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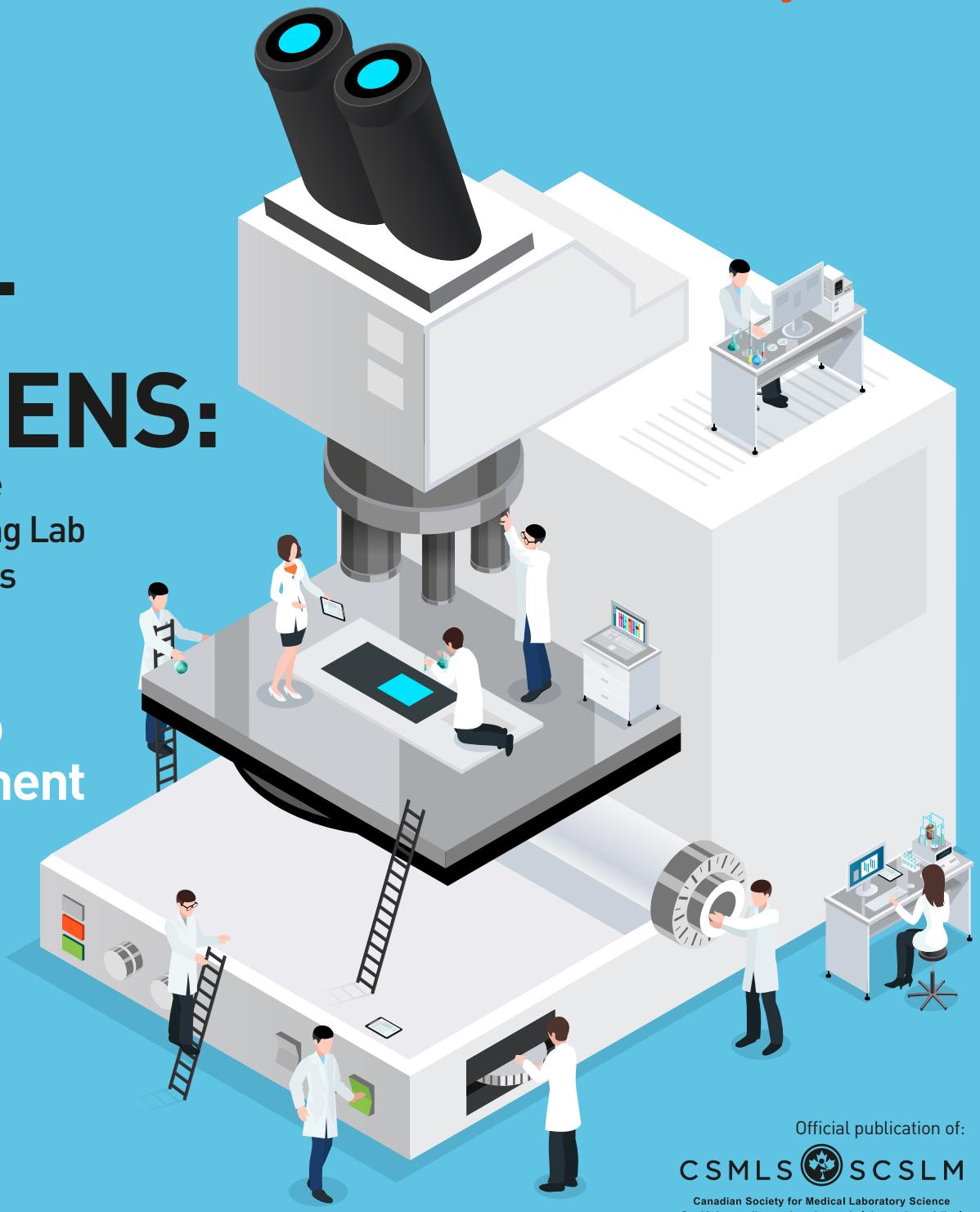
SHIFT HAPPENS:

Demystifying the Processes Driving Lab Protocol Changes

The Path to Enlightenment

Lobby Day 2018



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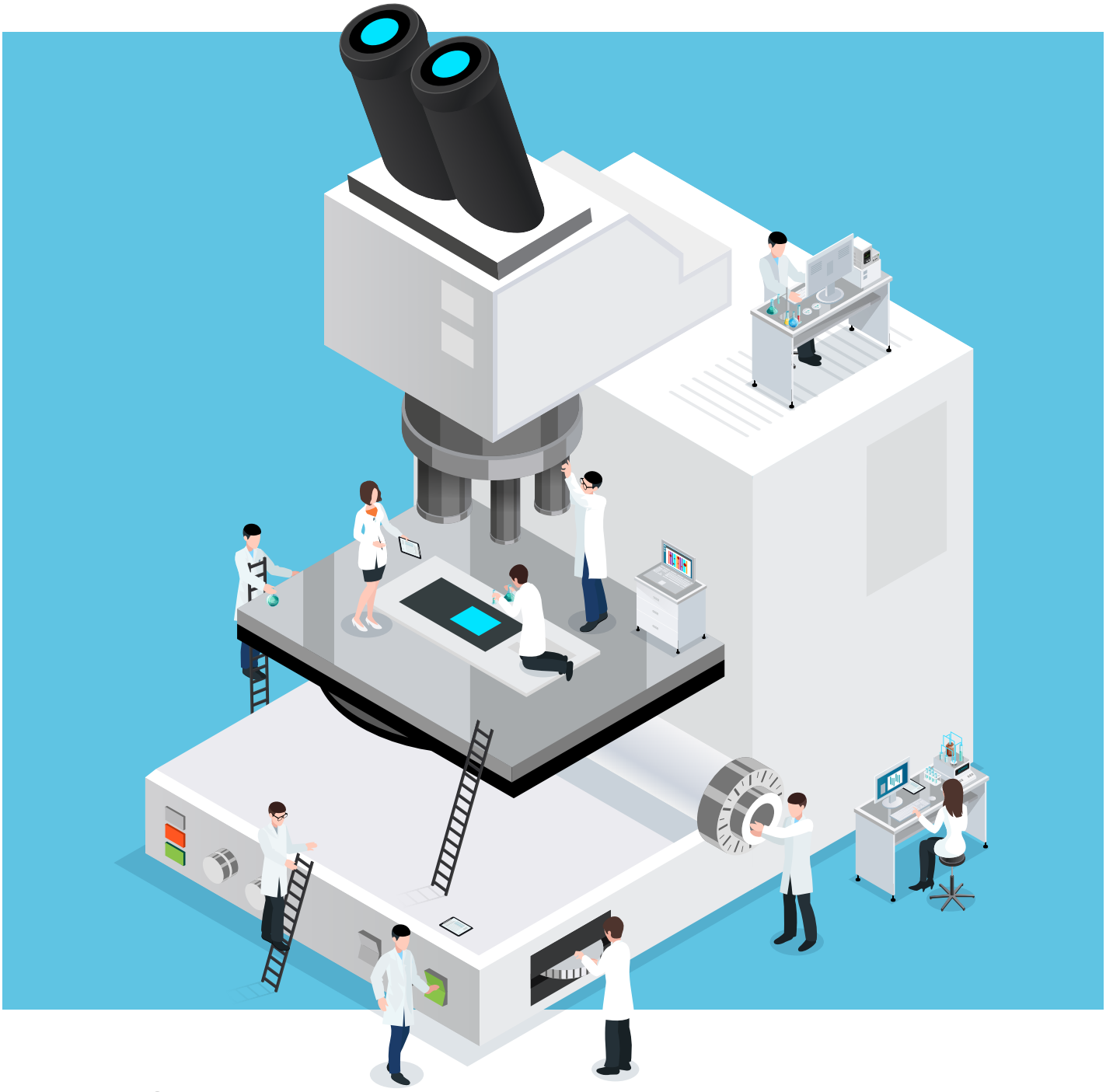

Shift Happens

Demystifying the Processes Driving Lab Protocol Changes

Almost 10 years ago, demand for vitamin D tests soared across Canada. In Ontario, over 700,000 people were tested in 2009, nearly 20 times the number tested five years earlier.[1] Supplement manufacturer Jamieson Labs was racing to keep up.[2] In Newfoundland and Labrador, the Eastern Health authority saw a 10-fold increase in the number of people wanting to be tested over a two-year period. Demand peaked in January 2009 at 5,000 tests a month.[3]

Surging interest in the test for blood levels of the sunshine vitamin was driven primarily by a slew of observational studies that suggested vitamin D sufficiency could protect against a variety of diseases and conditions, including diabetes, depression, multiple sclerosis, prostate cancer and breast cancer. Mainstream media headlines like "Knowing Your Vitamin D Levels Might Save Your Life" in *O, The Oprah Magazine*[4] and "Scientists taking vitamin D in droves" in *The Globe and Mail*[5] were common.

At the time, provincial health authorities still covered the cost of the vitamin D blood test. The problem was that there was no scientific evidence that it was necessary for people who were otherwise healthy. Lynn Wade, Eastern Health's Director of Laboratory Medicine at the time, told the CBC that, at $25 per test, it was costing them a fortune to tell people who weren't already taking a vitamin D supplement to do so.[3] Eastern Health decided to stop funding vitamin D testing in July 2009, except for people with eligible health conditions.[3]

Other provinces made decisions on their own timelines. The Ontario Health Technology Assessment Committee (OHTAC), a committee of the Ontario Ministry of Health and Long-Term Care (MOHLTC), recommended that Ontario should stop funding tests for healthy people. As a result, the MOHLTC revised the vitamin D test protocol on the Schedule of Benefits for Laboratory Services (SOB-LS) in December 2010, restricting community lab testing to people with rickets, osteoporosis, osteopenia, malabsorption syndrome, renal disease or for people taking drugs known to affect vitamin D metabolism.[6]

The provincial decision had an immediate impact on the volume of tests performed at community labs. "Our insured volumes went down substantially," said Audrey Palmer, Director of Government Contracts Management at LifeLabs Medical Laboratories, a privately-held lab testing company based in Toronto. "After vitamin D testing was restricted, patients did have the option to pay, but the overall volumes were significantly lower." LifeLabs also absorbed the impact of the change by reallocating staff and equipment.

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For the vitamin D test, a review of the evidence-based science needed to catch up with runaway consumer demand affecting the way the test was being deployed and funded. More typically though, protocol changes to lab services are informed by medical evidence from the outset; for example, over a decade ago, the Canadian Task Force on Preventive Health Care recommended two screening tests for people over the age of 50 with average risk for colorectal cancer. The recommendation was based on evidence from randomized controlled trials conducted in the 1990s. The studies showed that screening with the fecal occult blood test (FOBT), coupled with flexible sigmoidoscopy for the estimated two to three per cent of people who tested positive on the FOBT, was

associated with reduced mortality and detection of colorectal cancer at earlier stages.[7]

That recommendation fed into review processes at the provincial level. In 1999, Cancer Care Ontario (CCO) convened an expert panel to develop recommendations for a colorectal cancer screening program.[8] The panel evaluated the evidence on existing fecal occult blood test kits and developed standards that determined the lab requirements for the program. CCO submitted their recommendations to the Ontario Ministry of Health and Long-Term Care (MOHLTC) in 2005. In January 2007, CCO and the MOHLTC announced a new colorectal cancer screening program called ColonCancerCheck, the first program of its kind in Canada involving public health screening for colorectal cancer with FOBT and colonoscopy as required.[8,9] The changes in approach to public health screening resulted in updates to the FOBT test on the SOB-LS. "The fecal occult blood test was already an insured test, but it was assigned a different code and value to reflect an entirely new screening program," explained Palmer. "We were very much a part of the process. It went very smoothly, with no surprises."

Revising the protocol for one test on the list of insured services can be a long process with multiple stakeholders. Modernizing and updating the whole list, however, is a different situation, especially if the list has not been updated for a long time. That situation occurred in Ontario about five years ago after the Ontario Auditor General conducted an audit of community lab service expenditures. The audit revealed that the SOB-LS had not been updated since it had been brought into force in 1999[10] and identified that there was no process in place to establish whether the province was getting value for money spent on lab services.

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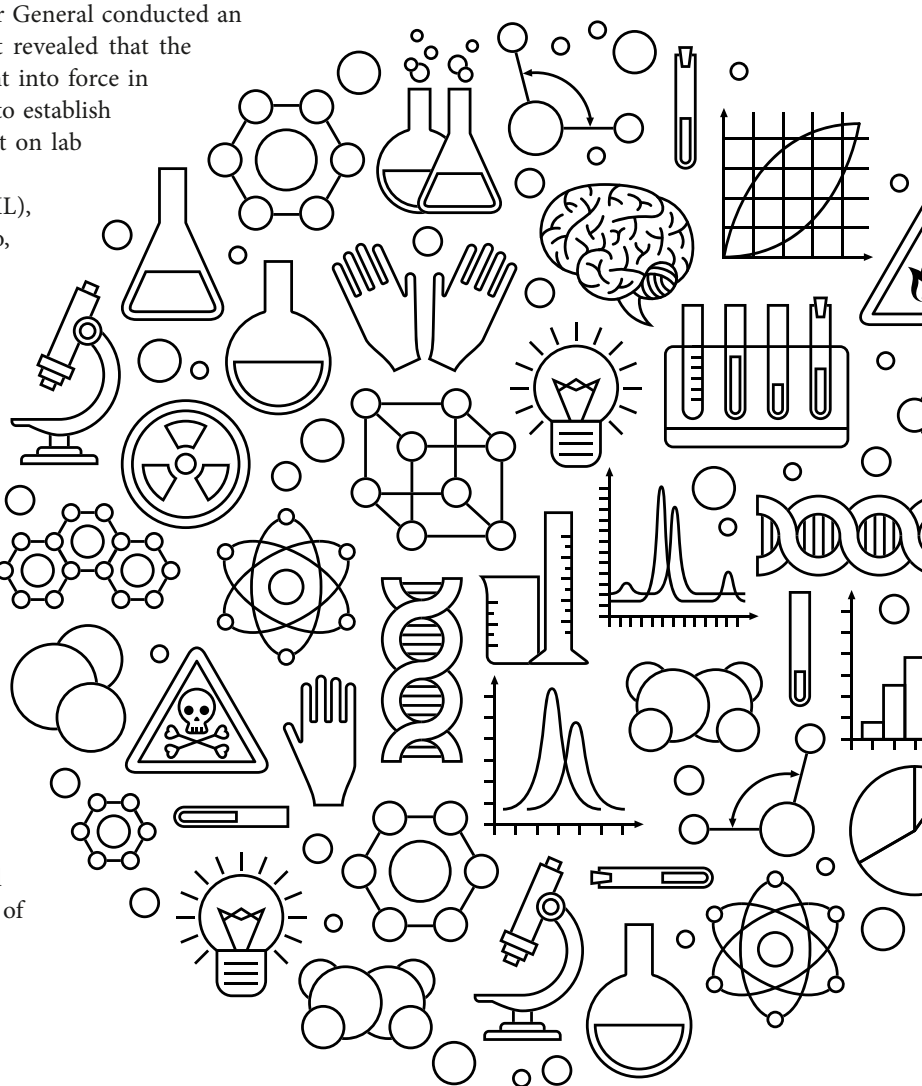
The Ontario Association of Medical Laboratories (OAML), which represents most of the community labs in Ontario, provided a recommendation on updates to the SOB-LS. As a community lab stakeholder, LifeLabs was involved in the consultation process to provide input on the new set of values. "The OAML recommendation was mainly around the relative value of tests to ensure that it was more reflective of changes in testing procedures that occurred over the last 20 years," said Palmer. "The intent was to reflect the shift to higher automation. Tests that were more manual were assigned a higher value, and those that were more automated and high volume were assigned a lower value."

The MOHLTC hired the business consulting company Deloitte to review stakeholder input and provide a final recommendation. "Deloitte engaged with community lab providers to understand our rationale. They challenged some values and they agreed or disagreed with others. For the most part, we agreed with their advice," said Palmer. The MOHLTC's final recommendation had to go through the typical provincial legislative process because the SOB-LS is part of



Ontario's regulations and legislation which govern the laboratory industry. The modernized SOB-LS passed into regulation in November 2017 and became retroactive to April 2017.

Besides updates in the values, some examples of the changes included revisions to fee codes to better differentiate between specimen collection and sample pick-up and the geographic region of collection and to address the economic disincentive and geographic challenge of providing lab services in remote areas. Also, a total of 110 obsolete fee codes were delisted for procedures that had been identified as no longer clinically relevant or had been replaced by other methods. "We were very involved in the SOB-LS modernization project," Palmer said. "For future updates, the MOHLTC intends to work together with community labs through a committee that will look at values as well as what goes on and comes off the list on a more regular basis." The MOHLTC confirmed that, under their Community Laboratory Modernization Strategy, they intend to revise and update the SOB-LS every two to four years for pricing, clinical relevance and technology changes. They are currently working on establishing a regular review process.

Each provincial health authority is responsible for revising lab test protocols in its jurisdiction. While the names of the organizations and stakeholders involved may be different, the processes are similar. In British Columbia, for example, the BC Agency for Pathology and Laboratory Medicine (BCAPLM) established the Test Review Committee responsible for reviewing, evaluating and making evidence-based recommendations informed by stringent evaluation criteria and consultation with experts.

As part of the decision-making process, the BC Ministry of Health consults with the Laboratory Operational Committee (LOC), which is comprised of major stakeholders in the laboratory services sector, including Ministry of Health representatives, medical and clinical practitioners, representatives of publicly-funded facilities and a member of the public. The LOC provides advice on: the provision of benefits, fee amounts, cancellations, testing technology and lab requisitions; development and implementation of lab protocols and guidelines; and policy issues. Ultimately, the Ministry of Health reviews the recommendations and makes final decisions under the *Laboratory Services Act*.

British Columbia's Laboratory Services Out-Patient Fee-For-Service Payment Schedule was updated in October 2016 and revised in January 2018. An example of one change is the addition of a new fee item for fentanyl urine screening by immunoassay that took effect March 1, 2017, partially replacing fentanyl testing performed by a more complex and expensive quantitative method. The update included a restriction that the previous testing method "can only be performed and payable following consultation with and approved by a laboratory medicine physician."[11] Another example of a change was the addition of the test for IgG anti-deamidated gliadin peptide (anti-DGP) antibodies on a provisional basis for a one-year period, effective January 1, 2018. The test is only available to patients up to 36 months of age or who are IgA deficient, and it may only be requisitioned by pediatricians and gastroenterologists.[12]

How have shifts in laboratory testing protocols affected your day-to-day work in the lab?

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While there is no master timeline for revisions to testing protocols, policies and procedures, changes are informed by medical evidence. Case in point: by late 2018, Ontario plans to transition from using the FOBT to a new test called the fecal immunochemical test (FIT) for screening people at average risk of colorectal cancer.[13] In British Columbia, the FIT was introduced as an integral part of the province's colon cancer screening program launched in 2013.[14] Studies have shown that the FIT has improved sensitivity with minimal loss of specificity for cancer detection, outperforms the FOBT and can detect advanced adenomas.[7, 8] For patients, the FIT is easier to collect, has no dietary restrictions and only requires one specimen.

Change in the workplace is inevitable, and medical labs are no exception. Protocol changes driven by unpredictable external factors, as happened with vitamin D testing, can lead to an immediate and considerable impact on staffing and equipment decisions. Thankfully, most protocol change processes are driven by medical evidence from the outset, involve stakeholder consultation and are implemented over a longer time horizon. Regardless of the timelines for protocol changes, medical lab professionals who understand the decision-making processes and keep their skills up to date in more than one discipline will be better equipped to adapt and embrace the changes when they occur. J

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