A First Phase Evaluation of Saskatchewan’s Lean Health Care Transformation: Final report

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The steering committee, comprising of six Saskatchewan-based Lean experts listed below, collaborated with the Lean evaluation team, providing expert advice and high level management support.

- Kathleen Peterson  Ministry of Health
- Maura Davies  Saskatoon Health Region
- Cheryl Craig  Five Hills Health Region
- Trish Livingston  Ministry of Health
- Max Hendricks  Ministry of Health
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In addition to the valuable support of the steering committee, the Lean research team has also identified a core group of advisors and Lean experts. These advisors gave substantial amounts of their time to review our evaluation framework, and to provide critical and clinically relevant information about the Lean Management System and other context or methodological issues. This expert group also includes knowledge users on a regional, provincial, and pan-Canadian level and consists of the following members:

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- Myles Cairns  Five Hills Health Region
- Patt Stuart  Prince Albert Parkland Health Region
- Candice Bryden  Saskatoon Health Region
- Teresa Watt  Mamawetan-Churchill Health Region
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>3P</td>
<td>Production Preparation Process</td>
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<tr>
<td>5S</td>
<td>Sort, Sweep, Simplify, Standardize, Sustain/Self-Discipline</td>
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<tr>
<td>AUS</td>
<td>Australia</td>
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<tr>
<td>CIHI</td>
<td>Canadian Institute for Health Information</td>
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<td>CIHR</td>
<td>Canadian Institutes of Health Research</td>
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<tr>
<td>CMOCs</td>
<td>Context-Mechanism-Outcome Configurations</td>
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<td>CMOs</td>
<td>Contexts, Mechanisms and Outcomes</td>
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<tr>
<td>DVM</td>
<td>Daily Visual Management</td>
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<tr>
<td>DVT</td>
<td>Deep Vein Thrombosis</td>
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<tr>
<td>EPOC</td>
<td>Effective Practice and Organisation of Care</td>
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<td>ER</td>
<td>Emergency Room</td>
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<td>FHHHR</td>
<td>Five Hills Health Region</td>
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<td>HbA1c</td>
<td>Glycated hemoglobin</td>
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<td>HQC</td>
<td>Health Quality Council</td>
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<td>HSMR</td>
<td>Hospital Standardized Mortality Ratio</td>
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<td>ICU</td>
<td>Intensive Care Unite</td>
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<td>ITS</td>
<td>Interrupted Time-Series</td>
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<td>IV</td>
<td>Intravenous</td>
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<td>JBA</td>
<td>John Black and Associates</td>
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<td>KPO</td>
<td>Kaizen Promotion Office</td>
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<td>LOS</td>
<td>Length of Stay</td>
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<td>MCRRHA</td>
<td>Mamawetan Churchill River Health Region</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<tr>
<td>PAPHR</td>
<td>Prince Albert Parkland Health Region</td>
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<td>PE</td>
<td>Pulmonary Embolus</td>
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<td>PLT</td>
<td>Leadership Team</td>
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<td>RPIWs</td>
<td>Rapid Process Improvement Workshops</td>
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<td>RTC</td>
<td>Releasing Time to Care</td>
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<tr>
<td>SHR</td>
<td>Saskatoon Health Region</td>
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<tr>
<td>U of R</td>
<td>University of Regina</td>
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<tr>
<td>U of S</td>
<td>University of Saskatchewan</td>
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<tr>
<td>VAP</td>
<td>Ventilator Acquired Pneumonia</td>
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1. Introduction

The Saskatchewan Ministry of Health (MOH) has made a commitment to achieve transformation of the provincial health system to produce ‘better health, better value, better care, and better teams’.

They have chosen to do this through a multi-million dollar investment in the implementation of Lean (Saskatchewan’s Lean Management System) across the province’s health care system, engaging consulting firm John Black and Associates (JBA) from the United States to establish the System in Saskatchewan.

The initial focus is on leadership, strategic alignment, training, and the creation of a supportive infrastructure, the Kaizen Promotion Offices (KPOs).

Given the scope and scale of the project and the commitment of resources, the Provincial Leadership Team (PLT) of the health system identified the need for a rigorous evaluation of the Lean initiative. The PLT is comprised of the CEOs of health regions, provincial health system support agencies, and the Deputy Minister of Health.

The PLT commissioned the Saskatchewan Health Quality Council to assemble an independent research team to design an evaluation plan and to gather baseline information.

This research team has worked with the Provincial Lean Steering Committee, composed of senior leaders and staff from Saskatchewan Health, provincial health regions, and HQC, to:

- identify stakeholders, and to
- facilitate our contact with key individuals to assist with understanding the existing provincial and regional data.

Through the HQC we have been provided with information related to existing data and activities co-ordinated by the HQC[1].

1.1 Background and Context:

Lean is a multi-faceted, patient-centred approach to manage and improve both quality and efficiency. The system utilises a continuous learning cycle that is driven by the ‘true’ experts in the processes of health care, being the patients/families, health care providers and support staff, with coaching and sponsorship from health region managers and leaders [2].

The approach is derived from the Toyota car company production line system: a continuous process improvement system incorporating structured inventory management, waste reduction and quality improvement techniques.

The Saskatchewan health care system is using a staged approach to implement Lean.

The initial phase centred on a project using Releasing Time to CareTM (RTC), a process improvement initiative, implemented in some regions in 2008. RTC uses Lean principles to facilitate the engagement of front-line nurses in improving quality of care and reducing waste in acute care medical and surgical wards.
This project was followed by the establishment of Lean Kaizen Promotion Offices (KPO) in five health regions, and in provincial health system organizations such as the Ministry of Health, 3S Health, Saskatchewan Cancer Agency, and Saskatchewan Health Quality Council.

The KPOs aim to train and certify 900 Lean leaders to lead quality improvement work by 2016 [4]. The Saskatchewan Health Quality Council (HQC) has a unique role as the Provincial Lean KPO with the responsibility for standardization and coordination of Lean training, events and planning across the province. As part of the Lean reform, all initiatives, such as major construction works, are required to use the highly structured Lean design principles encapsulated in the Production Preparation Process (3P).

In Saskatchewan the Lean Management system is used in combination with a strategic management and policy deployment system, called Hoshin Kanri, and daily visual management, the latter being an approach where staff members take the time each day to evaluate their progress using the key elements of daily huddles and visibility walls.

1.2 Overall purpose of the project

This project aimed to

a) evaluate the early stages of the implementation of Lean (Saskatchewan’s Lean Management System) in the provincial health system; and

b) develop a competitive grant application for the Canadian Institutes of Health Research (CIHR), and other research funding agencies.

The first phase evaluation collected baseline data and established the framework and methods for use for an ongoing evaluation of the multi-year process of implementing Lean.

The research plan includes a fully articulated logic model to guide the multi-year evaluation.

2. Activities in the baseline study

2.1 Work completed during baseline

The first phase contract required a methodological report describing how the evaluation design was developed, including ‘the development and feasibility testing and refinement of specific qualitative and quantitative methods to be used in the proposed evaluation.’ The following describes the activities undertaken and their contributions to methodological development.

Activities in the first phase have included:

- Consultation with stakeholders through a Steering Committee, a core group of expert advisors and a stakeholder workshop;

- Semi-structured interviews with nine key decision- and policy-makers to identify priority issues for the evaluation;

- A first round of interviews with decision-makers and KPO representatives in ten regions;
• A systematic review of literature relating to the use of Lean in health systems internationally. A copy of the full literature review is provided in Appendix 1;

• An implementation mapping study examining the Lean activities undertaken in five health regions, with a particular focus on rapid process improvement workshops (RPIWs) and 5S activities. Both the selection of the regions and the focus on RPIWs and 5S were endorsed by the Steering Committee and the HQC. Please see section five of this report (5. Lean implementation mapping);

• Visits to each of the four focus regions to conduct a set of semi-structured interviews with patients, service providers, and leaders;

• An iterative process of theory development which identified the key mechanisms to be explored in the multi-year evaluation and the outcomes indicators to be collected;

• The first stage of an economic evaluation, examining the costs of Lean implementation. In the multi-year evaluation this will be extended to a cost-benefit evaluation;

• Endorsement of the key focus areas for the multi-year evaluation by the Steering Committee;

• The selection of baseline data for key outcomes indicators. Please see section 8.3 (Selecting outcome measures) of this report.

Each of these activities has contributed to methodological development for the multi-year evaluation, and each is discussed in greater detail below.

The report structure

The requirement for combining a realist evaluation with a collaborative approach to developing the multi-year evaluation was warmly welcomed by the research team.

This combination, however, had significant implications for the ways in which the work has been undertaken. Realist evaluations are iterative in design: later stages of the work evolve from and build on earlier stages and also require refinements to products from earlier stages. Research questions are refined over time; program theories are refined over time; the nature of the data necessary to test those theories is consequently also refined over time.

This has certainly been the experience of the first phase of the evaluation, and it is a feature of the design of the multi-year evaluation as well.

Such a process presents a challenge in structuring a coherent report.

However, we have sought to overcome this through the following report structure:

• Providing a brief description of consultative and collaborative processes undertaken (primarily) in the early stages of the project.
Focusing on the issue of theory related to the evaluation content of the report and discussing both the kinds of theoretical work undertaken and the products of that work.

Describing each of the sub-studies undertaken through Phase 1 and the contribution that each has made to the development of the Phase 2 evaluation designs.

Finally, we describe in some detail the multi-year evaluation approach for our Phase 2 evaluation design.

2.2 Consultation and collaborative processes

Key Informant interviews

The process of baseline-data collection, development of the longitudinal evaluation framework and methods for the Saskatchewan Lean Management System commenced with semi-structured interviews conducted by research team members with nine key decision- and policy-maker informants. The interviews were designed to elicit their priorities for evaluation.

The conversations identified the need to use both qualitative and quantitative methods to evaluate issues such as sustainability, the pace of change, effectiveness, cost-effectiveness, availability of resources, staff engagement and specific initiatives such as RPIWs.

These issues were utilized in the interviews conducted with stakeholders in five regions, and thus determined the nature of the data available from those interviews.

Stakeholder workshop

The research team facilitated an interactive stakeholder consultation workshop on June 24, 2013. Forty-nine stakeholders attended, including knowledge users and decision makers, such as clinicians, patients, families and managers, representing twelve health regions across the province. The overarching question explored during this meeting was ‘For whom, how and under what circumstances is the Lean Management System effective in improving care, health, value and teamwork?’

Participants worked in assigned small groups, facilitated by research team members. The groups described the behavior changes, reasoning, and outcomes of work being conducted in the following areas: Kaizen Basics; RPIWs; Leadership Training; Value Stream Mapping; Kaizen Promotion Office; Visual Daily Management; and Hoshin Kanri.

The outcomes were transcribed and collated to develop an initial draft of multi-year research questions, to inform development of the questions asked in a subsequent round of interviews, and to inform the first phase of theory development. Program theory maps for many of these activities are included in the theory maps in Appendix 2.

2.3 Initial KPO visits

Using the input from the stakeholder meeting, the research team developed a number of key questions to collect additional background information during face-to-face visits with the health regions.
Between July and October 2013, the research team conducted 10 interviews with KPO representatives in the following health regions: Five Hills, Mamawetan-Churchill, Sun Country, Kelsey Trail, Swift Current, Prince Albert-Parkland, Saskatoon, Provincial KPO, Regina-Qu’Appelle and 3S Health. Lean methods and principles were, at the time, in the early stages of implementation in the province.

Questions focused on the

- nature of Lean interventions underway, and the
- way in which the interventions are prioritized and evaluation data currently collected.

The KPO leaders provided information on data collection and quality of data, identifying potential facilitators and barriers related to carrying out key aspects of the research. They provided insight into context specific implementation strategies, reflecting the uniqueness of each of the health regions.

Notes from the initial interviews were recorded on paper and then validated by the interviewees.

The information was collated and grouped, then used to:

- Develop our second round of interview questions, and to
- validate both the quantitative data collection strategy and also the
- Lean intervention mapping (see section 5 Implementation mapping).

2.4 Steering Committee meetings

The steering committee was comprised of six Saskatchewan-based Lean experts who consulted with the Lean evaluation team, providing expert advice and high level management support.

The first meeting of the Saskatchewan-based research team with the Lean Evaluation Steering Committee was held on March 7, 2013. The aim of the meeting was to select the best research team and approach for the Lean evaluation. The research team listed in this report was awarded the contract to conduct the phase one research in April 2013.

The second meeting was held on May 13, 2013, with the aim of discussing the proposal and to make a decision on the final research approach for the baseline study and methodological development. Max Hendricks (Ministry of Health) suggested that an economic analysis including the total costs of the Lean implementation should be included. The economic analysis is discussed further in Section 5 below.

The third meeting was held on January 6, 2014 to discuss the research progress based on the progress report submitted to the Saskatchewan Health Quality Council in November 2013. On the basis of this report the steering committee recommended that ‘Hoshin Kanri’ be included in the evaluation. Hoshin Kanri is reflected in the overarching program theory and to some extent in the outcomes of interviews conducted in Phase 1.
On April 24, 2014, the Lean research team provided an update for the steering committee members on the phase one evaluation. It was recommended and the team agreed to interview an additional Lean decision maker from the Ministry of Health (Kathleen Peterson) and to include changes in organizational culture in the Lean program theory.

Empowerment and leadership change are both manifestations of organisational culture change and of mechanisms which are expected to generate outcomes. Learning organisation theory has been selected as the most relevant formal theory relating to the kinds of culture change that Lean seeks to create.

The steering committee also endorsed the focus on empowerment and leadership change, and on patient safety and efficiency as the primary outcomes of interest, for the multi-year evaluation proposal.

2.5 Advisors

In addition to the valuable support of the steering committee, the Lean research team utilises a core group of advisors and Lean experts. The advisors gave substantial amounts of their time to:

- Review our evaluation framework;
- Provide critical and clinically relevant information about the Lean Management System and other context or methodological issues;
- Provide support in terms of the ‘power calculations’ for the quantitative evaluation of Lean;
- Assess the feasibility of the quantitative data analyses;
- Give advice and feedback in terms of the final selection of patient safety indicators, and on
- Discuss the clinical relevance and transferability of relevant findings identified in the literature.

2.6 Selected Health Regions for baseline data collection

More than 40,000 people work in Saskatchewan’s health care system, providing services to over 800,000 patients every year. We considered geographical factors to ensure a good mix of rural, urban, and northern representatives, First Nations and Metis community members.

All regions have individuals, staff and patients who have and have not been involved with Lean initiatives or training.

The following health regions have been selected and agreed to participate.

- Saskatoon Health Region  Phase 1
- Five Hills  Phase 1
- Prince Albert-Parkland  Phase 1
- Mamawetan-Churchill  Phase 2

3. Theory in the Lean evaluation

Several types of theory are relevant to the Lean evaluation. These include:
• **Realist evaluation theory** - the underlying philosophy and assumptions that guide the research and evaluation process;

• **The program logic model** which aligns inputs, activities, and outputs with their anticipated outcomes (see section 3.2 The Program Logic Model);

• **The draft program theory diagrams** which demonstrate the mechanisms by which outcomes are hypothesised to be generated, as described below. Program theories fit ‘behind’ the program logic model, explaining how and why particular inputs and activities are expected to generate particular outcomes;

• **Context-Mechanism-Outcome Configurations (CMOCs)**. These are sets of more detailed hypotheses which outline the circumstances in which particular mechanisms are expected to operate and the interim outcomes they generate. It is a tenet of a realist approach that mechanisms only ‘fire’ when the circumstances are right.

• **Formal theories**, sometimes known as substantive theories, which provide prior bodies of theory, research and knowledge. These have been used to inform the draft program theory diagrams, and may also assist in the interpretation of findings from the multi-year evaluation.

Each of these levels is discussed below.

### 3.1 Realist evaluation theory

The term ‘realist evaluation’ is drawn from Pawson and Tilley’s seminal work, Realistic Evaluation[2].

As the name suggests it is an approach grounded in realism, a school of philosophy which asserts that both the material and social worlds are ‘real’ and can have real effects; and that it is possible to work towards a closer understanding of what causes change.

The realist approach includes the following assumptions and we outline their implications for the Lean evaluation.

1. **Social programs are an attempt to create some kind of change.**

   The implementation of Lean aims to improve the quality and efficiency of the Saskatchewan health system.

2. **Programs ‘work’ by enabling participants to make different choices, understanding that choice making is constrained by participants’ previous experiences, beliefs and attitudes, opportunities and access to resources.**

   Different types of decision makers will influence Lean outcomes, from those in senior positions at the central level through unit administrators, team leaders, practitioners and patients. A wide variety of factors will affect the decisions that they make.

3. **Making and sustaining different choices requires a change in participant’s reasoning such as their values, beliefs, attitudes, or the logic they apply to a particular situation, and/or the resources, such as information, skills, material resources, support, they have available to them.**

   This combination of ‘reasoning and resources’ is what enables the program to ‘work’ and is known as a program ‘mechanism’. Programs ‘work’ in different ways for different people, being that is, and programs can trigger different change mechanisms for different participants.
Lean provides a variety of resources to support changed decision making, including professional development programs and a series of Lean tools.

The health system, through its endorsement of Lean, also provides resources including funding, staffing, time, and ‘permission’ to undertake Lean activities.

Each of these resources has the potential to trigger different mechanisms in different contexts.

Understanding the overall pattern of outcomes from Lean therefore requires the evaluation to work ‘at a middle level of abstraction’, to avoid becoming swamped in the detail. Such understanding also requires the selection of priorities and foci within the evaluation.

4. The context in which a program operates will make a difference to the outcomes the program achieves. The context features aspects such as social, economic and political structures, organizational context, program participants, program staffing, geographical and historical context, and so on.

Context can influence program mechanisms and outcomes in many different ways.

Organisational culture varies across regions and across types of health units. Professions and occupations have different norms. Culture, gender and socialisation shape patterns of decision-making. Organisation priorities may influence the ways in which, or the extent to which, particular Lean approaches are implemented, who it targets, who it reaches and so on.

Access to resources to implement decisions, and opportunities to implement decisions, can also influence reasoning itself, as well as whether or not desired choices can be put into action.

5. Because there is always an interaction between context and mechanism, that interaction is what determines the program’s impacts or outcomes: Context + Mechanism = Outcome.

Testing the ‘CMO hypotheses’ requires data about each element of the hypothesis; the context, mechanism, and outcome. It also requires analytic techniques that can identify the relationships between them.

6. Because programs work differently in different contexts and through different change mechanisms, programs cannot simply be replicated from one context to another and be expected to automatically achieve the same outcomes.

Good understandings about ‘what works for whom, in what contexts, and how’ are, however, portable.

At the macro level, it cannot be assumed that Lean will work in the same ways, or to the same extents, in different kinds of health units or different regions.

At the micro level, it cannot be assumed that a solution generated in one setting will necessarily work in another setting.

However, a realist evaluation should generate a deep understanding of how and why Lean, or lean tools, works well in some contexts and less well in others. This may assist policy makers and administrators to adapt to their own contexts, and thus to improve outcomes. This is entirely consistent with the ‘local solutions’ principle of Lean itself.

A realist approach assumes that programs are ‘theories incarnate’. That is, whenever a program is implemented, it is testing a theory about what ‘might cause change’, even though that theory may not be explicit.
One of the tasks of a realist evaluation is therefore to make the theories within a program explicit, by developing clear hypotheses about how, and for whom, the intervention might ‘work’.

The evaluation then tests those hypotheses.

3.2 The Program Logic Model

The logic model is a first step to represent the implementation of Lean in Saskatchewan and the complex links between Lean activities and outcomes. The model differentiates the unique features of Lean, including the system changes and outcomes that may be attributed to Lean during our long-term evaluation.

The original tender to undertake the baseline study for the evaluation included a first draft of the program logic model for Lean.

The model, based on Watson et al’s original paper[3], was refined using,

- preliminary results from the literature review on Lean,
- interviews,
- outcomes from published patient safety research,
- exploration of existing patient outcome databases,
- consultation with international methodological experts, and
- input from the Lean steering committee, and Lean implementation mapping, being the extent of the implementation of Lean across four selected health regions.

The Inputs section is an inventory of infrastructure put in place to enable the implementation and maintenance of Lean. Inputs include fiscal, material (e.g., information technology; offices) and human resources.

Activities fit logically aside Inputs to describe how Lean is rolled out into the health system. The activities mainly comprise the Kaizen Basics workshops, Lean leadership training, Rapid Process Improvement Workshops (RPIWs), and protocols and policies, for Lean tools such as reorganisation of the workplace (5S) and daily visual management (DVM).

A detailed understanding of the resources used to introduce Lean is essential to measuring its cost and evaluating its cost-benefit, which is detailed later in the methodology section.

The Outputs and Intervention Activities sections describe and measure the implementation of Lean.

The Outputs and Outcomes sections demonstrate the impact of Lean.

- Outputs represent the interface between implementation and impact by reflecting the system and behavioural changes that occur due to Lean.
- By measuring Outputs we aim to explain how the implementation of Lean links to its aims of better teams, better care, better value and better health.
- In addition, we aim to understand the contexts in which Lean will achieve its aim of better teams, better care, better value and better health, including the factors that facilitate its impact.
Our preliminary investigations indicate that leadership and empowerment are key tenets in the implementation of Lean for which we have developed theories to be tested.

The Outcomes section focuses on what the implementation of Lean produces for the end-user – the Saskatchewan population.

- The immediate outcomes relate to the direct impact of Lean on teamwork, staff satisfaction and other measures of service delivery.
- Intermediate and long-term outcomes are less directly accountable to Lean but comprise the long term aims of improved efficiencies and health outcomes.

Based on our extensive review of the published literature and data availability in Saskatchewan we have chosen to focus on patient safety as the main outcome to be measured. More detail is provided later in the methodology section.

The arrows represent the interplay that can occur between the various sections. For example, the outcomes of Lean will impact on the context of the health of the Saskatchewan population and on the types of activities that will become priorities. The arrows represent the necessary fluidity of the Lean process and the logic model.

Figure 1 depicts the logic model for Lean in Saskatchewan Health.
Figure 1: Logic model for the Evaluation of the implementation of Lean in the Saskatchewan health system
3.3 Lean Program Theory Diagrams

Lean program theory diagrams represent the next level of theoretical work. The research team see the proposed evaluation as an unprecedented opportunity to develop a distinctive understanding of how Lean works, in what settings and why.

This approach will:

- set this evaluation apart from the existing evidence for Lean by rigorously investigating the mechanisms and contexts by which Lean impacts on patient safety and
- identify the essential ingredients and processes required for Lean to influence professional practice and patient outcomes.

We have developed a set of program theory diagrams based on the findings from the pilot study, including the literature review, key stakeholder workshops and interviews, and preliminary exploration of existing datasets.

The program theory diagrams provide sketches of the ways in which Lean and Hoshin Kanri are ‘supposed to work’ and therefore are framed in the positive. These diagrams ‘sit behind the arrows’ in the program logic, describing how and why the program is expected to work.

There are multiple diagrams in the program theory.

**Hoshin Kanri and Lean in the Saskatchewan Health System - Draft Program Theory.**

This diagram (Figure 2) provides an overview of the program theory for Lean and Hoshin Kanri as a whole.

- The bottom line of the diagram sketches the main types of activities conducted as part of the implementation of the program.
- The next line shows the immediate outcomes that might be expected from each of these activities.
- The third level represents a series of main program mechanisms fired by the interaction of the activities and their immediate outcomes.

The caramel coloured boxes highlight the changes to leadership and staff empowerment.

- Subsequent levels of the diagram represent the short-term, intermediate and longer term outcomes that the mechanisms, operating together, are expected to generate.

Improved quality of health care and reduced errors and adverse incidents are both indicators of improved patient safety and are shown in this diagram as intermediate outcomes.

In this diagram:

- The coloured boxes represent primary areas of investigation for the multi-year evaluation.
- Arrows represent primary causal pathways between these elements.

It should not be assumed that these are the only causal relationships at play. Indeed, complexity theory suggests that all elements of the level will interact in complex ways to generate complex patterns of outcomes.
There are then more detailed diagrams for each of the main kinds of activity. These are provided in Appendix 2. Additional maps for other mechanisms and aspects of formal theory have also been developed. If required, these are available from the research team.

**How Lean changes leadership practice**

Preliminary findings from key stakeholder interviews identified that a key tenet of the Lean approach is the empowerment and skill development of leaders in the health system. Figure 3 depicts how Lean works to change leadership practice.
Leadership and Patient Safety

This diagram depicts the draft theory to be tested for the links between leadership, system change and patient safety.

**Figure 4: Leadership and Patient Safety**

How staff are empowered in Lean and Staff empowerment, team processes and patient safety.

Change by leaders, however, is not enough to generate improved patient safety. Empowerment of staff is also hypothesised to be critical. This requires theorising on how,

- staff are empowered by Lean (Figure 5) and how
- staff empowerment itself then operates as a mechanism for improved patient safety (Figure 6)

**Figure 5: Lean and Staff Empowerment**
Figure 6: Lean and Patient Safety

Distributed Quality Improvement / Efficiency Improvement Expertise

Our program theory also suggests that Lean will improve patient safety and efficiency by distributing quality improvement and efficiency improvement expertise and responsibility broadly across the organisation (Figure 7).

Figure 7: Lean and QI
Lean and Patient Safety: Prevention of errors.

Finally, particular Lean tools also contribute in particular ways to improving patient safety. Some of these are represented in Figures 8 (Prevention of errors) and 9 (Responses to mistakes) below.

Figure 8: Lean and Patient Safety

Figure 9: Lean Tools and Patient Safety

These program theory diagrams will provide the basis for the development of research instruments for the multi-year evaluation such as surveys and interview guides.

The diagrams will be refined as the multi-year evaluation unfolds, as part of the process of ‘refining program theory’.
3.4 CMO configurations and hypotheses to be tested in the evaluation

The program theory diagrams have been informed by realist thinking however they do not specify,

- the multiple aspects of context which one might expect are required for the particular theory to operate as intended,
- what alternate mechanisms might fire in less conducive contexts, or
- the range of outcomes that might be expected in different contexts.

A Realist program theory, developed in the form of Context-Mechanism-Outcome configurations, undertakes these tasks. This summarises the hypotheses that will be tested through the evaluation.

Note that the outcomes for all of these hypotheses are improved patient safety and/or improved efficiency, using the outcomes indicators described in section 8.3

The overarching hypothesis to be tested through the multi-year evaluation is:

*Empowerment of staff and changes to leadership practices are concurrently intermediate outcomes of Lean and primary mechanisms by which Lean generates improvements in patient safety and efficiency.*

Our overarching hypothesis subsumes six questions:

- How does Lean empower staff?
- In what contexts are staff empowered / not empowered?
- How do empowered staff contribute to patient safety and efficiency?
- How does Lean change leadership practices?
- In what contexts are leadership practices changed / not changed?
- How do changed leadership practices contribute to patient safety and efficiency?

Our working hypotheses, about the processes by which intermediate and final outcomes are generated, are reflected in the program theory diagrams (above and in Appendix 2) and can be summarised as follows:

3.4.1 Empowerment

1.1. *Lean empowers staff* to improve patient safety and efficiency by:
   1.1.1. creating a learning organisation in which the understanding of and skills in quality improvement and efficiency improvement are widely distributed - the ‘distributed expertise’ mechanism; (Figure 7)
   1.1.2. requiring multi-disciplinary participation in the application of Lean tools; (Figure 6)
   1.1.3. providing specific tools which empower staff in specific ways; (Figures 5 and 8)
   1.1.4. providing specific tools to address safety outcomes in specific ways. (Figures 8 and 9)

1.2. *Empowerment of staff contributes to patient safety and efficiency* (Figures 5 and 6) by:
   1.2.1. enabling any staff member to ‘stop the line’, thus preventing mistakes from turning into errors;
   1.2.2. changing power dynamics within teams, improving communication within work teams, thus decreasing the likelihood of errors;
1.2.3. creating a culture in which new ideas are valued and analysed rather than ignored or dismissed, enabling improvements to benefit patient safety to be suggested and developed.

1.3. *Empowerment of staff will occur most strongly where:*

1.3.1. leaders at all levels consistently apply participatory leadership approaches;
1.3.2. multiple Lean tools are introduced concurrently or in relatively quick succession, led by skilled facilitators, generating staff power in relation to a number of different aspects of the work environment;
1.3.3. leaders effectively implement, monitor and reinforce no-blame responses to mistakes;
1.3.4. work is not ‘over-standardised’ - staff retain autonomy and flexibility to respond to need;
1.3.5. sites or units are smaller and/or have flatter hierarchies.

1.4. *Staff will not be empowered where:*

1.4.1. there is poor ‘vertical integration’ such as between the priorities at central, regional and site levels, generating perceived lack of relevance at the local level;
1.4.2. resources are not available to put intended improvements into operation and/or maintain changes, generating wasted time and frustration;
1.4.3. there is insufficient attention to, and time for, appropriate communication and relationships.

3.4.2 Leadership

1.5. *Lean changes leadership practices* (Figures 3, 4 and 5) by:

1.5.1. the provincial adoption of Lean, authorising attention to change management, with a focus on safety and attention;
1.5.2. providing an integrated set of tools for particular tasks. This creates both structure and confidence to tackle change management and focuses leadership attention on patient safety;
1.5.3. changing attitudes or beliefs about appropriate leadership and management styles or tasks, through the intensity of Lean leadership training;
1.5.4. increasing transparency, which in turn acts to hold leaders accountable for improving safety and efficiency.

1.6. *Leaders contribute to patient safety* (Figure 4) by:

1.6.1. creating or supporting a ‘learning organisation’ culture;
1.6.2. using data effectively to identify real problems and the root causes of problems, rather than making assumptions;
1.6.3. empowering staff by creating appropriate autonomy, providing information, enabling access to resources, enabling access to professional development;
1.6.4. a consistent implementation of no-blame approaches to mistakes and errors.

1.7. *Leaders are more likely to adopt positive, empowering, learning-oriented leadership approaches where:*

1.7.1. leaders themselves are empowered having the appropriate autonomy, information, support, access to resources and access to professional development, to implement Lean
1.8. **Leaders are less likely to adopt positive, empowering, learning-oriented, leadership approaches where:**

1.8.1. their own workloads are so high as to generate barriers to effective learning such as high levels of stress, levels, lack of time, exhaustion;

1.8.2. they experience dissonance between the espoused values and principles of Lean and its implementation such as a lack of information about priorities and directions and a lack of autonomy;

1.8.3. there is poor ‘vertical integration’ such as between the priorities at central, regional and site levels, generating perceived lack of relevance at the local level.

These hypotheses have been developed specifically for the areas to be investigated in depth through the multi-year evaluation of patient safety, leadership and staff empowerment.

It should be noted that these constitute ‘initial theories’ about how Lean will work and that they will be significantly refined over the course of the multi-year evaluation.

Further hypothesis, if required, can be developed throughout the evaluation.

### 3.5 Formal theory

In the early stages of the Phase 1 study, the research team selected Diffusion of Innovations theory[4] and Behaviour Change theory as guiding theoretical frameworks.

It had been assumed that Cain et al’s paper[5] on the diffusion of innovations in health might help understand how Lean has diffused through the health care system while Mitchie et al’s[6] Domains of Behaviour Change may help to understand change (or lack of it) on the part of individual workers.

While these may still prove relevant, we have now selected formal theories that are more closely related to our primary research foci. The selected theories are:

- Learning organisations theory – using Argyris [7-9]’ theories of learning organizations;
- Reinertsen’s theory[10] for transformational leadership for health care.
- Kanter’s Structural Empowerment Theory[11]
- Complex adaptive systems theory (for example as used in Plsek, 2003)[12]

Our construct, or working theory, of empowerment is drawn from Kanter[11] where power refers to ‘the ability to do’. The model assumes that empowering more people ‘increases the total capacity for effective action’.

According to this model, empowerment requires:

- autonomy to make decisions,
- participation in decision-making, and
- the ability to mobilise resources being the ‘whatever is needed for the doing’.

People are more likely to be empowered when they have access to information, support, and opportunities for professional development appropriate to their roles. One of the roles for leaders in this model is to ensure that staff can access and mobilise the necessary resources.
Participation in decision-making varies at different levels of organisations. Kanter’s model assumes that flattening hierarchies and delegating decision making as close as possible to the level of implementation will increase empowerment.

For this study:
- The ‘ability to do’ refers to the ability to improve patient safety and/or efficiency outcomes.
- Professional development includes training in Lean tools and participation in Lean activities.
- Information includes access to data as well as information about priorities, plans and processes for their implementation.

Our construct of desirable leadership behaviours is drawn in part from Reinertsen’s[10] theory of transformational leadership for health care systems and in part from Senge’s and Argyris and Schon’s[7-9] work on learning organisations (see e.g. Agyris 1974, 1978, 1993).

These formal theories have been used in the construction of the hypotheses we seek to test and will be used to help analyse and understand the findings from the multi-year evaluation.

Reinertsen’s theory of transformational leadership suggests that the challenges for leadership are to:
- reframe core cultural values, create improvement capability, collaborate across competitive boundaries,
- create a business environment that simultaneously drives business results and community benefit,
- drive system-level, rather than project-level changes, and to
- maintain a constancy of purpose over the long-term transformational journey.

Learning organisation theory suggests that the roles of leaders are to design systems, steward the vision of the organisation, and to create opportunities for both single loop and double loop learning.

- Single loop learning refers to coming up with a new solution to a problem within the existing vision, values and assumptions of the organisation.
- Double loop learning refers to bringing the vision, values and assumptions themselves into question, refining or reforming them in such a way as to make new solutions possible.

Our understanding of change processes is informed by complexity theory, and in particular complex adaptive systems theory (see for example Plsek, 2003).

Amongst other things, this assumes that:
- the action of agents following ‘simple rules’, including their own internalised rules, will generate patterns of outcomes;
- the quality of relationships matters;
- structures, processes and patterns all matter to generating change, or maintaining the status quo;
- change processes require both innovation and assessment of the effectiveness of innovations, with only successful innovations kept;
- adaptation is constant and not subject to control from above; and that
- change is non-linear.
In this study, Lean tools operate as a form of ‘simple rule’ to structure change in both structures and processes. Complex patterns of change will occur in different kinds of organisations and in different contexts.

This complexity, in part, underlies our choice of realist evaluation as the methodology for the review. It has been developed as a method that is appropriate for use in complex systems (see e.g. Pawson, 2013).

4 Literature Review

We have reviewed the evidence regarding the impact of complex health service interventions (including Lean) in healthcare.

Previous investigations reflect the challenges researchers confront in the evaluation of complex, real world, large scale health service interventions. There is no international agreement on the patient safety outcomes that should be measured to understand the extent of patient safety issues and the impact of interventions.

We used the process measures and study outcomes reported in the literature to inform the methodological development for the multi-year evaluation.

An information scientist developed a focused keyword search strategy.

- This was translated into other databases using the appropriate controlled vocabulary as applicable and language restrictions were not applied.
- MeSH terms were not available thus, low specificity and high sensitivity of the search strategy led to a high number of search hits to be screened.

Summary of Findings:

Below is a brief summary of the findings from the Literature review on Lean management in healthcare. The full literature review can be found in Appendix 1.
Sufficiently well designed, conducted and reported studies, so as to enable inclusion, were proportionality very small.

- Of the 499 search-hits, only 30 studies met the inclusion criteria for our literature review on Lean management in health care.

Main findings from the review include a high level of variation in terms of the definitions and Lean concepts reported in the literature.

- Nine (30%) of the studies referred to the Toyota Management System as applied to healthcare
- Other studies tailored their work to fit with the Virginia Mason Production System, Henry Ford Production System and Thedacare Improvement System,
- Only one study[13], referred to the use of a formal Lean program theory[14-22].
- Twelve (40%) of the studies did not make reference to any management system[23-34].

Although the Cochrane EPOC study design and quality criteria were considered, we found
- the majority of the included studies employed a pre-post comparison design at one single time point[13-41], and
- only one study reported the use of interrupted time series design in examining lean effects in healthcare settings[42].

International literature was sought and reviewed.

- twenty-five (83%) studies were conducted in the United States and United Kingdom[14, 16-19, 21-39, 42].
- five studies (16%) were conducted in Australia, Canada, Ireland and Sweden[13, 15, 20, 40, 41].

Regarding implementation activities:

- thirteen (43%) studies reported the use of only one type of implementation activity[14, 24-27, 29-31, 34, 36, 37, 39, 40], while
- seventeen (56%) reported the combinations of different types of implementation activities in executing the lean initiatives[13, 15-23, 28, 32, 33, 35, 38, 41, 42].

Value stream mapping was the most frequent independent Lean activity reported from the primary study investigators. Other implementation activities include 5S, Rapid process improvement workshops (RPIWs) and Lean basics workshop.

Lean was applied in various settings across the healthcare system:

- Two (6%) studies reported the application of Lean in more than one setting[35, 36].
- Twelve (40%) studies reported the implementation of Lean activities in emergency department and hospital laboratory setting[13, 16-21, 29, 32, 33, 42, 43].
- Four studies (13%) considered in-patient units, five studies (16%) were conducted in outpatient units, two studies (6%) in pharmacy units, one (3%) in a home care setting and one (3%) in a radiology unit[23, 27, 28, 34, 39, 41].
- Also, one study each reported the application of Lean in more than one setting encompassing mental health, in-patient psychiatric ward, outpatient and emergency department[35, 36].
The outcomes reported were categorized into patient outcomes, professional outcomes and health system outcomes.

- Twenty-two (73%) of the studies reported on system improvement outcomes which includes; referral rates, length of stay, re-admission rates, dispensing time, surgical error rates, turn-around time, admission rates, staff over time, turnover time, wait times, cycle time, medication filling rates, triage time, patient journey time, time to see a physician, total processing time, number of safety reports, collection time, disposition time, medication round time and nursing shift time[13, 15-20, 22, 23, 25-32, 35, 37-42].
- Professional outcomes were reported by nine (30%) studies including; employee satisfaction, care provider productivity, number of steps saved, nursing time spent with patients and staff overtime[14, 15, 22, 24, 32, 33, 38, 39, 41].

Patient outcomes were employed by six (20%) Lean investigations and the indicators used were mortality, complications, patient satisfaction, patient safety and quality metric indicators, out of hospital rates and re-admission rates [16, 22, 34-36, 39].

Variation in the effects reported after Lean implementation in various healthcare settings was evident from the review. Effects reported for the final review were categorized into positive, negative and null effects.

The majority of the positive impacts of Lean implementation in healthcare management with empirical rigor around improvement of health systems even though a little proportion of these results were statistically significant. Little focus was observed for professional and patient outcomes.

- Nineteen (88%) from twenty-six studies reported about positive health systems improvement[13, 17-22, 28-30, 32, 34-38, 41, 42],
- Three (3%) studies reported on improved professional outcomes, and
- Only one (3%) study reported a null effect after Lean implementation in the hospital laboratory[14, 34, 39].

In terms of the statistical significance of the effects reported:

- Only 23 (22%) out of 103 outcomes used, reported on statistical significant improvements, and
- Six studies, (20%) reported negative and null effects after the application of Lean for system improvement purposes with none of them achieving statistical significance[17, 24, 25, 27, 29, 40].

In conclusion, research on the application and wide-scale implementation of lean principles in healthcare is limited with the majority of the primary studies reported lacking explicitly stated concepts, research designs, appropriate analysis, and outcome measures.

Furthermore, little has been documented about the failed attempts or barriers to implementation, adoption and sustainability of Lean principles in healthcare.
This literature review has established that appropriate implementation of Lean tools and principles in health care management may be associated with improved efficiency in systems improvement, patient outcomes and professional practice. The results should be interpreted with caution taking into account the various settings in which these studies are conducted. More so, there is a huge potential for publication bias in the literature about Lean management in healthcare due to the low number of publications reporting on negative and null effects of Lean implementation in healthcare management. This further hinders the transferability and comparability of the results.

To maximize the quality of the evidence underpinning this model that is now been utilized widely in the area of healthcare it is recommended that future research and studies reporting the effects of Lean intervention in healthcare management, should incorporate Cochrane EPOC standards into their study design and methodology.

Due to the complexity associated with healthcare systems, future Lean evaluations in healthcare systems should adopt a Realist approach, which takes into account the various contexts, mechanisms and circumstances that are important to understand how Lean works, for whom, and when.

Please see Appendix 1 of this report for the full literature review on Lean in health care including the search filter used and databases searched.

5 Implementation Mapping

Attributing outcomes to an intervention depends in part on being able to demonstrate that there is, at the least, a logical relationship between the activities implemented and the outcomes achieved. This function will be provided in the multi-year evaluation through implementation mapping. Tracking implementation over time will also help to understand whether the focus of implementation changes over time.

- We investigated the extent of the implementation of Lean across four selected health regions during the baseline period (2012/2013). The four selected health regions were Saskatoon (SHR), Prince Albert Parkland (PAPHR), Five Hills (FHHR), and Mamawetan Churchill River (MCRRHA).
- We catalogued and analyzed rapid process improvement workshops (RPIWs) and 5S events because they are the most frequently used implementation activities. We captured the focus of the event, the location (i.e. hospital), the unit, and the service line level.

The results were analysed to capture the main aims and foci of implementation activities, and number of events (in effect, the ‘program dose’). We have also identified and grouped similar implementation activities per health region. This data will also inform the economic calculations (e.g. total costs of the Lean implementation) at baseline and for the multi-year evaluation.
Baseline results

The 2012 Lean implementation data are available only for the Saskatoon and Five Hills Health Regions because both health authorities began to implement Lean in 2012, whereas the remaining phase two regions started in 2013.

In total, 38 RPIWs and 15 5S events were held in Saskatoon (SHR) and Five Hills (FHHR) in 2012.

A year later, with the entry of two further regions, the implementation activities increased dramatically and 63 RPIWs and 60 5S events were conducted in the four health regions in 2013.

Overall, 161 RPIWs and 5S events were held in the four health authorities selected for the baseline data collection. In table 1, the total numbers of RPIW and 5S events conducted by health region can be found for the baseline period (2012/2013).

Table 1: Total Number of RPIWs and 5S workshops in the four selected health regions

<table>
<thead>
<tr>
<th>Region</th>
<th>Workshop</th>
<th>2012</th>
<th>2013</th>
<th>Year total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Five Hills</td>
<td>SS</td>
<td>2</td>
<td>17</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>RPIW</td>
<td>0</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Mamawetan Churchill River</td>
<td>SS</td>
<td>0</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>RPIW</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Prince Albert</td>
<td>SS</td>
<td>0</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>RPIW</td>
<td>0</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Saskatoon</td>
<td>SS</td>
<td>13</td>
<td>23</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>RPIW</td>
<td>23</td>
<td>30</td>
<td>53</td>
</tr>
<tr>
<td><strong>TOTAL WORKSHOPS</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>161</strong></td>
</tr>
</tbody>
</table>

Aim and focus of the Lean implementation activities per Health Region

Saskatoon Health Region (SHR)

From 2012 to 2013, SHR conducted 89 5S and RPIWs.

Out of the 53 RPIWs and 36 5S activities,

- Twenty-four RPIWs and one 5S event aimed to reduce lead time, the total time a patient must wait to receive a care service.
- Eighteen RPIWs were performed to eliminate errors and to avoid waste. Out of the 18 RPIWs, 13 events were held in the Royal University Hospital, two in St. Paul’s Hospital and two in Saskatoon City Hospital.
**Five Hills Health Region (FHHR)**

During the baseline period FHHR conducted, 19 5S events, and 20 RPIWs.

- Seven RPIWs were conducted to reduce lead time. Six of the seven RPIWs were conducted in the Moose Jaw Union Hospital, and one in the Primary Health Clinic
- Three RPIWs were conducted aimed to eliminate error and waste at the Moose Jaw Union Hospital.

**Prince Albert Parkland Health Region (PAPHR)**

During the baseline period PAPHR conducted 24 events, 11 5S events and 13 RPIWs.

- Six of the 13 RPIWs aimed to reduce lead time (four in Victoria Hospital, and one each in the Parkland Integrated Health Centre, and in the Herb Bassett Home).
- Four 5S events focused on standardization and were held in the Victoria Hospital.

**Mamawetan Churchill River (MCRRHA)**

MCRRHA) is a phase two Health Region. The implementation of Lean started in 2013, and 9 5S events were held.

- The events had varying foci such as eliminating overstocks, waste, and improving daily visual management (DVM).

As the focus for implementation activities is decided at the local level, the information provided here reflects local priorities.

We will continue to map the implementation activities as part of the multi-year evaluation of implementing the Saskatchewan Lean Management System to identify differences in implementation and, if we can, explain how those differences might translate into different outcomes.

### 6 Lean Interviews

Realist evaluation uses qualitative data to gain a deeper understanding of how aspects of context affect whether or how interventions ‘work’; to investigate the ‘reasoning’ of decision-makers, at all levels, from senior system-level decision-makers to patient families, and thus understand the mechanisms generating changed outcomes, and to explore perceptions of outcomes, as distinct from quantitative outcomes indicators.

Formal theory is used to help explain patterns of findings.

In the baseline study, interviews have been used both to collect early data on experiences of implementation and to develop hypotheses for further investigation in the multi-year evaluation.
6.1 Methods

Ethical approval was obtained from the University of Saskatchewan Behavioral Ethics Board and operational approval granted from regional authorities as per their usual protocol.

Kaizen Promotion Office (KPO) Directors or their equivalent, from four health regions in Saskatchewan, one large urban, two small urban, and one northern, were asked to identify patients, front-line staff and leaders who had participated in RPIWs within the previous six months and who might be amenable to discussing their experiences of Lean for this project.

The research assistant had extensive previous experience in interviewing, and received additional training in the fundamentals of realist approaches. While our aim was to conduct ten interviews at each site, recruitment was a challenge. A minimum of three attempts were made to contact each individual and an alternate list of potential participants was requested when there was insufficient participation from the original list.

Fifty-two potential participants were contacted for a participation rate of 51.9%. A total of 26 face-to-face and one telephone interviews were conducted; six from the large urban region; seven from one small urban region and eight from the other small urban region; and six from the northern region. The interview guide for staff and patients is provided in the Appendix 3.

The roles of respondents were varied and included one CEO, five Directors, four Managers, four Allied Health clinicians, three Registered Nurses, two Clerical/Administrative staff, two Physicians and six patients. Qualitative research is not intended to be representative of the entire population under study. It is intended to produce knowledge that is transferable from one context to another. In a realist approach, this goal is approached by analyzing ‘what it is about the context’ that affects whether and how interventions work, and why.

Audiotaped interviews were conducted in a private space by the trained research assistant using a semi-structured interview guide. The guide was designed to collect information about changes to their work in the health system or experiences in the health system over the past two years, the respondents’ experience in Lean and what they most value about it; changes that they attributed to Lean in relation to patient care and outcomes, relationships between patients and staff, staff and co-workers, and staff and leaders; adaptations of tools for the local context; the pace of change; concerns about Lean and adequacy of resources.

Verbatim transcripts of the interviews were obtained and reviewed in detail by the two primary members of the qualitative team. Coding was conducted independently by each researcher followed by extensive discussion between the researchers. Summaries were presented to three other members of the qualitative research team, who also had full access to the verbatim transcripts, for feedback and further discussion prior to Context-Mechanism-Outcome configurations (CMOCs) being developed by the primary qualitative researchers.

The draft CMOCs were presented back to the entire research team and revised based on the discussion.
6.2 Overview of Findings

A learning organization can be defined as a group of people working together collectively to enhance their capacities to create results they really care about[1].

A learning organization is one which facilitates the learning of its members and continuously transforms itself[44].

According to Peter Senge[1], a learning organization displays five main characteristics: systems thinking; personal mastery; mental models; a shared vision and team learning.

<table>
<thead>
<tr>
<th>Senge’s five main characteristics of a learning organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 'Systems thinking: organizations are systems of relationships. To become more successful, we need to analyze these relationships and find the problems in them. This allows an organization to eliminate the obstacles to learning.</td>
</tr>
<tr>
<td>2. Personal mastery: An individual holds great importance in a learning organization, with continuous self-improvement.</td>
</tr>
<tr>
<td>3. Mental models: this is the company culture and the diverse theories and mindsets that serve as a framework of the functioning the organization.</td>
</tr>
<tr>
<td>4. Shared vision: All employees share a common vision. Personal goals must be in sync with the goals and vision of the organization.</td>
</tr>
<tr>
<td>5. Team learning: The importance of dialogue and group discussion'[1]</td>
</tr>
</tbody>
</table>

We propose that Lean helps to better position a system as a learning organization. It serves as a complex and highly structured system with the potential to overcome organization inertia by introducing a consistent philosophy and a set of related tools. The tools concurrently change work processes and work roles, creating a province-wide learning organization with broadly aligned goals.

The learning environment created by Lean encourages consideration of a broad range of stakeholder perspectives and novel ideas to address locally relevant issues, without the fear of failure that characterized the system in the past. Argyris & Schon[8] suggest that learning involves the detection and correction of errors.

Single-loop learning involves the search for another strategy that will address a problem and work within the governing variables of the organization. Lean, in contrast, shifts the strategy to ‘double-loop’ learning, in which the governing variables, the underlying norms, policies and objectives, are themselves subject to critical scrutiny.

6.2.1 A province wide system

As a comprehensive, province-wide system, Lean makes explicit the importance of shared goals across the health regions. Senge considers this ‘shared vision’ to be pivotal is creating a common identity that provides a focus and energy for learning.

Within Lean, visibility is critical to creating mindfulness and orienting the attention of all involved towards quality improvement. Diverse stakeholders work together to test different improvement strategies - this takes people out of their own orbits and provides a more ‘systems’ perspective.

The Hoshin Kanri process sets the agenda for the entire province, although some participants from smaller health regions suggested that this agenda is not always a good match with their priorities.
This creates significant additional work as these regions attempt to meet the needs of their own region as well as address provincial priorities in an environment where resources are scarce.

Many participants indicated that Lean is the ‘best hope yet’ for true system transformation. Many leaders reported a sense of optimism that a ‘broken’ health care system could be transformed by virtue of a patient-centred, efficiency-oriented approach.

6.2.2 Outcomes

A number of respondents were able to identify early outcomes for patients achieved as a result of Lean activities. These included
- faster access to mental health care
- reduced time during admission
- reduced patient falls
- increased efficiency
- reduced errors in medications, and
- more patient-friendly information.

Many of these outcomes have positive implications for patient safety and some are clear indicators of improved quality of care. Others reported improved efficiency as a result of better organized workplaces. Some respondents, however, reported that changed processes were not monitored or sustained.

Most patient participants could not identify any change in their own care over the previous two years, and the one who could do so believed that the quality of care had declined. Patient representatives who had participated in Lean activities were, however, optimistic that improvements would result. It should be noted that the majority of patients interviewed had significant involvements with the health system other than as patients: two were retired health staff, two had significant voluntary roles, and one had participated in many Lean activities.

When asked about the effects of Lean on aboriginal patients, participants agreed unanimously that the positive outcomes achieved by Lean will benefit all patients, regardless of their background. There is, however, no evidence available as yet to test these beliefs and it remains possible that this result reflects social desirability bias, being one will say what one believes to be the ‘right’ or socially desirable answer to give.

Very few respondents identified any impact on relationships between patients and staff, staff and co-workers, or staff and leaders. The great majority reported that relationships were already positive and said that they would ‘speak up anyway’, regardless of Lean’s intention of empowering staff to speak out about issues that require attention. It is not clear if this is a result of the selection process for interviews, and if so, to what extent.

6.2.3 How Lean works

Lean transforms some participants ‘mental maps’[7] regarding how to act in situations, including the manner in which they plan, implement and review their actions. This was more apparent with leaders than with other staff, suggesting that intensity of training and/or Lean implementation experience is necessary for the mental map to be affected.
With a clear focus on improving the patient experience, it appears that Lean generally serves to democratize the usually hierarchical health care system and levels the playing field by giving a voice to groups that have been typically disenfranchised by the health care system, such as patients, family members and front-line staff. Patient and leader participants placed a high value on patient participation in the process.

One leader reported that having patients involved ‘changes the direction of what we thought we were gonna (sic) do’ and by increasing awareness of the whole patient experience, reduced the silo mentality:

...see it through their eyes, coming through a process ...you know you always just think it’s...your appointment, not recognizing all of the work flow that has to happen, to make that appointment occur, and then the follow up for you to get the care you need.

Both leaders and front-line staff welcomed the involvement of leaders on the shop floor as prescribed by Lean.

Lean provides structured, ‘common sense’ processes and tools to derive quantitative evidence and conduct key measurements of quality related to locally relevant issues, including patient safety. Lean challenges the long-held ‘mental models’ held by agents within the system through the use of locally relevant evidence[1]. In most cases these were well-received by respondents who seemed reassured by the ‘common sense’ nature of the measures. One respondent however was frustrated by the resources invested to achieve ‘grade five...common sense stuff’. Others reported seeing things in new ways: ‘Why didn’t we think of this before?’

Measurement is an aspect of Lean highly valued by leaders, particularly for its ability to provide irrefutable evidence about why change is necessary to staff. Measurement also acted to correct perceptions about the exact nature of problems and to provide evidence of the success of changes, thus providing a positive feedback loop to reinforce engagement.

Some leaders reported difficulty identifying what might be ‘locally meaningful’ data and advised they required additional support with this. Physicians also appreciated, and were reported by others to appreciate, the objective nature of the evidence provided by Lean activities. Physician engagement was described as necessary for specific changes to be implemented and valued because engaged physicians encourage buy-in by others, including other doctors.

Patient participation was valued by many respondents and worked by enabling staff and leaders to ‘see through different eyes’.

'We see it from different eyes...we’re learning those little pieces that make a difference to the patients... you know, when the shoe’s on the other foot, it’s different’

Some leaders acknowledged that Lean works by pulling many aspects of systems improvement together: it is the synergistic outcome of multiple strategies that builds success. This awareness did not seem to be shared by staff or patients. This may in part reflect the role of leaders of maintaining an overview and in part the focus on leader training and engagement at this early stage of implementation.

A greater level of understanding by leaders as compared to front-line staff and patients was a common pattern across the interviews.
6.2.4 Leaders and Lean

The highly structured nature of Lean provides leaders with a comprehensive set of interdependent tools. These in turn instil confidence in many that they can enact system change.

Leader participants clearly recognized that the implementation of Lean is a journey, not a ‘quick fix’, and an investment of time, energy and resources will be required over the long term to reap the range of benefits anticipated from Lean.

The structure of Lean, however, can be rigid, prescriptive and stifling at times, and can disempower leaders who feel the need to adapt tools and programs to their local contexts. Some leaders reported major discrepancies between implementation processes they experienced and the espoused values of Lean: lack of clear information even when it was specifically requested, lack of ability to set local priorities, and lack of flexibility to adapt tools to local contexts.

Several participants described the current situation in which Lean is only partially implemented as ‘living in two different worlds’. Several leaders remarked on the lack of role clarity and ambiguous nature of accountability for some activities while others were unclear about how priorities and directions were being established.

‘We just sort of struggle with what’s the big picture because ... we get to one spot and then we’ll move to another spot...you’re often feeling like you’re unsure. ... I don’t want to question the process, in that I believe in it, and I see the improvements that are happening, but I just want to know what I need to do. ...when you don’t know, it’s really hard to feel good about yourself and the work you’re doing’

‘I’m part of senior leadership and I’m not sure who out there somewhere is determining what we’re focusing on’

The ‘frantic’ pace of implementation has been both a blessing and a curse for leaders.

- The positive side of rapid implementation is that those who have been trained can quickly implement their skills in Lean project and see results in a short amount of time.
- The negative side is that leaders are overloaded, overwhelmed and overworked and many staff are experiencing change fatigue. Several participants have spent vacation time engaged in Lean activities because no other time was available. Others reported working after hours.

Certain aspects of the training process, in particular the Deep Dive and Module Marathon, were significant sources of discomfort, anxiety and even physical symptoms for some leaders.

Patient representatives volunteer their time to participate. In effect, it would appear that part of the cost of implementation has been shifted from the public to the private sphere.

Leaders commonly demonstrated a high level of commitment to ensuring the success of Lean implementation and felt accountable to do their best, particularly with regards to removing barriers to quality improvement initiatives.

Lean is seen by leaders to have significant potential to improve care, but there was little sense that cost efficiencies would be realized, at least in the short term.
6.2.5 Empowerment

The program theory developed by the research team sees empowerment of staff as a primary mechanism through which Lean will generate higher level outcomes.

Lean activities such as RPIWs directly empower participants — staff, leaders and patients. When the processes are well run, the participants’ ideas and their understandings of the implications of proposed changes for particular work roles and the system as a whole are taken into account. This was the experience for the great majority of respondents who had participated in such processes.

If processes are not well run, the results may be experienced as tokenism. One patient representative reported three good experiences in Lean activities and one very negative experience, in which they were delegated menial work and their time in the ‘report back’ was minimized.

This may have been an outcome of lack of experience on the part of the process leader — a number of leader respondents reported being ‘thrown in at the deep end’ for their first running of an RPIW. If this is the case, instances should become less frequent over time. It may also reflect imbalance in participant numbers. Most participants in Lean processes are staff and in RPIWs, only one is a patient. The patient runs the risk of becoming a ‘token’ or symbol of the entire patient group, rather than an equal participant [11]. For a discussion of the effects of, and on, token participants, see in particular Chapter 8, Kanter (1993).

Disempowerment can also result if there are not representatives from all necessary work roles included in processes. One manager reported:

“I had someone present me with my standard work...and I was really offended. ...the old term is ‘not about me without me’.”

‘Permission to fail’ and ‘permission to improve innovations in future’ reduced the pressure to get things right the first time and thereby encouraged experimentation with new ways of operating. They also provided a tool to encourage participation by reluctant staff, ‘let’s just try it and see’.

There is as yet no evidence that staff empowerment extends beyond direct participation in Lean activities — either that those who participated are empowered after an activity, such as an RPIW, has completed or that those who do not participate directly are empowered. This may in part be a function of the questions asked in interviews: the interviews were conducted before the focus on empowerment, leadership and patient safety had been determined.

We did find evidence of changes to leadership and of patient safety outcomes. We therefore hypothesize that staff empowerment is a later outcome — in particular, that it will follow from more embedded changes in leadership style - and would expect to see some greater change in future.

This is consistent with Kantor’s theory of workplace empowerment which suggests that multiple structural elements are required, including access to information, participatory leadership styles, the ability to access resources to do one’s work and to mobilize resources to get things done, decentralization and autonomy, access to professional development and mentoring.

Lean would appear to have potential to affect many of these elements, but time, consistency and implementation of all facets of the system within organisations and regions are likely to be required.
6.2.6 Implementation

Leader participants consistently described there being a work overload created for them by Lean requirements, a load in addition to their other responsibilities. Those from smaller health regions noted that the scarcity of key resources such as IT and KPO support have made it impossible to conduct follow-up audits in the prescribed manner. An increased burden on certain departments was noted as a result of Lean.

While clinical teams are only directly affected by the specific change processes that they engage in, for example the RPIWs for their own patient stream, every change process has the potential to affect the work load for support units:

‘Our department has gotten ten-fold busier because we support all of the departments’.

This both threatens the sustainability of changes in those other departments and increases stress for staff in support units.

There was some concern that processes for selecting the foci for improvement activities were not sufficiently planned or coordinated. Concerns included:

- poor prioritization, so that areas in which RPIWs were conducted did not tackle high-priority issues and thus could only net small gains;
- doing activities in the wrong order, so that the work of a later activity undermined the results of an earlier one; and
- failing to capitalize on learnings by transferring solutions to common problems to other similar units.

These issues were seen to cause inefficiencies in Lean itself as well as undermining efficiency gains in the health system.

Not all leaders or staff have been in agreement with the provincial implementation of Lean. Some leaders indicated that some managers who were not supporters of Lean have left the system as a result and this was generally seen as positive as they were not considered a ‘good fit’.

Leaders also noted that there are front-line workers who are very resistant to change working in the system and struggle with the Lean system. Senge[1] notes that resistance to learning can occur in people who feel threatened by change or believe they have a lot to lose.

As the organizational culture shifts and a critical mass of staff embrace Lean, the thought is that these individuals will become late adopters. The Japanese terms used in the Lean implementation in Saskatchewan appear to be primarily resisted by those who have not undergone extensive training.

While numerous attempts to improve quality have been implemented to some extent in pockets across the province in the past, the outcomes of these previous initiatives were very limited. Participants noted that the outcomes of current Lean activities are not always successful either, but considered this to be part of the learning process for all involved.

Concern was expressed by some leaders that Lean would not continue to be sustained by the Ministry of Health over the long-term, relegating this initiative to the pile of discarded quality improvement fads and making some individuals hesitant to invest the needed time and energy.
The diversity of organizational cultures of the various health regions, agencies and even units became apparent in the interviews. The implementation of Lean influenced and was influenced by the local culture. For example, one health region appeared to embrace Lean because it was consistent with their explicit drive for excellence. Another seemed more reluctant, perhaps because provincial and district priorities were less well aligned. Despite this broad range of cultural characteristics, the over-arching values inherent in Lean - patient-centeredness, safety, and efficiency - appeared to resonate with most participants.

6.2.7 Suggestions for improvements from interviews

Some respondents made suggestions about specific strategies that they believed could be implemented, either to improve efficiencies in the health system or to improve efficiencies in Lean itself. These included suggestions for:

- a patient swipe card (likened to a ‘frequent flyer card’) for ‘sign in’ of frequent patients;
- a process for sharing strategies developed through Lean processes which have passed the 180 day mark and demonstrated efficiency improvements with other similar health units;
- using volunteers and/or improving communications and/or signage to assist patients when changes are introduced.

Despite the Lean focus on quality improvement, respondents did not seem aware how they could or should put these suggestions forward. It might be that Lean tools provide structures and pathways for particular kinds of improvements but do not provide avenues for other ideas, unrelated to the particular task, to be put forward or considered.

6.2.8 Summarising a realist analysis

The table in Appendix 4 summarises some of the key patterns in contexts, mechanisms and outcomes (CMOs) identified during this first phase of the evaluation. Each row in the table should be read as a whole: ‘In this context, this mechanism causes (or contributes to) this outcome.’ Usually, a number of contextual factors are required for a mechanism to ‘fire’; and mechanisms may have multiple outcomes at different levels of a system. Earlier outcomes, where they are sustained, then become part of the context for subsequent changes. Thus an element that appears as an outcome in one row may appear as a feature of context in subsequent rows.

The table represents both a product from the first phase of the evaluation and a basis for further investigation in the multi-year evaluation. We have, therefore, included CMOs which relate to our priority areas for investigation in the multi-year evaluation even where there are gaps in the data. Question marks indicate inferences drawn by the researchers as distinct from data drawn directly from interviews: these should be considered hypotheses which might be tested in future rounds of the evaluation.
7. Economic evaluation

In this section, we describe the general methodology related to estimation of cost for the Lean implementation in Saskatchewan. There are two types of costs, direct and indirect, which we account for in the cost estimations.

The indirect cost of Lean is primarily due to the opportunity cost of personnel time used in Lean events. We estimate the opportunity cost of participants’ time devoted to the events using their market wage rate. The exact wage rate, however, for each participant is not available. Therefore we use a range of wage rates (low, average, and high) from the 2011 Saskatchewan Wage Survey for the corresponding positions/titles of Lean participants. For the participants with unknown designations and job titles, we use the Saskatchewan average wage rate in the health care sector. These wage rates do not include any benefits or other contributions paid by the employer, and they show the 2011 wages. To deal with this, we adjust them using inflation rates from 2011 to 2014, and include relevant benefits and contributions paid by the employers.

The direct cost of Lean is the second component that needs to be taken into account. The major contributing factor to the direct cost is consulting fees paid to the John Black and Associates during the course of the Lean implementation. The others are the physician remuneration and honorariums paid to the patient/family representatives, travel, accommodation, and other incidental expenses. It is likely that the daily responsibilities of Lean event participants could be backfilled by other employees with overtime payments. In this case, additional payments over usual rate would be the incremental cost due to the Lean implementation. We will determine the extent of overtime payments and account for the cost due to this source in our final publication which will be submitted to a peer-reviewed journal.

For the baseline study, using the general approach described above, we estimated a preliminary cost of an RPIW. The table shows that the cost of an RPIW ranges from $31,000 to $38,000. However, these results do not include costs associated with the JBA consultants’ time, travel, and other incidental expenses, or overtime payments due to backfilling.
Table 2: Average cost for an RPIW (preliminary results)

<table>
<thead>
<tr>
<th>Team</th>
<th>Total number of hours</th>
<th>Low (25th percentile)</th>
<th>Average</th>
<th>High (75th percentile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team Leader</td>
<td>112.5</td>
<td>5699</td>
<td>6282</td>
<td>6952</td>
</tr>
<tr>
<td>Sub-Team Leader</td>
<td>103.12</td>
<td>5224</td>
<td>5759</td>
<td>6372</td>
</tr>
<tr>
<td>KPO support</td>
<td>159.37</td>
<td>7991</td>
<td>8809</td>
<td>9748</td>
</tr>
<tr>
<td>Lean Leader Participant</td>
<td>45.69</td>
<td>2362</td>
<td>2604</td>
<td>2881</td>
</tr>
<tr>
<td>Physician</td>
<td>15.51</td>
<td>2909</td>
<td>2909</td>
<td>2909</td>
</tr>
<tr>
<td>Patient/Family</td>
<td>40.08</td>
<td>374</td>
<td>721</td>
<td>1069</td>
</tr>
<tr>
<td>Other Team Members</td>
<td>156.46</td>
<td>5428</td>
<td>5907</td>
<td>6342</td>
</tr>
<tr>
<td>Printing/supplies [1]</td>
<td>n/a</td>
<td>150</td>
<td>200</td>
<td>250</td>
</tr>
<tr>
<td>Travel/accommodation [2]</td>
<td>n/a</td>
<td>1125</td>
<td>1500</td>
<td>1875</td>
</tr>
<tr>
<td>JBA Consultant</td>
<td>not included</td>
<td>not included</td>
<td>not included</td>
<td>not included</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$31,262</strong></td>
<td><strong>$34,691</strong></td>
<td><strong>$38,398</strong></td>
<td></td>
</tr>
</tbody>
</table>

Note: It is assumed that there is one team leader, sub team leader and KPO support person in each event. [1] We assume that the cost of printing and supplies is incurred in week -3 and the event week with an average weekly cost of $100. Then we inflated (deflated) it by 25% for high (low) scenario. [2] There might be travel, accommodation, parking, and other incidental expenses. We assume an average of one out-of-region person who will be travelling for the event. An average cost of $1,500 is assumed and inflated (deflated) by 25% for high (low) scenario. The cost due to JBA consultant time is not included in the estimations above.

8. Methodological development for the multi-year evaluation

8.1 Multi-year evaluation approach

Consistent with the Phase 1 evaluation of Lean, the evaluation design we propose for the multi-year evaluation combines a realist evaluation with a cost-benefit economic evaluation. A realist approach[2, 45] was initially suggested by the Health Quality Council in its request for tender for the Phase 1 evaluation because of its utility in evaluating complex interventions.

The Lean intervention is complex in almost every way that a realist approach envisages. It involves huge numbers of decision-makers, from senior personnel at central levels through all levels of the service delivery system to patients and families. Their motivations and reasoning, and the constraints affecting their decisions, of course vary widely. It comprises many parts, including an overall management philosophy and system; changed roles for leadership and training to support them to undertake those roles; changed expectations of staff and various training programs to support them; a variety of Lean tools for particular tasks and Kaizen Promotion Offices (KPO) to support implementation across the system.

Lean is only expected to generate its higher level impacts when all of the elements come together, operating as a system to change the system into which it is introduced – but each of its constituent elements may operate somewhat differently in different contexts. It is being introduced in a wide variety of contexts – different regions, different kinds of health services, different levels of the
health system, with a huge variety of occupations and professions. It has been introduced at
different times in different regions and consequently will be at different levels of maturity in
different places. It will take a significant period of time to be fully implemented, meaning that the
health system around it and the broader social, political and economic systems in which that sits will
change around it. To the extent that it is effective, it will generate many kinds of outcomes at many
levels of the system, thereby changing the context in which it needs to work.

A realist approach offers specific strategies for coping with this complexity in an evaluation:

a) Select a specific focus for the evaluation. In the multi-year evaluation, with the specific
endorsement of the Saskatchewan Health Quality Council, we will focus on improved
patient safety as the primary outcome of interest and on changed leadership and staff
empowerment as the main mechanisms of interest.

We will examine both acute care and primary care, but with some greater focus on acute
care. This is because of its relevance for patient safety, the high costs of and potential for
observable economic effects in hospital care, and because Phase 1 regions commenced
implementation in the hospital sector in 2012. Phase 1 acute settings should therefore be
more advanced during the evaluation period and outcomes should be more apparent.
Within acute care, we propose a nested case study examining Emergency Departments.
James Stempien, Head of the ED program for Saskatchewan Health, is a lean leader and a
member of our team.

b) Develop middle range program theory to guide the evaluation. During Phase 1 we developed
three theory tools: a traditional program logic chart which aligns inputs, activities and
anticipated outcomes; a series of more specific program theory diagrams; and a set of draft
Context and Mechanism hypotheses for patient safety outcomes (see Appendix 4).

The CMOs were developed by analysing interview data from the Phase 1 evaluation against
the relevant program theory diagrams and thus represent the first stage in refining
understanding of how, and in what contexts, Lean does and does not contribute to changing
leadership roles, staff empowerment and patient safety. They will provide the basis for
development of new instruments in Phase 2 (see Appendix 4). As data is collected, the
CMOs will be progressively refined and extended, providing more nuanced understanding of
how and why different patterns of outcomes are generated.

c) Select indicators and develop instruments to test and refine program theories. Iterate
evaluation methods to refine understandings over time. Realist evaluation requires data
about outcomes, about the mechanisms that generate those outcomes, and about the
contexts that affect whether and how outcomes are generated. Our outcome indicators are
aligned with our program logic and selected aspects of our patient safety, leadership and
staff empowerment program theories.

Semi-structured interviews and focus groups will be used to refine information about
mechanisms of change and to develop understanding about how aspects of context affect
whether and how those mechanisms operate. Additionally, an ethnographic study will be
conducted as part of the in-depth study of Emergency Departments, providing observational
data and in-depth information from multiple stakeholders to examine processes of change.
In the second year, purpose designed surveys will be developed, based on outcomes from the first year’s qualitative data, and used to assess the commonality (or otherwise) of relevant mechanisms and their relationship to relevant aspects of context.

Implementation data, for example, how many RPIW are conducted on what topics in which kinds of health services in which regions, will enable us to relate aspects of implementation to mechanisms and outcome patterns.

d) **Use appropriate analytic techniques.** Realist analysis uses comparisons within the program but across contexts to identify and explain complex patterns of outcomes. It requires disaggregation of outcomes data according to the features of context that are hypothesised to affect, and mechanisms that are expected to generate, outcomes. We will use this strategy at multiple levels.

Firstly, we will, as far as data types allow it, make comparisons between acute and primary settings and Phase 1 and Phase 2 regions, to assist with attribution of outcomes to Lean. The hypothesis here is that if Lean is more effective when implemented more completely, acute settings in Phase 1 regions should show stronger impacts than primary settings in the same regions, and Phase 1 regions should show stronger impacts than Phase 2 regions.

Secondly, in the first year, we will disaggregate outcomes data using contextual data that is already available in the health system and/or Lean implementation data, being health region, health service type, and so on.

In the second and subsequent years, purposive samples will be constructed to examine specific CMOs and variations in outcomes patterns as they emerge. Quantitative methods (e.g. correlations analysis) may be used to identify relationships between particular contexts and outcome patterns, while realist qualitative analysis[46] will be used to identify causal processes (i.e. relationships between mechanisms and outcomes) and to investigate relationships between context and mechanism. As survey data, as described above, becomes available, other disaggregated analyses may also become possible.

The economic evaluation component will operate for the program as a whole by incorporating the findings from quantitative analysis to the economic evaluation (see Section 7).

A funding application has been developed which seeks core funding to support the primary components of the multi-year evaluation and has been provided under separate cover.
8.2 How activities in the baseline study contributed to the evaluation design

(1) We conducted a synthesis of Lean investigations published in the international literature relevant to the design of the multi-year evaluation. We focused on the Lean concepts used in health care, Lean program theories, methods, and outcomes reported.

The outcomes reported by the investigators were used to inform the selection of the outcome measures for the multi-year evaluation. The literature review on Lean highlighted the magnitude of the Lean undertaking in Saskatchewan. We found no documentation of any system-wide application of Lean in the international literature. The literature review on Lean also emphasized the importance of a program theory to support the evaluation of the Lean implementation in Saskatchewan.

(2) Attributing outcomes to an intervention depends in part on being able to demonstrate that there is, at least, a logical relationship between the activities implemented and the outcomes achieved. Implementation mapping serves this function and will also help to understand whether the focus of implementation changes over time.

We captured rapid process improvement workshops (RPIWs), and 5S events because they are the most frequently used activities and we will continue to map the implementation activities as part of the multi-year evaluation. Our aim is to identify differences in Lean implementation and if we can explain how those differences might translate into different outcomes.

(3) The qualitative data from the first round of Lean interviews were used to gain a better understanding of how aspects of context affect the effectiveness of Lean or how Lean works and to better understand the mechanisms generating differences in outcomes. We use a Lean program theory to explain patterns of findings. During the baseline study, we have used interviews in the four selected health regions to develop hypotheses which will be tested and refined in the multi-year investigation.

(4) Finally, a methodology for the estimation of cost for the Lean implementation in Saskatchewan has been developed and tested in the baseline study. We have estimated direct and indirect costs.

The indirect cost is primarily due to the opportunity cost of personnel time used in Lean events, which has been estimated using market wage rates. Direct costs include consulting fees paid to the John Black and Associates, physician remuneration and honorariums paid to the patient/family and so on.

In the multi-year evaluation, we will conduct a cost-benefit analysis to identify efficiencies related to Saskatchewan’s Lean Health Care Implementation. These could be potential cost savings in the form of lower utilization of healthcare services (i.e. length of stay in hospitals, readmission rate, and emergency care visits), and efficiency gain through waste reduction such as materials and inventories.

Please see the next section below (8.3 Selecting Outcome Measures) for the selected quantitative outcome measures for the multi-year evaluation in Saskatchewan.
### 8.3 Selecting Outcome Measures

For the purposes of this evaluation we have summarised patient outcome measures that have been recommended in the international literature (Table 3). The majority of these outcomes arose from the article ‘Selecting indicators for patient safety at the health system level in OECD countries’[47]. Table 3 has been grouped into types of measures and relevant part of the health system, and availability of this data in Saskatchewan.

**Table 3: Patient Safety Outcome Measures**

<table>
<thead>
<tr>
<th></th>
<th>Primary Care</th>
<th>Emerg. room</th>
<th>Surgical</th>
<th>Medical</th>
<th>ICU</th>
<th>Whole of system / other</th>
<th>Data availability/ Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MISTAKES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication errors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DATA UNAVAILABLE. The National Incident Reporting System is voluntary and does not represent accurate error rates. In addition, it is not routinely available.</td>
</tr>
<tr>
<td>Prescription errors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wrong blood type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DATA AVAILABLE. (minor limitations)</td>
</tr>
<tr>
<td>Wrong site surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DATA AVAILABLE. (minor limitations)</td>
</tr>
<tr>
<td><strong>QUALITY OF CARE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preventable hospitalisations for chronic diseases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DATA AVAILABLE. Canadian Institute for Health Information (CIHI): Hospitalization for Ambulatory Care Sensitive Conditions database</td>
</tr>
<tr>
<td>HbA1c levels in diabetic patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DATA AVAILABLE. Health Quality Council (HQC) will recommence reporting on this later in 2014.</td>
</tr>
<tr>
<td>Falls in hospital</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DATA AVAILABLE. (minor limitations) Data is available through HQC.</td>
</tr>
<tr>
<td>Injury hospitalisation rate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DATA AVAILABLE. (Minor limitations)</td>
</tr>
<tr>
<td>Immunization rates e.g. childhood, influenza</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PENDING. (Major limitations).</td>
</tr>
</tbody>
</table>
Table 3: cont.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Data Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical cancer screening</td>
<td>PENDING. Data may be available through the Saskatchewan Cancer Agency and/or using the HQC data – MSB</td>
</tr>
<tr>
<td>Adverse event notifications</td>
<td>DATA UNAVAILABLE. The National Incident Reporting System is voluntary and does not represent accurate event rates. In addition, it is not routinely available.</td>
</tr>
<tr>
<td>Standardised hospital deaths</td>
<td>DATA AVAILABLE. CIHI Hospital Standardized Mortality Ratio (HSMR) via HQC.</td>
</tr>
<tr>
<td>Special Care Unit LOS (in hospital)</td>
<td>DATA AVAILABLE (minor limitations) via HQC</td>
</tr>
<tr>
<td>Deaths in Special Care Unit (in hospital)</td>
<td>DATA AVAILABLE (minor limitations) via HQC</td>
</tr>
<tr>
<td>Hospital visits due to falls in LTC</td>
<td>DATA AVAILABLE (minor limitations) via HQC</td>
</tr>
<tr>
<td><strong>AVOIDABLE COMPLICATIONS / DETERIORATION</strong></td>
<td></td>
</tr>
<tr>
<td>Deep Vein Thrombosis (DVT) and Pulmonary Embolus (PE)</td>
<td>DATA AVAILABLE. All of the listed measures are available through the CIHI Health System Performance data via HQC.</td>
</tr>
<tr>
<td>Intravenous (IV) site infections</td>
<td></td>
</tr>
<tr>
<td>Wound infection rates</td>
<td></td>
</tr>
<tr>
<td>Decubitus ulcer</td>
<td></td>
</tr>
<tr>
<td>In-hospital hip fracture</td>
<td></td>
</tr>
<tr>
<td>Minor procedure infections</td>
<td></td>
</tr>
<tr>
<td>Proportion of patients transferred to Intensive Care (ICU)</td>
<td></td>
</tr>
<tr>
<td>Ventilator-acquired pneumonia (VAP)</td>
<td></td>
</tr>
</tbody>
</table>
Table 3: cont.

<table>
<thead>
<tr>
<th>SAFE PATIENT FLOW</th>
<th>DATA AVAILABLE. These are available or will soon be available from ED Waits/Patient Flow initiative via HQC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of patients leaving the Emergency Room (ER) without being seen by doctor</td>
<td></td>
</tr>
<tr>
<td>Length of stay (LOS) in the ER</td>
<td></td>
</tr>
<tr>
<td>ER waiting room times</td>
<td></td>
</tr>
<tr>
<td>Time from inpatient bed request to transfer</td>
<td></td>
</tr>
<tr>
<td>‘Alternate level of care’ in-hospital bed days</td>
<td></td>
</tr>
</tbody>
</table>

Quantitative Methods

Based on international recommendations and data availability, combined with our aim to evaluate the impact of Lean across the whole health system, we intend to collect the following quantitative measures of patient safety:

Quality of care

Preventable hospitalisations for chronic diseases; HbA1c levels in diabetic patients; falls in hospital; injury hospitalisation rate; immunization rates e.g. childhood, influenza; cervical cancer screening; and standardised hospital deaths.

Avoidable complications / deterioration

DVTs and PEs; IV site infections; wound infection rates; decubitus ulcer; in-hospital hip fractures; minor procedure infections; proportion of patients transferred to ICU; and ventilator-acquired pneumonia.

Safe patient flow

Proportion of patients leaving the ER without being seen by doctor; LOS in the ER; ER waiting room times; time from inpatient bed request to transfer; and ‘Alternate level of care’ in-hospital bed days.

We will use an interrupted times series design examining indicators of patient safety in the form of a multiple baseline approach. This research design represents a robust method of measuring the effect of an intervention as a trend over time. It is a useful design when recruitment of a control cohort is impractical, e.g. due to changes in hospital policy or, as in this case, where an intervention is staggered resulting in different stages of implementation across the province.
It is also amenable to Saskatchewan’s approach of collecting and displaying indicators over time using run charts or Statistical Process Control methods.

We have used existing readmissions data to calculate power for the interrupted time series design as per the figures and table below. This example power calculation indicates that the nature of the data being measured is statistically appropriate and can be analysed at the health service level.

Figure 10: Saskatchewan hospital monthly readmissions within 30 days, April 2010 to March 2012.
Figure 11: Saskatchewan Health Regions hospital monthly readmissions within 30 days, April 2010 to March 2012.

Table 4: Required effect sizes to yield at least 80% power assuming moderate autocorrelation for hospital readmissions (regions combined):

<table>
<thead>
<tr>
<th># post months</th>
<th>Required change in readmission rate (per 1000 hospitalizations per month)</th>
<th>Relative change in slopes*</th>
<th>Required change in # readmissions (per month)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>-7.5</td>
<td>261%</td>
<td>95</td>
</tr>
<tr>
<td>12</td>
<td>-3.9</td>
<td>136%</td>
<td>49</td>
</tr>
<tr>
<td>18</td>
<td>-2.8</td>
<td>98%</td>
<td>35</td>
</tr>
<tr>
<td>24</td>
<td>-2.4</td>
<td>84%</td>
<td>30</td>
</tr>
<tr>
<td>30</td>
<td>-2.0</td>
<td>70%</td>
<td>25</td>
</tr>
</tbody>
</table>
Table 5: Required effect sizes to yield at least 80% power assuming small autocorrelation for hospital readmissions (regions combined):

<table>
<thead>
<tr>
<th># post months</th>
<th>Required change in readmission rate (per 1000 hospitalizations per month)</th>
<th>Relative change in slopes*</th>
<th>Required change in # readmissions (per month)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>-6.0</td>
<td>209%</td>
<td>76</td>
</tr>
<tr>
<td>12</td>
<td>-2.8</td>
<td>98%</td>
<td>36</td>
</tr>
<tr>
<td>18</td>
<td>-2.1</td>
<td>73%</td>
<td>27</td>
</tr>
<tr>
<td>24</td>
<td>-1.7</td>
<td>59%</td>
<td>21</td>
</tr>
<tr>
<td>30</td>
<td>-1.4</td>
<td>49%</td>
<td>18</td>
</tr>
</tbody>
</table>

These health outcomes measures will serve as one of two primary outcomes of interest for the multi-year evaluation. The other primary outcome of interest is improvement in efficiency, discussed in Section 7.

9. Summary and Conclusion

This baseline-study aimed to:

- evaluate the early stages of the implementation of Lean (Saskatchewan’s Lean Management System) in the provincial health system, and to

The literature review highlighted the magnitude of the Lean undertaking in Saskatchewan. We found no evidence of any system-wide attempt to apply Lean elsewhere in the world. It also highlighted the paucity of both program theory and formal theory to support either the implementation or the evaluation of Lean-style initiatives.

We believe that this baseline study has made a contribution in this regard, by developing draft program theory at multiple levels, hypothesising key change mechanisms and the contextual factors likely to support or impede their operation, and identifying appropriate formal theories to support future theoretical development.

The multi-year evaluation will provide an unprecedented opportunity to develop this work further and thus to make a significant contribution to health improvement science.

The implementation mapping process has identified:

- the most frequently used Lean tools in the early stages of implementation as RPIWs and 5S, and the
- common foci of those tools as being time saving, waste reduction and error reduction.

A system for collecting and analysing data about these events has been developed and trialled and is ready for use in the multi-year evaluation. The weakness of this approach is that it cannot monitor the integrated and coherent application of the full range of Lean tools. Some respondents in baseline interviews identified this as essential to achieving the cultural change necessary to drive sustained, system-wide impacts.
Limiting the range of tools studied is a practical necessity, both in terms of reporting at site level and of collection and analysis at the evaluation level.

We believe that the two tools, RPIWs and 5S, will provide sufficient indication to allow analysis of the relationship between implementation and outcomes. The other data collection strategies, interviews, focus groups and the ethnographic study in ED, will also counteract this weakness to some extent.

The interviews have identified both strengths and weaknesses in the early implementation of Lean, including the:

- high personal costs to some staff, particularly those in leadership positions in hospitals and health units, and the
- inadequate resourcing of the support systems such as IT and maintenance implicated in changes across all units.

For Lean to be maintained and the desired outcomes achieved, attention to these fragilities in the implementation system will be necessary.

The baseline study processes have demonstrated the feasibility of qualitative sampling and of realist analysis of the data obtained. In the multi-year study, questions more closely aligned with the program theory and the hypotheses under investigation will be possible.

A costing methodology, which can be applied in the multi-year evaluation, was developed through the economic study. The methodology was demonstrated by estimating indirect costs for an RPIW. A more detailed costing for more of the tools should be available by the end of June 2014.

Outcome indicators for the multi-year evaluation have been selected and aligned against the program theory. In their own right, these will be used to examine the outcomes of Lean at multiple levels, and within the economic evaluation to undertake a cost-benefit analysis.

Our mixed-methods approach for the multi-year evaluation of Lean in Saskatchewan is based on:

- qualitative interviews,
- case studies,
- an interrupted time-series (ITS) study examining indicators of patient safety in the form of a multiple baseline approach.

This research design represents a robust method of measuring the effect of an intervention as a trend over time.

It is a useful design when recruitment of a control cohort is impractical, e.g. due to changes in hospital policy or, as in this case, where an intervention is staggered, resulting in different stages of implementation across the province. It is also amenable to Saskatchewan's approach of collecting and displaying indicators over time, using run charts or Statistical Process Control methods.

Framing these methods within an overall realist evaluation will provide an unprecedented opportunity to develop a distinctive understanding of how Lean works, in what contexts and why.
This approach will set this evaluation apart from the existing evidence for Lean and will make a significant original contribution to health improvement science.
References:


Appendices:

Appendix 1: Literature review on Lean
Appendix 2: Theory maps
Appendix 3: Interview guide for staff and patients
Appendix 4: Patient Safety CMOCs