SYNERGIA

Safe Use of Opioids National Formative Collaborative Evaluation

A report for the Health Quality & Safety Commission

Dr Sarah Appleton-Dyer

Nishadie Edirisuriya

Alanna Soupen

Angela Boswell

8 November 2016

Synergia Ltd
P.O. Box 147 168
Ponsonby
Auckland 1144

www.synergia.co.nz

Contents

List of figures

List of tables

GLOSSARY

Care bundle: a structured way of improving the processes of care and patient outcomes; a small, straightforward set of evidence-based practices that, when performed collectively and reliably, improve patient outcomes.

Collaborative methodology: a short-term (6 to 15-month) learning system that brings together a large number of teams from hospitals or clinics to seek improvement in a focused topic area.

Control chart: a graph used to study how a process changes over time.

Expert faculty: a group of subject matter experts that was convened to recommend opioid-related outcome measures, and to support care bundle development; comprised of palliative care specialists, pain specialists and nurses, anaesthetists, medication safety specialists and pharmacologists.

Improvement science: a concept which focuses on exploring how to undertake quality improvement well.

Laney P' chart: a type of P chart that is used for large datasets.

Learning session: a national event where participating collaborative teams come together to share their improvement work and learn from each other; training is provided about the use of quality improvement tools and methods.

P chart: a type of control chart that is used to look at variation in yes/no type data.

Shared workspace: a secure, interactive website where members can add, update and manage their own content.

1 ACKNOWLEDGEMENTS

We would like to acknowledge the support of the stakeholders who took part in and contributed to this evaluation. This includes staff from the Health Quality & Safety Commission (the Commission) and district health boards (DHBs) that participated in the key informant interviews and focus groups. Their views and experiences have enabled the evaluation to provide a comprehensive insight into the Safe Use of Opioids National Formative Collaborative (the collaborative) and its outcomes.

2 EXECUTIVE SUMMARY

This report presents an evaluation of the Commission-led Safe Use of Opioids National Formative Collaborative. The collaborative was part of the National Medication Safety Programme that aims to greatly reduce the number of New Zealanders harmed each year by medication errors in our hospitals, general practices, aged residential care facilities and across the entire health and disability sector.

The goal of the collaborative was to reduce opioid-related harm in DHB hospitals, create care bundles for the safe use of opioids, and build capability in medication safety and improvement science.

2.1 The collaborative

The collaborative was a partnership between the Commission and teams from 20 DHBs across New Zealand, and MercyAscot, a private hospital. The collaborative was established in October 2014 and ran until the end of June 2016. The collaborative was unique in its:

- focus on reducing opioid-related harm in hospitals and working at a national scale
- focus on co-developing bundles of care with the sector, while also enhancing medication safety and quality improvement capability
- formative nature, whereby DHBs were encouraged to identify opioid-related harm from a list of key harm areas and potential interventions because there was no established bundle of care
- engagement of international experts from the Institute for Healthcare Improvement (IHI) to support the collaborative.

2.2 Evaluation approach

Synergia evaluated the application of the collaborative methodology and its role in reducing opioid-related harm, developing bundles of care, increasing DHBs' improvement science capability, creating a reusable clinical network, and supporting the development of an approach to effectively measure the implementation and achievements of the collaborative.

A process and outcome evaluation was conducted using a mixed methods approach. Synergia was not commissioned to undertake a value for money analysis.

2.3 Strategic fit

The collaborative contributes to the Commission's strategic priorities including consumer engagement, building leadership, developing the sector's capability for improvement and embedding measurement and evaluation. The extent to which this was achieved is explored through identifying the key outcomes of the collaborative and the processes that achieved this.

2.4 Care bundles and evidence-based interventions

The collaborative has enabled participating teams to contribute to a growing evidence base around opioid-related harm, identify and test interventions to address this harm, and informed the development of care bundles. To support the robustness of the bundles, the

Commission engaged sector and academic experts in a Delphi process, and further review from the Expert Faculty. This resulted in:

- 'emerging care bundles – opioid-induced constipation, opioid-induced ventilatory impairment and uncontrolled pain' (three separate care bundles for the three individual harm areas)
- 'emerging composite care bundle – opioid-related harm'.

The term 'emerging' is used because, while there was evidence for some of the individual interventions within each bundle, there is a lack of evidence on the effectiveness of the bundles of interventions when used collectively. As with other bundles of care, they will be further tested by the sector.

2.5 Reductions in opioid-related harm and raising the profile of medication safety

The collaborative set itself an aspirational target of a 25% reduction in opioid-related harm in the areas that participated. DHBs tested a range of interventions and collected data through a baseline and improvement period. This data indicates that:

- although 20 DHB teams and one private hospital started the collaborative, four DHBs did not collect data to contribute to the measurement approach
- reductions in harm could be calculated for 12 out of 17 hospitals that collected adequate baseline and improvement period data (including MercyAscot). A reduction in harm was achieved by seven out of the 12 hospitals
- seventeen DHBs trialled interventions to improve opioid medication safety processes[1]
- improvements in medication safety processes were achieved by 13 hospitals
- baseline data on medication safety processes was not reported by four hospitals.

Appendix 1 identifies the harm areas, interventions and reductions in harm for each DHB. The following dashboard focuses on the seven DHBs that achieved a reduction in opioid-related harms, as evidenced by a special cause or a statistically significant reduction.

[1] For the purposes of this report, 'medication safety processes' refer to interventions and processes tested through the collaborative to reduce opioid-related harms for patients.

Harm reduction dashboard

DHB level reduction

DHB	Constipation harm reduction
Counties Manukau DHB	–60%*
Lakes DHB	–44%*
Bay of Plenty DHB	–42%*
Capital and Coast DHB	–26%

DHB	Nausea and vomiting harm reduction
Auckland DHB	–13%

DHB	Respiratory Depression harm reduction
Mercy Ascot	–74%
Northland DHB	–56%**

Harm level reduction

Constipation	
Range of harm reduction	–26% to –60%
Number of DHBs that achieved over 25% harm reduction	4
Number of DHBs that achieved between 20% – 25% harm reduction	–
Number of DHBs that achieved between 10% – 19% harm reduction	–

Nausea and vomiting	
Range of harm reduction	13%
Number of DHBs that achieved over 25% harm reduction	–
Number of DHBs that achieved between 20% – 25% harm reduction	–
Number of DHBs that achieved between 10% – 19% harm reduction	1

Respiratory Depression	
Range of harm reduction	–56% to –74%
Number of DHBs that achieved over 25% harm reduction	2
Number of DHBs that achieved between 20% – 25% harm reduction	–
Number of DHBs that achieved between 10% – 19% harm reduction	–

National level harm reduction

Overall reduction in harm from opioids	
Range of harm reduction	–13% to –74%
Number of DHBs that achieved over 25% harm reduction	6
Number of DHBs that achieved between 20% – 25% harm reduction	0
Number of DHBs that achieved between 10% – 19% harm reduction	1

* Relative difference was statistically significant.

** The relative difference was calculated differently for Northland DHB than for other DHBs. Please refer to the overview table in Appendix 1 for further detail.

2.6 Changes in improvement science capabilities

Staff participating in the collaborative demonstrated an increase in their knowledge of improvement science over time.

- The number of DHB team members who said they had a moderate to high level of **improvement science knowledge doubled between learning sessions 1 and 3.**
- **Improvement science knowledge increased for 59%** (n=22) of the DHB team members; others already had a good understanding.
- Learning session survey respondents **increased their use of Plan-Do-Study-Act (PDSA) cycles**.

"I guess from a professional point of view, learning about PDSA cycles and the methodology. It's been really useful for me, a different way of thinking." (DHB 1)

2.7 Strength of the clinical network

To develop a reusable clinical network to support other medication safety initiatives and build sector leadership, the Commission facilitated national learning sessions and harm-based telephone conferences, and promoted regional networks. This supported learning across DHBs and the development of effective relationships or networks.

Nearly all learning session 3 survey respondents (91%, n=59) were willing to be part of a sustained clinical network. Ongoing support and communication with staff, increasing

opportunities to network and having the resources and time to engage were identified as important for achieving this.

"As a small hospital, the bigger DHBs are coming out with just as many challenges, so that's nice. Everyone's very happy to share the things that they've come up with, so you're not having to reinvent the wheel." (DHB 7)

2.8 Consumer engagement and benefits

Nationally, consumers were involved in the collaborative steering group, others were engaged to share their experiences of opioid-related harms through patient stories and some attended the learning sessions. For example, consumer team members from Lakes, Canterbury and Waitemata DHBs attended at least one learning sessions.

Hospitals engaged patients in informing and providing feedback on medication safety processes tested by the DHBs. DHB teams also shared patient stories at learning sessions. Consumer representatives were engaged at five of the DHBs.

Benefits for patients suggested through the evaluation included:

- improvements in opioid medication safety processes
- improvements in opioid-related patient care
- improvements in patient information and health literacy
- reductions in constipation, nausea and vomiting, and respiratory depression.

2.9 DHBs' engagement and application of improvement science

The Commission's national collaborative team highlighted the significance of all 20 DHBs signing up to be part of the collaborative at the start. The learning session surveys indicate that nearly all attendees rated their DHB's engagement as moderate to high.

The use of improvement science was supported by the development of multidisciplinary or inter-professional teams at most of the DHBs.

Most DHBs used improvement science. The DHB teams found improvement science valuable for supporting quality improvement and medication safety. Some teams had also shared their learnings with other areas of the hospital. Nearly all indicated that they would use improvement science in the future.

2.10 Effectiveness of the measurement approach in demonstrating improvement

The collaborative used data to identify reductions in harm. An online shared workspace was used to support DHBs in recording and sharing this data.

DHBs provided monthly reports and used the shared workspace to record their PDSA cycles. DHBs began reporting on their progress in June 2015 and provided monthly reports for nine months. Data from the shared workspace indicates that DHBs completed between 0 to 31 PDSAs, with an average of 15. It is likely, however, that this under-represents the work undertaken by the DHBs.

While this system supported data collection, the formative nature of the measurement approach made it difficult to aggregate data and identify the level of harm reduction across DHBs. The effectiveness of the measurement approach would have been strengthened through a more prescriptive approach. This could have involved shared definitions and measures of harm, and requiring baseline data to be collected within a specific time period. We understand, however, that the collaborative adopted a formative approach to build sector capability and ownership of the work.

2.11 Value of the Commission in supporting the collaborative

The evaluation highlighted the value of the support from the Commission's project team, particularly in relation to improvement science. DHB teams also noted the value of the learning sessions and particularly having support from international experts, such as Dr John Krueger (IHI). Others thought that some of the improvement science sessions were repetitive or too technical, and not all had the time to fully benefit from the support available.

2.12 Key barriers and enablers

Key factors that supported the collaborative related to the commitment and engagement of the DHB teams and their previous experience with improvement science, and the support provided by the Commission.

Key barriers to the success of the collaborative related to the capacity of the DHB teams to engage in the collaborative, the level of administration and time commitment, and the formative approach to identifying and measuring harms.

2.13 Key considerations

The evaluation has highlighted the following key considerations for conducting similar work.

- When adopting a formative approach to understand an area with little evidence of what works, consider initially engaging with a smaller sample of DHBs to develop an evidence base prior to engaging at a national level. This would avoid some of the challenges that related to the dual and parallel focus of developing an evidence base and building capability.
- The balance between being formative and prescriptive. While the former has benefits for engagement and capability building, it posed challenges for aggregating data to understand reductions in harm across the DHBs.
- Ensuring that the theory and technical language relating to the methodology are presented in a way that helps DHBs to apply the methodology. DHBs would have liked more practical examples that would better support DHBs to identify opportunities to apply the methodology to their clinical practice.
- Providing DHBs with clearer guidance on the commitment that is required in terms of time and resources.
- Responding to the variations in the capacity of DHBs, perhaps by providing more analytical support to those with small teams.

- Support the current clinical networks to engage in ongoing testing to further refine the bundles for the safe use of opioids.
- Support clinical networks to broaden their focus on medication safety and have opioids embedded into their programme of work.
- Consider the representation of a Māori cultural and consumer advisor on future Expert Faculty groups convened by the Commission. This will support improvement in consumer engagement and responsiveness to Māori at a national level.

3 Introduction

Opioids are a group of pain relief medicines that include morphine, codeine and oxycodone. They are a class of medicines that are very effective in managing severe pain. Effective pain control is particularly important for recovery from injury, surgery and illness. Patient safety is also an important aspect of effective pain control.

Opioids are also a class of medicines most commonly implicated in patient harm. There is limited evidence on the interventions that are effective in reducing opioid-related harm to support the development of best practice or a bundle of effective interventions.

In response to this gap, the Health Quality & Safety Commission (the Commission) led the Safe Use of Opioids National Formative Collaborative (the collaborative). The collaborative is part of the National Medication Safety Programme that aims to greatly reduce the number of New Zealanders harmed each year by medication errors in our hospitals, general practices, aged residential care facilities and across the entire health and disability sector.

The goal of the collaborative was to reduce harm from opioids in district health board (DHB) hospitals and build capability in medication safety and quality improvement. The collaborative also sought to create care bundles for the safe use of opioids in hospitals.

The collaborative began in October 2014 and ran for 20 months (until the end of June 2016) in partnership with representatives from 20 DHBs from across New Zealand, and MercyAscot, a private hospital.[2] The collaborative was unique in its:

- focus on reducing opioid-related harm in hospitals on a national scale
- focus on co-developing a bundle of care with the sector, while also enhancing medication safety and quality improvement capability
- formative nature, whereby DHBs were encouraged to identify their own harm areas and interventions
- engagement of international experts from the Institute for Healthcare Improvement (IHI).

The Commission works towards the New Zealand Triple Aim for quality improvement. The collaborative was designed to support each aspect of the Triple Aim.

This document presents a process and outcome evaluation of the Safe Use of Opioids National Collaborative from February 2015 to July 2016. The evaluation explored the role of the Commission in the collaborative, and the experiences and achievements of the DHBs both in terms of reducing opioid-related harms in hospital and increasing their medication safety and quality improvement capability.

3.1 Report structure

Following this introduction, the report provides an overview of the collaborative. Outcome and process data are then used to identify the development of a care bundle for reducing

[2] From this point forward DHB hospitals and teams will be used to refer to the 20 DHBs and MercyAscot.

opioid-related harm in hospitals, harm reduction achieved at each DHB and changes in medication safety and improvement science capability. The report then explores consumer engagement, the development of a sustainable clinical network and considerations for exploring value for money. The report then focuses on the implementation of the Model for Improvement Methodology through the collaborative and key considerations.

4 Safe Use of Opioids National Formative Collaborative

The Commission's *Open for Better Care* campaign focused on medication safety and targeted high-risk medicines. The collaborative was started, as part of this focus, in October 2014 and ran to the end of June 2016, as a partnership between the Commission and DHBs. In this respect, the Commission worked alongside DHBs to facilitate their buy-in and ownership of the collaborative.

The collaborative aimed to reduce opioid-related harm in DHB hospitals, build capability in medication safety and quality improvement, and create care bundles to improve opioid safety. Similar approaches have been adopted in Australia, Canada and the United States of America, where collaborative methodologies have been incorporated into national medication safety and harm reduction plans. A unique aspect of the approach adopted by the Commission was the formative nature of the approach, its national scale and in-hospital focus.

The limited evidence on effective interventions to reduce opioid-related harm and the multiple types and definitions of opioid-related harms were also unique aspects of the context within which the Commission and DHBs were seeking to achieve change.

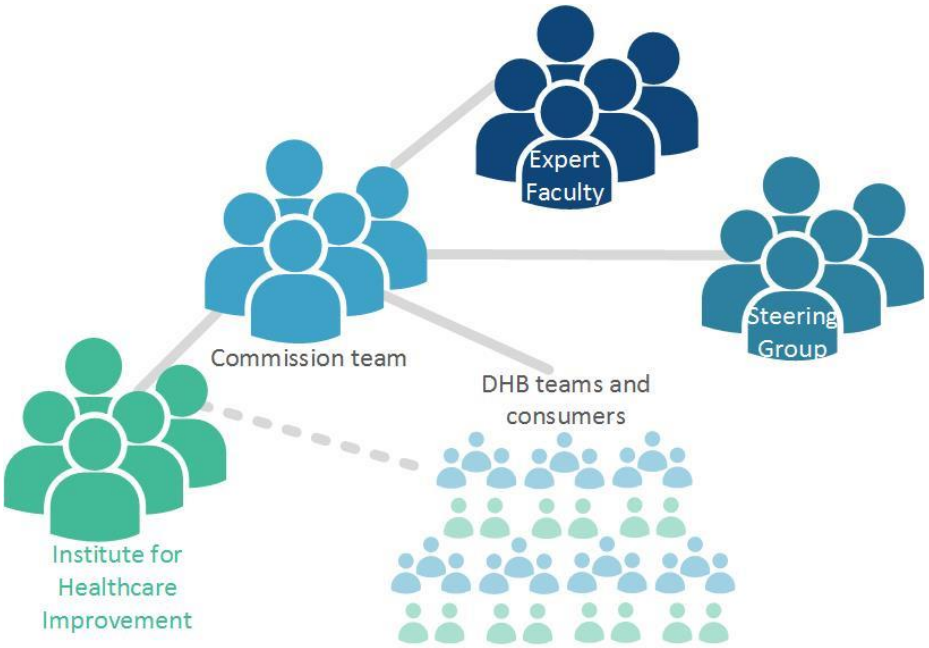
The Commission worked collaboratively with 20 DHB hospitals and one private hospital to establish this evidence and inform the development of a bundle of interventions to reduce opioid-related harm. DHBs were encouraged to identify their own high harm area from a list and use their expertise and experience to identify the interventions that they would implement to address these harms. The identification and testing of these interventions was supported by the application of improvement science to support learning and continuous improvement.

4.1 Infrastructure of the Safe Use of Opioids National Formative Collaborative

The collaborative was led by the Commission and supported by the Expert Faculty, a national clinical lead, the collaborative Steering Group and the Commission team.

- The Expert Faculty was made up of subject and quality improvement experts.
- The Steering Group provided overall guidance and governance to the collaborative.
- The Commission's national collaborative team managed the collaborative and provided support to the DHB teams.
- The DHB teams applied the Model for Improvement at the local level.
- Consumers were engaged in the collaborative through sharing patient stories, actively participating in some DHB teams and learning sessions, and testing interventions.
- IHI provided independent expert advice and mentoring.

The following diagram represents the structure of the collaborative.



4.2 Why focus on opioids?

The harm from inappropriate opioid use can include potentially life-threatening over-sedation and respiratory depression (opioid-induced ventilatory impairment leading to respiratory arrest, if not recognised and corrected). The most commonly identified harms include nausea, vomiting, constipation, delirium, hallucinations, falls, hypotension and aspiration pneumonia.

The extent of this harm has been demonstrated internationally and locally, and is the reason opioids have featured at the top of the US Institute for Safe Medication Practices High-Risk Medicines list since 1989. This high rate of harm and the potentially fatal harm that can result from opioid-induced ventilatory impairment mark opioids as 'high-risk' medicines – indicating that special care is required when they are prescribed, dispensed, supplied, stored and administered.

Given the strong evidence for the high-risk of harm associated with opioid use, the Commission's Medication Safety Expert Advisory Group identified that high-risk medicines (and specifically opioids) should be a key focus of Commission's medication safety campaign. However, no universally accepted bundle of evidence-based interventions to reduce harm related to opioids existed, with evidence for any one intervention identified being modest.

The collaborative was proposed to the Commission's Board members to address this gap and to develop a bundle of care in New Zealand. The unique approach resulted in a number of discussions and feedback from the Board. Notes from these discussions indicate that the collaborative was considered to be valuable for:

- creating a reusable clinical network for further work to decrease harm from high-risk medicines

- targeting the safe use of opioids in hospitals, which provided a tightly defined area to develop and implement interventions. This approach to targeting opioid-related harm was seen as a more feasible first stage than approaches that aimed to tackle broader issues of addiction and poisoning that occur in the community
- providing an avenue to spread quality improvement capability
- placing consumer or patient understanding of their treatment at the centre, and supporting participation in joint decision-making.

In 2014, the safe use of opioids was identified as a focus of the high-risk medicines campaign, which was the fourth topic in Commission's *Open for Better Care* Campaign.

4.3 Collaborative focus

Underpinning all the Commission's work and focus of efforts are the principles of the New Zealand Triple Aim. In considering how these principles can effect change and improvement in the harm caused by the use of opioids, the Commission considered where they could make the greatest impact and get the best value for money. To achieve improvements in opioid-related harms for all populations, the Commission sought to work with all 20 DHBs across New Zealand.

This required the Commission to engage with each of the DHBs and identify a means of encouraging and supporting them to take ownership of the collaborative. The flexibility and formative nature of the collaborative was considered to be important for supporting this. This enabled DHB hospitals to identify their own areas of opioid-related harms from a list identified by the Expert Faculty[3] and the interventions that they would implement to address them.

The application of improvement science (Model for Improvement for testing these interventions) was designed to support improved quality, safety and experience of care for patients.

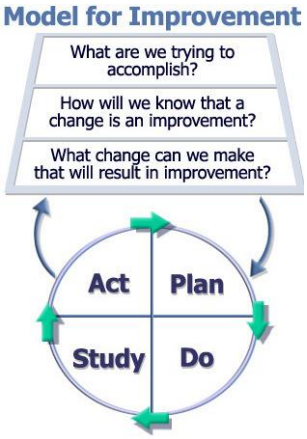
The collaborative also aimed to support the Commission's strategic priorities. These priorities and the collaborative's contribution to them are identified in Section 6.

4.4 Breakthrough Series: Institute for Healthcare Improvement's Collaborative Model for Achieving Breakthrough Improvement

The national project team involved five staff from the Commission. This included expertise in medication safety and quality improvement, which was bolstered by the engagement of the team from the IHI in the United States of America, in particular, Dr John Krueger.

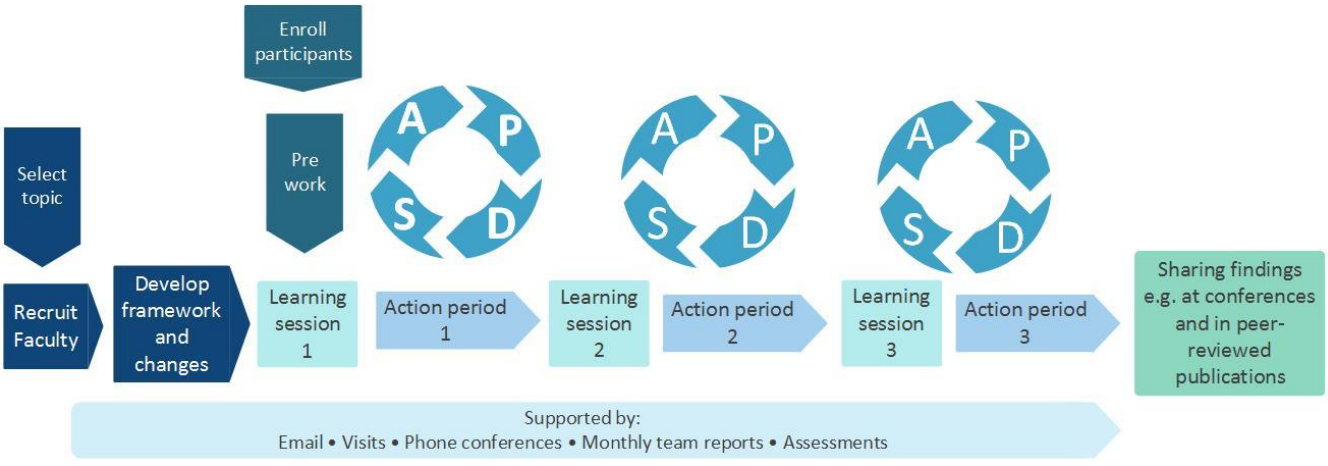
[3] An Expert Faculty of palliative care specialists, pain practitioners, anaesthetists, medication safety and quality improvement specialists to work with the collaborative (details are provided in Appendix 2).

Dr John Krueger works as a health care executive and health care consultant. He has developed integrated pain management programmes and worked on population safety interventions related to opioid safety. Dr Krueger has a background in medication safety, reliability, public health and quality improvement. Dr Krueger provided regular support to the national project team and supported engagement with DHBs through learning sessions and telephone conferences.



The IHI collaborative methodology is underpinned by the Model for Improvement. The model promotes improvement and testing changes on a small scale by using Plan-Do-Study-Act (PDSA) cycles. This approach seeks to understand if changes in an outcome of interest are due to natural variation or relate to a special cause, that is, the intervention(s) that a hospital might use to reduce opioid-related harm.

The collaborative used the IHI Breakthrough Collaborative Methodology. The collaborative involved three two-day national learning sessions and a one-day national workshop that brought together representatives from the DHB hospitals. Four regional one-day workshops were hosted prior to the national meetings to build engagement. The learning sessions sought to increase attendees' understanding of improvement science. The sessions also provided an opportunity to share learning across DHBs and/or the specific harm areas that they were working on. Site visits from the project team to DHB hospitals were also designed to support the quality improvement capability of the hospitals by providing site-specific feedback. The following diagram represents the IHI Breakthrough Collaborative Methodology that the collaborative followed.



4.5 Understanding outcomes

The collaborative set an ambitious national aim of a **25% reduction in opioid-related harm,** a percentage reduction decided upon by the Expert Faculty group.[4] Other key outcomes of the collaborative included **improvements in medication safety and quality improvement capability** across the DHB hospitals, the **creation of an evidence-based bundle of interventions** and the **development of clinical networks**.

To track a reduction in harm, each participating DHB had to identify a harm area to focus on. DHBs began by reviewing their own indicators of opioid harm, using a range of tools and local data, for example, the Global Trigger Tool. In addition, they considered events from pharmacy reporting systems, coding data, complaints and local incident or event reporting. Areas of harm that DHBs identified were constipation, nausea and vomiting, uncontrolled pain and respiratory depression.

Each DHB had to decide which area(s) or ward(s) of the DHB would be participating in the collaborative. DHBs were required to consistently measure their progress using the IHI's self-assessment tool.

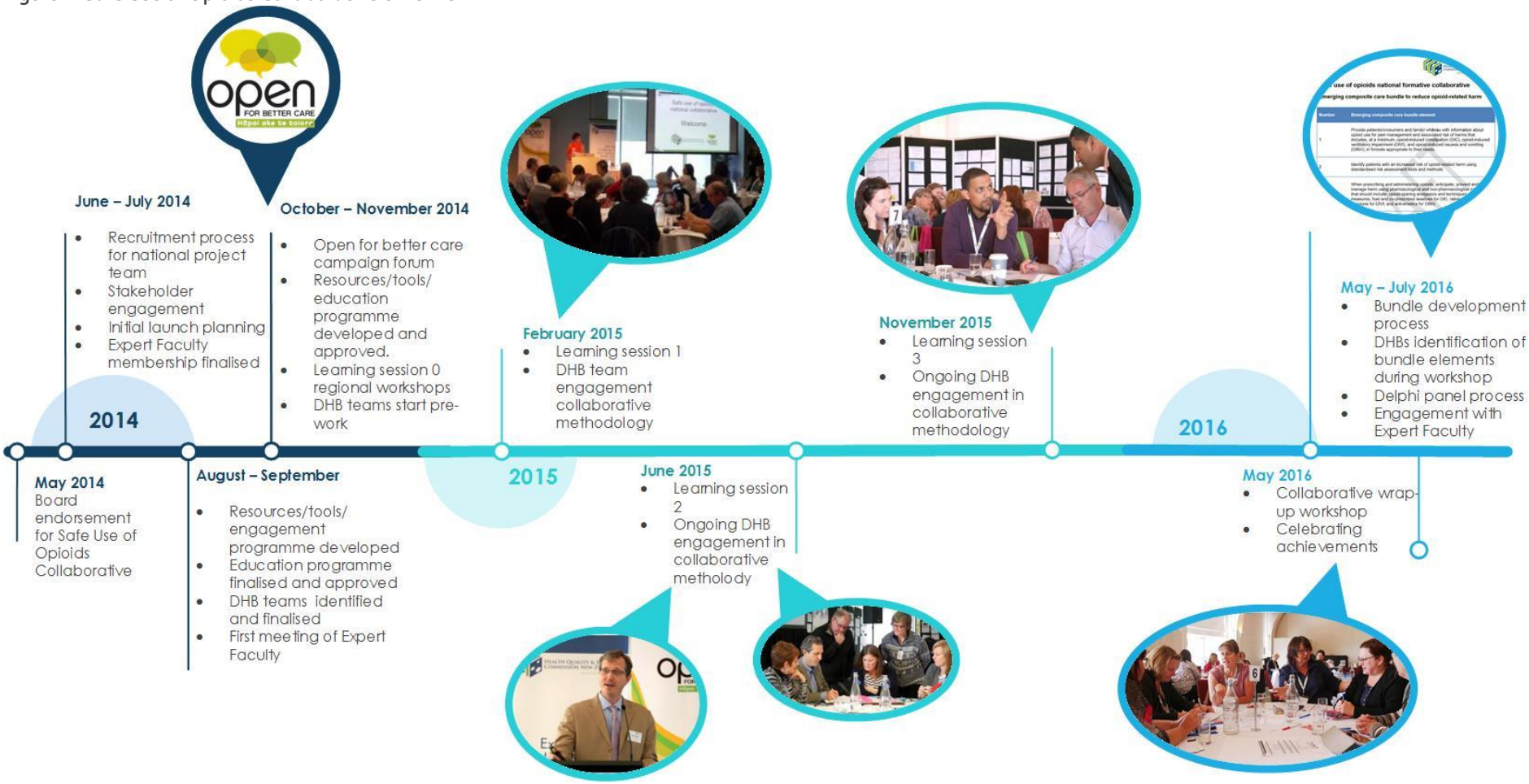
During the collaborative, participants assessed the viability of the manual collection of data with the aim of developing valid, reliable measures without undue strain on the health care sector workforce. Using these measures, the DHBs collected data through a baseline and improvement period. An analysis of this data supported the DHBs, the Commission and the evaluation to identify any reductions in harm, as well as the interventions associated with any reductions in harm.

Improvements in medication safety and quality improvement capability were identified through surveys, interviews and focus groups with DHBs. The Commission set up a Delphi process to use clinical expertise to review and identify the interventions to be included in the emerging care bundles.

The timeline in Figure 1 (next page) provides an overview of the collaborative.

[4] An Expert Faculty of palliative care specialists, pain practitioners, anaesthetists, medication safety and quality improvement specialists to support the collaborative.

Figure 1: Safe Use of Opioids Collaborative timeline



5 EVALUATION AIMS AND OBJECTIVES

The evaluation aimed to evaluate the effectiveness of the collaborative methodology as an approach to reducing opioid-related harm, and identify key considerations to support the success of the collaborative.

The objectives of the evaluation were to evaluate the application of the collaborative approach and its role in:

a) reducing opioid related-harm in participating DHB areas

b) identifying a set of evidence-based interventions to create a bundle of care to reduce opioid-related harm that can be spread across the health sector

c) increasing the capability within DHBs in improvement science (principally the use of the Model for Improvement)

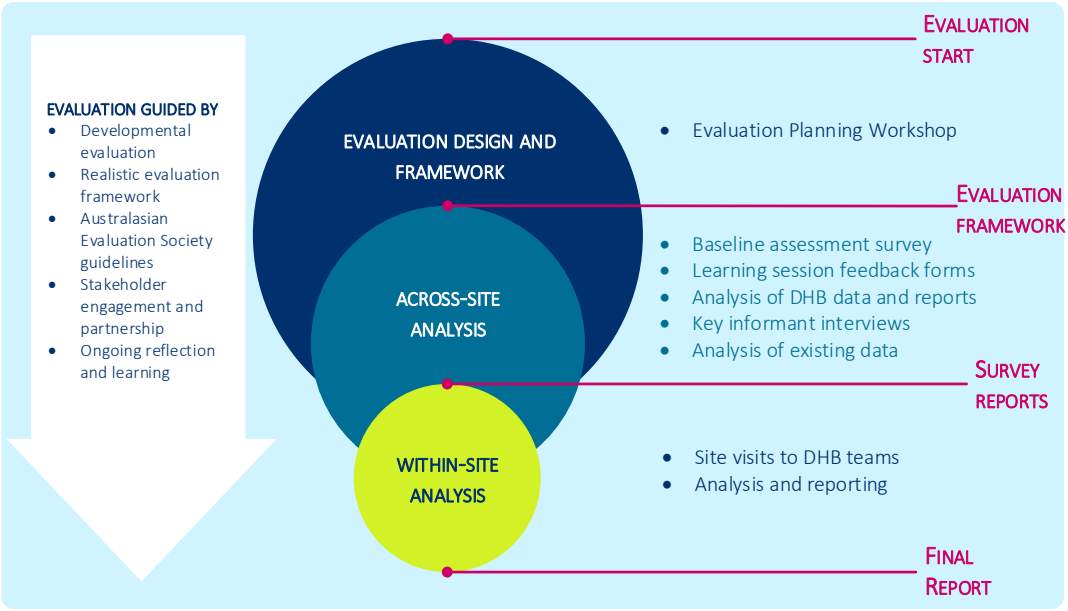
d) creating a reusable clinical network for further work in medication safety

e) supporting the development of the measurement approach (measures, data collection, analysis and reporting) at a national and DHB level that are effective in demonstrating change and/or improvement.

5.1 Evaluation approach and methods

The evaluation adopted a mixed-methods approach. This included data collection across all DHBs and a more in-depth analysis of a sample of DHBs. Figure 2 presents an overview of the evaluation approach.

Figure 2: Evaluation approach, methods and key phases



The analysis across all DHBs examined the implementation and outcomes of the collaborative across all participating DHB teams. This phase included the collection and analysis of data from the following sources:

- learning session feedback forms to support continuous improvement of the learning sessions
- learning session evaluation surveys to track changes in medication safety and quality improvement capability from DHB staff who attended the learning sessions
- analysis of DHB data from the baseline and improvement period to identify any reductions in harm and improvements in opioid medication safety processes used in the hospitals.

The evaluation also engaged a sample of DHB hospitals in site visits. These site visits were designed to provide a more in-depth insight into the implementation and outcomes of the collaborative from the perspective of the DHB teams. A total of six DHB hospitals were visited; three after the first six months in July–August 2015 and the second three towards the end of the collaborative in May 2016. We also conducted a telephone interview with one of the DHBs that did not collect any data through the collaborative.

DHB sites were selected to provide insights from those that appeared to be experiencing success, as well as those that were finding things more challenging. This was designed to provide feedback to support the ongoing development of the collaborative.

Consultation with the Commission, the learning session 1 survey report and an analysis of the Commission's data on progress at each DHB informed the selection of DHB sites. The sites were selected to include a range of geographical locations, rural/urban and high/low application and/or progress with the actions needed to support the collaborative at a DHB level.

The DHB site visits involved focus groups and interviews with 38 staff. This evidence was important for providing a deeper understanding of the views and experiences of the DHBs. Six interviews with project team staff were also completed for the evaluation.

5.2 Limitations

Key limitations of the evaluation related to the availability of data on harm reduction for both the baseline and improvement period for all DHBs. While most of the 17 DHBs that engaged fully in the collaborative collected data, it was not always consistently collected over the baseline and improvement period. This challenged the ability of the evaluation to identify reductions in opioid-induced harm across all 17 DHBs. The level of data collection, including the samples sizes, variations in definitions of harm and simultaneous implementation of different improvement processes also challenged the potential for the evaluation to attribute changes in harm to specific interventions or processes.

Another key limitation related to the voices of consumers. It would have been valuable to understand the consumers' experiences of the interventions tested through the collaborative. This would have provided a useful insight into those that they considered to be most useful. A consumer perspective may have also identified a broader range of consumer benefits that were not identified through the DHB data collection.

6 STRATEGIC FIT

The programme contributes to the Commission's strategic priorities through:

- **engaging consumers** in developing information to support a better understanding of opioid-related harm on patients, and developing and providing feedback on interventions to reduce harm. Benefitting consumers through reducing opioid-related harms and improving medication safety
- **building leadership** nationally through the project team's facilitation of the collaborative, and supporting regional and local leadership through the promotion of knowledge sharing and regional networks
- **developing the sector's capability for improvement** through providing national, regional and local support that has increased the medication safety and quality improvement capabilities of DHB teams
- **embedding measurement and evaluation** into the programme through developing a measurement approach to collect data on harm reduction and improvements in medication safety processes. Commissioning an evaluation of the collaborative.

Evidence on how the collaborative supported these priorities is explored throughout the evaluation report.

7 EMERGING COMPOSITE BUNDLE OF CARE BUNDLES AND EVIDENCED-BASED INTERVENTIONS

The IHI developed the concept of 'bundles' to help health care providers more reliably deliver the best possible care for patients undergoing particular treatments with an inherent risk of harm. An IHI's definition of a bundle is a 'structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices – generally three to five – that, when performed collectively and reliably, have been proven to improve patient outcomes'[5].

The formative nature of the collaborative resulted in an increased evidence base for interventions that have the potential to reduce opioid-related harm in hospitals. This bundle of interventions provides an important contribution to the limited existing evidence on what can reduce opioid-related harm in hospitals. The level of the evidence varied across the DHB hospitals, depending on the amount of data that each hospital collected during the baseline and improvement period. While this evidence was practice based, the Commission considered that the identification of specific interventions to be included in an emerging bundle of care would benefit from review by leading academic and sector experts. This was achieved through a Delphi process.

The Delphi process is designed to increase transparency and rigor to consensus-based exercises. Delphi supported the Commission to understand how strong or weak the various elements were in terms of group consensus (usually by way of the median), the degree to which the values for each element differed from the mean (standard deviation), and the degree of agreement on the rating of the elements between the raters in the panel (coefficient of consensus, which is based on the kappa statistic).

The evidence from the DHBs on reducing levels of harm and the associated interventions was used to inform the process for refining and developing the emerging bundles of care. Specifically, the Delphi process was used to develop:

- 'emerging care bundles – opioid-induced constipation, opioid-induced ventilatory impairment and uncontrolled pain' (three separate ones for the three individual harm areas)
- 'emerging composite care bundle – opioid-related harm' (the composite bundle).

The term 'emerging' is used because, while there was evidence for some of the individual interventions within each bundle, there is a lack of evidence surrounding the bundle of interventions when used collectively.

[5] Resar R, Griffin FA, Haraden C, Nolan TW. Using Care Bundles to Improve Health Care Quality. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2012. (Available on www.IHI.org)

These emerging care bundles will be further tested within the sector. It is anticipated that the bundles will be tested by some of the DHBs involved in the collaborative with support provided from the Commission.

The development of individual **'emerging care bundles'** for constipation, opioid-induced ventilatory impairment and uncontrolled pain, and the **'emerging composite care bundle'** for the safe use of opioids involved three steps.

1. DHB teams identified the '**elements'** (interventions) they believed should go into the three harm bundles at a national workshop on 4 May 2016; these were refined by the national collaborative team and the details checked with the DHB project leads; three bundles were confirmed.

2. The three harm bundles were then reviewed by **Delphi panels** convened specifically for the task; members scored the bundle elements based on their suitability for inclusion in an 'emerging composite care bundle' (covering all three harm areas); a consensus was achieved after the first round.

3. The collaborative's **Expert Faculty** was reconvened to finalise three harm bundles and to create the emerging composite care bundle.

    - At a workshop in June 2016, Expert Faculty members participated in a Delphi round to finalise the three harm bundles (a consensus was achieved, subject to editing of the elements).
    - Expert Faculty members then agreed the emerging composite care bundle elements; these were further refined by the Commission's **national collaborative team** after the meeting, and two Delphi rounds with the Expert Faculty were conducted and a consensus was reached.
    - The elements of the three harm bundles were then edited to align them with the emerging composite care bundle element wording; the Expert Faculty then participated in two further Delphi rounds before a consensus was reached on the harm bundle elements.
    - DHB teams have been involved at various stages of this bundle development process.

Further detail on the Delphi process can be found in Appendix 2.

7.1 Emerging composite care bundle

At the time of the evaluation, the emerging composite care bundle for opioid-related harm was one of the first of its kind. To be included in the composite care bundle, an element had to:

- have an average Delphi rating of at least 3 (contribute at least an average level of value to the bundle or having at least a moderate level of evidence)
- have a consensus level of at least 60%.

merging composite care bundle.

Table 1 below identifies and describes the five elements included in the emerging composite care bundle.

Table 1: Emerging composite care bundle

	Emerging composite care bundle element
1	**Patient/whānau information** Provide patients/consumers and family/whānau with information about opioid use for pain management and associated risk of harms that includes, at a minimum, opioid-induced constipation (OIC), opioid-induced ventilatory impairment (OIVI) and opioid-induced nausea and vomiting (OINV), in formats appropriate to their needs.
2	**Identify patients at increased risk** Identify patients with an increased risk of opioid-related harm using standardised risk assessment tools and methods.
3	**Utilise pharmacological and non-pharmacological approaches** When prescribing and administering opioids, anticipate, prevent and manage harm using pharmacological and non-pharmacological approaches that should include: opioid-sparing analgesics and techniques; dietary measures, fluid and co-prescribed laxatives for OIC; rational use of naloxone for OIVI; and anti-emetics for OINV.
4	**Monitor and document to identify harm and the effectiveness of any related interventions** Monitor and document to identify harm (sedation level and respiratory rate, bowel movements, nausea and vomiting, pain behaviours/indicators) and effectiveness of any related interventions, using evidence-based guidelines and methods.
5	**Regular staff education** Regularly educate staff about pain management and opioid use, opioid-related harms and risk reduction strategies. Education includes assessment of knowledge and skills, educational intervention(s) and reassessment.

This composite bundle reflects the key interventions that were tested in the sector to support a reduction in opioid-related harms in hospitals. The data that informed this bundle is explored in detail in the following section.

8 REDUCTIONS IN OPIOID-RELATED HARM AND RAISING THE PROFILE OF MEDICATION SAFETY

The collaborative set an aspirational target of achieving a 25% reduction in the level of opioid-related harm during the testing period. During the collaborative, DHBs were testing interventions aimed at reducing opioid-related harms. The specific harm areas were identified and selected by the DHBs from the list of harms agreed by the Expert Faculty.

DHBs were supported to collect data through a baseline and improvement period. While DHBs were encouraged to complete this process at the same time, there was naturally some variation in the specific timing of the baseline and improvement periods. The timing of baseline data collection was also affected because three DHBs, Whanganui DHB, Hawke's Bay DHB and South Canterbury DHB, did not find any harm in their initial chosen area and needed to identify another harm area.

The Commission provided a shared workspace for the DHBs to capture data through the collaborative. The aim of the workspace was to share documents between DHBs participating in the collaborative. This structure helped the Commission to provide support and feedback to DHBs.

8.1 Relative difference in opioid-related harm

Baseline and improvement period data was available to calculate reductions in harm for 12 out of the 17 participating hospitals (including MercyAscot). The remaining five hospitals did not collect baseline data. However, data on improvements to opioid-related medication safety processes at these hospitals was available. An overview of this data is provided in Appendix 1.

To assess the level of harm reduction at participating DHB hospitals, the relative difference between the average proportion of harm during the baseline period and the average proportion of harm during the improvement period was calculated. Relative differences are useful for understanding the reduction in harms, because the baseline and improvement period sample sizes were often quite different.

The use of ratios to identify the relative differences in harm takes into account the sizes of the different samples. These ratios are expressed as percentages in this report to identify the percentage reduction in harm.[6]

[6] Relative differences were calculated by expressing the change in the level of harm as a percentage of the level of harm during the baseline period. The same method was used to calculate relative differences in the implementation of medication safety processes. However, the baseline and improvement samples consisted of different sets of patients, because the collaborative took place in hospitals over a long period of time. Therefore, although the level of harm during the baseline period is the denominator in the calculation of relative differences, it is not appropriate to use it as an 'n' or sample size value. For this reason, it has not been possible to report sample sizes for relative differences.

In line with the improvement science approach, statistical process control charts were used to identify whether the process was exhibiting a special cause variation in data that supported the improvement.

Following this, the Commission used a two-sample test of proportions to calculate the statistical significance of any differences observed. This test identifies if the differences between two proportions are significant, that is, due to the interventions and not by chance.

The small baseline sample sizes at some DHBs and the inconsistency of data collection across the baseline and improvement period meant that the relative difference in harm between baseline and improvement did not always accurately represent DHBs' progress. For these reasons, caution needs to be taken when interpreting p-values (statistical test results). The identification of a special cause is perhaps more useful and appropriate for interpreting the quality improvement data collected by DHBs.

8.2 Constipation

Constipation was identified as a harm area by 10 DHBs. In reflection of the formative collaborative approach to reducing harm, DHBs were able to define their own measurement of constipation and identify the interventions that they chose to test (Table 2).

Table 2: DHBs focusing on reducing the harm from opioid-related constipation for patients: measurements and interventions

DHB	Measurement	Interventions
Bay of Plenty	Percentage of patients identified with constipation (≥3 days since bowels last opened) who were prescribed regular and pro re nata (PRN – as needed) opioids	• Bowel monitoring (recording of bowel activity) • Prescribing of laxatives • Co-prescribing of laxatives (prescribing opioids and laxatives on the same day) • Regular administration of laxatives
Capital and Coast	Rate of opioid-induced constipation (bowels not opened in 72 hours post-commencement of an opioid)*	• Bowel monitoring • Co-prescribing of laxatives • Administration of prescribed laxatives in the past 24 hours
Counties Manukau	Rate of opioid-induced constipation (bowels not opened ≥3 days) (length of stay >24 hours)	• Co-prescribing of laxatives • Administration of =/>1 dose of co-prescribed laxatives • Bowel monitoring
Hawkes Bay	Percentage of patients receiving opioids who experienced constipation (no bowel activity ≥3 days) during admission*	• Bowel monitoring (documentation of bowel activity) • Patient and staff education
Lakes	Percentage of patients identified with constipation (≥3 days since bowels last opened) who were prescribed opioids during admission*	• Bowel monitoring (Early Warning System bowel monitored every shift) • Laxative given proactively • Non-pharmacological interventions (Kiwicrush and prunes)

DHB	Measurement	Interventions
		• Changing ondansetron position on post-operative nausea and vomiting sticker • Reducing ondansetron administration
MidCentral	Percentage of patients identified with constipation (≥3 days since bowels last opened) who were prescribed regular opioids	• Co-prescribing of laxatives • Bowel monitoring ('days since bowels last opened' used in clinical notes) • Bowel monitoring (bowel function documented in clinical notes) • Patient and staff education
Nelson Marlborough	Percentage of patients identified with constipation (≥3 days since bowels last opened) who were prescribed regular opioids	• Co-prescribe laxatives • Bowel monitoring ('days since bowels last opened' used in clinical notes) • Bowel monitoring (bowel function documented in clinical notes)
Taranaki	Percentage of patients identified with constipation (≥3 days since bowels last opened or enema required) who were prescribed regular opioids	• Bowel monitoring • Laxative charted • Co-prescribing of laxative • Administration of laxative
Waikato	Percentage of patients identified with constipation (≥3 days since bowels last opened) who were prescribed opioids during admission*	• Bowel monitoring (bowel activity documented daily) • Laxative prescribed at the same time as opioid
West Coast	Percentage of patients who received opioids who experienced constipation (≥3 days since bowels last opened)*	• Bowel monitoring (recording of bowel movement) • Regular administration of laxative charted

* Including any opioid, that is, regular and/or pro re nata.

8.2.1 Improvements in opioid-related harm

Changes to the level of opioid-related harm could be calculated for 7 out of the 10 DHBs focusing on constipation. Changes in harm could not be calculated for three DHBs, because they did not collect reliable baseline and improvement data, Hawke's Bay, Taranaki and West Coast DHBs). It is useful to note that these DHBs did collect data during the improvement period, which is described in this section. Hawke's Bay also experienced difficulties in identifying opioid-related harms, which impacted on its ability to collect baseline data.

Table 3 summarises the relative difference in opioid harm between the baseline and improvement period for each DHB. The table also identifies if the variation indicated the presence of a special cause, statistical differences between the baseline and improvement period (p-value), and the baseline and improvement sample sizes (number of patients involved in the testing).

Table 3: Improvements in opioid-related harm: constipation

DHB	Relative difference in harm	Special cause indicated?	Statistically significant at the 0.05 level?	Baseline sample size (no. of patients)	Improvement sample size (no. of patients)
Counties Manukau	-60%	✓	✓	60	275
Lakes	-44%	✓	✓	107	176
Bay of Plenty	-42%	✓	✓	90	529
Nelson Marlborough	-33%	No	No	42	338
Capital and Coast	-26%	✓	No	18	140
MidCentral	-15%	No	No	66	262
Waikato	+12%	No	No	69	133

A review of Table 3 indicates a reduction in harm at six of the DHBs and an increase for one DHB (Waikato DHB). Changes in the level of relative difference, however, must be interpreted alongside the data relating to a special cause, statistically significant differences and the size of the baseline and improvement period samples. The interpretation of this data is presented in the following sections, alongside the data on improvements in medication safety processes.

8.2.1.1 Relative reductions in opioid-related harm and a special cause

Four DHBs achieved at least a 25% relative reduction in opioid-related constipation that could be attributed to a special cause. This special cause provides evidence that the reduction in harm was influenced by the medication safety improvement processes tested by the following DHBs:

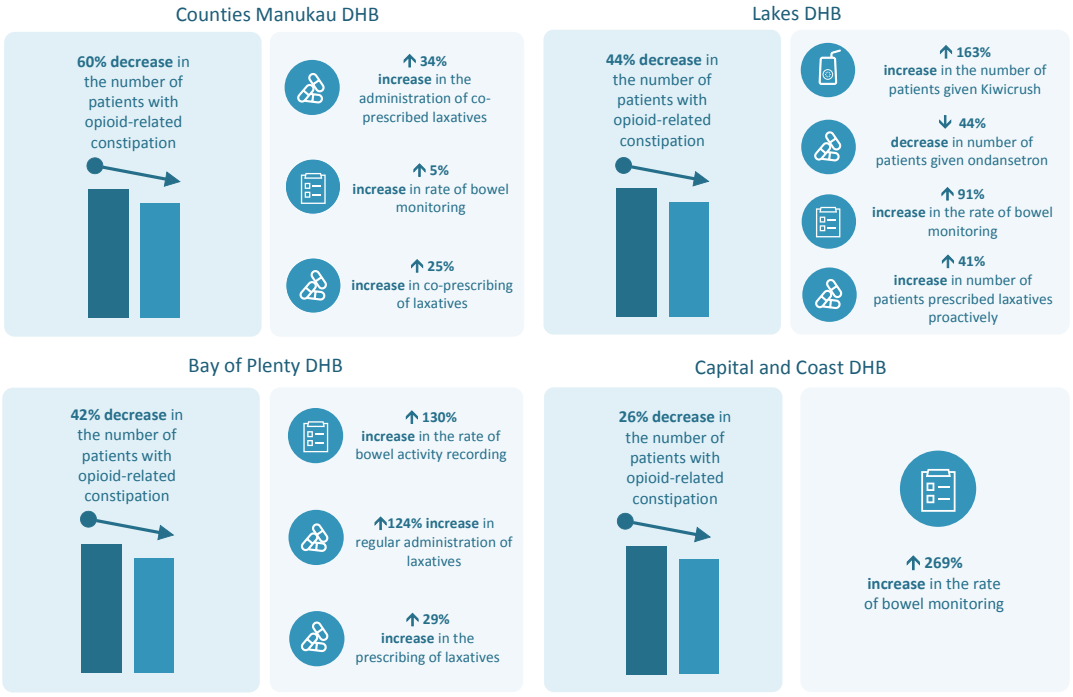
- Counties Manukau
- Lakes
- Bay of Plenty
- Capital and Coast.

Reductions in opioid-related harm were also statistically significant for three of the DHBs. While the result for Capital and Coast was not statistically significant at the 0.05 level ($p=0.331$), its p-value must be interpreted with caution due to the small baseline sample size (18 patients) relative to the improvement period (140 patients).

Each of these four DHBs exceeded the aspirational national aim of achieving a 25% reduction in opioid-related harm in their test area or ward.

8.2.1.2 Medication safety processes that supported a reduction in opioid-related harm and a special cause

The medication safety processes[7] that supported reductions in opioid-related harm with a special cause indicated are identified in the following infographics. The infographics focus on the medication safety processes that achieved a statistically significant increase in the use of these processes between baseline and the improvement period. Detail on all of the process measures and reductions in harm are presented in Appendix 1.



While no baseline data was available for the co-prescribing of laxatives at Capital and Coast DHB, the control chart for this process measure shows an increase in the rate of co-prescribing laxatives over time (Figure 16, Appendix 3). The proportion of people during the improvement period for which co-prescribing occurred was 69%.

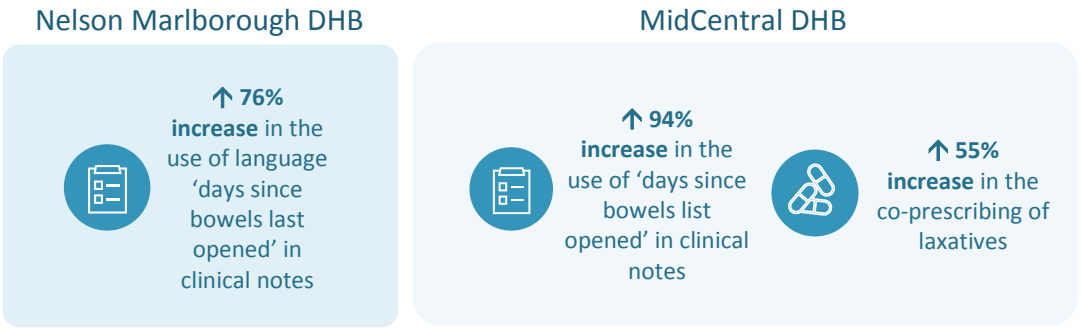
8.2.1.3 Relative differences not attributed to a special cause

The reduction in opioid-related constipation during the improvement period for Nelson Marlborough DHB and MidCentral DHB could not be attributed to a special cause, and results for both DHBs were not statistically significant. The data, however, did indicate a

[7] For the purposes of this report, 'medication safety processes' refer to interventions and processes tested through the collaborative to reduce opioid-related harms for patients.

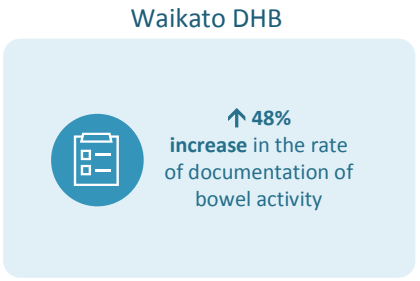
reduction in the number of patients who had not had a bowel movement in three or more days.

These DHBs were adopting similar interventions to other DHBs, with the data suggesting a statistically significant improvement in opioid medication safety processes aimed at reducing the harm caused to patients from constipation.



8.2.1.4 Suggested increases in opioid-related harm

At Waikato DHB, opioid-related constipation was 12% higher during the improvement period (n=133) than during the baseline period (n=69). However, no special cause was indicated by the control chart tests suggesting that the difference observed is due to normal variation (Figure 15, Appendix 3).



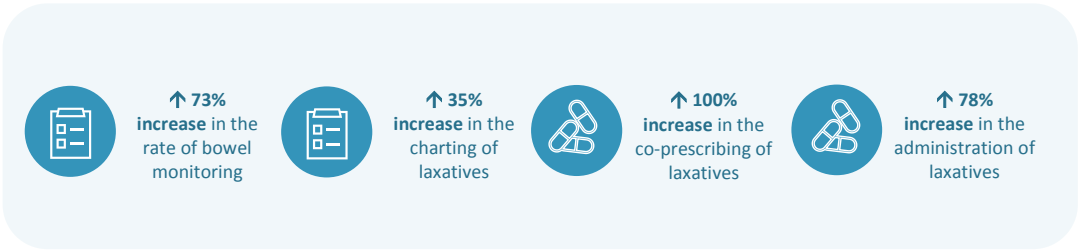
Waikato DHB achieved a statistically significant improvement for one of its two process measures, the rate of documentation of bowel activity.

8.2.2 Insights from Taranaki, Hawke's Bay and West Coast DHBs

Taranaki, Hawke's Bay and West Coast DHBs did not collect baseline data on the level of opioid-related constipation in their hospitals. However, they did collect data during the improvement period that provides an indicator of reductions in harm during the improvement period. Specifically, the control charts for Taranaki DHB and Hawke's Bay DHB indicated that opioid-related constipation decreased over time and that this variation was also due to a special cause, that is, the interventions being implemented by the DHBs (Figure 17 and Figure 18, Appendix 3).

Taranaki DHB collected baseline and improvement data for the testing of its four interventions. Statistically significant increases in the implementation of all four interventions were observed.

Taranaki DHB: statistically significant improvements to process measures



Hawke's Bay DHB and West Coast DHB did not collect baseline data for their process measures. However, control charts show that the interventions (process measures) to reduce the harm caused through opioid-related constipation for patients improved over time for both DHBs.

At Hawke's Bay DHB, the overall rate of documentation of bowel activity during the improvement period was 27%. The rate of documentation of bowel activity increased during the improvement period. Variation can be attributed to a special cause because documentation of bowel activity began to increase as teams tested and introduced various change ideas (Figure 19, Appendix 3).

Although patient and staff education was identified as a change idea, and activities were undertaken in this area, no data was formally collected.

At West Coast DHB, the overall rate for the charting of regular administration of laxatives during the improvement period was 63%. The overall rate of recording of bowel movement for the improvement period was 54%. The use of both process measures appears to have increased over time during the improvement period (Figure 20, Appendix 3).

8.3 Nausea and vomiting

Auckland and Southern DHBs identified nausea and vomiting as their harm area. Table 4 summarises how each of these DHBs measured nausea and vomiting, and the medication safety interventions that they sought to implement.

Table 4: DHBs focusing on reducing opioid-related nausea and vomiting for patients: measurements and interventions

DHB	Measurement	Interventions
Auckland	Reduction in the incidence of nausea and/or vomiting (1 or more incidents) from opioids in the acute stage of discharge (5 days post-discharge)	• Correct analgesic choice and dose of opioid at discharge • Correct quantity of opioid prescribed at discharge
Southern	Percentage of patients with nausea and vomiting in the period 24 hours post-surgery	• Preoperative assessment to identify at-risk patients • Anti-emetics offered to high-risk patients • Ice blocks (non-pharmacological) • Analgesia guideline to avoid use of opioids • Staff education

8.3.1 Improvements in opioid-related harm and medication safety processes

Auckland DHB

13% decrease in the number of patients with opioid-related nausea and vomiting

Reductions in the level of nausea and vomiting-related harm could only be calculated for Auckland DHB because Southern DHB did not collect reliable data during the timeframe required for inclusion in this evaluation report. The baseline data was considered to be unreliable because it did not reflect the experience or observations of staff. Subsequently, the analysis of improvements over time focuses on Auckland DHB.

Auckland DHB collected data from 100 patients during the baseline and improvement period. This data suggests a reduction in opioid-related harm. To support reductions in harm, Auckland DHB trialled interventions to improve the accuracy of choice, dose and quantity of opioids prescribed at discharge. However, no statistically significant improvements to these processes or differences that could be attributed to a special cause were observed.

8.3.2 Insights from Southern DHB

Southern DHB collected harm data (harm during the improvement period was 29%) and process measures during the improvement period for two interventions.

Southern DHB

Pre-operative assessments were conducted for **93% of patients** during the improvement period

37% of high-risk patients received anti-emetics during the improvement period

While Southern DHB did not collect data to measure progress on its three other interventions, efforts to implement these interventions were under way during the improvement period. They included:

- testing the use of ice blocks to relieve nausea and vomiting, which staff considered made a difference for patients in the surgical ward
- ensuring prescribers had enough information about using other analgesics in combination with or instead of opioids to reduce or eliminate the use of opioids as a first-line analgesic
- staff and patient education initiatives.

8.4 Uncontrolled pain

Waitemata DHB, Canterbury DHB and Whanganui DHB selected uncontrolled pain as their harm area. The harm definitions and the interventions implemented by the DHBs are identified in Table 5.

Table 5: DHBs focusing on reducing uncontrolled pain for patients: measurements and interventions

DHB	Measurement	Interventions
Waitemata	Percentage of audited patients with uncontrolled pain (consecutive pain score of ≥7/10 in 24 hours, or ≥3 pain scores of ≥7/10 pain in 24 hours that are not consecutive)	• Pain assessed and documented • Analgesia offered • Analgesia regularly administered • Intravenous Therapy Patient Controlled Analgesia (PCA) and Patient Controlled Epidural Analgesia (PCEA) monitoring
Canterbury	Proportion of patients with uncontrolled pain in the first 24 hours of admission (uncontrolled pain was defined as a pain score >3/5)	• Increase oral morphine dose • Reduce intravenous morphine dose
Whanganui	Percentage of audited patients with uncontrolled pain (consecutive pain score of ≥7/10 in 24 hours, or ≥3 pain scores of ≥7/10 pain in 24 hours that are not consecutive)	• Patient and staff education

8.4.1 Understanding changes in uncontrolled pain

Waitemata DHB and Canterbury DHB both collected baseline and improvement data on the level of harm and their interventions.

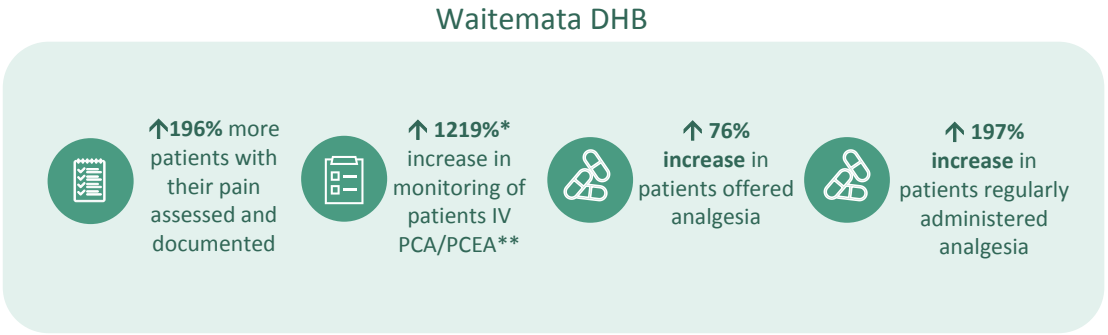
For both DHBs, the proportion of harm recorded for the improvement period was 60% higher for Waitemata DHB and 49% higher for Canterbury DHB. However, an analysis of this data suggests that:

- variation is routine and not due to a special cause, such as a change in the underlying medication safety processes
- while the result for Canterbury DHB is statistically significant (p=0.004), this finding must be interpreted with caution due to the small baseline period data sample (patients audited over 3 weeks) compared with the improvement period data sample size (patients audited over 42 weeks). Further, the small baseline sample size may mean that the proportion of harm recorded for the baseline period does not accurately reflect the level of harm prior to the improvement period
- it is also possible that the observed increases were due to improved documentation processes during the collaborative. At Waitemata DHB, for example, the assessment and documentation of pain was 13% at baseline and 39% during the improvement period, representing a relative increase of 196%.

Discussions with key experts on opioid-related harm suggest that uncontrolled pain may be better used as a balancing measure, rather than an outcome or avoidable harm. While uncontrolled pain is not a desirable outcome, the complexities of patients' experiences of pain, including its psychological and physiological nature, suggest that pain is more useful as a balancing measure. The Commission team also noted that variability in approaches to pain management suggests standardised protocols could be investigated as part of a system-wide approach.

8.4.2 Improvements in opioid-related medication safety processes

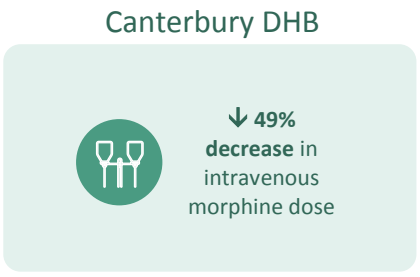
Waitemata DHB achieved statistically significant improvements in all four of its medication safety processes during the improvement period.



* There was a 52% absolute increase in the monitoring of patients' IV PCA/PCEA.
** PCA = Patient Controlled Analgesia; PCEA = Patient Controlled Epidural Analgesia.

A key success for Canterbury DHB was reducing its intravenous morphine dose by 49%; a means of administering opioids that is associated with increased harms according to experts in the field.

As a result of the shift from intravenous to oral administration, oral morphine doses increased by 24% during the improvement period. The result was not statistically significant, with control chart tests indicating that the variation was not related to any underlying changes to processes. The level of change, however, warrants continued monitoring by the DHB to further understand these improvements and the benefits or harms for patients.



8.4.3 Insights from Whanganui DHB

Whanganui DHB did not provide any baseline data for analysis, due to shifting its focus from constipation to uncontrolled pain (it did not identify any constipation-related harm in its areas). It did collect data relating to uncontrolled pain during the improvement period, the control chart on the level of harm during its improvement period shows that the level of uncontrolled pain decreased during the improvement period. Control chart tests indicate that this variation was not routine and the changes were due to the underlying processes (Figure 22, Appendix 3).

When the measurement summaries were created for DHBs, Whanganui DHB had not yet collected data on the process measures. It did report that the following initiatives were under way:

- staff education:
  - pain study days and fortnightly education sessions for nurses
  - pharmacy bulletins on respiratory depression, fentanyl patches, timely administration of medication
  - prescriber education
- patient engagement and education:
  - patient feedback was collected on the value of an information leaflet
  - patient education prior to surgery on reporting pain and pain relief options
- audits to check compliance with agreed protocols, such as opioid administration times
- nurses documenting patient pain using an Early Warning Score chart
- including pharmacists as part of the daily pain round.

8.5 Opioid-induced ventilatory impairment

MercyAscot and Northland DHB identified opioid-induced ventilatory impairment as their harm area. The harm definitions used by the DHBs and the interventions that they implemented are identified in Table 6.

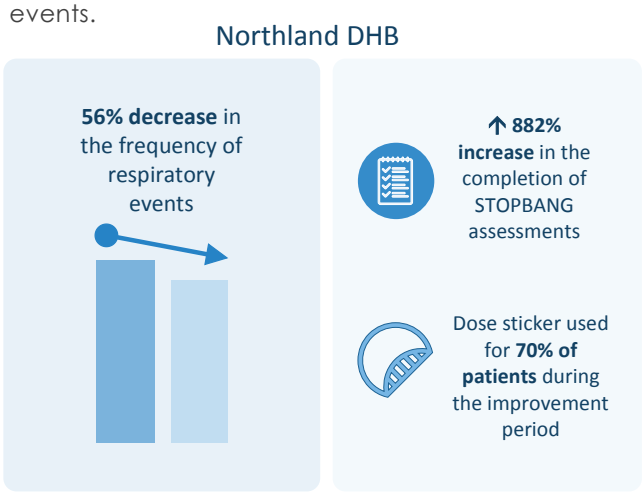
Table 6: DHBs focusing on reducing opioid-related respiratory depression for patients: measurements and interventions

DHB	Measurement	Interventions
MercyAscot	• **Respiratory depression**: proportion of patients with episode of respiratory depression (respiratory rate 8–10 and sedation score ≥2). • **Days between two respiratory depressive events** • **Days between naloxone use:** patient administered naloxone once or more frequently as respiratory depression reversal agent)	• Respiratory rate monitoring • Sedation monitoring • Staff education as part of annual training • E-learning package for staff
Northland DHB	• **Days between two respiratory depressive events** (≥8 respiratory rate and increased sedation requiring interventions, naloxone, or increased or higher level of care)	• Use of STOPBANG assessment to identify high-risk patients • Capturing cumulative opioid dosing using a sticker

8.5.1 Improvements in opioid-related harm and medication safety

The level of harm during the improvement period was lower for both MercyAscot and Northland DHB. Improvements in the process measures were also observed for both DHBs.

At Northland DHB, the average number of days between two respiratory depression events increased from 15 days during baseline to 33 days during the improvement period. This represents a 56% decrease in the frequency of opioid-related respiratory events.

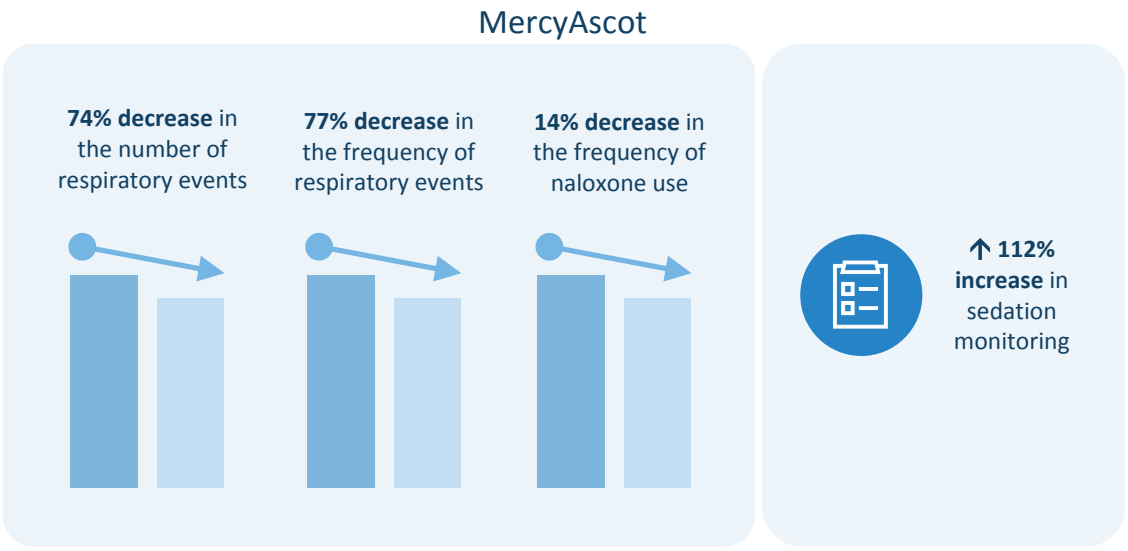


Control chart tests suggest that this variation is due to a special cause, because the number of days between respiratory events began declining after the STOPBANG assessment began. While the p-value is not statistically significant at the 0.05 level (p=0.058), caution is needed when interpreting this analysis due to the small number of patients in the baseline period (15 patients) and improvement period (18 patients).

It is useful to note that Northland DHB recorded the level of harm by measuring the number of days between respiratory events. Increases in the number of days represented a decrease in harm so that a positive relative difference represented a harm reduction. This was different compared with other DHBs where a positive relative difference would represent an increase in harm.

To ensure consistency in the presentation of harm reduction figures, the relative difference between the average frequency of respiratory events during the improvement period and baseline period has been used. This has been calculated by using the average number of days between respiratory events as a proxy for how often events occurred, for example, if the average number of days between two events was 5 weeks, the frequency would be calculated as one event every 5 weeks. For Northland DHB, the frequency of events decreased from one every 14.8 days during baseline to one event every 33.4 days during improvement. This represents a 56% relative decrease in the frequency of events.

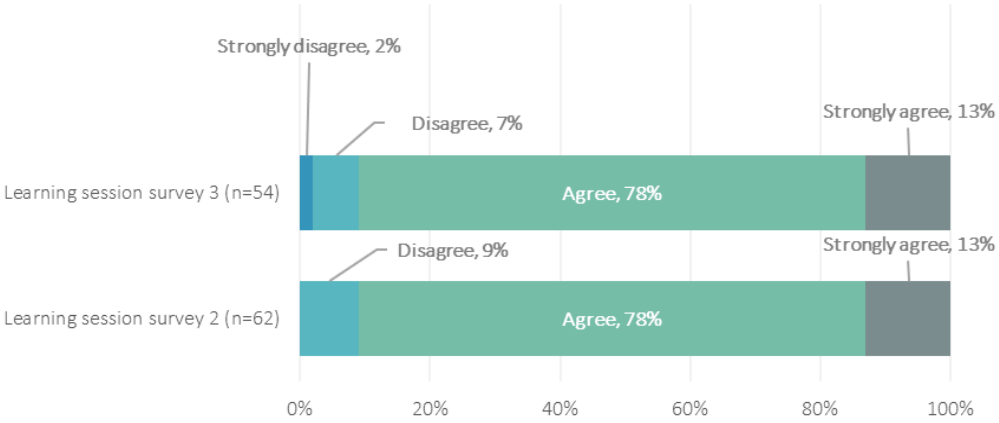
MercyAscot used three outcome measures to assess the level of opioid-related respiratory depression in its hospital. Opioid-related harm during the improvement period (n=269) was lower than for the baseline period (=116) for all outcome measures. Control chart tests indicated that variation for all three measures was due to a special cause. These differences were not statistically significant.



8.6 Role of the collaborative in reducing opioid-related harm

Nearly all of the learning session 2 (91%) and learning session 3 survey respondents (91%) agreed or strongly agreed that being a part of the collaborative had increased the focus on opioid-related harm at their DHBs (Figure 3). It should be noted when interpreting these responses that, while most DHB team members attended multiple learning sessions, a small proportion of survey responders at learning sessions 2 and 3 attended as one-offs.

Figure 3: Learning session attendees' perspectives on whether the collaborative had increased the focus on opioid-related harm at their DHBs



Visits by the evaluation team also highlighted the focus and support that the collaborative had given to medication safety, and specifically to reducing the harm from opioids. Some DHBs indicated that they already had a focus on medication safety prior to the collaborative.

In the learning session surveys and site visits, most DHBs reported they were confident that care bundles would be developed and reduce opioid-related harm at the testing site. Other DHBs had not yet gathered enough data to make a judgement about the reduction in harm or were not able to record baseline measurements.

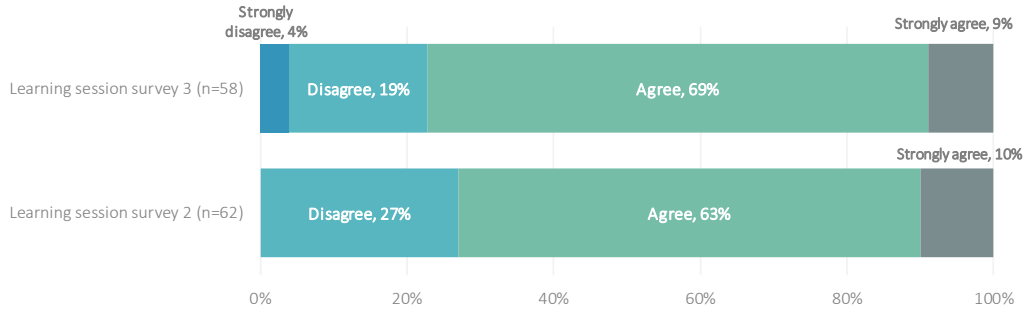
Most of the staff interviewed at the site visits focused on the specific testing site for the collaborative when describing the reductions in harm. Some of the interviewees, however, identified the sharing of medication safety processes across the hospital. Others planned to do further work and engage the community in reducing opioid-related harm. This included initiatives to increase the awareness of providers outside the hospital.

8.6.1 Raising the profile of medication safety

Most learning sessions 1 and 2 survey respondents thought that being part of the collaborative had increased the profile of medication safety at their DHB:

- 73% of attendees at learning session 2 and 78% of attendees at learning session 3 agreed or strongly agreed that being part of the collaborative increased the profile of medication safety at their DHB (Figure 4).

Figure 4: Learning session attendees' perspectives on whether the collaborative had raised the profile of medication safety at their DHBs



Most DHBs felt that the collaborative had raised the profile of medication safety or strengthened an existing focus on medication safety. This focus resulted in an increased awareness and openness to reducing the harm from opioids for some staff. The emphasis from the Commission enabled reducing harm from opioids to reach the medication safety agenda in hospitals.

> *"It's kind of like if you buy a red car, and then suddenly you see every red car on the road. So for me, being part of it, you're part of the opioid collaborative, so every time somebody mentions something to do with pain, your ears prick up a bit more. Maybe you take it in a bit more than what you potentially did. You have that magnifying glass on everything, so from that perspective, it's on the agenda." (DHB 6)*

A few of the staff at one of the DHBs noted that raised awareness about opioid safety was still limited to the testing sites within the hospital but was beginning to spread to non-testing wards.

One stakeholder thought that the timing of the opioid collaborative clashed with the timing of other medication safety initiatives, and thus reduced its impact.

9 EFFECTIVENESS OF THE MEASUREMENT APPROACH IN DEMONSTRATING IMPROVEMENT

The collaborative used a shared workspace and regular reporting to collect quality improvement data to understand the reductions in opioid-related harm achieved by the DHBs. This data was used to calculate improvements, including reductions in harm and improvements in process measures. Key indicators for understanding the effectiveness of this system included the establishment of baseline data by the DHBs, the development of data collection plans and monthly reporting.

9.1 Establishing baseline

While most of the DHB teams had collected process and outcome measures, the establishment of baseline data was identified as an indicator for the effectiveness of the measurement system in the evaluation design and planning phase. By learning session 2, in June 2015, most (72%, n=69) participants indicated that their DHB had established a baseline. The collection of baseline data was influenced by a range of factors, the most common were:

1. time available to collect baseline data
2. clarity of the data needed for baseline
3. previous experience of improvement science
4. data not easily collectable.

Insights from the key stakeholder interviews note that, while baseline data may have been collected by DHBs, some were collecting this data while also testing interventions. Some of the DHBs had a very small sample size or limited number of data collection points during this period. This impacted on the ability to confidently identify changes in opioid-related harms for all DHBs.

Some DHB teams expressed the desire for more clarity and structure around the definition of harm and how to collect baseline data. They felt making these decisions on their own was confusing and challenging, with one DHB stakeholder saying they preferred the structure of previous Commission projects.

> *"With previous projects that were done with the Commission, where they've prescribed what they want to be collected … if this was the same it would have made it a lot easier … we spent a lot of time learning the process … you spent a lot of the eighteen months learning about that as opposed to actually gathering data, and actually doing the project." (DHB 5)*

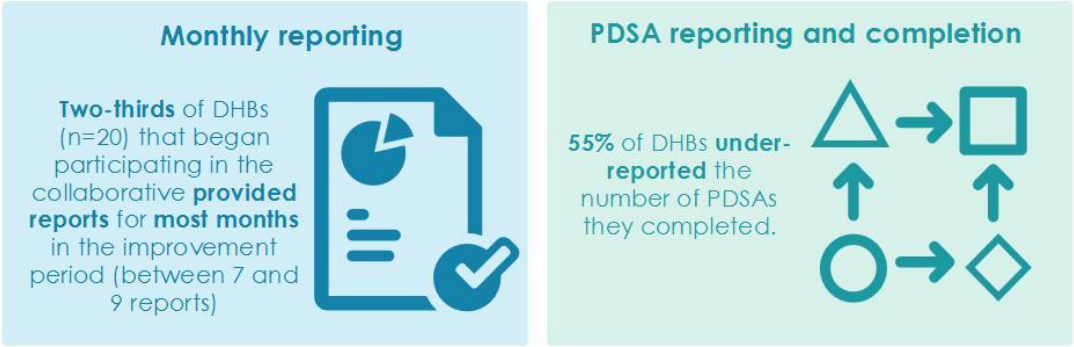
When reflecting on this process, key stakeholders, including the project team, felt that the effectiveness of the measurement approach would have been strengthened if the DHBs had been given a specified timeframe within which to collect baseline data. They felt that this was important for supporting the robustness of the data and the effectiveness of the measurement approach. Having DHBs at the same stage would have also been helpful for informing the discussions and focus at the learning sessions.

Achieving this, however, may have required some capability building prior to the testing of the collaborative. Some of the DHBs had greater improvement science capability and capacity to collect data than others. The consideration of a targeted approach to developing DHB teams' capability may have also been effective as a precursor to project initiation.

9.2 DHB reporting

DHBs provided monthly reports and used the shared workspace to record their PDSA cycles.

DHBs began reporting on their progress in June 2015 and provided monthly reports for nine months, until February 2016, to the Commission. Reporting included DHBs' self-assessment of their progress, the number of PDSAs completed and their level of engagement.



* PDSA = Plan-Do-Study-Act

Reports were submitted every month for 45% of DHBs (n=20; one DHB collected data for eight months rather than nine). Two DHBs (10%) did not submit any monthly reports on their progress.

Two-thirds of DHBs also submitted between seven and nine reports on the number of PDSAs completed, while 40% (n=20) of DHBs provided these reports for all nine months. One DHB did not provide any reports, as they did not have the capacity to engage in these cycles.

The Commission used this data to produce monthly dashboards; one to identify any reduction in harm and another to support project management.

9.2.1 Plan-Do-Study-Act

DHBs were also encouraged to log their completed PDSAs in the shared workspace. Data from the shared workspace indicates that 55% of DHBs (n=20) under-reported the number of PDSAs in their monthly reports. Data from the shared workspace suggests that DHBs completed between 0 to 31 PDSAs, with an average of 15. Insights from the DHB teams and the Commission also support the view that the shared workspace data is likely to under-report the number of PDSAs.

When reviewing this data, it is useful to note that some DHBs were still developing their understanding of PDSAs. For example, in one telephone conference observed by the evaluation team, a DHB suggested that it had implemented one PDSA when it had

actually engaged in four. Regardless, this data does demonstrate engagement in using PDSAs to improve medication safety processes and reduce opioid-related harm.

9.2.2 Shared workspace

All DHB team members were invited to the shared workspace, with 61 DHB team members accessing the shared workspace. All DHB teams had at least one member who accessed the shared workspace.

The site visits suggest that the value of the shared workspace varied between DHB teams. Some stakeholders thought that the ability to compare their DHB's progress with other DHBs was useful. It was also considered to be a useful resource to support shared learning, with DHBs accessing information on the interventions trialled by other DHBs.

A few participants said that they did not use the shared workspace very often because they found using it difficult. Others felt that the face-to-face networking opportunities with other DHBs were more useful for them.

9.2.3 Understanding effectiveness of measurement data

The collaborative used improvement data to understand reductions in opioid-related harm and improvements in processes. The project team also made a conscious decision to allow the DHB teams to identify their own harm definitions and measures. The project team noted that this approach enabled the DHB teams to choose definitions based on their clinical expertise and population.

The effectiveness of the measurement approach would have been strengthened if the harm areas were underpinned by shared definitions and measures. A more systematic approach to establishing baseline data would have supported a more effective measurement approach.

Other programmes facilitated by the Commission use Quality and Safety Markers to support a consistent approach to measuring change. Opioid-related harms, however, are multiple and identifying one or two key process and outcome markers is more challenging, and this is reflected in international experiences as well. Quality and Safety Markers should be explored for testing the emerging care bundles.

10 CHANGES IN IMPROVEMENT SCIENCE CAPABILITIES

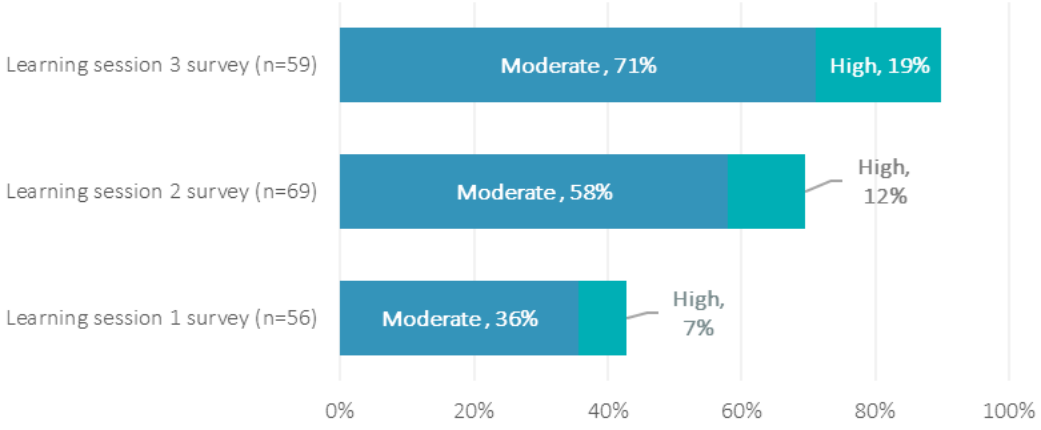
A key strategic priority of the Commission is to develop the sector's improvement science capability. To support this, the collaborative developed the sector's capability in improvement science, and the Model for Improvement, more specifically.

The challenge of this approach was the notion of *'building the plane, whilst flying it'*, while the benefits were a sector- and practice-based bundle of care for reducing opioid-related harms. The other benefits were the changes in the quality improvement capability of most staff involved in the collaborative. This section draws on findings from surveys at the learning sessions facilitated by the Commission and interviews with staff to identify the impact of the collaborative on staff improvement science knowledge.

10.1 Changes in improvement science knowledge over time

Survey respondents reported an increase in their level of knowledge of improvement science methodologies over time. The number of DHB team members who said they had a moderate to high level of improvement science knowledge doubled between learning sessions 1 and 3 (Figure 5).

Figure 5: Learning session attendees' knowledge of improvement science methodologies

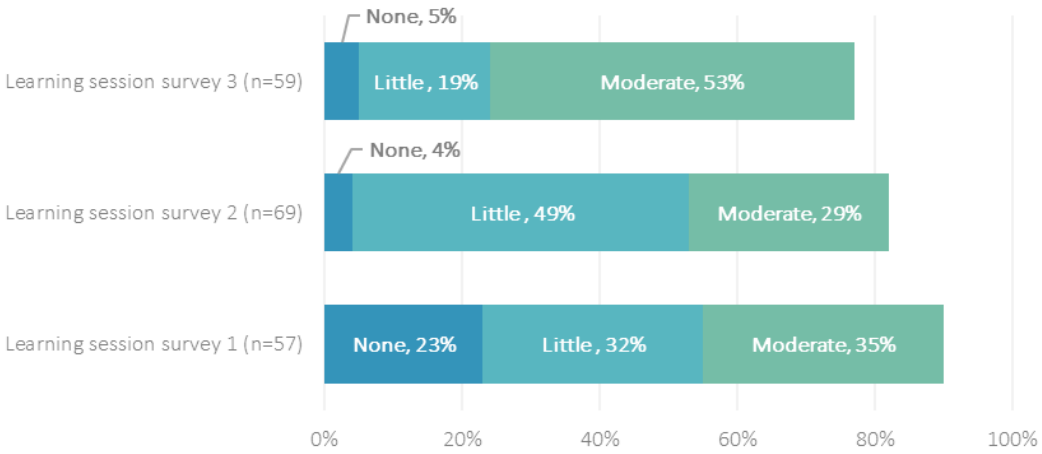


The level of improvement science knowledge increased for 59% of the DHB team members between learning sessions 1 and 3. Most reported that they shifted from having little to moderate knowledge during the collaborative.

All but one of the survey respondents indicated that the collaborative had enhanced their knowledge and experience of quality improvement tools and methods.

Survey respondents were also asked about their experience with using the PDSA tool as part of learning cycle (Figure 6 – next page). The data clearly highlights the increase in the use of PDSAs during the course of the collaborative.

Figure 6: Changes to learning session attendees' experience of the Plan-Do-Study-Act tool



10.1.1 Insights from DHB team members

Most stakeholders included in the DHB site visits experienced an increase in their improvement science capabilities due to their involvement in the collaborative. Some felt that they had acquired a new skill set and others felt it provided a formalised structure to their existing understandings of how to achieve quality and safety improvements in hospitals.

> *"I guess from a professional point of view, learning about PDSA cycles and the methodology. It's been really useful for me – a different way of thinking." (DHB 1)*

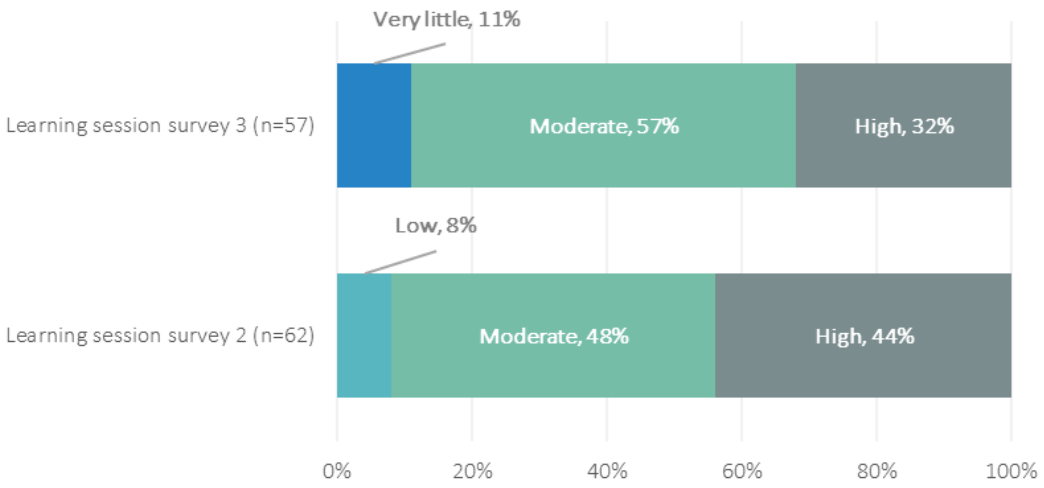
> *"I came into it not really understanding PDSAs and to the extent … to the formalisation that they (the Commission) were talking about, so I guess [not knowing] the science behind [it]… I learned a lot." (DHB 6)*

10.2 DHB engagement and use of improvement science

Overall, most DHBs indicated that they were engaged in the collaborative and the application of improvement science.

The learning session surveys indicate that nearly all respondents rated their DHB's engagement in the collaborative as moderate to high (Figure 7 - next page). There was a slight decrease between the sessions from 92% to 88%.

Figure 7: Learning session attendees' perceptions of their DHB's engagement



In general, DHB team members interviewed during site visits appeared to be engaged in the collaborative and motivated to apply improvement science principles within their DHB. However, time and resource constraints were major barriers for DHBs, particularly for reporting and completion of paperwork, for example, PDSA cycle documentation.

10.3 DHB use of improvement science

All DHBs included in the site visits reported using the collaborative's improvement science tools and processes. They generally did not apply these exactly as intended all of the time because they felt some were too formal or theoretical to be applied routinely in clinical practice. However, the surveys suggest that most DHBs found the improvement science processes to be valuable and something that they could continue or adapt for use in the future.

Some of the interviewees indicated that not being able to meet the reporting and attendance requirements of the collaborative made them feel demotivated and like they were *'failing'*. One team leader felt that the 25% target would better support engagement if it was more achievable and took into consideration individual DHB's contexts and resource and time constraints. They felt that this would better support more DHBs to use the methodologies. This feedback is interesting, because the aim set was intended to be at the national level, and DHB teams set their own harm reduction targets.

10.3.1 Intended use of improvement science in the future

In the learning session 3 survey, session attendees were asked whether they would use the improvement science knowledge, principles and tools they had learned during the collaborative in the future.

Nearly all (98%, n=49) survey respondents reported that they would use the improvement tools, knowledge and methods they gained during the collaborative in the future. Only one respondent suggested that they would not use the methods in the future.

One DHB included in the site visits noted that using the methodology was resource intensive and felt that the Commission would need to invest further resources into DHBs if

they wanted them to continue with improvement science methodologies in the future. Others, however, highlighted the importance of support from leadership within the hospital to acknowledge the importance of using improvement science processes to improve practice and uptake.

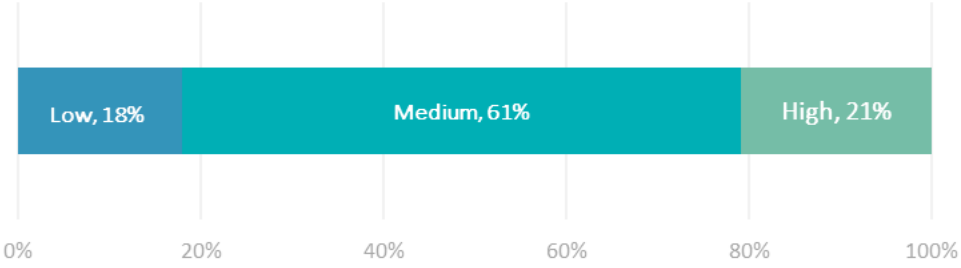
11 STRENGTH OF THE CLINICAL NETWORK

The evaluation design and planning phase highlighted the importance of identifying the role of the collaborative in supporting shared learning and the development of a clinical network. The Commission was interested in understanding the local, regional or content focus of a clinical network, and its potential to be sustainable or reused to support other medication safety initiatives.

11.1 Shared learning between DHBs

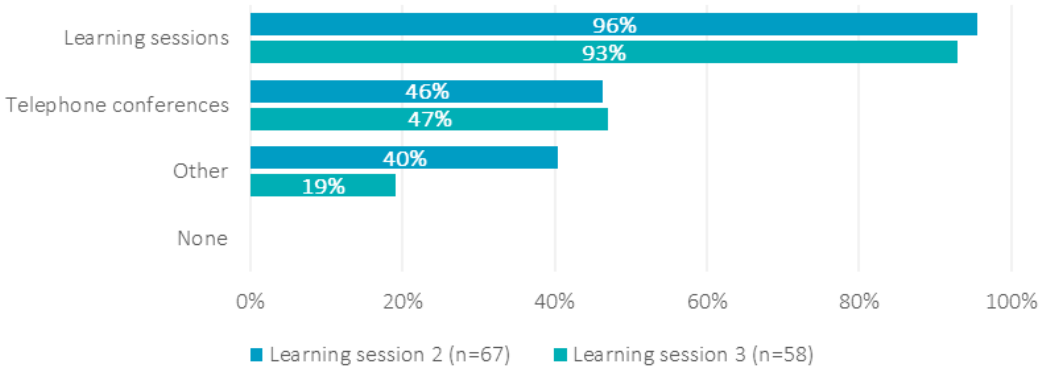
Over three-quarters (82%, n=56) of learning session 3 survey respondents indicated that they had achieved a medium or high level of shared learning with other DHBs during the collaborative (Figure 8).

Figure 8: DHB team members' level of shared learning after learning session 3 (n=56)



Survey respondents were asked to identify the aspects of the collaborative that supported shared learning (Figure 9). Almost all (93%) attendees identified the value of the learning sessions. Other aspects that supported learning included email, networking and the shared workspace.

Figure 9: Factors that supported DHB shared learning



When discussing shared learning at the DHB site visits, staff noted the value of sharing information and insights, particularly with DHBs focusing on the same harm areas.

"Initially we started off with general teleconferences for everybody and now we are doing harm-based teleconferences. So I think that is something that's quite positive and gave an opportunity for the DHBs working on similar harms to share ideas as opposed to everybody talking about different (harms)." (DHB 1)

DHB team members noted the benefits of sharing and learning from one another's successes, as well as the challenges (Figure 10). This sense of openness and trust established across the DHB teams was highly valued. A project team member highlighted the significance of the DHB teams working together and sharing learnings, which was perceived to be a unique occurrence in the sector, as these teams often work within their own organisations.

"As a small hospital, the bigger DHBs are coming out with just as many challenges ... so that is quite nice … you can see what everybody's doing. Everyone's very happy to share the things that they've come up with … so you're not having to reinvent the wheel." (DHB 6)

Figure 10: DHB staff sharing insights at learning session 3

A couple of stakeholders suggested that the differences in approaches adopted by the DHBs did not support a strong network or set of ties for their DHB.

"If we had another DHB that was doing exactly what we were doing, we could say "how are you finding it, what problems are you having", and that could be a good network … The study days, I found them quite helpful in the sense of … a networking perspective. But I don't think there's been close ties generated really." (DHB 3)

Others found the shared workspace more useful for understanding the work being undertaken through the collaborative and learning from others. The shared workspace was used to collate all DHB project material, which could be accessed by people from other DHB teams.

11.2 Value and sustainability of the ongoing clinical network

Most DHBs described the value of the clinical networks developed through the collaborative. The network between the five South Island DHBs provides a good example of this. This network is supported by the Quality and Safety Group of the South Island Alliance,[8] with the Chair, Mary Gordon, stating that:

> *"Working as a collaborative is key to driving change as it enables DHBs to learn from each other in a collaborative environment, share their experiences and trialing improvements that will help feedback into shaping future practices for all DHBs. We know our members are working hard to support and promote the collaborative across the South Island, and it is great to see DHBs developing resourceful solutions to their current opioid-related issues that will directly improve quality of care experienced by patients."*

To maintain and build on this value, nearly all learning session 3 survey respondents (91%, n=59) were very willing or quite willing to be part of a sustained clinical network. The top five factors that attendees identified as being important for sustainability were:

- ongoing support and communication with staff
- increasing opportunities to share and network
- provision of resources and adequate time to engage
- national strategic direction and leadership
- appreciating teams by celebrating success.

One of the project team members felt that the clinical networks would be sustainable if there was some national support to nurture the networks. Challenges identified to sustain these networks were:

- that networks are based on people's personal relationships
- the need for people to see value in being part of the network and contribute to it for them to be sustainable
- the need to ensure that, when these networks shift to focusing on medication safety, the remit does not become so broad that it inhibits DHBs from identifying and taking specific actions.

11.3 Testing the emerging care bundles

Some of the DHBs were also keen to support testing of the emerging care bundles. However, they would like a clearer understanding of what this would involve, to be able to make an informed decision. This in part reflected their capacity to continue to collect data, as well as the need for support from senior players within their organisation to do so. The DHBs were also used to the Commission facilitating the networks, and

> *"Ongoing engagement opportunities. Building up of a formal infrastructure for engagement, interaction or collaboration." (Learning session survey feedback)*

[8] www.sialliance.health.nz/CDF_ModuleNews/Display/Details/164?NewsSetId=32&PageId=22806

consideration needs to be given to who will take on this leadership.

All except one respondent who completed the learning session 3 survey would be willing to use the emerging bundles of care. Staff, however, highlighted the importance of DHB ownership, capacity and formalising structures and leadership to support this.

Key factors that would support DHB teams in using the emerging bundles of care included:

- engagement and commitment from across the hospital
- time and resources
- education and support
- promotion and leadership
- communication and clarity from the Commission
- effectiveness and efficiency.

> *"Effectiveness of the bundle, makes meaningful sense and good ideas which are not laborious." (Learning session survey feedback)*

Factors that would challenge spread included:

- time and resource constraints
- disengaged staff and negative attitudes
- competing priorities and poor management
- poor support and staff education
- workflow and unexpected events.

12 CONSUMER ENGAGEMENT AND BENEFITS

Consumers were engaged in the collaborative at a national level and locally by the hospitals. Nationally and locally, consumers were engaged to share their experiences of opioid-related harms. Patients shared their stories in written and video format. These stories highlighted the impact of opioid-related harms on patients.

Importantly, the stories also highlighted the opportunity for opioid-related harms to be reduced in hospitals. Violet's story, for example, demonstrated the importance of recognising and responding to opioid-related harm as early as possible.[9]

A story shared by Violet noted that, even when she informed hospital staff of her constipation, on more than one occasion, nothing was done. Violet was so fed up that she went home, exhausted.

The next day, she tried to resume mobilising and to eat but was extremely nauseated and her abdomen was very bloated and uncomfortable. Her bowels had still not moved despite taking Laxsol as prescribed since discharge and she said she felt the build up getting 'bigger and bigger'.

Violet described the following two hours as a time when she 'wished she was dead' from the time she had to ask her husband to administer the enema, to being petrified it would not work and she would have to go to ED for a manual removal, to sitting on the toilet screaming for an hour while holding a pillow over her abdominal wound, to finally passing a motion and then fainting.

Two other patient stories also identified the discomfort and harm caused by opioid-related constipation.

The patient stories were shared by the national collaborative team and made available on the Commission's website. The stories were important for engaging the sector in reducing opioid-related harms. At a hospital level, they also supported an opportunity for learning and improving medication safety processes. For example, Violet's story identified the following learnings.

- Co-prescribing laxatives with opioids is essential to minimise constipation.
- Targeted patient education can never be underestimated in reducing harm from opioids.
- Description of bowel movement (preferably utilising a standardised tool like the Bristol Stool Chart) is as important as recording the actual action.
- Once constipation is identified – treat it promptly and prior to discharge.
- LISTEN to the patient – they provide the most accurate individual assessment of constipation, or what is important to them.

[9] http://www.hqsc.govt.nz/assets/Medication-Safety/collaborative/PR/LS3/violets-patient-story-Dec-2015.pdf

12.1 Hospital engagement with consumers

The collaborative promoted patient engagement at a hospital level. Hospitals engaged patients in informing and providing feedback on medication safety processes tested by the DHBs through PDSAs. For example, patients provided feedback on posters and resources designed to support patient education and improve health literacy in understanding the important and potential side effects of opioid use.

DHB teams shared patient stories at learning sessions, to identify successful interventions and support shared learning.

Consumer partnership was achieved through the engagement of consumer representatives on the project team at the following DHBs:

- Waitemata
- Bay of Plenty
- Lakes
- Counties Manukau
- Canterbury.

12.2 Consumer benefits

The improvement science approach gathers data on processes and reductions in harm, rather than capturing feedback directly from patients. The patient stories, however, highlight patients' support for reducing opioid-related harms.

> *"It's not a happy experience. It's hard on the tummy and feels like it cuts you in half – not pleasant. I am glad we are being proactive with preventing this."*

While the evaluation was not designed to identify benefits from the perspectives of patients, the data on the reduction in harms provides evidence of the types of benefits that can be achieved for patients. These include:

- improvements in opioid medication safety processes
- improvements in opioid-related patient care
- improvements in patient information and health literacy
- reductions in constipation, nausea and vomiting, and respiratory depression. This could have resulted in:
  - reduced length of stay and readmissions
  - reduced need to access additional health care support
  - improvements in patients' wellbeing and recovery.

The collaborative was also noted for its role in providing patient benefits that extended beyond geographical boundaries and specific groups.

"The national collaboration looks at the big picture, consequently results and work done won't be exclusive to certain group or geographical areas. There is a great amount of experience transferred throughout the national collaboration, to the extent that it will influence the implementation of regional and local projects."

12.3 Responsiveness to Māori

Responsiveness to Māori was not a key theme in the interviews. When sharing progress at the learning sessions, however, two of the DHBs noted the role of kaumātua in supporting responsiveness to Māori. Kaumātua are Māori elders who have many important roles, including preserving traditions and knowledge, providing leadership, and nurturing the younger generations.

In the collaborative, some DHBs engaged kaumātua to support engagement with Māori patients and to support the responsiveness of interventions and related resources. This approach, however, was largely dependent on the initiative of a few DHBs. For example, MidCentral DHB consulted with its local kaumātua to help develop a patient information poster.

There was less evidence of responsiveness to Māori at a national level, although it was highlighted as being important during the set-up phase of the collaborative.

The use of mihimihi and waiata at the national meetings was a strong focus; this aligned with the Commission's increased focus on the use of tikanga and acknowledgement of Māori and obligations to the Treaty of Waitangi. Mr Tu Williams, Chair of the Commission's Te Roopu Māori, opened and closed all three national learning sessions.

13 DHB ENGAGEMENT IN THE COLLABORATIVE

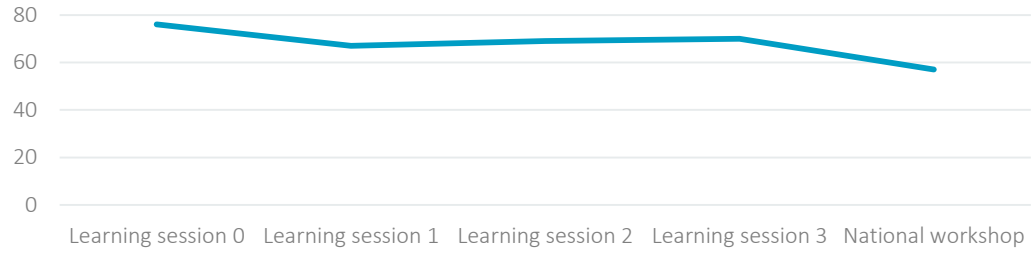
Overall, most of the DHBs were well engaged in the collaborative. This section identifies their engagement in the learning sessions and telephone conferences, as well as the use of multidisciplinary teams by DHBs and other DHB-based support.

13.1 DHB engagement in learning sessions and teleconferences

The Commission facilitated four learning sessions and a national workshop. Learning session 0 and the national workshop were extra meetings facilitated by the Commission and outside the IHI collaborative model. Learning session 0 was designed to build engagement prior to learning session 1. This session was conducted regionally, hence the higher rate of attendance at this session (Figure 11). The national workshop was designed to support the transition of the collaborative to the next phase of work – testing the emerging care bundles.

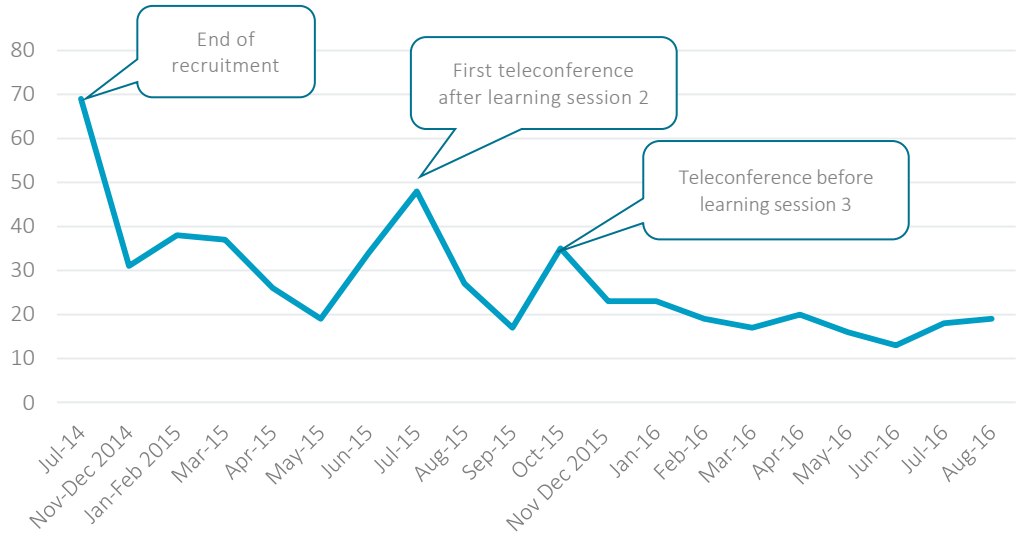
Attendance at the national learning sessions was relatively consistent over time (Figure 11). While participants included in the DHB site visits appreciated that the Commission funded travel and accommodation to support attendance, some felt that this required too much time away from work and eventually stopped attending. All of the DHBs had at least one person attending all of the learning sessions, except the two DHB teams that were not participating in the testing. Attendance at the final national workshop was lowest of all the national meetings; this may have been because the funding to support attendance was lower than for the three main learning sessions.

Figure 11: Number of DHB team members attending learning sessions over time



Attendance at teleconferences decreased during the course of the collaborative but fell much more sharply over time, compared with attendance at the learning sessions (Figure 12 – next page). DHB teams participated in between 3 to 17 of the 18 teleconferences facilitated by the project team during the collaborative. Most DHB teams participated in 11 teleconferences.

Figure 12: Teleconference attendance over time



13.2 Formation of multidisciplinary teams

Most DHBs included in the site visits reported that they had formed multidisciplinary teams that were actively working toward achieving the aims of the collaborative. For example, the Waitemata DHB team involved surgeons, nurses, anaesthetists, pharmacists, consumers and physiotherapists. One project team member also noted the significance of DHBs forming interprofessional teams because most professions do not work in this way. They noted the value of bringing health professionals together to work on harm reduction.

Interviewees suggested that key factors that supported the success of multidisciplinary teams were team leaders' previous experience of working in medication safety, good existing relationships between staff and high levels of motivation from individual team members.

One DHB felt that it had a multidisciplinary team 'in theory' but not in practice because competing priorities impacted on the capacity of some staff to fully engage.

> *"Every one of our doctors is being pulled five different ways within that non-clinical time. So we find it hard to have them engage with the process, they supply the ideas and what they wanted to happen, but really none of the labour or involved with making it happen." (DHB 5)*

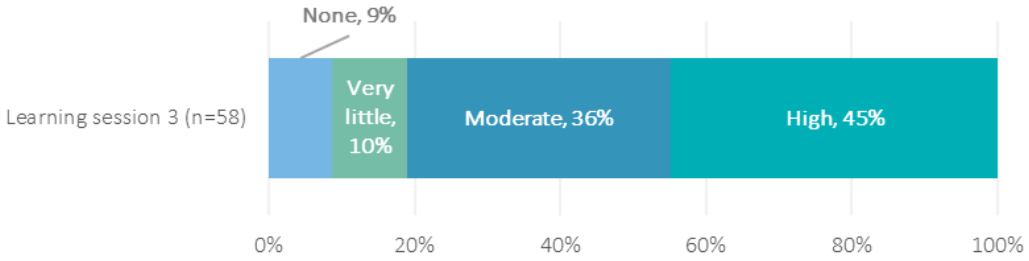
Despite some of the challenges experienced by the 17 DHBs, they demonstrated a high level of commitment and engagement with the collaborative.

13.3 Support from DHBs

While most respondents indicated a moderate or high level of support from their quality improvement teams in the surveys (Figure 13; 81%, n=58, see next page), the site visits

noted variations in the level of access that staff had to their quality improvement advisor.

Figure 13 Learning session 3 attendees' perceptions of the support received from the DHB quality improvement team



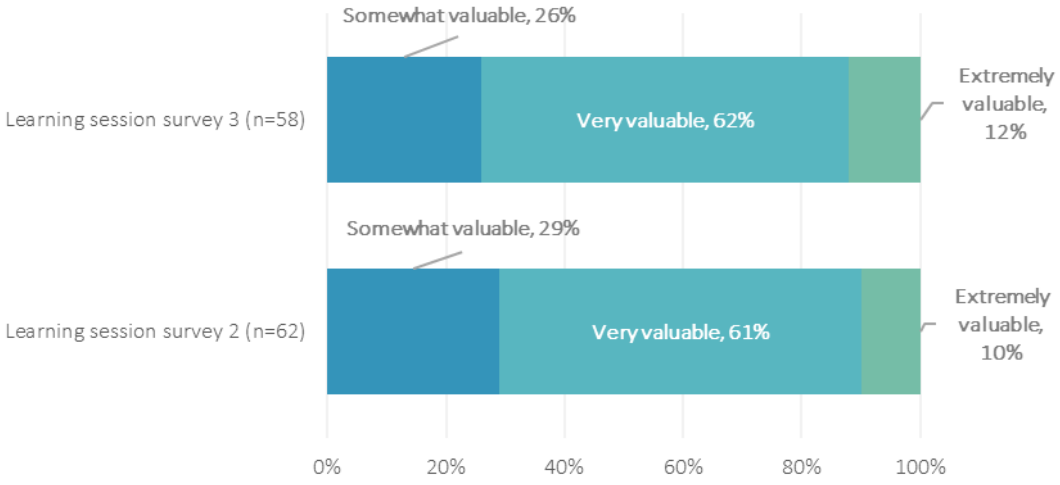
Support from leadership also varied. At times, this made it more challenging for teams to fully engage in the collaborative.

14 VALUE OF THE COMMISSION IN SUPPORTING THE COLLABORATIVE

The Commission provided a range of support to the DHB teams, including regional, harm-based and national teleconferences, learning sessions, site visits and one-on-one support. These activities were designed to support the collaborative, with the site visits being particularly valuable for understanding and supporting the DHBs. Sites were visited at least once (except Tairawhiti DHB), with an average of two visits per DHB. A total of 36 visits were completed across the DHB teams.

Surveys for learning sessions 2 and 3 asked how valuable the Commission's national opioid team had been in supporting the DHB teams' participation in the collaborative (Figure 14). Most respondents (88%) thought the national opioid team at the Commission was very or somewhat valuable in supporting their DHB team through the collaborative. The value provided by the Commission was stable over time.

Figure 14 Learning session attendees' perceptions of the value of support provided by the Commission's national opioid team



14.1 Support with improvement science

DHB teams valued the improvement science support provided from the Commission's national collaborative team. Stakeholders felt that being able to seek guidance, particularly through face-to-face or teleconference meetings, helped them to understand the theory and finer details of the methods.

> *"With his mind for detail, and his statistics, and run charts … he was … thinking about the detail, and I'm not a detail person. And so it was good to do the face-to-face time … In the end, once we were starting to get our head around it, he became more reassuring. But the first couple of times I talked to him, I was thinking, oh god, oh god, this is just going to be … so hard." (DHB 2)*

DHBs noted that the guidance from the national collaborative team helped them focus on the processes of medication safety. They thought this was useful because, as clinicians, they felt they focused mainly on clinical outcomes, while the sessions shifted their focus to the process and methods.

14.2 Value of the learning sessions

DHBs generally found the content of the learning sessions useful for supporting the aims of the collaborative. Dr John Krueger's presentations, having international speakers and the red ball exercise were highlighted as particularly valuable for facilitating learning.

> *"For people who learn kinetically, or learn by doing, the red ball exercise … I would love to replicate it because it was so valuable … it was a real lightbulb moment for me, and I think for other people in the room." (DHB 2)*

> *"It helped me understand the processes behind it a little better … if we wanted to, we could probably be a bit more skilled in making something like a driver diagram now." (DHB 3)*

> *"I think they provided some really good international speakers which was really motivating." (DHB 6)*

Other stakeholders found the learning sessions useful overall but thought that some of the sessions on improvement science were too repetitive or technical. They felt that the sessions could have included more 'practical' information that could be feasibly applied in a clinical setting.

> *"From the past two learning sessions there was a lot of repetition … in terms of teaching the methodologies. And I guess it was good for those people who did not attend learning session 1 but those of us that attended both did not really come out with anything new and useful that we could add on to what we already knew." (DHB 1)*

> *"So many of us in the hospital setting are clinically focused and clinically based and this was coming from a process (point of view). Maybe they (the Commission) didn't look enough at how it (the methodology) integrates with clinical practice." (DHB 3)*

One DHB completed online improvement science modules as part of an initiative at its DHB. Stakeholders from this DHB felt the online modules helped them to better 'make sense' of the content provided in the learning sessions.

14.3 Accessing support from the Commission

While in general stakeholders felt that the Commission was available and willing to provide support when needed, some did not think that the Commission was aware of the competing time and resource demands in a hospital, and the impact that this had on their capacity to access support.

> *"He helped us a lot with our driver diagram … that helped consolidate my understanding about driver diagrams better. It comes back to resource though, because we're always chasing our tail, it's them that are chasing us, rather than us chasing them for things." (DHB 4)*

Some DHBs felt that the project support team did not fully understand and appreciate that they were short on staff and had several competing priorities.

Two DHBs felt that providing support through conducting some of the statistical analysis for DHBs, or funding to employ support staff, would have been useful. These DHBs felt that advice and guidance on what they should be doing was valuable but they did not have the capacity to meet these requirements.

> *"We don't have the add-on to Microsoft Excel that produces run charts. For a small DHB, we're happy to measure numbers and happy to supply that data. But to insist that the data [is] supplied in a set format without the tools necessarily being available … I know standardisation is a good thing, but maybe the collaborative should supply the tools." (DHB 5)*

15 CONSIDERING VALUE FOR MONEY

Synergia was not commissioned to conduct a value for money analysis. Understanding value for money, however, aligns to the Triple Aim and is important for the Commission. It was also considered to be useful to identify key costs.

Two-year expenditure for the collaborative is shown in Table 7 below. The total costs of the collaborative were NZ$1,111,000, which also includes a 28% overhead margin assigned to the internal cost components. The highest cost category was clinical leadership or expert advice (NZ$407,000). The next two significant cost areas are both networks and capability building ($272,000) and project management ($277,000).

Table 7: Two-year opioid collaborative expenditure

2014/15 and 2015/16	Networks and Capability Building	Clinical leadership and expert advice	Project management	Measurement and evaluation	Consumer engagement	Total
Total Commission costs	**$272,000**	**$407,000**	**$277,000**	**$134,000**	**$21,000**	**$1,111,000**

This investment supported the project over an 18-month period and achieved:

- a reduction in opioid-related harms at 12 hospital test areas; and potentially more following ongoing data collection and spread of the emergent care bundles
- changes in medication safety processes at 17 hospital test areas, improvements at 13 and potentially all DHBs through the spread of the emergent care bundles
- increases in the DHB teams' improvement science and medication safety capabilities
- development of clinical networks and shared learning across the DHB teams.

The Commission may wish to conduct a value for money analysis for the emergent care bundles. To achieve this, it would be useful to identify:

- total medication, intervention and staff time costs at DHBs
- opioid-related harms
- avoidable deaths and mortality outcomes
- readmissions, length of stay
- Emergency Department visits and admissions
- disability associated life years and quality associated life years (longer term study
- mortality ratios.

16 ENABLERS AND BARRIERS TO IMPLEMENTATION

16.1 Enablers

Commission-facilitated support

- Accessibility of the national collaborative team.
- Technical and analytical support from the national collaborative team; particularly on the use of improvement tools and methods.
- Funding travel and accommodation to support DHB teams' attendance at national learning sessions.
- Presentations from international speakers, particularly Dr John Krueger.
- Harm-based learning session discussions and telephone conferences.
- Learning session activities that supported learning and understanding of quality improvement with practical exercises.
- Using technology to engage with DHB teams, teleconferences and the shared workspace.

DHB team enablers

- The importance of reducing patient harms and improving medication safety.
- Positive perceptions of the Commission and its work.
- Commitment and engagement from the DHB teams.
- Existing engagement of some DHB team leaders in improving medication safety.
- Existing interdisciplinary relationships in the DHBs.

Applying improvement science and measuring improvement

- Existing DHB experience with improvement science.
- Opportunities for DHBs to gain feedback on their data collection and approach, particularly site visits.
- Some teams also valued the flexibility of the collaborative, for example, being able to pursue and identify their own harm areas and determine their own measures and indicators for measurement.

16.2 Barriers

Capacity of the DHB teams

- Time and resources were the biggest challenge for DHB teams, because this work was completed on top of their existing workload.
- Capacity was particularly challenging for the smaller DHBs. For example, one of the DHBs that did not fully participate in the collaborative would be without a pharmacist if it had sent them along to the learning sessions.
    - One of the DHBs with a small surgical unit felt that the national collaborative team did not fully understand its resource and time constraints. For example, the patients often did not stay overnight making it difficult to collect data every day.
- Level of administration and reporting.
- Competing priorities and the fact that staff 'wear many different hats' made it difficult to follow the improvement journey step by step.

- An under-estimation of the workload involved in participating in the collaborative.
- Limited access to a quality improvement advisor for some DHBs.
- Lack of engagement from some DHB project leads at the start of the collaborative.
- Lack of support for some DHBs at the more senior levels of the organisation.

Commission-facilitated support

- Challenge of some DHBs identifying their own harms and focus areas.
- Variations in the definitions used across the collaborative (for some DHBs).
- Theoretical or repetitive nature of some learning session presentations.
- The shared workspace worked more as a data repository than a platform for learning and sharing. Some DHB team members had difficulty accessing the workspace or did not use it.
- Managing 20 DHBs was too difficult within the timeframe.

Applying improvement science and measuring improvement

- Limited time to collect baseline data.
- Understanding the requirement for baseline data collection. Some of the DHBs would have liked more guidance on the type of data to collect. While some level of flexibility was needed to get buy-in from DHBs, flexibility around the definition of harm made data difficult to aggregate and made reporting on the outcomes of the collaborative challenging.
- High level of data collection.
- The large number of DHBs focusing on constipation; some felt that a more even allocation would have supported the collaborative to learn more about other harm areas.
- Format and structure of improvement science; this was difficult for some DHBs to adhere to alongside their day-to-day clinical work.

17 OVERVIEW AND KEY CONSIDERATIONS

The evaluation has highlighted the role of the collaborative approach in supporting DHB hospital teams to:

- reduce opioid-related harms by at least 25% in seven hospital test areas, and implement improvements in opioid-related medication safety processes in 17 hospital test areas (13 of which were significant)[10]
- identify a set of evidence-based interventions to create an emerging bundle of care that can be further tested and spread across the health sector
- raise the profile of medication safety and opioid-related harms at DHBs that were not already using improvement science to support this
- increase DHB teams' capabilities in improvement science
- develop clinical networks that, with some support from the Commission, could be reused to support other medication safety work
- collect, collate and analyse data to demonstrate change and improvement, although there was some variation in the level of reporting and use of the shared workspace across DHBs.

These achievements were supported by a range of activities. The evaluation highlights the particular value of:

- the creation of a collaborative learning environment that moves beyond geographical boundaries to support learning across all DHB teams
- the sense of trust and openness achieved through the collaborative, between the DHBs and the Commission to support shared learning and resources
- the commitment and engagement from DHB teams, both to the collaborative and to testing the care bundles and being part of an ongoing clinical network
- the leadership and support from the national collaborative team
- the improvement science expertise of the national project team and the additional support provided by international experts, such as Dr John Krueger.
- the Delphi process and the Expert Faculty.

17.1 Key considerations

This section identifies ideas for improvements or key considerations for undertaking this type of work in the future.

Developing the sector's capability for improvement

- The dual focus on developing an evidence base and building capability challenged the establishment of robust data collection processes and the reliability of some of the baseline and improvement period data. When adopting a formative approach in an area with little local or national evidence

[10] Four hospitals stopped participating in the collaborative and four implemented medication safety processes but did not collect improvement data.

of what works, consider an initial engagement phase with a smaller sample of DHBs, to develop the evidence base to inform the care bundles.
- Supporting all DHBs to enhance their improvement science capabilities could still be enabled through testing the emerging bundles, rather than engaging them all in developing the evidence base.
- Learning through the work of this innovative collaborative by recognising the time that it takes for DHBs to engage and get up to speed in terms of capability and understanding to support the work of a collaborative.

Learning sessions and applying improvement science

- Balancing the focus between theory and technical language relating to improvement science and the provision of applicable information on data and measurement. DHBs would have liked more practical examples that would better support DHBs to identify opportunities to apply the methodology to their clinical practice.
- One option could also be to use the series of workshops as an opportunity for DHBs to bring their data along for 'deep dive' sessions. This would support opportunities for learning and understanding the importance of systematic data collection processes.
- Providing DHBs with clearer guidance on the commitment that is required in terms of time and resources.
- Responding to the variations in the capacity of DHBs, perhaps by providing more analytical support to those with small teams.
- Supporting DHBs to communicate the importance of medication safety at their hospitals to encourage support and engagement from across the organisation.

The balance between being formative and prescriptive

- Providing clearer guidance on the baseline data requirements and the timeframe within which this must be collected. This should include clarity of the requirements and timeframe for using the collaborative methodology including the baseline data collection period and a timeframe for establishing a harm area to focus on.

Clinical networks

- Support the current clinical network to continue to broaden its focus on medication safety, while continuing to engage in testing the bundles.
- Share stories of success and progress of the DHBs who sign up to test the emerging bundles of care to promote uptake and spread of the bundles in other DHB areas.

Consumer engagement and responsiveness to Māori

- Consider the representation of a Māori cultural advisor and consumer advisor on the Expert Faculty, to support improvement in consumer engagement and responsiveness to Māori at a national level.
- Clarify and agree the level of consumer engagement that is considered to be important for this type of work at a national, regional and local level.
- Explore the potential to engage consumers in evaluation to provide a more in-depth insight into consumer experiences and benefits.

APPENDIX 1: SUMMARY OF DHB INTERVENTIONS, HARM AREA AND CHANGES ACHIEVED

DHB	Interventions to improve medication safety processes	Harm area	Baseline sample size	Proportion of patients harmed during the baseline period	Improvement sample size	Proportion of patients harmed during the improvement period	Relative difference in harm	Relative reduction?	Relative reduction with special cause?	Improvement to at least one medication safety process?	Statistically significant improvement to at least one process?
Bay of Plenty	• Bowel monitoring (recording of bowel activity) • Prescribing of laxatives • Co-prescribing of laxatives (prescribing opioids and laxatives on the same day) • Regular administration of laxatives	Constipation	90	49%	529	29%	–42%	✓	✓	✓	✓
Capital and Coast	• Bowel monitoring • Co-prescribing of laxatives • Administration of prescribed laxatives in the past 24 hours	Constipation	18	50%	140	37%	–26%	✓	✓	✓	✓
Counties Manukau	• Co-prescribing of laxatives • Administration of =/>1 dose of co-prescribed laxatives • Bowel monitoring	Constipation	60	40%	275	16%	–60%	✓	✓	✓	✓
Hawke's Bay	• Bowel monitoring (documentation of bowel activity) • Patient and staff education	Constipation	0	No baselines collected	328	21%	No baselines collected	No baselines collected	No baselines collected	No baselines collected	No baselines collected
Lakes	• Bowel monitoring (Early Warning System bowel monitored every shift) • Laxative given proactively • Kiwicrush given • Number of patients who have eaten prunes • Ondansetron prescribed • Ondansetron given	Constipation	107	55%	176	31%	–44%	✓	✓	✓	✓

DHB	Interventions to improve medication safety processes	Harm area	Baseline sample size	Proportion of patients harmed during the baseline period	Improvement sample size	Proportion of patients harmed during the improvement period	Relative difference in harm	Relative reduction?	Relative reduction with special cause?	Improvement to at least one medication safety process?	Statistically significant improvement to at least one process?
MidCentral	• Co-prescribing of laxatives • Bowel monitoring ('days since bowels last opened' used in clinical notes) • Bowel monitoring (bowel function documented in clinical notes) • Patient and staff education	Constipation	66	12%	262	10%	–15%	✓	No	✓	✓
Nelson Marlborough	• Co-prescribe laxatives • Bowel monitoring ('days since bowels last opened' used in clinical notes) • Bowel monitoring (bowel function documented in clinical notes)	Constipation	42	24%	338	16%	–33%	✓	No	✓	✓
Taranaki	• Bowel monitoring • Laxative charted • Co-prescribing of laxative • Administration of laxative	Constipation	0	No baselines collected	160	9%	No baselines collected	No baselines collected	No baselines collected	✓	✓
Waikato	• Bowel monitoring (bowel activity documented daily) • Laxative prescribed at the same time as opioid	Constipation	69	48%	133	53%	12% **	Warrants further exploration	No	✓	✓
West Coast	• Bowel monitoring (recording of bowel movement) • Regular laxative charted • Regular administration of laxative	Constipation	0	Insufficient baseline	142	8%	Insufficient baseline	Insufficient baseline	Insufficient baseline	Insufficient baseline	Insufficient baseline
Auckland	• Correct medicine choice and dose of opioid at discharge • Correct quantity of opioid prescribed at discharge	Nausea and vomiting	40	28%	100	24%	–13%	✓	✓	✓	No
Southern	• Preoperative assessment to identify at-risk patients • Anti-emetics offered to high-risk patients • Ice blocks (non-pharmacological) • Analgesia guideline to avoid use of opioids • Staff education	Nausea and vomiting	No baselines collected	No baselines collected	192	29%	No baselines collected	No baselines collected	No baselines collected	No baselines collected	No baselines collected

DHB	Interventions to improve medication safety processes	Harm area	Baseline sample size	Proportion of patients harmed during the baseline period	Improvement sample size	Proportion of patients harmed during the improvement period	Relative difference in harm	Relative reduction?	Relative reduction with special cause?	Improvement to at least one medication safety process?	Statistically significant improvement to at least one process?
MercyAscot	• Respiratory rate monitoring • Sedation monitoring	Respiratory depression	116	4%	269	1%	–74%	✓	✓	✓	✓
Northland	• Use of STOPBANG assessment to identify high-risk patients • Capturing cumulative opioid dosing using a sticker	Respiratory depression	Not applicable *	14.8*	Not applicable*	33.4*	–56%	✓	✓	✓	✓
Canterbury	• Reduce oral morphine dose • Reduce intravenous morphine dose	Uncontrolled pain	168	23%	2179	34%	49% **	Warrants further exploration	No	✓	✓
Waitemata	• Pain assessed and documented • Analgesia offered • Analgesia regularly administrated • Intravenous Therapy Patient Controlled Analgesia and Patient Controlled Epidural Analgesia monitoring	Uncontrolled pain	121	10%	95	16%	60% **	Warrants further exploration	No	✓	✓
Whanganui	• Patient and staff education	Uncontrolled pain	0	No baselines collected	81	27%	No baselines collected	No baselines collected	No baselines collected	No baseline or improvement data collected	No baseline or improvement data collected

NOTE: Tairawhiti, Hutt, Wairarapa and South Canterbury DHBs participated in the collaborative by attending some of the learning sessions and teleconferences, however, they did not actively contribute to testing.

*At Northland DHB, the number of days between respiratory events was used as a proxy for the frequency of respiratory events. Therefore, the figures for the level of harm during baseline and improvement represent the number of days between respiratory events during each period.

** As noted in the main report, this increase could reflect an improvement in monitoring, as well as the challenges of measuring uncontrolled pain.

APPENDIX 2: THE COMMISSION'S DELPHI PROCESS

Rationale for Delphi panel process

A process to create the Safe Use of Opioids National Formative Collaborative's (the collaborative's) care bundles was discussed with district health board (DHB) teams, with advice from the Institute for Healthcare Improvement (IHI).

To add rigour to the process for identifying the bundle elements (and operational definitions), the Health Quality & Safety Commission (the Commission) decided to use a modified Delphi technique (a data-oriented approach to consensus-based problem-solving).

Delphi panels were convened for each of the three harm bundles, where there was adequate DHB quality improvement data, namely constipation, opioid-induced ventilatory impairment, and uncontrolled pain harm areas.

The role of each panel was to review the harm bundle elements that the DHBs had identified (based on testing, international literature and their clinical experience) and consider whether each element would be suitable for inclusion in the emerging care bundle to be tested further by DHBs during 2016–17.

Each element represented an intervention to reduce harm. For example, a possible element relating to constipation might be an intervention such as co-prescribing laxatives for patients receiving opioids.

Delphi process

This process was adapted from Dr John Krueger's *Modified Delphi Consensus Care and Quality Bundle Creation* © 2015 John Krueger MD, MPH.

1. A list of harm bundle elements was sent to Delphi panel members for analysis and consideration for the emerging composite care bundle.

2. The goal of this process was to critically evaluate the evidence and develop an informed collective opinion about the value of each for inclusion in the emerging care bundle. Delphi panel members were asked to score each harm bundle element based on their own experiences, and having considered the published evidence provided, and the DHBs' quality improvement data.

3. Members voted anonymously but, at the end of the session, were allowed to see how all the other members of the evaluation cohort voted collectively for each bundle element and to see the average, median and standard deviation and coefficient of consensus. Perfect consensus is 100%, whereas for the purposes of this process, **a goal for consensus was 60%**.

4. If consensus was not reached in the first voting round, the Commission would consider holding a second voting round.

5. Members could anonymously add their comments and assessments for the group to see, however, at no time were the group participants allowed to directly communicate with one another. All comments were shared around the group members.

6. During the voting session, members scored the harm bundle elements using the following methodology. Whole numbers were used at all times.

Scoring	Value	Explanation
Strongly Disagree With Adding Element	1	No Value – The element adds no value to the care bundle performance and has low evidence.
Disagree With Adding Element	2	Poor Value – Adds very little to care bundle and/or evidence is low to moderate.
Neutral	3	Average Value – Adds some value to care bundle and/or evidence is moderate to moderate-high.
Agree With Adding Element	4	High Value – Adds significant value to the care bundle and/or evidence is high to very high.
Strongly Agree With Adding Element	5	Highest Value – Adds the most benefit to the care bundle and/or evidence for use is very high.

7. Members scored the value of each of the bundle elements and entered the values into the following grids.

Harm area: Constipation

Number	Element (representing an intervention to reduce opioid-related harm)
1	Co-prescribe and administer laxatives at time of opioid administration.
2	Monitor and document bowel activity (ie, minimum daily) and appropriate actions taken.
3	Include non-pharmacological interventions in care plan (eg, dietary and/or fluid prescription).
4	Provide patients/consumers and their families/whānau with information about bowel health and strategies to prevent and manage opioid-related constipation, and in formats appropriate to their needs.
5	Assess staff knowledge about opioid-related constipation prevention and management and provide education to address deficits in knowledge.

Harm area: Opioid-induced ventilatory impairment

Number	Element (representing an intervention to reduce opioid-related harm)
1	Assess to identify high risk patients (eg, STOPBANG; trigger for risk (ie, high opioid dose, increased sedation, low respiratory rate, threshold administration rate – opioid dose per hour)).
2	Consider opioid-sparing pain management options.
3	Monitor and document for opioid-induced ventilatory impairment (OIVI) as per local guidelines.
4	Manage narcosis episodes using standard protocols (eg, administration of naloxone, ventilatory support).
5	Provide patients/consumers and their families/whānau with information about opioid use and risk, and in formats appropriate to their needs.
6	Assess staff knowledge about OIVI prevention and management and provide education to address deficits in knowledge.

Harm area: Uncontrolled pain

Number	Element (representing an intervention to reduce opioid-related harm)
1	Assess, monitor and document pain severity, efficacy of pain management and adverse effects (eg, use of observation charts).
2	Use pain medication dosing guidelines for appropriate route of administration and optimal pain management.
3	Offer regular analgesia and give additional analgesia where pain is not relieved (with attention to patient safety as well as comfort).
4	Provide patients/consumers and their families/whānau with information about pain management and safe opioid use and risks, and in formats appropriate to their needs.
5	Assess staff knowledge about pain prevention and management and provide education to address deficits in knowledge.

Outcome of Round 1 scoring

Scoring occurred via email on 16 and 17 June 2016. Generally, the results for the three harm bundles showed 'good', to 'relatively good consensus', so a second scoring round was not required. A spreadsheet of the Delphi analysis is available from the Commission (on request). The results of the Delphi panel scoring were shared with the Delphi panel members on 22 June, and also with the collaborative's Expert Faculty to inform their decisions for finalising the three harm bundles, and for developing the elements of the emerging composite care bundle.

Delphi panel membership

Various professional membership organisations in New Zealand were approached for nominations (list available on request). Associate Professor Pam Macintyre was invited because she was identified as being an expert in pain management. Names were received from the organisations, and details about the Delphi process were confirmed with each panel member. A pre-scoring teleconference was held prior to brief the panel members about the rationale and process.

Name	Designation	Panels
Irene Minchin	Clinical Nurse Specialist Acute Pain, Nelson Marlborough DHB	• Uncontrolled pain
Dr Paul Hardy	Clinical Leader Pain Management, Capital and Coast DHB	• Uncontrolled pain • Opioid-induced ventilatory impairment
Dr Frances James	Consultant Clinical Psychologist, Counties Manukau DHB	• Uncontrolled pain
Dr Bruce Foggo	Palliative Medicine Specialist and Medical Team Leader, Mercy Hospice, Auckland	• Uncontrolled pain • Constipation
Associate Professor Pam Macintyre	Director, Acute Pain Service, Royal Adelaide	• Uncontrolled pain • Opioid-induced

	Hospital and University of Adelaide	ventilatory impairment
Emma Griffiths	Pharmacist, MercyAscot, Auckland	• Uncontrolled pain • Constipation
Erica Gleeson	Acute Pain Nurse Specialist, MidCentral DHB	• Opioid-induced ventilatory impairment • Constipation
Dr Anne Denton	Clinical Pharmacist and Facilitator, Hawke's Bay DHB	• Opioid-induced ventilatory impairment • Constipation
Teena Robinson	Nurse Practitioner, Southern Cross, Rotorua	• Opioid-induced ventilatory impairment • Constipation

Rationale for convening the Expert Faculty

The Expert Faculty, originally convened in October 2014 to identify measures for the collaborative, was invited to reconvene to assist with bundle development and sign-off. An overseas expert who was not part of the original faculty was invited to strengthen nursing representation on the group. Not all of the original faculty members were available to contribute to the process. A teleconference was held to brief faculty members about progress to date and the rationale for coming together again.

A workshop was held on 27 June 2016 for the Expert Faculty members to meet (having considered the: 1) published evidence; 2) DHBs' quality improvement data; and 3) Delphi panel voting outcome concerning the harm bundle elements) and based on their own knowledge and experience to:

1. reach agreement on the harm bundles that had been subject to the Delphi process

2. create the emerging composite care bundle for opioid safety for further testing.

Workshop outcomes

At a workshop, faculty members participated in a Delphi round to finalise the three harm bundles; a consensus was achieved subject to some editing of the individual elements. The Delphi process was the same as that used for the Delphi panels convened earlier.

Faculty members then workshopped and compiled the emerging composite care bundle elements.

Post-workshop bundle refinements

The emerging composite care bundle elements were then further refined by the national collaborative team, with further support from Dr John Krueger (IHI). Two Delphi rounds of the Expert Faculty were conducted to wordsmith each bundle element before a consensus was finally reached.

The elements of the three harm bundles were then edited by the national collaborative team to align them with the emerging composite care bundle elements wording. The

Expert Faculty then participated in two further Delphi rounds before a consensus was reached on the wording for the elements for the three harm bundles.

Analyses for the scoring of each Delphi round, and details about the refinements to bundle element wording following each scoring round, are available from the Commission, on request, as are copies of the final bundles.

Expert Faculty membership

Associate Professor Maureen Cooney was co-opted onto the Expert Faculty as an extra nursing representative and overseas member. The workshop on 27 June was also attended by Dr John Krueger (IHI). Overseas members attended via web meeting.

Name	**Designation**
Sue King (retired)	Nurse Practitioner – Pain Management, Waikato Hospital
Dr Murray Hunt	Palliative Care Specialist, Waipuna Hospice, Tauranga
Caroline Tilah	Executive Director (Operations) Quality Improvement and Patient Safety (QIPS) Directorate, Capital and Coast DHB
Dr Carol McAllum	Palliative Care Specialist, Waipuna Hospice, Tauranga
Associate Professor Maureen Cooney	Nurse Practitioner, Pace University (New York)
Professor Stephan Schug	Chair of Anaesthesiology, Royal Perth Hospital
Dr Wendy Pattemore	Palliative Care Specialist, Nurse Maude Hospice, Christchurch
Avril Lee	Clinical Lead, National Collaborative Team, Health Quality & Safety Commission
Beth Loe	Medication Safety Specialist, Health Quality & Safety Commission
Gillian Bohm	Principal Advisor Quality Improvement, Health Quality & Safety Commission

APPENDIX 3: EXAMPLE CONTROL CHARTS

Figure 15: Proportion of patients with constipation over time at Waikato DHB

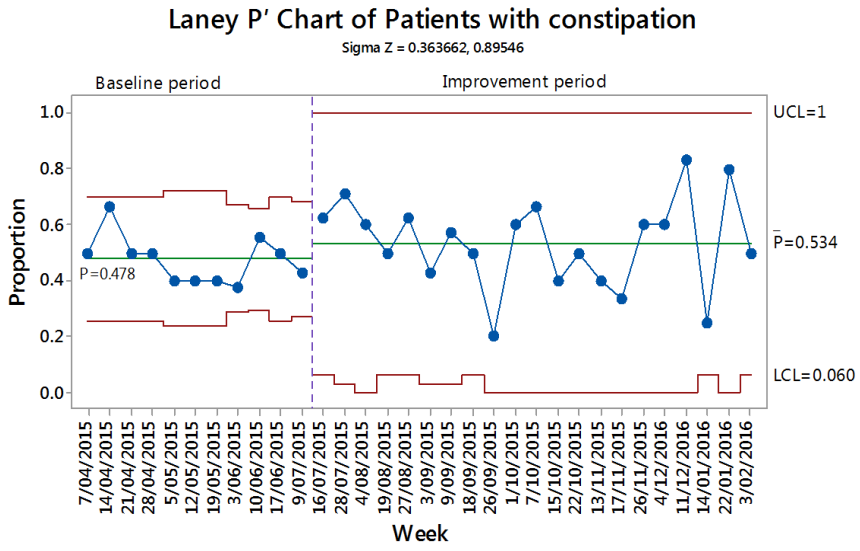


Figure 16: Control chart for co-prescribing of laxatives at Capital and Coast DHB

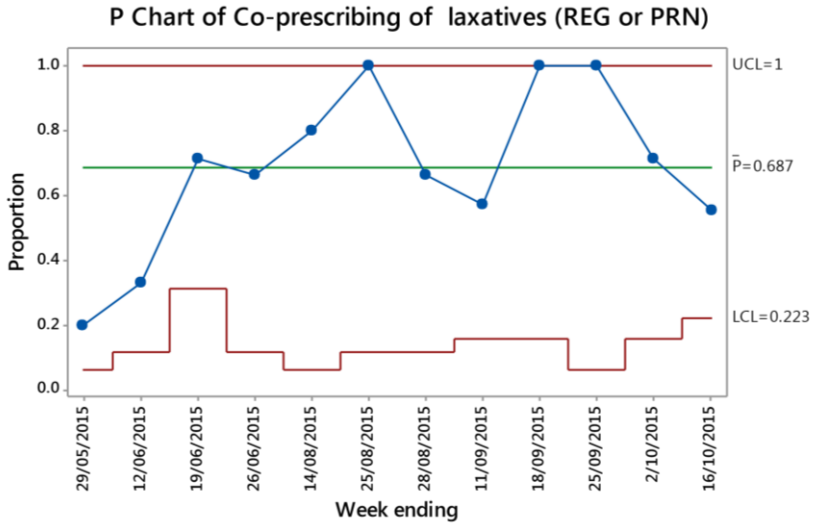


Figure 17: Control chart for proportion of patients with constipation over time at Taranaki DHB

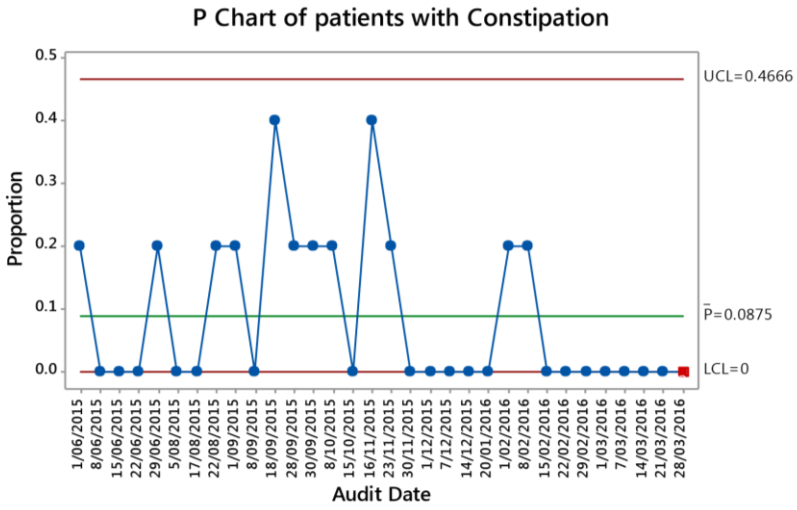
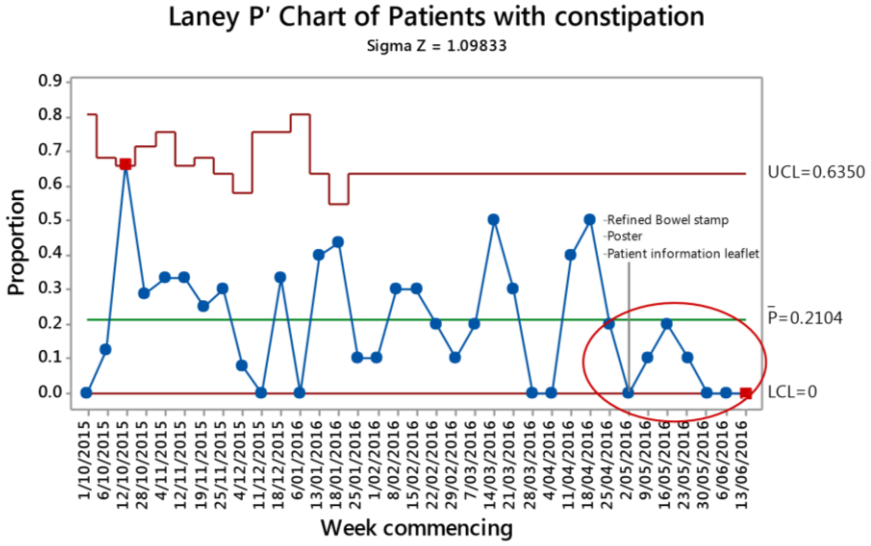


Figure 18: Control chart for proportion of patients with constipation over time at Hawke's Bay DHB



Tests are performed with unequal sample sizes.

Figure 19: Control chart for the rate of bowel chart documentation over time at Hawke's Bay DHB

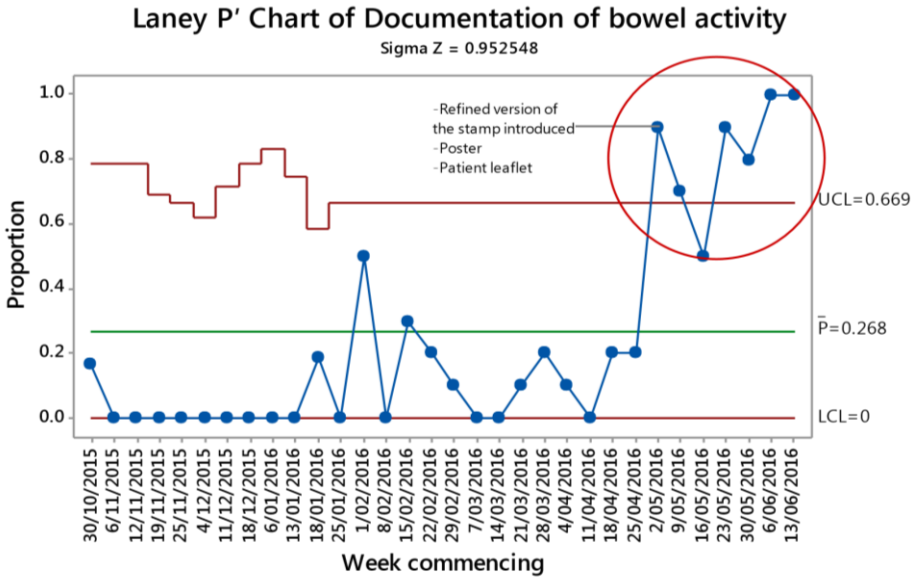


Figure 20: Control chart for charting the regular administration of laxatives over time at West Coast DHB

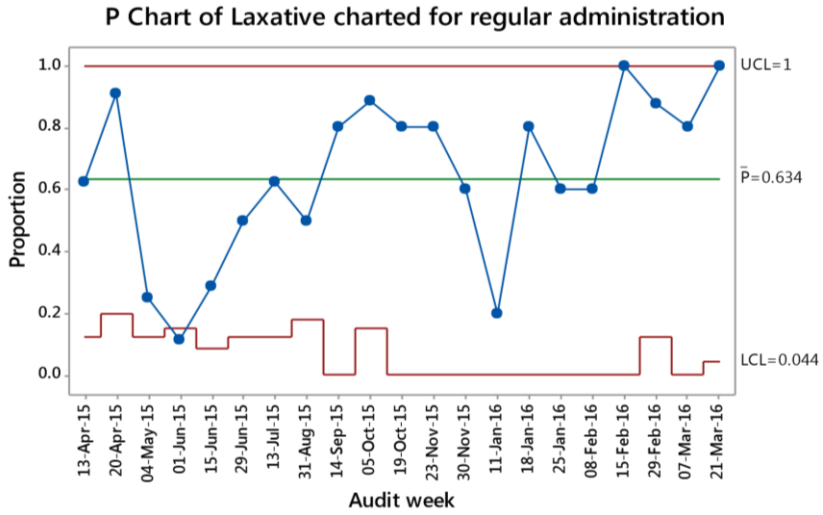


Figure 21: Control chart for bowel movement recording over time at West Coast DHB

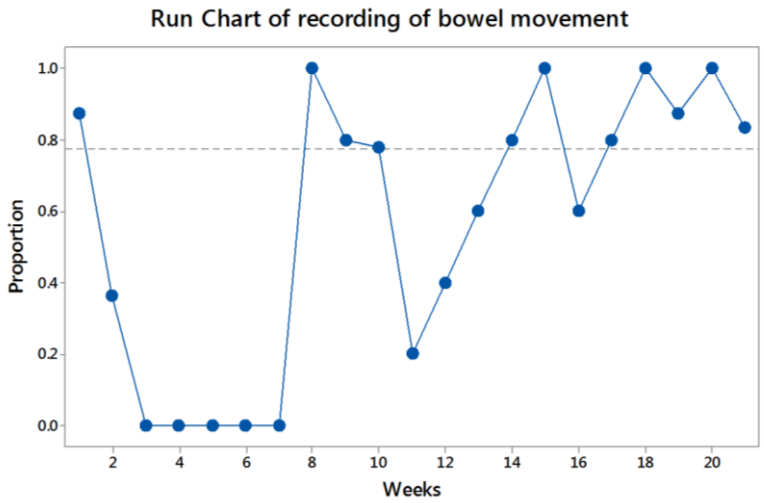


Figure 22: Control chart for the proportion of patients with uncontrolled pain at Whanganui DHB