
Prepared for the Health Quality and Safety Commission

Medication safety programme: measurement and evaluation

Summary report

30 July 2013

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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 provides an overview of the project and summarises our key findings and recommendations.

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

Table 1 Project deliverables

Report title	Content
Summary report (this report)	<ul style="list-style-type: none"> • Overview of the project approach <ul style="list-style-type: none"> – Project process • Key findings and recommendations
Report A: A framework for measuring medication-related harm	<ul style="list-style-type: none"> • A framework for the measurement of medication-related harm • Testing the framework <ul style="list-style-type: none"> – Methodology – Results from data analysis in 4 DHB sites • Implications for implementing the framework
Report B: Evaluating eMM	<ul style="list-style-type: none"> • Defining the eMM Programme • Exploring eMM system design and implementation <ul style="list-style-type: none"> – Findings from two rounds of site visits • Measuring systems design <ul style="list-style-type: none"> – Evaluating eMM

2. Overview of the project

2.1 Objectives

Our project aimed to provide the HQSC with information that:

- Enables them to form a judgement on the relative value of the current eMM initiatives, in terms of their likely impact on patient safety and their cost effectiveness
- Guides decisions on future regional and national roll out of the eMM initiatives, by providing advice on implementation lessons and the change process, and
- Provides a framework for the sustainable, on-going measurement and evaluation of medication-related harm for the Medication Safety Programme.

2.2 Context

We were engaged by the Health Quality and Safety Commission (HQSC) to undertake an evaluation of the implementation of electronic medication management (eMM) initiatives in four DHB sites: Southern, Taranaki, Counties-Manukau and Waitemata. The evaluation is focused on the DHB hospital setting (including admissions and discharge but excluding referrals from the community/primary care).

eMM refers to the electronic versions of two initiatives – electronic medicine reconciliation (eMR) and electronic prescribing and administration (ePA), including their use as both stand alone and/or integrated modules.

These initiatives have been implemented in various ways and degrees in DHB sites across New Zealand (i.e. different elements and versions (paper/electronic) and in different wards or to different target groups). The four DHBs we are looking at are also at varying stages of implementation.

2.3 Project process

2.3.1 An evolving framework

The initial aim of this project was to develop a measurement and evaluation framework that incorporates measures that address all the components of the Triple Aim. The Triple Aim objectives span benefits relating to individuals (e.g. in the form of improved quality and safety), the wider population (an equity objective) and the health system itself (an efficiency objective). And as noted above, we also sought to align with the approach being taken for the wider indicator work.

We prepared a draft framework that built on the indicators from earlier eMM studies, with the addition of measures around safety/harm, cost effectiveness and productivity, and assessment of the electronic system including the implementation/change management of the initiative.

2.3.2 Issues encountered

General concerns were expressed by stakeholders regarding the practical ability to measure a number of these indicators (for example, whether it is possible to measure medicines wastage, under cost effectiveness), and the resource implications for DHBs in collecting the data. Questions were also raised as to the number and relevance of some of the eMM process and outcomes measures, and to the practical ability to attribute indicators such as readmissions to medication-related adverse events.

At that stage in the project, we also identified practical issues with robustly measuring the safety improvements (reduction in harm) delivered by the eMM initiatives:

1. Firstly, the New Zealand data on the burden of harm is based on a 2001 study. We were uncomfortable with using this as a benchmark as it is dated and unlikely to reflect the current situation. This means we don't have a good feeling for the baseline level of harm.
2. We also faced the problem of small numbers. This is because the incidence of medication-related harm is small in the context of the sheer overall numbers (whether the denominator is admissions, doses etc). This is not to say that these figures are clinically insignificant; far from it. But the point is that detecting a change in a relatively small number poses issues with regard to the statistical significance of the change and means that we are unable to assess with any degree of rigour of the impact that eMM initiatives have had on medication-related harm.

2.3.3 Re-focusing

Following discussion of these concerns and issues, we were directed to focus on creating a framework to measure medication-related harm. To address the concerns regarding the resource implications of data collection by DHBs, we developed an approach for measuring harm that uses existing systems for capturing medication-related data.

Our overall approach, including revised methodology, has therefore comprised the following stages.

- **Project scoping and eMM programme definition.** We found that there were considerable questions as to the desired end state of the eMM programme, as well as the development pathway, and that the interventions themselves were lacking well-codified definition. Work to define the desired end state of eMM and the national implementation pathway was subsequently undertaken by the eMM Programme Office.
- **Assessing the costing profile.** We developed a template for assessing the costs of the programme, which was populated by the eMM Programme Office for each DHB. The resulting total cost estimate provides an indication as to the level of benefits required in order to justify the eMM initiatives from a cost-benefit perspective. The task of establishing the costing profile of the eMM programme was undertaken by the eMM Programme Office.
- **Two rounds of site visits.** It was agreed that we would use semi-structured interviews and focus groups with key DHB staff in order to collect qualitative information on systems design and implementation, rather than requiring data extracts from the eMM systems. These discussions explored, in a qualitative way, the DHBs' experiences with

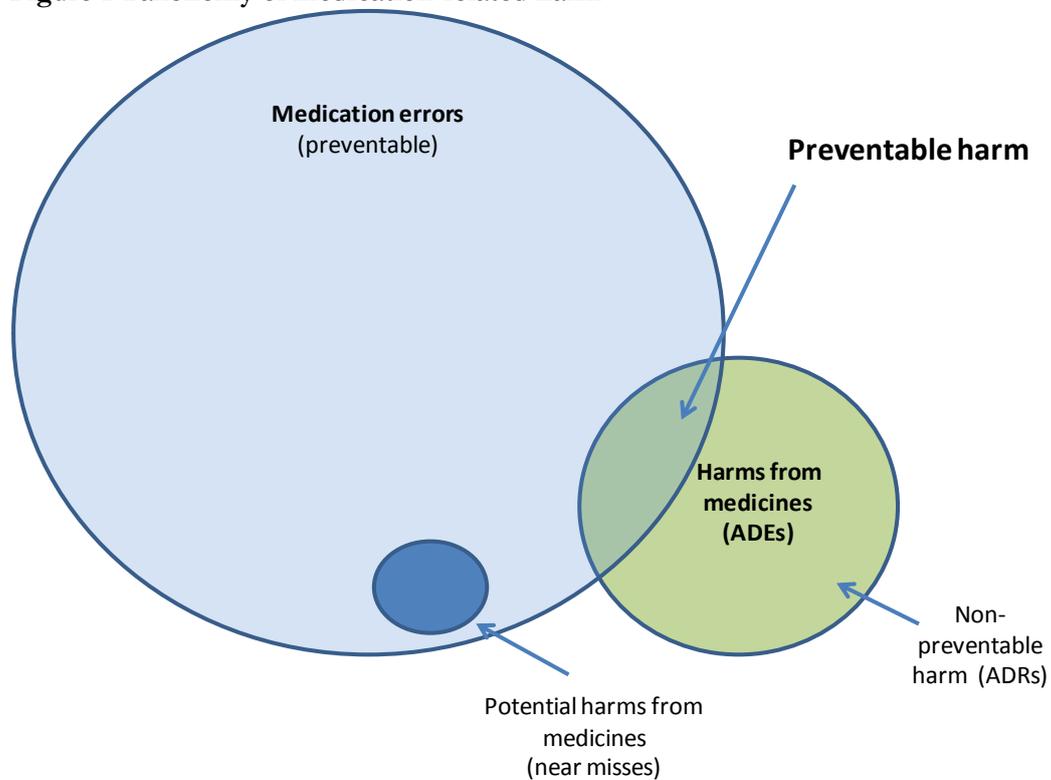
systems design and implementation, and the workflow productivity impacts of the eMM systems.

- **Developing an overarching framework** for the measurement and evaluation of medication-related harm for the Medication Safety Programme.
- **Data collection and analysis** – we trialled our proposed framework for measuring medication-related harm by collecting data from the range of existing data sources, and undertaking a linking exercise in order to analyse the burden of medication-related harm and the contributing factors. We also analysed post-eMM data where it was made available to us.
- **Preparing an integrative report** that brings together the findings of these work streams (this document).

3. Measuring medication-related harm

We based our measurement 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 taxonomy of harm we employed and the measurement framework we developed are set out below.

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).

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	Delivery	Dose (includes strength, commission and omission)
Severe harm	Supply	
Moderate harm	Medication history-taking	Medicine
Mild harm	Prescribing/ordering	Patient
No harm 3	Dispensing	Route
No harm 2	Administration	Time
No harm 1	Monitoring	Unspecified
No specific patient involved	Unspecified	
Unspecified		
Medicine name		

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 detail in Report A. In summary, we encountered the following issues:

- **Existing systems are not designed to measure harm.** Each of the existing data collections we identified has been designed for a particular purpose, which is not specifically the measurement of harm.
- **There are 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 they are not designed or required to do so).
- **Much information is ‘unspecified’.** For much of the 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. This required us to apply judgement in coding the data.
- **We were unable to code preventability.** We found it close to impossible to code preventability from any of the data collections provided. We were therefore unable to distinguish preventable from non-preventable harms, and unable to estimate the large blue ‘medication errors’ circle in our taxonomy diagram. 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.
- **Our approach to trial the framework is highly resource intensive** and not recommended for on-going measurement. We have concluded from this that it is 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.

The key implications for implementing the framework are the need for:

- Nationally-standardised definitions and classifications
- A more systematic and rigorous approach to the management of data than was evidenced in our investigations
- Linking to measurement systems in primary and community care settings, and
- Data to be collated and analysed, the results interpreted, and findings used to inform quality improvement decision making.

4. Summary of and comment on site findings

4.1 Four different approaches to implementation

The four different DHB sites have taken four very different approaches to implementation. Within these sites, there are three significant efforts to implement ePA. Each of the sites is different culturally and in implementation philosophy. Each has a significant amount to offer. We summarise the feedback we heard from the sites as follows:

- Southern is the original reference site for ePA and is the site that is most familiar with the application. There has been significant development of workarounds and significant local fixes to the system. There is a very strong, almost evangelical belief in the system, and a concerted effort to roll the system out. Because of the level of **familiarity with the application, and because of the extent of local tailoring**, there is a weighing of the benefits of implementation of ePA very much in favour of the counterfactual, namely the risks of a paper based system.
- Taranaki has a very well developed pharmacy implementation with long-term and extensive implementation of e-pharmacy and Pyxis. Taranaki has probably the technically strongest team, the most ambitious roll-out in terms of breadth of scope (rather than number of beds) and has the closest scrutiny of what is happening at the ward level. **Taranaki is looking for the issues and is finding them.** Taranaki has the most comprehensive sense of what is needed to make ePA fully successful and is looking at the system as it is today, but with the issues and problems that might happen with a full hospital roll-out.
- Waitemata has pragmatically taken from both sites and has a substantial implementation in place, rapidly. Again, the pharmacy team is highly competent, and highly engaged. Waitemata has learnt through collaboration and sharing from both Taranaki and Southern and is attending to a roll-out that is likely to be the **closest to what other large hospitals in NZ will experience.** Waitemata is taking what appears to be the closest look at the alerts environment and is able to give a good exposition of the issues that will need to be managed in a general roll-out beyond the pilot sites.
- Counties Manukau is implementing eMR. The learning is important, but this is not where the main game is.

4.2 Site level observations show consistent themes

4.2.1 All the heat and noise is about ePA

There are a range of very significant commonalities from all of the sites. The commonalities that we have identified are as follows:

- **The application is emergent.** The initial impression on a visit to St Vincent's is that ePA is a mature application. It clearly is not. The implementation in St Vincent's is partial and has taken seven years of effort. There is at least three to five years of effort in development of ePA for New Zealand.
- **Considerable on-going effort is required to maintain and further develop the system.** Even ignoring the effort to implement the system, there will need to be considerable effort in maintaining and developing the decision support that underpins the system. The system is electronic and the quality management intelligence that comes from the system will be very useful, and will need to be used.
- **The vendor is unresponsive.** We would struggle to find any positive comment about the vendor in the site interviews. The pervasive view is negative; that the vendor is willing to play customers off against each other, that it is not able to deliver to timetable, if at all, and that it does not have the programming depth or level of organisation to carry the project through to the sites' satisfaction. Implementation and training support from the trainer is seen as weak. Enhancements are seen as expensive if they happen at all.
- **The application is out of date and difficult to work with.** As important as the vendor issues are concerns that the application structure itself is fragile. There is an undercurrent of comments around the difficulty and fragility of the rules engine, the difficulty of making simple fixes, etc.
- **A relatively common view of important fixes and developments.** On the positive side, the programme office has managed to pull together a comprehensive view of all issues and has made a good attempt to organise that view into a possible series of releases. Consistent across the sites, there is no faith that the vendor can give a secure timeframe for these fixes.

4.2.2 The differences are also important

The differences across the sites are also important to observe and also explain some of the context of the site experiences:

- **The primary difference is in how the risks are weighed.** Southern clearly has a view that the risks of paper charts are greater than the risks of ePA. The close inspection in Taranaki shows that the nature of errors changes, but certainly is not eliminated. The errors and the extent of harm identified in Taranaki are significant. In the weighing of risks, two sites see the risk as significant whereas Southern does not, possibly for the reasons expressed below about the philosophical difference in managing the application.
- **There is a philosophical difference of what can be done on site and what needs to be done in the application.** Taranaki feels that it has asked for a mature application and been delivered an integrated ePA application that does not work. In particular, the application has been promised for some years and there is a trail of broken promises. In Southern, there is a high level of familiarity with the system and a number of work-around breakthroughs. Southern is very much in reference site development mode.
- **All are running different versions.** The issues in one site do not easily reconcile to issues in another site, as each site has a different implementation. The version being used in Southern is three or four versions older than the Taranaki version.

- **Southern has a very high level of tailoring of the system**, which has been useful, but will be problematic as it moves to another version or if it is not able to move fast enough to document its procedures.
- **Different backgrounds in the pharmacy departments:** Taranaki has a long history of innovation in pharmacy and has a highly developed hospital pharmacy environment. ePA tends to take away from that environment. Whereas, in Southern, the system is very much driven by a doctor; the pharmacy department is relatively small and, because of that, operationally focussed. The pharmacy department is not on the Southern project board.

4.2.3 There are some non-controversial but important findings

There are some issues that can come off the table immediately.

- **There is no desire in any of the sites to resile from ePA.** All of the sites and all of the implementation teams have committed very significant national, DHB and personal resource to establishing the pilots and the subsequent roll-out on the pilot sites. No one is stepping away from the pilots. The benefits of the pilots, namely modernisation of the therapeutic aspects of a hospital, with electronic tools and decision support, are self-explanatory.
- **The roll-out pattern is well established.** All stakeholders speak highly of the roll-outs in all of the sites. The pattern of early preparation, pre go-live training and intensive post implementation support, is the same, and is successful.
- **The project is a clinical project supported by IT.** The configuration of the implementation team with an IT literate project pharmacist, a strong nurse advocate, supported by a senior clinician, and with IT support, is an agreed pattern of interests and involvement.
- **The critical elements of IT support are clear** and enabling of other activities. The roll-out of wireless and the upgrading of supporting PC's and portables is understood well and not overly costly. This infrastructure then enables other administrative and clinical support functions.

eMR is non-controversial

Another finding is that the eMR roll-out appears to be in hand and we make no further comment on it. Clearly, there will be additional cost, namely additional pharmacy resource, which will reveal itself in additional staffing or crowding out of other activities. But the roll-out is more straight forward, the implications are containable and Orion, the vendor, is performing well enough that there is smoke and noise, but not on the scale of the concerns around ePA.

4.3 Our suggestions for moving forward

We make some positive suggestions for moving forward.

4.3.1 First, know your baseline

The programme is still very opaque and is still working with an unexpected lack of formality. Therefore, some of the questions that should be easy to answer cannot be answered with finality or mandate. One such question is – what is the likely roll-out of ePA? The following was developed by the programme team and is its expectation of what is likely to happen. Such a roll-out plan has not been formally mandated but is more a general statement of expectation. This roll-out forecast is, we suggest, the baseline that the programme could be measuring itself against. It is dependent on satisfactory progress by the vendor on the critical functionality (Release 0) required for existing sites to expand, and new sites to initiate, roll-out.

Table 3 Rollout forecast – ePA

As at 14 June 2013

DHB	Beds total	Implemented beds / percentage of total							
		2013		2014		2015		2016	
Auckland	1125			250	22.22%	700	62.22%	950	84.44%
Bay of Plenty	484			100	20.66%	300	61.98%	420	86.78%
Canterbury	1389			800	57.60%	1100	79.19%	1250	89.99%
Capital & Coast	680							550	80.88%
Counties Manukau	950					350	36.84%	750	78.95%
Hawke's Bay	366							280	76.50%
Hutt Valley	385							300	77.92%
Lakes	228					100	43.86%	200	87.72%
Midcentral	506							380	75.10%
Nelson Marlborough	353							300	84.99%
Northland	327							250	76.45%
South Canterbury	211					60	28.44%	180	85.31%
Southern	743	450	60.57%	743	100.00%				
Tairāwhiti	125							110	88.00%
Taranaki	236	120	50.85%	150	63.56%	200	84.75%	210	88.98%
Waikato	928			100	10.78%	650	70.04%	800	86.21%
Wairarapa	92							65	70.65%
Waitemata	1048	300	28.63%	600	57.25%	800	76.34%	950	90.65%
West Coast	271					150	55.35%	250	92.25%
Whanganui	162							120	74.07%
Assumption 1:	Implementation timeframe range from 6 to 24 months								
Assumption 2:	Bed numbers are not fixed and vary due to operational requirements								
Assumption 3:	Current product scope excludes specialist functions such as paediatrics and oncology								
Assumption 4:	Uptake speed will vary and product scope could increase pace as increased functionality gets delivered								

Desired end state is increasingly clear but needs further work

The desired end state is that all New Zealand public hospitals will implement ePA and eMR systems. Following are the major sub-points to that statement:

- Electronic prescribing is the computer-based electronic generation, transmission and filling of a medication chart by a clinician with prescribing rights.
- Electronic prescribing includes clinical decision support to reduce prescribing error rates and automated order verification as part of the prescribing process.
- Electronic administration records and assists the process of administering medicine to a patient. It assists components of the ‘five rights’ of safe administration (right patient, right drug, right dose, and right route at the right time).

In our view, the release structure needs to become increasingly specific in terms of ‘bottom lines’ and enhancements for different medical settings. From our perspective, for instance, extension of the application into paediatrics versus adult medicine is a whole new ball game,

and a whole new release. We would recommend against it until the issues in adult medicine have been addressed. This is acknowledged given its status as a possible Release 1 (and not Release 0) enhancement deliverable.

4.3.2 ePA is an emergent application

The ‘fit for purpose’ ePA and eMR systems are expected to continuously evolve and their functionality and connectivity improved to better meet user needs. The first good attempt at setting out the structure of that functionality for ePA is expressed in R-1, etc. In essence, first make it safe in adult medicine, and then make it safe in other areas of medicine, and then integrate. The one exception is the need to integrate, as soon as possible, the New Zealand Universal Medicines List.

4.3.3 Focus on safety and adult medicine first

There is some hope that, with concentrated effort from the vendor, that the product could be made safe in adult medicine. From what we hear from the site visits, our recommendation is that there is no further roll-out until the existing safety issues are addressed. Moreover, it would be important to put the vendor, and other sites, on notice that this is the view from the pilots.

We do not believe that the vendor is capable of supporting a roll-out to paediatric wards in Canterbury. We do believe that it may be possible, but only with considerable, site specific development, but that the vendor cannot do the basics (Release 0) at the same time as extending into this new area.

4.3.4 Now is the point to standardise

There are three versions and one of those versions is heavily modified. This is an unnecessary level of complexity and misses a golden opportunity to standardise the application and to have a whole of system approach to the development path.

One example is the alert environment: the genesis of the alert environment appears to have been with early work with Southern. Consequently, Waitemata has taken this work as its own and is more active in managing and developing the decision rules as it rolls out. There is an opportunity to standardise the alert environment and to implement that environment through all hospitals. Likewise, Southern’s solution to the Insulin issue may be applicable to all sites. The programme has been strong on innovation, but now needs to be strong on standardisation and implementation.

There are costs and benefits to individual sites in this approach and pilot sites with their subsequent roll-outs may suffer some loss. Taranaki will not get the integrated solution that it wants as quickly as it needs – but it is not going to anyway. Southern’s approach to fixes and workarounds will need to be more thoroughly documented and tested, but may have a greater whole of system impact. The programme as a whole will move faster as the workload is spread around.

The national Programme Office is currently completing work on national processes to support a standard implementation of the ePA and eMR solutions. The challenge is to balance standardisation with the identification of local innovations; to evaluate these

innovations and, if found suitable, to include them in the national product for future national roll-out.

4.3.5 Programme structure needs to be formalised

We are aware that a lot of effort has gone into developing a national Programme Office, to focus on implementation and providing a national focus. However we saw clear evidence that there are still split accountabilities and a general need to formalise the programme in the manner is generally regarded as standard practice. For example, the likely national roll-out pathway was not documented; we needed to develop this through facilitated sessions with the Programme Office.

Our suggestion is that the regional and national programme teams are brought together as one sector team, with one sector-oriented implementation; thus balancing both national and local interests. The programme office will need to work to the sector including DHBs and not just to the Ministry of Health and HQSC.

4.3.6 Explore lateral options

Over time, it would be highly desirable to move to what we would call a standards approach rather than a vendor driven approach. There are other competitive products in the market and it may be that the threat of competition or actual competition could speed up the pace of change.

Appendix 1 Contributors

4.4 People interviewed

Persons interviewed in Southern:

- Andrew Bowers
- Richard Jocelyn
- Craig MacKenzie
- Dorothy Browne
- Kirsten Simosen
- Chris Still
- Chris Lodge
- Jodie Healey
- John Simpson
- Margot Love

In Counties Manukau:

- Dr Mary Seddon
- Marie Lewis
- Ashika Maharaj
- Anne Goddard
- Sanjoy Nand
- Nazanin Falconer
- Hannah O'Malley
- Gillian Robb

In Taranaki:

- Elizabeth Plant
- Tracey Watson
- Tania Williams
- Paul Dobson
- Anthea Machin
- Molly Perkins
- Kanak Ramyasiri
- Brett Greiner
- Katherine Fraser-Chapple
- Claire Barnfather
- Jackie Sewell

- Christopher Hopkins
- Kanaka Ramyasiri
- Ngaio Crook
- Gail Geange

In Waitemata:

- David Ryan
- Marilyn Crawley
- Dr John Scott
- Rachana Puliyananda Uthaiiah
- Ariel Hubbert

4.5 Expert contributors

Expert input on Report A was received from:

- Nirasha Parsotam (HQSC)
- Desiree Kunac (New Zealand Pharmacovigilance Centre)
- Dr Michael Tatley (New Zealand Pharmacovigilance Centre)
- Dr Chris Cameron (Capital and Coast DHB)

Contributions to Report B were received from:

- Anton Venter (eMM Programme)

The following experts assisted with the first round of site visits:

- Gayl Humphrey (National Institute for Health Innovation)
- June Tordoff (Centre for Health Systems, Otago University)