A Realist Investigation of Lean Sustainability in Pediatric Healthcare

by

Rachel Flynn

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Faculty of Nursing
University of Alberta

Abstract

Background: Lean is a management system aimed at maximizing value by reducing waste and reconfiguring organizational processes that originated from the Toyota manufacturing industry. Lean is increasingly implemented as a quality improvement management system for healthcare. We conceptualize Lean as a complex intervention when implemented in the context of healthcare. Research has been conducted on the implementation of Lean in healthcare, however no evidence has been gathered on the sustainability of Lean efforts. The contextual factors and mechanisms that influence the sustainability of Lean in healthcare have not been well studied.

Purpose: The purpose of this dissertation was to develop, test and refine an initial program theory on Lean sustainability in pediatric healthcare. Sustainability is an important yet understudied implementation outcome.

Methods: This dissertation was underpinned by scientific realism, using the context (C) + mechanism (M) = outcome configuration (Oc) (CMOcs) heuristic to explain under what contexts, for whom, how and why Lean efforts are sustained or not sustained in pediatric healthcare. It consisted of three research phases and four related papers: (I) a conceptual debate paper on the potential for nurses to contribute to and lead improvement science; (II) a debate paper on the complexity of Lean and implications for research designs and methods; (III) research phases 1 and 2, initial program theory development and a realist review to further develop and refine the initial program theory; (IV) a realist evaluation using case study research design to test the program theory developed and refined during research phases 1 and 2. Thirty-two qualitative realist interviews were conducted with multiple stakeholder groups

across four pediatric units in the context of the Saskatchewan Lean Management System, Canada.

Findings: The following findings were identified and addressed in this dissertation:

Phase 1 Seven CMOc hypotheses underpinned the initial program theory.

Phase 2 Five CMOc hypotheses from the initial program theory were substantially supported after synthesis: 'sense-making', 'value congruency', 'staff engagement', 'empowerment' and the 'ripple effect' or causal pathway between Lean implementation outcomes that then served as facilitating or hindering contexts for sustainability. Overall, there was variation with the conceptualization and measurement of sustainability.

Phase 3 Five CMOcs emerged from the realist interview data, two of which were substantiated from Phase 2 'sense-making and value congruency' and the 'ripple effect' from early implementation. The remaining three CMOcs addressed a 'lack of fit between Lean and healthcare and a lack of customization to context', 'innovation fatigue' and the 'positive and negative effects of Lean customization to context' on sustainability.

Conclusions: These dissertation findings depicted the complex nature to sustaining Lean efforts and the differences in the perceptions and degrees of adoption across the hierarchy of the organization. The approach and nature of implementation was also critical to shaping contexts for sustainability. Customization to context was also important to Lean sustainability. These findings have important implications for sustainability research, in understanding the determinants of sustainability for complex health interventions.

Preface

This thesis is an original work by Rachel Flynn. The research project, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board, Project Name "A Realist Investigation on the Sustainability of Lean in Pediatric Healthcare", Pro00063634, September 13, 2016.

One paper has been published, two are under review and the fourth is in preparation for publication.

Paper one has been published as Flynn R, Scott SD, Rotter T, Hartfield D. The potential for nurses to contribute to and lead improvement science in health care. *Journal of Advanced Nursing*. 2017; 73(1), 97-107. doi:10.1111/jan.13164. I was responsible for the conceptualization, composition, writing and submission of this paper. Drs. Scott, Rotter and Hartfield contributed to the intellectual development of this paper.

Paper two has been submitted as Flynn R, Rotter T, Scott SD. Lean in healthcare, is it too complex for the already complex systems of healthcare? Implications on research designs and methods. *BMC Health Services Research* (submitted 30 May 2018). I conceived and drafted the arguments for this paper. Drs. Scott and Rotter contributed to the structure and focus of the arguments for this paper. Both commented on and revised this paper. All authors read and approved the final manuscript.

Paper three has been submitted as Flynn R, Newton AS, Rotter T, Hartfield D, Walton S, Fiander M, Scott SD. The sustainability of Lean in pediatric healthcare: a realist review. *BMC Systematic Reviews* (revise and resubmit 3 July 2018). I was responsible for the literature search, data extraction and analysis; manuscript composition, writing and

submission of this paper for publication. Dr. Scott was the primary supervisor for this doctoral research and provided guidance on the conceptual development of this review. Dr. Newton provided guidance on realist synthesis and the review process and contributed to the study conception and development. Dr. Rotter provided expert guidance on Lean management. Ms. Walton assisted in data screening and data extraction and intellectual discussion around CMO extraction and synthesis. Ms. Fiander guided and performed the search strategies for this review. Drs. Scott and Newton oversaw data extraction and synthesis. I drafted and edited the final manuscript. All authors participated in critically appraising and providing feedback on the intellectual content of the manuscript. All authors read and approved the final manuscript.

Paper four is in preparation for publication as Flynn R, Scott SD, Rotter T, Hartfield D. Newton M. Ripple- effects from outcomes of implementation to contexts for sustainability - a realist evaluation of Lean sustainability in pediatric healthcare. (Target journal: *BMC Health Services Research*, October 2018). I was responsible for participant recruitment, data collection, data cleaning and analysis; manuscript composition and writing. Dr. Scott was the primary supervisor for this doctoral research and provided guidance on the conceptual development of this evaluation. Dr. Newton provided guidance on realist methodology. Dr. Rotter provided expert guidance on Lean management, data recruitment and data collection. Dr. Hartfield provided guidance on change management and how to write CMOcs in a meaningful way for practitioners. Drs. Rotter, Newton and Hartfield contributed to manuscript composition and edits at various stages of manuscript construction. In the papers I use the term “we” for any actions taken (e.g., we conducted), this to represent the doctoral committee for publication purposes. Drs. Scott and Rotter contributed to overall concept formation of the dissertation.

Dedication

"Love the life you live, and live the life you love"

I dedicate this dissertation to my one and only, my best friend and husband Stacky. Thank you for all of your amazing support and belief in me, you always go along with the journey no matter how mad the idea. Your positivity and support allowed me to seize this opportunity in life and truly enjoy the PhD process.

Also, to my mum and dad, Freda and Kevin, you have always encouraged me to achieve what I want from life. You have always fostered my curious mind and love of questioning, sharing ideas, learning and science.

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To those that participated in my research, thank you for all of your insights and time. To Dr. Gill Westhorp and Dr. Justin Jagosh, thank you for your excellent mentorship in realist methods, I believe after 5 years, I have some clue now. I really appreciate how you both have challenged my thinking. To Dr. Susan Samuel, thank you for your mentorship and research opportunities, I thoroughly enjoyed our collaboration. To the Faculty of Nursing, thank you for all of the committee, collaboration, learning and leadership opportunities, over the past 5 years, they all added to my positive experience as a doctoral student. To the administrative and support staff, in particular Heather, Tracy, Anita, Martin and Janet, thank you for helping me so much along the way.

To my husband Stacky and our families, thank you for always encouraging me to reach for the stars, laugh and keep perspective on the most important things in life. I highly doubt you will read this… and I don't blame you, but I do hope that you all know how

grateful I am for each of you in my life. Maybe one day, I will get a proper adult job, but until then keep guessing what it is that I do!

Finally, let me say ‘thank you’ to my old and new friends, who supported me through the doctoral journey, that always motivate me to be and do better and most importantly always make me laugh and realize what a great life I had as a PhD student.

During my doctoral studies, I was supported by Alberta Innovates Health Solutions Clinician Fellowship, Knowledge Translation Canada Graduate Studentship, Women and Children’s Health Research Institute, and the Alberta Registered Nursing Educational Trust. I am very grateful for the opportunities provided from these awards, thank you.

Table of Contents

List of Tables

List of Figures

Chapter 1. Introducing the knowledge gap

Background

Healthcare systems are increasingly under pressure to reduce expenditure, decrease patient waiting times and continuously improve.[1] No one superior healthcare system exists in relation to cost-effective and efficient healthcare delivery. Different healthcare systems share many of the same challenges (e.g., high waiting times, high readmissions, policy issues, financial burden, and poor patient outcomes).[2, 3] Research evidence highlights that countries with the highest rates of healthcare expenditure (e.g. United States, Canada) do not necessarily result in the best health outcomes for patients.[2] This creates the argument that in order to achieve a high quality healthcare system it is not the type of system (e.g., public vs private) that matters most but rather the process of the system and how that system is managed.

The challenge with trying to improve healthcare systems from a process and management approach is the complexity of the processes embedded within healthcare systems, the complexity of healthcare systems themselves and the abundance of improvement strategies to manage these complexity problems. There is also a lack of research evidence on what improvement strategies work in what circumstances for whom and why and how to sustain improvement efforts in practice.[4] Quality problems are common in healthcare systems, yet many of these problems are predictable and preventable.[5] The complex and disjointed processes within a healthcare system are one reason for quality problems. The more complex a process is the greater the likelihood of error.[6] Healthcare systems are comprised of diverse agents (e.g., patients, multidisciplinary healthcare providers, administrators, managers and policy makers) that learn, self-organize, coevolve and are interdependent.[7] These elements make healthcare systems challenging to manage, change or improve. This evidence suggests that efforts to improve the quality of

healthcare should focus on the process of delivery that target the different levels of a healthcare system.[8] Internationally there is increasing demand for service redesign as an approach to improve quality, increase efficiency and decrease expenditure.[9] One significant challenge is how to effectively do this while simultaneously ensuring continuous quality improvement (QI) and that the best available research informs healthcare practices.[10]

Lean

One proposed potential solution to dilemmas of healthcare quality and inefficent complex healthcare processes is Lean, a QI management system that originated from the automotive manufacturing industry of the Toyota Production System in the 1930s.[11] Lean originated from the Japanese language in the Toyota Production System in an effort to improve the industry's production by removing ‘muda’ (waste), ‘mura’ (inconsistency) and ‘muri’ (overburden). Lean is based on the assumptions that waste and value should be determined by the customer (patient in healthcare) and that value is created by either reducing waste or increasing value added activities that do not cause increased cost, thus doing more with less.[12, 13]

Through a baseline scoping review (March 2013-March 2014)[14] it was identified that Lean interventions in the international healthcare literature are poorly articulated, leading to many relevant studies not being included in evidence synthesis. Subsequently, an operational definition of Lean was developed[15] and was applied in this doctoral research on the sustainability of Lean in pediatric healthcare. This operational definition states that: Lean is a complex, multicomponent set of philosophies, diagnostic processes and management activities aimed at maximizing value by reducing waste.[15] Lean offers ways to rethink the current way a system is doing things and think of more efficient ways to do it.[16] The values of quality and efficiency in

Lean have made it an attractive approach for healthcare systems to adopt.[16, 17] According to the Institute for Healthcare Improvement,[18] the implementation of Lean holds the promise of reducing wasted time, money and energy in healthcare; creating a system that is efficient, effective and responsive to the needs of patients.

Knowledge gap

Despite the documented potential of Lean for healthcare improvement, previous research on Lean in healthcare has focused on Lean as a collection of stand-alone operational tools driven to deliver quick wins, while concomitantly failing to understand factors that influence the successful implementation and sustainability of Lean to healthcare.[19-23] There is no evidence on how to successfully embed and sustain Lean in clinical practice or on the conditions and generative mechanisms that trigger the sustainability or otherwise of Lean in healthcare (e.g., Lean tools, Lean values, Lean training). A scoping review on Lean Management in healthcare identified a lack of reporting on the follow up and sustainability of Lean implementation in the 43 included studies.[15]

Due to the well-known challenges of improving healthcare delivery and achieving organizational change, a growing body of research known as implementation science has sought to understand the challenges of implementing organizational change in healthcare such as quality improvement strategies and studies ways to improve the implementation of organizational changes in healthcare.[24] However, even when initial implementation efforts of organizational changes are successful, interventions or programs do not necessarily continue as originally implemented, that may not be sustained as expected[25] and often fail to become a routinized part of care.[26] Interventions may be adapted or partially continued as a result of issues such as the

introduction of new evidence, changes in priority, the availability of resources or other contextual factors.[26] Unintentional de-implementation can occur as a result of factors such as local staffing conditions, lack of resources or competing demands.[27]

Research motivation

Understanding processes that relate to implementation and determining how to foster the sustainability of effective organizational changes are as important as understanding how to implement them in the first place. Far less research attention has been given to the question of what influences the sustainability of organizational improvements.[28] A systematic review by Greenhalgh and colleagues stated that there is a dearth of studies on organizational change which focus on the sustainability of complex service innovations.[29] The sustainability of organizational change efforts are important to investigate and attempt to understand because despite large financial and resource investments for organizational redesign and improvements, there is limited understanding how to sustain these changes.[30]

It is necessary to determine whether there is a return on such large scale investments and to identify whether the implemented change is delivered and sustained as expected or not. Policy makers and other stakeholders are increasingly concerned with the long term impact of such investments.[26] Research on the sustainability of organizational changes in healthcare, such as Lean are sorely needed.[31] The causal mechanisms and contextual factors shaping the sustainability of systemic change such as Lean have not been well studied or understood.[32, 33] Questions that address in which circumstances, how and why Lean is or is not sustainable in pediatric healthcare have not been addressed to date. These knowledge gaps point to areas of research that require further exploration.

What I mean by 'sustainability'

The construct of sustainability was drawn from the National Health Service (NHS) Institute for Innovation and Improvement Sustainability Model (SM).[34] In this model sustainability refers to "the continuation or the integration of a new practice within an organization whereby it has become a routine part of care delivery process and continues to deliver desired outcomes, whereby the ways of thinking and attitudes behind processes and outcomes have changed and the new practice has become the new way of working."[35]

The NHS SM identifies 10 key factors that increase the likelihood of sustainability and continuous improvement. These factors are grouped into three domains: Process, staff and organization (Table 1.1). The process domain explores the credibility of the new practice (Lean) and the extent to which staff believe it will increase efficiency, make jobs easier and be continued when current staff leaves. The staff domain assesses frontline staff awareness of and involvement in organizational changes and the commitment of clinical and organization leaders. The organization domain: assesses the new practice (Lean) fit with existing organizational culture, strategic aims and infrastructure (such as staff, facilities, policies, procedures and communication systems).[35]

Table 1.1 National health services sustainability model (NHS SM)

National health services sustainability model factors (process, staff and organization)
Process Factor 1: Benefits beyond helping patient: Whether in addition to helping patients there are other benefits that will make a difference to daily working lives or make things run more smoothly such as reduced waste or duplication. **Process Factor 2**: Credibility of the benefits: Whether benefits to patients, staff and the organization are visible, are believed by staff and can be described clearly. **Process Factor 3**: Adaptability of improved process: Whether changed processes will continue to meet the need of the organizations and can be maintained when an individual or group of people who initiated it are no longer there. **Process Factor 4**: Effectiveness of the system to monitor progress: Whether data are easily available to monitor progress or assess improvement and whether there are systems to communicate this in the organization.
Staff Factor 5: Staff involvement and training to sustain the process: Whether staff play a part in the implementation of changes to processes and the extent of training and development of staff to help sustain these changes **Staff Factor 6**: Staff attitudes towards sustaining the change: Whether staff ideas are taken on board, the opportunity they are given to test these ideas and their belief that this is a better way of doing things that should be preserved. **Staff Factor 7:** Senior leadership engagement: Whether credible and respected senior leaders are seen as promoting and investing their own time in changes. **Staff Factor 8:** Clinical leadership engagement: Whether credible and respected clinical leaders are seen as promoting and investing their own time in changes
Organization Factor 9: Fit with the organization's strategic aims and culture: Whether the changes being made are seen as an important contribution to the overall organizational aims. **Organization Factor** 10: Infrastructure for sustainability: Whether staff, facilities, equipment and policies and procedures are adequate to sustain new processes.

Dissertation research phases and overview

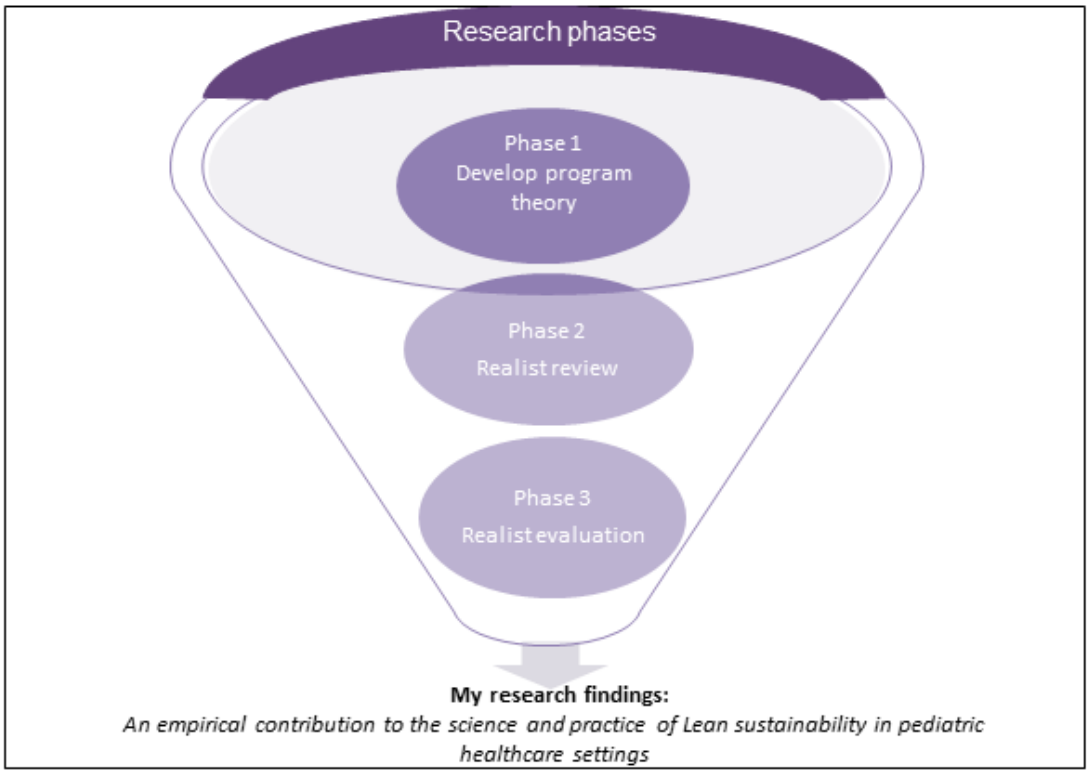
This paper-based dissertation represents the output of my doctoral research program on the sustainability of Lean in pediatric healthcare and reflects the sequential development of ideas throughout my studies. The overall aim of this doctoral research was to generate, test and refine a program theory on the sustainability of Lean in pediatric healthcare using a realist approach. The purpose was to understand in which circumstances, how and why Lean is or is not sustainable in pediatric healthcare. The main objectives were to:

a) Develop a program theory on Lean sustainability in healthcare, to begin to articulate the components of the intervention, the expected implementation processes, and how they are expected to lead to sustained behavior change;
b) Further refine this program theory through a realist synthesis of existing literature on Lean sustainability in the contexts of pediatric healthcare;
c) Test whether the program theory reflects reality, through realist interviews in multiple pediatric units involved in a system-wide Lean transformation;
d) Suggest how the program theory for this complex intervention might be refined.

The overarching research question that guided this doctoral research was: *For whom, under what circumstances, how and why are Lean efforts sustainable or not sustainable in pediatric healthcare?*

This doctoral research aids in the theoretical development of the sustainability of Lean in pediatric healthcare. It also offers further scientific contribution to other research conducted on Lean in my research context.[36-39] This doctoral work comprised of three research phases (Figure 1.1), each phase informing the next.

Figure 1.1 Dissertation research phases



Realist philosophy of science

The three research phases mentioned above were guided by scientific realism, a philosophy of science that positions itself between the poles of positivism (there is a single reality that can be measured) and constructivism (there is no universal objective truth).[40] This philosophy of science asserts that both the material world 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 by bringing explanatory forces and theories of explanation to the surface.[41] Realism believes in a mind-independent reality, that there is an absolute reality, or one singular true reality but human minds are incapable of having full knowledge about it in every given moment of time.[42] Thus constructions of reality can be fallible. Scientific realism argues that it is possible to work

towards a closer understanding of the nature of reality, through observation and testing in the form of realist evaluation.

Realist evaluation

My dissertation work was grounded primarily in the work of Pawson and Tilley, scientific realism and realist evaluation.[41] Realist evaluations are theory-driven that search for and refine explanations of program effectiveness.[43] Programs are theories incarnate that are embedded, active and a part of open systems.[44] One key quest of realist evaluation is to bring to the surface theories that explain "what works for whom in what circumstances and why?", rather than merely does it work?[41] Realist evaluation opens up the 'black box' between an intervention and its outcome. Realist research begins with a program theory which details how the intervention is intended to work, formulated as context (C) + mechanism (M) = outcome (O) configuration (CMOc).[41] A CMOc is a hypothesis that the program works (O) because of the action of some underlying mechanism (M), which only comes into operation in particular contexts (C). [45(pp184)]

Realist evaluators aim to identify the underlying causal generative mechanisms that explain 'how' outcomes are caused under certain contexts. Causal mechanisms are *"underlying entities, process or structures which operate in particular contexts to generate outcomes of interest."* [46(pp368)] I followed Dalkin et al.[47] understanding of mechanisms as a combination of a resource offered by an intervention into a specific context and the change in reasoning by an individual that leads to an outcome. These causal mechanisms may only activate when under certain conditions.[41] Realist evaluation examines how individuals reason in response to the resources offered by any intervention leads to change under certain conditions. In other words, explaining how it is that X produces Y, given the conditions of Z.[48] The development, testing

and refinement of CMOcs in a realist evaluation provides causal explanation of how and why a program works.[49] Empirical data (qualitative, quantitative or both) are used to test and refine program theories through the CMOc heuristic[50] and identify how the intervention works in practice.

Appropriateness of realist evaluation to study Lean

A basic assumption of realist evaluation is that programs are complex interventions introduced into complex social systems.[43] Pawson characterizes program complexity under the acronym – VICTORE (Volition, implementation, context, time, outcomes, rivalry and emergence) (Table 1.2).

Table 1.2 Key characteristics of program complexity under realist evaluation[43]

VICTORE characteristics of program complexity	**Description**
Volitions	The "choice architecture" of a program including how program subjects might respond to a program or intervention.[43(pp34)]
Implementation	The implementation chains of an intervention/program which "are prone to inconsistency and interpretation, blockages, delays, and unintended consequences."[43(pp36)]
Context	The context of an intervention refers to the circumstance in which it plays out. Pawson outlines a "four I's" framework: Individuals (characteristic and capacities of stakeholders in the program); Interpersonal relations*;* Institutional settings*;* and Infrastructure (which refers to the

VICTORE characteristics of program complexity	Description
	wider social, economic, and cultural setting of a program/intervention.[43(pp37)]
Time	The history and of timing of an intervention. The effects of History, timing and sequencing are another source of complexity when evaluating programs.[43(pp38)]
Outcomes	Measuring change outcomes are multitudinous, casual chains are plural and often difficult to measure.[43(pp39)]
Rivalry	The pre-existing policy landscape in which the program is embedded – this primarily refers to "other, contiguous programs and policies may share or oppose the ambitions of the intervention under study and actions of stakeholders and subjects under study.[43(pp41)]
Emergence	Potential emergent effects, long-term adaptations, and unintended consequences associated with the program/intervention.[43(pp42)]

Complex interventions, such as Lean can have many potential "active ingredients" that are non-linear and multifaceted in nature and dependent on social context. As a result, complex interventions pose methodological challenges and require adaptations to the standard design of trials.[51-53] A realist approach offers methodological strengths to unpack the 'black box' of complex interventions[54] in comparison to traditional synthesis approaches (e.g., systematic reviews) and traditional trials (e.g., randomised control trials). A realist approach offers ways to address how, when, why and where the intervention works or not through the generation of an

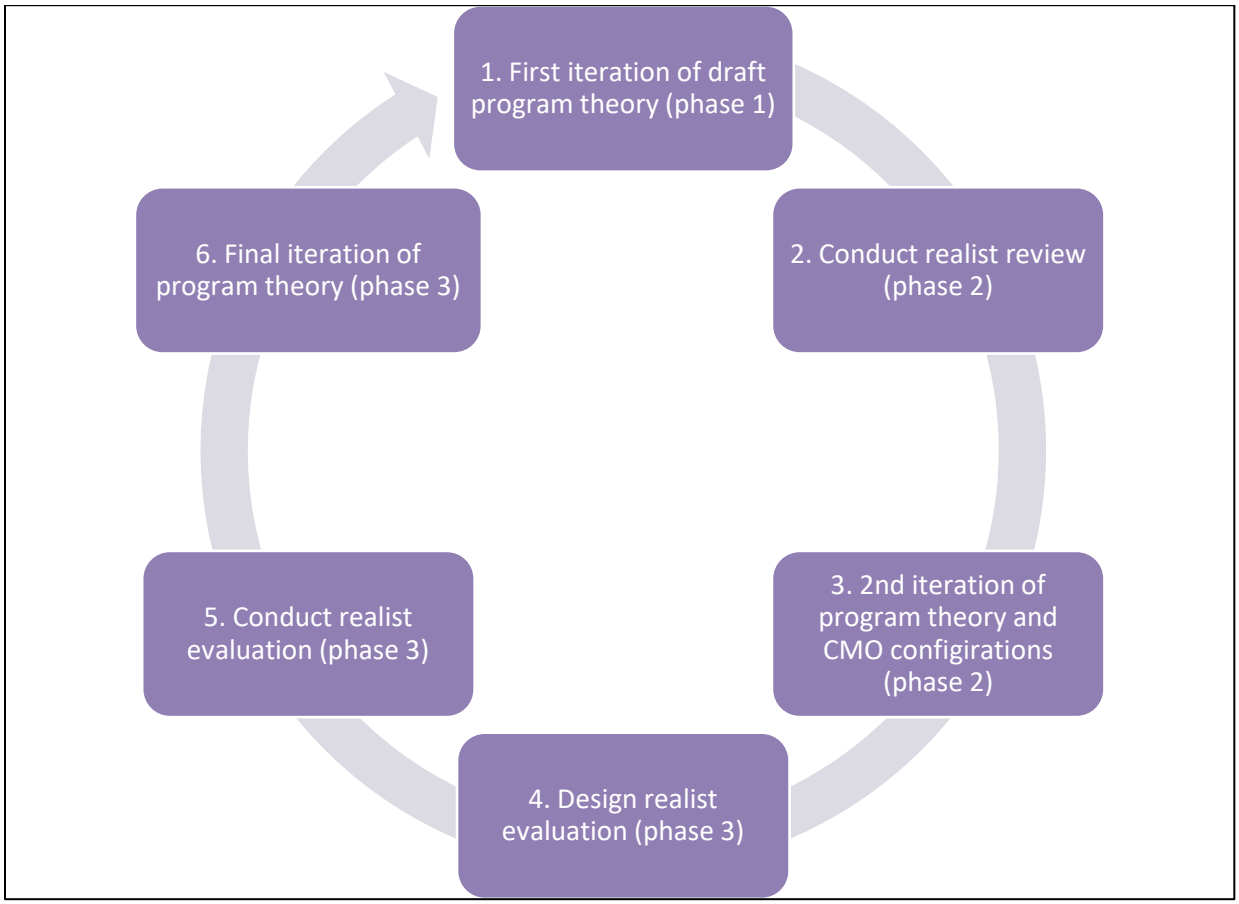
explanatory program theory.[54] It offers a way to unpack and explain the possible causes and contextual factors of change and to generate a middle range theory of explanation. A middle range theory can explain a relatively specific phenomenon which can be tested empirically and may be useful across a range of contexts.[41]

The ontological and epistemological assumptions to scientific realism situated well with the purpose of my mode of inquiry to develop knowledge to understand for whom and in what contexts Lean efforts sustain in pediatric healthcare, and what facilitates or hinders its sustainability and why. It is important that evaluations on complex healthcare interventions, such as Lean, do not only assess the impact of the overall intervention but also look at the context, the participants and process involved in the sustainability of the intervention.[54]

Realist methodology and evaluation cycle

The three research phases were guided by the realist evaluation cycle of a) theory hypothesis generation (phase 1and 2; paper 3 - chapter 4), b) theory hypothesis observation and specification (phase 3; paper 4 - chapter 5).[41] My doctoral research process is depicted through a research process flow chart adapted from Westhorp[55] (Figure 1.2).

Figure 1.2 Research process flow chart [55]



Initial program theory development

The first phase of my research was to develop an initial program theory that attempts to explain the strategies and mechanisms that trigger the sustainability or non-sustainability of Lean in healthcare. The initial program theory was developed from an exploration of the existing literature on Lean, the sustainability of quality improvement interventions and formal theories that help to understand behaviour change and the embedding of organizational change in complex systems. This research phase was also informed by a logical model on Lean implementation from a multi-year realist evaluation.[36] The logical model illustrated the causal

path from Lean implementation to Lean impact through inputs, intervention activities, outputs and outcomes.

A program theory incorporates both the components of the intervention and an understanding of how the intervention interacts with context.[56] It is important to gather this information because the effect of complex interventions such as Lean can play out differently in different settings due to factors such as the capacity to implement, the context and the "active ingredients" of the intervention.[57] In this phase I developed an initial program theory map (appendix 1) and seven CMO hypotheses (appendix 2) that were further refined during phase two, a realist review and subsequently tested during phase three, a realist evaluation. Further detail on research phases 1 and 2 is provided in chapter four and further detail on phase 3 is provided in chapter 5.

Theoretical guidance

Each research phase was guided by NHS SM and Normalization Process Theory (NPT). NPT is a middle range theory used to understand the implementation, embedding and integration of evidence-based innovations into healthcare settings as a result of people working individually and collectively to enact them.[58] NPT focuses on the factors that facilitate or impede routine embedding of evidence based innovations to practice. This middle-range theory is concerned with the social organization of the work (implementation), of making practices routine to everyday (embedding), and of sustaining embedded practices in their social contexts (integration).[59] The key theoretical constructs to NPT are: coherence, cognitive participation, collective action and reflexive monitoring.[59] The constructs of NPT offer potential mechanisms that promote or inhibit the embedding of complex interventions into routine everyday practice

and the likelihood of sustainability.[58, 59] A more detailed description of the four constructs to NPT are provided in Table 1.3.

Table 1.3 Normalization process theory constructs[60]

Normalization process theory constructs	Description
Coherence This is the **sense-making work** that people do individually and collectively when they are faced with the problem of operationalizing some set of practices.	**1.1 Differentiation**: An important element of sense-making work is to understand how a set of practices and their objects are different from each other. **1.2 Communal specification**: Sense-making relies on people working together to build a shared understanding of the aims, objectives, and expected benefits of a set of practices. **1.3 Individual specification**: Sense-making has an individual component too. Here participants in coherence work need to do things that will help them understand their specific tasks and responsibilities around a set of practices. **1.4 Internalization**: Sense-making involves people in work that is about understanding the value, benefits and importance of a set of practices.
Cognitive Participation This is the **relational work** of what people do to build and sustain a community of practice around a new technology or complex intervention.	**2.1 Initiation**: When a set of practices is new or modified, a core problem is whether or not key participants are working to drive them forward. **2.2 Enrolment**: Participants may need to organize or reorganize themselves and others in order to collectively contribute to the work

Normalization process theory constructs	Description
	involved in new practices. This is complex work that may involve rethinking individual and group relationships between people and things. **2.3 Legitimation**: An important component of relational work around participation is the work of ensuring that other participants believe it is right for them to be involved, and that they can make a valid contribution to it. **2.4 Activation**: Once it is underway, participants need to collectively define the actions and procedures needed to sustain a practice and to stay involved.
Collective Action This is the **operational work** that people do to enact a set of practices, whether these represent a new technology or complex healthcare intervention.	**3.1 Interactional workability**: This refers to the interactional work that people do with each other, with artefacts, and with other elements of a set of practices, when they seek to operationalize them in everyday settings. 3.2 **Relational integration**: This refers to the knowledge work that people do to build accountability and maintain confidence in a set of practices and in each other as they use them. **3.3 Skill set workability**: This refers to the allocation work that underpins the division of labour that is built up around a set of practices as they are operationalized in the real world. **3.4 Contextual integration**: This refers to the resource work - managing a set of practices through the allocation of different kinds of

Normalization process theory constructs	Description
	resources and the execution of protocols, policies and procedures.
Reflexive Monitoring This is the **appraisal work** that people do to assess and understand the ways that a new set of practices affects them and others around them.	**4.1 Systematization**: participants in any set of practices may seek to determine how effective and useful it is for them and for others, and this involves the work of collecting information in a variety of ways. **4.2 Communal appraisal**: participants work together - sometimes in formal collaboratives, sometimes in informal groups to evaluate the worth of a set of practices. They may use many different means to do this drawing on a variety of experiential and systematized information. **4.3 Individual appraisal**: Participants in a new set of practices also work experientially as individuals to appraise its effects on them and the contexts in which they are set. From this work stem actions through which individuals express their personal relationships to new technologies or complex interventions. **4.4 Reconfiguration**: appraisal work by individuals or groups may lead to attempts to redefine procedures or modify practices - and even to change the shape of a new technology itself.

Summary of papers

This dissertation comprises of four papers for publication. The papers have been formatted to the specifications of the journals to which they have been published or submitted. The first two papers (chapter 2 and 3) are foundational works that form the basis for this three phase doctoral research. The third paper (chapter 4), a realist review represents research phases 1 and 2. The final paper (chapter 5), a realist evaluation represents the findings from phase 3. In the following paragraphs, I provide a short summary of each of the four papers and elaborate on the connections between them.

Paper 1: The potential for nurses to contribute to and lead improvement science in healthcare

Paper one was a debate article in which I explored the potential of nurses to lead improvement science.[61]

Objective: The motivation and purpose of this paper, was to demonstrate how nurses can lead and play an integral role in improvement science, thus situating my doctoral research as a nursing clinician scientist studying improvement science, specifically the sustainability of complex healthcare improvement interventions.

Description: This debate paper creates the argument that nurses have the potential to contribute to and lead improvement science activities. This paper pays particular attention to how the philosophical, theoretical, political and ethical positions either enable or hinder nurses' ability to contribute to and lead improvement science. This paper illustrates that up to now the potential for nurses to lead improvement science activities has not been fully used. The paper argues for the need to include improvement science in nursing education curricula and for advanced nursing roles in this field.

Linkage: The discussion from paper one pointed to nurses' potential to lead improvement science, setting the platform for my doctoral research in this field.

This paper is published as:

Flynn, R., Scott, S. D., Rotter, T., and Hartfield, D. (2017). The potential for nurses to contribute to and lead improvement science in healthcare. *Journal of Advanced Nursing*, *73*(1), 97-107. doi:10.1111/jan.13164

Paper Two: Lean in healthcare, is it too complex for the already complex systems of healthcare? Implications on research designs and methods

Objective: I created this paper to argue for the need for realist methods to better understand how and why, in what contexts Lean works or works or not in healthcare.

Description: In this second foundational paper, I explored the complexity of Lean for improvement in complex healthcare systems. Secondly, I discussed the implications of such complexity on the research designs and methods used to evaluate Lean; adding to more recent arguments for theory informed methodological approaches, such as realist synthesis and realist evaluations. This paper proposed two domains of complexity to Lean as an intervention for healthcare improvement: a) the complexity of the components of Lean and b) the complexity of healthcare systems in which Lean is implemented. This paper situated my rationale for choosing realist methods to evaluate Lean sustainability in pediatric healthcare.

Linkage: The evidence and position of paper two demonstrated that theory-informed research, such as realist synthesis and realist evaluation, is necessary to better understand complex interventions for healthcare improvement. This paper formed the basis for paper three, a realist review and paper four, a realist evaluation on Lean sustainability in pediatric healthcare.

This paper is under review as:

Flynn R, Rotter T, Scott SD. Lean in healthcare, is it too complex for the already complex systems of healthcare? Implications on research designs and methods. *BMC Health Services Research* (Under review, July 2018).

Paper Three: The sustainability of Lean in pediatric healthcare: a realist review

Objective: The objective of paper three was to further develop and refine the initial program theory on the sustainability of Lean, and to explore contexts and mechanisms that contribute to the sustainability of Lean efforts across pediatric healthcare.

Description: Paper three, a realist review of Lean sustainability in pediatric healthcare, encompassed phase 1 and 2 of the realist evaluation cycle (Figure 1.2). Realist reviews are driven by the question: *"what works, how, for whom, in what circumstances and to what extent?"*[41] I selected a realist review, as it offers a way to unpack and explain the possible causes and contextual factors of change and to generate a middle-range theory of explanation. Realist reviews were developed by Pawson[45] to explain why interventions may or may not work, in what contexts and under what circumstances. The findings of the realist review refined the initial program theory on the sustainability of Lean. The initial program theory was developed prior to the realist review and realist evaluation.

Linkage: The findings from the realist review informed the data collection and analysis of paper four and also aided the refinement of the program theory on the sustainability of Lean in pediatric healthcare.

This paper is in-press as:

Flynn R, Newton AS, Rotter T, Hartfield D, Walton S, Fiander M, Scott SD. The sustainability of Lean in pediatric healthcare: a realist review. *BMC Systematic Reviews* (In-press, August 2018).

Paper Four: Ripple-effects from outcomes of implementation to contexts for sustainability - a realist evaluation of Lean sustainability in pediatric healthcare.

Objective: The purpose of this paper was to test and further refine the initial program theory that was developed during research phases 1 and 2 of this doctoral research.

Description: In this paper, using a realist evaluation framework I employed a case study research design to evaluate the sustainability of Lean in pediatric healthcare. I conducted thirty-two qualitative realist interviews with various stakeholder groups across four pediatric units at one acute hospital. The findings refined the initial program theory on the sustainability of Lean in pediatric healthcare.

This fourth paper is being prepared for submission as:

Flynn R, Rotter T, Hartfield D, Newton M, Scott SD. Ripple- effects from outcomes of implementation to contexts for sustainability - a realist evaluation of Lean sustainability in pediatric healthcare. (Target journal: *BMC Health Services Research*, October 2018).

Together, these three research phases and four papers constitute my doctoral thesis, which forms the basis of my future program of research.

Summary of dissertation and key terms

To understand in which circumstances, how and why Lean is or is not sustainable in pediatric healthcare, this dissertation identifies contextual factors and mechanisms that contribute to the sustainability or otherwise of Lean. This was done by the processes of program theory development, testing and refinement, through realist synthesis and realist evaluation. The four distinct but related papers that comprise this dissertation focus on improvement science (chapter 2), the complexity of Lean and value of realist methods (chapter 3), and the development and testing of a program theory (chapter 4 and 5). The concluding chapter 6 focuses on the refinement of the program theory, general conclusion and implications of my findings for future research, policy and practice.

The key terms used throughout this body of work are provided on Table 1.4.

Table 1.4 Glossary of key terms

Terminology	Explanation
Organizational change	Company or organization going through a transformation. Organization change occurs when business strategies or major sections of an organization are altered.[62]
Quality improvement	The combined and unceasing efforts of everyone—healthcare professionals, patients and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development.[63] QI refers to the application of improvement practices using tools and methods to implement, test, improve and scale-up effective QI practices.[64]

Terminology	Explanation
Lean	There are two defining characteristics of Lean: Lean philosophy and Lean activities. Lean philosophy is a set of core ideas that make up Lean. This is made up of two components: a commitment to Lean principles and a commitment to continuous improvement Lean principles refer to an overarching set of principles aimed at transforming workplace culture. These include a focus on: eliminating waste; improving the flow of patients, providers and supplies; and ensuring all processes add value to customers. Further, Lean principles suggest that problems are identified and addressed by front line staff members as it is believed that the people doing the work are best suited to create solutions. Commitment to continuous improvement refers to the acknowledgement that Lean doesn't occur as a single intervention but instead requires a dedication to continually improving the workplace. Lean activities are a set of management practices, tools, or techniques that can be directly observed and are prescribed to improve the workplace. There are two types of Lean activities: assessment activities and improvement activities. Lean assessment activities work as analytic tools to identify waste and areas of possible improvement. These activities allow team members to see problems and identify opportunities to reduce waste and make improvements, but do not prescribe specific solutions. Lean assessment activities include Value Stream Mapping (VSM); spaghetti diagrams; Rapid Process Improvement Workshop's (RPIW's); Gemba walks; and root cause analysis. Lean improvement activities suggest specific ways to reduce waste and improve the workplace and set up new working practices. These include actions and concepts such as: 5S (sort, set, sweep,

Terminology	Explanation
	standardize, sustain) events; Levelled production; Daily Visual Management (DVM) (including Kanban supply management); Standard Work; and Stop the Line techniques.[15]
Improvement science	The aim of improvement science is to build an evidence base on how healthcare providers and systems can improve their work by translating this evidence into practice.[65]
Implementation science	Implementation science is defined as the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice to improve the quality and effectiveness of health services and care.[66]
Realist methodology	A theory driven, interpretative approach to uncovering underlying middle-range theories (or logics) driving interventions and their multiple components, as well as illuminating the contextual factors that influence mechanisms of change to produce outcomes.[67(pp3)]
Program theory and refined program theory	Refers to a variety of ways of developing a causal modal linking program inputs and activities to a chain of intended or observed outcomes, and then using this model to guide the evaluation.[68(pp30)] A 'refined theory' is the product of a realist review. In the process of conducting a review, some aspects of the initial rough theory may have been proved wrong. Others may have been supported with strong evidence. Many (perhaps most) will have been refined to some extent.[69(pp11)]
Middle-range theory	An implicit or explicit explanatory theory that can be used to explain specific elements of programs or how program logic manifests in implementation. "Middle-range" means that it can be tested with the observable data and is not abstract to the point of addressing larger social or cultural forces (i.e., grand theories). MRT is sought at the outset and examined iteratively throughout the review.[67(pp3)]

Terminology	Explanation
Context-mechanism-outcome configurations (CMOc)	CMO configuring is a heuristic used to generate causative explanations about outcomes in the observed data. A CMO configuration may be about the whole program or only to certain aspects. One CMO may be embedded in another or configured in a series ('ripple effect' in which the outcome of one CMO becomes the context for the next in the chain of implementation steps). Configuring CMOs is a basis for generating and/ or refining the theory that becomes the final product of the review.[67(pp3)]
Context	Context can be defined as all factors that are not part of the program or intervention itself, the "backdrop" to implementation, yet does interact, influence, modify, facilitate or hinder the intervention and its effectiveness (in our case the sustainability of Lean efforts).[70]
Mechanisms	Mechanisms are the combination of resources (intended and unintended) offered by a social program under study (Lean) and the response to those resources (cognitive, emotional, motivational reasoning etc.) by stakeholders.[41] Mechanisms will only activate in the right conditions (contexts).
Outcomes	Outcomes are a result of a program firing multiple mechanisms which have different effects on different subjects in different situations, and so produce multiple outcomes. Realist evaluators examine outcome patterns in a theory testing role. Outcomes are analyzed to discover if conjectured mechanism/context theories are confirmed.[41(pp217)]
Implementation	Implementation is an actively planned and deliberately initiated effort with the intention to bring a given intervention into policy and practice within a particular setting. These actions are undertaken by agents who either actively promote the use of the intervention or adopt the newly appraised practices. Usually, a structured implementation process consisting of specific implementation strategies is used and underpinned by an

Terminology	Explanation
	implementation theory. The implementation process is an active, multistage, iterative and dynamic process that does not usually occur in a linear fashion.[71(pp6)]
Setting and system levels	Four levels of change in health system: the individual (micro level), the group or team, the organization (meso level) and the larger system or environment (macro level) in which individual organizations are embedded.[72(pp283)] Setting refers to the specific physical location, in which the intervention is put into practice and interacts with context and implementation.[71(pp6)]
System, process and clinical problems	Clinical: a**:** involving direct observation of the patient clinical diagnosis, b**:** based on or characterized by observable and diagnosable symptoms clinical treatment.[73] Process: A series of actions or steps (procedures) taken to achieve a particular end (outcome).[74] System: a: a set of detailed methods, procedures and routines created to carry out a specific activity, perform a duty, or solve a problem, b: an organized, purposeful structure that consists of interrelated and interdependent elements (components, entities, factors, members, parts etc.). These elements continually influence one another (directly or indirectly) to maintain their activity and the existence of the system, in order to achieve the goal of the system.[74]

List of abbreviations

Quality improvement (QI), National Health Services Sustainability Model (NHS SM), Context + Mechanism = Outcome configuration (CMOc), Normalization Process Theory (NPT)

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Chapter 2.

Paper 1: The potential for nurses to contribute to and lead improvement science in healthcare

This paper is published as:

Flynn, R., Scott, S. D., Rotter, T., and Hartfield, D. (2017). The potential for nurses to contribute to and lead improvement science in healthcare. *Journal of Advanced Nursing*, *73*(1), 97-107. doi:10.1111/jan.13164.

Abstract

Aim: A discussion of how nurses can contribute to and lead improvement science activities in healthcare.

Background: Quality failures in healthcare have led to the urgent need for healthcare quality improvement. However, too often quality improvement interventions proceed to practice implementation without rigorous methods or sufficient empirical evidence. This lack of evidence for quality improvement has led to the development of improvement science, which embodies quality improvement research and quality improvement practice. This paper discusses how the discipline of nursing and the nursing profession possesses many strengths that enable nurses to lead and to play an integral role in improvement science activities. However, we also discuss that there are insufficiencies in nursing education that require attention for nurses to truly contribute to and lead improvement science in healthcare.

Design: Discussion paper

Data Sources: This paper builds on a collection of our previous work, a 12-month scoping review (March 2013-March 2014), baseline study on a quality improvement management system (Lean), interviews with nurses on quality improvement implementation and supporting literature.

Implications for Nursing: This paper highlights how nurses have the philosophical, theoretical, political and ethical positioning to contribute to and lead improvement science activities. However up to now, the potential for nurses to lead improvement science activities has not been fully used.

Conclusion: We suggest that one starting point is to include improvement science in nursing education curricula. Specifically, there needs to be increased focus on the nursing roles and skills needed to contribute to and lead healthcare improvement science activities.

Keywords: improvement science, nursing, nursing education, quality improvement

Introduction

Healthcare is a highly complex field and faces many challenges. The demands on healthcare systems are growing and inadequacies have become widespread.[1-4] The three critical factors responsible for these challenges are the:

A. increase in the proportion of ageing and older people in our population and with multiple chronic conditions; [4]

B. rapid advancements in technology, information access, medical innovations and costly treatments; [5]

C. a high level of reporting on the inefficiencies of healthcare systems.[6-8]

Unfortunately, there are no 'magic bullets' to solve these problems.[9] The need to improve healthcare quality has intensified within the past decade.[3, 10, 11] Two seminal reports from the Institute of Medicine have led to healthcare quality improvement (QI) being widely recognized as a priority area of need. In 2000, the Institute of Medicine (IOM) published *To Err Is Human: Building a Safer Healthcare System*.[12] This report signalled the urgent need for improvement in patient safety and quality of care. *Crossing the Quality Chasm: A New Health System for the 21st Century*,[13] closely followed. This report outlined a vision for safe, high quality care that is evidence-based, patient-centered and systems-oriented. These publications have had a great impact on the drive for QI across all disciplines in healthcare.

Background

QI in healthcare is an approach to achieving and sustaining changes that lead to better care and a better healthcare system. QI refers to the application of improvement practices using tools and methods to implement, test, improve and scale-up effective QI practices.[14] There are challenges to QI in healthcare, with QI interventions failing to achieve or sustain

their proposed outcomes.[15, 16] The QI domain has attracted concern that it lacks rigorous scientific evidence[17, 18] and QI approaches often proceed on the basis of intuition and anecdotal evidence.[19] Whilst it may be understandable that there is a belief that action over evidence leads to faster improvements in healthcare, the evidence has shown that QI interventions that appear to be based on anecdotal evidence and preliminary findings often result in no significant improvements and are minimal and local in scale.[20]

QI involves change, but not all changes lead to an improvement.[21] For healthcare to fully benefit from QI, we need to be sure that the changes are made systematically and incorporate both scientific knowledge and the best available research evidence.[22] A lack of rigorous evaluation studies of QI interventions results in the reasons for the success or failures of QI interventions being unknown and the knowledge is lost.[22, 23] Such knowledge gaps have led to the development of improvement science.

Improvement science

Improvement science is a new field of science, which attempts to provide a scientific evidence base for healthcare QI interventions[24] and incorporates QI research, the implementation of QI interventions and the scientific evaluation of QI interventions.[25] Improvement science involves a scientific process for identifying the most effective QI interventions to improve and sustain healthcare services and outcomes.[26] The overarching goal of improvement science is to ensure that QI efforts are scientifically based akin to the scientifically-based practices we seek to implement.[19] From an improvement science stance, QI efforts should be based on sound evidence with rigorous assessment, implementation, adoption, evaluation, spread and sustainability.

The aim of improvement science is to build an evidence base on how healthcare providers and systems can improve their work by translating this evidence into practice.[27] Stevens[28] discusses how the shift in healthcare towards evidence-based practice and improvement requires nurses to gain new competencies to deliver improvement that is evidence based. From our collective experiences we argue that nurses have the potential to contribute to and lead in this movement. However, we recognize and discuss in this paper that nursing education is falling short in improvement science.

Purpose

The purpose of this paper is to discuss how nurses can contribute to improvement science in healthcare. We pay particular attention to the philosophical, theoretical, political and ethical positions that underpin the nursing discipline and profession and how these positions either enable or hinder nurses' ability to contribute to and lead improvement science. We discuss two areas that require change for nursing to fully contribute to and lead in improvement science: a. the inclusion of improvement science education in nursing programs; and b. the increase of advanced nursing roles, such as nurse clinician scientists in healthcare improvement science.

Our paper defines nursing according to Parse[29] that nursing is both a discipline and a profession. The purpose of the discipline of nursing is to advance the knowledge of nursing through philosophical paradigms, theoretical development and research (the science of nursing). The purpose of the profession is to provide care to patients through the application and use of the art and science of nursing science. Our discussion refers to the term 'nurses' as

the personnel that make up the nursing profession and provide care to patients that is based on regulatory standards and education from the discipline of nursing.[29]

The central questions to this discussion paper are:

- Where does nursing 'fit' in improvement science?
- Considering the tenets underpinning the nursing discipline and profession, do nurses have the potential to contribute to and lead improvement science in healthcare?

Data sources

This discussion paper is:

- based on our previous work, a 12 month scoping review (March 2013-March 2014) and baseline study on Lean[30, 31] a quality improvement management system;
- informed by descriptive interviews with nurses and other frontline healthcare providers regarding the implementation of QI interventions in their work place;[32]
- supported by a review of the literature on improvement science, quality improvement and nursing; and
- informed by the combined professional experiences of our authors as nursing researchers, an improvement science research chair, a nursing graduate student and a medical director for quality improvement.

The collection of these research and professional experiences have led us to this discussion paper that nursing has the potential to lead improvement science but that potential is currently underused in nursing education curricula and healthcare.

Discussion

The positions of nursing in contributing to and leading improvement science

Nurses are the largest service provider in healthcare and is at the centre of patient care. As such, nurses are in the ideal position to contribute to and lead improvement science in healthcare. Nurses are hands on caregivers at the forefront of any healthcare system and are essential to any system of healthcare. Their work involves assessing, planning and evaluating patient care needs, advocating for patients, assuring their care is safe and that patients are satisfied with the care they receive.[11]

The work of nurses' requires intellectual and organizational competence. The quality of care that nurses provide shapes patient safety, satisfaction, comfort and outcomes.[33] Nurses are ideally positioned in the healthcare system to examine and understand the environment, to identify the strengths and weaknesses of healthcare systems and to identify the key elements needed for improvement science in healthcare.[33-35]

Nursing roles have advanced, with the emergence of roles such as clinical nurse specialists, clinical nurse educators, advanced nurse practitioners and, more recently, nursing clinician scientists. All nurses are required to integrate research and clinical practice.[36] Nursing as a profession has developed its own disciplinary way of thinking with its own body of knowledge, theory and research, [37] equipping nurses with in-depth research skills across a broad range of research designs and methods. All of these factors mean that nurses have the potential to contribute to the advancement of improvement science in healthcare.

There is trend towards frontline led evidence-based continuous quality improvement interventions in healthcare. Releasing Time to Care (RTC) is one example of an intervention for conducting continuous quality improvement. RTC is led by nurses. The aim of RTC is to

increase the autonomy of nursing staff so as to continuously improve patient care.[38] A qualitative evaluation of RTC implementation in Saskatchewan, Canada demonstrated that the implementation of a nurse-led and system wide QI intervention has the potential to empower nurses to lead continuous QI.[38] An important dimension to the RTC is the capacity, such as allocated resources, for nurses to be able to engage in continuous QI and the capability, such as training, for nurses to become knowledgeable and skilled in the area of continuous QI.

In RTC however, the role of the nurse is to implement the intervention, the quality improvement work. We argue that nurses have the ability to lead on-the-ground QI work and that nurses have the philosophical, theoretical, ethical and political underpinnings to potentially contribute to and lead improvement science activities.

Philosophical and theoretical positions

The philosophical positioning of nursing is such that there are multiple ways of knowing and explaining phenomena.[39] Carper [40] developed the epistemological basis that there are four fundamental yet different ways of knowing in nursing, being the empirical, the ethical, the personal and the aesthetic. These patterns of knowing in nursing have the potential to:

- advance improvement science, both complimenting and expanding the paradigm of evidence-based practice;
- provide substantial empirical knowledge to improvement science; and to
- add dimensions of ethical, personal and aesthetic knowledge, where the patient is central to improvement.

Chinn and Kramer[41] discuss emancipatory knowing, the capacity to critically assess the status quo of nursing, identify why it is that way and creates the way for change. This type

of knowledge can be expressed through engagement in improvement science. Chinn and Kramer[41] argue that there has been a lack of focus on emancipatory knowing in nursing in the past and describe that the process of emancipatory knowledge (praxis) when done collectively in nursing can lead to substantial change. We relate this to improvement science in nursing and the potential of nurses to contribute to and lead substantial improvements in healthcare. This form of knowing identifies the need for action inclusive of the ways of knowing in nursing to influence and improve praxis.

Theory development is an essential process to the development and advancement of improvement science. Theory can help to identify areas of poor quality in healthcare and enhance improvement science.[42] Theory is also valuable in the evaluation of QI interventions. Theory-driven evaluations allow researchers to ask 'how and in what contexts does the QI intervention work or can be amended to work?' Framing the evaluation of QI interventions from this perspective is more useful for complex context sensitive QI interventions.[43]

Nursing, as a frontline caring profession, has the potential to contribute to the theoretical advancement of improvement science; incorporating the needs of patients. Nursing practice can be viewed as both a starting point for knowledge-theory development for improvement science and as an end point, where researchers can test these theoretical developments.[44] Thus, during the course of practice nurses can assist researchers in the development and testing of theories in improvement science. In turn theoretical development and knowledge development in improvement science can advance and improve nursing practice. This could lead the way for the theoretical advancement of improvement science by bridging the gaps of research and practice and combining the 'art and science' of improvement.

Ethical and political positions

Nursing, as a profession, has ethics at its core, both in practice and in research.[45] Nurses, at the centre of patient care, are ethically responsible for providing safe, compassionate and competent care[46] and thus have the potential to be a major force for improvement science. Nurses involved in the delivery of care have the potential to play a role in improvement science and, from an ethical standpoint nurses also need to be a part of it.

Nurses who fail to engage and contribute to improvement science may jeopardize the incorporation of nursing into improvement changes. This could ultimately lead to the de-professionalization of nursing.[33, 47] Many QI interventions and research studies focus on quantity, efficiency, waste reduction and cost and not incorporating the ethical values of nursing and, more importantly, the values of patients.[47] Hence, to ensure that improvement science in healthcare aligns with nursing and patient values, nurses need to actively engage in improvement science.

Nurses are strategically positioned to make significant improvements to healthcare and to lead policy development for healthcare improvement. Nurses often play a key role in resolving conflicts, they deal with a multitude of personalities and challenging behaviors on a daily basis. Nurses are team players, negotiators, problem solvers and communicators.[48] Each of these skills establishes the nurse as a valuable member at the political table. A political role for nursing involves being knowledgeable about current healthcare issues, epidemics, costs, laws and health policy.

The need for nursing perspectives and knowledge in the political arena has been a longstanding argument; however, the appointment of nurses to these roles, or the desire for

nurses to want such roles, has been slow.[49] Despite the advancement of nursing leadership and management education, the enhancement of policy education in nursing has yet to keep pace.[50]

Implications for nursing

As the largest providers of direct patient care by numbers, nursing is in a position to be central to improvement science efforts.[4] The philosophical, theoretical, ethical and political positions underpinning nursing equip nurses with the potential to contribute to and lead improvement science in healthcare. Nurses have an important voice in the need to improve the quality of patient care and to improve current healthcare systems. In 2011 the IOM released recommendations to expand opportunities for nurses to lead collaborative improvement efforts and identified the need to prepare and enable nurses to lead change to improve healthcare.[51]

These acknowledgments of nurses are applauded, however, this paper discusses some areas of weakness for nurses to lead in improvement science. Within the current constraints and inefficiencies of many existing health systems it is a challenge for nurses to perform in the best way and to lead in the quest for high quality healthcare.[52] For example, as a practice-based profession, nurses receive limited opportunities to engage and receive the education, research training and practical skills necessary to improve the systems where they work. There is also the limited promotion of bedside nurses into political, administrative or different clinical roles where they are in the position to lead improvement science and bridge the science and practice of QI.

We argue that there are two main areas that must change for nurses to fully contribute to and lead improvement science in healthcare, being:

A. including improvement science education in nursing programs; and

B. increasing advanced nursing roles, such as nurse clinician scientists in healthcare improvement science.

Including improvement science education in nursing programs

We argue that improvement science education for undergraduate and graduate nursing students is equally important as the actual quality improvement and patient safety practices of nurses working in healthcare systems. The major drive for better quality and safety in healthcare systems lends urgency to a transform of undergraduate and graduate nursing curricula to one that matches the values and needs of practice.[53, 54] Undergraduate nursing education needs to transform so that novice providers have the knowledge, skills and attitudes to be competent in improvement science and to provide high quality and safe care.[55] QI principles and skills should be a required and core component of the educational curriculum for undergraduate nurses.[56, 57] Nurses need to be prepared and competent to work in complex environments, where they have responsibility to improve healthcare process and delivery. This is one responsibility of nursing education. [33]

There are many resources available to provide guidance and support to establish quality and safety curricula for healthcare providers (undergraduate and postgraduate) from academic centers, quality and safety organizations, as well as healthcare organizations. The Institute for Healthcare (IHI) Improvement Open School is a key resource for building a QI course for an undergraduate nursing curriculum. The IHI is a non-profit organization that is a leading innovator, convener, partner and driver of results in health and healthcare improvement worldwide. The IHI offers a wide range of resources and teaching tools to help

healthcare professionals lead effective improvement efforts. The IHI offers free online educational courses for students on quality, improvement capability, patient safety, safety, leadership, person and family centered care and other healthcare topics.[58] The World Health Organization (WHO) has a Multi-Professional Patient Safety Curriculum Guide that is another rich collection of resources that is available in six languages. This includes a list of recommended foundational topics, as well as accompanying teaching resources and tools for both quality improvement and patient safety.[59] In addition, the Quality and Safety Education for Nurses (QSEN) developed six core competencies for undergraduate nursing curriculum: patient-centred care, teamwork and collaboration, evidence-based practice, quality improvement, safety and informatics.[60] The QSEN was developed to prepare nurses with the knowledge, skills and attitudes to continuously improve the health systems where they work. These core competencies have been piloted at 15 nursing schools across the United States of America. Murray et al.[61] report the implementation of the QSEN competencies at one of the pilot schools. The QSEN initiative is a useful resource for future nursing schools looking to implement improvement science to their curriculum.

Graduate nursing education needs to better understand health quality improvement sciences to identify, test and scale up effective QI approaches.[26, 62] The introduction of improvement science to graduate nursing education will develop expertise in improvement science research, leadership and change management skills to lead improvement across systems. We argue that these changes cannot be successfully achieved in the traditional boundaries of 'silo' education. Quality and patient safety are important issues for all the health disciplines. Improvement science should be taught using a transdisciplinary approach where the health sciences learn as a team the principles, skills and knowledge of improvement

science that can be implemented in practice using a collaborative interdisciplinary team approach. Despite the argument for patient safety and QI education to be embedded in healthcare education[55] and nursing education;[54, 60, 63, 64] QI education is not consistently offered across the spectrum of health sciences and does not appear to be valued as a major component to health professional trainee education. For example, In the USA and Canada only 25% of medical schools incorporate instruction on these topics, the majority of which only include lectures and small-group discussion.[65] This discrepancy places the education of healthcare professionals at odds with the current emphasis on QI and patient safety in clinical practice.

From our own experiences at the University of Saskatchewan and University of Alberta at two provinces of Canada there are elements of improvement science across health sciences curricula but there is no dedicated improvement science course offered to the health sciences including nurses. This shortcoming led to the curriculum development of a QI course for health sciences (nursing, medicine, pharmacy and nutrition, dentistry, allied health and public health) for undergraduate and graduate students at the University of Saskatchewan.

The University of Saskatchewan's' QI curriculum has two levels, course level I tailored to the needs, skills and knowledge base of undergraduate students and course level II tailored to the needs, skills and knowledge base of graduate students. Course level I for undergraduate health science students will have a strong focus on applied health quality improvement activities and interventions (e.g. Plan- Do- Study- Act, PDSA cycles) designed to improve patient safety and patient-oriented care (e.g. how to reduce central line infections among newborns). Course level II will be tailored towards the needs of graduate health science students and their research activities (e.g. conduct a systematic review to identify

effective intervention to prevent pressure ulcers). The curriculum will cover important improvement science topics such as: The fundamentals for improvement, the life cycle of a QI project, patient safety, human factors and safety, team work and communication, root cause analysis, healthcare associate infections, leadership and QI, patient-centered care, quality cost and value, measuring for improvement and models for improvement. The curriculum will be implemented using a two-phase implementation strategy including a paper based pilot implementation with lectures, videos, tutorials and QI activities in 2016. In phase two, courses will be offered as an online course with direction provided by a course coordinator. This QI curriculum will be funded by the University of Saskatchewan's curriculum innovation fund. The Saskatchewan Health Regions will fund the level II continuous education course which will be offered as an online course. The curriculum development is in accordance with the relevant professional competency frameworks such as the Canadian physician competency framework (CanMEDS), the Canadian nurse practitioner framework, the professional competencies for Canadian pharmacists and the competency profile for physiotherapists in Canada. The transferability of this QI curriculum will also be tested across universities in Netherlands, Germany and Australia.

At the University of Alberta, health science students formed a quality improvement student led group the Edmonton Healthcare Improvement Network (EHIN), as an Institute for Healthcare Improvement (IHI) Open School Chapter. The aim of the IHI Open School Chapter is to bring students from different health sciences with a shared interest in learning about quality improvement.[66] EHIN was formed at the University of Alberta because of the recognized need and desire by our health science students to learn about and engage in QI. Currently improvement science is not a mandatory competency in our nursing education or

healthcare systems. Reasons for this are unclear, but one may postulate this may be due to lack of space for new material in already crowded curricula; lack of expertise amongst faculty to develop and teach improvement science given these are relatively new concepts in healthcare and the lack of opportunity for interdisciplinary learning in our current educational system, which is key to learning and applying quality and safety concepts. Since 2013 the Royal College of Physicians and Surgeons of Canada has included QI and patient safety training as a competency requirement for specialty residents.[67] This competency framework is one that other health sciences and nursing could use for its own curriculum.

Competency in improvement science and patient safety should be a requirement of both the regulatory bodies for nursing and those of other healthcare providers. This will require a focus on developing quality and safety competencies, a scholarly basis for improvement science and practice and a knowledge of the interventions that are effective for improving and transforming healthcare.[35] Nurses guided by improvement science have the potential to be a powerful force for evidence-based quality improvement in healthcare.[4]

Increase of advanced nursing roles in healthcare improvement science

Nurses have begun to identify the knowledge, skills and attitudes necessary to work in the healthcare systems that are rooted in continuous quality improvement. These include teamwork, collaboration, patient-centered care, quality improvement, safety and informatics.[68-70] As healthcare shifts its focus to improvement science, the comprehensive knowledge held by nurses on how healthcare systems work and the needs of patients should be used more effectively.[71] One way to address this gap is the creation of nurse clinician scientist roles in improvement science.

The development of such roles would enable the integration of improvement science and quality improvement work into the day-to-day operations and real-world practice of frontline healthcare providers. This would offer front line staff, such as nurses, the time and resources to participate in improvement science and improvement decision making.[33] The development of advanced roles of nurses in improvement science provides professional extension of the scope of nursing and enables nurses to be key players in the movement to sustain our healthcare systems.

To achieve changes valued by the patients, nurses need to be centrally involved in improvement activities such as research, practice and decision making.[72] Improvement science should be a priority focus area for nursing research.[73] Improvement research from the ontological and epistemological views of nursing would contribute to building a body of scientific knowledge based on understanding patient-centered outcomes, contextual factors, ethical factors, the impact of QI on nursing values and the impact of nursing on QI outcomes.[33]

As a practice-based profession, many nurses do not receive opportunities to conduct research and contribute to improvement science.[74] The engagement of bedside nurses in improvement science will prepare them for the use of QI tools, for seeking the best research evidence, for measuring care outcomes and in the use of empirical data to assess their current practice.[35] Engaging research nurses in improvement science will assist in bridging the theory-practice gap by furthering collaborations between the clinical and academic environments.[72] Bridging these two domains enables nurses to be collaborative leaders in improvement science, as a collaborative approach is a requirement for successful improvement work. Jones andWoodhead[75] provide a learning report by The Health

Foundation on the collaborative capability building improvement approaches taken by five health and social care trusts across the UK. The report provides evidence on how to create a collaborative capability and capacity building environment, which is conducive to driving and sustaining quality improvement. The case studies in this report demonstrate how critical bridging practice and educational training is for improvement capability capacity and sustainability.

Our previous research evaluating the function of a frontline improvement team established as part of health system reform,[32] found that the majority of nurses did not have time to engage in, contribute to or lead improvement efforts. Historically, this had not been a part of their job description and typically most viewed improvement work as an extra task to be done 'off the side of one's desk'. In addition, most health systems only have funding to support a small number of quality improvement experts, who as individuals, are unable to reliably sustain large improvement efforts.

To overcome the challenge of sustaining continuous quality improvement in a time of fiscal constraint, some health systems [health system name, National Health Services, Intermountain Health, Children's Hospital of Philadelphia (CHOP) and others] educate practicing nurses (and other providers) in improvement methodologies to build the improvement science capability and capacity of teams. The goal of educating nurses and other frontline providers is to establish a system where the quality lens is applied to everyday practice. At CHOP, this was referred to as the 'Innovation Unit' model and applying rigorous education, with some initial support from improvement experts, resulted in successfully engaging staff in quality improvement work in a sustainable manner, with improved outcomes.[76] QI work and improvement science needs to be collectively valued by healthcare

systems, organizations and units so that a culture can develop where improvement is viewed as something nurses and other healthcare professions do every day. All nurses have a responsibility to advance and progress the discipline and we share the viewpoint that improvement science education and the advancement of nursing roles in improvement science is a key approach to achieving this.

"*Everyone in healthcare has two jobs when they come to work every day: to do their work and to improve it.*"[22(pp 3)]

Conclusion

The key points in this paper demonstrate that the nursing profession is philosophically, theoretically, politically and ethically positioned to contribute to and lead improvement science activities in healthcare. We note some fundamental limitations needing to be addressed for nurses to reach their full potential as leaders of improvement science. By reforming nursing education to have a substantial focus on improvement science and research, leadership, business management and healthcare policy, these limitations can be addressed. Such areas of education are vital for the next generation of nurses, facing the ever growing complex world of healthcare. There also needs to be a greater opportunity for nurse clinician scientist roles in improvement science, where nurses can attempt to close the practice-science gap of quality improvement, bridging the research and practice of QI in healthcare. Improvement science has the potential to reform healthcare systems around the globe. This is an opportunity for to nurses to take the lead in redesigning healthcare systems using their research skills, theoretical development and clinical expertise on patient values, needs and care. Nurses can be central to the movement of making health systems sustainable and this

paper argues that education is the critical starting point for nurses to become leaders of improvement science.

List of abbreviations

Quality improvement (QI), Institute of Medicine (IOM), Releasing Time to Care (RTC), World Health Organization (WHO), Quality and Safety Education for Nurses (QSEN) Edmonton Healthcare Improvement Network (EHIN), as an Institute for Healthcare Improvement (IHI), Plan- Do- Study- Act, PDSA, Children's Hospital of Philadelphia (CHOP)

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Chapter 3.

Paper 2: Lean in healthcare, is it too complex for the already complex systems of healthcare? Implications on research designs and methods

This paper is submitted as:

Flynn R, Rotter T, Scott SD. Lean in healthcare, is it too complex for the already complex systems of healthcare? Implications on research designs and methods. BMC Health Services Research (submitted 30 May 2018).

Abstract

Background: Lean has gained increasing attention for its potential in healthcare improvement, proposed to increase efficiency and eliminate waste. However, its translation to the complex system of healthcare is not proving to be an easy task. The majority of studies reporting Lean implementation in healthcare have been narrow in their application, of weak research design and have failed to demonstrate how Lean can lead healthcare to system wide improvements. This failure may be a result of weak research designs and methods that do not capture the complexity of Lean in healthcare. We pose the question: Is Lean too complex for the already complex systems of healthcare? We argue that there are two domains of complexity to Lean as an intervention for healthcare improvement: a) the complexity of the components of Lean and b) the complexity of healthcare systems in which Lean is implemented. Due to this complexity of Lean, we argue for more robust research designs and alternative methodologies in order to understand if Lean works well in healthcare or not.

Discussion: First, this paper explores the complexity of Lean for improvement in complex healthcare systems. Second, we discuss the implications of such complexity on the research designs and methods used to evaluate Lean; adding to current arguments for theory informed methodological approaches, such as realist synthesis and realist evaluations. We created this paper to argue for the need for alternative approaches such as realist methods to better understand how and why, in what contexts Lean works or works or not in healthcare, this evidence is currently lacking.

Summary: The current knowledge base of Lean implementation in healthcare lacks evidence on when, how and why different components and activities of Lean work in different contexts. This lack of evidence is partly due to the insufficient research attention given to the

complexity and variability of healthcare contexts in which Lean is implemented. Without empirical research that assesses the complexity of Lean, it cannot be determined if Lean is a suitable approach for health system improvement.

Key words: complex interventions, complex adaptive systems, research design, realist evaluation, realist synthesis, Lean

Background

The premise for this debate paper is based on the question: *Is Lean too complex for the already complex systems of healthcare?*

Lean thinking derived from Toyota, was developed to improve Toyota's production system by removing waste, inconsistency and overburden.[1] The intent of Lean is to do more with less, by reducing waste, standardizing processes, adding value and thus increasing efficiency.[2] Five core principles to Lean are: 1) specify the value desired by the customer, 2) identify the value stream for each service, 3) make the service flow continuously and standardize services around best practice allowing them to run more smoothly, 4) introduce 'pull' between all steps where continuous flow is impossible with focus upon the demand from the customer, and 5) manage towards perfection so that non-value adding activity will be removed.[3] The promise of Lean in healthcare is to improve quality by reducing waste and facilitate flow in work processes.[4,5] Lean was first introduced into various healthcare settings and organizations between 2001-2002 in the United States (US) and the United Kingdom (UK).[6] Despite purported potential benefits of Lean for healthcare quality improvement (QI), we argue in this paper that:

a) Lean is a complex intervention when translated to healthcare QI, with highly varying concepts that have not been well understood.
b) Lean philosophy, principles and activities of Lean are not entirely consistent with complex healthcare systems and have not been adequately understood
c) The translation of Lean to healthcare does not account for healthcare as complex adaptive system and has not been rigorously studied

d) The evidence base on Lean implementation in healthcare lacks sufficient and rigorous evaluation research designs and methods and;
e) Realist approaches can help to better understand complex health interventions, such as Lean.

This debate was based on a) the evaluation of Lean implementation across the Saskatchewan Healthcare System, known as the "Largest Lean Transformation" in the world[7, 8] b) synthesis studies on the current evidence base of Lean implementation[9] and Lean sustainability[10] and c) a research program focused on implementation research and the translation of complex health interventions.[11] We draw upon complexity theory,[12] complex adaptive systems theory,[13] the UK's Medical Research Council (MRC) guidance on the development and evaluation of complex interventions[14, 15] and seminal realist methods literature.[16-21]

Objectives

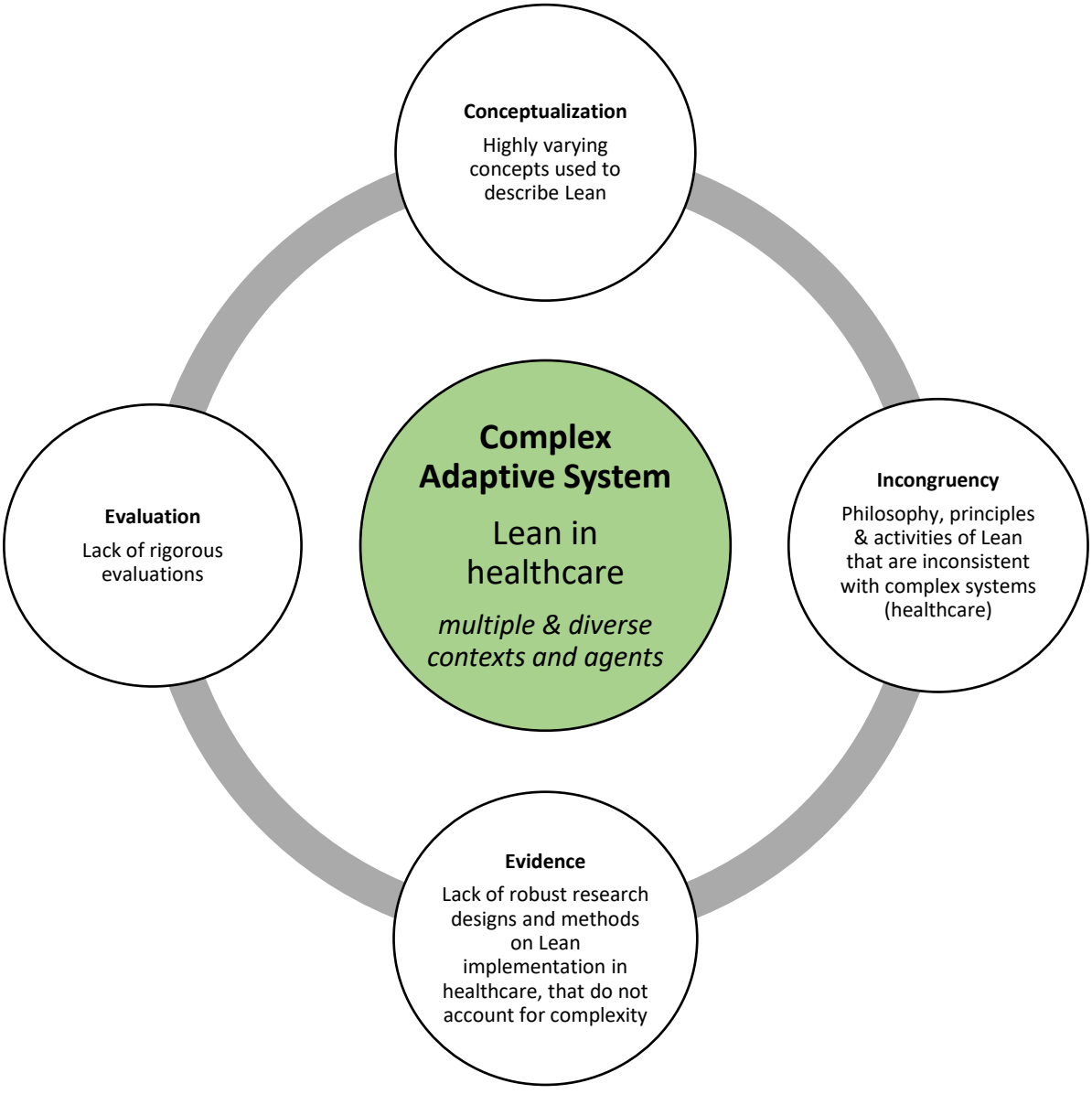
Our objectives for this debate paper are threefold:

1. Demonstrate that Lean is a complex intervention for healthcare QI,
2. Explain how Lean philosophy, principles and activities are not entirely consistent with complex systems (such as healthcare), and have not been well studied and;
3. Discuss how realist approaches can be utilized to rigorously study Lean implementation and sustainability in healthcare.

Our paper compliments the argument that randomized control trials (RCTs) and experimental designs may not be the most appropriate approaches to evaluate complex interventions.[15, 22-24] Similarly, we discuss the use of realist methodologies (synthesis and

evaluation) for such research. Figure 3.1 illustrates our key arguments on the complex issues of Lean in the context of healthcare presented in this paper.

Figure 3.1 The complex issues of Lean in the context of healthcare



Discussion

Argument: Lean is a complex intervention for healthcare QI, with highly varying concepts that have not been well understood

Lean was not intended to be complex. It was intended to be a simple philosophy and management system for continuous improvement in the car manufacturing industry. The philosophy of Lean is to reduce waste, add value and create efficiency, through a set of activities and core principles. However, we argue in the context of healthcare Lean is a complex intervention for improvement. Complex health interventions consist of numerous interacting components and can result in a wide range of potential outcomes.[12, 14] Complex interventions target many levels of an organization or system and require behavioural changes of those delivering or receiving the intervention.[14, 15] Lean consists of multiple, interacting elements that are social and context-dependent.[4] Lean may evolve and change the conditions or contexts in which they worked in the first place, due to continuous feedback and learning loops.[4, 25] Thus, we consider Lean as an evolving, complex multicomponent intervention that is difficult to implement across healthcare contexts. Duncan, Paley and Eva[26] suggest that the complexity of a complex intervention is the difficulty in determining the active ingredients, the most important factors and mechanisms of causation that lead to certain outcomes, not that the intervention is complex in any other sense or that the intervention is non-linear.

Also, Lean is not well-defined, and wide variation exists as to how Lean is conceptualized and described in healthcare.[27-30] The lack of common definition and meaning of Lean, in healthcare, adds to the complexity of its application. Some literature describes Lean as both a philosophy and a practical way to improve care processes[31, 32] or as a management system, foundational to all management activities and day-to day operations,[33, 34]

while others have shown how some healthcare settings describe and use Lean as a 'tool kit' for improvement.[6, 25, 35, 36] Findings from realist review of 33 articles,[37] found a wide range of Lean applications in healthcare, all reporting positive results; however, most were of narrow application (i.e. as a tool for a specific improvement activity) with limited organizational reach (i.e. one clinical unit) and were of unclear or weak study designs (i.e. only ten studies had an explicitly stated and transparent research methodology).[37] Kaplan et al.[33] argue that using Lean in such a silo nature of narrow application, will not result in long term sustained improvements. The perception of what Lean means also adds complexity to its success in healthcare. Perceptions of Lean such as a cost cutting, waste reduction and staff lay off tactic,[38] demonstrates a lack of common understanding of Lean in healthcare. Lean has also become combined with other with other quality-improvement methods (e.g. Six Sigma, Plan-Do-Study-Act cycles) and the competing voices of policy makers, managers, clinical leaders and management consultants,[38] challenging the distinction and standardization of what Lean means in healthcare.

Due to this evident variation on the conceptualization of Lean in the healthcare literature, members of our team developed an operational definition of Lean for the purposes of a Cochrane systematic review. The operational definition states that Lean is a complex multicomponent intervention with a set of philosophies, diagnostic assessment processes and improvement activities aimed at maximising value for the patient by reducing waste.[39] Two defining characteristics of Lean are: 1) Lean philosophy, consisting of Lean principles and continuous improvement, and 2) Lean activities, which include Lean assessment activities and Lean improvement activities.[39] These characteristics are defined in Table 3.1.

Table 3.1 The key characteristics that underpin the Lean operational definition[39]

Term	Description
Lean philosophy	Lean philosophy is made up of Lean principles and continuous improvement.
Lean principles	An overarching set of principles aimed at transforming workplace culture. These include a focus on eliminating waste; improving the flow of patients, providers, and supplies; and ensuring all processes add value to customers. Further, Lean principles suggest that problems are identified and addressed by frontline staff members as it is believed that the people doing the work are best suited to create solutions.
Continuous improvement	The acknowledgment that Lean does not occur as a single intervention but instead requires ongoing efforts and interventions aimed at improving the workplace.
Lean activities	A set of management practices, tools, or techniques that can be directly observed and are prescribed to improve the workplace. There are two types of Lean activities: assessment activities and improvement activities.
Lean assessment activities	Analytic tools to identify waste and areas of possible improvement. These activities allow team members to see problems and identify opportunities to reduce waste and make improvements but do not prescribe specific solutions. Lean assessment activities include Value Stream Mapping (VSM), spaghetti diagrams, Rapid Process Improvement Workshop's (RPIWs), Gemba walks, and root cause analysis.
Lean improvement activities	Specific ways to reduce waste, improve the workplace, and set up new working practices. These include actions and concepts such as 5S events, leveled production, Daily Visual Management (DVM) (including Kanban supply management), standard work, and stop the line techniques.

Argument: Lean philosophy, principles and activities of Lean are not entirely consistent with complex healthcare systems and have not been adequately understood

The application of Lean philosophy, principles and activities from the manufacturing industry to healthcare may be conceptually challenging for many in healthcare.[4, 5] The principles of 'customer, value and waste' in particular, are more complex under the lens of healthcare. One fundamental challenge for Lean in healthcare is identifying the customer.[25, 40, 41] 'Customer' has a variety of meanings in healthcare, for example, patients, family, caregivers, decision makers, healthcare providers and taxpayers are all 'customers' of the healthcare system, each with their own unique needs.[5] There is divergence in the definition of customer and how customer value is transferred between Toyota and healthcare.[42] Hence, it is unclear who Lean should be directed towards and how it should be implemented.[25, 41]

Another fundamental challenge is specifying 'value' in healthcare. There is the question of how and who should specify the 'value' to be created in healthcare and whether value should be perceived from the individual patient experience or collective beliefs.[41] Three dimensions to value in healthcare have been proposed: 1. Clinical value (achieving the best possible patient outcomes); 2. Operational value (efficiency, accessibility and continuity of care); and 3. Experiential value (experiences of patients and providers, reflected in patient satisfaction and employee work life).[8, 43] In a recent study by Goodridge et al.[8] some leaders reported major discrepancies between implementation processes and Lean values. The concept 'waste' also carries complexities in healthcare. Despite the adaptation of seven wastes from the Toyota Production System to seven healthcare wastes, [30] it remains unclear who defines waste and the best way to measure waste. A common ground by all appropriate stakeholders in healthcare on who and what defines waste is needed.[30]

Lean activities consist of their own 'Lean language' and ways of working, which may not seamlessly fit with the perspectives of the healthcare providers or patients. There is also a knowledge gap as to what Lean tool or activity is most effective for healthcare improvement. No existing empirical evidence base exists on how and why certain Lean tools work or not and under what contexts they work.

Argument: The translation of Lean to healthcare does not account for healthcare as complex adaptive system and has not been rigorously studied

Toyota is a high volume, low variety industrial system with consistent input and output metrics. In contrast, we consider healthcare to be a complex adaptive system, with high variation, a diverse set of agents (e.g., patients, multidisciplinary healthcare providers, administrators, managers and policy makers), complex human processes and different strategic performance indicators to Toyota.[8] Waring and Bishop[38] suggest that Lean implementation in healthcare will more than likely be a highly contested process, due to the complex socially constructed adaptive systems of healthcare. Lean may become reinterpreted and reshaped by different social actors to ensure it fits with their vision for clinical practice. Complex adaptive systems consist of individual agents, free to act in ways that are not always predictable, whose actions can change the context for other agents.[44] Healthcare systems are deeply embedded with culture norms and organizational customs that are not easy to change, which can hinder the introduction of interventions such as Lean.[38]

The contexts in which interventions are implemented can have a direct effect on the uptake and outcomes of health interventions.[23, 45, 46] Context involves the situation, setting or organization in which the intervention is deployed. Contexts may vary widely, within and

between healthcare settings.[4] However, consideration of the intervention and its context seldom happens in QI implementation and research.[47] A failure to understand how and why contextual factors influence Lean implementation and the complexity of the context will impact its use and sustainability in healthcare.[48, 49] We and others argue that Lean cannot be simply translated from a manufacturing context to a healthcare context and assume that it can offer the same benefits.[6, 25]

Argument: The evidence base on Lean implementation in healthcare lacks sufficient and rigorous evaluation research designs and methods

There is a lack of evidence that demonstrates implementation of Lean in healthcare to the same level and degree of success as Lean in Toyota.[50] The majority of studies reporting Lean implementation in healthcare to date have been narrow in their application based on weak research design (e.g., QI case study, anecdotal, or no design stated) and have not demonstrated whether and how Lean can lead healthcare to a system wide improvement.[4, 6, 41,51, 52] In a systematic review on Lean,[52] only 20.2% of the included studies explicitly used a theoretical framework and ten of the eighteen included papers were found to have an appropriate method, compatible with studying complex socio-technical systems. Another review that assessed the evidence of Six Sigma and Lean in the healthcare industry,[51] found that the level of evidence supporting the use of Lean QI tools was weak, with an average evidence score of 5.7, on a scale that ranged from 4-7, with 4 indicating stronger research design, data presentation and analysis. Another study on Lean found that only four of 43 included studies had a follow-up period greater than 2 years, demonstrating a lack of evidence on sustainability.[39] A case study of Lean in a large UK public hospital reported that many of

the Lean interventions implemented were superficial in both impact and link to Lean.[34] There is the issue that case studies are coined Lean without the appropriate level of reliability, based on only one or two Lean principles.[36] This creates the concern about a developing evidence-base that is based on inaccurate knowledge. The limited evidence base for Lean in healthcare to date has been plagued by an over reliance on research designs and methods that do not capture the complexity of Lean and its translation to healthcare, a complex adaptive system.

There is also a lack of theoretical knowledge that explains how these factors interrelate, facilitate or impede the successful implementation of Lean to the healthcare system.[37] There are potentially mistaken assumptions about the strengths and weaknesses of Lean in the nature of healthcare, a very different system to Toyota, this may lead to ill-thought-out implementation and poorly articulated evaluations. There is a paucity of evidence on the relationship between Lean and complexity,[52] an area that we feel needs urgent attention, in this current climate of increasing Lean implementations across healthcare, some at a system-wide, financially rocketing scale.

Evaluations of Lean are difficult, due to the potential interdependent relationships amongst the various components (e.g., philosophy, principles, activities, tools, and agents) which are difficult to parse out.[24, 53, 54] Historically, randomized controlled trials (RCTs) and systematic reviews have been considered the gold standard to inform evidence-based medicine, practice and policy making and are the dominant approaches used to study complex interventions.[14, 56] However, it can be argued that complex health interventions cannot be evaluated adequately by RCT's.[15, 22-24, 57] RCTs generally do not examine the interactions and relationships between the contexts in which complex interventions are implemented and the interventions themselves.[58, 59] Evaluations of healthcare improvement interventions take place

in environments that are rapidly changing thus; evaluating the context in which the intervention was implemented is as important as evaluating the effect of the intervention.[54]

We believe, like others have argued, that the social relations, processes and contexts of the intervention must be evaluated alongside outcomes and effectiveness.[20, 22, 53-55] Theory-driven evaluations are one approach that address this issue. The purpose of theory-driven evaluations are to provide information on how and why the program achieves such a result.[17] Theory driven evaluations of Lean implementation in health care are necessary to understand how and why Lean may work in healthcare.[8] Theory development can better determine what features of a complex intervention and its context most likely influence outcomes and determine sustainability.[55] In an effort to address the challenges noted, the Medical Research Council (MRC) published a framework for the design and evaluation of complex interventions to improve health.[56] The 2000 MRC framework proposed a four phased approach for the development and evaluation of complex interventions, involving phase 1: defining components of the intervention, phase 2: defining trial and intervention design, phase 3: methodological issues for the trial and phase 4: promoting effective implementation. The framework acknowledges that evaluation of complex interventions requires both qualitative and quantitative evidence.[56] The MRC framework has since been updated to reflect more innovative methods for evaluation.[14, 15]

The most recent guidance from MRC recommends greater attention to development and pilot work, the integration of process and outcome evaluations, and the need to tailor complex interventions to local context.[15] Process evaluations, can be used alongside an RCT to assess fidelity, barriers and facilitators to implementation, and identify contextual factors associated with variation in outcomes.[15, 60-62] We agree with the MRC guidance that process

evaluations may provide useful information for understanding the implementation of complex intervention, however they do not provide explanatory, mechanistic causation of outcomes. Lamont et al.[63] also discuss other evaluation approaches to evaluate complex health and care systems depending on needs and resources and argue for closer partnerships between researchers and service leaders. Qualitative studies have also been reported to add value alongside RCTs, to explore contextual issues relevant to implementation of interventions.[64, 65] We concur with the argument by Van Belle et al.[22] that a realist approach to evaluation may have the potential to make significant contributions to understanding complex interventions that are aimed at health improvement.

Argument: Realist approaches can help to better understand complex health interventions

We propose that realist approaches would be useful for understanding Lean in healthcare. Modes of realist enquiry (i.e. realist syntheses and realist evaluations) delve into what is known as the 'black box' of complex interventions by examining the interactions between mechanism, context and outcome in existing evidence.[66] As argued by Moore and Evans,[67] future research on complex health interventions needs to ensure that contextual influences are appropriately situated within theories of change and the systems in which interventions occur be understood before implementation occurs. Like, Patterson et al.[68] we argue that complex contextual models based on program theories can better help to understand indicators of change for complex interventions, rather than linear cause and effect models.

Realist synthesis and evaluation are mechanism-orientated approaches to causal explanation.[22] Underpinned by scientific realism, these approaches are grounded by the belief that social interventions are complex and are influenced by context and underlying mechanisms that can exist beyond what is known or observable. Causality occurs when a mechanism is triggered and produces an observable outcome, in a specific context, referred to as the (C) + mechanism (M) = outcome (O) configuration (CMOc) heuristic.[20]

Realist reviews offer a way to unpack and explain the possible causes and contextual factors of change and to generate a middle range theory of explanation. Realist reviews advocate that within complex interventions there are multiple layers of explanation that merit exploration.[69] We support the argument by Greenhalgh, Kristjansson, and Robinson,[70] for the need to shift the balance in the hierarchy of evidence from strictly empirical (i.e., RCTs and systematic reviews(SRs)) to one that embraces theory (i.e., realist evaluations and realist reviews). The selection of theory-informed approaches should be based on the research question posed and findings from such work can build upon the evidence gained from RCTs and SRs.

Realist evaluations are gaining momentum as a means to understand the "active ingredients", context, mechanisms and outcomes (C + M = O) of complex interventions.[20] A realist evaluation approach centralizes its efforts using problem focused approaches that emphasize interdisciplinary and complexity to understand and address the important healthcare issues.[54] Realist evaluations have the potential to address our unanswered question on Lean complexity for healthcare improvement, for example, how, under what contexts, for whom and why is Lean too complex for healthcare? Realist evaluations offer a paradigm through which the world is seen as an open system of dynamic structures, mechanisms and

contexts that influence the implementation adoption and outcomes of an intervention which evaluations aim to capture.[20] Fletcher, Jamal, Moore et al.[24] illustrate how realist principles can be integrated into all phases of the MRC framework, that can impact the theorizing of complex interventions and answer wider range of questions about what works for whom and under what circumstances. Westhorp[71] demonstrates some common elements to complexity theory and realism, and its use for realist evaluations. We support the case that realist evaluations have the potential to fill some of the knowledge gaps regarding how and why Lean works or not in healthcare.

Summary

Lean is a complex intervention for healthcare improvement, and currently lacks evidence on how, why and under what contexts Lean is working for healthcare improvement at a system-wide level. To date there has been very little evidence to suggest that Lean implementation in healthcare could reach the same level of success as achieved by Toyota, and as we have demonstrated some may argue that it will not. This paper highlights that though the intention was for Lean to decrease clinical variation and complexity when applied to healthcare, the application of Lean to health care resulted in the core concepts and activities of Lean becoming more complex.

The current knowledge base of Lean implementation in healthcare lacks evidence on when, how and why the different components and activities of Lean work in different contexts. This lack of evidence is partly due to the insufficient research attention given to the complexity and variability of healthcare contexts in which Lean is implemented. We highlight weaknesses to traditional methods such as systematic reviews and RCTs to evaluate complex

interventions and propose realism and realist approaches to synthesize and evaluate complex interventions such as Lean. The development of this knowledge will aid in the assessment of Lean as an evidence-informed intervention for healthcare improvement. It is only ethical to commit time, effort and resources to interventions where there is sound evidence that the intervention targets mechanisms that can realistically produce change.

List of abbreviations

Quality improvement (QI), randomized control trials (RCT's), Medical Research Council (MRC), context, mechanisms and outcomes (C + M = O), United Kingdom (UK)

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Chapter 4.

Paper 3. The sustainability of Lean in pediatric healthcare: a realist review

This paper is submitted as:

Flynn R, Newton AS, Rotter T, Hartfield D, Walton S, Fiander M, Scott SD. The sustainability of Lean in pediatric healthcare: a realist review. BMC Systematic Reviews (submitted 17 April 2018).

Abstract

Background: Lean is a quality improvement management system from the Toyota manufacturing industry. Since the early 2000's, Lean has been used as an intervention for healthcare improvement. Lean is intended to reduce costs and improve customer value through continuous improvement. Despite its extensive use, the contextual factors and mechanisms that influence the sustainability of Lean in healthcare have not been well studied. Realist synthesis is one approach to 'unpack' the causal explanations of how and why Lean is sustained or not in healthcare.

Objective: We conducted a realist synthesis using the context (C) + mechanism (M) = outcome (O) heuristic; to further develop and refine an initial program theory with seven CMO hypotheses, on the sustainability of Lean efforts across pediatric healthcare.

Methods: Our search strategy was multi-pronged, iterative and purposeful in nature; consisting of database, grey literature and contact with three healthcare organizations known for Lean implementation. We included primary research studies, published and unpublished case studies or reports, if they included Lean implementation with a pediatric focus and sustainability outcomes. We used Normalization Process Theory, the National Health Services Sustainability Model, an operational definition for Lean and a comprehensive definition for sustainability as guidance for data extraction and analysis. Our initial program theory with was refined using a blend of abductive and retroductive analytical processes.

Results: We identified six published primary research studies, two published quality improvement case studies, and three unpublished quality improvement case reports. Five CMO hypotheses from our initial program theory were substantially supported after synthesis, 'sense-making and value congruency', 'staff engagement and empowerment' and the "ripple

effect" or causal pathway between Lean implementation outcomes that served as facilitating or hindering contexts for sustainability. Overall, there was variation with the conceptualization, and measurement of sustainability.

Conclusions: This study is the first to examine Lean sustainability in pediatric healthcare using realist methods. Future research should examine whether the predictors of implementation are the same or different to sustainability and evaluate the underlying mechanisms that influence the sustainability of Lean. There is also a need for research to develop and test conceptual models and frameworks on sustainability.

Review Registration: PROSPERO - CRD42015032252.

Keywords: realist review, Lean, sustainability, complex intervention, quality improvement, implementation science, pediatric healthcare**.**

Background

The goal of Lean management systems are to reduce costs and increase value for customers through the creation of a continuous Quality improvement (QI) culture.[1, 2]. Lean originated from the Toyota automotive manufacturing industry in the 1930's.[1] Toyota is one of the world's most successful companies in the car manufacturing industry. In 2012, Toyota was the largest automobile manufacturer by production and in 2014, Toyota was the twelfth-largest company in the world by revenue.[3] Given these presumptive positive outcomes of Lean management, it has become an attractive option for healthcare systems faced with demands to improve quality, increase efficiency and decrease expenditure.[4] Internationally, Lean is increasingly applied to healthcare systems for improvement. Successful implementations of Lean in healthcare report waste reduction and increased efficiency; [5-8] while unsuccessful implementations have described Lean as inappropriate for healthcare, and reported superficial adoption, system dysfunction and disengaged staff.[9-11]

Given the complexity of healthcare systems, [12] contrary findings in the literature are not surprising. In addition to healthcare complexity, the extent of Lean implementation varies substantially.[10, 14] Virginia Mason a private, non-profit, medical centre in Seattle, United States, for example, adopted Lean as a guiding philosophy across all departments and management systems—a macro level implementation; but most healthcare organizations adopt Lean at meso levels in efforts to improve a specific process or procedure. Seventy-three percent of Canadian health regions have indicated that Lean was a component of their organizational strategy,[15] yet few regions have embraced it as their overarching approach to transform organizational culture and performance. The distinction between meso and macro

adoption of Lean may be crucial to better understand the sustainability of Lean implementation efforts in healthcare.

Lean was not intended to be complex. It was intended to be a simple philosophy and management system for continuous improvement in the car manufacturing industry. The philosophy of Lean was to reduce waste, add value and create efficiency, through a set of activities and core principles. However, we argue in the context of healthcare Lean is a complex intervention for improvement. There are a number of reviews on Lean in healthcare[5-7, 13] but none on the sustainability of Lean efforts or Lean in pediatric healthcare. Sustainability is a key implementation outcome, yet remains one of the least understood issues for implementation research.[16] Implementation of interventions for improvement are meaningless without including long-term sustainability efforts.[17] There are two defining characteristics of Lean: Lean philosophy and Lean activities. Lean philosophy is made up of two components: a commitment to Lean principles and a commitment to continuous improvement.[18] Lean implementation requires engagement of providers, followed by establishment and embedding of improvement behaviours.[19] Considering these long-term aspects of Lean, evaluating sustainability is imperative.

In order to address the question of sustainability of Lean implementation in healthcare settings, it is necessary to understand the contextual factors and mechanisms that lead to outcomes. There is an argued case to shift from knowing whether a complex QI intervention works or not, to understanding the causal relationships between contexts and the outcomes of the intervention.[20] A realist review is one approach to uncover some of the contexts and mechanisms that influence the sustainability of Lean. This approach will help address *for*

whom, under what circumstances, how and why are Lean efforts sustainable or not sustainable in pediatric healthcare?

Review question

The purpose of this review was to develop and refine an initial program theory on Lean sustainability in healthcare and to address the research question: *For whom, under what circumstances, how and why are Lean efforts sustainable or not sustainable in pediatric healthcare?* This realist review sought to: a) identify core mechanisms that generate or contribute to the sustainability or non-sustainability of Lean efforts across pediatric healthcare settings, b) to identify contextual factors triggering core mechanisms, and c) to contribute to the theoretical development of the sustainability of Lean efforts in pediatric healthcare.

Methods

Rationale for realist approach

The review followed established realist guidance.[21-24] Realist synthesis are useful to make program theories explicit by developing testable hypotheses on the mechanisms by which complex interventions are successful or not, and how certain contexts can trigger different mechanisms that in turn generate different outcomes.[25, 26] Interventions such as Lean can have many potential change processes and outcomes that are non-linear and multifaceted in nature and dependent on social context.[27] A realist approach offers methodological strengths to unpack the 'black box' of interventions in comparison to traditional synthesis approaches.[28] From a realist standpoint, to understand the effectiveness of an intervention one

needs to develop an understanding of the mechanisms (M) and the contexts that affect whether or not they operate (C) in order to generate an outcome (O) (C+M=O).[21]

Initial program theory development and CMO mapping

A program theory can be used to frame and evaluate how, for whom, why and under what contexts complex interventions work or not.[29] Prior to this review, we developed our initial program theory on Lean sustainability in healthcare using a multifaceted approach: 1) iterative brainstorming sessions within the review team, 2) realist methodological expertise (see acknowledgements), a scoping search of literature on Lean, QI and sustainability, 3) use of a Lean operational definition,[18] 4) use of substantive theory (Normalization Process Theory (NPT))[30-31] and a sustainability model (National Health Service (NHS) Institute for Innovation and Improvement Sustainability Model (SM));[32-33] and 5) use of the NHS SM definition for sustainability,[32] and a comprehensive definition of sustainability.[34]

The NHS SM provided process, staff and organization contextual factors that potentially explain and increase the likelihood of sustainability and continuous improvement, [32] while NPT offered insights into the potential mechanisms that promote or inhibit the embedding of complex interventions into routine everyday practice and the likelihood of sustainability.[30, 31] These underpin each of the initial CMO hypotheses from our initial program theory.

Using the context (C) + mechanism (M) = outcome (O) heuristic, our initial program theorizing comprised of mapping the terrain of contexts, mechanisms and outcomes. Subsequent to that, seven initial CMO hypotheses were formulated, these hypotheses reflect our initial program theory. It became evident that unpacking the causal pathways in

implementation are a necessary precursor to theorizing and testing sustainability CMO's. We hypothesized that outcomes at implementation (e.g., shared understanding, improved team work), the resources provided during implementation (e.g., Lean training) and the scale of implementation (micro, meso or macro), shapes the contexts (e.g., value congruency, high performing teams), mechanisms (e.g., sense-making, staff engagement, empowerment, accountability) and outcomes for the sustainability of Lean efforts. This concept known as the 'ripple-effect' is premised on the idea that Lean is a series of "events in the history of a system, leading to the evolution of new structures of interaction and new shared meanings." [35(pp. 267)] Our initial program theory (appendices 1and 2) depicts that Lean becomes a complex intervention when implemented to a complex adaptive system (healthcare) across multiple levels of a system (micro, meso, and macro) to multiple stakeholders (organizational leaders, clinical leaders, and frontline staff). Our seven initial CMO hypotheses were categorized according to these elements.

Search methods

Consistent with a realist approach, our search strategy was multi-pronged, iterative and purposeful in nature. We developed search strategies for the following databases which were searched from date of inception until June 2016: Medline (OVID), EMBASE (OVID), CINAHL (Ebsco), and Dissertation Abstracts (ProQuest). The search strategy consisted largely of keywords since the databases searched did not contain controlled vocabulary for Lean management concepts. Methodological filters were not used, since the goal of a realist review is to identify both qualitative and quantitative reports. We also searched for the term 'pediatric' and synonyms in an EndNote database of 5000 references compiled from searches for a systematic review on lean management in healthcare.[36]

We conducted reference list searches for each included source. Our grey literature search was purposeful and multi-pronged, undertaken on the following organizational web sites: Institute for Healthcare Improvement (http://www.ihi.org) and the Agency for Health Care Research and Quality (AHRQ) (http://www.ahrq.gov); and Google. All web sites were searched for the terms Lean, healthcare and healthcare synonyms; we scanned the first three pages of Google results. We also contacted three organizations known to implement Lean in healthcare settings: Saskatoon Children's Hospital, Cincinnati Children's hospital and Virgina Mason. Our search strategy is provided in (appendix 3).

Screening methods and inclusion criteria

Following a two-stage process, two reviewers (RF and SW) independently screened the titles and abstracts of all records (Stage 1), and then independently screened the full text (Stage 2) of any document that made it through Stage 1. For inclusion, documents had to discuss Lean implementation (exclusively or blended, that is Lean and another QI approach) as defined by our operational definition, [18] with a pediatric focus (exclusively or blended, that is pediatric and non-pediatric foci in the same study), and sustainability outcomes as defined by NHS SM[33] and Moore et al.[34] For sustainability outcomes, documents had to provide: a) measures of sustainability and/ or, b) a critique or review of ideas related to how Lean is or is not sustained in pediatric healthcare, and/ or c) stakeholders opinions or accounts of how Lean is or is not sustained in pediatric healthcare. Documents were not excluded based on methodological quality. Due to feasibility reasons we only included documents in the English language. For stage 1 screening, we applied the inclusion criteria to the titles and abstracts of

our search results, all yes and unsure documents moved forward to stage 2 screening, which consisted of full-text screening based upon the inclusion criteria.

CMO contribution and methodological quality

Adopted from Wozney et al., [37] we assessed each document in terms of the richness and relevance of content to Context, Mechanism, and Outcomes. Each document was rated as low/none contribution (no or little information), medium contribution (some information), and high contribution (well-described information). We also assessed relevance by objective (empirical) versus subjective (anecdotal) evidence. Empirical evidence was determined as research based data (e.g., qualitative or quantitative findings), primarily found in the results section of included documents. A document was classified as providing anecdotal evidence when no empirical evidence supported the author's interpretations, typically found in the discussion sections of the included documents. We used and adapted the Mixed-Methods Appraisal Tool (MMAT)[38] to assess methodological quality of the included primary studies, resulting in a methodological rating of 0%, 25%, 50%, 75%, and 100% (with 100% being the highest quality). We adapted the MMAT for multi-method studies by assessing each segment of a multi-method study separately and then selecting the lowest quality rating. Documents were not excluded based on MMAT score, the purpose was to examine and gain insight into the rigor of existing research in this field. Documents were also not excluded based on anecdotal evidence- our main concern was finding information with strong CMO contribution. This information was logged during data extraction.

Data extraction

Using a standardized data extraction form on Microsoft excel, we extracted descriptive information from each document (e.g., QI initiative purpose, stakeholder type, setting, theory and level of change). We applied Colquhoun et al.[39] three conditions for classification of a theoretical basis, [39] in order to understand to what extent the sustainability evaluation in each document was guided by theory. We also extracted intervention and contextual factors, mechanisms, outcomes and any evidence or information related to our initial program theory and CMO hypotheses on the sustainability of Lean efforts. To promote consistency, a coding dictionary was developed and used during data extraction. Two authors (RF and SW) conducted and cross-checked data extraction decisions for each of the included documents. No discrepancies arose during this process. The two authors that conducted data extraction (RF andSW) met at after independently completing two extractions and met twice weekly during data extraction.

Data analysis and synthesis

Data analysis and synthesis were iterative, using a multi-stepped approach to identify and organize information from the included documents. The purpose was to understand what about the contexts where Lean implementation occurred, triggered certain responses (mechanisms) by stakeholders that contributed to the sustainability or otherwise of Lean efforts (outcomes).

Drawing from abductive and retroductive analysis,[40, 41] (RF) examined each document for evidence that supported, refuted or refined our initial CMO hypotheses. This form of synthesis required the researcher to move between theory and data, analyzing data that were not in the initial program theory (abduction) and moving between theory and observable data

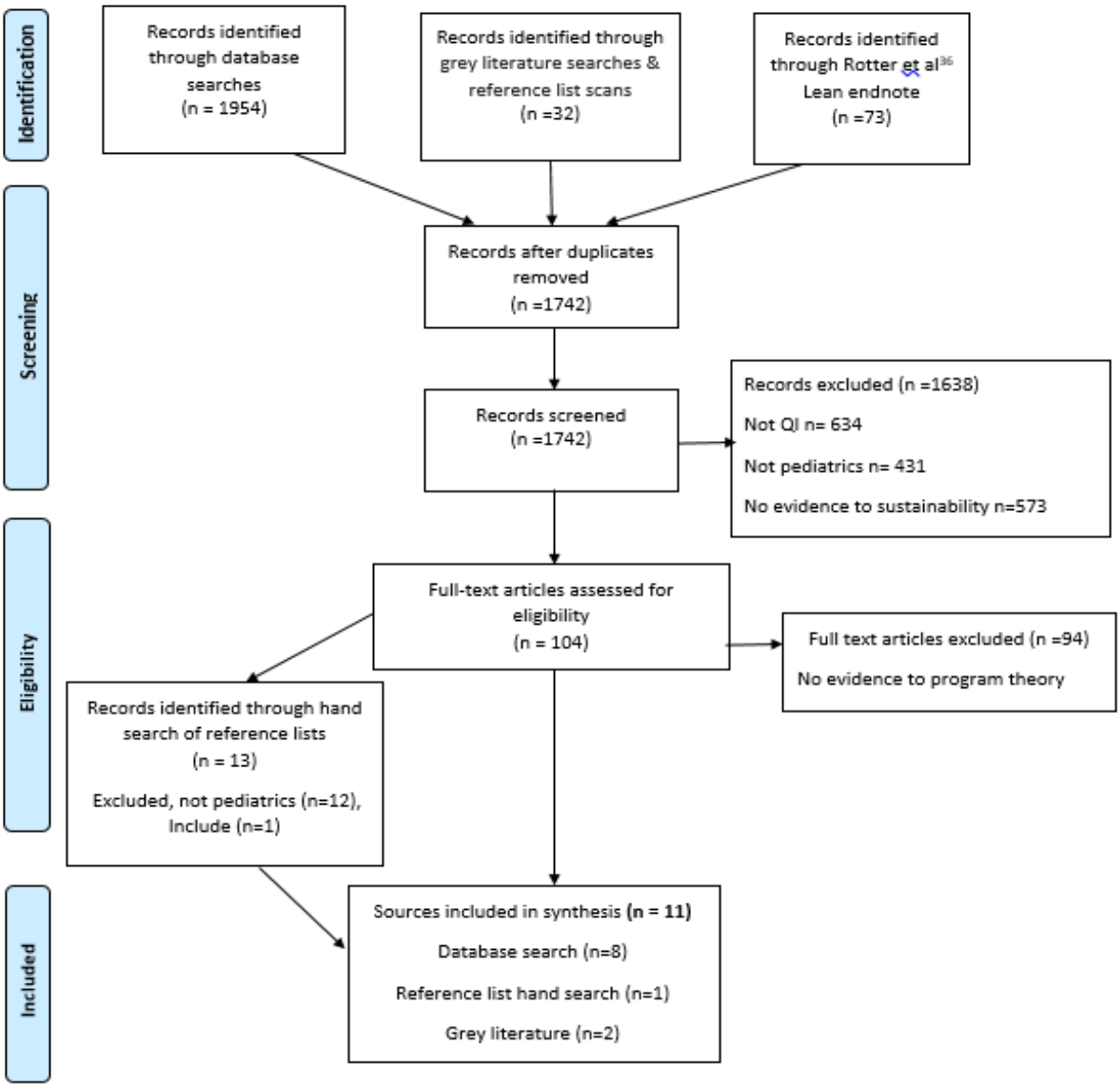
(retroduction). This analytical approach enabled the formation of new ideas beyond the initial theoretical basis of our initial program theory and CMO hypotheses and required the researcher to bring assumptions on what factors contribute to Lean sustainability and *a priori* knowledge on Lean implementation in one health system to question the conditions for a theoretical basis. Retroduction involved inductive and deductive logic where the research team theorized what causal powers may be at play to produce observed patterns in the data. This involved using the teams' insights and experiences on Lean in healthcare and implementation science. Abductive reasoning involved theorizing the best possible explanations of observed outcomes, thinking about the potential mechanisms and contexts that produced certain outcomes, where data was missing. Data gathered from the included documents that were not explained by our initial CMO hypotheses were used to refine our initial program theory. This process was tracked through reflective notes, integration of NPT and NHS where applicable and through regular team discussion.

Results

We identified 2059 references from all search methods; 317 were duplicate. We screened titles/abstracts of 1742 documents; reviewed full text of 104; and included 11 documents. We obtained no additional data by contacting Saskatoon Children's Hospital, Cincinnati Children's hospital and Virgina Mason. Eleven documents[42-52] were included in the review and were used to refine the initial CMO hypotheses; 8 documents from our database search,[42-49] 1 from our citation search[51] and 2 documents from our grey literature search[50, 52] (Figure 4.1). Results are organized by document characteristics, CMO contribution and methodological quality, sustainability outcomes, evidence in relation to initial CMO

mapping and program theory and; finally, the five CMO hypotheses from our initial program theory that were substantively supported by evidence on sense-making and value; staff engagement and empowerment, at the organizational, clinical leadership level and frontline healthcare provider level and the 'ripple-effect' from implantation to sustainability.

Figure 4.1 Adapted PRISMA 2009 flow diagram[68]



Document characteristics

Of the 11 included documents, six were published primary research studies,[42, 43, 45, 47-49] two were published quality improvement case studies,[44, 46] and three were unpublished quality improvement case reports[50-52] found from our citation searching[51] and grey literature searching[50, 52] (Table 4.1). Of the 11 documents, seven used Lean exclusively,[44, 45, 48, 49-52] two used Lean and Six Sigma;[42, 43] one used a combination of Lean, Six Sigma and the Institute for Healthcare Improvement (IHI) Model for Improvement;[46] and another used Lean with "other" QI classic methods.[47] Improvements were targeted at the meso (e.g., unit or organization level) (n=8)[42-49] and macro (e.g., policy, system) (n=3)[50, 51, 52] levels of the healthcare system. No improvement targeted the individual, micro level. Documents focused on a variety of problems, clinical (n=1),[42] process (n=2),[43, 48] clinical and process (n=1),[46] or process and system problems (n=7).[44, 45, 47, 49-52]

All documents used a multi-disciplinary team approach to lead implementation,[42-52] six of which also included a physician lead within the multi-disciplinary team.[42, 43, 47, 48, 49, 51] Many reported organizational leadership involvement (n=8)[44, 45, 46, 48, 49, 50, 51, 52] and, or clinical leadership involvement (n =7).[43, 45, 46, 47, 50-52] One reported patient involvement.[43] There was variation between the use of internal QI support coaches[44, 45, 47] versus external Lean experts or consultants.[48, 49, 50, 51, 52]

Table 4.1 Document characteristics

Author, year, country	Design	Theoretical framework	QI method and QI purpose	Study purpose	Implementation leaders	Setting and system level
Primary research studies (n=6)						
Tekes, 2015, USA[42]	Pre-post/survey	No mention at all	Lean Six Sigma, Clinical	Determine if multidisciplinary LSS approach could reduce reliance on head CT in pediatric hydrocephalus population by 50% within 6 months, 24/7	Multi-disciplinary team, project leader (neuroradiology's) and a physician champion	Division of pediatric radiology and neuro radiology (meso)
Czulada, 2015, USA[43]	Multi-methods	No mention at all	Lean Six Sigma, Process	Describes the inclusion of a family advisor on an improvement project team to	Multi-disciplinary team, medical director, nurse manager, family advisor	Pediatric intensive care unit (meso)

				increase communication opportunities		
Author, year, country	**Design**	**Theoretical framework**	**QI method and QI purpose**	**Study purpose**	**Implementation leaders**	**Setting and system level**
Harrison, 2016, USA[45]	Mixed-methods	Explicit statement of theoretical framework and/or constructs applied to the research	Lean, Process and system	Examine how internal organizational context affected the implementation and outcomes of organization-wide Lean initiatives and rapid cycle Lean process redesign projects, which were embedded within the 'initiatives	Senior leadership support, middle management, multi-disciplinary teams, internal or external Lean experts, Organizations (added Lean to existing QI practices)	Five organizations, one was a pediatric care continuity (meso)

Northway, 2015, Canada[47]	Multi-methods	No mention at all	Lean and other QI "classic" methods, Process and system	Report the long-term sustainability of a standardized transfer protocol	Multi-disciplinary team, physician and clinical leaders, external Lean experts	Pediatric intensive care unit (meso)
Author, year, country	**Design**	**Theoretical framework**	**QI method and QI purpose**	**Study purpose**	**Implementation leaders**	**Setting and system level**
Mazzacato, 2014, Sweden[48]	Mixed-methods	Explicit statement of theoretical framework and/or constructs applied to the research	Lean, Process	Explain how different emergency services adopt and adapt the same hospital-wide lean-inspired intervention and how this is reflected in hospital process performance data	Hospital management strategic-hospital wide lean inspired program. Multi-disciplinary improvement teams, internal improvement coaches, physician leaders	Seven emergency service departments (2 pediatric) (meso)

Mazzacato, 2012, Sweden[49]	Mixed-methods	No mention at all	Lean, Process and system	To unpack how and why such a lean application may work	Multi-disciplinary team, physician lead, internal process improvement coaches, hospital management	Pediatric emergency unit (meso)
Author, year, country	**Design**	**Theoretical framework**	**QI method and QI purpose**	**Study purpose**	**Implementation leaders**	**Setting and system level**
Quality Improvement reports (n=5)						
Wong, 2016, Canada [44]	Commentary/Descriptive	No mention at all	Lean, Process and system	Illustrate how an implicit mental model pervades in the healthcare system based on deeply held but unexamined assumptions that arise from heuristics and	Multi-disciplinary team, process improvement team and senior hospital management support	Pediatric eye clinic (micro)

				biases, that can be examined by objective data and how we can build a new mental model		
Author, year, country	**Design**	**Theoretical framework**	**QI method and QI purpose**	**Study purpose**	**Implementation leaders**	**Setting and system level**
Luton, 2015, USA[46]	Commentary/Descriptive	No mention at all	Lean, Six Sigma, IHI Model for Improvement, Clinical and process	To describe how a program to prevent feeding errors was developed, implemented and evaluated	Multi-disciplinary team, QI project manager, Executive Task force support (leaders)	Newborn centre (three discrete NICUs, milk bank and formula room) (meso)
Carman, AHRQ, 2014, USA[50]	Commentary/Descriptive	No mention at all	Lean, Process and system	to examine the ways in which each organization has implemented Lean and identify	Executive managers, CEO, clinical managers, external Lean consultants,	Five case studies of organizations that implemented

				the factors that influenced progress within individual Lean projects and on the ultimate outcomes	management engineers, and multi-disciplinary frontline teams	Lean- blended adult and pediatrics. Case 1, four hospitals, 3 is pediatrics (macro)
Author, year, country	**Design**	**Theoretical framework**	**QI method and QI purpose**	**Study purpose**	**Implementation leaders**	**Setting and system level**
Hung, AHRQ, 2016, USA[51]	Multi- methods	Explicit statement of theoretical framework and/or constructs applied to the research	Lean, Process and system	Study the scaling and sustainability of Lean redesigns as an organization wide initiative, with a particular focus on analyzing contextual factors affecting the success of	Ambulatory care system wide Lean initiative, executive leadership, external Lean consultants, clinical leaders, physicians and multidisciplinary frontline staff	Ambulatory care system with primary care departments (includes pediatrics) across Palo Alta Medical Foundation (macro)

				implementation efforts		
Rotter, 2014, Canada[52]	Multi-methods	Explicit statement of theoretical framework and/or constructs applied to the research	Lean, Process and system	Evaluate the early stages of the implementation of Lean (Saskatchewan's Lean Management System) in the provincial health system	Ministry strategy policy makers, executive management support, external Lean consultants, clinical leaders Kaizen Promotion Office, multidisciplinary teams,	Saskatchewan Healthcare System (twelve regions) - focus on four regions for realist evaluation (pediatric data) (macro)

CMO contribution and methodological quality

The methodological quality (Table 4.2) of the six primary research studies varied, three scored 75%,[42, 48, 49] two scored 25% [45, 47] and one had no score, 0% [43] on the MMAT. Relevance (CMO contribution) also varied across the primary research studies. Two studies with an MMAT of 75% had high contribution, [48, 49] however in contrast, the third study with an MMAT of 75%, had low contribution.[42] One study that scored 25% on the MMAT had a high contribution.[45] The remaining two studies with MMAT scores of 25% and 0% had medium contribution.[43, 47] Of the quality improvement case reports (n=5), four had medium contribution [44, 46, 50, 51] and one had high contribution.[52]

Table 4.2 CMOc contribution and methodological quality

Published primary research studies (n= 6)					
Author, year, country, citation	**Design**	**MMAT score**	**Objective versus subjective data**	**CMO contribution level**	**Theory**
Tekes, 2015, USA[42]	Quantitative descriptive (pre-post survey)	75%	Objective data	Low	None
Czulada, 2015, USA[43]	Multi- methods	0%	Objective data	Medium	None
Harrison, 2016, USA[45]	Mixed-methods	25%	Objective data	High	Consolidated Framework for Implementation

					Research (CFIR)
Northway, 2015, Canada[47]	Quantitative descriptive	25%	Objective data	Medium	None
Mazzacato, 2014, Sweden[48]	Mixed-methods	75%	Objective data	High	Realist
Mazzacato, 2012, Sweden[49]	Mixed-methods	75%	Objective data	High	None
Published quality improvement case studies (n=2)					
Author, year, country, citation	**Design**	**MMAT score**	**Objective versus subjective data**	**CMO contribution level**	**Theory**
Wong, 2016, Canada[44]	QI project Commentary/Descriptive	n/a	subjective data	medium	None
Luton, 2015, USA[46]	QI project Commentary/Descriptive	n/a	Subjective data	Medium	None
Unpublished quality improvement case report (n=3)					
Author, year, country, citation	**Design**	**MMAT score**	**Objective versus subjective data**	**CMO contribution level**	**Theory**
Carman, AHRQ,	Case report Commentary/Descriptive	n/a	Objective data	Medium	None

2014, USA[50]					
Hung, AHRQ, 2016, USA[51]	Case report Multi-methods	n/a	Objective data	Medium	Consolidated Framework for Implementation Research (CFIR)
Rotter, 2014, Canada[52]	Evaluation report Multi-methods	n/a	Objective data	High	Realist

Sustainability outcomes

There was variation as to how sustainability was defined and measured. For example, six documents referred to sustainability as a change that had lasted over a certain period of time ranging from six months to four years.[42, 43, 46- 49] Outcome measurements were not widely reported and the description on sustainability was poor, primarily consisting of descriptive and experiential accounts (e.g., "Long-term sustainability requires staff engagement, charismatic champions and leaders, and a culture that sustains the change despite staff turnover").[47] Of the six primary research studies, three reported positive sustainability outcomes,[42, 43, 49] and three reported mixed (positive and negative) sustainability outcomes.[45, 47, 48]

All the primary research studies reported clinical, process and performance outcomes as the proxy measure for sustainability.[42, 43, 45, 47-49] For example, one study reported, *"process changes were implemented, resulting in an increased mean documented communication rate from 13% pre intervention to 65% post intervention that was sustained for more than 2 years (P<.001)."*[43] One of the studies that reported mixed outcomes stated that, *"we lack hard data on these measurable outcomes of their long-term sustainability."*[45] The same study reported some negative outcomes that the implementation of Lean had short-term gains and failed to achieve more widespread and sustained improvements; these data was gathered through qualitative interviews.[45] Outcomes reported from the remaining included documents were based on subjective data from descriptive QI reports,[44, 46] or case study reports that had collected primary objective data but presented summary findings.[50, 51, 52]

Examining the evidence in relation to initial CMO mapping and program theories

By using a realist approach, we have been the first to uncover some of the contexts and mechanisms that influence the sustainability of Lean efforts in pediatric healthcare. Three substantial issues have emerged and have supported our initial program theory.

First, the degree of success or failure in the sustainment of Lean efforts relies on the ways in which people 'make sense' of Lean, align their values, and the values of the organization to the values of Lean. Sense-making (the process through which people assign meaning to experience),[77] staff engagement and empowerment were identified as core mechanisms to the sustainability or non-sustainability of Lean efforts. The activation of these mechanisms was facilitated or hindered by Lean resources, such as Lean education,[42, 46, 47, 50] Lean training,[43, 45, 49, 50, 52] external Lean consultants,[45, 48, 49, 50-52] internal QI support coaches,[44, 45, 47] and knowledge translation strategies.[42, 43, 47] The degree to which these mechanisms were activated or not was influenced by certain conditions or contextual factors, such as external pressures to use Lean,[43, 45, 46] a culture shift prior to implementation (organizational readiness),[44] an existing QI structure[43, 44] staff turnover,[45, 47, 48] the silo nature of healthcare, [49] the complexity of care processes,[48] the fit between Lean and local context;[47, 48] and other competing needs or demands.[47] It is important to note that none of the contextual factors identified were unique to pediatric contexts. The relationship between these contexts and mechanisms led to multiple heterogonous outcomes on the sustainability of Lean efforts.

Second, outcomes from Lean implementations shifted to become the contexts for sustainability. That is, in some cases, there was a 'ripple- effect' where outcomes from implementation served as facilitating or hindering contexts that triggered mechanisms for the

sustainment or otherwise of Lean efforts. For example, "sense-making" and value congruency are outcomes at implementation that serve as contexts in sustainability which then trigger staff engagement and empowerment to lead and sustain Lean efforts. Hence, the efforts taken and approaches used at implementation are critical to the success of sustaining Lean efforts.

Implementation approaches and processes contributed to the sustainability or non-sustainability of Lean efforts across our included documents. The use of multi-disciplinary led teams,[42-52] patient involvement,[43] physician leads,[42, 43, 47, 48-51] organizational leadership involvement [44-46, 48-52] and, or clinical leadership involvement [43, 45, 46, 47, 50-52] contributed to the sustainability of Lean efforts. For example, large-scale transformation was reported to have greater likelihood of sustainability than small-scale incremental QI improvements,[48] with top-down leadership commitment.[44] However it was noted in another document that a top-down implementation approach was less well received and sustained.[51] These contradictory findings demonstrate that top-down approach was equivocal in terms of sustainability. External Lean consultants were also reported as a facilitator to sustainability.[48]

Finally, Lean is complex in the context of healthcare, its implementation and sustainability are complex as it occurs across multiple levels of organizations[53] within complex adaptive systems[54] with multiple stakeholders. Contexts, mechanisms and outcomes at one layer of a health system (e.g., organizational leadership) had an impact on the contexts mechanisms and outcomes at another level (e.g., clinical leadership), demonstrating the need for a theoretical complexity lens to the implementation and sustainability of Lean in healthcare.

Substantially supported CMO hypotheses

Value and vision congruency, sense-making as motivations to sustain Lean efforts

CMO hypothesis 1: *If the values of organizational leaders are congruent with Lean philosophy, and leaders receive Lean leadership training (C), then organizational leaders are more likely to make-sense of, appreciate, and feel motivated to implement Lean (M), in turn they become Lean messengers, promoting Lean philosophy to clinical leaders of the organization (O).*

Six documents [42, 44, 45, 48-51] substantiated our initial CMO hypotheses that value congruency and coherence between all levels of the organization and Lean philosophy and activities are critical to the sustainability of Lean efforts. Contexts where, Lean "fits", makes sense and aligns with the values of the organization in its entirety and the people that make up that organization are critical to sustainability. For example three documents reported that Lean value congruency should begin at the organizational level, *"where clear goals/vision aligned with institutional and departmental priorities and mission"* [42] and "*where there is top-down commitment, where CEOs and senior executives need to understand and embrace Lean thinking by integrating it into their philosophy and operating strategy.*" [44] A third document reported that, "*the degree to which leaders aligned the Lean initiative with their organizational vision had important consequences for the overall initiative and for projects embedded within it."*[44]

CMO hypothesis 4: *If there is congruency between Lean philosophy and the personal-level reasoning of the clinical leaders and front-line healthcare providers, and clinical leaders and frontline healthcare providers receive Lean leadership training (C), then Lean is more likely*

to make sense and fit within the context (M), in turn motivating clinical leaders to become Lean messengers, promoting Lean philosophy to frontline staff (O).

Three included documents supported our initial CMO hypotheses that the processes of value congruency and sense-making are mechanisms that trigger either a positive or negative behavioural response by stakeholders, resulting in the outcome of sustained Lean efforts.[45, 48, 49] One document reported, "*clinical staff who believed that the overriding purpose of Lean was cost cutting rather than improving patient experience"*, these participants saw Lean as an added burden to their work.[45] Another discussed issues of differing values and the experience of conflicting loyalties for process leaders between hospital management and their department and how this lack of strategic alignment hindered institutionalization of Lean changes.[48] In another document, Lean efforts made-sense and created standardized work and clear roles for some staff but for others this approach made them feel their work was more narrowly regulated.[49] Contexts where there was a team approach to Lean activities facilitated different professions (e.g., nurses and physicians) to make sense of each other's work and how their work related to that of others and patient needs.[49]

In relation to important contextual factors required to sustain Lean efforts, one document reported that initial specific education to establish a common language and way of thinking about QI was critical to the success of integrating these processes into the culture.[46] In relation to context, another document had some senior leaders report that process improvement was already a part of their organizations culture thus introducing Lean was not foreign to staff, however others argued that some staff didn't understand how Lean was integrated into the larger QI strategy in the organization[51] potentially causing a lack of

congruency and the need for continued sense-making activities (e.g., education, training, messaging).

Frontline staff engagement and empowerment as mechanisms to sustain Lean efforts

CMO hypothesis 6: *If contexts exist where staff are engaged, have received Lean training and the opportunity to lead Lean efforts (C), then staff are more likely to become empowered to use Lean (M), and can then see beneficial outcomes from Lean, have improved satisfaction leading to increased sustained use of Lean efforts(O).*

Seven documents reported that engaging healthcare professionals in designing, overseeing, and managing their own processes and opening new lines of communication through the hospital hierarchy was a contributor to the context of sustainability of Lean efforts.[44-48, 50, 52] Engagement was triggered through active input from frontline staff on things that were important to them, aligning their values with Lean.[45] For example, one document reported that, "*Lean activities enabled staff to provide input into redesigning processes that were important to them. Employees grew more satisfied because of improvements in patient experiences, employee collaboration, efficiency, and opportunities to spend more time with patients."*[45] Staff engagement was sustained by soliciting their ideas at the end of their shifts.[44] Integrated multidisciplinary staff engagement broke down silos,[40] build trust and improved communication channels.[46, 49-51] However, a multidisciplinary team approach did not always work well, with some professions feeling a sense of unwillingness to work together from another.[49] As a counter theory, lack of congruency between values was reported as barrier to engagement, where there was poor alignment between the problems identified and the changes introduced.[48]

CMO hypothesis 7: *If there are contexts where there are visible benefits from Lean implementation, and a collaborative multi-disciplinary team approach to Lean implementation, with audit and feedback of changes (C), this triggers staff motivation and empowerment to sustain Lean efforts (M), then Lean efforts become integrated and sustained in practice (O).*

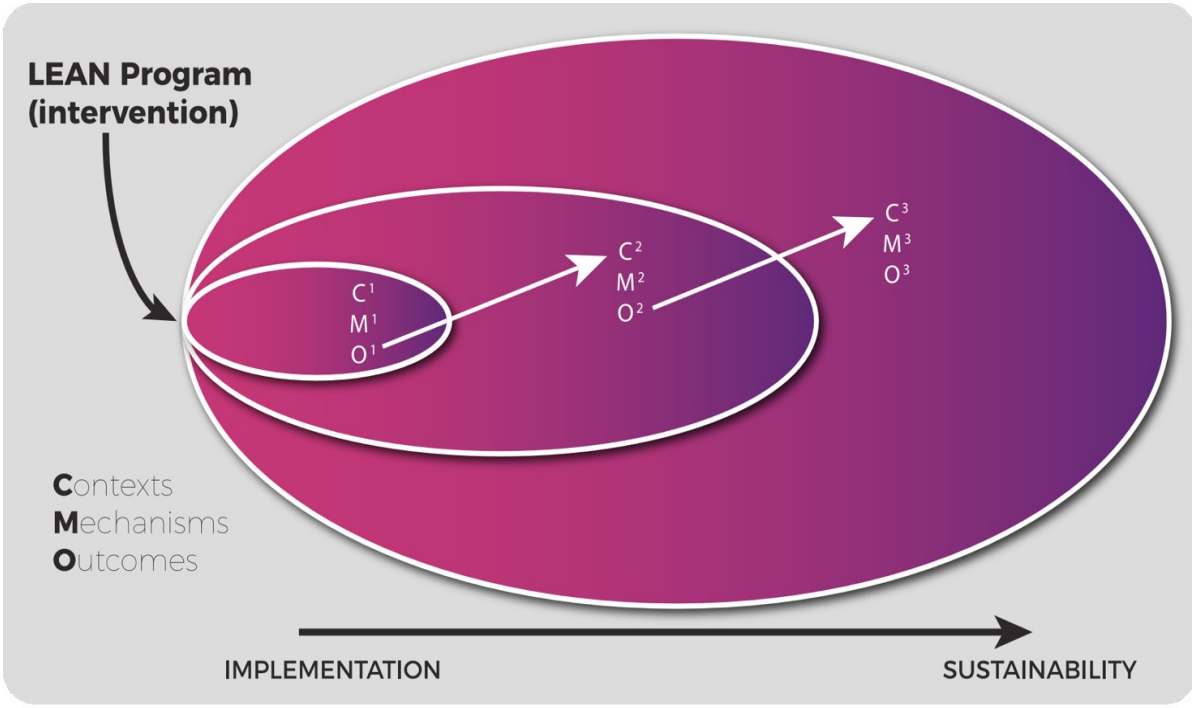
Engagement was reported as a "trigger" for staff empowerment,[49] staff who were more engaged felt more empowered. Staff empowerment was reported in four documents.[44, 49, 50, 52] In one document, it was hypothesized that Lean empowers staff in contexts where there is multi-disciplinary participation in the application of Lean tools and that staff empowerment itself then operates as a mechanism for improved patient safety.[52] Empowerment was triggered through reflective time and the authority to identify and eliminate waste.[44, 50] Another found that the team approach empowered frontline staff to manage and share ideas for improvement.[49] However, others in the same study reported that changes were occurring too fast with a frustrating amount of numerous modifications to care processes,[49] this could be a sense of 'innovation fatigue.'

Ripple- effect

The concept of the 'ripple-effect' enabled a better understanding of the causal relationship between Lean implementation and sustainability, and how processes from implementation to sustainability occur. Our review findings demonstrated instances where outcomes of Lean implementation served as facilitating contexts for subsequent stages of sustainability ($C^1M^1O^1 --> C^2M^2O^2$)[55] as illustrated in figure 4.2. This concept of a 'ripple-

effect' was substantiated in CMO hypothesis 5 and 6, where staff engagement was an outcome at implementation, in turn a context for sustainability, which triggered mechanisms of staff empowerment and outcomes of sustained Lean efforts.

Figure 4.2 The 'ripple-effect'[55]



*Ripple-effect: O1→C2, O2→C3.
Example from review: O5→C6 engagement (outcome of hypothesis 5) becomes a new context (context for hypothesis 6)

Discussion

Lean has been implemented in several pediatric settings and healthcare systems in the absence of an understanding as to why (or why not) it works, how it works or not, for whom and in what contexts. This lack of evidence can negatively impact the likelihood of sustaining Lean efforts. Sustainability was not an exclusive focus in the documents included in this review. Rather, it was an evaluation aspect of successful Lean implementation. Typically, sustainability was referred to as a 'point of time' or through process, performance and clinical outcome measures to Lean sustainability. Similarly, a scoping review of 43 studies on Lean Management in adult only healthcare settings,[36] identified a lack of reporting on the follow up and sustainability of Lean implementation. Some of the evidence sourced in our review was experiential or anecdotal. This echoes Greenhalgh and colleagues[56] who suggested that there is a dearth of studies which focus on the sustainability of complex service innovations. Also, supported by our review findings, there is heterogeneity in the literature on how sustainability is conceptualized[16, 17] and the timeframes appointed to measure sustainability outcomes. [16]

In our review, only four documents used formal theory,[45, 48, 51, 52] all of which were implementation theories [45, 51] or realist evaluations.[48, 52] None of the documents in this review were underpinned by a sustainability theoretical framework, model or measurement tool. There is a lack of conceptual models and frameworks on sustainability,[16, 17] a recognized priority but challenging area for future research, where it is unknown if the predictors of implementation and sustainability are the same or different from each other.[16]

Sense-making and value congruency

As demonstrated through this review, sense-making about Lean may occur at implementation but is also crucial to sustainability, if the philosophy, principles and activities of Lean do not make sense to those tasked with implementing or using Lean than it is unlikely Lean efforts will be adopted and subsequently sustained. This finding supports and substantiates CMO hypotheses 1 and 4 from our initial program theory (Table 4.1). The more people value the change being implemented as important or worthwhile the more likely that they will engage in the implementation efforts. [53] Some empirical evidence has shown when staff and managers did not understand Lean this had a negative meaning throughout the organization.[54]. Sense-making is associated with productive self-organization,[57] a process whereby natural order forms irrespective of the intervention's intentions.[58] Creating and maintaining an institutional culture underpinned by shared vision and values are central to Lean success.[59] Supportive culture with leadership engagement and team involvement was an identified facilitator to maintaining Lean efforts,[13] demonstrating that engagement must occur across different layers of the organization.

Another challenge with implementing and subsequently sustaining Lean efforts as intended was the dichotomy between the vision and values of Lean with those of the organization and/or key stakeholders within an organization. Without alignment of vision and values from senior leadership to the frontline teams, Lean may be reinterpreted and reshaped to ensure that it fits with the visions and values of the multiple stakeholders, which may also vary, making Lean efforts a highly contested process.[10] Under such conditions with potential conflict and disagreement Lean efforts are unlikely to be maintained as originally intended.

For example, Kim et al.,[60] reported the misunderstanding of Lean as a cost cutting measure, created fear in staff and disengagement in Lean. Another study reported on the overuse of 'Japanese' terminology for Lean principles and activities by external Lean consultants in healthcare that do not resonate with health professionals or a patient centred approach. The authors from this study suggest the need to appeal to the personal values and reasoning of the potential adopters.[61] Another published paper on the "promise of Lean in health care" reported that Lean needs to be seen as a mindset that governs how one looks at the business or process. Human skills such as communication, problem solving, teamwork and strong leadership are vital for Lean implementation success. It is resolute that organizational culture and poor change management are predominant reasons for Lean failures.[62]

Active multidisciplinary staff involvement in leading Lean efforts was recognized as critical to sustainability. This finding is supported by Lean literature in other healthcare contexts.[6, 7, 13, 54] Leadership support was also found in our review to be critical to sustaining Lean efforts, a finding that is shared across other published Lean healthcare literature. [4, 11, 59, 62, 63] Despite the recognition of the importance of these concepts to the embedding, normalization or sustainability of Lean efforts, there is a paucity of rigorous literature that explores or tests these concepts in Lean in healthcare.

The 'ripple-effect'

We hypothesized that outcomes at implementation (e.g., shared understanding, collaborative improved team work collaboration), contextual factors at implementation (e.g. external Lean consultants versus internal QI coaches) and the scale of implementation (micro, meso or macro), shapes the contexts (e.g., value congruency, high performing teams),

mechanisms (e.g. sense-making, staff engagement, empowerment, accountability) and outcomes for the sustainability of Lean efforts. This supports the argument by Pluye and colleagues[64] that program implementation and sustainability are not distinct processes but are connected to each other. However other existing evidence has shown that the conditions that facilitate implementation may diminish overtime,[65, 66] hence the conditions for sustainability are also susceptible to losing presence and influence, leading to discontinuation.

Strengths and limitations

A limitation of this review is that we only sourced 11 relevant documents. This paucity of literature demonstrates a knowledge gap and weak evidence base on Lean sustainability in pediatric healthcare. The quality of the literature that served the basis of this review must also be acknowledged as a limitation, making unpacking CMO hypotheses challenging. There is a clear need for more rigorous evaluative studies on Lean sustainability in healthcare. We experienced positive reports about Lean, however not always based on rigorous research design and method. Theorizing during this process came from expertise on Lean in healthcare, healthcare improvement experts and implementation scientists. Data from this review do support some CMO hypotheses from our initial program theory. A strength of this review is that its results are being tested in a subsequent realist evaluation on the sustainability of Lean efforts across four pediatric acute care units at one hospital in Saskatoon, Saskatchewan, Canada. Our realist evaluation takes place in a health system-wide transformation of Lean known as "the Largest Lean transformation in the world." [67] This is an important next step to test our initial program theory and substantiated CMO hypotheses. A limitation of much of the

research on Lean in healthcare, and thus, this review, is the lack of reporting and measurement on sustainability.

Conclusions

This is the first realist review on the sustainability of Lean, a widely implemented complex QI intervention across health systems worldwide. This review demonstrates instances of a causal pathway between implementation and sustainability and a 'ripple effect' from implementation to sustainability. Our findings also demonstrate that sense- making, value congruency during implementation are important contextual factors that trigger the likelihood of sustained Lean efforts. Engagement served as an outcome at implementation and shaped contexts for sustainability as demonstrated through the 'ripple-effect.' Empowerment was an important mechanism that triggered the likelihood of sustained Lean efforts. This review also shows that there are many evidence gaps in relation to the sustainability of Lean efforts and that there is a need for rigorous research to evaluate the underlying factors influencing the success and sustainability of Lean across different healthcare settings.

It remains unknown how a complex QI intervention or program like Lean goes from implementation to normalized behaviour, where sustainability efforts are no longer required or have ceased. It is also unknown what about Lean is most important to sustain, what about Lean efforts are sustained in reality (e.g., Lean activity, practice change, culture change) and how to measure the success of Lean efforts in terms of sustainability. There is a need for the development and pilot testing of program theories and tools to evaluate the sustainability of complex interventions in healthcare. Sustainability research on healthcare improvement interventions is critical to enable better implementation, measurement and reporting. There is

a need for further exploration into the mechanisms found in our review and what they mean for sustaining complex QI interventions. We are testing and further refining these mechanisms in pediatric healthcare contexts through a realist evaluation.

List of abbreviations

Quality improvement (QI), National Health Services Sustainability Model (NHS SM), Context + Mechanism = Outcome (CMO, Normalization Process Theory (NPT), Mixed-Methods Appraisal Tool (MMAT)

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Chapter 5.

Paper 4. Ripple- effects from outcomes of implementation to contexts for sustainability - a realist evaluation of Lean sustainability in pediatric healthcare

This paper is prepared for submission as:

Flynn R, Rotter T, Newton AS, Hartfield D, Scott SD. Ripple- effects from outcomes of implementation to contexts for sustainability - a realist evaluation of Lean sustainability in pediatric healthcare.

Abstract

Background: In 2012, the Saskatchewan Government mandated a system-wide Lean implementation across healthcare. The aim was to achieve better health, better value, better care and better teams. Research has been conducted on the implementation processes of this system-wide Lean implementation. However, no research has been done on the sustainability of these Lean efforts. The research presented is the final phase to a larger realist investigation on the sustainability of Lean in pediatric healthcare. We used the context (C) + mechanism (M) = outcome (O) realist heuristic to explain under what contexts, for whom, how and why Lean efforts are sustained or not sustained in pediatric healthcare.

Methods: Guided by a realist evaluation framework we employed a case study research design. We conducted qualitative realist interviews with various stakeholder groups across four pediatric hospital units 'cases' at one acute hospital. Interview data was analysed using an integrated approach of CMO categorization coding, CMO connecting and pattern matching through cross case comparison.

Results: We conducted thirty-two interviews across four pediatric cases. Five CMO configurations (CMOcs) emerged from our realist interview data. These configurations illustrated a 'ripple-effect' from implementation outcomes to contexts for sustainability. Sense-making and staff engagement were prominent mechanisms to the sustainment of Lean efforts. Failure to trigger these mechanisms resulted in resistance. The implementation approach, messaging and language used influenced mechanisms and outcomes for sustainability, more so than Lean itself.

Conclusions: The mandated, top-down, externally led nature of implementation and lack of customization to context served as potential pitfalls. The language, messaging and training

approaches used triggered mechanisms of innovation fatigue, poor ‘sense-making’ and a lack of engagement for frontline staff. Sense-making and staff engagement are critical aspects from early implementation as they enable normalization and sustainment. Overall, there was variation between leadership and frontline staff’s perceptions on how embedded Lean was in their contexts, and the degree to which participants supported Lean sustainability. This research illuminates important contextual factors and mechanisms to the social process of Lean sustainment and further work needed to build a science on the sustainability of complex interventions for healthcare improvement.

Key words: sustainability, normalization, Lean, quality improvement, realist evaluation

Background

Lean is aimed at maximising value for customers by reducing waste and reconfiguring organizational processes.[1, 4] Lean is increasingly recognized as a potential approach to improve complex problems in healthcare.[5] Lean has been implemented in a variety of healthcare settings (e.g., emergency departments, outpatient clinics, pediatric care),[7-10] through a variety of implementation approaches (e.g., mandated at macro level, driven by frontline staff at meso level of a system), targeting various levels of healthcare systems (macro, meso or micro). It has also been conceptualized in multiple ways (e.g., a philosophy or management system versus quality improvement (QI) tools).[11-14]

Previous research on Lean implementation in healthcare has not addressed the contextual factors and mechanisms that influence the sustainability of Lean efforts.[15-19] Understanding these factors that contribute to its lasting effect are as important as understanding how to implement Lean in the first place.[20] Sustainability is an important yet understudied implementation outcome.[21, 22] These knowledge gaps require further exploration.

The aim of this research was to generate, test and refine a program theory on the sustainability of Lean efforts in pediatric healthcare using a realist approach. We conceptualized sustainability as "*the continuation or the integration of new practice within an organization whereby it has become a routine part of care delivery and continues to deliver desired outcomes, whereby the ways of thinking and attitudes behind processes and outcomes have changed and the new practice has become the new way of working."*[23]

Previous work: A realist investigation on Lean sustainability in pediatric healthcare

This paper presents the final phase of a multi-phase realist investigation on the sustainability of Lean efforts in pediatric healthcare. Realist investigations are driven by the question: *"what works, how, for whom, in what circumstances and to what extent?"*[24] The emphasis of a realist investigation is to understand generative causation and how causal mechanisms are shaped and constrained by context, which when combined generate outcomes.[25] A realist investigation is underpinned by the context (C) + mechanism (M) = outcome (O) configurations (CMOcs) heuristic. [24] The overarching question that guided our research was: *For whom, under what circumstances, how and why are Lean efforts sustainable or not sustainable in pediatric healthcare?* Our main research objectives were to: a) identify the contexts and mechanisms associated with the sustainability of Lean efforts across pediatric healthcare settings, b) test and refine our initial program theory and substantiated CMOcs, and c) to contribute to the theoretical development of the sustainability of Lean efforts in healthcare. Phase 1 consisted of initial program theory development (appendices 1 and 2). Phase 2 consisted of a realist review to further develop and refine our initial program theory. Five CMOcs were substantiated in the realist review (table 5.1). Phase 3, reported in this paper, was a realist evaluation to test and refine our program theory and CMOcs developed during phase 1 and 2 of this research.

Table 5.1 Refined CMOcs from realist review findings

Refined CMOCcs from realist review findings
CMOc 1: If the values of organizational leaders are congruent with Lean philosophy, and leaders receive Lean leadership training (C), then organizational leaders are more likely to make-sense of, appreciate, and feel motivated to implement Lean (M), in turn they become Lean messengers, promoting Lean philosophy to clinical leaders of the organization (O).
CMOc 2: If there is congruency between Lean philosophy and the personal-level reasoning of the clinical leaders and front-line healthcare providers, and clinical leaders and frontline healthcare providers receive Lean leadership training (C), then Lean is more likely to make sense and fit within the context (M), in turn motivating clinical leaders to become Lean messengers, promoting Lean philosophy to frontline staff (O).
CMOc 3: If contexts exist where staff are engaged, have received Lean training and the opportunity to lead Lean efforts (C), then staff are more likely to become empowered to use Lean (M), and can then see beneficial outcomes from Lean, have improved satisfaction leading to increased sustained use of Lean efforts(O).
CMOc 4: If there are contexts where there are visible benefits from Lean implementation, and a collaborative multi-disciplinary team approach to Lean implementation, with audit and feedback of changes (C), this triggers staff motivation and empowerment to sustain Lean efforts (M), then Lean efforts become integrated and sustained in practice (O).
CMOc 5: Outcomes of Lean implementation served as facilitating contexts for subsequent stages of sustainability (C1M1O1 --> C2M2O2).11 This concept of a 'ripple-effect' was substantiated where staff engagement was an outcome at implementation, in turn a context

for sustainability, which triggered mechanisms of staff empowerment and outcomes of sustained Lean efforts.

Each research phase was guided by two middle-range theories, the National Health Service Institute for Innovation and Improvement Sustainability Model (NHS SM)[23, 26] and Normalization Process Theory (NPT).[27, 28] The NHS SM identifies 10 key factors that increase the likelihood of sustainability [26] NPT is used to understand the implementation, embedding and integration of evidence-based innovations into healthcare settings as a result of people working individually and collectively to enact them.[27] These middle-range theories helped us to understand the contextual factors and mechanisms that trigger Lean sustainability or not. Phase 3 occurred in the context of the Saskatchewan health system, Canada. Saskatchewan is the first province in Canada to apply Lean across the entire healthcare system.

Evaluation context: Lean implementation in the Saskatchewan health system

Saskatchewan, Canada has a population of just over 1,000,000 people. Prior to 2017, Saskatchewan had 13 defined health regions, overseeing 40,000 employees with a variety of care services (e.g., community care, acute care and ambulatory care).[29, 32, 33] A Lean management system was mandated in stages across this province to achieve healthcare improvement and transformation.

Lean principles were first implemented in the Saskatchewan health system in acute care medical and surgical wards through the Releasing Time to Care (RTC) mandated project.[30] The mandate occurred from 2008-2010.The aim of RTC was to increase nursing

staff autonomy, to continuously improve patient care.[30] Implementation of Lean in the Saskatchewan health system has evolved since RTC.

In 2012, formal support for RTC ended and the Saskatchewan Ministry of Health committed a multi-million dollar investment to implement a broader system-wide Lean transformation, led by an external consulting group.[31] This has been titled "*the largest Lean transformation in the world*."[32] The overarching aim was to create "better health, better value, better care, and better teams."[33] Early-stages of this implementation focused on leadership training, and the creation of Kaizen Promotion Offices (KPOs) to provide supportive infrastructure for the Lean transformation.[34] This was intended to build internal capacity and capability for continuous quality improvement.[35] The Saskatchewan Lean management system was used in combination with Hoshin Kanri, and daily visual management[36] and used a variety of Lean tools and activities. Details on the concepts, activities and tools as understood and used by the Saskatchewan Lean Management System are presented in Table. 5.2. The Saskatchewan Ministry of Health[33] proposed that, "Lean empowers employees to find ways to improve. It focuses on identifying and reducing waste. In healthcare, that would include things like excess inventory, time spent waiting for services, and inefficient processes that reduce time spent on direct patient care."

Table 5.2 Saskatchewan Lean management system: concepts, activities and tools

Concept, activity, tool	Description
Lean	Lean is a patient-centred approach to identifying and eliminating all non-value-adding activities and reducing waste within an organization.[84]
Hoshin Kanri	Hoshin Kanri is a management method that comes from the Lean approach to

Concept, activity, tool	Description
	improvement and is used to deploy strategic priorities throughout an organization.[84]
Kaizen basics workshops	Kaizen means "continuous improvement" or "change for the better." Typically, it's a short team-based improvement effort.[84] Kaizen basics workshops are training workshops with the purpose of introducing the basic concepts of Lean as a continuous quality improvement approach and exposing the healthcare staff to Lean terminology. It takes one workday with KPO support personnel (a Kaizen specialist) participating as an instructor/facilitator of the event.[34]
Rapid process improvement workshops	RPIW is a week-long event where teams of patients and family members, staff and clinics focus on one problem, identify the root causes, and create and test solutions. By week's end, they are ready to implement the solution in the workplace. The team checks the solution at 30, 60 and 90 days to see if it has worked and has been sustained.[84]
5S event	Five terms beginning with “s” used to create a clean and well-organized workplace, which in turn promotes teamwork and safety, cuts costs and improves productivity: *Sort*: Separate the necessary from the unnecessary items. *Simplify*: Find the best place for everything and keep it in its place.

Concept, activity, tool	Description
	Sweep: Identify potential problems and deal with unsafe conditions or damaged items or equipment. *Standardize*: Define how a task should be done and communicate this best practice to everyone involved. *Self-discipline*: Ensure the area remains clean and organized and that everyone maintains the new processes.[84]
Mistake proofing	Mistake proofing examines the root cause for mistakes and aims to prevent them before they create defects. Making proofing also eliminates rework and reduces costs.[84]
Kanban	A way of automatically signalling when new parts, supplies or services are needed, in the quantity needed, and at the time they're needed. A Kanban signal is usually a card, indicating the need to reorder supplies. However, it can be a special container or another type of visual cue.[84]
Production Preparation Process (3P)	3P is a Lean tool used when a totally new process or design is required. Often used in facility design, the goal is to ensure quality, safety, flow and efficiencies are built into the new design. 3Ps are typically week-long events involving a team of providers, staff and patients.[84]
Value Stream Map	A visual tool used to help see and understand the flow of patients, supplies, or information through the healthcare

Concept, activity, tool	Description
	experience. It maps all actions currently required to deliver a service or product and provides a big picture perspective that focuses on improving the whole from the standpoint of the patient.[84]
Gemba	Place where the work is performed i.e. hospital floor or cafeteria.[84]
Lead time	The total time of the patient experience process being observed. This is measured with a stopwatch. For example: From the time the patient walks into the hospital until the time they are through admitting. From the time the patient registers for day surgery until the time they are discharged home.[84]
Waste	Waste is anything that does not add value through the eyes of the patient. There are seven identified wastes in healthcare. They are: *Inventory*: Too much. For instance, anything kept for 'just in case'. *Motion*: Having to walk to multiple locations in search of supplies or information. *Defects*: Errors that make it to the patient. *Transportation*: Moving patients from room to room or various other locations. *Processing*: Capturing patient information in multiple locations.

Concept, activity, tool	Description
	Overproduction: Creating 100 packages when only 15 are needed in the week. *Time*: On the part of the patient or staff.[84]

Foundational work on how Lean is intended to work in Saskatchewan health system

The decision to implement the Saskatchewan Lean management system was made without establishment of an evidence-based program theory that explains how Lean is supposed to work. From 2013- 2015, an external evaluation was commissioned by the Saskatchewan health quality council. Rotter et al.[36] conducted a multi-year realist evaluation on the early stages of Lean implementation, whereby they developed a program logic model and draft program theory on the Saskatchewan Lean management system. The draft program theory provided a sketch of the ways in which the Lean management system is 'supposed to work'. This logical model and draft program theory informed our subsequent research.

This large-scale Lean transformation and previous realist evaluation on early stages of implementation created a novel opportunity for our research on the sustainability of Lean across multiple pediatric healthcare settings. There is no prior evaluation on Lean sustainability in Saskatchewan and none specific to pediatric healthcare. Pediatric healthcare was an interesting context for us to study under the Saskatchewan Lean management system due to the development of the provinces first children's and maternal hospital based on Lean.

Ethical approval

Ethical Approval for this study was granted by the University of Alberta Health Research Ethics Board (appendix 4) and the University of Saskatchewan Behavioural Research Ethics Board. Institutional approval was provided by the Saskatoon Health Region, Inter-professional Practice, Education and Research office.

Phase 3: A realist evaluation

Design and methodology

We followed a realist evaluation methodology framework[25] with an explanatory case study research design. [37] We conducted qualitative realist interviews[38] to test and further refine our initial program theory (developed in phase 1), the CMOcs substantiated in our realist review (phase 2) and to explore new emerging relevant CMOcs. One central tenet of realist methodology is that programs work differently in different contexts;[25] hence, we chose to conduct interviews across various cases (units) where Lean implementation had occurred in the context of the Saskatchewan health system to further test and refine: *For whom, under what circumstances, how and why are Lean efforts sustainable or not sustainable in pediatric healthcare.*

Data collection methods

The realist interviews explored participants' perceptions of Lean, implementation processes and factors (contexts and mechanisms) that enabled or hindered the sustainment of Lean efforts. Interviews were conducted using semi-structured interview guides (Appendix 5). All interviews were conducted in person or by telephone by lead author (RF), audio recorded and transcribed. Realist interviews explicitly discuss the program theory with the participants, giving them the opportunity to confirm, refute or refine the theory, this is described as the teacher-learner cycle.[25]

Recruitment and sample

We defined a 'case' as a pediatric unit involved in Lean implementation from one acute hospital setting. To develop an understanding of how Lean efforts are embedded in

practice, we purposefully selected four pediatric units (a pediatric inpatient unit, outpatient unit, pediatric intensive care unit (PICU) and neonatal intensive care unit (NICU). All staff from each included case were invited to participate in the interviews to gain broad and diverse perspectives. Staff was invited to participate through communication by the unit managers at each case and the Director of children's services. A range of perspectives via professional roles were purposefully sought in order to contribute to refinement of the program theory.

Data analysis

Interviews were analysed by RF using a realist evaluation framework and the Context (C) + Mechanism (M) = Outcome (O) configuration (CMOc) heuristic.[25] We followed Maxwell's[39] categorising and connecting strategies for data analysis. Consistent with a comparative case study design, RF firstly analysed each case separately as a 'whole study' and then analysed and summarized similar and/or opposing evidence across the four included cases through data triangulation and pattern matching.[39] During categorization, C, M, O coding for each case was done by a process of data extraction using a bespoke form and coding using NVivo 11 software. Cross case comparisons were made to determine how the same causal mechanisms played out in different contexts and produced the same or different outcomes. Data connecting involved pattern matching across cases and CMOcs and higher abstraction. This was done using Microsoft Word 13 and Microsoft Excel 13.

A visual model (Appendix 6) was developed to show CMOcs patterns across cases. These patterns denote the causal pathways leading to program outcomes. [25, 40] Building upon our previous realist review we showed how CMOcs can be linked to each other - with some outcomes of early implementation becoming an aspect of context for sustainability, this is known as the 'ripple effect'.[41]

Analysis was iterative, going 'back-and-forth' between the program theory and the CMOcs from phase 2 and the data gathered in phase 3. The intent was to deliberately attempt to refine and specify the program theory on the sustainability of Lean in pediatric healthcare. We also drew upon our middle-range theories to explain contextual factors and causal mechanisms for the sustaiability of Lean in the research context.

Validity

Under a realist lens the focus of validity is the judgement of the degree to which the researcher has encapsulated the multiple perspectives pertaining to a given situation. [42 (pp82)] We followed Pawson et al.[43] criteria to enhance the trustworthiness of data collection and documentation. These criteria, with the acronym TAPUPAS, stands for transparency, accuracy, purposivity, utility, propriety, accessibility and specificity. We outline the steps we took to meet the TAPUPAS criteria in table 5.3.

Table 5.3 TAPUPAS Quality standards framework[43]

TAPUPAS	Quality standards description	Link to phase 3 of research
Transparency	The process of knowledge generation should be open to outside scrutiny. For knowledge to meet this standard, it should make plain how it was generated, clarifying aims, objectives and all the steps of the subsequent argument, so giving readers access to a common understanding of the underlying reasoning.	We have discussed our aims, theoretical guidance, setting, methods and process of data analysis.

TAPUPAS	Quality standards description	Link to phase 3 of research
Accuracy	All knowledge claims should be supported by and faithful to the events, experiences, informants and sources used in their production. For knowledge to meet this standard, it should demonstrate that all assertions, conclusions and recommendations are based upon relevant and appropriate information.	We used participant's quotations to accurately report the perspectives gathered and show how these perspectives informed the CMOcs identified during analysis.
Purposivity	The approaches and methods used to gain knowledge should be appropriate to the task in hand, or 'fit for purpose'. For knowledge to meet this standard, it should demonstrate that the inquiry has followed the opposite approach to meet the stated objectives of the exercise.	We identified that a realist evaluation of multiple stakeholders across multiple cases experiencing the program in question would enable us to explore the CMOcs identified during the realist review. We conducted triangulation using date from a realist review and evaluation to address our research question. We also used middle-range theory during each of those research phases.
Utility	Knowledge should be appropriate to the decision setting in which it is intended to be used, and to the information need expressed by the seeker after knowledge. For knowledge to meet this standard, it should be 'fit for use', providing	We gathered multiple perspectives of multiple stakeholder professions across multiple cases in the decision setting studied. We also demonstrate limitations to data collection and other sources of

TAPUPAS	Quality standards description	Link to phase 3 of research
	answers that are as closely matched as possible to the question.	knowledge that would have added to utility.
Propriety	Knowledge should be created and managed legally, ethically and with due care to all relevant stakeholders. For knowledge to meet this standard, it should present adequate evidence, appropriate to each point of contact, of the informed consent of relevant stakeholders. The release (or withholding) of information should also be subject to agreement.	We followed ethical procedures of informed consent for all participants and the ethical guidelines of the research boards that granted ethical approval. Each participant read and signed informed consent before each interview. Data was audio recorded, transcribed and anonymized.
Accessibility	Knowledge should be presented in a way that meets the needs of the knowledge seeker. To meet this standard, no potential user should be excluded because of the presentational style employed.	This reporting uses academic language for journal publication standards. This research will also be fed back to the organization in the form of an evidence brief form and lay language summary presentation.
Specificity	The knowledge must pass muster within its own source domain, as perceived by its participants and proponents.	We followed RAMSES II reporting standards for realist evaluations.[86]

Findings

Participant demographics and Lean training and involvement

Thirty-two realist interviews were conducted; nine participants from case 1, three participants from case 2, seven participants from case 3 and four participants from case 4, and

nine participants that were across cases. The total sample consisted of registered nurses (n=9), unit managers (n=5), physicians (n=4), allied health professionals (n=4), clinical nurse educators (n=2), care assistants (n=2), senior leaders (n=4), and parents (n=2). Of the 32 participants, 30 were female and two were male. The majority of participants had been working in their profession from 1-5 years (n=9), 31-35 years (n=6), 6-10 years (n=4) or 16-20 years (n=4). The remaining participants had been working in the profession between 11-15 years (n=3), 21-25 years (n=2), 26-30 years (n=2) or 36-40 years (n=2). The majority of participants had been working in their current role 1-5 years (n=14), or 6-10 years (n=9).

We also collected information about the type of Lean training participants had received, types of Lean activities they had participated in, their first exposure to Lean and their current awareness of Lean implementation. Participants could have been involved in one or more Lean training event and/or Lean activity. Seventy-five per cent of the total participants had received the Kaizen basic Lean training offered through the organization. The most prevalent Lean activities were visual daily management huddles (n=22), visibility walls/wall walks (n=21) and 5s events (n=19). Lean exposure responses ranged from one to six years ago, the most common response was approximately 3 years ago (n=10). Twenty-eight participants (88%) were aware of Lean events currently taking place on their unit.

CMO configurations

Five CMOcs were evident through the realist interviews. None of which were identical to the CMOcs from our realist review. This resulted in refuting and refining our initial program theory. We have arranged our findings according to these five configurations. We present the most prominent quotes from participants to illustrate each CMOc.

'Ripple effect': The funded, mandated, top-down, externally led nature of Lean implementation

CMO configuration 1: *The early stages of Lean implementation were funded, mandated, and top-down in nature (C), driven by an external consultancy firm that initially focused on training senior leadership (C). Frontline staff did not feel involved in Lean changes, and they felt pressured to adopt Lean (M). The lean language used did not make sense to staff (M). Training failed to demonstrate a connection between Lean and healthcare, this led to misunderstandings and negative perceptions of Lean. There was a resistance to Lean, a lack of support for Lean and potential staff retention issues (O) which had a 'ripple effect' on contexts for sustainability.*

The top-down, mandated, externally led Lean implementation was viewed negatively by majority of the frontline staff participants. Some staff felt that Lean was a cost cutting measure, a "fashion fad", something that was pushed on them. It was mentioned that implementation was too quick and did not have a clear purpose. The use of an external consultancy company was also viewed negatively by the majority of unit managers. Participants were conscious of the estimated costs of the consultancy company's fees and felt that this money could have been used more appropriately. The consultancy company was viewed as an outsider pushing a message that didn't connect with healthcare. In contrast, some unit managers and senior leaders did value the top-down, mandated approach used, stating that changes would not have occurred to the same degree without such an approach.

Media was also mentioned to have a powerful influence over participant's perceptions and attitudes towards Lean. The portrayal of Lean in the media was primarily negative. This was perceived to have triggered negative perceptions of Lean by frontline staff and the

general public. Lean training by the consultancy company did not make staff feel involved in Lean changes. The Lean language used by the company did not make sense for many participants and initial implementation efforts failed to connect Lean to the context of healthcare. These factors triggered outcomes of resistance from early-stages of implementation. Quotes to support this CMOc are presented in Table 5.4.

Table 5.4 Evidence to support CMOc 1

Evidence to support CMOc1	
Contexts	
Mandated and externally led implementation	"The whole Lean concept I think was good, but I think it was the whole [consultancy name] company and the incredible amount of money that went to them that really just like pushed it over the edge. I think if it would have just maintained a quality improvement Lean process thing it would be far more accepted. It was the [consultancy company name] thing that just kind of made it – and the thing [consultancy company name] as lots of people have said it came from an American concept. And we are not an American concept. (interview 29, case 2, registered nurse) "It was externally sort of put on people, rather than asking them if there were elements of this model that were workable in their work environment. (interview 20, case 3, clinical nurse educator)
Role of media on perceptions	"I think the media has played a huge role in peoples' opinions of what Lean is and what actually is involved with Lean. For a while there, everything that didn't go right was, "Well pfft, friggen' lean." (interview 22, case 3, unit manager**)**

Evidence to support CMOc1	
Mechanisms	
Disconnect	"Yeah. I think it's the way the health region maybe initially rolled it out that there's still a disconnect from the frontline workers because unless they were made to go to Kaizen basics there was no buy in. And unless they can see outcomes from the change, again it's…yeah things are going on but I don't know what they are. (interview 22, case 3, unit manager)
Implemented by external consultancy: negative perception	"Well I think they had all these masses of people, again, who really didn't understand unit workings that came in and took things apart and put them back together but didn't really understand and didn't come back and follow up on any problems. (interview 20, case 3, clinical nurse educator) "I think people definitely like the idea, but a lot of people are against it because of how it kind of was presented and rolled out. So, I think there's a lack of understanding of really what Lean is." (interview 23, case 3, registered nurse) "I think in hindsight, as a consultant group, they could have worked more with us, instead of imposing on us." (interview 9, senior leader)
Didn't feel involved or valued, felt pushed to adopt	"I personally felt talked down to by the whole thing. I felt that giving me an example would have done the same as watching how many of us fold up a paper airplane how many times and do whatever. The video, that was okay. But just the general talking to of people I just thought was not appropriate." (interview 25, case 4, registered nurse) "Well I think because it's really, it's hard to understand it when you're just being taught, when you're not really

Evidence to support CMOc1	
	involved in the process in detail and not many of the staff have been." (interview 5, case 1, clinical nurse educator)
Outcomes	
Resistance	"There was some resistance and for sometimes good reason because sometimes they knew – like I say again, what works well for one area doesn't necessarily work well for everybody. So, I think that's how it became negative is they felt like – and there's people coming from other areas that don't know your area and so a lot of people felt "Well what do they know trying to tell us how to do this." (interview 28, case 2, registered nurse)
Staff retention	"I'm not sure how much of this is the change and those kinds of things but a lot of our older staff have left. I don't know if it was too much change at once or what, but we have lost a lot of our senior staff." (interview 2, case 1, registered nurse)

Lack of fit between Lean and healthcare and a lack of customization to context

CMOc 2: *The complexity and dynamic nature of healthcare and the unique needs of pediatric patients (C), was perceived as incongruent with the nature of Lean. The translation of Lean to patient care did not make sense for many staff and Lean efforts felt impersonal. Lean training failed to make the connection between Lean and healthcare clear for staff (M) and early stages of implementation led by the consultancy company failed to customize Lean to the local context, this triggered pitfalls to the success of Lean, such as feelings of disconnect and negative perceptions of Lean (M), resulting in a resistance and a lack of support for Lean continuation (O).*

In addition to the externally led, mandated implementation of Lean, there was a lack of fit between Lean principles and the healthcare context (e.g., cars versus patient care). There

was also a lack of customization to context during early stages of implementation. This resulted in some negative effects, particularly for frontline staff and their support of Lean continuation. The lack of customization to local context triggered mechanisms of disconnect, lack of coherence and negative perceptions about Lean.

Pediatric healthcare was discussed as a complex field which requires a family-centred and flexible approach to care, which did not align with Lean. Despite these contextual issues, there were evident shared values between Lean principles and participants' professional values, such as patient safety, efficiency and waste reduction. However, Lean principles were primarily viewed as incongruent with healthcare. The training provided failed to translate Lean concepts, principles and their meanings from a manufacturing perspective to a healthcare perspective. This hindered sense-making processes. These contextual issues and subsequent mechanisms influenced the degree of support for Lean continuation. Quotes to support this CMOc are presented in Table 5.5.

Table 5.5 Evidence to support CMOc 2

Evidence to support CMOc 2	
Contexts	
Complexity of healthcare	"It's confusing to me anyways. Lean, yes, we're pairing things down to its simplest form. But healthcare isn't simple. It's very complex and very different. Again, into the grey. Whereas on paper and people talking maybe a streamline black and white thing, healthcare is not black and white. There is a lot of situations that make it different from this patient to this patient and there's no one way that is perfect. So I don't know." (interview 25, case 4, registered nurse)

Evidence to support CMOc 2	
	"From what I know about lean, I don't really support it. It was a model that came from industry. Healthcare's much more complex than industry. We're not making widgets on an assembly line. We're dealing with people and life and death events in this unit. They're children. So, to try and minimize things and put it in an industrial model I think is really illogical, if not cruel." (interview 20, case 3, clinical nurse educator).
Factors unique to pediatrics	"And I think the other, another challenge is that we have such a variety of ages and diagnoses it's hard to make sure you've got everything for every patient in every unit." (interview 5, case 1, clinical nurse educator) "As long as there's a room for the patient-centered, family-centered care that realizes it's not, yeah. That's the two to debate, whether it's like, you're functioning like systems, like efficiency, that kind of thing versus the family and being flexible and that kind of thing. So merging those two can be hard I guess sometimes." (interview 3, case 1, registered nurse)
Mechanisms	
Felt a disconnect between Lean and healthcare	"We're not a factory. And a lot of things are laid out like it's supposed to be for a factory, so it doesn't always work that way, because we have so many different situations, so many different patients, there's so many variations whereas a factory often is the same thing over and over again." (interview 2, case 1, registered nurse)
Lean feels impersonal	"The other thing too I think for me and I don't think it was intentional, but I think maybe for me it felt at times when we were trying to manage as a Lean organization, it felt a

Evidence to support CMOc 2	
	little but more impersonal, less personal with your frontline staff." (interview 16, case 2, unit manager) "Yeah. Well I guess, it's sometimes feels like a factory, the Lean, and when we're trying to give more personal care, it just seems very sometimes it can feel very impersonal with Lean. So, I think that's why maybe it doesn't work in some ways. (interview 2, case 1, registered nurse)
Outcomes	
Degree of support	"So I think that there would be more buy in if it didn't seem like something that was so out there. Because really, the fundamentals of lean are really just we're going to make it better and we're going to, you know, make less waste and create some efficiency and make sure that our processes are doing the things they need to do to give patients the best care. And I think that if it would have been maybe rolled out a little bit more like that, it probably would have had some more uptake." (interview 19, case 1, unit manager)
Don't see that Lean has made a difference	"No. But that could be just from a lack of possibly not understanding it right? Have I seen? No, I haven't. But, like I said, I don't get to see the financial benefits of it. I don't see those numbers or anything concrete and really when I come to work, you know, I have to work in the foundation and under the structure and the integrity and the values of this, but also, these people that I'm working for, these babies and the families, they're what my major focus is, right? So, I don't pay attention sometimes to those things." (interview 13, case 4, social worker)

Rapidly evolving healthcare contexts overtime – 'innovation fatigue'

CMOc 3: *Lean was implemented in areas that experience constant change (C), early-stages of implementation involved a large number of Lean events for training purposes (C), frontline staff felt overwhelmed from the constant change, they were unsure what changes were due to Lean and felt that Lean was the latest fad (M), this led to negative perceptions of Lean, resistance and lack of support by frontline staff (O).*

The constant changes occurring in the work environment led to feelings of confusion and uncertainty about what changes were as a result of Lean or something else, such as the changes occurring in relation to the new children's hospital development within this context. The degree of constant change also triggered feelings that Lean would not "stick", and that it was another "make-work" project. Unit managers expressed that staff were overwhelmed and staff engagement in Lean was a challenge. These challenges were also coupled with a lack of follow up regarding the Lean changes implemented. These contextual issues and mechanisms produced negative perceptions and an unawareness of what changes were due to Lean efforts. Quotes to support this CMO configuration are presented in Table 5.6.

Table 5.6 Evidence to support CMOc 3

Evidence to support CMOc 3	
Contexts	
Context of constant change	"You know, it's difficult for me to figure out what's done because of lean and what was just changed on this unit because I feel like we have so much change that I don't necessarily know what was changed due to Lean." (interview 19, case 1, unit manager)
Mechanisms	

Evidence to support CMOc 3	
Feeling of innovation fatigue, don't believe Lean will stick	I think part of why people don't buy into things is that constant change. One month we're doing it this way. Six weeks later or six months later, well we're not doing that anymore because we've run out of money or we've run out of momentum or the people whose job that was to roll that forward are gone or whatever. You know, so when people see that after a while it's like how important is that? I'm not even going to listen because in six months is going to be something different." (interview 20, case 3, clinical nurse educator)
Difficult to keep staff engaged	"I think for me, the challenge has been trying to find a way to keep staff engaged with it, right? I think pediatric outpatients had a lot of Lean, Quality Improvement work done through it, like a lot, before my time. And you know when I first started there and talked about it you could just see employee's facts go up as they were Quality Improvement exhausted, like they kind of hit a wall with it." (interview 16, case 2, unit manager)
Staff feel overwhelmed	"I find a lot of times the staff are really overwhelmed. And they, like they try, like with the new staff have lighter assignments and I just feel a lot of them are struggling, and I don't know if there's enough support." (interview 4, case 1, unit assistant)
Feel Lean may not stick due to lack of follow up	"The follow through. Like there just isn't – there hasn't been follow through. It's like you go downstairs and you see all these things on the wall that you're supposed to – the idea was that whichever provider was in the room was like to indicate and like they're just there. They're on the wall. You know some clinics use them. Some clinics don't. Some multi-disciplinary clinics work –

Evidence to support CMOc 3	
	function differently than other multi-disciplinary clinics so there just isn't the follow through. And I think that at the time some of the concepts of you know what we chose to do as an RPIW or whatever were based on the desires or the – of the manager at the time. And really weren't what was necessarily important." (interview 29, case 2, registered nurse) "Lean needs to be consistently monitored, there needs to feedback to the group that was working on the change, I wish there was more information to patients on the changes being made" (interview 35, parent from patient advisory group)
Outcomes	
Unsure what changes are Lean	"I don't know, I support for sure teamwork and principles of it, but I don't feel like I'm fully educated on Lean itself, I just take bits and pieces maybe and don't really realize what's Lean and what's not, and it's more principles that Lean has adopted that I maybe agree with, but do I fully support Lean? Not totally sure." (interview 3, case 1, registered nurse) "Yeah, I don't know what Lean is compared to other change." (interview 8, case 3, registered nurse)
Negative perceptions	"I think there's a negative sort of view on Lean as a whole. I think it's seen as something that – or at least my perception of people's perceptions is that people view it negatively. That it's sort of affected and negatively impacted how we do work around the hospital. That's just a general sense is that people are annoyed by it. That

Evidence to support CMOc 3	
	it's made getting, accessing resources, equipment, those types of things more challenging. And that's just what I hear from nursing colleagues." (interview 27, case 3, physician)

Process of Lean customization to context- positive and negative effects

CMOc 4: *The contract of the external consultancy leading Lean implementation ended (C), placing the continuation of Lean on internal senior leaders and unit managers (C). This led to a process of customization of Lean to local context, through a variety of ways (drop Lean language, less Lean activities, greater involvement of frontline staff). This customization of Lean and shift in implementation triggered positive and negative responses for frontline staff, unit managers and senior leaders (M). As a result, only some Lean efforts became embedded. However, there was variation and discrepancy between senior leaders and unit managers compared to frontline staff on perceptions of how embedded Lean efforts are and the degree to how much they support the continuation of Lean (O).*

In 2014, Lean implementation by the consultancy company ended and the continuation of Lean was placed on internal senior leaders and unit managers. This led to the process of Lean customization to local context. This process involved removal of the Lean Japanese language and a less stringent implementation of Lean activities and principles. There was a shift to better involve and engage frontline staff to lead Lean changes. Unit managers recognized staff involvement as an important factor for the normalization of Lean in everyday practice. This customization process was seen as a positive transition by unit managers. It removed Lean elements that did not resonate with staff. Unit managers believed that this would improve staff involvement, engagement and buy-in. Although it was recognized that

the word Lean had negative connotations for frontline staff buy-in, the customization of Lean to the local context did not make a difference to how Lean was perceived and supported by frontline staff. In contrast, customization actually led some participants to believe that Lean was no longer used or embedded in practice. There was a clear discrepancy between stakeholder groups across various levels of the system, in how much they felt Lean had become embedded in their everyday work and the degree to which they supported the continuation of Lean efforts. Quotes to support this CMOc are presented in Table 5.7.

Table 5.7 Evidence to support CMOc 4

Evidence to support CMOc 4	
Context	
Customization of Lean to the context	"I think now that the contract has moved away and we're not – [name of consultancy company] are not acting as the consultants for those events but we're actually having internal people that are running those. I would say that we're less sticky about that. Like we're not as sticky – we still use the tools but the terminology within the tools is not as stringent." (interview 16, case 2, unit manager).
Mechanism	
Driven by managers	"I think it's driven by our managers, that's why I see but I know that it's driven from above them as well, but I don't think it's driven by the ward nurses or the unit aides I think, you know our leader is saying you know, we're going to go this direction, we're going to do this, so. (interview 3, case 1, registered nurse)

Evidence to support CMOc 4	
Stringent Lean elements don't resonate with staff	"Yeah. I think taking a step back too I think when we initially started down kind of a Lean process stuff as a region, we were really focusing on kind of the terms and definitions of those types of things. And I think that didn't really resonate with staff, or some staff." (interview 16, case 2, unit manager) "The terminology, again, staff hated the terminology and it wasn't real to them. And so, I would often change phrases to stuff that made sense to them. And like one of them was like on the Gemba. They hated that phrase. They didn't get it." (interview 33, case 1, unit manager)
Recognition that staff need to be involved	"We know that staff need to be involved and we're much better at just figuring out how to involve them. And I think staff are expecting now to be involved. They're expecting to be asked." (interview 33, case 1, unit manager)
Outcomes (perceived)	
Buy- in is better with removal of external consultancy company	"Not knowing that everything we do is related to the Lean principles. And I think that's the change. Like everything isn't labelled Lean anymore, it's quality improvement. So, I think taking that lean [name of consultancy company] label away has helped with the buy in. (interview 22, case 3, unit manager)
Lean language no longer used	"Yeah, I feel like people don't just use the word Lean. They're not like 'oh, Lean is doing this to us and that to us' it's just these are the changes. So, people don't necessarily blame or label it as Lean. I think when I first came back, people were like, 'oh there's this Lean thing', and they were talking about it more now- or sorry, they were talking about it then in 2013 when I came back. But now I don't hear the

Evidence to support CMOc 4	
	word Lean ever, like ever, ever. (interview 3, case 1, registered nurse)
Degree that Lean is still on people's minds	"I feel like the terminology just even isn't used as much, and so it's not kind of in people's minds as much I don't think." (interview 5, case 1, clinical nurse educator)
Degree people think that Lean is embedded	"I think it's embedded on everyday work. And the nurses are seeing it. Whether they're labelling it as lean or not. (interview 22, case 3, unit manager) "Yeah and so because we've been so exposed to it and because we're working on current problems and we always have Children's Hospital in mind. We're always working towards that. So, it is really embedded in our day to day life. And it's just become a new way of doing things." (interview 33, case 1, unit manager)
Degree people support Lean	"I would support it. I think I'm one of those that drank the kool-aid in the beginning. There's so much of it that we do that we don't even think about anymore. So, I think that's part of it. I think I would support it for sure." (interview 18, case4, unit manager) ´I do support Lean, maybe in a modified way, it can be a struggle to get family involvement because the standards are so regimented, I mean for some of the RPIWs for family members to commit five eight hour days is very difficult, but that family voice is so important, so I don't think they should be so regimented for those reasons." (interview 35, parent from parent advisory group)

Shared values and sense-making processes for normalization

CMOc 5: *The context of early-stages of implementation (C), failed to trigger sense-making processes necessary for staff to understand Lean and potentially engage and begin to embed Lean into their practice (O). Shared values were evident between Lean principles and staffs' professional values as healthcare providers. However, value congruency without clear sense-making processes resulted in lack of adoption of Lean behaviours as part of normalized frontline practice. Sense-making processes were hindered by a failure of initial Lean training efforts to translate the principles of Lean into the context of healthcare that would resonate with staff (M). Lean language and the lack of staff involvement in Lean changes also hindered sense-making processes and feelings of engagement. This resulted in negative perceptions of Lean, a lack of buy in and support for the continuation of Lean from frontline staff (O).*

The continuation of Lean efforts and the normalization of Lean in every day practice relied on how staff 'made sense' of Lean and whether the values of Lean aligned with their own personal and/or professional values. These were core mechanisms to the sustainability of Lean that were important from early stages of Lean implementation. Lean values of efficiency, patient safety, and waste reduction were congruent with participants' professional values as healthcare providers. However, Lean training failed to translate how the principles of Lean aligned with the context of healthcare. Sense-making by frontline staff was hindered by a) the implementation approach used (top-down, use of an external consultancy firm), b) the Lean training received by the consultancy company and c) the type of Lean messaging by media and the consultancy company. It is important to note that this was not the case for the unit managers, who supported the continuation of Lean. Quotes to support this CMO configuration are presented in Table 5.8.

Table 5.8 Evidence to support CMOc 5

Evidence to support CMOc 5	
Contexts	
External consultancy company's implementation approach and training	"I don't know if that Kaizen basics, I feel, like it wasn't a good use of the health regions money. Because they're paying me almost $40 an hour to sit there and watch a car-processing line and then, for the person to not actually be able to answer the difficult questions." (interview 7, case 3, respiratory therapist) "It was externally sort of put on people, rather than asking them if there were elements of this model that were workable in their work environment. (interview 20, case 3, clinical nurse educator)
Mechanisms	
Degree of shared values	"It does, yeah definitely, as a nurse I want to be prepared, I want to have supplies ready, I want to have, like when we go into a room I want to have everything I need, I want to kind of know, you know, the important information about that patient, I want to, I want to be organized, you know, I want to know where my stuff is, supplies are, where everything is right off the bat. I want to, yeah, like it definitely as a core, as a nurse, I definitely can see the benefits of it and the same values, in most ways." (interview 2, case 1, registered nurse)
Degree of sense-making	"It was at first difficult for me to understand why we were taking a business model that is strictly business and applying it to a service field. But the more I looked at it, I did realize that there were some benefits that we could definitely take out of that as far as Kanban and that kind of

Evidence to support CMOc 5	
	stuff. I guess less waste. It's probably the main benefit. But I do think it's difficult to take a business model and really apply it to a service industry. (interview 19, case 1, unit manager)
Lack of involvement and sense-making	"I think it kind of comes back to your other question. I think it's got to be cross-disciplinary in the sense that if you are going to institute system change it's got to involve all the system's players. And so maybe part of my ignorance is just a reflection of the fact that not everybody is included in sort of an understanding of what the goals are as a system." (interview 27, case 3, physician)
Engagement and sense-making	"Okay, why doesn't it stick? Well, staff engagement has got to be there. That's a big one. And even getting staff to volunteer for this RPIW that we just did, I had to talk about it at huddle every day, every day, every day, every day to get- I wanted two people from each level of nursing. We have different levels of nursing in the unit. And even then, like some of them weren't engaged. They still didn't really know what they were doing. But you know, I make it interesting. We were talking about patient flow in the new facility. And then once they got engaged in it they thought this is really cool and they liked it. And they're like, "If we ever do anything like this again, I want to be involved in it." (interview 18, case 4, unit manager)
Outcomes	
Embedded changes, unsure if due to Lean	"Yes. They've made a new system. Again, I don't know if it's stemming from the lean. But we talk about safety every morning at our wall walks and huddles for the pediatric ward. And they of course just the bedside nursing staff or charge nurses don't always know and hear

Evidence to support CMOc 5	
	what's going on in the other units as we don't need to know either. But the managers are doing that and it's being reported up higher and keeping closer tabs on it. So yes, I think safety reporting is actually coming out." (interview 25, case 4, registered nurse)
Degree of support for Lean	"You know not very strongly actually. I would say medium. I can see in some areas that it would be beneficial (interview 28, case 2, registered nurse) I think that the whole general philosophy that people have about Lean nobody would ever give credit to Lean because they're just so – like the whole dogma is like "Oh that was such a waste of time." But I think if you really look at it there were some good things that came from it just nobody would ever want to give credit to Lean." (interview 29, case 2, registered nurse)

Discussion

'Ripple-effect'

The 'ripple-effect' is based on the idea that a program (Lean) is a series of "*events in the history of a system, leading to the evolution of new structures of interaction and new shared meanings*."[44(pp267)] The 'ripple-effect' in our research shows the causal relationship between Lean implementation and sustainability, and how implementation processes and outcomes shape sustainability. Our realist interviews primarily illustrate how implementation outcomes (e.g., resistance, lack of customization to context and negative perceptions), nature of implementation (e.g., training that did not connect the meaning of Lean to healthcare,

external Lean consultants that were not from healthcare), and the implementation approach (e.g., mandated top-down approach) shape the contexts (resistance, lack of customization and negative perceptions and variation in Lean training and exposure); mechanisms (e.g., degree of sense-making, staff engagement, awareness); and outcomes (e.g., degree of support, continuation and normalization) for the sustainability of Lean efforts.

Our findings also highlight incongruence between leadership (i.e., senior leaders and unit managers) versus frontline healthcare providers in relation to the degree of normalization and continued support of Lean. Similar to recent research findings by Goodridge et al.[45], our research revealed that major gaps remain in the normalization and sustainment of Lean efforts into everyday practice, particularly among frontline staff. For the purposes of this discussion, we would like to focus on four key points that have influenced the normalization process in our research findings:

1. The use, approach and effect of an external consultancy company to lead early-stages of implementation
2. The importance of customization to context
3. The importance of shared values, sense- making and engagement for normalization
4. The interface of Lean along the hierarchical structures of healthcare and the resulting incongruence between leadership and frontline staff.

The use, approach and effect of an external consultancy to lead early-stages of implementation

In our research, the use of an external consultancy company to lead implementation was primarily perceived negatively, as an outsider that did not understand healthcare. Concern

about the cost of the consultancy company was also raised. Over $19 million Canadian dollars (CAD) in consulting fees were paid for a 2-year term[34] with a total annual cost over $23 million CAD for Lean in Saskatchewan (2012–2014).[34] There is variation about whether top-down large-scale transformations or bottom-up, small-scale incremental improvements are more effective.[8, 46, 47, 48] Braithwaite[48] argues that complex systems, such as healthcare, will not change because one mandates a solution. Instead, complex systems adapt overtime to suit their own norms, values, practices and contexts.[49] Our research confirms an adaptation over time but begs the question: how much adaption is acceptable in order to determine if Lean efforts are sustained?

Training and messaging by the consultancy company, as an implementation approach, had negative effects for some participants. The early-stages of implementation focused on senior leadership capacity building, through Lean leadership training. The focus on senior leadership resulted in an unintended negative consequence, that frontline staff did not feel involved and instead felt pressured to adopt Lean. Yet staff engagement is critical to the success of adoption.[8, 46] A recent study on the implementation process of Lean in Saskatchewan[45] found that those with Lean leadership training, were more likely to see potential in the value of Lean and support the use of Lean for their work. Another study demonstrated that hospitals using expert Lean consultants led to greater progress than those that employed generalist consultants.[8] The consultants in Saskatchewan were Lean experts, however their approach to implementation and external role were perceived as barriers to buy-in.

The nature and type of Lean training and participation in Lean activities has implications for the extent of normalization. Though training and resources are important to

any implementation of organizational change, [31] simply receiving training is not sufficient. Our findings show that the nature and approach of the training and resources used are critical to change. Training needs to involve and engage participants and closely emulate the local environment.[50] The most efficacious training is tailored to context, the target audience and based on evidence and feedback.[50-53] Our findings highlighted that initial training failed to demonstrate a connection between Lean and healthcare which triggered negative perceptions and resistance to Lean. This shows that perhaps it is not the mode of delivery that needs consideration but the messaging used during training.

In contrast to the above findings, senior leadership noted that without the use of a consultancy company and a mandated top-down implementation approach, changes may not have occurred or occurred at a much slower pace. Contrary to our findings, Fine[54] suggested that Lean engages frontline staff, in the sense that staff develop and make the changes. This poses the question of whether a top-down implementation approach and use of a consultancy company contributed to the lack of staff engagement in our research context. As discussed by Braithwaite[48] people resist change that is imposed by others and that mandated change is never given the same weight as clinically driven change.

The importance of customization to context

Similar to our realist review findings, the degree to which mechanisms occurred was influenced by external pressures to use Lean,[55] the complexity of care processes,[8] the fit between Lean and local context;[8, 55] and other competing needs or demands,[56] such as the constant change in healthcare environments. Early stages of implementation led by the consultancy company failed to customize Lean to local contexts, this triggered some pitfalls to the normalization of Lean in practice (e.g., feelings of disconnect, negative perceptions, resistance to Lean and a lack of support for Lean).

The constant change and "innovation fatigue" experienced by participants was one critical contextual factor. Similar to other findings, this can result in Lean being considered another "fashion fad" or "flavor of the month,"[54] that can lead to potential negative effects on adoption. Complexity was also raised as an important contextual factor, which can affect adoption and normalization.[49, 53] A failure to understand how and why the complexity of context influences the process of normalization will impact the use and sustainability of Lean in healthcare.[57-60] Our findings supplement the existing argument that it cannot be assumed that the translation of Lean from manufacturing to healthcare without consideration of context will offer the same benefits as achieved by Toyota.[16, 55]

It is well supported that context is critical to the degree of success in the implementation of large-scale interventions.[61-64] Contextual factors can have a direct effect on the uptake and outcomes of interventions.[62, 63] Complex interventions that struggle to integrate into existing contexts are unlikely to be normalized.[53] It is also important to note differences in terms of macro level (system) contexts. Examples of successful Lean implementations in

health systems across America (e.g., Virginia Mason, Seattle Children's Hospital) may prove different in the context of Canadian healthcare where funding models, insurance models, and governance are different.

Waring and Bishop[19] suggest that Lean is likely to be adapted to ensure it fits with the contexts for clinical practice. The process of customization to existing contexts may facilitate the normalization of interventions,[65] such as Lean. In the context of our research study, when the consultancy company contract ended this led to a process of customization to the context. However, despite this shift from overt Lean implementation to implicit implementation, there was still variation to the degree to which people supported the continuation of Lean. There was clear discrepancy between leadership and frontline staff perceptions on how much they supported the continuation of Lean. This poses questions around the process and timing of customization to context, the degree of influence of early-stages of implementation on sustainability and the influence of organizational hierarchical structures on sustainability.

The importance of shared values, sense- making and engagement for normalization

In addition to a receptive context, Greenhalgh et al.[66] argued there also needs to be a good fit between the program being implemented and the needs and values of the potential adopters. The degree that staff values an intervention or program from early-stages of implementation is associated with the degree of effective adoption.[67-69] In our findings, the nature of the Lean training, poor knowledge translation strategies (e.g., education, training, audit and feedback) and external Lean consultants hindered frontline staff engagement and sense-making. Our realist review found that the more people value the change being implemented the more likely they will engage in the implementation efforts.[70] However, our

realist interviews showed that despite shared values with Lean (e.g., patient safety, efficiency, waste reduction), normalization did not occur due to failed sense-making processes from early-stages of implementation. These issues make Lean implementation a highly contested process.[19, 71]

To facilitate normalization, it is necessary to appeal to the values and reasoning of potential adopters.[71] Fine et al.[54] argue that those who truly make sense of Lean will see its value for their work and subsequently begin to apply it. This study describes the idea of the "tipping point" where leaders no longer had to "push" Lean ideas out to staff. Instead, staff "pull" Lean and demand it for themselves [54(pp 34)] It appears this was the intention in Saskatchewan, when there was the shift in the implementation approach. However, reflecting on our findings, it seems the "tipping-point" has not come to fruition yet. Sense-making about Lean may occur during early stages of implementation but is equally as important to maintain for the normalization and sustainability of Lean efforts. Another pitfall in our findings that affected sense-making processes was the ways in which Lean was messaged, the lack of "stickiness" to the Lean messaging used, in other words the lack of natural appeal for frontline staff.[72, 73] The concept of "stickiness" is required for effective messaging and uptake.

Our findings also demonstrated that frontline staff engagement was hindered by poor messaging, lack of sense-making processes and the implementation approach used. Engagement of nurses has already been found to be an issue with regards to Lean implementation in Saskatchewan. In 2014, a survey conducted by the Saskatchewan Union of Nurses[73] found a statistically significant negative effect of Lean on nurse engagement. Physician involvement is also widely addressed as a critical factor to implementation and QI success.[74-75] Our study had limited physician participation, the reasoning for poor

participation is unknown yet mirrors previous work on Lean implementation in Saskatchewan.[45] Future research that solely focuses on physician perspectives on the Saskatchewan Lean management system would be valuable.

Misunderstandings of Lean also creates staff disengagement.[76] Misunderstandings may be triggered from the overuse of 'Japanese' Lean language that does not resonate with all health professionals. Several studies have reported that the conceptualization of Lean in healthcare is unclear and varied[1, 76-79] and may be conceptually challenging for staff.[17, 63] Another issue is the blending of several QI methodologies with Lean, without clear definitions. This makes it difficult to differentiate Lean from other approaches and thus it is hard to evaluate what successes or failures are attributed to Lean or not. There needs to be more consistent and standardized conceptualizations of Lean and clearer differentiations between QI approaches in order to distinguish Lean from other QI approaches. This duty should be a collaborative role of research and leaders in healthcare improvement. These findings compare with existing change management evidence. For example, the PROSCI ADKAR Model[80] outlines five outcomes that an individual must achieve for change to be successful: awareness of the reasons for change**,** desire to engage in the change, knowledge about how to change as a result of training, ability to implement the change, and reinforcement to ensure change sticks.

The interface of Lean along the hierarchical structures of healthcare

There were ample differences in interview responses between leadership and frontline staff. Frontline staff portrayed more negative perceptions of Lean in comparison to their unit managers or senior leaders. Similarly, a recent survey on Lean implementation processes in

Saskatchewan using NPT[27] found that respondents in leadership positions were much more likely to view Lean implementation and outcomes positively. The results of this survey also found wide variation between the perspectives of leaders and frontline staff regarding the NPT constructs of coherence, cognitive participation and reflexive monitoring.[27] This survey illustrated issues around staff familiarity with Lean principles and activities and perspectives that Lean is not currently a part of their work.[28] It appears that part of these issues are a result of the silo and hierarchical nature of healthcare.[81, 82] This idea of the interface of Lean along the hierarchical structures of healthcare and the impact of professional role status along that hierarchy on the success of Lean implementation requires further exploration. These structures and roles in healthcare may impede the ability to achieve alignment from senior leadership to frontline staff.[83] Alignment is the consistency of plans, visions, resources, actions and results to support system-wide goals.[83] Clear accountability structures and integration are needed for system-wide alignment. Furthermore, cultural transformation of the organization must be secured alongside procedural and structural changes in order to deliver and sustain desired improvements.[84] Our findings did show a failure of integration across the organization. Previous work has recognized the hierarchical nature of healthcare and professional silos as a barrier to Lean success.[85] The term organizational democracy, such as a multi-professional collective perspective has been noted as significant to Lean management styles for successful adoption.[79] However it remains unclear how to achieve such changes in highly entrenched hierarchical systems.

Conclusions

Ripple-effect

Our research demonstrates a 'ripple-effect', that is a causal link between implementation and sustainability. Specifically, our findings highlighted how certain outcomes at implementation serve as contexts for sustainability or failed sustainment. For example, early –stages of implementation were mandated and used an external consultancy company. This company was not from healthcare and not from Canada. The context of Lean implementation and this external consultancy company had many negative effects that led to implementation outcomes of resistance. This outcome had a 'ripple-effect', serving as hindering contexts for sustainability. Thus, contextual and early-stage implementation factors facilitate or hinder and have a causal link to sustainability. Sustainability is hinged on the degree of success at early-stages of implementation.

In addition to the impact of the use of an external consultancy on sustainability, we identified sense-making and engagement as critical mechanisms to sustainability. Failure to trigger sense-making at initial implementation can have negative effects on engagement and buy-in. Sense-making is facilitated or hindered by certain messaging, training and language used during initial stages of implementation. The degree of sense-making and engagement by staff at early-stages of implementation had a ripple-effect on sustainability. The less people engage or make sense of Lean the less likely it will be sustained in everyday practice.

The interface of Lean with the hierarchical structures and professional silos of healthcare also play a role to the degree of normalization of Lean. The traditional hierarchical structures and silos in healthcare may impede the ability to achieve alignment from senior leadership to frontline staff and thus hinder the likelihood of embedding Lean in everyday

practice. These structures can hinder engagement, distributed leadership and frontline staff empowerment, key elements for sustaining organizational change.

The customization of Lean to context was also critical to the degree of sustainability. Context is already known to have a direct effect on the uptake and outcomes of interventions. However there remains knowledge gaps and questions about the timing of and approach to customization and requires further exploration.

We hope that this research, illuminating the 'ripple-effect' of implementation to sustainability and the influence of the implementation approach used and sense-making processes on engagement and normalization, can inspire new ideas for sustaining complex interventions in healthcare.

Sustainability

Our research also identified challenges to evaluating sustainability of complex interventions. There is variation in the literature on the conceptualization of sustainability, measurements and outcomes of sustainability. We recognize like others that there is a need for the development and pilot testing of theoretical frameworks and tools to evaluate the sustainability of complex interventions in healthcare. Without such guidance, it is difficult to develop a science on the sustainability of QI efforts and complex interventions in healthcare. Further work using other methods is needed to examine and further test the mechanisms identified in our realist evaluation in other contexts for theory development and to identify predictors of sustainability.

List of abbreviations

Quality improvement (QI), National Health Services Sustainability Model (NHS SM), Context + Mechanism = Outcome configuration (CMOc), Normalization Process Theory (NPT), Kaizen Promotion Offices (KPOs)

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Chapter 6. Summary, Conclusions and Recommendations

Introduction

In this concluding chapter, I provide a road map of my dissertation and the resulting four papers. I discuss the knowledge contributions that emerged from the four papers in relation to sustainability research, improvement and implementation science. I describe associated strengths and limitations of this dissertation. I also discuss the relevance of this dissertation to nursing, research, practice and policy. I conclude by highlighting how I will build upon this doctoral work for my future program of research.

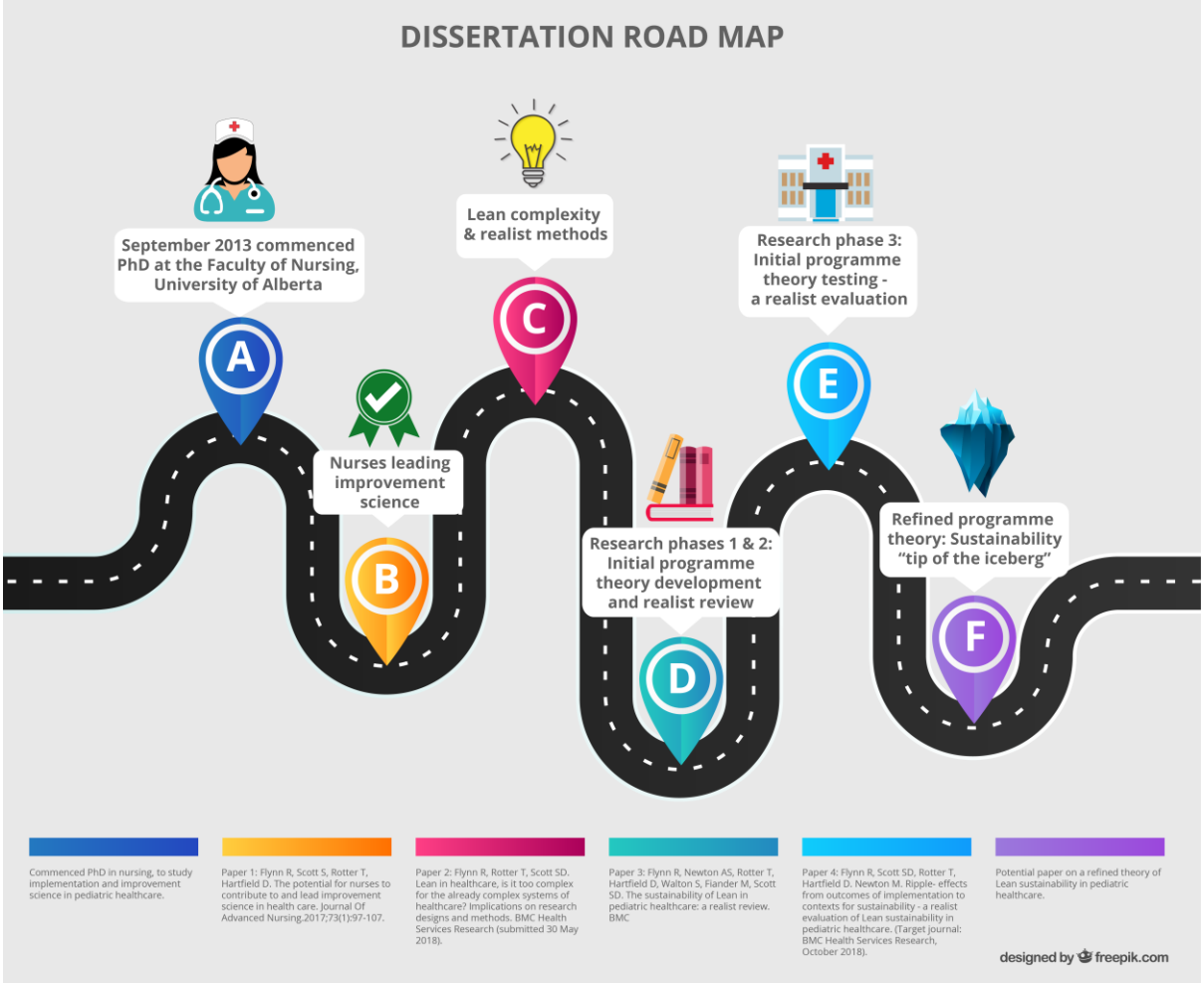
Road map of my dissertation

My dissertation used a realist approach to develop, test and refine a program theory on Lean sustainability in pediatric healthcare. Specifically, I explored key mechanisms and contexts that triggered the sustainability of Lean, a complex intervention for healthcare improvement. The purpose of my dissertation was to:

a) Develop a program theory on Lean sustainability in healthcare;
b) Further refine this program theory through a realist synthesis of existing literature on Lean sustainability in the contexts of pediatric healthcare;
c) Test whether the program theory reflects reality, through realist interviews in multiple pediatric units involved in a system-wide Lean transformation;
d) Suggest how the program theory for this complex intervention might be refined.

The road map of my dissertation research and subsequent outputs is outlined in Figure 6.1.

Figure 6.1 Dissertation road map



Following the first step of the realist evaluation cycle [1] I developed an initial program theory map, and seven mapping context (C) + mechanism (M) = outcome (O) configurations (CMOcs)[1] on Lean sustainability in healthcare. In the development of this initial program theory I drew upon Normalization Process Theory (NPT),[2-4] the National Health Services (NHS) Sustainability Model (SM)[5, 6] and a logical model on the Saskatchewan Lean management system.[7] This initial program theory provided a detailed picture of how Lean is expected to work, in particular, how Lean efforts become sustained. It depicted that Lean is a complex intervention implemented to a complex adaptive system (healthcare) across multiple

levels of a system (micro, meso, and macro) to multiple stakeholders (organizational leaders, clinical leaders, and frontline staff). The seven initial CMO hypotheses (appendix 2) were categorized, according to these elements.

From this initial program theory, I conducted a realist review of Lean sustainability in the pediatric healthcare literature (chapter 4). The purpose of the realist synthesis was to further refine our initial program theory based on pediatric literature. The CMOcs from phase 1 were used as a heuristic to guide synthesis. Realist reviews are useful to synthesize the evidence of complex interventions, to unpack the complexities, contexts and mechanisms of an intervention.[8] The focus of a realist review is to unpack underlying program theories and then to examine existing evidence to see if the theories are pertinent or not.[9, 10] The search strategy was multi-pronged, iterative and purposeful in nature, including database, grey literature and citation searching. I also contacted three organizations known to implement Lean in healthcare settings: Saskatoon Children's Hospital, Cincinnati Children's hospital and Virgina Mason. Details on screening, extraction and synthesis are provided in chapter four. A total of eleven documents were included in the realist review. The findings resulted in five CMOcs on sense-making and value; staff engagement and empowerment, at the organizational, clinical leadership level and frontline healthcare provider level and a ripple-effect from implementation to sustainability (Table 6.1) This resulted in a 2nd iteration of the initial program theory.

Table 6.1 Refined CMOcs from realist review findings

Refined CMOCcs from realist review findings
CMOc 1: If the values of organizational leaders are congruent with Lean philosophy, and leaders receive Lean leadership training (C), then organizational leaders are more likely to make-sense of, appreciate, and feel motivated to implement Lean (M), in turn they become Lean messengers, promoting Lean philosophy to clinical leaders of the organization (O).
CMOc 2: If there is congruency between Lean philosophy and the personal-level reasoning of the clinical leaders and front-line healthcare providers, and clinical leaders and frontline healthcare providers receive Lean leadership training (C), then Lean is more likely to make sense and fit within the context (M), in turn motivating clinical leaders to become Lean messengers, promoting Lean philosophy to frontline staff (O).
CMOc 3: If contexts exist where staff are engaged, have received Lean training and the opportunity to lead Lean efforts (C), then staff are more likely to become empowered to use Lean (M), and can then see beneficial outcomes from Lean, have improved satisfaction leading to increased sustained use of Lean efforts (O).
CMOc 4: If there are contexts where there are visible benefits from Lean implementation, and a collaborative multi-disciplinary team approach to Lean implementation, with audit and feedback of changes (C), this triggers staff motivation and empowerment to sustain Lean efforts (M), then Lean efforts become integrated and sustained in practice (O).
CMOc 5: Outcomes of Lean implementation served as facilitating contexts for subsequent stages of sustainability ($C^1M^1O^1$ --> $C^2M^2O^2$).[11] This concept of a 'ripple-effect' was substantiated where staff engagement was an outcome at implementation, in turn a context for sustainability, which triggered mechanisms of staff empowerment and outcomes of sustained Lean efforts.

Following from phase 2, I conducted a realist evaluation using case study design (chapter 5), to test if the hypothesized and refined CMOcs from research phases 1and 2 were relevant in practice, across different pediatric contexts. I conducted qualitative realist interviews[12] with participants from multiple stakeholder groups to gain a diverse perspective on my program theory. Realist interviews are conducted to make inferences about a phenomenon and test them against additional data.[13] Specifically, I evaluated how contextual factors, implementation processes and intervention resources triggered different mechanisms (i.e., sense-making or coherence, value congruency engagement, collective action) that led to behavior change and the sustained normalization of Lean efforts into everyday practice. This phase of the research resulted in five CMOcs presented in Table 6.2

Table 6.2 Refined CMOcs from realist interview findings

Refined CMOcs from realist interview findings
'Ripple- effect': The funded, mandated, top-down, externally led nature of Lean implementation **CMOc 1:** The early stages of Lean implementation were funded, mandated, and top-down in nature (C), driven by an external consultancy firm that initially focused on training senior leadership (C). Frontline staff did not feel involved in Lean changes, and they felt pressured to adopt Lean (M). The lean language used did not make sense to staff (M). Training failed to demonstrate a connection between Lean and healthcare, this led to misunderstandings and negative perceptions of Lean. There was a resistance to Lean, a lack of support for Lean and potential staff retention issues (O) which had a 'ripple-effect' on contexts for sustainability.
Lack of fit between Lean and healthcare and a lack of customization to context **CMOc 2:** The complexity and dynamic nature of healthcare and the unique needs of pediatric patients (C), was perceived as incongruent with the nature of Lean. The translation of Lean to patient care did not make sense for many staff and Lean efforts felt impersonal.

Refined CMOcs from realist interview findings
Lean training failed to make the connection between Lean and healthcare clear for staff (M) and early stages of implementation led by the consultancy company failed to customize Lean to the local context, this triggered pitfalls to the success of Lean, such as feelings of disconnect and negative perceptions of Lean (M), resulting in a resistance and a lack of support for Lean continuation (O).
Rapidly evolving healthcare contexts overtime – "innovation fatigue" **CMOc 3:** Lean was implemented in areas that experience constant change (C), early-stages of implementation involved a large number of Lean events for training purposes (C), frontline staff felt overwhelmed from the constant change, they were unsure what changes were due to Lean and felt that Lean was the latest fad (M), this led to negative perceptions of Lean, resistance and lack of support by frontline staff (O).
Process of Lean customization to context- positive and negative effects **CMOc 4:** The contract of the external consultancy leading Lean implementation ended (C), placing the continuation of Lean on internal senior leaders and unit managers (C). This led to a process of customization of Lean to local context, through a variety of ways (drop Lean language, less Lean activities, greater involvement of frontline staff). This customization of Lean and shift in implementation triggered positive and negative responses for frontline staff, unit managers and senior leaders (M). As a result, only some Lean efforts became embedded. However, there was variation and discrepancy between senior leaders and unit managers compared to frontline staff on perceptions of how embedded Lean efforts are and the degree to how much they support the continuation of Lean (O).
Shared values and sense-making processes for normalization **CMOc 5:** The context of early-stages of implementation (C), failed to trigger sense-making processes necessary for staff to understand Lean and potentially engage and begin to embed Lean into their practice (O). Shared values were evident between Lean principles and staff professional values as healthcare providers. However, value congruency without clear sense-making processes resulted in lack of adoption of Lean behaviours as part of normalized frontline practice. Sense-making processes were hindered by a failure of initial Lean training efforts to translate the principles of Lean into the context of healthcare that would resonate with staff (M). Lean language and the lack of staff involvement in Lean

Refined CMOcs from realist interview findings
changes also hindered sense-making processes and feelings of engagement. This resulted in negative perceptions of Lean, a lack of buy in and support for the continuation of Lean from frontline staff (O).

The findings from chapter 5 depicted the complex nature to sustaining Lean efforts and the differences in the perceptions and degrees of adoption across the hierarchy of the organization (i.e., frontline healthcare providers versus management). Findings also demonstrated how the approach and nature of implementation influenced people's perceptions of Lean. Implementation outcomes subsequently shaped contexts for sustainability (i.e., resistance as an outcome at implementation becomes a hindering context for sustainability efforts). The customization of Lean was also critical to the sustainability of Lean efforts, interestingly for some participants they thought Lean was no longer happening, however managers said Lean was embedded but that not all staff were aware of what changes had occurred as a result of Lean. Unit managers and senior leaders stated that it did not matter to them if staff knew whether changes were a result of Lean or not, what mattered was that ways of thinking had shifted to doing and leading quality improvement work.

Refined program theory refinement

In this chapter, to close the loop of the realist evaluation, I provide the refined program theory. This final iteration is based on the integration of findings from each research phase. The process of integration involved taking the refined CMOcs from each phase and bringing them together to form a refined program theory. This process involved going back and forth from the initial program theory to the findings from each phase and examining the most

substantiated CMOcs. I present this refined program theory using the 'tip of the iceberg' metaphor, described as "a small, often unrepresentative portion of something much larger or more complex that cannot yet be seen or understood."[14] (Figure 6.2).

The purpose of the 'tip of the iceberg' visual is to portray the complexities, observable and unobservable contextual factors, resources and reasoning's' that trigger Lean efforts becoming sustained in practice. The outcome in this visual is the ideal scenario that positive behavior change occurs, and Lean efforts are embedded.

Figure 6.2 Refined program theory: sustainability "tip of the iceberg"

Now I draw on the work of others that explain some of the research findings. As suggested by Clark et al.[15] outcomes were generated by dynamic interactions between components of the intervention, implementation processes, with aspects of context and a wide range of other potentially influential and unpredictable factors. Similarly, my findings demonstrate that the adoption and sustainability of Lean efforts in practice was very different for different people. This was a result of participants' professional roles on the hierarchy of the health system. Lean efforts were more embedded in the minds and hands of senior leaders and unit managers rather than frontline healthcare providers. The research also showed that Lean may be embedded in one setting and not in another due to a multitude of factors that may be unpredictable and/or unobservable.

Van de Ven's work on the central problems in the management of innovation[16] provides some explanations for my research findings. This work discusses four central problems in the management of innovation: developing ideas into good currency, managing attention, part-whole relationships, and institutional leadership. My research offers some insight into understanding these issues, specifically my work deals with the social processes by which people become invested or not in an innovation and push them into good currency. Elements from Diffusion of Innovation theory[17] also provide potential explanations, in particular the five factors that influence adoption: Relative advantage - the degree to which an innovation is seen as better than the idea, program, or product it replaces; compatibility - how consistent the innovation is with the values, experiences, and needs of the potential adopters; complexity - how difficult the innovation is to understand and/or use; trialability - the extent to which the innovation can be tested or experimented with before a commitment to adopt is made and; observability - the extent to which the innovation provides tangible results. It is

evident from the findings in chapter 5 that there were discrepancies in how consistent Lean was with the values of adopters and how complexity negatively influenced sense-making process.

The NHS SM[5, 6] served as an appropriate middle-range theory to identify and explain contextual factors that influence the likelihood of Lean sustainability. Factors such as staff involvement and training to sustain the process, staff attitudes towards sustaining the change, credibility and adaptability. NPT[2-4] served as an appropriate middle-range theory to identify and explain mechanisms of change and provided an explanatory model of the normalization of Lean in everyday practice. As identified processes of individual and communal sense-making (coherence), degree of cognitive participation and collective action influence the degree to which Lean efforts are embedded. The logical model was helpful to show infrastructure for implementation, Lean activities and the intended outcomes of the Saskatchewan Lean Management System; however, it did not address the complexity of translating Lean to healthcare or provide explanations of what works, for whom, in what respects, to what extent, in what contexts, and how?

In the following section, I discuss other evidence gaps uncovered from my dissertation work, and the relevance of my research to implementation science, nursing and improvement science.

Other evidence gaps uncovered

This doctoral work uncovered two evidence gaps in need of future research:

a) The conceptualization and measurement of sustainability; and
b) The effects of the complexity of the intervention and context on sustainability.

Conceptualization and measurement of sustainability

The findings from phase 2 identified variation as to how sustainability was defined and measured. Outcome measurements were not widely reported and the description on sustainability was poor, primarily consisting of descriptive and experiential accounts. None of the documents in this review were underpinned by a sustainability theoretical framework, model or measurement tool. One important outcome of this research is the need for future empirical work on the conceptualization and measurement of sustainability. Implementation science has seen growth over the past 40 years on theory, implementation or knowledge translation strategies, barriers and facilitators to implementation, design and evaluation of implementation. However, there is a recognized need for future research and evidence on the sustainability, scale-up and spread of interventions. There is a lack of conceptual models and frameworks on sustainability,[18, 19] a recognized priority but challenging area for future research, where it is unknown if the predictors of implementation and sustainability are the same or different from each other.[18]

Findings from phase 2, demonstrated that sustainability was not an exclusive focus in the documents included in this review. Rather, it was an evaluation aspect of successful Lean implementation. Typically, sustainability was referred to as a 'point of time' or through process, performance and clinical outcome measures to Lean sustainability. This echoes Greenhalgh and colleagues[20] who suggested that there is a shortage of studies which focus on the sustainability of complex service innovations. Understanding how to address issues of sustainability has been described as "one of the most significant translational research problems of our time."[20] There is a paucity of empirical research to better understand sustainability and to design improved implementation strategies to increase the likelihood that short-term healthcare improvement successes will be sustained.[21, 22]

Complexity

My research also identified the need to consider the complexity of interventions and contexts in which interventions are implemented for evaluation research. An intervention cannot be implemented or bring about sustained improvement without the sufficient knowledge on how the complexity of the healthcare system influences its success.[23] A failure to understand how and why these factors influence Lean implementation will impact its use in healthcare. Paper 2 (chapter 3) of my dissertation was driven by the question: Lean in healthcare, is it too complex for the already complex systems of healthcare? My thinking that underpinned this question and paper was that previous research and knowledge gathered on Lean in healthcare has not employed rigorous research designs and methods that capture both the complexity of the intervention and the context. This failure results in uncertainty as to whether Lean works for healthcare or not. The organizational structure of the healthcare system may inhibit Lean implementation by healthcare providers and managers.[24] The significance of the influence of context to successful implementation is well recognized.[25-29] There are key social, cultural and environmental factors that facilitate or hinder implementing practice change.[30] However in the true intention of Lean implementation to healthcare the complexity of the context was not considered. A realist philosophy of science and realist methods adequately reflect complexity.[31-33] My dissertation work in paper 2 (chapter 3), identified the need for greater attention to complexity in sustainability evaluation research.

Relevance to implementation science

The field of Implementation Science seeks to understand ways to improve the uptake of complex health interventions in healthcare.[34] As this science has matured researchers have

recognized that the implementation of interventions, which often requires substantial resources, is meaningless without long-term sustainability efforts.[35] Policy makers and other stakeholders are increasingly concerned with the long-term viability and impact of such investments.[19] Sustainability is a key implementation outcome, yet remains one of the least understood issues for implementation research.[18] There is a lack of consensus on the conceptualization of sustainability, and timing to evaluate sustainability outcomes. My work contributes to the planning and design of sustainability evaluations and for the future development of strategies to sustain effective healthcare improvement interventions. My work also adds to the existing evidence base on organizational context and the importance of customization or tailoring to context, well-established findings in implementation science research.

Relevance to nursing and improvement science

The opening paper to my dissertation frames the overarching impetus for this doctoral research and my passion for health systems quality improvement and nursing. The purpose of this paper was to show that nurses have the potential to significantly contribute to and to lead in the field of improvement science in healthcare.[36] Nurses are at the forefront of any healthcare system and are essential to any system of healthcare. Nurses are ideally positioned in the healthcare system to examine and understand the environment, to identify the strengths and weaknesses of healthcare systems, and to identify the key elements needed for improvement science in healthcare.[36] This paper argues how the philosophical, theoretical, ethical and political positions that underpin the nursing discipline and profession can enable nurses' ability to contribute to and lead improvement science. The paper also demonstrates areas that require change to enable nursing to fully contribute to and lead in improvement

science: a). the inclusion of improvement science education in nursing programs; and b). the increase of advanced nursing roles, such as nurse clinician scientists in healthcare improvement science. I hope that my pursuit of QI evaluation research will contribute to nurse leadership in this field.

Implications for Research

My dissertation findings have several implications for research. Firstly, my work is timely because it directly responds to the current emphasis and call for research on sustainability of interventions.[18-22] My findings illustrate potential determinants of sustainability and factors that affect sustainability through the CMO realist heuristic. My work also contributes to advancing methods for sustainability research through application of realist approaches to study this phenomenon.

Secondly, realist methods address how and why an intervention works or not under what contexts, realist evaluations provide causal explanations. My work contributes to process evaluations on the barriers and facilitators to the implementation of an intervention. Realist methods provide underlying causal explanations. Papers 2, 3, and 4 (chapters 3, 4, and 5), demonstrate the value of realist methods to capture the complexity of an intervention and the context in which it is implemented. This may have implications for future research on complex interventions for healthcare improvement.

Finally, the refined program theory provides CMOcs that can be tested in future work and can be built upon in the quest to understand determinants and predictors of sustainability. This dissertation provides a refined program theory that can be further tested and refined across different contexts and other complex interventions. It is unknown if these research findings would be similar in different healthcare contexts (e.g., adult acute care). Potential

future research would be to test the refined program theory in such settings. This would contribute to layering and refining our program theory to a middle-range theory. This work can help to address a key question on whether implementation and sustainability have different predictors and require different theoretical frameworks.[18] Findings from my research phases showed a causal link from implementation to sustainability and illustrate the need for deeper examination into this 'ripple-effect.' As outlined by Pawson and Tilley [1] my dissertation work is not intended for generalization but can be used for theory accumulation in future evaluation work.

Finally, this research provides a sense of potential future research on the conceptualization and measurement of sustainability for health services evaluation research. The findings in phase 2 (chapter 4) demonstrated poor conceptualization and measurement of sustainability in the Lean literature and wider health services literature. Each phase of my research highlighted the use of NHS SM and NPT to understand sustainability from a social process lens, which may also aid future research from this perspective.

Implications for Practice and policy

This dissertation has implications for both practitioners and policy makers. For practitioners who are involved in supporting Lean implementation efforts (e.g., senior leaders, unit managers, educators) this study begins to identify ways in which pre-existing contexts influence the manner in which people respond to the intervention. My findings provide important insights into factors that led to resistance, this can offer potential areas for practitioners to better support implementation efforts on-the-ground. For example, it may be that implementation training is championed by someone local to the context that can connect Lean principles to patient centred care. In addition, having an audit and feedback system in

place that could overcome issues around lack of follow up and feelings that Lean is a "waste of time."

These findings may also provide guidance for policymakers driving Lean implementation and transformation of the Saskatchewan health system. These findings can offer an important point for reflection and assessment of how, for whom, under what circumstances, are Lean efforts working or not. My dissertation has important findings regarding the nature, degree and approach to implementation, alongside issues of customization to context that may be valuable for policymakers to consider for future Lean or system transformations in healthcare. My research emphasizes how decisions made on implementation have a knock-on effect to sustainability processes.

Strengths and limitations

One strength of my dissertation is that it is the first study to attempt to understand sustainability of a complex intervention such as Lean through a realist lens. It is also the first realist evaluation on the sustainability of Lean in pediatric healthcare. This dissertation used multiple sources of data to inform the development and refinement of the program theory, drawing upon literature and participants insights. Realist evaluation stresses the use of multiple data forms and gathering points to elucidate program theories.[37, 38] This work also contributes to the existing knowledge base and previous foundational work done on the Saskatchewan Lean management system. This dissertation demonstrated existing challenges with evaluation research and sustainability research that will hopefully inform future work.

One limitation of this work was the sampling in phase 3 which consisted primarily of registered nurses and very few physicians and parents. More perspective from these

stakeholders would have been valuable and allowed for comparison of data across stakeholder type. However, this did not limit realist analysis where we firstly identified CMOcs from individual data and then within and across cases, irrespective of profession. Another additional limitation is that we did not obtain participation from the consultancy company used, thus the inferences made about the influence of the mandated external implementation approach only came from the perspectives of those internal to the organization.

It is also important to note that since this study, the Saskatchewan Lean management system has evolved with the introduction of other methodologies such as the Intermountain Health model of improvement, targeting physicians.[39] There have also been changes to the number and types of Lean activities implemented. It is unknown the impact this evolvement will have on sustainability and to what degree adaptation can occur and still be considered sustained or not.

Building on this work

My career goal is to develop a program of research on the sustainability of complex interventions for healthcare improvement, specifically in the contexts of maternal and child health. To build on my dissertation work, I will complete post-doctoral training in the development and evaluation of a tool to measure the sustainability of complex health interventions. During my post-doctoral fellowship, I will (a) systematically search the existing literature to understand what current tools and approaches exist to measure and predict sustainability; (b) develop a tool to measure sustainability outcomes, and (c) pilot test the usability of this tool across pediatric health settings that are currently evaluating an

intervention to improve infant pain assessment and management in acute pediatric hospital settings. This research will be conducted in three phases that build upon each other:

1. An integrative review addressing what models, theories, frameworks and tools currently exist to measure and predict the sustainability of complex health interventions
2. Tool development to measure predictors of sustainability as perceived by healthcare providers working in complex healthcare settings
3. Usability testing of the sustainability tool developed from Phase 1 and 2, for the ImPaC resource study- an evidence-based, online, and interactive tool designed to improve infant pain assessment and management in neonatal, infant clinical settings (CIHR funded $3,823,346, 2016-2023, Dr. Bonnie Stevens, PI, University of Toronto).

This research will contribute to the methodological advancement of sustainability and my research program on the sustainability of complex health interventions.

Conclusion

My dissertation promotes nurses to be leaders in improvement science and practice. My dissertation work is the intended starting point to a nursing program of research on the sustainability of complex interventions for healthcare improvement. My dissertation encourages an understanding of complex interventions through a realist lens which captures complexity. Through my dissertation, I have examined the implications of Lean complexity and healthcare system complexity on evaluation research designs and argued for the need for alternative approaches such as realist methods. I conducted a realist investigation of Lean using both realist synthesis and realist evaluation, specifically realist interviews. The refined

program theory accumulated from the findings of the realist review and interviews is a rich source for future research questions. To contribute to current dialogues, my future research program will aim to identify determinants of sustainability to inform future implementations in healthcare improvement. The research findings, methodological, and theoretical contributions of this dissertation have the potential to stimulate further research and impact the sustainability of complex interventions for healthcare improvement. The creative methods may generate new insights and research directions at a critical point of sustainability research development.

List of abbreviations

National Health Services Sustainability Model (NHS SM), Context + Mechanism = Outcome configuration (CMOc), Normalization Process Theory (NPT)

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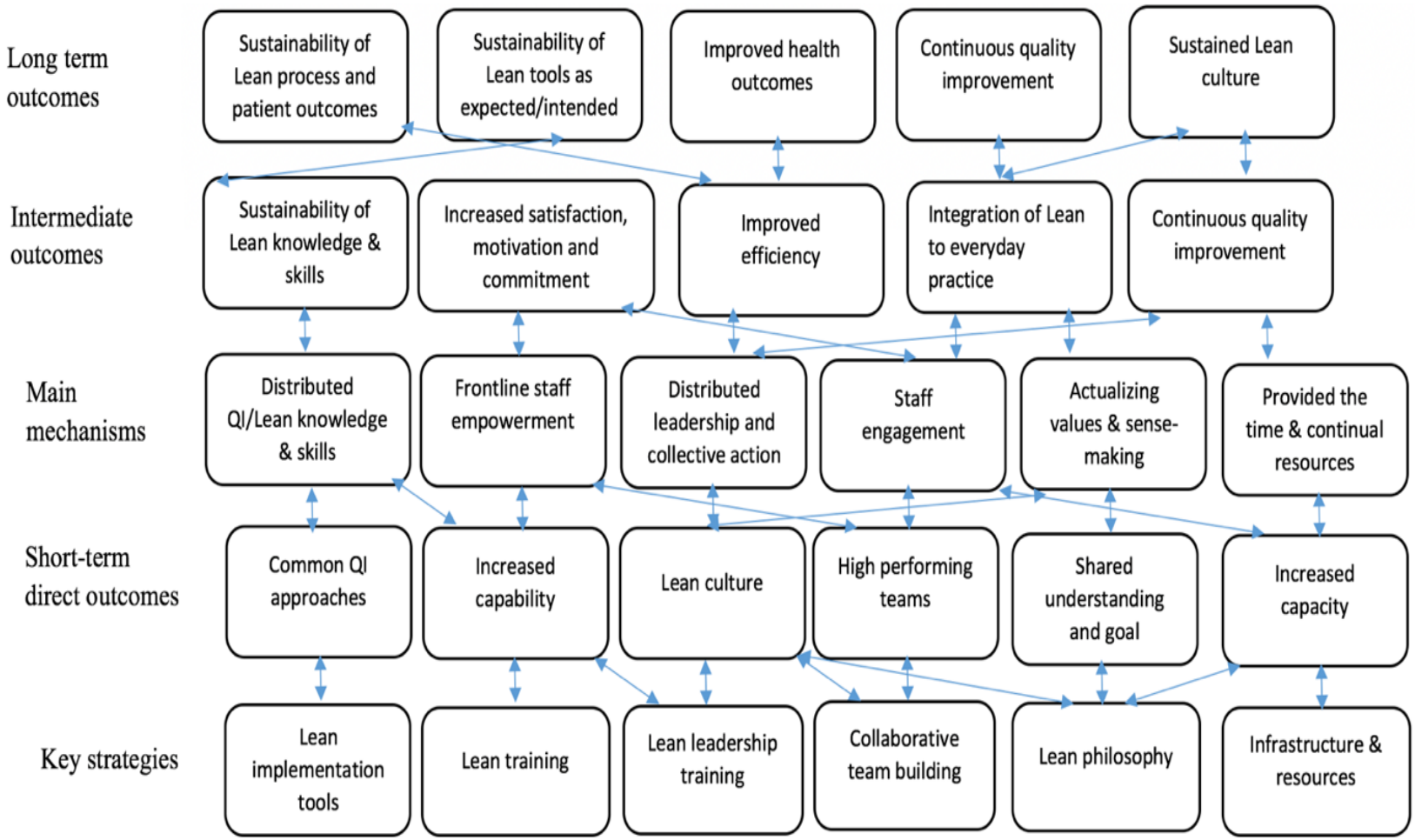
Appendix 1 Initial program theory map



Appendix 2 Initial program theory development work: CMO mapping and hypotheses

System Level: Organizational Leadership Level (macro or meso)			
CMO hypothesis 1: *"If the values of organizational leaders are congruent with Lean philosophy, and leaders receive Lean leadership training (C), then organizational leaders are more likely to make-sense of , appreciate, and feel motivated to implement Lean (M), in turn they become Lean messengers, promoting Lean philosophy to clinical leaders of the organization (O).*			
Context (C1)	**Mechanism (M1)**	**Outcome (O1)**	**Link to formal theory**
The degree of congruency between Lean philosophy and the values of the organizational leaders and the extent of other contextual forces (e.g., political and economic environments) The degree and nature of Lean leadership training for organizational leaders	The degree of sense- making about how Lean is relevant to organization Realization of the fit between the Lean philosophy and the organizations vision and/or mandate The degree of appreciation of the Lean philosophy from organizational leaders	The extent of Lean capacity building at top level of organization The extent to which organizational leaders are motivated to be "Lean leaders" and "Lean messengers" "*Messaging efforts*" The extent to which organizational leaders use their influence to promote "message" Lean to clinical leadership **Ripple-effect: 01 → C2 "Messaging efforts"* (outcome of hypothesis 1) becomes a new context (context for hypothesis 2)	NHS SM organization factor 9 Fit with the organization's strategic aims and culture NPT coherence internalization: understanding the value, benefits and importance around a set of practices. NPT coherence individual specification: participants need to do things that will help them understand their specific tasks and responsibilities around a set of practices.

CMO hypothesis 2: *If there are strong "messaging" efforts from organization leaders in promoting Lean, in a way that resonates with clinical leaders and frontline staff (C), then people are more likely to see value in Lean, gain a shared cohesive understanding of Lean benefits throughout the organization (M), thus creating increased buy-in and engagement to Lean efforts(O).*			
Context (C2)	**Mechanism (M2)**	**Outcome (O2)**	**Link to formal theory**
**Ripple-effect 01 → C2* The degree of messaging about the value and purpose of Lean by organizational leaders to the wider organization The degree of congruency between Lean philosophy and personal-level reasoning of the clinical leaders and frontline healthcare providers The degree of credible and respected senior leaders are seen as promoting and investing their own time in Lean efforts	The nature of how organizational leaders promote "message" Lean (i.e. "you have to do it", or "that is a new mandate") (resource); will trigger a degree of receptivity and value (positively or negatively) by the clinical leaders and frontline staff	The degree of shared understanding about Lean benefits The degree of buy-in, uptake, engagement for doing Lean activities by organizational leaders, clinical leaders and frontline staff	NPT coherence communal specification: sense- making relies on people working together to build a shared understanding of the aims, objectives and expected benefits of a set of practices. NPT cognitive participation initiation: when a set of practices are new or modified, a core problem is whether or not key participants are working to drive them forward NHS SM staff factor 7 Senior leadership engagement
CMO hypothesis 3: *If frontline staff believe that Lean is more than the "latest quality improvement trend" in a context with good staff morale and continued resources for Lean efforts (C), then frontline staff will have greater trust and belief in the long-term benefits of Lean (M), resulting in improved Lean implementation and positive influences for a continuous quality improvement culture (O).*			
Context 3 (C3)	**Mechanism 3 (M3)**	**Outcome 3 (O3)**	**Link to formal theory**
The degree of staff turnover, staff morale,	The extent to which stakeholders in the organization believe that Lean is there for	Inefficiencies or efficiencies in Lean implementation	NHS SM organization factor 10 Infrastructure for sustainability

type of unit culture and level of innovation fatigue The extent of time, continual resources (e.g., staff, facilities, equipment, policies and procedures) and staff capacity (training, audit and feedback, communication channels, senior leadership support) provided for sustainability	the long-term and not just the "latest quality improvement trend" (response) The degree of trust built by frontline staff in the Lean approach, the changes taking place and the support from leadership	Increased workload (i.e., stress, burnout) or supported workload (i.e., reduced stress, burnout) Frustration or satisfaction with Lean efforts Facilitated or hindered culture for continuous quality improvement	
System Level: Clinical Leadership Level (meso)			
CMO hypothesis 4: *If there is congruency between Lean philosophy and the personal-level reasoning of the clinical leaders and front-line healthcare providers, and clinical leaders and frontline healthcare providers receive Lean leadership training (C), then Lean is more likely to make sense and fit within the context (M), in turn motivating clinical leaders to become Lean messengers, promoting Lean philosophy to frontline staff (O).*			
Context 4 (C4)	**Mechanism 4 (M4)**	**Outcome 4 (O4)**	**Link to formal theories**
The degree of congruency between Lean philosophy and personal-level reasoning of the clinical leaders and front-line healthcare providers The degree of Lean training received by clinical leaders and frontline healthcare providers	The degree of sense- making process to understand how Lean is relevant for practice and patient care Realization of the extent in which Lean philosophy fits to their particular health care context or mandate The degree of appreciation of Lean philosophy from clinical leaders and frontline healthcare providers	The extent to which clinical leaders are motivated to be "Lean leaders" and "Lean messengers" The extent to which clinical leaders use their influence to promote "message" Lean to frontline staff **CMO1 and CMO4 are about messaging efforts, however, the nature of the messaging*	NPT coherence internalization: understanding the value, benefits and importance around a set of practices. NPT coherence individual specification: participants need to do things that will help them understand their specific tasks and responsibilities around a set of practices.

		may be different at different levels of systems	
CMO hypothesis 5: *In contexts where there are positive relationships between the clinical leader and frontline staff, and clinical leaders play an active role in Lean implementation (C), then frontline staff are more likely to believe in their leader's commitment to Lean, engage in Lean activities themselves (M), leading to buy in and continued support of Lean efforts (O).*			
Context (C5)	**Mechanism (M5)**	**Outcome (O5)**	**Link to formal theories**
Competing demands on clinical leader and their workload, affecting time commitment Lean Positive or negative relationships (e.g., trust, communication) between clinical leader and frontline staff Leadership approach used by clinical leaders' (hierarchical versus distributive) The degree that clinical leaders play active role in promoting, participating and investing own time in Lean assessment and improvement activities	The extent to which frontline staff believe in managers commitment to Lean The degree of frontline staff feeling engaged	The extent of continued buy-in and engagement by frontline staff The degree of continued input and support of Lean efforts and use of Lean activities **Ripple-effect: O5→C6 engagement(outcome of hypothesis 5) becomes a new context (context for hypothesis 6)*	NHS SM staff factor 8 Clinical leadership engagement
System Level: Frontline Healthcare Provider Level (micro or meso)			

CMO hypothesis 6: *If contexts exist where staff are engaged, have received Lean training and the opportunity to lead Lean efforts (C), then staff are more likely to become empowered to use Lean (M), and can then see beneficial outcomes from Lean, have improved satisfaction leading to increased sustained use of Lean efforts(O).*			
Context 6 (C6)	**Mechanism 6 (M6)**	**Outcome 6 (O6)**	**Link to formal theories**
**Ripple-effect 05 → C6* Engaged staff. Core values of frontline healthcare providers that align or impede their motivation; pre-existing levels of feeling empowered, pre-existing levels of work satisfaction; pre-existing attitude and buy-in of clinical leader; pre-existing relationships between clinical leader and frontline healthcare providers. Level of morale in the department. Silo or collaborative nature of the system, degree of relationships and collaboration between various stakeholder professions The degree of Lean training that frontline staff receive and are given the	The degree to which frontline staffs' ideas are considered, and opportunities that they are given to test these ideas and their belief that Lean is a better way of doing things and should be sustained The degree of engagement triggers empowerment of frontline staff in Lean efforts (co-production of Lean customization to local contexts with frontline healthcare providers	The extent to which benefits to patients, staff and the organization due to Lean implementation are visible; leading to increased satisfaction, increased sustainability of Lean activities over time Level of satisfaction, motivation and commitment by staff The degree of sustained Lean efforts	NPT Cognitive participation enrollment: participants may need to reorganize themselves and others in order to collectively contribute to work involved in new practices. This is complex work that may involve rethinking individual and group relationships between people and things. From MHS SM staff factor 5 Staff involvement and training to sustain the process NHS SM staff factor 6: Staff attitudes towards sustaining the change NPT cognitive participation: legitimation: ensuring that other participants believe it is right for them to be involved and that they can make a valid contribution to it.

opportunity to drive or lead Lean efforts at the unit level			
CMO hypothesis 7: *If there are contexts where there are visible benefits from Lean implementation, and a collaborative multi-disciplinary team approach to Lean implementation, with audit and feedback of changes (C), this triggers staff motivation and empowerment to sustain Lean efforts (M), then Lean efforts become integrated and sustained in practice (O).*			
Context 7 (C7)	**Mechanism 7 (M7)**	**Outcome 7 (O7)**	**Link to formal theories**
The extent to which the benefits to patients, staff and the organization due to Lean implementation are visible The degree of collaborative team building and multi-disciplinary team approach to Lean activities	The degree of "healthy" audit and feedback loops, communication of outcomes The degree staff feel heard, believe in Lean outcomes and feel engaged and empowered to sustain Lean efforts	The extent of Lean integration to everyday practice The degree of sustained Lean efforts	NHS SM process factor 2: Credibility of the benefits NHS SM process factor 1: Benefits beyond helping patient

*Red font to illustrate 'ripple-effect'

Appendix 3 Review search strategy

	Database: CINAHL via EbscoHost **Search Date: June 8, 2016**	
#	**Query**	**Results**
1	(TI (lean and (admitting or clinic or clinics or emergency department? or emergency medicine or emergency room? or emergency service? or family practice? or general practice? or healthcare or health care or hospital? or hospitali#ed or inpatient? or intensive care or ICU or "length of stay or nursing" or oncology or outpatient? or patient care or pharmacist? or pharmacy or physician? or practitioner? or primary care or readmission? or surgeon? or surgery or surgical or trauma center? or trauma centre? or trauma service? or trauma care or ward or wards))) OR (AB (lean W4 (admitting or clinic or clinics or emergency department? or emergency medicine or emergency room? or emergency service? or family practice? or general practice? or healthcare or health care or hospital? or hospitali#ed or inpatient? or intensive care or ICU or "length of stay or nursing" or oncology or outpatient? or patient care or pharmacist? or pharmacy or physician? or practitioner? or primary care or readmission? or surgeon? or surgery or surgical or trauma center? or trauma centre? or trauma service? or trauma care or ward or wards)))	147
2	(TI (lean and (approach or business model? or care or collaborat* or design* or enterpri?e or healthcare or health care or implementation? or industry or initiative? or intervention* or leader* or management or methodolog* or method? or organi?ation* or plan or planning or philosophy or practice or practices or principles or principle or process improvement? or production or program? or program or programs or quality or redesign* or reengineer* or restructur* or reorgani* or safety or sigma or strategy or strategies or thinking or tool or tools or workshop*))) OR (AB (lean W3 (approach or business model? or care or collaborat* or design* or enterpri?e or healthcare or health care or implementation? or industry or initiative? or	500

	intervention* or leader* or management or methodolog* or method? or organi?ation* or plan or planning or philosophy or practice or practices or principles or principle or process improvement? or production or program? or program or programs or quality or redesign* or reengineer* or restructur* or reorgani* or safety or sigma or strategy or strategies or thinking or tool or tools or workshop*))) OR (TI think lean OR AB think lean)	
3	(TI (lean W3 (workflow? or efficienc* or efficient*))) OR (AB (lean W3 (workflow? or efficienc* or efficient*))) OR (TI (Lean and waste) or AB (lean W3 waste))	21
4	(TI (lean technique? or lean manufacturing)) OR (AB (lean technique? or lean manufacturing)) OR (TI (lean basics or lean training) OR AB (lean basics or lean training))	551
5	(TI (fishbone and (ishikawa? or diagram? or analys* or chart? or lean))) OR (AB (fishbone W2 (ishikawa? or diagram? or analys* or chart? or lean))) OR (TI pareto diagram* OR AB pareto diagram*)	17
6	(TI (quality lost function* or quality function deploy*)) OR (AB (quality lost function* or quality function deploy*)) OR (TI (5S and (lean or production or industr* or manufactur* or quality improv* or management or CQI)))	209
7	(AB (5S W5 (lean or production or industr* or manufactur* or quality improv* or management or CQI))) OR (TI (5S W15 (sort or shine or sweep or straighten or standardi*))) OR (AB (5S W15 (sort or shine or sweep or straighten or standardi*)))	5
8	(TI (5s W3 (event? or method? or methodolog* or model? or process or processes or safety or waste or quality))) OR (AB (5s W3 (event? or method? or methodolog* or model? or process or processes or safety or waste or quality))) OR (TI takt time OR AB TAKT TIME)	8

9	(TI kanban OR TI (poka yoke? or poka yok?) OR AB (poka yoke? or poka yok?) OR TI DMAIC OR AB DMAIC) OR (TI (Define W2 Measure W2 Analy?e W2 Improve W2 Control) OR AB (Define W2 Measure W2 Analy?e W2 Improve W2 Control)) OR (TI total productive maintenance OR AB total productive maintenance)	27
10	(TI single minute exchange? OR AB SINGLE MINUTE EXCHANGE OR TI jidoka OR AB jidoka) OR (TI value stream map* OR AB value stream diagram*) OR (TI (7 wastes or seven wastes or (7S W5 (waste? or lean or management or production or organi?ation))))	32
11	AB (7 wastes or seven wastes or (7S W5 (waste? or lean or management or production or organi?ation)))	87
12	(TI (7S and (quality improv* or cqi or total quality or lean or production or industr* or manufactur* or quality improv* or management or CQI)) OR AB (7S W10 (quality improv* or cqi or total quality or lean or production or industr* or manufactur* or quality improv* or management or CQI))) OR (TI ((total quality or quality assurance or quality improvement) and lean) OR AB ((total quality or quality assurance or quality improvement) W10 lean)) AND (TI (standardi?ed work or standardi?ed workflow?) OR AB (standardi?ed work or standardi?ed workflow?) OR TI standard work OR AB STANDARD WORK)	6
13	(AB (((PDSA or PDCA or TQIS) W3 (cycle or process or processes or intervention or quality or lean or improv*)) or ("plan do study" or "plan do check"))) OR (TI (((PDSA or PDCA or TQIS) AND (cycle or process or processes or intervention or quality or lean or improv*)) or ("plan do study" or "plan do check")))	263
14	(TI ((wait* time? or reduc* wait*) and lean) or AB ((wait* time? or reduc* wait*) W4 lean))	11
15	(TI (lean and (overcrowd* or patient* flow?)) or AB (lean W4 (overcrowd* or patient* flow?)))	2
16	TI (TOYOTA OR GEMBA OR KAIZEN) OR AB (TOYOTA OR GEMBA OR KAIZEN)	104

17	TI (innovation? W2 collaborat*) OR AB (innovation? W2 collaborat*)	15
18	TI ((PROCESS MAP? or process mapping)) OR AB ((PROCESS MAP? or process mapping))	895
19	TI ((mistake proofing or value-stream map? or incident learning)) OR AB ((mistake proofing or value-stream map? or incident learning))	382
20	TI (((shewhart or shewart or deming) W3 (cycle or method*))) OR AB (((shewhart or shewart or deming) W3 (cycle or method*)))	16
21	TI process failure mode OR AB "process failure mode"	6
22	TI (failure mode? W2 Effect? analys*) OR AB (failure mode? W2 Effect? analys*)	80
23	TI FMEA OR AB FMEA	82
24	TI ((breakthrough W3 (series or project or collaborative?))) OR AB ((breakthrough W3 (series or project or collaborative?)))	57
25	TI rapid process improvement? OR AB rapid process improvement?	78
26	TI ((rapid cycle W3 (improvement or quality or process or processes))) OR AB ((rapid cycle W3 (improvement or quality or process or processes)))	47
27	TI quality improvement? tool? OR AB quality improvement? tool?	189
28	TI ((virginia mason or releasing time to care or productive ward)) OR AB ((virginia mason or releasing time to care or productive ward))	158
29	TI LEAN MANAGEMENT	47
30	((MH "Quality of Health Care+") OR (MH "Quality Management, Organizational") OR (MH "Quality Improvement+") OR (MH "Quality Assessment+") OR (MH "Quality of Nursing Care") OR (MH "Quality Circles") OR (MH "Quality Assurance+")) AND TI LEAN	285
31	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30	3,638

32	(MH "HOSPITALS, PEDIATRIC") OR (MH "Pediatric Physical Therapy") OR (MH "Pediatric Units+") OR (MH "Intensive Care Units, Pediatric+") OR (MH "Pediatric Occupational Therapy") OR (MH "Society of Pediatric Nurses") OR (MH "Pediatric Oncology Nursing") OR (MH "National Association of Pediatric Nurse Associates and Practitioners") OR (MH "Association of Pediatric Oncology Nurses") OR (MH "Childhood Neoplasms") OR (MH "Rehabilitation, Pediatric") OR (MH "Pediatric Cardiology") OR (MH "Pediatric Surgery") OR (MH "Pediatric Nurse Practitioners")	23,771
33	(MH "Pediatricians") OR (MH "American Academy of Pediatrics")	2,303
34	(MH "Intensive Care Units, Neonatal") OR (MH "Neonatal Assessment+") OR (MH "Neonatal Intensive Care Nursing") OR (MH "Intensive Care, Neonatal+") OR (MH "Congenital, Hereditary, and Neonatal Diseases and Abnormalities+") OR (MH "Anemia, Neonatal+") OR (MH "Neonatal Sepsis") OR (MH "Neonatal Nurse Practitioners")	89,149
35	(MH "Infant+") OR (MH "Infant, Newborn+") OR (MH "Child+") OR (MH "Infant, Low Birth Weight+")	324,826
36	(MH "Adolescent, Hospitalized") OR (MH "Adolescent Health Services") OR (MH "Adolescent Psychology") OR (MH "Adolescent Psychiatry") OR (MH "Adolescent Medicine")	4,686
37	(MH "Childhood Neoplasms") OR (MH "Early Childhood Intervention")	5,815
38	(MH "Perinatology")	152
39	(MH "Adolescence")	229,318
40	TI (adolescent? or child or children or juvenile? or teen? or teenager? or youth or infant? or neonat* neo-nat*)	139,009
41	TI ((paediatric* OR pediatric*)) OR AB ((paediatric* OR pediatric*))	52,339
42	TI newborn? OR AB newborn?	5,016
43	AB ((adolescent? or child or children or juvenile? or teen? or teenager? or youth or infant? or neonat* neo-nate? or neo-natal*) W6 (care or healthcare or health or medical or hospital? or GP or general practitioner? or nurse or nurses or nursing or family practice? or general practice or family medicine or surger* or surgeon* or specialist?))	24,593
44	SO ADOLESCEN* OR PEDIATRIC* OR PAEDIATRIC* OR CHILD? OR CHILDREN? OR JUVENILE? OR CHILDHOOD	88,001
45	MW CHILD OR CHILDREN OR PEDIATRIC* OR PAEDIATRIC*	301,207

46	S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45	565,279
47	S31 AND S46	495

Appendix 4 Research ethics approval

Notification of Approval - Amendment

Date:	November 15, 2016
Amendment ID:	Pro00063634_AME3
Principal Investigator:	Rachel Flynn
Study ID:	Pro00063634
Study Title:	**A Realist Investigation on the Sustainability of Lean in Pediatric Healthcare**
Supervisor:	Shannon Scott

Approved Consent Form:	Approval Date	Approved Document
	9/13/2016	Information&InformedConsent_PatientAdvisory_RF_V02
	9/30/2016	Information&InformedConsent_PatientAdvisory_RF_V03
	9/13/2016	Information&InformedConsent_HCPandManager_RF_V02
	9/30/2016	Information&InformedConsent_HCPandManager_RF_V03
	11/15/2016	PhD_Information&Consent_HCP&Manager_14Nov16_V05
	11/15/2016	PhD_Information&Consent_PatientAdvisory_14Nov16_V05

Approval Expiry Date:	Tuesday, September 12, 2017

Thank you for submitting an amendment request to the Research Ethics Board 1. This amendment to add a second interview to the study methods has been reviewed and approved on behalf of the committee. The following have been approved:

- InitialContactLetter_Director_RF_V01 (November 8, 2016)
- PhD_Information&Consent_PatientAdvisory_14Nov16_V05
- PhD_Information&Consent_HCP&Manager_14Nov16_V05

Sincerely,

Anne Malena, PhD
Chair, Research Ethics Board 1

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Appendix 5 Realist interview guides

Interview topic guide on Lean integration in child health

Lean was initially launched in the Saskatchewan healthcare system in 2012 as a provincial strategy to improve the quality of healthcare. Since that time, a large number of Lean initiatives have been undertaken throughout the province and many healthcare providers have been affected by, exposed to or involved in Lean.

The purpose of this interview is to better understand how Lean is integrated into child healthcare in the Saskatoon Health Region. We are interested in hearing the perspectives of healthcare providers, unit managers, senior leaders and patient advisors about whether and how Lean has become integrated into practice and understanding how Lean is perceived to affect the quality of healthcare.

This interview will take approximately 45 minutes. You will also be asked to complete 12 questions relating to your demographic and professional characteristics.

The interview is in 2 parts. Part A includes general questions about your training and involvement in Lean and how familiar the principles and activities of Lean feel for you. Part B provides a series of questions about how Lean is integrated in your work; there are also options to indicate if you feel the item is not relevant to your situation.

Participation in this research is voluntary. You can stop the interview at any time. Also know that any personal information collected will be de- identified. This research project has been approved on ethical grounds by the University of Alberta and University of Saskatchewan Research Ethics Boards. If you have concerns about this study, you may contact the University of Alberta Research Ethics Office, at (780) 492-2615 or University of Saskatchewan Ethics Office, at (306) 966-2975. These offices have no direct involvement with this project.

For more information on the study itself, please contact Rachel Flynn, Faculty of Nursing, University of Alberta at: Rachel.flynn@ualberta.ca or 1780-729-0089.

Interview Guide for Healthcare Providers

Part A. General Questions about Lean

1. What Lean principles are you familiar with?
2. Can you tell me about your involvement in Lean? (e.g., Lean activities)
3. What Lean /tools activities are you familiar with?
4. Can you tell me how using Lean principles/ tools/ activities in your work feels for you?
5. What extent do you believe Lean to be embedded in your work/organization?

Part B. Detailed questions about the integration of Lean

6. How is Lean different to your previous usual ways of working?
7. How and to what extent have Lean principles/activities become a normal part of your work?
8. What are the challenges to integrating Lean into your everyday work?
9. What factors have been critical to how integrated Lean is in your work?
10. Tell me an example of when something was tried under Lean in your work setting that did become integrated? What is your understanding of why it did become integrated into practice?
11. Tell me an example of when something was tried under Lean in your work setting that didn't become integrated? What is your understanding of why it didn't become integrated into practice?
12. How has Lean affected the nature of your work?
13. Tell me about any benefits from using Lean that you see for your work?
14. How strongly would you say you support the use of Lean for healthcare?
15. Can you tell me your main reasons for supporting Lean or not?
16. What do you think are the core values of Lean?
17. How are Lean values congruent/incongruent with your own values?
18. How and by whom has the continued use of Lean been driven in your organization?
19. What factors unique to pediatric healthcare facilitate or hinder the continuation of Lean?

Interview Guide for Unit Managers/Senior Leaders

Part A. General Questions about Lean

1. What Lean principles are you familiar with?
2. Can you tell me about your involvement in Lean? (e.g., Lean activities)
3. What Lean activities are you familiar with?
4. Can you tell me how using Lean principles/ activities in your work feels for you?

Part B. Detailed questions about the integration of Lean

1. How and to what extent have Lean principles/activities become a normal part of your work/ unit/organization?
2. What are the challenges to integrating Lean into the everyday work of your unit/organization?
3. What factors have been critical to how integrated Lean is in your work/ unit/organization?
4. Tell me an example of when something was tried under Lean in your work setting that did become integrated? What is your understanding of why it did become integrated into practice?
5. Tell me an example of when something was tried under Lean in your work setting that didn't become integrated? What is your understanding of why it didn't become integrated into practice?
6. How has Lean affected the nature of your work/unit/organization?
7. Tell me about any benefits from using Lean that you see for your work/unit/organization?
8. How strongly would you say you support the use of Lean for healthcare?
9. Can you tell me your main reasons for supporting Lean or not?
10. What do you think are the core values of Lean?

11. How are Lean values congruent/incongruent with your own values/ teams values/ organizations values?
12. How and by whom has the continued use of Lean been driven in your organization?
13. What factors unique to pediatric healthcare facilitate or hinder the continuation of Lean?

Interview Guide for Patient Advisory Group

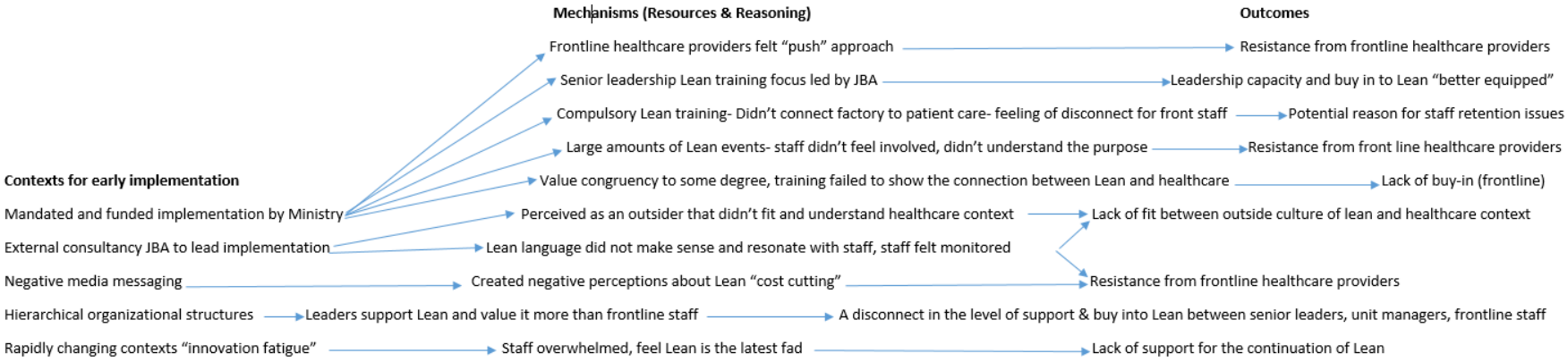
Part A. General Questions about Lean

1. What Lean principles are you familiar with?
2. What Lean activities are you familiar with?

Part B. Detailed questions about the integration of Lean

3. Tell me about your involvement in Lean?
4. Tell me about any values of Lean that you see for patients/child health?
5. How would you know a unit is using Lean? How would it be different to a unit not using Lean?
6. Do you support the use of Lean? Why?
7. Please give an example of something that has been tried under Lean?
8. What factors are important for Lean to work and to be continued?
9. How does Lean makes a difference to child healthcare?
10. How does Lean influence child health outcomes?

Appendix 6 Context, mechanism and outcome configurations: a visual model



Process of customization to local context, External consultancy JBA contract ended

***Ripple-effect:** *negative outcomes of implementation (e.g., resistance, lack of customization and negative perceptions), resources (e.g., poor training that did not connect the meaning of Lean to healthcare, external Lean consultants that were not from healthcare), and the scale of implementation (e.g., mandated top-down approach at macro level) shaped the contexts (resistance, lack of customization and negative perceptions and variation in Lean training and exposure) mechanisms (e.g., sense-making, staff engagement, awareness) and outcomes (e.g., degree of support, continuation and normalization) of Lean efforts.*