Large-System Transformation in Health Care: A Realist Review

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Context: An evidence base that addresses issues of complexity and context is urgently needed for large-system transformation (LST) and health care reform. Fundamental conceptual and methodological challenges also must be addressed. The Saskatchewan Ministry of Health in Canada requested a six-month synthesis project to guide four major policy development and strategy initiatives focused on patient- and family-centered care, primary health care renewal, quality improvement, and surgical wait lists. The aims of the review were to analyze examples of successful and less successful transformation initiatives, to synthesize knowledge of the underlying mechanisms, to clarify the role of government, and to outline options for evaluation.

Methods: We used realist review, whose working assumption is that a particular intervention triggers particular mechanisms of change. Mechanisms may be more or less effective in producing their intended outcomes, depending on their interaction with various contextual factors. We explain the variations in outcome as the interplay between context and mechanisms. We nested this analytic approach in a macro framing of complex adaptive systems (CAS).

Findings: Our rapid realist review identified five "simple rules" of LST that were likely to enhance the success of the target initiatives: (1) blend designated leadership with distributed leadership; (2) establish feedback loops; (3) attend to history; (4) engage physicians; and (5) include patients and families. These principles play out differently in different contexts affecting human

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behavior (and thereby contributing to change) through a wide range of different mechanisms.

Conclusions: Realist review methodology can be applied in combination with a complex system lens on published literature to produce a knowledge synthesis that informs a prospective change effort in large-system transformation. A collaborative process engaging both research producers and research users contributes to local applications of universal principles and mid-range theories, as well as to a more robust knowledge base for applied research. We conclude with suggestions for the future development of synthesis and evaluation methods.

Keywords: health policy, health care reform, organizational innovation, complex adaptive systems, realist evaluation, realist review.

Background

MOST OF THE PUBLISHED LITERATURE ON CHANGE IN HEALTH care describes relatively small-scale initiatives typically carried out by a single health care organization or service. An evidence base thus is urgently needed for large-system transformation (LST), as there is no agreed-on definition of LST in the literature. In this article we offer our working definition:

> Large-system transformations in health care are interventions aimed at coordinated, systemwide change affecting multiple organizations and care providers, with the goal of significant improvements in the efficiency of health care delivery, the quality of patient care, and population-level patient outcomes.

The relatively sparse literature on LST highlights the crucial influence of political and institutional context. For example, Carolyn Tuohy compared the process of large-scale changes in health care in the United States, Canada, the United Kingdom, and the Netherlands and demonstrated different institutional logics (respectively, "mosaic," "incremental," "big bang," and "blueprint") in these different political contexts and health systems (Tuohy 1999). While we acknowledge the significance of political analyses in informing LST efforts in health care, we also need evidence for the social mechanisms by which transformative

efforts may achieve their impacts in different contexts, which we address here.

In 2001, the Institute of Medicine (IOM) produced a landmark report entitled *Crossing the Quality Chasm*, which endorsed the idea that health care systems are complex adaptive systems (CAS) (IOM 2001). This report followed an important publication on CAS in 1998 (Zimmerman, Lindberg, and Plsek 1998) and emerged at the same time as an influential series of papers in the *British Medical Journal* (e.g., Plsek and Greenhalgh 2001, Plsek and Wilson 2001), which emphasized the value of a CAS lens to better understand how to improve and transform health systems.

These publications argued that although CAS are complex and unpredictable, they are amenable to guided transformation by applying simple rules that are sufficiently flexible to allow for adaptation, an important operating principle for potential agents of health system transformation. In contrast to many top-down LST efforts, a CAS approach seeks to draw out and mobilize the natural creativity of health care professionals to adapt to circumstances and to evolve new and better ways of achieving quality (Lanham et al. 2009). To improve processes and outcomes, the key is to create positive conditions for change by supporting a work environment conducive to harnessing both relationships and the skills and capacities of individuals in the system.

The implications for planning are far-reaching. The agent of change must give up notions of "control" over the process of change and should avoid language that emphasizes "overcoming resistance" (Plsek and Wilson 2001; Sterman 2006). Instead, efforts should be directed toward iterative planning and practice cycles that build on an understanding that successful action is less about meeting targets and more about shifting the system's behavior through generic guidance and steering mechanisms. Changing the principles by which people carry out their work is much more important than attaining a predefined target (which may have been arbitrary in the first place).

Implementing change in CAS requires constant monitoring and adaptation to new contexts. Building in principles and resources that support a learning environment (Senge 1990) allows organizations to take full advantage of local knowledge in generating continuous improvements. Similarly, evaluating change in LST, as informed by a CAS lens, means adopting appropriate goals and objectives, not overspecifying

multiple outcomes, and paying attention to positive movement in generic processes that support improvement.

All this means that the evidence base for achieving LST cannot take the form of hard and fast statements about "what works." Rather, richly described case studies of LST efforts will lend themselves to (at best) making broad statements about "what tends to work, for whom, in what circumstances" and to explaining the fortunes of particular programs as mechanisms in context. A well-matched approach to generating such statements and explanations in empirical studies is realist evaluation (Pawson and Tilley 1997). A realist review (the secondary research equivalent to realist evaluation) is an interpretive, theory-driven narrative summary that uses cross-case comparison to understand and explain how and why different outcomes have been observed in a sample of primary studies (Pawson et al. 2005). The working assumption behind realist review is that a particular intervention (or class of interventions) triggers particular mechanisms of change somewhat differently in different contexts. In realism, it is mechanisms—defined as "underlying entities, processes, or [social] structures which operate in particular contexts to generate outcomes of interest" (Astbury and Leeuw 2010, 368)—that trigger change rather than interventions themselves. In other words, realist reviews focus on "families of mechanisms" rather than on "families of interventions." An explanation of the interplay of context, mechanism, and outcomes is then sought. The reviewer constructs one or more "mid-range theories" (i.e., more fine-grained than "grand theories" but still open to flexible interpretation in different contexts) to account for the findings. A realist review methodology focuses on the types of interactions between local context and specific mechanisms of change that make up the foundation of CAS and, more specifically, LST for CAS. An international collaborative study to develop methodological guidance and reporting standards for realist review is ongoing (Greenhalgh et al. 2011).

A CAS perspective draws attention to the basic rules or principles of action of a system and its environmental parameters, and a realist perspective seeks to unpack and explore particular mechanisms and how they interact with the context. Ensuing policy recommendations avoid elaborate checklists or specific instructions for change. Rather, the recognition of complexity tied to a focus on "theories of change" allows (indeed, requires) researchers to begin by examining the local context and expressing findings as broad principles of action and contingent

approaches ("in situations like X, try Y and watch out for Z"). It has been argued that the conclusions from a realist review may be more helpful to policy than those of Cochrane-style systematic reviews and meta-analyses, which address a narrower set of questions framed in explicitly experimental terms in which context has been "controlled for" or reduced to a handful of predefined variables whose influence is assumed to be constant and predictable ("what is the impact of intervention X on outcome Y, and what is the influence of mediating variables M_1, M_2 and M_3?") (cf. Berwick 2008).

In this article we describe a realist review of approaches to large-system transformation (LST), taking account of the policy contexts in which they were undertaken. In the discussion, we return to more general theoretical and methodological issues and consider the extent to which the broad principles and contingent lessons identified by the realist approach proved useful to the policymakers who commissioned the review. We also look at the implications—both empirical (wider lessons for those seeking to implement or support LST) and methodological (wider lessons for realist reviewers and those contemplating commissioning such reviews).

The KAST Project

The Knowledge to Action for System Transformation (KAST) project was designed to provide a rapid systematic review and synthesis of knowledge about LST for the provincial Saskatchewan Ministry of Health in Canada. The review was funded by the Canadian Institutes of Health Research (CIHR), under a pilot "Evidence on Tap" program and its "Expedited Knowledge Synthesis" mechanism (CIHR 2011). The Saskatchewan ministry requested the six-month synthesis project (April to September 2010) to guide four major policy development and strategy initiatives: patient- and family-centered care, primary health care improvement, "lean" management for health care, and shorter surgical wait times (the "Saskatchewan Surgical Initiative").

In this rapid review for a specific policy sponsor, we defined a systematic review as a review of the literature according to an explicit, rigorous, and transparent methodology rather than as an exhaustive and comprehensive summary of every paper ever published on the topic (Greenhalgh et al. 2004). We applied realist methodology (Pawson

2002a, 2002b; Pawson et al. 2005), a principle of which is to address policymakers' needs in context. For example, within the geographic and political boundaries of the Saskatchewan health system (which neither we nor the sponsors of the review were in a position to change), we sought to inform the structural, process, and policy changes needed to support change in each current initiative. We distinguished among research, theory, and practice knowledge (Best and Holmes 2010; Van de Ven 2007) and posited that a synthesis of all three kinds of knowledge would be necessary to make inferences about the factors influencing large-system transformation and how they might interact dynamically over time.

The four preliminary objectives for the synthesis were the following:

1. Identify a range of examples of LST that were more or less successful, and in those examples, determine the role of the provincial government, including its policy development and implementation.
2. Develop a deeper understanding of the mechanisms that contribute to success in LST and how these play out in different contexts.
3. Identify barriers and challenges to LST, and recommend what roles the government might play in addressing (or working around) them.
4. Identify options for monitoring and evaluating the processes and outcomes for LST.

Our research questions were the following:

1. What are the key mechanisms or social processes that influence or drive successful large-system transformation in the health care sector?
2. What are the contextual factors that have the most impact (positive or negative) on large-system transformation efforts in the health care sector?
3. If there are identifiable "transition" points in large-system transformation efforts, how do the key mechanisms and contexts interact to produce these changes?
4. What is the role of government in large-system transformation efforts?

Methods

Framing the Problem with Policymakers' Input

A preliminary step in realist review is dialogue among the research team members as well as with the intended user(s) of the review, to clarify its focus and prioritize questions. The steering committee, convened by the Saskatchewan Ministry of Health, was made up of senior representatives from relevant ministry divisions, regional health authorities, and a provincial quality council. The committee met three times with the research team and periodically by teleconference, and they all exchanged emails throughout the project. The ministry provided to the research team the principal (i.e., updated during the project's life span) background documents on the four strategic initiatives; they described and discussed the relevant context; and the committee added input to the draft high-level statements extracted and synthesized from the literature to ensure clarity and accessibility of language and meaning for the diverse stakeholders for whom the output of the review was aimed.

There was broad agreement that even though there was much scope for improvement in Saskatchewan (care was, in general, far from patient or family centered; primary health care provision was variable and limited in scope; the duplication of local and regional health systems was inefficient; and surgical waiting lists were long), there was also a high degree of inertia in the system and (perceived) limited motivation for change, which ministry staff members hoped to change. Thus, although the steering committee wanted us to answer the realist question "what works for whom under what circumstances?" they also needed specific recommendations for ways that the government (i.e., the Saskatchewan Ministry of Health) could work to effect, support, and sustain transformation in the four areas previously identified as priorities.

This prioritization linked well with our chosen realist approach. Conventional change management research tends to focus on defining a set of abstracted variables and quantifying the (assumed) causal links between them—such as "top management support," "dedicated budget," and "training." In contrast, the *mechanisms* that are the focus of realist review are considered to work either wholly or largely through the perceptions, reasoning, and actions of human actors. In other words, the mechanisms set out *how* the people on whose efforts LST depends actually use program resources such as top management support, financial resources, or

training to make the changes happen and sustain them—and how their efforts play out differently in different contexts (Astbury and Leeuw 2010).

Creating an Interpretive Dialogue

We knew that academic publications on LST were sparse and that many high-quality studies on this topic were situated in the gray literature. We also were aware that evidence on LST is complex and nuanced, that it is interpreted differently by different stakeholders, and that (hence) there are few, if any, a priori truths. For these epistemological reasons, we chose to undertake the review alongside a series of dialogues. In addition to the steering committee, we convened an expert panel and a consultation group.

The international expert panel was composed of eight leaders from Canada and the United Kingdom, whose expertise spanned systematic reviews, system transformation, and the four strategic topic areas we had been charged with informing (patient- and family-centered care, surgical wait lists, quality improvement, and primary health care renewal). The research team maintained an interactive dialogue with these experts, mostly via email. Discussion among the experts was prompted at strategic points throughout the review with a view to gaining critical feedback on the research questions, the literature review methods, and the presentation and interpretation of findings.

In addition, toward the end of the review period, we became aware that many of the gaps that we had identified in the literature, particularly the lack of granularity in published findings, might be filled in by the expertise of those currently or very recently involved in transformation efforts. To that end, a consultation group of forty-four international leaders participated in a short online survey in which they were asked to comment on the preliminary findings to help refine recommendations for government action based on their knowledge and experiences.

Search Methods

Realist review recognizes the limitations of fixed search protocols and instead encourages iterative searching that begins with a broad

direction, is refined through progressive focusing, and responds flexibly to emerging findings (Pawson et al. 2005). The initial search protocol addressed health services and macro-systems transformation in relation to health care reform, surgical initiatives, "lean" culture, patient-centered care, and primary health care renewal. Members of the research team and expert panel provided search terms from which the list of key terms for each concept was built (see table 1). The published literature was searched using these terms and the subject headings in the databases MEDLINE and EMBASE from 2000 to the present. Numerous iterative searches were performed in these databases, resulting in nearly 1,000 potential references. Two members of the research team reviewed the titles and abstracts for relevance based on broad inclusion criteria, including the use of a theory-driven approach to identifying the underlying mechanisms that were driving change (particularly the ways in which human agency drew on program resources to achieve goals), using methods or descriptions that were consistent with a complex systems and/or realist perspective, a focus on whole or partial system transformation with lessons that could be applied on a macro level, the adaptability of the findings to a Saskatchewan context, a focus on the "why" and "how" of system transformation, and articles written by major authors in the field. From the nearly 1,000 references, 211 were selected for further review based on these criteria. Two of the team members again reviewed all 211 references, based on titles and abstracts, and assigned them to one or more of five categories (LST broadly construed, lean culture, patient- and family-centered care, primary health care renewal, and shorter surgical wait times), depending on the document's scope and content. When the team members were unsure which, if any, mechanisms of change were evident in a particular paper, we sought advice from our wider research group (up to four of whom considered the paper and discussed the candidate mechanisms). When two reviewers disagreed on whether to select a reference for full review, their disagreement was resolved by discussion. Of the 211 references considered, 114 were reviewed in their entirety.

Based on discussions among the team members, the expert panel, and the ministry, the depth and type of the searches evolved. We searched the references from papers in each of the five topical categories for other relevant papers and hand-searched six journals from health, business, and sociology dated 2000/2010 and known to publish papers on LST. We also reviewed the full texts of 64 papers from the six journals.

TABLE 1
Preliminary Search Terms by Concept

Health Services and Transformation	Health Care Reform	Surgery	Lean and Quality Improvement	Patient-Centered Care and Primary Health Care Renewal
Health Services	Quality of health care	Health care access	Lean culture	*Patient-Centered Care*
Health care system	Organizational efficiency	Surgical ward	Lean practices	Patient-centered care
Health services, e.g., adolescent, community, child, community health nursing, community mental health, community, pharmacy, home care, maternal, occupational, preventive, dental, emergency, health services for the aged, indigenous mental health, nursing, personal, pharmaceutical, rehabilitation, reproductive, rural, suburban, primary, regional health planning, community health planning, regional medical programs, U.S. Department of Veterans Affairs, comparative health system, "delivery of health care," "delivery of health care, integrated," managed care programs, telemedicine, multi-institutional systems	Health care reform	Lean organizations	Patient-focused care
	Health care reform (methods)	Organizational efficiency	Medical homes
	Health policy	Quality of health care	Patient-centered nursing
	Organizational culture	Value-optimizing services	*Primary Health Care Renewal*
	Organizational policy	Releasing time to care	Primary health care
	Policymaking	Toyota production method	Integrated health services
	Cooperative behavior	Waste (eliminating or reducing)	Polyclinics
	Engagement		Interdisciplinary care
	Systems theory		Multidisciplinary care
	Complex adaptive systems		Integrated care
	Organizational models		Coordinated care
			Chronic disease management
Systems Transformation		Surgery		
Organizational innovation		Surgical specialties, e.g., general, colorectal, gynecology, neurosurgery, obstetrics, ophthalmology, orthopedics, otolaryngology, plastic, thoracic, traumatology, abdominal, ambulatory, breast, cancer, cardiovascular, ear, nose, throat, elective, emergency, endocrine, eye, geriatric, head and neck, minimally invasive, orthopedic, pediatric, pelvis, thorax, transplantation, urologic		
Entrepreneurship transformation processes				
Organizational case studies				
Organizational changes				
System changes				
System transformation				
Comparative health systems				
Changes in organization and administration				

Building on these searches and the resulting papers, we undertook an extensive search of the gray literature in consultation with the expert panel and the ministry. These searches involved reviewing a variety of government websites in Canada, the United States, the United Kingdom, Australia, New Zealand, and the European Union. Publications from specific organizations known to be involved in transformative efforts in the four content areas of interest were also searched, for example, the Canadian Policy Research Network, U.S. Department of Veterans Affairs, Kaiser Permanente, Commonwealth Fund, OECD Health Working Papers, and Western Canada Waiting List Project (the full list is available from the authors). The searches were adapted iteratively in the light of feedback from the research team as they extracted information from the research papers. For example, it became increasingly clear that some of the search terms being used to locate literature related to "lean" initiatives were producing a large volume of literature closely related to quality improvement but having little or no relevance to lean activities. Search strategies were revised accordingly to produce results better suited to our needs.

Of the gray literature searched, we considered 232 papers or titles and abstracts. After reviewing the full text of the 114 references from the initial search, the 64 papers from the six hand-searched journals, and the 232 papers or reports from the gray literature, we decided on the final sample of papers included in this review: 16 related to surgical wait lists, 18 related to lean for health care, 15 related to patient-centered care (from a systems perspective), 20 related to primary health care redesign, and 15 related to transformation of large health care systems (84 total; see appendix).

Synthesis Methods

At least one team member reviewed each paper in detail, and all the members of the research team involved in the review process selected several articles across the five categories for review. Through an iterative process, review strategies and data extraction guidelines were calibrated so that (broadly speaking) each document's extraction "highlights" contained a similar level of detail. Data were extracted from each article in relation to the mechanisms and how they interacted with context, combining to influence the fortunes (either positively or negatively) of the LST efforts. These context-mechanism-outcome relationships were

reviewed for each topic area and across topic areas. We identified and highlighted common crosscutting themes in what we initially called "high-level evidence statements" but that we subsequently renamed "simple rules" (broad principles of change for which interpretive flexibility would be needed in different contexts), which might be most useful to Saskatchewan change leaders in their efforts to transform the province's health care system. For an example of the transformation of articles to extractions to key findings to simple rules, see table 2.

Using an online survey format, we presented each of the high-level statements to the consultation group members, who were asked to comment on how each resonated with their own experience of large-system transformation and/or knowledge of the literature on such initiatives. They were asked to comment specifically on what a governmental agency could do to support or facilitate the achievement of each statement. Of the ninety-eight people from ten countries invited to participate in the consultation group, forty-four completed the online survey and provided around one hundred pages of qualitative comments that were used to inform our final conclusions and recommendations.

Findings

Contextual Influences in the Primary Studies Reviewed

The eighty-four empirical studies of LST varied considerably in certain variables including, but not limited to, setting, demographics, type of health system, external influences (e.g., prevailing economic climate), level and source of funding, type of leadership, level of commitment of top management to the LST project, and the nature and quality of the IT infrastructure. These contextual influences affected how the projects unfolded to produce a variety of outcomes, varying from unqualified "success" to unqualified "failure." Specifically, and resonating with the principles of realist philosophy, mechanisms—that is, how and to what extent the actors drew on project resources to try to effect change—played out differently in different contexts. A number of differences in the context-mechanism-outcome configurations appeared to relate particularly to one or more of the simple rules covered in this review; others appeared relatively consistent across all the statements.

Simple Rules from the LST Literature

We next describe the five "simple rules" that emerged in our search for broad principles that would apply across all LST programs but that must be applied differently in different contexts, along with some references from the literature.

Simple Rule 1. Engage individuals at all levels in leading the change efforts. That is, this simple rule states that leadership must be both designated (i.e., someone must be formally in charge of the program) and distributed (i.e., professionals and partner organizations and teams must share responsibility for mobilizing the efforts and delivering program components).

Both in the literature that was reviewed and from the experiences of the consultation group, sustained commitment to change at the most senior levels of an organization or system appeared to be almost invariably linked to the presence of distributed leadership throughout the organization or system (Blunt, Harris, and NESTA 2009; Spillane 2005). The essence of distributed leadership, which is contrasted with the notion of the "heroic" and charismatic individual leader, was summarized as follows:

> [Distributed leadership] does not require an individual who can perform all of the essential leadership functions, only a set of people who can collectively perform them. Some leadership functions (e.g., making important decisions) may be shared by several members of a group, some leadership functions may be allocated to individual members, and a particular leadership function may be performed by different people at different times. The leadership actions of any individual leader are much less important than the collective leadership provided by members of the organization. (Yukl 1999, 292)

Distributed leadership means focusing on the practices and relationships involved in leadership as well as developing shared and evolving leadership through purposeful mentoring strategies. In the health care sector in particular, the complex layering of both the system and the multiple levels of professionalized autonomous practice means that distributed leadership is not only optimal but also necessary for large-scale transformative change to take place. The realist analysis revealed several mechanisms by which distributed leadership helps achieve LST. In particular, as the worked example in table 2 illustrates,

TABLE 2
How Simple Rules and Mid-Range Theories Were Derived from the Data (Using "Leadership" as the Worked Example)

Stage in Analysis	Output of Stage
Read and reread primary studies to gain familiarity with the data.	All primary studies broadly defined "leadership" as essential to success of large-system change. Most studies emphasized importance of "strategic leadership" and "top management buy-in." Several also talked of "distributed," "collective," "collateral," and "emergent" leadership.
Systematically extract statements of high-level principles and theoretical orientations made by authors of primary studies.	Examples of distributed leadership: • "Top-down" leadership alone cannot achieve whole-system change because (a) health systems are complex; (b) power is distributed among professional groups; (c) care is necessarily multidisciplinary; and (d) professions have their own norms and hierarchies (Chreim et al. 2010). • Processual theory (a "grand theory" about organizational change): we need to go beyond studying traits (e.g., qualities of "successful leaders") and use richly described longitudinal case studies to explore the context and process through which distributed leadership emerges and evolves dynamically in a way that cannot be planned in advance (Chreim et al. 2010). • Neoinstitutional theory (a "grand theory" about how institutions operate): the behavior of health care systems is strongly influenced by macro-level social forces, including professional norms, regulatory frameworks, and accepted ways of working (Harrison and Kimani 2009).
Systematically extract empirical findings from primary studies.	Examples of empirical findings on distributed leadership: • "In mobilizing and sustaining internal and external commitment to the redesign, the leaders of the transformation derived influence from their preexisting personal resources and network ties, as well as their formal authority. Their informal sources of influence included personal ties, status, knowledge, and past experience in improvement efforts" (Harrison and Kimani 2009, 46). • "The leaders we identified typically did not identify themselves as leaders. When asked about their leadership, they invariably took a modest approach and downplayed the importance of their roles"; "No single agent (individual or group) had full authority, resources, or expertise to lead the change. These elements were distributed across a number of actors who pooled their resources and abilities to bring about change" (Chreim et al. 2010, 197, 198).

Continued

TABLE 2
Continued

Stage in Analysis	Output of Stage
	• "... by themselves, improvement teams ran up against the limits of traditional intra-organizational boundaries. Often teams could not obtain the commitment of resources or the cooperation from other departments needed to effect change" (Lukas et al. 2007, 317).
Extract mid-range theories of leadership *explicitly* described or *implicit* in authors' accounts in primary studies.	Examples of mid-range theories invoked for distributed leadership: • Social capital theory (explicit, Chreim et al. 2010). • Freidson's theory of professions (explicit, Chreim et al. 2010). • Social influence theory, especially homophily: "The ability to influence is associated with the credibility and legitimacy that is attributed to those in leadership positions" (implicit, Chreim et al. 2010, 195). • Activity theory and distributed cognition—i.e., the notion that in order to achieve a complex task, members of a team work interactively and in an ongoing way that accommodates their separate inputs (Diamond 2007).
Pursue further relevant literature (e.g., papers cited by authors of primary studies) for new theories and/or additional detail.	Examples: • Buchanan et al. 2007; Carroll and Edmondson 2002; Ferlie et al. 2005 (all cited in Harrison and Kimani 2009).
Summarize findings in "simple rule."	Leadership must be both designated (i.e., someone is formally in charge of the program) and distributed (i.e., responsibility for mobilizing effort and delivering program components is shared among professionals and across partner organizations and teams).

distributed leadership invokes social capital theory (that different individuals have different types and levels of access to material and nonmaterial resources), Freidson's theory of professions (that professions are "closed shops" with their own internal logics and codes of conduct and whose members seek to self-organize), and social influence theory (that people are influenced by others with whom they share their social and professional background).

The primary literature on LST further suggests that the alignment between top leadership and distributed leadership depends on a number

of specific contextual features. First, it depends on the *mission*, *vision*, and *strategies* that set the system's direction and priorities, which need to be clearly laid out and known by everyone at all levels of the system (Institute for Healthcare Improvement 2005; Harrison and Kimani 2009; Lukas et al. 2007). Second, it depends on the informal *values* and *norms* of the system, including organizational culture ("the set of values and beliefs that cause people to behave in certain ways"; see Institute for Healthcare Improvement 2005, 5). If informal norms are flexible and include enough scope for people to behave differently, they can embrace new behaviors that will contribute to shifts in the underlying culture (Institute for Healthcare Improvement 2005). Third, it depends on the *human resources capacity* (Harrison and Kimani 2009) developed specifically to support the transformation initiatives proposed. Fourth, it depends on what Harrison and Kimani call "external conditions" that can create pressures for change (2009), such as political climate, policy mandates, and governmental initiatives (see also Lukas et al. 2007). Fifth, it depends on the degree of the system's *integration* (the more tightly woven/integrated it is, the easier that systemwide change tends to be; and the larger and more complex the system is, the more difficult that the alignment of goals across the system can be). Finally, it depends on the amount and consistency of *funding* for change initiatives over time.

In the realist analysis, we identified the following mechanisms through which the alignment between top leadership and distributed leadership might be achieved in practice:

1. An *explicit alignment* of formal vision and goals by top and middle managers in order to make them consistent with resource allocation and actions at all levels of the system, including integration to bridge intraorganizational boundaries (Lukas et al. 2007). This mechanism works by reducing the level of cognitive dissonance experienced by organizational actors, since the changes they are being asked to implement align with high-level statements about where the organization is heading and why.
2. *Active management* of the change strategy, perhaps through a designated change agent(s) dedicated solely or mainly to managing the process of change. This mechanism works by both generating a sense of energy and reducing the amount of time and effort needed from members of the organization who do not have time

to make the change (Chreim et al. 2010; Harrison and Kimani 2009).

3. *Small-scale pilot projects* (which work by demonstrating to actors that the change is possible and worthwhile) (Brown and Duthe 2009; Caldwell et al. 2008; Harrison and Kimani 2009; Lukas et al. 2007; McGrath et al. 2008). Once the pilot project has provided proof of concept, organizational members will be more willing to scale it up to a larger system change.
4. *Assurance* that the people will not be penalized for taking actions that are part of the change strategy implementation. This works by reducing the level of personal risk that actors must take to engage with a change initiative (Institute for Healthcare Improvement 2005; Small and Barach 2002).

Simple Rule 2. Establish feedback loops. Almost without exception, successful LST efforts were recognized and sustained through the careful identification of measures and judicious disclosure of those measures to those both inside and outside the organization. However, the literature also contains evidence that measurement can have counterproductive effects. For example, "Continuous measurement of processes is important, as is the choice of measures, because what gets measured influences behavior. People may have an incentive to do the wrong thing if it will improve the metric" (Institute for Healthcare Improvement 2005, 9). Furthermore, transformative processes that are not easily measured (or cannot be measured at all) may be at the heart of what is observed. Evaluation demands a careful blending of quantitative measures and accountability with qualitative methods such as interviews, ethnographic observation, and storytelling to make sense of the transformation effort.

Two contextual factors affect the successful use of measurement in LST: (1) the degree of the leadership's commitment to reporting measurements throughout the system (in all cases) and beyond the system (when such distribution would support the goals of the transformation) (Loftus 2010); and (2) the quality of the information infrastructure capable of reporting key indicators (e.g., an electronic patient record that allows secondary aggregation of data for audit and performance management purposes) (Brokel and Harrison 2009; Brown and Duthe 2009).

The mechanisms using measures and metrics that contribute to successful LST are as follows:

1. The active participation of all (relevant) stakeholder groups to determine the nature and range of measures to be used. Adequate representation is critical to identifying the full range of what needs to be measured and to avoiding measures that will influence behaviors in negative unintended ways.
2. The actors' confidence and trust in the validity of the measures. This is achieved by selecting metrics that are seen to accurately capture what is intended to be measured (e.g., identifying a metric that both clinicians and patients agree actually measures "patient-centeredness") (Boudreaux, Cruz, and Baumann 2006; Burstrom 2009; Conway et al. 2006).
3. The actors' understanding of "what the numbers mean" (including a nuanced understanding of what a change—or lack of change—in a particular metric signifies). This is achieved by clarifying concepts and achieving consistency and transparency of definitions, calculations, and reporting mechanisms (Stoop, Vrangbaek, and Berg 2005).
4. The actors' ability to influence and revise those measures and metrics that prove to be unfit for the purpose or in which they lose confidence. This is achieved by regular internal reviews of the selected measures, including reviewing outcomes from preliminary pilot projects in order to revise and improve the metrics by which a wider rollout of the project will be evaluated.
5. The actors' perception that the measures are consistent and are being applied systemwide. This is achieved by using standard measures throughout the system, including consistency between primary and secondary care and between clinical and administrative systems.
6. The inclusion of incentives for (or penalties for not) acting on feedback from reported measures (including patients' feedback). These must be sustained and systemic rather than one-off or short term, but their impact on behavior must be clearly understood so as to avoid gaming.

Simple Rule 3. Attend to history. The literature strongly suggests that the success of an LST depends on local history, but both the

authors of published studies in our sample and our consultation group sought to avoid a deterministic view of history. In other words, although a careful analysis of what has gone before is an important preliminary step when setting out to transform a health system, lessons from the past should not be seen as predictions of how things will unfold in the future. Rather, past "failures," critical events, or near-misses (which are likely to reveal weaknesses in individuals, teams, or systems) should be viewed as opportunities for sensitive discussion and judicious planning for how similar situations might be avoided and/or managed if they recur. Contextual factors that appear to influence particularly how the project takes account of history include the change leaders' awareness of and interest in the history of past change efforts; and the existence and availability of historical accounts, both personal and documentary, of earlier system change initiatives (Harrison and Kimani 2009).

Two mechanisms by which the use of such accounts might improve the success of an LST effort are

1. Educating the leadership throughout the system about previous change efforts and their outcomes, contextual factors and mechanisms that were influential and/or unsuccessful (and why) in past efforts for change, and the relationships between past efforts and current efforts.
2. Building on familiar and valued ideas and activities. In their review of Denver Health's system redesign, Harrison and Kimani concluded that "grounding the redesign's vision and change strategy in familiar ideas and activities reduced the likelihood of resistance by stakeholders loyal to Denver Health's past" and that "system changes are more likely to succeed when they are mutually reinforcing and well aligned with preexisting system features" (2009, 46, 52).

Simple Rule 4. Engage physicians. Based on the evidence presented in the literature (as well as on the experience of the research team and expert panel), the role of physicians appears crucial to health care transformation, for several reasons. First, transformative initiatives have often been endorsed and championed by care providers in the health care system who had less power (nursing professionals) or were operating on the periphery of the system (salaried public employees). Second, many physicians have historically (and currently do in Saskatchewan)

operated as independent, fee-for-service contractors, with a collegial regulatory framework that is focused more on protecting the profession and detecting extreme examples of poor practice or unethical behavior than on monitoring quality. This gives them a great deal of power and autonomy when responding to transformative efforts. Historically, in many health systems, physicians have been the principal players in either opposing change efforts or supporting successful transformative efforts, and in such cases physician champions have taken a lead role. This has led many experts to point to physicians' engagement as critical for change efforts to be successful (Kirkpatrick et al. 2009; McDonald, Harrison, and Checkland 2008).

Although the literature identified in this review emphasized the central importance of physicians in LST, our consultation group expressed some unease at singling them out. They felt that LST depends on the cooperation of all professional and administrative groups but that because of their different status and position in the health system, nonphysicians are often already more disposed to supporting the change effort (and/or have less power to resist the effort). In other words, it is not that physicians alone are needed to achieve LST but that they have often been reluctant to engage in change efforts and may have veto (or wrecking) power over initiatives broadly endorsed by others. Those contextual factors that appear to influence the effectiveness of physicians' engagement efforts are their relationship to other care providers institutionally, historically, politically, and individually (Kirkpatrick et al. 2009; McDonald, Harrison, and Checkland 2008); the relationship between and among physicians' organizations, health care systems, and governmental agencies (Hasselbladh and Bejerot 2007); any history of previous attempts to effect change and physicians' responses to those attempts (Kirkpatrick et al. 2009); and the strength and commitment of professional licensing and regulatory bodies (e.g., Colleges of Physicians) responsible for monitoring quality, enacting disciplinary measures, and certifying competence (Grol 2006).

Taking these contextual influences into account, there may be four influences on the mechanisms of physicians' engagement in LST:

1. The alignment of professional and regulatory drivers. In particular, physicians' engagement is more likely when a quality assurance framework that monitors quality indicators is linked to incentives, professional development and recertification, and,

ultimately, disciplinary measures (Crampton and Starfield 2004; Sibthorpe 2005).
2. The strength of incentives. This may require a change in the incentive structure, for example, moving from exclusive fee-for-service to mixed remuneration models, including capitation, salaried, and pay-for-performance.
3. Facilitation and guidance through the process, for example, through a dedicated change manager or facilitator (Chreim et al. 2010).
4. Professional directives and examples through the engagement of physician leaders and colleges/associations in all aspects of the change process (Chreim et al. 2010; Kirkpatrick et al. 2009).

Simple Rule 5. Involve patients and families. An extensive literature suggests that involving patients and families in the change effort often helps deliver improvements in care processes, gains in health literacy, and more effective priority setting (Blunt, Harris, and NESTA 2009), as well as more appropriate and cost-effective use of health services and better health outcomes (Chessie 2009; Coulter 2005; Thompson 2003/2004). The ongoing involvement of service users appears to enhance outcomes compared with one-off consultations (Mitton et al. 2009). Furthermore, patients clearly do not exist in isolation; their families also often contribute significantly to their health and well-being and their effective accessing and use of services (conversely, the absence of family support may account for poor access and poor outcomes) (Conway et al. 2006). It is perhaps self-evident that the more service users that are involved in the change process, the more "patient centered" the services will become. But health care providers, patients, and families may differ on what they regard as "patient- [and family-] centered care" or on how to measure this construct. During this review, the Saskatchewan policymakers refined their definition of patient and family centeredness as four core constructs of dignity and respect, information sharing, participation, and collaboration. The literature suggests that having defined the constructs, a shared agreement and a commitment to them can then be used for specific practices for implementation, for example, by practitioners (Audet, Davis, and Schoenbaum 2006).

Our expert panel strongly affirmed the importance of the principle of patient centeredness and of seeking patients' and families' input to LST efforts, but they also considered this to be a problematic area. First,

they felt that "patient and family centeredness" was generally defined badly and used in a somewhat ideological way ("impossible to disagree with"). Second, the gap between principle and practice was perceived to be particularly wide here. There are very few examples of a successful effort to truly engage patients in LST (but see Greenhalgh et al. 2009). The contextual factors that tend to improve the success of efforts to draw on the experience and expertise of patients and families in LST include the historical role of patients in health care system decision-making and change efforts (including the culture of the health care system and the value it places on patients' and families' voices); the (perceived) success of previous efforts in this area; and the existence of specific processes and methods for involving patients and their representatives in feedback and decision making throughout the system (Bauman, Fardy, and Harris 2003; Blunt, Harris, and NESTA 2009; Davis, Schoenbaum, and Audet 2005; Fraenkel and McGraw 2007).

The mechanisms by which the patients' and families' involvement help achieve a system oriented to patient-centered care are the following:

1. Heightened awareness by policymakers and change agents of patients' perspective and priorities, especially when the engagement is sustained (Mitton et al. 2009).
2. Heightened sense of validity. A perception by both staff and service users that metrics reflect patients' priorities, since they are based on patients' and families' input (Thompson 2003/2004).
3. Heightened sense of equity. A perception by staff and service users that the metrics are inclusive and equitable through the representation of traditionally underrepresented groups and by the deliberate inclusion of patients' and families' voices that are typically or historically silent in the decision-making processes. (Chessie 2009; Thompson 2003/2004)

Conclusions

This rapid realist review identified five simple rules for LST, which in retrospect are somewhat unsurprising: (1) engage individuals at all levels in leading change efforts; (2) establish feedback loops; (3) attend to history; (4) engage physicians; and (5) involve patients and families. Our review also highlighted those elements of contexts that affect how

these simple rules are carried out and the mechanisms by which they affect human behavior and thereby contribute to change.

For each of the five simple rules for LST, there are mid-range theories that support and elucidate ways of conceptualizing the issues. Table 2 shows the mechanisms that appear to be operating in relation to distributed leadership. "Establish feedback loops" draws on the mid-range behaviorist theory of the role of feedback loops (positive and negative) in modifying human behavior (e.g., Holmes et al. 2012). "Attend to history" draws on the theory of path dependence (e.g., Tuohy 1999), which explains that how things unfold in the future depends on how they have been unfolding to date. "Engage physicians" can be theorized partly by social influence theories (e.g., Dearing and Kee 2012), that powerful and respected actors are more influential than less powerful and less respected ones. Finally, "Involve patients and families" draws on (among others) theories of experience-based design (Bate and Robert 2007), that service models designed by and with users will be more fit for the purpose and therefore "work better."

Additional work is needed to find more applications of these theories to case studies of LST, identifying areas of overlap and divergence and laying the groundwork for further tests and tailoring of these theories to LST principles.

The realist analytic lens places much emphasis on human agency and on reasoning—rational and irrational, cognitive and emotional—which links the resources provided for a change effort to the outcomes achieved in it, taking account of context. Change requires human input and human qualities such as energy, commitment, some understanding, a sense that one is doing the right thing and acting reasonably in the circumstances, and a belief that what one is doing will be worthwhile, effective, and appropriately rewarded. Even when all these elements are present, they will have different effects in different contexts. This article, which was based on a rapid review of a restricted literature and should therefore be seen as preliminary, articulated some of the context-mechanism-outcome configurations that have begun to explain why some LST initiatives produce significant and sustained change and others do not.

The strengths of this study rest on those of the realist methodology embedded in a collaborative policy research framework. Clear questions frame the "what works, for whom, under what circumstances" inquiry, which offers results more useful to policymakers than do those

from a narrower, Cochrane-style review. The emerging mid-range theory describes context-mechanism dynamic interplay in ways that resonate with the policymakers' experience and serve to illuminate and guide the refinement of strategies. In particular, surfacing guidance on "how" interventions work, rather than just "what" works, combines with a greater understanding of complex adaptive systems to suggest "simple rules" that offer principles for future initiatives. For example, the evidence on top-down and distributed leadership reinforced the ministry's growing emphasis on the need for transformative leadership development as critical to success and crosscutting all transformation initiatives.

A second strength of the study is the degree to which the work was embedded in the system's transformation change structures. This coproduction way of working (Van de Ven 2007) tends to accelerate transformation. The review itself offers a foundation for developing and refining strategic communications that can influence the system's culture and promote the sustainability of change (Scheirer and Dearing 2011).

A final strength is the contribution of this review to implementation science. There is a growing recognition that the theory and methods of evidence-based medicine that largely apply to individual interventions are not well suited to studies of implementation in systems. There is a pressing need for further development of the science for community and systems interventions (Trickett et al. 2011).

One limitation of this study largely derives from the truncated six-month time frame specified by the funder. The six-month frame was both a blessing and a curse. On the one hand, it aligns well with the rate of change in the systems that the review is meant to inform, and it forces a greater discipline in focusing efforts with greater priority. On the other hand, six months is very short for reviewing complex, fragmented, and difficult-to-find literature. As a consequence, the research team and the steering committee had few opportunities for greater reflection. This in turn both limited how much we realistically could achieve from an academic perspective and reduced opportunities for the synthesis to be more fully integrated in and useful for the policymakers' transformation work.

A second, and perhaps more important, limitation of this study was not with the methodology but with what was *not* in the literature or identified by our consultation group. The five simple rules described here may be necessary for large-system transformation but are probably not sufficient. It is common in health care circles, for example, to refer to a "burning platform" as an essential catalyst for LST, yet the literature

did not identify this explicitly as one of the five enabling factors, in part owing to the focus of the review and synthesis on possible government action. Most "burning platforms" are perceived to be externally driven (e.g., extreme budget crisis, very public examples of health system failure); without such a perceived set of contextual factors in Saskatchewan now, this review concentrated more on elements related to that province. This and other elements therefore may be missing from our final set of simple rules, not because they are unimportant, but because there is not yet a research literature on them.

The way we think that the research agenda on LST should continue includes both research theory and practice. First, we need to refine and improve the methodology for realist reviews, including better specification of the terminology and theoretical assumptions (Greenhalgh et al. 2011). Second, we recommend greater use of realist evaluation studies in complex change efforts. We need ways to compare and contrast lessons learned across case studies, ideally by designing and coordinating prospective comparative case studies that use common terminology and measures to study similar interventions across varying contexts. Finally, the field must better understand the role of political context in transformational change, and also what many people consider to be the pivotal contribution of a current "burning platform" in the historical context of change.

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APPENDIX

Final Sample of Papers Reviewed

Aggarwal, M. 2009. Primary Care Reform: A Case Study of Ontario. PhD diss., University of Toronto.

Audet, A.M., K. Davis, and S.C. Schoenbaum. 2006. Adoption of Patient-Centered Care Practices by Physicians: Results from a National Survey. *Archives of Internal Medicine* 166(7):754–59.

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