Rapid Synthesis

Creating Rapid-learning Health Systems in Canada

Appendix A:
Research literature about rapid-learning health systems

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EVIDENCE >> INSIGHT >> ACTION

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90-day response

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APPENDIX A: Research literature about rapid-learning health systems

Insights from the research literature about rapid-learning health systems

We identified only a small amount of new research literature through our updated searches:
1) no new systematic reviews about rapid-learning health systems;
2) one new primary study about rapid-learning health systems, which was focused on a Veterans Health Administration program (see the first row of Table 3 in Appendix A); and
3) one new descriptive case of a rapid-learning health system, which was focused on a nascent initiative in Switzerland (see the first row of table 4 in Appendix A).

We provide the full set of identified literature in Tables 2-4 below, which (as noted above) is available as a separate document. We summarize below the key messages from this research literature, but readers more interested in assets and gaps can proceed directly to the next sub-section.

We found two systematic reviews and two qualitative studies that complement our proposed definition and characteristics of rapid-learning health systems:

- one low-quality systematic review examined attempts to adopt the rapid-learning health system paradigm, with an emphasis on implementation and evaluating the impact on current medical practices, and it identified three main themes:(1)
  - clinical data reuse (i.e., building learning health systems by extracting knowledge from geographically distributed data collected in daily clinical practice),
  - patient-reported outcome measures (i.e., using patient reporting mechanisms for collecting health-related quality indicators),
  - collaborative learning (i.e., using peer specialists for both capturing the indicators of healthcare delivery and encouraging changes through support/pressure);
- another low-quality systematic review examined the spectrum of ethical issues that arise in a rapid-learning health system and it grouped the 67 distinct ethical issues within four phases of the rapid-learning health system: (2)
  - designing activities: the risk of negative outcomes (e.g., reducing the quality and usability of results) from designing learning activities less rigorously so they are not classified as research, and the risk of inadequate engagement of stakeholders (which can affect the success of the learning activity due to a lack of established trust and support),
  - ethical oversight of activities: the conflict between current oversight regulations and a learning health system, which can delay or even prevent learning activities from being conducted due to confusion regarding which learning activities require ethical oversight, and an inconsistent and burdensome oversight process,
  - conducting activities: risks of misguided judgments regarding when and how participants should be notified and asked for consent, and the conflict between current data-management practices and regulations, and the goals of a learning health system,
  - implementing learning: difficulties with changing practice in a timely manner (e.g., due to conflicts with the current research infrastructure or current financial incentives), issues of transparency (e.g., due to underperforming providers or commercial interests), and unintended negative consequences from implementation (e.g., widening health disparities or increasing the risk of liability);
- the same review identified three types of strategies to address these ethical issues:(2)
  - clear and systematic internal policies and procedures to determine which learning health system activities require ethical review, how data sharing and data protection should be handled, and how to inform patients in routine and systematic ways about learning health system activities being conducted,
  - training and guidance for ethics committee members to learn how to apply ethical principles in the context of learning health system activities, and for researchers to learn about ethics guidelines,

  - simplified ethical review and consent process to make it easier for learning health system activities to be conducted, including implementing dedicated ethical review process, standardizing and harmonizing the ethical review process across multiple research sites, and streamlining the consent process;
- one qualitative study identified seven ethical issues arising in the transition to learning health systems:(3)
  - ethical oversight of learning activities (i.e., distinguishing which learning activities should go to an ethics review board),
  - transparency to patients about learning activities (i.e., determining whether and how to disclose information to patients about ongoing learning activities),
  - potential tensions in improving quality and reducing costs (i.e., concern that moving toward continuous learning is not always in the financial interest of organizations),
  - ethics of data sharing and data management (i.e., potential implications of sharing electronic data for patient privacy),
  - lag time between discovery and implementation (i.e., recognition of shortcomings of the current system in both identifying and implementing evidence-based practices),
  - transparency to patients about quality (i.e., determining whether and how to inform patients about underperforming providers or groups),
  - ethics of randomization for care and quality-improvement initiatives (i.e., concern that randomizing individuals to the placebo arm might fail to provide them with potential benefits); and
- another qualitative study identified six sources of learning, including intelligent automation, clinical decision support, predictive models, positive deviance, surveillance, and comparative effectiveness research.(4)

We also did not find particularly germane evidence about the impacts of the characteristics taken as a whole or individually, or about factors that stimulated the development and/or consolidation of a rapid-learning health system, however, we did find two systematic reviews and a number of primary studies that spoke to aspects of these issues:

- one high-quality systematic review found a lack of evaluative research about the capacity of human-resource information systems (i.e., systems dealing with the management of human resources, such as recruitment, teaching, planning and resource allocation) to enable learning health systems;(5)
- one low-quality systematic review examined attempts to adopt the learning health system paradigm, with an emphasis on implementation and evaluating the impact on current medical practices, and found minimal focus on evaluating impacts on healthcare delivery and patient outcomes;(1)
- one study examined factors allowing a health system to become a learning health system:(6)
  - five themes emerged about the process of transitioning towards a learning health system: 1) visionary leadership or influence of a key individual; 2) adaptation to a changing healthcare landscape; 3) external funding, 4) regulatory or legislative influence; and 5) mergers or expansions,
  - six challenges emerged: 1) organizational culture; 2) data systems and data sharing; 3) funding learning activities; 4) limited supply of skilled individuals; 5) managing competing priorities; and 6) regulatory challenges,
  - eight strategies were identified to support transformation: 1) strong leadership; 2) setting a limited number of organizational priorities; 3) building on existing strengths; 4) training programs; 5) 'purposeful' design of data systems; 6) internal transparency of quality metrics; 7) payer/provider integration; and 8) within academic medical centres, academic/clinical integration;
- one study identified four key factors supporting the successful implementation of a rapid-learning health system: 1) clinician engagement with primary research and existing research evidence; 2) ongoing collection of robust data; 3) flexibility of the model in order to adapt to new challenges; and 4) culture change;(7)
- one study identified six principles to advance an organization's learning capabilities, as a core element of a rapid-learning health system: 1) draw on the wisdom of groups and value connections; 2) embrace sense-making over decision-making in dealing with the unexpected; 3) bring diverse perspectives to complex challenges; 4) animate people, provide direction, update regularly, and interact respectfully; 5) appreciate the power and ubiquity of emergent change and the limitations of planned change; and 6) concentrate on small wins and characterize challenges as mere problems;(8)

- one study revealed that implementing a mechanism to share data and research evidence (via electronic health records) may not be sufficient for creating a rapid-learning health system, and the study identified:(9)
  - four key barriers for the timely sharing of data and research evidence via electronic health records: 1) different electronic health record systems do not record clinical data items consistently; 2) providers are rarely incentivized to maintain good data quality on the basis of research use alone; 3) legal and ethical constraints in many countries limit linkage of data and its use for research without consent; and 4) researchers are largely unaware of potential benefits offered by electronic systems to support research, and do not therefore create demand for wider deployment,
  - four solutions to address these barriers: 1) promoting the mandatory adoption of information-exchange standards for the exchange of data across electronic health record systems; 2) provide good clinical reasons for data quality and detailed record keeping (e.g., audit or decision support); 3) promote international consensus as to how and when data can be linked without consent, and develop systems for managing consent to extraction or study participation across systems; and 4) conduct well-publicized pilot deployments and evaluations;
- one study explored the perspectives of health-system leaders regarding the operationalization of a rapid-learning health system and identified 10 themes related to operationalization: 1) align the learning infrastructure and learning health system activities in support of the system's strategic goals; 2) align learning with employee incentives; 3) integrate cultural and operational silos; 4) balance learning and work flow; 5) shift the focus of learning from process improvement to improving outcomes; 6) address challenges in the current healthcare environment that have an impact on learning; 7) balance the need to execute and evaluate operational activities given limitations of evaluation methodologies; 8) support 'make-or-buy' decisions for learning (e.g., build an application or learning tool in house versus purchase the product from a vendor); 9) integrate the oversight of the research-quality improvement continuum; and 10) determine the costs and value of learning (i.e., not adding additional costs to the health system through operationalizing the learning health system);(10)
- one study examined residents' attitudes about quality improvement, which may have implications for the implementation of rapid-learning health systems, and it identified four barriers to residents' participation in quality-improvement initiatives: 1) challenges with understanding the vision of quality improvement; 2) confusion about basic aspects of quality improvement; 3) the perception that residents' contributions to quality improvement are not valued/valuable to the quality-improvement process; and 4) challenges with prioritizing responsibilities relating to quality improvement compared with other responsibilities;(11)
- two studies examined the development of core competencies to support the implementation of rapid-learning health systems:
  - the first study examined the development and refinement of a Learning Health Systems Training Program for resident physicians and found that:(12)
    - challenges encountered during the implementation of the program included scheduling, mentoring, data standardization, and iterative optimization of the curriculum for real-time instruction,
    - successful methods for teaching the curriculum included diverse multidisciplinary educators, just-in-time instruction, tailored content, and mentored projects with local health system impact; and
  - the second study identified 33 core competencies for learning health system researchers to guide the development of training programs, which were grouped into seven domains: 1) systems science; 2) research questions and standards of scientific evidence; 3) research methods; 4) informatics; 5) ethics of research and implementation in health systems; 6) improvement and implementation science; and 7) engagement, leadership, and research management.(13)

Although we did not find research literature that used the characteristics of learning health systems to document assets and identify gaps, we did find a number of descriptive case studies of rapid-learning health systems:

- the descriptive case studies showcased various rapid-learning health systems, including for a health system as a whole, as well as some implemented in specific organizations (e.g., academic health centres) and sectors (e.g., specialty care) and for specific categories of conditions (e.g., chronic diseases and cancer), categories of treatments (e.g., surgery and palliative care), and populations (e.g., children and youth);

- the descriptive case studies generally focused on the key factors influencing the successful implementation of rapid-learning health systems, with the following common themes emerging:
  - meaningful stakeholder engagement, partnership and co-production being key pillars in the development and implementation of rapid-learning health systems,(14-18)
  - a robust data infrastructure being a central component of rapid-learning health systems (e.g., data need to be systematically and consistently captured, readily available, and shared; the system must allow multi-institutional data sharing; standardized technological approaches should be used to reduce the burden of data entry such as electronic health record-based data collection forms; and patient-centred metrics are critical),(16; 19-22)
  - leadership-instilled culture of learning required,(14; 16; 19)
  - strategic and operational assistance required to support the development of core competencies in various areas (including implementation science, systems redesign, health services research, and health information technology),(19; 23)
  - clear set of performance and quality measures required to evaluate the development and implementation of rapid-learning health systems (including public reporting on performance and quality);(17; 19) and

one descriptive case study highlighted the need to proceed in sequence: 1) assembling the core team and clarifying terms; 2) learning from existing models; 3) tailoring the model to the specific setting or sector; and 4) building the learning health system using rapid-cycle testing.(15)

Methods and tables underpinning these insights

The following tables provide detailed information about the relevant research evidence identified for this rapid synthesis. The ensuing information was extracted from the following sources:

- documents exploring the conceptual and theoretical underpinnings of rapid-learning health systems – the focus of the document, year of publication, definition of learning health system, and key findings;
- systematic reviews - the focus of the review, key findings, last year the literature was searched, and the proportion of studies conducted in Canada;
- primary studies - the focus of the study, methods used, study sample, jurisdiction studied, key features of the intervention and the study findings (based on the outcomes reported in the study); and
- descriptive cases of rapid-learning health systems – the case characteristics, the key features of the rapid-learning health systems, and the implementation considerations.

For the appendix table providing details about the systematic reviews, the fourth column presents a rating of the overall quality of each review. The quality of each review has been assessed using AMSTAR (A MeaSurement Tool to Assess Reviews), which rates overall quality on a scale of 0 to 11, where 11/11 represents a review of the highest quality. It is important to note that the AMSTAR tool was developed to assess reviews focused on clinical interventions, so not all criteria apply to systematic reviews pertaining to delivery, financial or governance arrangements within health systems. Where the denominator is not 11, an aspect of the tool was considered not relevant by the raters. In comparing ratings, it is therefore important to keep both parts of the score (i.e., the numerator and denominator) in mind. For example, a review that scores 8/8 is generally of comparable quality to a review scoring 11/11; both ratings are considered "high scores." A high score signals that readers of the review can have a high level of confidence in its findings. A low score, on the other hand, does not mean that the review should be discarded, merely that less confidence can be placed in its findings and that the review needs to be examined closely to identify its limitations. (Lewin S, Oxman AD, Lavis JN, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP): 8. Deciding how much confidence to place in a systematic review. *Health Research Policy and Systems* 2009; 7 (Suppl1):S8).

All of the information provided in the appendix tables was taken into account by the authors in describing the findings in the rapid synthesis.

Table 1: Summary of findings from documents exploring the conceptual and theoretical underpinnings of rapid-learning health systems

Focus of document	Year of publication	Definition of learning health system	Key findings
Examining the LADDERS paradigm for planning, implementing, and evaluating sustainable change in learning health systems (24)	2018	None identified (although the author refers to the work of the Institute of Medicine)	Drawing from the implementation sciences, the author proposes the LADDERS paradigm for planning, implementing and evaluating sustainable change in learning health systems. The acronym stands for: Leadership, Alignment, Data, Demonstration, Evaluation, Replication, and Sustainability. This paradigm is a synthesis of those elements regularly cited by health-system leaders implementing successful transformational changes.
Exploring a continuum model for distinguishing various levels of community engagement in learning health systems (25)	2018	A learning health system is "designed to generate and apply the best evidence for the collaborative health care choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care."	Integrating a team-based culture of engagement in the learning health system is critical. The authors formulated seven recommendations: "1) explore ways to intentionally integrate the community voice when defining and establishing a learning health system; 2) utilize the concept of community engagement as a continuum; 3) identify ways to include the patient or the community at every possible level; 4) inform and advise a patient of their options and opportunities; 5) provide education and information about the health record and response; 6) be open to challenging feedback that may inform the process; identify ways to include the feedback in the ongoing continuous quality improvement process; 7) maintain high-quality engagement throughout the learning health cycle."
Describing the framework and progression of a national learning health system, as well as the advantages of and challenges to public-health involvement in a learning health system (26)	2015	A learning health system is defined as "a platform that seeks to leverage health data to allow evidence-based real-time analysis of data for a broad range of uses, including primary care decision making, public health activities, consumer education, and academic research."	The article highlights 10 core values of learning health systems: 1) person-focused; 2) privacy; 3) inclusiveness; 4) transparency; 5) accessibility; 6) adaptability; 7) governance; 8) cooperative and participatory leadership; 9) scientific integrity; and 10) value.
Examining how learning health systems can learn and 'forget', (or programmatically decommission, obsolete practices) (27)	2017	The author suggests the need for the definition of learning health system to evolve (from definition 1 to definition 2). • Definition 1: "A system with explicit systemic learning mechanisms characterized by the use of information to generalize lessons within the system." • Definition 2: "A system with explicit systemic learning and decommissioning mechanisms characterized by the use of information to both generalize lessons from within the system and maintain efficient system function through controlled decommissioning or forgetting."	The author argues that learning health systems need to find ways to remember processes that shape quality and safety (using data that often resides beyond electronic health records), but also need to 'forget' (or programmatically decommission) obsolete practices.
Examining the path to continuously learning health care in America (28)	2013	A learning health system is defined as "one in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the care process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the care experience."	A continuously learning health system has the following characteristics: • Science and Informatics o real-time access to knowledge o digital capture • Patient-Clinician Partnerships o engaged, empowered patients

Focus of document	Year of publication	Definition of learning health system	Key findings

			• Incentives
			  o incentives aligned for value
			  o full transparency
			• Continuous Learning Culture
			  o leadership-instilled culture of learning
			  o supportive system competencies
			
			The report highlights 10 recommendations to implement a continuously learning health system
			Foundational Elements
			• The digital infrastructure: Need to improve the capacity to capture clinical, care-delivery process, and financial data for better care, system improvement, and the generation of new knowledge.
			• The data utility: Need to streamline and revise research regulations to improve care, promote the capture of clinical data, and generate knowledge.
			Care Improvement Targets
			• Clinical decision support: Need to accelerate integration of the best clinical knowledge into care decisions.
			• Patient-centered care: Need to involve patients and families in decisions regarding health and health care, tailored to fit their preferences.
			• Community links: Need to promote community-clinical partnerships and services aimed at managing and improving health at the community level.
			• Care continuity: Need to improve coordination and communication within and across organizations.
			• Optimized operations: Need to continuously improve healthcare operations to reduce waste, streamline care delivery, and focus on activities that improve patient health.
			Supportive Policy Environment
			• Financial incentives: Need to structure payment to reward continuous learning and improvement in the provision of best care at lower cost.
			• Performance transparency: Need to increase transparency on healthcare system performance.
			• Broad leadership: Need to expand commitment to the goals of a continuously learning healthcare system.

Examining the progress toward building a rapid-learning health system in the United States (29)	2014	A rapid-learning health system "learns as quickly as possible about the best treatment for each patient − and delivers it. It makes optimal use of information technology and electronic health record (EHR) capabilities and new databases with tens of millions of patients' records. A rapid-learning system enables and speeds up all elements in the knowledge production and adoption process: discovery science, new drugs development, testing and approval, comparative	There are key barriers to the implementation of a rapid-learning health system, including: the concept being too ambitious for America's pluralistic health system; advancing biomedical science is going to prove more difficult than expected (even with massive new databases, learning networks, and analytic tools); and capacity constraints (e.g., in software capabilities or the number of data scientists able to analyze massive datasets).

Focus of document	Year of publication	Definition of learning health system	Key findings
		effectiveness research, physician and patient decision support, and incentives for best practices. A rapid-learning system builds learning networks, delivery systems, and professional societies that use EHRs and computerized databases to assess performance, adopt best practices, assess results, and feedback these lessons."	
Describing an ethics framework for a learning healthcare system (30)	2013	A learning health system is a system "in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care."	The proposed ethics framework consists of seven obligations: 1) to respect the rights and dignity of patients; 2) to respect the clinical judgment of clinicians; 3) to provide optimal care to each patient; 4) to avoid imposing nonclinical risks and burdens on patients; 5) to reduce health inequalities among populations; 6) to conduct responsible activities that foster learning from clinical care and clinical information; and 7) to contribute to the common purpose of improving the quality and value of clinical care and healthcare systems.
Examining how to conceptualize and create a global learning health system (31)	2013	Uses the Institute of Medicine's definition of a learning health system: "one in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and health care."	To achieve this vision of a modern learning health system giving best care for citizens, a number of actions are needed: • embrace the learning health system concept as a core philosophy; • alter the rhetoric from 'secondary use' to 'co-use'; • establish explicit governance, privacy and consent protocols, and a robust oversight mechanism with effective potential sanctions that makes possible a functioning system; • establish a norm of reciprocity; • learn from and about the learning process; • invest in systematic analysis of learning organization national or population-level data; • recognize the value of the minimal additional costs in making learning system data available; and • recognize the importance of enterprise-wide activity.
Identifying the fundamental scientific and engineering research challenges to achieving a national-scale learning health system (32)	2015	Uses the Institute of Medicine's definition of a learning health system: "one in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and health care."	The article highlights the following system-level requirements that a high-functioning learning health system must satisfy: 1. A learning health system trusted and valued by all stakeholders • defining, measuring, and tracking confidence and trust • building confidence and trust in the data inputs • building confidence and trust in the process • generating value while building confidence and trust in the outputs • building confidence and trust in the system as a whole 2. An economically sustainable and governable learning health system • private sector incentives and markets • the role of the public sector in the learning health system • conceptualizing value in the context of the learning health system • the learning health system and the healthcare/health system as a whole 3. An adaptable, self-improving, stable, certifiable, and responsive LHS

Focus of document	Year of publication	Definition of learning health system	Key findings
			• an adaptable learning health system • a self-improving learning health system (that builds trust in the system) • a certifiable learning health system • a stable learning health system (through trust and confidence) • a responsive learning health system 4. A learning health system capable of engendering a virtuous cycle of health improvement • rapidly creating knowledge that engenders learning • communication within the learning health system: What mechanisms will enable communication of methods used and results obtained, in actionable forms, to all stakeholders with interest in the results? • building a smart system: How can the learning health system become smart enough? • learning about learning, research about research • key questions specific to health improvement
Examining the fundamental properties of a highly participatory rapid learning system (33)	2010	A federated national learning system in which "data remain in place until they are needed elsewhere for a particular purpose. Predicated on a policy framework that ensures public trust in the process, organizations that are members of a learning system are eligible to place queries to all other members who would then provide relevant information to address the query."	Achieving this vision "will require mutually reinforcing technologies, standards, and policies created in specific anticipation of nationwide implementation. The national program to achieve EHR meaningful use will contribute many but not all of these."
Describing an evolving learning health system at Group Health Cooperative, the six phases characterizing its approach, and examples of organization-wide applications (34)	2012	A rapid-learning health system "leverages recent developments in health information technology and a growing health data infrastructure to access and apply evidence in real time, while simultaneously drawing knowledge from real-world care-delivery processes to promote innovation and health system change on the basis of rigorous research."	The conceptual foundation of the rapid-learning health system has both human and technological aspects. The six phases of the rapid-learning health system are: • internal and external scan (i.e., identify problems and potentially innovative solutions); • design (i.e., design care and evaluation based on evidence generated here and elsewhere); • implement (i.e., apply the plan in pilot and control settings); • evaluate (i.e., collect data and analyze results to show what does and does not work); • adjust (i.e., use evidence to influence continual improvement); and • disseminate (i.e., share results to improve care). The rapid-learning health system model "promotes bidirectional discovery and an open mind at the system level, resulting in willingness to make changes on the basis of evidence that is both scientifically sound and practice-based. Rapid learning must be valued as a health system property to realize its full potential for knowledge generation and application."
Identifying and reflecting on current strategies and	2011	A transformative, patient-centred learning health system is "a system designed to generate and apply the best evidence for	Ten common themes emerged about the importance of a patient-focused culture in the content, structure and functioning of a patient-centred, learning health system:

Focus of document	Year of publication	Definition of learning health system	Key findings
programs advancing public understanding of a transformative, patient-centred learning health system (35)		care; provide evidence discovery as a natural outgrowth of patient care; and strive for innovation, quality, safety, and value in health care."	• Listening: Each patient-clinician interaction starts with uninterrupted attention to the patient's voice on issues, perspectives, goals and preferences. • Participatory: Health outcomes improve when patients are engaged in their own care. • Reliable: All patients should expect proven best practice as the starting point in their care. • Personalized: With proven best practice as the starting point, science-based tailoring is informed by personal biological traits, circumstances and preferences. • Seamless: Care delivered by multiple providers in multiple settings should be fully integrated and seamless. • Efficient: Patients, their families and clinicians should expect care to be appropriate to the need, available resource and time required. • Accountable: All relevant aspects of the clinical experience, including patient perspectives, should be captured and routinely assessed against expectations. • Transparent: Information on the outcomes of care − both effectiveness and efficiency − should be readily accessible and understandable to patients and their families. • Trustworthy: Patients should expect a strong and secure foundation of trust on all dimensions − safety, quality, security, efficiency, accountability and equity. • Learning: The patient is an active contributor to and supporter of the learning process.
Exploring strategies for accelerating the development of the digital infrastructure for the learning health system (36)	2011	A learning health system is "a system designed to generate and apply the best evidence for care; provide evidence discovery as a natural outgrowth of patient care; and strive for innovation, quality, safety, and value in health care."	Ten common themes and principles emerged: • build a shared learning environment • engage health and healthcare, population and patient • leverage existing programs and policies • embed services and research in a continuous learning loop • anchor in an ultra-large-scale systems approach • emphasize decentralization and specifications parsimony • keep use barriers low and complexity incremental • foster a socio-technical perspective, focused on the population • weave a strong and secure trust fabric among stakeholders • provide continuous evaluation and improvement
Identifying promising areas for application of engineering principles to the design of a learning healthcare system (37)	2011	A learning health system is "a system designed to generate and apply the best evidence for care; provide evidence discovery as a natural outgrowth of patient care; and strive for innovation, quality, safety, and value in health care."	Eleven common themes emerged: • the system's processes must be centered on the right target − the patient • system excellence is created by the reliable delivery of established best practice • complexity compels reasoned allowance for tailored adjustments • learning is a non-linear process • emphasize interdependence and tend to the process interfaces

Focus of document	Year of publication	Definition of learning health system	Key findings
			• teamwork and cross-checks trump command and control • performance, transparency and feedback serve as the engine for improvement • expect errors in the performance of individuals, but perfection in the performance of systems • align rewards on key elements of continuous improvement • education and research can facilitate understanding and partnerships between engineering and the health professions • foster a leadership culture, language and style that reinforce teamwork and results
Examining issues important for improving the development and application of evidence in healthcare decision-making (38)	2007	A learning healthcare system "is designed to generate and apply the best evidence for the collaborative healthcare choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care."	Among the most pressing needs to achieve the learning healthcare system are: • adaptation to the pace of change • stronger synchrony of efforts • culture of shared responsibility • new clinical research paradigm • clinical-decision support systems • universal electronic health records • tools for database linkage, mining and use • notion of clinical data as a public good • incentives aligned for practice-based evidence • public engagement • trusted scientific broker • leadership
Describing an architectural framework to guide the development and implementation of learning health systems (39)	2017	Uses a 2006 definition of the Institute of Medicine: a learning health system is a system in which "science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience."	The authors propose the use of architectural frameworks to develop learning health systems which would adhere to a recognized vision while being adapted to their specific organizational context. An architectural framework is a high-level description of an organization as a system (including structures and components, inter-relationships among these, and guiding principles). Learning health systems are generally described and compared based on: • their focus (domain-specific vs multi-domains); and • their scale (single health organizations versus multi-organizations/regional versus national) The proposed architectural framework for learning health systems includes five dimensions: • goal dimension; • scientific dimension; • social dimension; • technical dimension; and • ethical dimension.

Focus of document	Year of publication	Definition of learning health system	Key findings
			The proposed framework also highlights six decision layers that model these dimensions: • the performance layer (identifying the goals pursued by a learning health system, as well as measures to track the achievement of these goals); • the scientific layer (identifying the learning activities that will be undertaken in a given learning health system, such as quality improvement or comparative-effectiveness research); • the organizational layer (capturing the chosen governance model and associated responsibilities); • the data layer (providing a common way to describe and share data across organizational boundaries); • the information technology layer (enabling a standardized manner of categorizing information and communication-technology assets, whether software, hardware or network related); and • the ethics and security layer (capturing the ethical and privacy dimensions of health data collection and use as they relate to security controls and measures).
Examining activities that are necessary for developing a rapid-learning health system (40)	2007	Not reported in detail	Four considerations are important for establishing learning health systems: • recognize that the patient is paramount; • trust is essential; • agreeing to agree on some things is elemental; and • learn what we can about the risks of findings that come from studies other than the randomized clinical trial.

Table 2: Summary of findings from systematic reviews about rapid-learning health systems

Type of review	Focus of systematic review	Key findings	Year of last search/ publication date	AMSTAR (quality) rating	Proportion of studies that were conducted in Canada
Systematic review addressing other questions	Examining the processes and impacts of developing, implementing and adopting human resource information systems (HRIS) in health organizations (5)	The review examined 68 publications in order to examine human resource information systems in health care. Human resource information systems (HRIS) are a subcategory of administrative systems within health organizations. These systems deal with the management of human resources, including recruitment, teaching, planning and resource allocation. HRIS has potential benefit in healthcare, but further research is needed to identify its usefulness, effectiveness and implementation barriers. The review aimed to assess evidence on HRIS across healthcare organizations, focusing on the methods employed and the focus of interest across studies. In collecting and interpreting the existing evidence on HRIS in healthcare organizations, this review found that few studies considered the socio-contextual and technological factors that influence the operation of HRIS in this context. These factors are crucial in considering the impact of this system. Many studies applied theoretical frameworks, but these frameworks varied across research. Most research in this area focuses on applied projects – in order to advance theoretical understanding, there must be an emphasis on the theory of HRIS development, implementation and use. The focus of studies varies, with high-income countries largely focusing on smaller-scale projects. Lower-income countries mainly focus on broader systems of decision- and policy-making. Finally, there are a limited number of studies focusing on the development and outcomes of HRIS projects as most current research emphasizes usage of HRIS. The review explored HRIS in healthcare, and found that there are important gaps in knowledge when it comes to the impact and effectiveness of these systems. As the cost and size of the healthcare system grows, the need for linkage between administrative data and clinical outcomes grows in importance. In order to enhance "learning" health systems, future research should broadly examine the value of information within health systems.	2014	8/9 (AMSTAR rating from McMaster Health Forum)	5/42
Systematic review addressing other questions	Examining attempts to adopt the Learning Health System paradigm, with an emphasis on implementations and	The review examined 32 documents, including 13 studies, in order to examine the attempts to adopt the Learning Health System paradigm.	2015	2/9 (AMSTAR rating from McMaster Health Forum)	Not reported in detail

Type of review	Focus of systematic review	Key findings	Year of last search/ publication date	AMSTAR (quality) rating	Proportion of studies that were conducted in Canada
	evaluating the impact on current medical practices (1)	A learning healthcare system is driven to generate and apply the best evidence for collaborative healthcare, while focusing on innovation, quality, safety and value. Patients are a major factor in this model of health provision, given the emphasis on collaboration and collective decision-making. This review examines the attempts to implement this model of medicine. The results of this review indicate that there has been very little action in terms of implementing learning health systems, despite a great deal of interest. It is possible that there is great trust placed in the learning health system without proper assessment of impact. This may have contributed to the low number of studies qualifying for inclusion in the review. A major focus should be placed on assessment and reporting, considering that many attempts to adopt this system of health have been attempted and not reported. Existing frameworks for assessing medicine applications can be used to assess the efficacy of learning health systems. Further, reporting of the evaluation of these systems must be comprehensive. Lack of consistency across studies diminishes quality and effectiveness, and makes it difficult to assess outcomes. Taken together, the Learning Health System paradigm must be of central focus to researchers moving forward. While the central tenets of this approach are supported by researchers, there is a lack of assessment. The impact of such a system must be evaluated in order to boost adoption.			
Systematic review addressing other questions	Examining the spectrum of ethical issues that is raised for stakeholders in a Learning Health System (2)	The review examined 65 studies in order to determine the spectrum of ethical issues raised for stakeholders in a "Learning Health Care System". A Learning Health Care System embodies an approach for integrating clinical research and clinical practice, in order to address problems of effectiveness and efficiency in the healthcare system. In such a system, knowledge generation should be embedded so that health systems can learn and grow. However, this blend of research and practice raises ethical dilemmas such as confidentiality and consent. This review aimed to summarize pertinent ethical issues in order to guide decision-making among healthcare professionals and policymakers. The ethical issues arising in Learning Health Care Systems can be broken down into different phases. In the phase of designing activities, ethical issues include the risk of negative outcomes that may result	2015	1/9 (AMSTAR rating from McMaster Health Forum)	Not reported in detail

Type of review	Focus of systematic review	Key findings	Year of last search/ publication date	AMSTAR (quality) rating	Proportion of studies that were conducted in Canada
		from activities that are not academically rigorous. As well, it is possible that stakeholders will not engage with this stage, which can affect trust and support in a learning activity. In the ethical oversight of activities, confusion surrounding ethical obligations and regulations can hinder progress. In conducting activities, the involvement of participants can lead to ethical difficulties with consent and data management. In implementing learning, main difficulties arise in changing practice efficiently, maintaining transparency, and reducing unintended negative consequences. The distinction between "research" and "practice" often creates ethical confusion, as many learning healthcare activities do not fit this dichotomy. Strategies to cope with these ethical problems include implementing policies and procedures, providing training and guidance for ethical committee members, and streamlining ethical review processes. The rights of individuals must be protected as healthcare quality improves. Future research should focus on clarifying these ethical dilemmas and contribute to improving the quality of healthcare.			

Table 3: Summary of findings from primary studies about rapid-learning health systems

Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
Describing a Veterans Health Administration program to foster the learning health system paradigm (41)	*Publication date:* 2018 *Jurisdiction studied:* U.S. *Methods used:* Solicited input from operational leaders for high-priority programs amenable to randomized implementation and evaluation	Six programs	National Center for Health Promotion and Disease Prevention; Geriatrics and Extended Care (two proposals); Office of Mental Health and Suicide Prevention (two proposals); and Office of Connected Care	To achieve successful program implementation and rigorous evaluation requires resources, specialized expertise, and careful planning. In addition, if the learning health system model is to be sustained, organizations will need dedicated programs to prioritize resources and continuously adapt evaluation designs.
Examining the implementation and early results of a learning health system (7)	*Publication date:* 2016 *Jurisdiction studied:* U.S. *Methods used:* "Learn From Every Patient" model of care developed by key stakeholders and experts and implemented at Nationwide Children's Hospital in Columbus, Ohio	131 children with cerebral palsy	"Learn From Every Patient" model of care that integrated clinical care, quality improvement and research. One experimental group and two control groups were included in the study. Patients in the "Learn From Every Patient" group were assigned to a care coordinator who aided in navigation.	The development of a learning health system has been called for by the US Institute of Medicine. This model of system improves care while simultaneously reducing costs, through practices such as electronic health records, prioritization of translational research, and the control of expenditures. This model of care was found to reduce healthcare utilization and associated costs, results that were confirmed by comparison to two control groups. This model of care improved clinical care and efficiency while contributing to a dataset. The coordination of care contributed to the success of the "Learn From Every Patient" model. Research was fully integrated into the model in order to provide evidence for improvements in care and cost. A major focus of this study was cost and return on investment. The implementation of this model of care was cost-effective and may serve as a road map for other systems that wish to reduce costs while improving care. The authors point to several key features should other healthcare systems consider implementing a similar model of care. Clinicians must be engaged with research and evidence in order to address important questions in the field. Keeping clinicians invested requires ongoing monitoring of research questions. The implementation of this program required adaptation to new challenges and "culture change" as new settings and expectations were encountered. Data entry must be monitored by staff with time and expertise.
Identifying core competencies for learning health system researchers to guide	*Publication date:* 2017 *Jurisdiction studied:*	197 articles were extracted for review	In addition to a literature review, key informant interviews, a survey and expert	Learning health systems combine research, data science and quality improvement. Through patient-clinician interaction, the quality and knowledge of the system are improved.

Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
the development of training programs (13)	U.S. *Methods used:* Iterative development process including a literature review, key informant interviews, a modified Delphi survey, and three expert panel meetings	14 individuals were consulted for key informant interviews An expert panel of 19 members was consulted to develop definitions of competencies	panels were conducted to develop core competencies for learning health systems. The first phase of the study included the literature review, interviews and expert panel consultations. The second phase involved the panel drafting competencies. The third phase included drafting the final list of competencies with a final consensus-development meeting. The bulk of the work on core-competency development occurred in three meetings with a 19-member expert panel. This panel included individuals with expertise in fields such as statistics, epidemiology and patient-centred research.	This project defined competencies as "knowledge- or skill-based assets that trainees should acquire during their training." The iterative development process resulted in the consolidation of seven key competency domains: (1) systems science; (2) research questions and standards of scientific evidence; (3) research methods; (4) informatics; (5) ethics of research and implementation in health systems; (6) improvement and implementation science; and (7) engagement, leadership and research management. Across these seven domains, 33 key competencies were identified. The authors intended these domains and core competencies to inform a framework for training programs for learning health systems researchers. The competencies stress the assets required to generate and apply evidence within health systems, and are intended to guide existing programs. The expert panel identified several skills that a research trainee should possess in order to succeed as a learning health system researcher. These skills, which should all relate directly to health services, include existing research competencies, and basic skills in epidemiology, biostatistics, clinical research, and behavioural and social sciences. Several characteristics of learning health system research were drawn out as having implications for researchers. First, this research must balance the need for rapid and practical evidence with the rigours of scientific standard – learning health system research may not need to meet the same demands as other medical research. Second, this style of research must be able to adapt to ongoing and rapid change. Third, health systems should be positioned to invest in this research, as it may not fit well with conventional funding opportunities.
Examining residents' attitudes about quality improvement and their implications for an effective learning health system (11)	*Publication date:* 2017 *Jurisdiction studied:* U.S. *Methods used:* Focus groups conducted among residents of the neurology, physical medicine and rehabilitation, and emergency medicine departments at the	45 residents at University of Utah School of Medicine	Focus groups were conducted with emphasis on the perceptions of quality improvement in learning healthcare systems among residents. Constructs were formed into themes following an iterative process.	This study aimed to understand resident attitudes about quality improvement in learning healthcare systems. Quality improvement is at the centre of learning health system growth, and thus should be of central importance to healthcare workers. Clinician engagement with quality improvement is key for the success of a learning health system. Overall, the results of this study suggest that there is an uncertainty and unsureness among residents in relation to quality-improvement initiatives. Five main themes emerged from discussions with residents: (1) understanding the vision is challenging; (2) there is confusion about the quality-improvement process; (3) residents did not feel valued; (4)

Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
	University of Utah School of Medicine			prioritizing quality-improvement work leads to overload; and (5) there are many positive aspects involved in quality-improvement work. Quality improvement should be central to the training of residents. The authors suggested a number of tactics to improve this process. Providing a mentored experience would guide resident learning and incentivizing the process would reduce frustrations and confusion. Concerns about the dichotomy of business and clinical goals should be dissolved. Finally, successful quality-improvement strategies should be integrated into training and care.
Examining the development and refinement of a Learning Health Systems Training Program for resident physicians (12)	*Publication date:* 2016 *Jurisdiction studied:* U.S. *Methods used:* A Learning Health Systems Training Program was developed by course leaders. Emphasis was placed on the overview of goals, followed by the concepts that comprise these goals. The curriculum aimed to build analytical, informatics, and systems-engineering skills.	Internal medicine residents and sub-specialty fellows were recruited based on interest and commitment to the program. Six applicants formed the initial cohort, and eight trainees formed the second cohort representing a greater diversity of specialty backgrounds.	First-ever Learning Health Systems Training Program was initiated for resident physicians at Duke University. The development of this program involved a number of disciplines and was delivered over the course of a year in two-hour sessions every two weeks.	Learning health systems require the application and generation of medical knowledge. To achieve this, physicians must be engaged with information, quality improvement, and systems-based practice – skills that are often not taught. The researchers initiated a Learning Health Systems Training Program to address these shortcomings and build skills among resident physicians. The implementation of learning health systems requires organizational structure and support, and a highly skilled workforce. This training program emphasized skills including quality improvement, informatics, statistical reasoning, and systems engineering and systems-based practice. The majority of participants in the program report satisfaction, but only half of the participants felt that contact with mentors was adequate. Many participants expressed interest in remaining involved in the program. In reviewing the program, the researchers drew on early successes and challenges. Successes resulted from a supportive environment, expertise, enthusiasm and financial support. Challenges included irregular attendance, immature data and challenges with mentorship. These challenges have been identified and addressed, with authors pointing to solutions such as greater IT support, greater mentorship, and project quality improvement. Overall, this program demonstrated a great deal of success that has had significant health-system impact. The authors recognize that the program teaches toward an ideal system that has not fully taken form. Thus, ongoing evaluation and feedback must continue to inform curriculum and development.
Exploring the perspectives of health-system leaders on operationalizing the learning health system (10)	*Publication date:* 2016 *Jurisdiction studied:* U.S.	41 system leaders from clinical and administrative areas from Geisinger health system	In-depth interviews were conducted with 41 key informants of the Geisinger Learning Health System group. Participants	The success of learning health systems, which emphasize the integration of learning across clinical, operational and research functions, relies on leadership from healthcare professionals. This project sought to gather perspective on learning health systems and learning activities from these leaders.

Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
	Methods used: Interview conducted with health system leaders		represented a mix of functional areas from the health system. Interviews fostered open discussion on learning health systems.	Ten major themes were identified from the interviews: (1) alignment of learning with system strategic goals; (2) alignment of learning with incentives; (3) integrating cultural and operational silos; (4) balancing learning and work flow; (5) shifting the focus of learning from process improvement to improving outcomes; (6) addressing challenges in current healthcare environment that have an impact on learning; (7) balancing the need to execute and evaluate operational activities given limitations of evaluation methodologies; (8) supporting "make-or-buy" decisions for learning; (9) oversight of the research-quality improvement-continuum; and (10) determining the costs and value of learning. The results of the interview suggested that leaders adopt a pragmatic approach to teaching and learning, and that efficiency can outweigh value. However, there was broad interest in receiving guidance in navigating the research-quality improvement-innovation continuum. This study found that leaders continue to face challenges and opportunities in learning health system quality improvement. The results suggested that organizations must take an active role in this learning, and that responsibility must be shared across the system.
Identifying ethical issues arising in the transition to learning health systems (3)	*Publication date:* 2016 *Jurisdiction studied:* U.S. *Methods used:* Semi-structured telephone interviews Participants were recruited using purposive sampling. Institutions that were considered to be learning health-care system leaders were targeted.	29 interviews were conducted with leaders within 25 healthcare institutions	Interviews were conducted with leaders from 25 healthcare institutions. Participants were sampled purposively, having been considered leaders in the learning healthcare system.	The transition to a learning healthcare system brings a number of ethical considerations. Identifying these considerations is key to realizing the goals of learning healthcare. Interviews with leaders in the learning healthcare system yielded discussion of seven ethical challenges: (1) ethical oversight of learning activities; (2) transparency of learning activities to patients; (3) potential tensions between improving quality and reducing costs; (4) data sharing and data management; (5) lag time between discovery and implementation; (6) transparency to patients about quality; and (7) randomizations for quality-improvement initiatives. Progress will only be achieved if these key ethical issues are addressed. The results of this research suggested that institutions must ask leaders about ethical issues.
Examining factors influencing the implementation of a system delivering clinical studies via a distributed electronic network linked to electronic health records (9)	*Publication date:* 2012 *Jurisdiction studied:* U.S. *Methods used:* The requirements for using electronic health records for	n/a	A functional prototype software delivering clinical studies via a distributed electronic network linked to electronic health records was designed. The barriers to adoption of this	Learning healthcare systems turn data into knowledge, use that knowledge to better inform practice, and create new data through advanced information technology. The Electronic Primary Research Care Network was a project aiming to use electronic health records to facilitate clinical research use. Three main requirements were identified in terms of facilitating clinical research using primary-care electronic health records: (1) identification of subjects from

Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
	clinical research were identified. Following this, a functional prototype of the software necessary for conducting this delivery of clinical studies was developed.		software were examined and considered.	clinical data, (2) appropriate security and privacy controls; and (3) collection of clinical study data. In conducting this study, a number of problems and potential solutions arose. First, extracting coded data from an electronic health record leads to the loss and inaccuracy of data due to inconsistencies across the system. A potential solution to this is the uptake of standard clinical concept representations. Second, data extraction standards can be unwieldy. To remedy this, information-exchange standards should be adopted. Third, clinicians are rarely incentivized to maintain good data quality. A possible solution is the provision of clinical reasons for this data quality. Fourth, there are legal and ethical constraints when it comes to this form of research. There must be international consensus on how data can be linked without consent, and privacy-enhancing technologies should be adopted. Last, the benefits of these electronic systems remain foreign to researchers. Well-publicized deployments should be conducted.
Examining how to advance an organization's learning capabilities, as a core element of learning health systems (8)	*Publication date:* 2017 *Jurisdiction studied:* U.S. *Methods used:* An environmental scan of the literature on learning health systems was conducted, followed by semi-structured interviews with clinic staff	In addition to a literature search, interviews were conducted with 127 staff members from Billings Clinic, an integrated healthcare delivery system in Montana	n/a	Literature on learning health systems focuses on the information technology that is needed to translate the knowledge derived from data. This process demands an understanding of the process of learning, a topic which is given insufficient attention. This study examined the literature and drew on evidence from semi-structured interviews in order to determine the principles that guide effective learning. Six key learning principles were derived: (1) draw on wisdom of groups and value connections; (2) embrace sense-making over decision-making in dealing with the unexpected; (3) bring diverse perspectives to complex challenges; (4) animate people, provide direction, update regularly and interact respectfully; (5) appreciate the power and ubiquity of emergent change and the limitations of planned change; and (6) concentrate on small wins and characterize challenges as mere problems. This study presented evidence of the success of these guiding principles through emerging initiatives at Billings Clinic. Relational coordination, a theory that explores the attributes contributing to team success with complex tasks, became a learning method in the ICU. Staff members cited the success of this initiative in interviews. A project with Safe and Reliable Healthcare led to a project between the inpatient medical unit and the emergency department, in which initial failure translated into ultimate success. Finally, Project ECHO (Extension for Community Healthcare Outcomes) saw mental health and addictions services brought to marginalized populations in Montana.
Examining factors allowing a healthcare	*Publication date:* 2016	25 healthcare institutions	Hour-long semi-structured telephone	The move to a learning healthcare system is supported, but limited guidance exists for institutions. This study interviewed leaders from 25 healthcare

Focus of study	Study characteristics	Sample description	Key features of the intervention(s)	Key findings
system to become a learning healthcare system (6)	*Jurisdiction studied:* U.S. *Methods used:* Semi-structured interviews conducted with leaders from 25 leading healthcare systems	Participants were recruited using purposive sampling, targeting institutions that were at the forefront of learning health systems change	interviews were conducted with institutional leaders at 25 healthcare institutions. Interviews focused on the process of transitioning to a learning healthcare system and the ethical issues encountered.	systems in order to understand the motivations for change, challenges, and strategies for success. The interviews resulted in five key themes that are essential to learning healthcare systems transformation, six challenges, and eight strategies to support transformation. The key themes described were: 1) visionary leadership or influence of a key individual; 2) adaptation to a changing healthcare landscape; 3) external funding; 4) regulatory or legislative influence; and 5) mergers or expansions. The main challenges described were: 1) organizational culture; 2) data systems and data sharing; 3) funding learning activities; 4) limited supply of skilled individuals; 5) managing competing priorities; and 6) regulatory challenges. The strategies that should be used to support transformation were: 1) strong leadership; 2) setting a limited number of organizational priorities; 3) building on existing strengths; 4) training programs; 5) "purposeful" design of data systems; 6) internal transparency of quality metrics; 7) payer/provider integration; and 8) academic/clinical integration within academic medical centres. The transition to a learning healthcare system is difficult. These findings should inform other institutions on the obstacles and keys to success for this transition.
Examining the role for learning health systems in quality improvement within healthcare providers (4)	*Publication date:* 2017 *Jurisdiction studied:* U.S. and U.K. *Methods used:* A literature review, semi-structured interviews, focus groups, and site visits were undertaken	Experts in the field of learning health services were identified from the literature. Participants were based in the United Kingdom and United States. A snowball approach to sampling was undertaken until a group of key experts emerged.	The first phase of this study included a literature review on learning healthcare systems. The second phase included in-depth semi-structured interviews or focus groups with experts identified from the literature review, as well as site visits. The third phase was a final deductive thematic analysis of the literature, interviews, focus groups and site visits.	Learning healthcare systems can improve quality of care by closing gaps in research evidence. However, this study focused on how learning healthcare systems might address the six dimensions of healthcare quality: safe, effective, patient-centred, timely, efficient, and equitable. Six types of learning health systems were identified in this study: 1) intelligent automation; 2) clinical decision support; 3) predictive models; 4) positive deviance; 5) surveillance; and 6) comparative effectiveness research. These types of learning health systems are broad and overlapping, and each has a unique impact on the dimensions of quality of care. Further research should explore issues of evaluation and monitoring for all forms of learning heath systems, in order to build an evidence base. Equity should be of primary focus within the learning healthcare-services community. This study found that learning health systems can have positive and negative impacts on quality, a finding that provides a framework and direction for future research.

Table 4: Summary of findings from descriptive cases of rapid-learning health systems

Case	Case characteristics	Key features of the rapid-learning health systems	Implementation considerations
Cardiovascular disease care system in the United States (42)	*Publication date:* 2017 *Jurisdiction:* United States *Level (e.g., national, regional, local)* National *Sector (e.g., cancer, mental health)* Cardiovascular care	The authors argue that the learning health system requires systematic redesign of the current system, focusing on four domains: 1) science and informatics; 2) patient-clinician partnerships; 3) incentives; and 4) development of a continuous learning culture.	The authors propose that the development of a learning healthcare system in cardiovascular care requires, for each of the four domains, a series of concrete next steps. They describe what a successful learning healthcare system would look like.
Cancer Learning Intelligence Network for Quality (CancerLinQ) (43)	*Publication date:* 2016 *Jurisdiction:* United States *Level (e.g., national, regional, local)* National *Sector (e.g., cancer, mental health)* Oncology	CancerLinQ gathers data through direct electronic feeds from the EHRs and practice management systems of participating oncology practices. Its primary objectives include: 1) provide real-time quality feedback; 2) provide personalized insights to physicians to choose the right therapy at the right time for each patient, based on published treatment guidelines and other knowledge bases; and 3) uncover patterns that can improve care (e.g., new, previously unseen patterns in patient characteristics, treatments, and outcomes that can lead to improvements in care and suggest new research hypotheses).	Data governance was guided by three key principles: stewardship, protection and transparency. CancerLinQ operationalized these principles in three ways: 1) creation of a data-governance oversight committee consisting of CancerLinQ volunteers and staff, including ethicists and patient advocates to provide input on the design, review, and implementation of data governance policies and procedures; 2) implementation of administrative, physical, and technical safeguards to protect against unauthorized access to patient information throughout all stages of the CancerLinQ lifecycle; and 3) appointing a CancerLinQ Privacy and Security Officer to oversee implementation of and compliance with the Health Insurance Portability and Accountability Act (HIPAA) policies and procedures.
Swiss Learning Health System (44)	*Publication date:* 2018 *Jurisdiction:* Switzerland *Level (e.g., national, regional, local)* National *Sector (e.g., cancer, mental health)* Various sectors	The goals of the Swiss Learning Health System are: "1) to establish a bridging mechanism between research, policy, and practice; 2) to build scientific capacities for health systems and services research; 3) to develop standards for the management of health information."	The establishment of a bridging mechanism between research, policy and practice is at the heart of the Swiss Learning Health System. This multi-stakeholder initiative rests on eight core values: 1) person-centredness; 2) inclusiveness; 3) transparency and accessibility; 4) privacy; 5) adaptability; 6) governance; 7) scientific integrity; and 8) quality and value for all.
A person-centred, registry-based learning health system for palliative care (15)	*Publication date:* 2018 *Jurisdiction:* U.S. and Canada	The learning health system coproduction model is centred around the partnership between the patient family and care team. Relying on an enriched information environment that includes "feed forward" patient-generated data available to clinicians in real time along with clinical/biomedical data, coproduction provides an ongoing record of a person's health status and	Developing a palliative care registry-based learning health system could proceed in four phases: 1) team assembly and clarification of terms; 2) learn from existing models; 3) tailoring of general model to the palliative-care context; and 4) building of the learning health system using rapid cycle tests of change.

Case	Case characteristics	Key features of the rapid-learning health systems	Implementation considerations
	Level (e.g., national, regional, local) Not reported *Sector (e.g., cancer, mental health)* Palliative care	associated treatments. The conceptual model is comprised of four inter-related subsystems: the person/family and clinician/care team service-delivery system; the patient-/family-facilitated network system; the research collaboratory system; and the collaborative improvement network system.	
Learning Networks care centres (16)	*Publication date:* 2018 *Jurisdiction:* U.S. *Level (e.g., national, regional, local)* National *Sector (e.g., cancer, mental health)* Various sectors	The network framework aligns participants around a common goal of improving health outcomes, transparency of outcome measures, and a flexible and adaptive collaborative learning system. Team collaboration is promoted by using standardized processes, protocols and policies, including communication policies, data sharing, privacy protection and regulatory compliance. Learning methods include collaborative quality improvement using a modified Breakthrough Series approach and statistical process control methods. Participants observe their own results and learn from the experience of others. A common repository (a 'commons') is used to share resources that are created by participants. Standardized technology approaches reduce the burden of data entry, facilitate care and result in data useful for research and learning.	There are numerous barriers to implementing the Learning Healthcare System vision, and collaboration can be difficult and expensive. Clinicians and patients must learn to engage with each other to coproduce healthcare services, and participants must learn how to share information and use their collective creativity and expertise to solve problems. Data need to be captured, readily available, and shared. Additionally, leadership and management of a Learning Network require a different style from more centralized organizational models. Unlike traditional healthcare structures, networks invite self-organization and individualized actions. Leadership takes place through influence. There may be little or no positional authority because the participants come from many different organizations.
Veterans Health Administration (19)	*Publication date:* 2017 *Jurisdiction:* U.S. *Level (e.g., national, regional, local)* National *Sector (e.g., cancer, mental health)* Various sectors	Key features of this learning healthcare system include: the provision of real-time access to knowledge; digital monitoring of the care experience; programs to develop engaged, empowered patients; salary plans that remove incentives based on volume of care; full transparency; a leadership-instilled culture of learning; and supportive system competencies.	Several takeaways from this program are presented to help inform the implementation of future systems: 1) big data needs to be augmented with deep data; 2) patient-centred metrics are needed to assess progress at the individual level; 3) real system improvement requires attention to all steps of the translation pathway; 4) translational researchers must be matched with clinical leaders; 5) spreading best practices requires a combination of top-down and bottom-up strategies; 6) better methods are needed to evaluate and learn from the numerous innovations occurring in clinical programs; 7) research and improvement efforts need better tools to reduce practice variation among facilities, clinics, and providers; 8) reducing variation will require better strategies to engage and assist low-performing sites; and 9) system improvement requires a focused set of performance measures.
Ontario's cancer services (17)	*Publication date:* 2015 *Jurisdiction:* Canada *Level (e.g., national, regional, local)*	Key features of this learning health system include: a Quality Council, which assembles and reports publicly on a provincial and regional picture of performance and quality; a Clinical Council, which ensures engagement of specialty discipline and disease site leaders; and a regional Provincial Leadership Council, which brings the regional vice-presidents together to align overall planning, performance measurement, and reporting activities.	Not reported

Case	Case characteristics	Key features of the rapid-learning health systems	Implementation considerations
	Regional *Sector (e.g., cancer, mental health)* Cancer		
Geisinger Health System (14)	*Publication date:* 2015 *Jurisdiction:* U.S. *Level (e.g., national, regional, local)* Various levels *Sector (e.g., cancer, mental health)* Various sectors	The framework of this Learning Health Care System (LHCS) focuses attention on nine key operational components: data and analytics; people and partnerships; patient and family engagement; ethics and oversight; evaluation and methodology; funding; organization; prioritization; and deliverables	Important lessons are presented around four main themes. First, a realistic assessment of the capacity and capabilities of the organization and its data and analytic infrastructure is critical to defining the scope of operationalization and setting expectations among leaders and staff. Second, it was found that patient and family engagement is core to the LHCS. Patient engagement requires trust, redefined relationships with the system, and consideration of health literacy so that patients can successfully navigate new LHCS practices. Third, integrating patients and their families, clinical care, and various modes of discovery requires a defensible ethical framework that undergirds a system of strong but flexible oversight. Fourth, supportive leadership is imperative for advancement of the LHCS model.
ImproveCareNow Network (22)	*Publication date:* 2015 *Jurisdiction:* U.S. *Level (e.g., national, regional, local)* Various levels *Sector (e.g., cancer, mental health)* Chronic care	A key feature of this learning health system involved the creation of EHR-based data collection forms. The automation of existing analytic reports enhanced their ability to store protected health information and track patient consent. A cohort identification tool was also deployed to support feasibility studies and hypothesis generation.	The process for creating EHR-based data collection forms requires groups to work individually with each vendor. A vendor-agnostic model would allow for more rapid uptake. The authors believe that interfacing network-based registries with the EHR would allow them to serve as a source of decision support. Additional standards are needed in order for this vision to be achieved, however.
Indiana University Center for Healthcare Innovation and Implementation Science (23)	*Publication date:* 2015 *Jurisdiction:* U.S. *Level (e.g., national, regional, local)* Various levels	Key features of this learning health system are: 1) effective sensors of its surrounding environment; 2) rapid bidirectional information transportation system; 3) knowledge storage system; 4) critical decision-making process using advanced analytics; 5) efficient, lean, and safe execution system; and 6) reliable data monitoring.	In order to achieve its stated goals, the IUSM and the ICTSI have positioned faculty and other resources to provide strategic and operational assistance to its partner healthcare delivery systems in areas such as implementation science, systems redesign, healthcare effectiveness, health-services research, and health information technology through the IU-CHIIS.

Case	Case characteristics	Key features of the rapid-learning health systems	Implementation considerations
	Sector (e.g., cancer, mental health) Chronic care		
PEDSnet (20)	*Publication date:* 2014 *Jurisdiction:* *U.S.* *Level (e.g., national, regional, local)*: National *Sector (e.g., cancer, mental health):* Pediatrics	PEDSnet is a clinical data research network which provides the infrastructure to support a national pediatrics learning health system. It includes eight academic medical centres and national data partners from the National Pediatric Learning Health System. PEDSnet implements flexible architecture which incorporates data models and national standards to support data integration, discovery and advanced analytics.	Data and information infrastructure are not consistent across state lines in the United States and pose significant barriers to multi-institutional data sharing. This requires PEDSnet to synchronize variables and values using a standardized approach set forth by the U.S. government. The National Library of Medicine is seen as an important facilitator in this process and can help serve as a national resource for defining all terms that support quality reporting from electronic health records.
Washington State's Comparative Effectiveness Research Translation Network (CERTAIN) (18)	*Publication date:* 2014 *Jurisdiction:* U.S. *Level (e.g., national, regional, local)*: Regional (Washington state) *Sector (e.g., cancer, mental health):* Surgery and transplantation	CERTAIN was initiated as a physician-led quality-improvement project and has emerged into a system which brings together hospitals and outpatient clinics across Washington state to leverage record-based data collection to link existing information with databases about patient function and quality of life. It has implications in vascular disease, spine surgery, gastrointestinal disease and urology. The CERTAIN network of clinical practice includes urban and rural settings, hospitals and outpatient clinics, as well as independent ownership facilities. Clinical cores focused on disease are involved where surgical or interventional techniques are options, and where there are important areas of clinical uncertainty.	Patient stakeholders are involved in each phase of the CERTAIN network and data-collection process, however, their lack of participation in the decision-making process has been a barrier to implementation. Retention has also proven to be a challenge in Washington state, as patients' misconceptions about different types of clinical research and the times required for participation have been more problematic, leading to missing data and attrition bias in study results. Revenue streams from providing access to CERTAIN data was suggested as an opportunity for program sustainability and may help in its implementation in other jurisdictions.
American Society of Clinical Oncology's CancerLinQ (21)	*Publication date:* 2013 *Jurisdiction:* U.S. *Level (e.g., national, regional, local):* National *Sector (e.g., cancer, mental health)*: Cancer	ASCO runs a program called CancerLinq, a learning information network for quality that collects clinical data in real time to analyze and compare with existing guidelines, and feeds this information to physicians on the ground to increase the quality and outcomes of care for patients in real time. CancerLinq operates on an iterative process of providing services at the point of care, in-taking data, transforming data, aggregating data and analyzing data based on peer review and feedback.	The preliminary success of CancerLinq was achieved in part with an open source electronic health record system to engage with regional and national compliance standards for specific procedures and guidelines. Clinicians were willing to sign data-use agreements and share data; this helped the CancerLinq prototype in California de-identify and enter data in accordance with the Health Insurance Portability and Accountability Act, ultimately leading to case enrollment of 130,000 cases.
Collaborative Chronic Care Networks (C3Ns) (45)	*Publication date:* 2013 *Jurisdiction:* U.S. *Level (e.g., national, regional, local):* National *Sector (e.g., cancer, mental health):* Chronic disease	C3N is a network-based production system that harnesses the collective experiences of patients, clinicians and researchers to distribute the production of knowledge, information and know-how for chronic-disease care. Progress measures and robust information-technology infrastructure help operating systems to reduce unwanted variation and rapidly adopt new practices. Pediatric working collaboratives and networks have made gains in care outcomes for children. Challenges of researchers not having enough information to treat specific population groups have been dealt with using the C3N program.	Transactional costs of time, money and effort can hinder the ability of organizations and researchers, physicians and patients from participating in C3N. A federated integrated IRB model was implemented in this program to ensure participating centres only need to rely on protocols approved through a central institutional review board. To mitigate challenges of academic norms (publishing for individual/institutional career advancement) have been dealt with using a "commons framework" which shares systematic, strategic, safe and informed patient information.

Case	Case characteristics	Key features of the rapid-learning health systems	Implementation considerations
			Data sharing is conducted through federated databases to de-identify information and allow for easy informational access.
Pediatric collaborative improvement networks (46)	*Publication date:* 2013 *Jurisdiction:* U.S. *Level (e.g., national, regional, local):* National *Sector (e.g., cancer, mental health):* Pediatrics	Pediatric collaborative improvement networks have been designed to close quality gaps, engage patients and caregivers in shared learning, and act as sources for accelerated translational research to improve children's health outcomes. Unlike traditional models, these improvement networks plan to persist until aims are achieved and improvement is sustained. The improvement networks described are amalgamations of the collaborative efforts taken by the Children's Oncology Group, Northern New England Cardiovascular Disease Study Group and Cystic Fibrosis Foundation. The networks focus on: high-impact conditions; health topics and safety issues; support from clinical content and quality improvement experts; use of the Model for Improvement which sets measurable targets for testing changes in small scales and "learns by doing"; infrastructure for monthly data collection and analysis; and learning workshops and physician and nurse engagement for issues such as infection control and diet management.	Start-up funding and ongoing grant-related funding challenges, as well as the "pay to play" concept for participant fees present barriers for low-revenue sub-specialties such as rheumatology and adolescent medicine. Furthermore, the relatively low amount spent on child health, even for those with chronic or rare diseases, present challenges in getting the attention of insurers or specialized pediatric-care facilities. Potential facilitators to the success of this program in other jurisdictions largely involve incentives for funding this multidisciplinary learning health system in other academic institutions and among lower-revenue specialties.
University of Wisconsin (46)	*Publication date:* 2017 *Jurisdiction:* Wisconsin, U.S. *Level (e.g., national, regional, local)*: Regional *Sector (e.g., cancer, mental health):* Academic health centres	In the University of Wisconsin, change domains were not restricted to any particular domain of health practice, but were instead catered toward integrating strategic planning processes, governance structure to establish enterprise-wide goal setting and improvement, as well as patient-centred design initiatives, health leadership, performance reporting and EHR-embedded tools for clinical decision-making set as primary targets of the learning health system. Performance was measured across the Triple Aim, and population health measurement was focused on publicly reported performance metrics.	Academic health centres have traditionally struggled with establishing clear learning health systems. These difficulties stem from variable organizational structures, a poor alignment of culture, strategy and resources, especially between hospital administration and faculty. Autonomy also threatens efforts to standardize care practices, often impeding efforts to implement evidence-based care between various hospital departments.

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