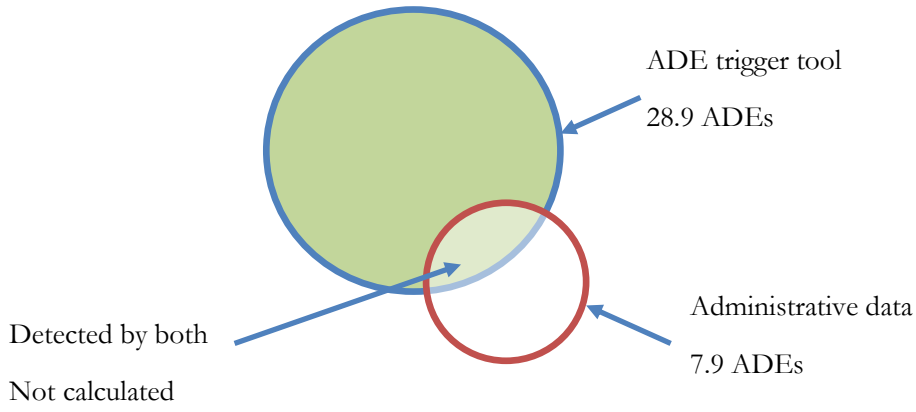
- The ADEs that were detected using the linked administrative data only
- The ADEs that were detected using the trigger tool only, and
- The ADEs that were detected by both the administrative data systems and the trigger tool.

As we were unable to distinguish between preventable and non-preventable harm, the circles in the diagrams together represent that area in the green circle in our taxonomy diagrams (ADEs) that were able to be detected by these systems. (The larger blue circle representing errors is therefore not shown).

Note that for Counties Manukau we were not provided with trigger tool data so were unable to calculate the overlap between the two data sources (i.e. the overlap between the harms detected by the trigger tool and those detected by administrative data).

Figure 6 ADEs detected per 100 admissions – Counties Manukau

ADE Trigger Tool data 2010-2011, administrative data 2012



Source: Seddon et al (2013) and Sapere analysis

Table 9 ADEs detected per 100 admissions and per 1,000 bed days – Counties Manukau

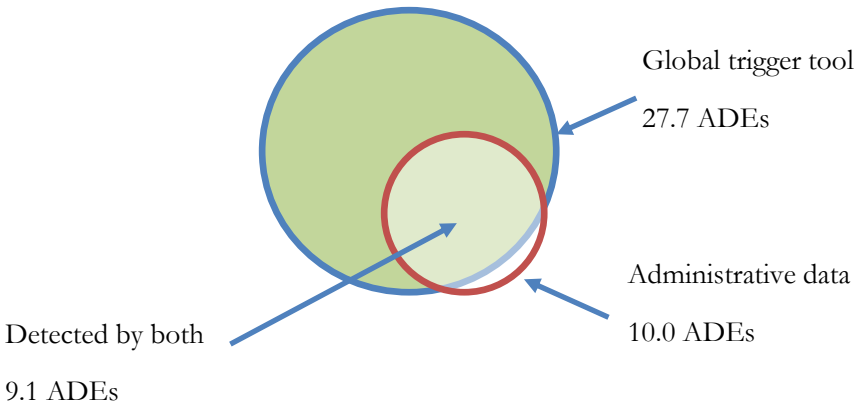
ADE Trigger Tool data 2010-2011, administrative data 2012

System	ADEs / 100 admissions	ADEs / 1000 bed days
ADE Trigger Tool & Administrative	Not calculated	Not calculated
ADE Trigger Tool only	28.9	38.0
Administrative data only	7.9	27.8
Total	Not calculated	Not calculated

Source: Seddon et al (2013) and Sapere analysis

Figure 7 ADEs detected per 100 admissions – Waitemata

2012 data



Source: Sapere analysis

Table 10 ADEs detected per 100 admissions and per 1,000 bed days – Waitemata

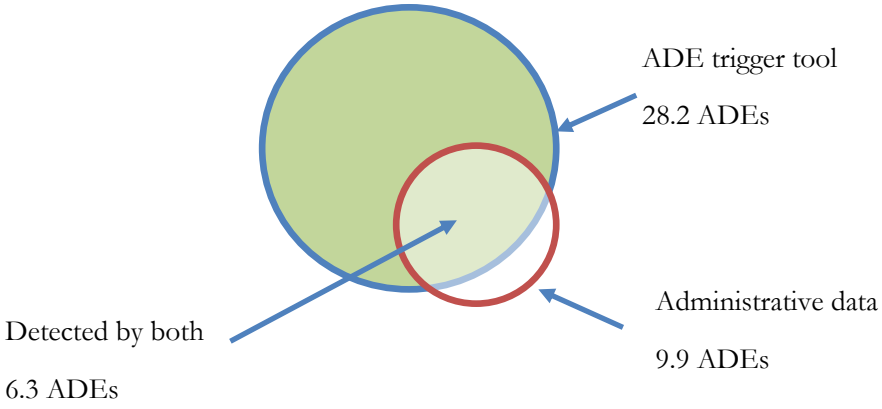
2012 data

System	ADEs / 100 admissions	ADEs / 1000 bed days
Global Trigger Tool & Administrative	9.1	18.4
Global Trigger Tool only	18.6	37.7
Administrative data only	0.9	22.2
Total	**28.6**	**78.4**

Source: Sapere analysis

Figure 8 ADEs detected per 100 admissions – Southern

2012 data



Source: Sapere analysis

Table 11 ADEs detected per 100 admissions and per 1,000 bed days – Southern

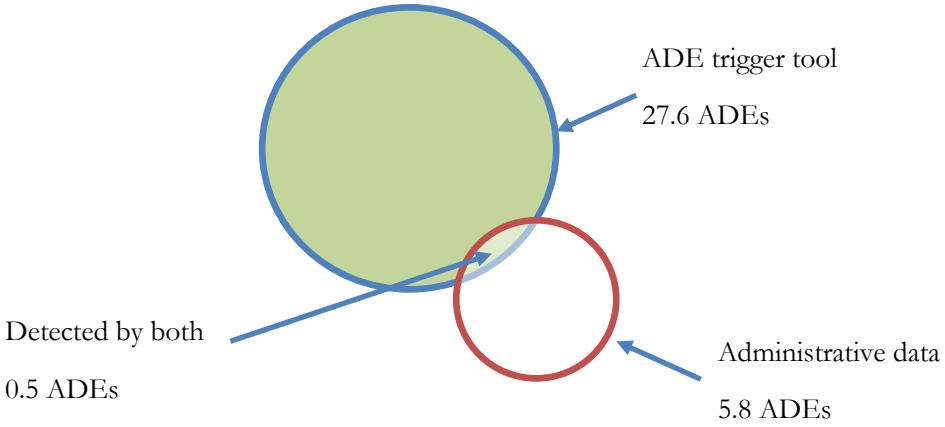
2012 data

System	ADEs/ 100 admissions	ADEs / 1,000 bed days
Adverse Drug Event Trigger Tool & Administrative	6.3	7.2
Adverse Drug Event Trigger Tool only	21.9	49.3
Administrative data only	3.6	28.4
Total	**31.8**	**84.9**

Source: Sapere analysis

Figure 9 ADEs detected per 100 admissions – Taranaki

2012 data



Source: Sapere analysis

Table 12 ADEs detected per 100 admissions and per 1,000 bed days – Taranaki

2012 data

System	ADEs / 100 admissions	ADEs / 1,000 bed days
Adverse Drug Event Trigger Tool & Administrative	0.5	0.9
Adverse Drug Event Trigger Tool only	27.1	49.4
Administrative data only	5.3	19.5
Total	**32.9**	**69.7**

Source: Sapere analysis

Estimating the intervention effect

We also sought to estimate the 'intervention effect', i.e. the change in the level and patterns of harm arising from the introduction of the eMM initiatives. If we assume that any non-preventable harms in our ADE time series would not be impacted by the eMM interventions, our estimates of ADE reduction are likely to reflect only a reduction in preventable harms.

We used a statistical regression model to test whether the mean number of ADEs is significantly reduced in the wards that implemented ePA and eMR. A generalised Poisson regression was used to model the number of ADEs by ward over the three year period in each site. We included a time trend to allow for natural growth, the month of the ADE to adjust for seasonality and a separate ADE mean for each ward. The effect of the implementation was modelled by fitting an intervention in the months for which the eMM initiative was in operation.

As a second stage a counter-factual prediction model was run using the parameters of the first model but excluding the intervention variable to estimate the number of ADEs in the absence of the interventions.

A significant point to note is that if the intervention increased the rate of reporting of ADEs but not necessarily the rate of ADEs this model will spuriously associate the increase in the rate of ADE reporting with an increase in the rate of ADEs. The methodology used in this analysis cannot account for variability of rates in the completeness or consistency of reporting driven by other factors. On this basis, caution should be exercised when interpreting the estimates of change for Taranaki, especially for the eMR impact. We include the estimate and figure for eMR as we believe it is instrumental to understanding complex issues involved in the evaluation.

It was only possible to model the harm reduction in the Taranaki DHB site even though all sites implemented one or more of the initiatives during the period for which we were provided administrative data. There were three reasons for this:

- In two sites the interventions were implemented in mid-November 2012 and 6-8 weeks of follow-up data was insufficient to evaluate an intervention that was still bedding in.
- In one site there was a change in the pharmacy intervention data system from 2011 to 2012, which produced an inconsistent time series because a significant number of earlier medication error events did not have any indication of harm or severity.
- In one site the date of the implementation of the intervention was not known.

Table 13 Estimates of change in harm for the four DHB Sites

Intervention	Counties Manukau	Waitemata	Southern	Taranaki[24]
ePA	Not implemented	Not modelled – insufficient follow-up	Not modelled – inconsistent time series	-4.1 ADEs / month p-value=0.26 *Not statistically significant*
eMR	Not modelled – insufficient follow-up	Not modelled - date of implementation unknown	Not implemented	+40.6 ADEs / month p-value<0.01 *Highly statistically Significant*

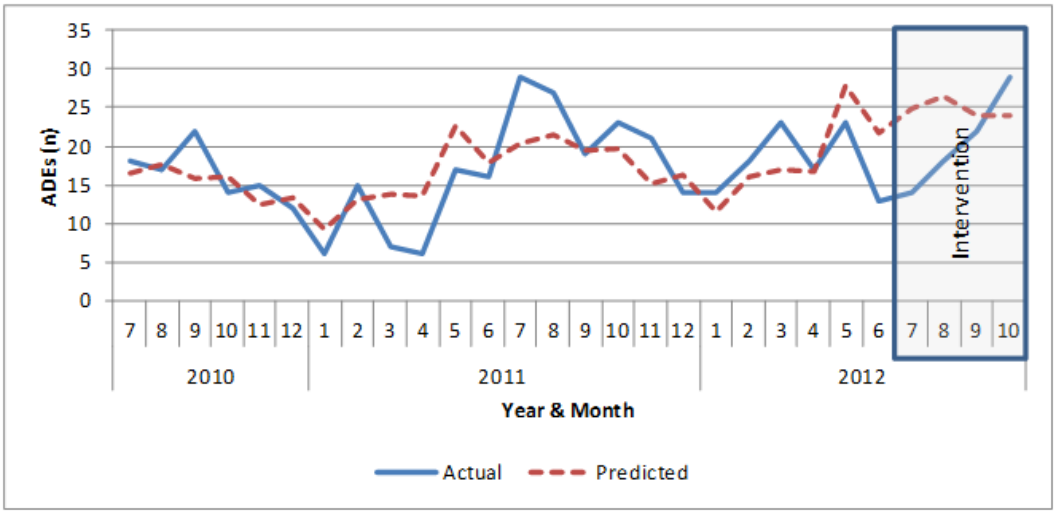
[24] Statistical significance in this context indicates the chance we will be wrong if we conclude there has been a significant impact in the mean number of ADEs following the intervention. The cut-off for the p-value is usually set at 0.05.

Source: Sapere analysis

Figure 10 presents the actual and predicted counterfactual ADE time series for the Taranaki DHB ePA ward (ward 1). The highlighted area of the figure indicates when the intervention was implemented. The net difference between the actual and projected counterfactual series for the intervention period (four months) is the estimate of harm reduction. This was estimated at 4.1 fewer ADEs per month of the intervention.

Figure 10 Taranaki ePA ward ADE intervention analysis

2010-2012 data

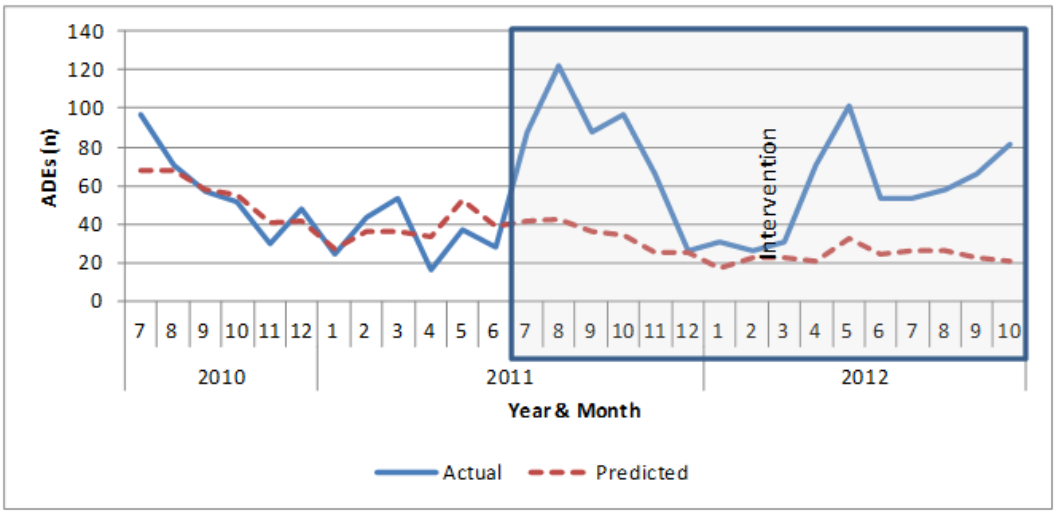


Source: Sapere analysis

Figure 11 presents the actual and predicted counterfactual ADE time series for the Taranaki DHB eMR ward (ward 5). The highlighted area of the figure indicates when the intervention was implemented. The net difference between the actual and projected counterfactual series for the intervention period (16 months) is the estimate of harm reduction. This was estimated at 40.6 more ADEs per month of the intervention.

Figure 11 Taranaki eMR ward intervention analysis[25]

2010-2012 data



Source: Sapere analysis

5.3.2 Key messages from the data

The key points from our analysis are:

1. Estimates of ADEs detected range from 28.6-32.9 per 100 admissions (69.7-84.9 per 1,000 bed days). This compares to, for example, those of Seddon et al (2013), which (using a standardised ADE trigger tool method) were 28.9/100 admissions and 38/1,000 bed days.

2. There are varying degrees of overlap of the ADEs detected by administrative data collections and trigger tool, though in all three sites the administrative sources detected some ADEs that the trigger tool did not.

3. The intervention effects we were able to measure in the Taranaki DHB site were -4.1 ADEs per month (not statistically significant) in the ePA intervention ward and +40.6 ADEs per month (statistically significant) in the eMM intervention ward.

4. The introduction of eMM systems may lead to increased reporting. Because administrative recording systems are incomplete and inconsistent, we were unable to distinguish between any changes in the actual rate of harm, from changes in the rate of reporting. So it is possible that any increases in recorded harm following implementation may be at least in part be due to behavioural changes in reporting rather than an increase in actual harm.

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[25] When interpreting this figure, as mentioned previously, one should note that increases seen in numbers of ADEs post the eMR intervention could likely be due to more frequent reporting due to the intervention rather than increases in the rate of harms.

6. Implications for implementing the framework

6.1 Unable to apply framework with existing data sets

The framework described in Chapter 4 sets out a conceptual ideal for measuring medication-related harm. The data analysis described in Chapter 5 explored the extent to which the range of existing data sources could populate this framework. We found that, because these existing data collections have been designed for other purposes, they are unable to tell us much about the harm. Moreover, our methodology for extracting harm-related information from these data sources is prohibitively time consuming.

We have concluded from this that is it not possible to implement our measurement framework in New Zealand, using the current data systems. This is not to say that the framework itself is not useful and cannot be applied – as it appears to have been successfully implemented in the UK. The HQSC may wish to consider talking with staff in the NHS National Reporting and Learning Service to find out more about its practical implementation and how it is used to inform quality improvement.

Comment on the detailed design of data collection systems is out of scope of our work, but regardless of whether existing systems are modified or a new system is implemented there are some fundamental elements that need to be considered. These are discussed in 6.2 to 6.5 below. Finally, section 6.6 offers a suggestion for a discrete piece of additional analysis that could be undertaken in relation to the use of trigger tool reviews.

6.2 Need for consistent definitions and classifications...

With the exception of the ICD-10 classification system, definition and categories vary across data systems and between DHBs. As discussed above, our manual coding process is very time intensive, and done retrospectively is highly unlikely to lead to robust or comprehensive coding of the variable of interest.

In order to implement the framework we have constructed, there is a need to develop and move towards nationally-standardised classification. This is required regardless of whether data are collected manually or electronically. We note that the categories we have developed differ from those in the current National Reporting System, so any changes made would also need to flow into this.

This would clearly constitute a significant and long-term programme of work, and would need to consider the implications for time series comparison (such as the ability to backcast historical data for monitoring and evaluation purposes).

6.3 ... as well as rigorous infrastructure

A more standardised approach to data collection would require more a systematic and rigorous approach to the management of data than was evidenced in our investigations. This includes the documentation of data collection systems and processes, including data dictionaries and coding protocols. It could also involve regular audits of coding procedures, to ensure standardisation in the way information is categorised by individual coders (both within and across DHBs).

6.4 Critical to link to primary and community

We know from the literature that points of patient transfer (e.g. between primary and secondary care, and between wards within a hospital) are areas of key risk of medication-related harm. Ideally, a measurement framework would span all health care settings. This would require a standardised approach across all settings. We therefore recommend that the development of any national approach to measurement in the DHB setting be co-ordinated with work to develop measurement systems in other care settings (e.g. any future work by New Zealand Pharmacovigilance Centre on further developing the MERP methodology).

6.5 Using the data

Implementing a data collection system is just the first step in managing medication safety. Data needs to be collated and analysed, the results interpreted, and findings used to inform quality improvement decision making (see Figure 12, below).

Our measurement framework provides an approach for catagorising data collected in step 1 in this process. It provides a framework for identifying patterns and trends, to guide the focus of analysis. This would need to be followed by root cause analysis, targeted on the patterns of key concern. This may involve targeted records review, and/or interviews with staff to investigate the reasons behind these trends and ascertain whether they signify systemic problems that need addressing. Where systemic issues are uncovered, this may prompt consideration of appropriate responses such as training, or the modification of systems or processes. We would encourage the sharing of such learnings.

Figure 12 Turning data into wisdom

6.6 Potential further analysis

The ADE trigger tool appears to mostly pick up ICD-10 Y-coded ADEs. While the Global trigger tool appears to do the same, it also picks up a greater number of pharmacy intervention ADEs, although this could be a product of Waitemata's Pharmacy intervention database capturing a different set of ADEs events compared to Southern and Taranaki.

The different hospitals have different rates of ADEs reported by the ICD-10 Y-coded ADE events and this appears to significantly affect the overlap between the trigger tool and the administrative data. In 2012 the rate of ICD-10 Y-code ADEs per 100 admissions was as follows: 4.4 in Counties Manukau, 3.0 in Waitemata, 6.8 in Southern and 1.6 in Taranaki. There reasons for the differences in these rates could be explored to determine whether the practice of coding these events is different between hospitals or whether the underlying the drivers of these events differ between hospitals.

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Appendix 1 Trigger Tools

Trigger tools help identify adverse effects and areas for improvement by auditing a small sample of patient notes regularly. A multidisciplinary team or pair of reviewers randomly selects a small sample of patient notes, such as 10 case notes every two weeks or 20 case notes every month. The reviewers are asked to set a 20-minute time period per case note review and to rapidly scan the notes to identify triggers or clues for potential harm. Any events identified are categorised by severity and type and used to inform safety improvement efforts. For all patient records reviewed, the length of stay is recorded, including admission and discharge days. This allows calculation of the number of adverse events per 1,000 patient days or per 100 patients. The aim is to track changes over time and demonstrate a reduction in monthly adverse events identified.[26]

The earliest trigger tools were designed to monitor the rates of medication-related events. One of these was the IHI Trigger Tool for Measuring Adverse Drug Events. A team from the Institute for Healthcare Improvement (IHI) in the USA developed and validated an Adverse Drug Event Trigger Tool with 13 triggers (e.g. abnormal lab values, use of antidotes) that staff/researchers can follow up to see whether they identify an adverse drug event.

The IHI ADE Trigger Tool is designed to capture patient harm rates and harm severity. It does not aim to capture all ADEs (Jackson and Lewis 2011a, p.22). A limitation of the ADE Trigger Tool is that harm caused by inappropriate patient use of medications or by omission of therapy are excluded. However such harms are commonly identified from the MR process – the CMDHB phase 1 eMR evaluation found that omission of a regularly used medicine was the common medication error for patient admissions. The authors therefore recommended modifications to the tool, and the Trigger Tool database used for the Phase 2 evaluation was updated to include harm caused by omissions, as well as near misses or errors with the potential to cause harm (Jackson and Lewis 2011a, p.22 and 25). The current CMDHB ADE Trigger Tool is presented below.

More recently the IHI has developed a Global Trigger Tool to detect/monitor a wider range of adverse events that can occur in the inpatient setting. This Global Trigger Tool examines events within six modules:

- Cares
- Medication
- Surgical
- Intensive Care
- Perinatal, and
- Emergency Department.

[26] The Health Foundation (2010) *Global trigger tools: Research scan*, The Health Foundation, London, p.3

Research has shown this tool detects ten times the number of events of a comparator tool and almost 90 times more than spontaneous reporting. (354 vs 35 vs 4 events from 795 records). The Global Trigger Tool is intended for use by a team of three health professionals including one physician. The other two members are usually nurses. The tool uses the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for classifying the severity of events.

The IHI states 'there should be no attempt by the reviewers to determine preventability during a review with the IHI Global Trigger Tool'.[27] For each hospital adopting this tool, the IHI recommends the team examine 10 randomly-selected sets of case notes each fortnight. This should minimize selection bias over time.

Although global trigger tools are being prioritised nationally and internationally, there is a lack of published evidence about the effectiveness and utility of these tools. The evidence that does exist tends to describe global trigger tools in general terms and in some cases to outline how these tools have been applied in different contexts (The Health Foundation, 2010).

Research has described the use of trigger tools to:

- Identify adverse event rates in hospital and primary care
- Monitor changes in adverse event rates over time
- Estimate whether an improvement initiative has helped to reduce adverse events (The Health Foundation, 2010).

[27] FA Griffin and RK, Resar (2009) IHI Global Trigger Tool for Measuring Adverse Events (Second Edition). IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2009.

CMDHB Trigger Tool

Trigger Tool - Adverse Drug Events (incl. Medication Errors & Medication Reconciliation)

Patient NHI:	**Audit date:**
Discharge date (dd-mm-yyyy):	**Specialty #1:**
Review Team:	**Specialty #2:**

Adverse Drug Events (ADE) - Triggers

Drugs

M1 Antihistamines/IV corticosteroid
M2 Vitamin K /Prothombinex
M3 Flumazenil
M4 Anti-emetics
M5 Naloxone
M6 Anti-diarrhoeal
M7 Calcium/sodium polystyrene sulfonate
M19 Laxatives

Lab values

L4 Serum glucose <3.0 mol/L
L1 C. difficile positive
L2 APTT >100 seconds
L3 INR > 4
M12 WBC <3 x 10^9/L
M13 Platelet count <50x $10^{9/}$L
M14 Digoxin Level >2 nmol/L
L5 Rising Serum Creatinine

Miscellaneous

M16 Falls and/or Hypotension or Oversedation
M17 Rash
M18 Abrupt Cessation of Medication
C11 Transferred to a Higher Level of care/ Rapid response team/Arrest
O2 – Non-trigger AE

Triggers	ADE Found Y	ADE Found N	Harm Category	Sub-Category	When	Where	Description of ADE

Clinical Context:	

Harm Category	
Category E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
Category F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalisation
Category G	An error occurred that may have contributed to or resulted in permanent patient harm
Category H	An error occurred that required intervention necessary to sustain life
Category I	An error occurred that may have contributed to or resulted in the patient's death

Classification of Harm	
1	Clostridium Difficile medication related infection
2	IV volume overload/electrolyte imbalance
3	Kidney damage due to renal contrast
4	Medication related cardiac event/arrhythmia
5	Medication related renal insufficiency
6	Medication related allergic reaction
7	Medication related bleeding
8	Medication related delirium, confusion, or over-sedation
9	Medication related diarrhoea
10	Medication related Glycaemic events
11	Medication related hypotension
12	Medication related nausea and vomiting
13	Other

To identify WHEN harm occurred, prior to, or during admission		WHERE did the harm occur? (Examples)
InPt	AE occurred **during this hospital admission**	EC, ICU, Theatre, Ward X, AT&R etc (during this admission)
Adm1	AE present on admission , occurred **within 30** days of admission	Ward X (prior admission at CMDHB), Another DHB, Private Hospital, Aged Care Facility, At Home
Adm2	AE present on admission , occurred **between 30 days and 12 months** of admission	Ward X (prior admission at CMDHB), Another DHB, Private Hospital, Aged Care Facility, At Home
Adm3	AE present on admission , occurred **greater than 1 year** of admission	Ward X (prior admission at CMDHB), Another DHB, Private Hospital, Aged Care Facility, At Home
Re-Admit	AE present on admission, related to prior discharge, occurred within 30 days of admission	Ward X (prior admission at CMDHB), Another DHB, Private Hospital, Aged Care Facility, At Home

Appendix 2 Administrative data coding

Here were present a comparison of the variables used in the four sites and across the three administrative data collections that that can be used to code Severity, Rights and Stage, against the coding categories proposed in our framework. In some systems no coded variable is available.

Table 14 ICD-10 Y-coded discharge data

Framework	Counties Manukau	Waitemata	Southern	Taranaki
Severity				
Death Severe harm Mild harm No harm 3 No harm 2 No harm 1 No specific patient involved Unspecified	May be able, in large part, to assume minor or greater harm but no other information or certainty to coding actual severity			
Right				
Dose Medicine Patient Route Time Unspecified	No information			
Stage				
Delivery Supply Medication history-taking Prescribing/ordering Dispensing Administration Monitoring Unspecified	No information			

Table 15 Incident reporting

Framework	Counties Manukau	Waitemata	Southern	Taranaki
Severity				
Variable name	*Actual incident severity*	*Reported severity level*	*Classification & Near_Miss*	*Severity*
Type	*List*	*List*	*List*	*List*
Death Severe harm Mild harm No harm 3 No harm 2 No harm 1 No specific patient involved Unspecified	Near miss Severity 5 – Minimum Severity 4 – Minor Severity 3 – Moderate Severity 2 – Major Severity 1 – Death	Near Miss Severity Level 1 Near Miss Severity Level 2 Severity Level 1 – Minimum Severity Level 2 – Minor Severity Level 3 – Moderate Severity Level 4 – Major Severity Level 5 - Serious	Near Miss SAC1 – Minimum SAC2 – Minor SAC3 – Moderate SAC4 – Major SAC5 - Serious	Potential/Near Miss Minor Moderate Major Serious
Right				
Variable name	*Specific incident type*	*Specific event type*	*Identifier & description*	*Specific incident type*
Type	*List*	*List*	*Free text*	*List*
Dose Medicine Patient Route Time Unspecified	Not give/taken Extra dose/duplication Incorrect dose/strength Incorrect medication/fluid Documentation illegible/incomplete/incorrect Incorrect time/schedule Incorrect infusion setup Incorrect patient Given/taken, not ordered Unavailable Given/taken, not signed for Incorrect route Adverse reaction/event Incorrect concentration Incorrect rate Given/taken after discontinuation Disposal inappropriate Signed for, not given/taken	Wrong dose/strength Wrong frequency Wrong medication/fluid	Possible to code but inconsistent and incomplete	Allergy Drug contaminated Duplication of drug (includes extra dose) Inadequate lab data/tests Incomplete documentation Incomplete prescription Incorrect charting Incorrect date/time Incorrect documentation Incorrect dosage/strength Incorrect dose formulation Incorrect drug Incorrect frequency

Framework	Counties Manukau	Waitemata	Southern	Taranaki
	Incorrect dosage form Allergic reaction Incorrect volume Expired Incompatibility Incorrect labelling Refusal of medication/fluid Contamination Incorrect site Interaction			Incorrect IV fluid Incorrect patient Incorrect rate Incorrect route Incorrect volume/delivery No error Omission (includes missed dose) Other medication error Self medication Unauthorised drug Unclear prescription
Stage				
Variable name	*Incident type*	*Description*	*Intervention & outcome*	*Incident type*
Type			*Free text*	*List*
Delivery Supply Medication history-taking Prescribing/ordering Dispensing Administration Monitoring Unspecified	No information	No information	Possible to code but inconsistent and incomplete	Administration After administration Charting Monitoring Post charting and pre admin Precharting Primary process Recharting/transcribing Self medication Supply – annotation Supply – dispensing Supply – impresting Supply – profiling/validation Supply – refilling Unknown

Table 16 Pharmacy intervention reporting

Framework	Counties Manukau	Waitemata	Southern	Taranaki
Severity				
Variable name	*Get dose & int grade*	*Ranking*	*Rank*	*Get dose & int grade*
Type	*List*	*List*	*List*	*List*
Death Severe harm Mild harm No harm 3 No harm 2 No harm 1 No specific patient involved Unspecified	Near Miss 1 – Minimum 2 – Minor 3 – Moderate 4 – Major 5 - Serious	1 Potential – Problematic 2 Potential – Minor or moderate 3 Potential – Serious 4 Potential – Severe or Fatal 5 Actual – Minor significance 6 Actual – Moderate significance 7 Actual – Serious or fatal significance	1 No or minor harm 2 Minor harm to patient 3 Moderate harm to patient 4 Major harm to patient 5 Serious/catastrophic harm 6 Contribution	Near Miss 1 – Minimum 2 – Minor 3 – Moderate 4 – Major 5 - Serious
Right				
Variable name	*Incident type*	*Primary*	*Type*	*Incident type*
Type	*List*	*List*	*List*	*List*
Dose Medicine Patient Route Time Unspecified	ADR Allergy Contraindication Dispensing error Documentation Duplicate Expired drug Extra dose Formulation Illegible Inappropriate Interaction Omission Pyxis error Route Self medication error Wrong dose regimen Wrong dose/rate/volume Wrong drug Wrong route	Absent or details blank Clozapine blood related Community related issue Completely Documented Dose/strength Duration of therapy Existing patient Form Frequency Full counselling Inappropriate dose for indication Incorrect dose/strength Incorrect form Incorrect frequency Incorrect medication Incorrect route of administration Incorrect roué Incorrect time of administration Medication	C1 Availability/funding/switching C2 IV /oral switch C3 Admin/formulation advice C4 Therapeutics C5 TDM/Labs C6 Adverse Drug Reaction C7 Patient education/compliance C8 Interaction advice I! Omission I2 Wrong dose I3 Wrong route I4 Illegible/incomplete I5 Allergy I6 Contraindication I7 ADR I8 Interaction I9 Wrong drug I91 Duplicate therapy I92 Inappropriate I93 Administration error I Admission discrepancy	ADR Allergy Contraindication Dispensing error Duplicate Extra dose Formulation Illegible Inappropriate Interaction Omission Route Self medication error Wrong dose regimen Wrong dose/rate/volume Wrong drug Wrong route

Framework	Counties Manukau	Waitemata	Southern	Taranaki
		Medication not restarted Missed existing patient Missed full counselling NBM – Med not administered Not applicable Not available documented Not documented Optimisation of therapy Other Other – see description Other administration error Precaution/contraindication Prescribed med not administered Renal dose adjustment Route Self medication not administered SR preparation crushed Stopped medication administered Unclear (handwritten) Unsigned medication administered Withhold medication administered Wrong label attached		
Stage				
Variable name	*Incident type*	*Description*	*Intervention & outcome*	*Incident type*
Type	*List*	*Free text*	*Free text*	*List*
Delivery Supply Medication history-taking Prescribing/ordering Dispensing Administration Monitoring Unspecified	Ad – Administration Rx – Prescribing Tx – Transcription Supply	Possible to code but inconsistent and incomplete	Possible to code but inconsistent and incomplete	Ad – Administration Rx – Prescribing Tx – Transcription Supply