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Laboratory medicine: The exemplar for value-based healthcare

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Abstract

Value-Based Healthcare (VBHC) aims to improve the overall quality, safety, and sustainability of healthcare while reducing delivery costs of more effective care. Despite advantages associated with VBHC transformation, the road to its adoption has been lengthy. Laboratory Medicine (LM) is in a prime position to lead the transition to VBHC because of its key role in diagnosis and treatment of patients. Laboratory medicine results inform/influence 50% to 70% of all clinical decisions. This article summarizes some issues associated with adoption of VBHC and related healthcare innovations and suggests potential approaches using LM-specific examples to help accelerate adoption. Laboratory medicine is both a useful model for VBHC implementation and facilitator for related innovation adoption by helping to target patient populations that would benefit most from specific interventions. The critical value of rapidly adopted diagnostic technologies used during the COVID-19 pandemic and economic recovery provide important insights about the need to embrace and accelerate VBHC implementation.

Introduction

Value-Based Healthcare (VBHC) and procurement aim to improve the overall quality, safety, and sustainability of healthcare while reducing the delivery costs of more effective care.[1] Unfortunately, the transformation to VBHC has been a long journey. Over the past two decades, healthcare systems have remained costly, complex, fragmented, and siloed despite substantial investment in VBHC and efforts to align healthcare delivery with changing population requirements with a view to reducing complexity and improving the patient experience.[2] The efforts to help drive VBHC evolution have provided some practical lessons related to its adoption.[3]

The need continues for a more efficient assessment of innovative products and treatment approaches that include improved patient outcomes and patient experiences in addition to all healthcare costs, including considering the total value to the healthcare system across care and budget silos.[4]

Laboratory Medicine (LM) is optimally positioned to provide leadership to support the transition to VBHC. Laboratory medicine helps improve patient outcomes and healthcare sustainability by reducing the time to diagnosis, providing effective interventions and care coordination, and supporting patient wellness care, screening, and monitoring. The COVID-19 pandemic highlighted the critical value and roles of LM in diagnosing and supporting management of the infection as well as being a key driver to economic recovery. A recent publication described the need to explain what value LM brings across a care pathway to a wider range of stakeholders.[5]

This article summarizes some of the issues associated with the adoption of VBHC and related healthcare innovations and suggests potential approaches, using LM-specific examples, to help accelerate VBHC adoption and implementation. Laboratory medicine is both a useful model for VBHC implementation and a facilitator for related innovation adoption by helping to target patient populations that would benefit most from the specific interventions.

What challenges are slowing the adoption of VBHC and procurement?

In 2009, the Canadian Institute for Health Information noted that one of the largest issues in the transformative process to outcome-based measurements is the speed with which system integration, data intelligence transfer, and adoption of innovation occur.[6] Several issues affect the speed of transformation to and adoption of VBHC and procurement. Timely evaluation of the benefits of innovations is often delayed due to limited clinical data. Comprehensive evidence packages are often not available when a new product or service is being trialed or adopted. Potential solutions include collecting and analyzing data in pilot studies[7] or using product registries (as part of an integrated supply chain structure).[8]

Budgets critically affect the adoption of innovation. Many integrated supply chain models have shown both savings and quality improvements, which help immediate sustainability

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issues.[8] However, often the savings due to the efficiencies of the procurement process used for older technologies are redirected away from department budgets and are not available to help support the adoption of innovations. These challenges, as well as potential approaches to address them, have also been described elsewhere.[9]

The budget recommendations for new technologies by technology assessment organizations such as Canadian Agency for Drugs and Technologies in Health, Strategic Clinical Networks, Ontario Health Technology Assessment Committee, and Institut national d'excellence en santé et en services sociaux would benefit from an effective process to approve funding of new technologies. Both the Ontario Health Agency and Quebec Health Innovation Bureau are attempting to address the adoption and funding challenges associated with innovations. A more robust budgeting methodology is needed that allows financial adjustments to enable the VBHC acquisition of more expensive innovations that provide better patient outcomes and are sustainable.

The value of Laboratory Medicine

Laboratory medicine plays a vital role in the delivery of healthcare, and its priorities are focused on patient safety and better patient outcomes. In addition to the well-known critical roles LM has played and continues to play during the COVID-19 pandemic and through recovery, its essential importance to healthcare is further illustrated by the requirement for a functioning accredited LM department and appropriately accredited staff for a Canadian hospital to operate.

Laboratory medicine provides unique VBHC solutions. Although LM's budget constitutes 3% to 5% of the total healthcare budget,[10-13] LM test results inform or influence 50% to 70% of all clinical decisions, including treatment plans.[14-16]

As more innovative testing and reporting technologies become available (eg, Precision Medicine [PM], molecular/genetic, Point-Of-Care Testing [POCT], bioinformatics, digital technologies), LM is becoming better recognized as a "best practices" VBHC leader supporting change in value- and outcome-based healthcare that fosters improved patient/family-centric care and health system outcomes. In addition, LM is a leader in supporting broader innovation adoption in other medical disciplines. Expanding VBHC applications using the innovations of LM can help improve system inefficiencies including the following:[17]

- Spending on high-cost low-value treatments;
- Limited number of patients receiving limited high-value, effective treatments;
- Few patients receiving care in a cost-effective setting (eg, hospital to home and hospital in the home);
- Variations in the quality of care provided to patients;
- Preventable medical errors that lead to worse outcomes and higher costs; and
- System complexity associated with high administrative costs and delays.

The role of LM in healthcare transformation and VBHC

Efforts to develop system-wide strategies or approaches to improve the quality of care and patient outcomes and safety while reducing costs are vitally important. Although there have been successes, widespread adoption of initiatives has been limited.

Laboratory medicine focuses on the right test for the right patient at the right time, properly interpreted to help inform development of optimal treatment plans for patients, which can reduce adverse events and/or side effects. Laboratory medicine can also be used to help define the effectiveness and optimize the use of a wide range of healthcare innovations.

Interestingly, most of the innovations associated with LM with a positive VBHC assessment also deliver on the quadruple aim of healthcare, specifically to improve patient outcomes, healthcare sustainability, health of general population, and care team well-being. Table 1 illustrates the quadruple aim with some examples from LM.

Illustrative case studies

In this article, we focus on three technologies: Precision Medicine (PM), Digital Pathology (DP), and point of care testing (POCT), and how they inform treatment decisions and support effectiveness and efficiencies within the hospital and healthcare environment, including the critical role in helping to manage COVID-19 and Antimicrobial Resistance (AMR) efforts.

- *Precision medicine*—Biomarkers can be used to diagnose disease or infection (eg, COVID-19), identify an individual's risk of developing a disease, disease prognosis, likelihood of a response to a particular intervention, or monitoring of clinical response or toxicity to a specific therapeutic treatment.[25]

  Before the COVID-19 pandemic, one of the most frequent applications of PM was as a companion diagnostic in association with cancer treatment. Recent advances have expanded the applications to include informing treatment plans for other diseases (eg, major depressive disorders[28-32]), a key driver of the COVID-19 pandemic economic recovery, managing AMR and antimicrobial stewardship, and newborn screening using next-generation sequencing.
- *Digital pathology*, also known as whole slide imaging or virtual pathology, involves high-resolution digital acquisition of images of entire stained tissue sections from slides that can be viewed on a computer monitor.[33] Digital pathology can also be shared electronically to engage experts remotely more efficiently and can be done in real time.
- *Point-of-care testing* refers to diagnostic tests performed at or near the patient by a healthcare professional or other qualified personnel.[34] Point-of-care testing permits faster testing and generation of results and

Table 1. LM VBHC examples that deliver on the quadruple aim

Improve patient outcomes • Multiplex genetic testing for BRAF, KRAS, and NRAS mutations in metastatic colorectal cancer can guide therapy based on specific mutations for better outcomes.[18] • In gram-negative bacteremia, mortality can be reduced by 58% using rapid identification and susceptibility techniques.[19]	Improve health of general population • PM aims not to extend life expectancy (although this is likely) but to improve long-term wellness by reducing or delaying disease severity. Eliminating disease onset—perhaps almost totally—is the major benefit to be gained.[20] • Rapid, highly sensitive tests could facilitate the earlier detection of influenza, and/or COVID-19, permitting appropriate medical management and a reduction in transmission.[21-24]
Improve healthcare sustainability • PM can reduce health costs by optimizing therapy and improving patient outcomes by lowering costs associated with suboptimal treatment(s).[25] • Combining evidence-based medicine and PM approaches will optimize medical practice.[20] • Use of rapid diagnostics reduces length of stay by 8 days ($P = .0001$; 34%) and time in ICU by 5.3 days ($P = .008$; 33%) in patients with gram-negative bacteremia.[19]	Improve care team well-being • Healthcare team well-being is linked to improved patient experiences and working in a place that has meaning and purpose.[26] • PM can give clinicians confidence to efficiently select the best therapies efficiently, with continual refinement in the approach to prescribing.[25] • The transmission of antibiotic-resistant bacteria occurs through contact among patients and healthcare workers.[27]

Abbreviations: ICU, intensive care unit; LM, laboratory medicine; PM, precision medicine; VBHC, value-based healthcare.

therefore timelier development of treatment plans at or close to the bedside or during outpatient encounters. Point-of-care testing can also enable remote or rural hospitals to better diagnose and manage patients, as well as inform treatment decisions despite laboratory unavailability (eg, due to resource and/or staff shortages).

Table 2 summarizes four LM examples that illustrate VBHC using the innovative technologies of PM, DP, and POCT. The first example features PM used to inform treatment decisions related to major depressive disorder. The second and third examples feature DP and POCT, respectively. In addition to providing more effective and/or rapid diagnosis to inform treatment plans, both technologies have been used to address staff shortages that may negatively affect the ability of a hospital to provide optimal care. The final example illustrates the role LM technologies has played and continues to play during the COVID-19 pandemic. The innovations in each of the examples provided have led to better patient access to care and improved outcomes while supporting a VBHC model.

Three common challenges had to be addressed in each of the examples to support adoption: the range of human resistance/acceptance to change; the use of new technologies (including training and trouble-shooting); and budget and organizational changes.

The DP example addressed these challenges by[38,41]: using a survey to define issues and needs; creating a multidisciplinary steering committee to engage stakeholders; applying effective surgical/pathology leadership coupled with efficient communication (on-site visits, regular video conferences); and funding (federal and provincial) to support organizational transition.

In addition to their use during the COVID-19 pandemic and its economic recovery, PM and POCT are rapidly expanding into AMR applications. Laboratory medicine tests diagnose infections (eg, identify types of viral vs bacterial infections) and inform treatment plans, including the appropriate use of antibiotics. For example, using matrix-assisted laser desorption ionization/time-of-flight mass spectrometry (MALDI-TOF MS) testing to help identify and manage patients with bacteremia reduced length of stay by 62.5% from 4.72 ($P < .031$) to 1.77 days ($P < .71$) and absolute mortality risk by 3.79%.[42]

Key learnings: What can be done?

All stakeholders, including governments, health leaders, management, and healthcare teams, must recognize that the health system transformation to VBHC and related procurement is a journey and there is no "quick fix." The transformation process needs to consider the journey with efforts placed on more quickly reaching the destination. The critical value of the rapidly adopted diagnostic technologies used during the COVID-19 pandemic and economic recovery provided important insights about the need to embrace and transition to VBHC more quickly.

Although mandating VBHC can stimulate adoption efforts, the hospital or healthcare system shift requires enabling solutions and their implementation plans be flexible and revised along the way. In addition to responding to a crisis (eg, the COVID-19 pandemic), there are common features that promote efficient innovation adoption, including[43-45]:

- Strong leadership and support from senior management team,
- Stakeholder and team alignment and "buy in,"
- An understanding of the benefits of adopting the innovation,
- Realistic timelines,
- Manageable and scalable initiatives (ie, start small and build),
- Processes to capture and analyze data and share learnings,

Table 2. Illustrative examples of laboratory medicine technologies supporting VBHC

Specialty supported	Issue	Technology	Solution/results
Psychiatry—Major depressive disorder (MDD)	• MDD has a prevalence of 8.2% in Canada.[35] • Estimated annual cost associated with MDD in Canada is at least $32.3 billion.[36] • Medications are the primary course of treatment; however[37]: ◦ <50% of patients respond well to their first prescription, and ◦ Overall treatment failure rates exceed 50%.	Precision medicine	Identify the neuropsychiatric medications likely to work best in patients using a pharmacogenomic test. Results • In a cohort of 1,871 Canadian patients with MDD, response rate improved by 31% in patients ($P < .01$) taking genetically congruent (little/no gene-drug interactions) vs incongruent medications.[32] • Symptom, response, and remission improvement 27.9%, $P < .01$, 25.7%, $P < .01$, 15.2%, $P < .01$ compared to incongruent medications.[32]
Surgical—Oncology	• Limited number of pathologists and pathology laboratories in eastern Quebec. There are ◦ About 1.7 million residents in the region. ◦ Of 24 sites with surgical oncology,[38] • Seven do not have pathology laboratory, • Five do not have a pathologist, • Five have one pathologist, and • Only seven have two or more pathologists. ◦ This leads to difficulties in recruiting surgeons if no pathologist is available and in recruiting pathologists without infrastructure support.	Digital pathology	• Centre hospitalier de l'Université Laval (CHUL) in collaboration with eastern Quebec surgeons and pathologists developed a telepathology solution. • Primary objectives: ◦ Provide uniform pathology coverage in the region, and ◦ Bring pathology close to communities (patient-centred). • Hospital staff prepared biopsy and slides, which were shared digitally with pathologists at CHUL. Results • Remote pathologists made diagnoses and provided reports to local physicians to inform treatment plans. • Hospitals were able to continue to operate with minimal disruption to patients (e.g., wait times). • After 3 years[38]: 1. 7,440 slides for urgent/primary diagnosis, 2. 98% concordance, 3. Average Turnaround Time (TAT) 20 minutes, 4. Expert opinion reports signed out: 68% within 24 hours and 85% with 72 hours.
"Labless" ER in remote/rural hospitals	• Shortage of laboratory technologists to run diagnostic laboratory. • Surrounding regional hospitals were short staffed and could not provide local support.	Point-of-care testing	• The Quinte Health Centre proactively used POCT technologies to address staffing issues and provide better at or near patient access to diagnosis. • POCT technology was validated for nursing and attending staff. Results • Enabled on site testing 24/7 for ER, faster TAT and greater savings, remote laboratory oversight. • Quinte Health Centre reported an estimated $420,000 in savings by adopting POCT.[39] • Quicker diagnosis and status updates enabled medical teams to more efficiently and effectively (and in some cases proactively) manage patients leading to better outcomes. • Similar initiatives have been introduced with Eastern Ontario Regional Laboratory Association (EORLA) and in rural New Brunswick.
COVID-19 infection	• Acute need for laboratory tests to diagnose COVID-19 and inform who may be infected and to help understand and manage where and how the virus is spreading.	Precision medicine Point-of-care testing	• LM needed to develop and implement a highly specific and sensitive molecular diagnostic test. Results • Collaboration to quickly develop, validate, and accredit COVID-19 tests. • Recruited and trained staff to run and interpret results of diagnostic testing. • Significantly increased volume of diagnostic COVID-19 testing from zero tests in January to the following national statistics for the period ending December 4, 2020[40]: ◦ >86,000 tests completed daily by December 4, ◦ >11 million tests completed in total.

Abbreviations: LM, laboratory medicine; POCT, point-of-care testing; VBHC, value-based healthcare.

- Completion of current initiatives before new ones are undertaken, and
- Institutional celebration of successes.

Despite investments made to move healthcare transformation toward to VBHC, adoption is slow; a faster pace would improve the quality of healthcare and increase sustainability. It is important to leverage the enablers noted above to help accelerate the transformation.

The examples described and technologies featured (eg, PM, DP, and POCT) are "real-world" LM situations. In each case, the use of the innovative testing technologies led to more accurate and efficient diagnoses that informed more effective treatment plans. The technologies can also be used as facilitators to target and align patients and other medical innovations to achieve better outcomes and support healthcare sustainability. The role of LM in VBHC is pivotal to achieving better healthcare and patient outcomes.

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