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**COMMENTARY**

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# What the Doctor Ordered: Improving the Use and Value of Laboratory Testing

*The importance of laboratory testing in medical diagnosis, in addition to its significant cost, makes it a primary target for quality improvement. Governments across Canada could improve total health system efficiency by implementing policies to reduce inappropriate laboratory testing.*

Christopher Naugler and Rosalie Wyonch

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## ABOUT THE AUTHORS

### CHRISTOPHER NAUGLER

is Department Head and Professor of Pathology and Laboratory Medicine, University of Calgary.

### ROSALIE WYONCH

is a Policy Analyst at the C.D. Howe Institute.

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A handwritten signature in black ink that reads 'Daniel Schwanen'.

*Daniel Schwanen*

*Vice President, Research*

## THE STUDY IN BRIEF

About 70 percent of medical decisions are based on the results of laboratory tests (Forsman 1996). If testing amounts to inappropriate over-utilization, it could lead to further unnecessary testing, inaccurate diagnosis and potentially inappropriate treatments that could be accompanied by adverse and unnecessary side-effects. A test may also be inappropriately underutilized – it should be ordered, but isn't – which leads to delayed diagnosis and treatment and potential worsening of the patient's condition.

The importance of laboratory testing in diagnosis, in addition to its significant cost, makes it a primary target for quality improvement. Reducing inappropriate laboratory testing would have the dual benefits of making the health system as a whole more efficient and improving patient outcomes and experience.

This *Commentary* investigates the use and cost of laboratory testing in Canada and finds variation across the country. To decrease the amount of unnecessary laboratory testing and the associated downstream medical costs, strategies must balance effectiveness with maintaining doctor and patient autonomy in choosing treatments. We propose a number of options for policymakers to reduce inappropriate laboratory testing: adjusting physician compensation to align incentives with improving appropriateness; utilization management via practice variation and feedback information; reforming requisition orders and care paths to more closely adhere to clinical guidelines; and development of provincial formularies for diagnostic testing.

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## In the Canadian healthcare system, laboratory tests are by far the most common medical activity.

Extrapolating from available data suggests that Canadians annually receive an average of 14-20 laboratory tests per capita (CIHI 2016-17; Alberta Health Services, unpublished data).<sup>1</sup> Physicians order laboratory tests for a number of reasons (Table 1), and their results have become a central feature of medical diagnoses for more than a century. It is commonly stated that 70 percent of medical decisions are based on the results of laboratory tests (Forsman 1996). The direct expenditures attributable to laboratory testing are in the range of 4 percent of total public healthcare budgets in Canada. Still, the amounts are large. For example, Ontario laboratory expenditures in 2015/16 were about \$2 billion (Auditor General of Ontario 2017), against a total healthcare budget of \$51 billion. If expenditures are similar for the rest of Canada, then about \$5.9 billion annually is spent by provincial and territorial governments on laboratory activities.<sup>2</sup>

The importance of laboratory testing in diagnosis, in addition to its significant effect on healthcare costs, makes it a primary target for quality improvement. Laboratory test results are stored for extended periods of time, making them amenable to data mining and benchmarking which enhances their attractiveness for value measurement and quality improvement. Inappropriate laboratory testing includes both under- and over-utilization.

Tests can also be ordered inappropriately during initial evaluation of a patient's condition or as repeat testing. If testing is inappropriate over-

utilization, it could lead to further unnecessary testing, inaccurate diagnosis and potentially inappropriate treatments that could be accompanied by adverse and unnecessary side-effects. A test may also be inappropriately underutilized – it should be ordered, but isn't – which leads to delayed diagnosis and treatment and potential worsening of the patient's condition. Minimizing inappropriate testing would have the additional benefit of reducing associated inappropriate medical treatments or reducing treatment delays that can prolong patient suffering and may increase the eventual cost of treatment.

### HEALTH SPENDING IN CANADA AND INAPPROPRIATE USE

In recent years, growth in healthcare spending has outpaced economic growth as measured by GDP. As a result, the sustainability of publicly funded healthcare is a matter of ongoing debate. In addition, aging, new treatments, rising patients' expectations, powerful provider groups and chronically slow productivity growth continue to exert pressure on the healthcare system.

Investigating healthcare spending by use of funds does not show an obvious culprit for the overall increase, meaning that constraining costs in the face of demographic and economic pressures is a challenge across all areas of the healthcare system (Figure 1). Over the last decade, hospital and physician spending have increased substantially. In 2016, they accounted for \$95 billion, equivalent

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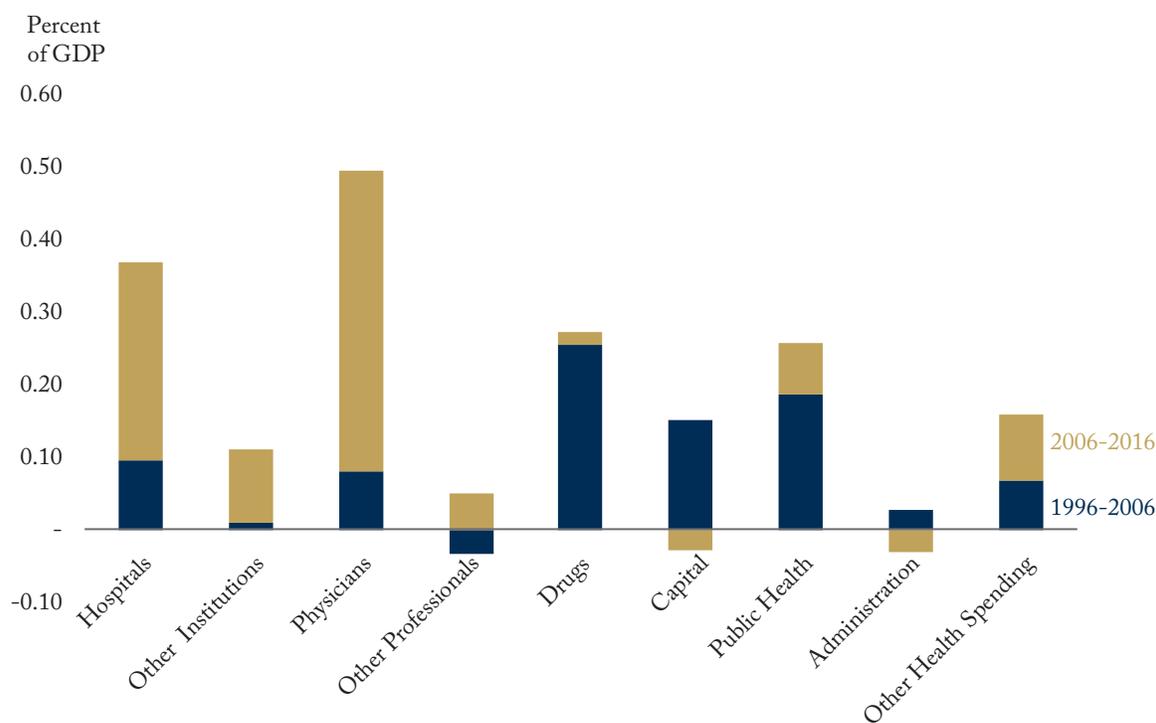
1 Data cover tests performed in Alberta, Ontario and Nova Scotia.

2 This value represents 4 percent of provincial and territorial government health expenditures in 2015 (CIHI NHEX 2018).

**Table 1: Reasons for Ordering a Laboratory Test and the Associated Risk of Misutilization**

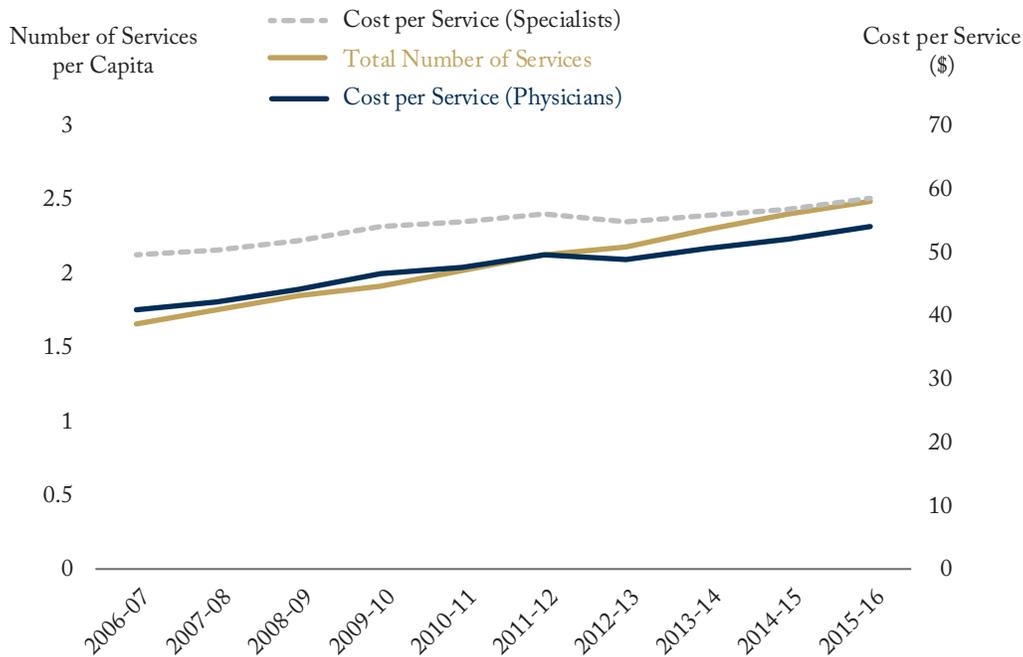
| Reason for Ordering a Test  | Risk of Misutilization  |
|---|---|
| Diagnosis: this may include ruling in or ruling out a medical condition or reducing the range of possible diagnoses.  | Moderate: a “shotgun” approach is often used where more tests than necessary are ordered.   |
| Monitoring: testing the level of a drug in the blood, monitoring the therapeutic effect of a drug, or monitoring the progression of a known disease or condition. | Low to moderate: guidelines exist for testing related to therapeutic drug monitoring. There is risk of repeating testing both too often and not often enough. |
| Screening: testing asymptomatic individuals for occult disease.   | Moderate to high: screening guidelines exist for most conditions but are often not adhered to with extra testing done outside of guidelines.                  |
| Research  | Low: testing is not covered by government insurance schemes in Canada and is done in accordance with vetted research protocols.                               |

Source: Authors' compilation.

**Figure 1: Change in Public Health Expenditures, 1996-2016**

Source: CIHI NHEX 2018, authors' calculations.

Figure 2: Physician Payments for Diagnostics and Therapeutic Services



Notes: This measure is the payments to physicians for the provision of therapeutic and diagnostic services. These are system costs related to these services, not direct expenditures of laboratory tests.

Source: CIHI National Physician Database, authors' calculations.

to 4.7 percent of Canada’s GDP. But public expenditures on health professionals (other than physicians) and administration have not increased relative to GDP. However, all other major categories of health spending have been outpacing economic growth. Therapeutic and diagnostic services are no exception: both the cost per service and the number of services per person have been increasing for the last decade (Figure 2).<sup>3</sup>

Because healthcare expenditures are generally growing faster than the economy, there is a need to contain costs to ensure Canada’s healthcare system remains fiscally sustainable. Clearly, cost constraint

should not reduce access to appropriate healthcare or the quality of care that patients receive. Inappropriate use of healthcare is not cost-effective; it is also unlikely to improve patient outcomes and may cause significant harm in some cases. Reducing inappropriate care would have the dual benefits of making the healthcare system as a whole more efficient and improving patient outcomes and experience.

Inappropriate treatments or overutilization of healthcare is not isolated to laboratory testing. “Appropriateness” in health care is a “complex, fuzzy issue that defines care that is effective

3 Within this group of services, prices vary considerably depending on the particular service and the province or territory where it is performed. An allergy/hyposensitization test, for example, costs \$19.24 (SK) to \$55.75 (MB), whereas cardiac catheterization costs between \$120 (Que.) and \$400 (MB) (CIHI NPDB, Table D.2, 2015-2016).

(based on valid evidence), efficient (cost-effective), and consistent with the ethical principles and preferences of relevant individuals, communities or society (WHO 2000).” A national campaign to educate clinicians and patients about potentially unnecessary treatments, Choosing Wisely Canada, has developed a list of more than 150 tests, treatments and procedures commonly used in various healthcare settings that are not supported by evidence or could expose patients to unnecessary harm. One investigation of unnecessary care found that up to 30 percent of tests, procedures and treatments associated with eight tests that span the healthcare system are potentially unnecessary (CIHI 2017).

Meanwhile, a 2015 survey of public perceptions showed that about one-quarter of Canadians felt they were recommended a test or treatment that they did not feel was necessary for their health. Nearly two-thirds (62 percent) of them felt that there is significant unnecessary healthcare across the system (CIHI 2017). Most people feel that unnecessary care is predominantly due to patient demand, but that physicians are primarily responsible for constraining it. Indeed, 90 percent of survey respondents said that patients need more support or tools to assist in making decisions about healthcare necessity.

Inappropriate care and wasting of resources in the medical system are challenges that are not unique to Canada. Across OECD countries, estimates suggest that one-fifth of health spending is inefficient (OECD 2017). The reasons for inappropriate testing or medical treatments are complex and are influenced by patients, physicians and administrative practices. Addressing inappropriate care or inefficient use of resources is an ongoing effort in all OECD countries. The

need to balance cost restraint with maintaining or improving the quality of care leads to two basic principles for reducing waste: stop doing things that don’t add value; and use the less expensive of equivalent options.

## THE PROBLEM OF LABORATORY TEST MISUTILIZATION

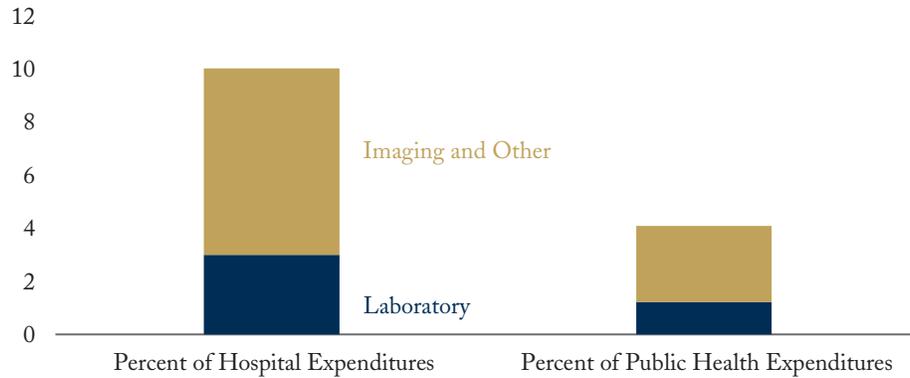
Although the direct costs of laboratory testing represent a relatively small component of overall healthcare expenditures in Canada, the downstream effects of testing in terms of further procedures, referrals and treatments create considerable potential for unnecessary care if the initial testing was inappropriate. Indeed, estimates of inappropriate laboratory testing are in the range of 16 percent to 56 percent (Zhi et al. 2013). Estimates of inappropriate laboratory testing vary significantly depending on the type of testing, the inappropriateness criteria and clinical phase.<sup>4</sup> One feature of existing research that quantifies inappropriate use is that overutilization is much more studied than underutilization.

For a laboratory or diagnostic-imaging test to be “appropriate,” it should be useful in the diagnosis, treatment or subsequent monitoring of a patient’s condition. This does not include tests that do not provide meaningful information relevant to the patient’s condition, tests that are reordered within a timeframe where results are unlikely to change or situations where testing is counter to clinical guidelines.

Laboratory testing rates in Canada have increased faster than overall population growth and funding increases (Bayne 2003). Hospital diagnostics (including laboratory, imaging and other activities) account for 4 percent to 10 percent of all

4 An earlier meta-analysis provides further evidence that estimates of inappropriate laboratory testing vary significantly with the clinical setting and test. Individual studies show inappropriate laboratory testing ranging from 5 percent to 95 percent (van Walraven and Naylor 1998).

**Figure 3: Hospital Diagnostic Expenditures, Ontario, 2016/17**



Notes: Data are sourced from CIHI’s Canadian MIS Database (MCDB) FY 2016-17 and the National Health Expenditure Database (2017).

hospital expenditures and 2 percent to 4 percent of total public health spending across the country (Figure 3).<sup>5</sup>

Meanwhile, data on imaging and other diagnostics performed in hospitals show significant variability in cost per test and the number of tests performed per capita (Figure 4), indicating significant clinical practice variation across the country. There is evidence that suggests that the proportion of testing that is inappropriate may also be increasing over time. For example, in Manitoba the volume of vitamin-D testing increased substantially from 2006/7 to 2012/13. At the same time, the proportion of tests that were appropriate decreased from 50 percent to 35 percent (Rodd et al. 2018).<sup>6</sup> A meta-analysis of internationally published research on inappropriate testing, however, found no significant changes in the

proportion of inappropriate testing over time (Zhi et al. 2013).

In recent years there has been considerable interest in optimizing laboratory test ordering in Canada (Naugler 2017), likely because all clinical laboratories in Canada are ultimately publicly funded (Ndegwa 2011). The overall approach to improving laboratory testing efficiency is known as “Utilization Management,” and the tools commonly used have been well described (Huck and Lewandrowski 2014). (See Box 1 for a detailed explanation of these tools.) As noted, inappropriate testing represents wasted resources for the health system without benefiting patients’ health outcomes.

### Laboratory Testing and Medical Error

All laboratory tests have potential for both false-positive and false-negative results. A false-positive

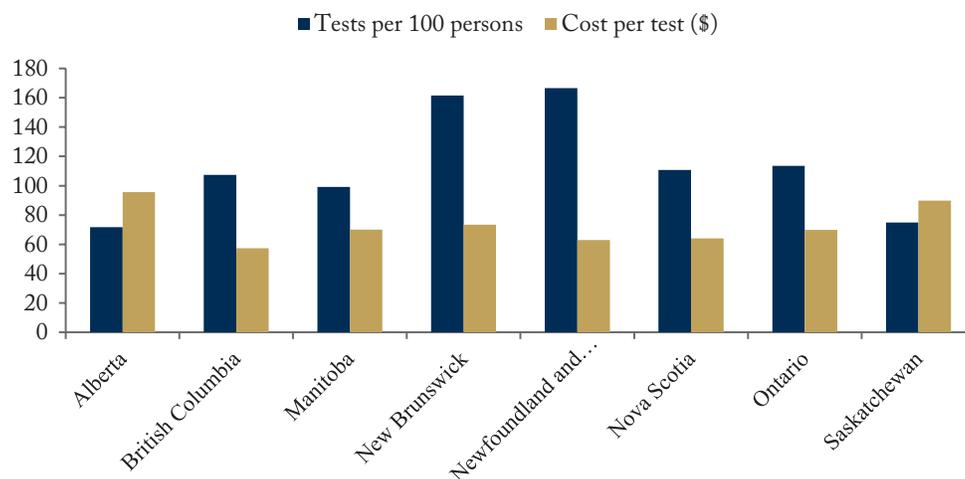
5 While Figure 3 shows data for Ontario only, the range refers to available data across provinces. The expenses of diagnostic tests are reported by modality for hospitals only (e.g., ultrasound, X-ray, CT scan, laboratory testing etc.) by fiscal year and by province. Only facilities with a cost-per-visit value have been included.

6 In this study, appropriate testing was defined as being in line with consensus clinical guidelines. More specifically, patients with a disease that affects bone or mineral metabolism (as defined by ATC codes and International Classification of Diseases).

### Box 1: Commonly Employed Utilization Management Tools

- Audit and feedback: Report cards are provided to practitioners, benchmarking ordering practices against clinical practice guidelines or peer-group performance.
- Requisition changes: Individual tests are removed from requisitions to try to decrease their use.
- Restrictions on who can order: Certain tests can be ordered only by specialists or by physicians in certain practice situations (e.g., emergency departments).
- Pathologist vetting of requests: Test requests are passed through a gatekeeper who approves or denies requests.
- Reflex testing: Certain tests are performed only after other tests have been done. This is sometimes also called cascade testing.
- De-listing or patient pay: Tests may be removed from the list of publicly insured tests, thus removing them from public budgets.
- Education: Providers consult with pathologists or are provided with education on improving their ordering of laboratory tests.
- Re-order interval restrictions: Certain tests with definable minimal re-order test intervals are barred if performed more frequently.

Figure 4: Variability In Hospital Diagnostic Imaging



Notes: Only tests that were reported in all provinces were included to ensure comparability. The figure above includes data for general radiography, mammography, interventional radiology, computed tomography, ultrasound, nuclear medicine, magnetic resonance imaging, electro-diagnostic labs, non-invasive cardiology and vascular labs.

Data for laboratory diagnostics were not available in most provinces. In Ontario and Nova Scotia, where data are available, variability in laboratory costs and test volumes is similar to that observed in imaging and other diagnostic activities.

Source: CIHI's Canadian MIS Database (MCDB) FY 2016-17. Population information is from Statistics Canada's 2016 census.

result may result in patients being diagnosed with a condition they do not have, while a false negative may lead a physician to incorrectly eliminate a condition as a cause of patient symptoms. These situations are examples of “medical error” in the form of over- and under-diagnosis, respectively.

Over-diagnosis – also known as medical waste and too much medicine – refers to the situation where little marginal value or even outright harmful medical care is provided (Hoffman and Cooper 2012, Berwick and Hackbarth 2012, Grady and Redberg 2010). The economic impacts of over-diagnosis have been extensively examined. A study on over-treatment in the US estimated that between US\$158 billion and US\$226 billion were wasted this way in 2011 (Berwick and Hackbarth 2012). Similarly, a Canadian study investigating inappropriate prescribing to older adults found that 42 percent of the women and 31 percent of the men in Canada filled potentially inappropriate prescriptions in 2013, costing public insurance plans a total of \$419 million (Morgan et al. 2016).

Meanwhile, under-diagnosis may also result in significant costs in the form of extended patient suffering and wasting of time and resources on inappropriate or inaccurate diagnosis and treatment. It may also increase the cost of the eventual appropriate treatment due to delayed diagnosis and associated worsening of the patient’s condition.

The economic impact of medical errors extends well beyond the costs of the tests and treatments themselves. Time spent by individuals receiving unnecessary care is time that could have been spent at work or on leisure activities. Furthermore, if individuals experience adverse side-effects associated with unnecessary treatment, then not only are there no benefits to spending money on the treatment, but there may be the additional cost of spending time in poor health and extra appointments to address the side-effects. In extreme cases, inappropriate use of medications can result in addiction, overdose and even death. Patients may also be under significant stress due to the

uncertainty of their health status, which impacts their overall well-being.

An under-recognized source of over-diagnosis is the proliferation of false-positive test results (Hoffman and Cooper 2012) and the effect this has on downstream health expenditures, patient anxiety and direct harms of treatment. When healthy patients are administered diagnostic tests, there is about a 5 percent chance that they will falsely test positive because the reference range of many tests is determined by calculating the central 95 percent inter-percentile interval or the mean  $\pm 2$  standard deviations for Gaussian distributions (for an expanded discussion, see Box 2). After a false-positive test result, the patient may either receive further testing or referral, or may receive a treatment for a condition they do not have. Any of these actions increases costs to the medical system and the patient in the form of wasted resources and lost time. In addition, as discussed above, taking medication when not sick can lead to side effects and other detrimental complications.

There are other functional aspects of laboratory testing, beyond the statistical properties that lead to false-positive or -negative results, which can increase the potential for medical error. Indeed, existing research shows that a large percentage of laboratory errors occur in the pre- and post-analytical phases with fewer mistakes occurring during analysis (Plebani 2006, Kalra 2004). Examples of errors that could be made during the pre-analytical phase are improper ordering, contamination or improper collection of test samples and misidentification of the patient or physician. Examples of post-analytical errors include results being delayed or reported incorrectly, as well as the laboratory and physician using different reference values to interpret results, to name a few.

While efforts to minimize error are present throughout the medical system, even very small error rates for high-volume activities like laboratory tests may lead to many medical

## Box 2: Laboratory Diagnostic Test Parameters and Potential for Error

The potential for both false-positive and false-negative laboratory test results stems from statistical properties that define their predictive value. Laboratory results are determined to be positive or negative by comparing the patient's result to the distribution of the same characteristic in the general population. Functionally, this means that a test result will be positive if there is a high confidence that the patient's result is different from the average in the population, which does not necessarily mean that they have the condition linked to the test. This means that some healthy individuals will have an abnormal test result, despite being healthy – a false-positive result. Similarly, individuals may have the disease being tested for, but their result falls within the reference range, producing a false negative.

To appropriately interpret results of laboratory tests, clinicians should be aware of how well the tests differentiate between health and disease. The predictive value of a test relates to its prevalence, sensitivity, specificity and efficiency.

- Sensitivity is the percentage of individuals with the disease who test positive.
- Specificity is the percentage of individuals without the disease who have a negative result.
- Prevalence is the true rate of a disease in the test population.

These parameters can be used to determine the positive and negative predictive value of a test – the percentage of individuals with a positive test result who truly have the disease and the percentage who test negative and do not.

$$\text{Positive Predictive Value} = \frac{\text{Prevalence} \times \text{Sensitivity}}{(\text{Prevalence} \times \text{Sensitivity}) + ((1 - \text{Prevalence}) \times (1 - \text{Specificity}))}$$

$$\text{Negative Predictive Value} = \frac{(1 - \text{Prevalence}) \times \text{Specificity}}{((1 - \text{Prevalence}) \times \text{Specificity}) + (\text{Prevalence} \times (1 - \text{Sensitivity}))}$$

A test with a high positive predictive value is useful in diagnosing a particular condition. Tests with high negative predictive values are useful in the elimination of possible causes, not necessarily for direct diagnosis. It is important to note that any test where sensitivity equals 50 percent and specificity equals 50 percent is no better than a coin toss in determining whether or not a disease is present.

errors. Inappropriate choice of laboratory tests is probably the most common pre-analytical error and inappropriate utilization and interpretation of results the most common post-analytical error (Plebani 2006). Improving the appropriateness of testing would, therefore, have the added benefit of reducing medical errors related to it.

### Approaches to Detecting Misutilization

In the Canadian setting, as elsewhere, utilization management efforts have been hampered by barriers to laboratory data acquisition and analysis, lack of tools for detecting inappropriate testing and a lack of clarity on how to select the most appropriate utilization management strategy for a given situation (Naugler 2017).

The current consensus in the medical literature is to define inappropriate laboratory test utilization based on compliance with clinical practice guidelines (Hauser and Shirts 2014). Indeed, utilization management interventions based on the enforcement of clinical practice guidelines can be highly effective in reducing test use. For example, following clinical recommendations against population-based screening for vitamin-D deficiency, Alberta changed requisition order forms to list approved reasons for ordering the test such as metabolic bone disease, abnormal blood calcium, malabsorption syndromes, chronic renal disease and chronic liver disease. The test order would only be accepted if one of the specified conditions was checked as the reason for the test. The result was a 91.4 percent reduction in the number of tests, representing direct annual savings of \$940,000 to \$1.5 million (Naugler et al. 2017).

The primary limitation of this approach is that clinical practice guidelines do not exist for the vast majority of laboratory tests. Even when guidelines do exist, they may vary among jurisdictions or even among professional groups in the same jurisdiction. For example, prostate cancer screening with the PSA test is recommended by the Canadian Urological Association (Izawa et al. 2011), but not by the Canadian Task Force on Preventive Health Care (Moyer 2012) or the US Preventive Services Task Force (Ciliska 2013).

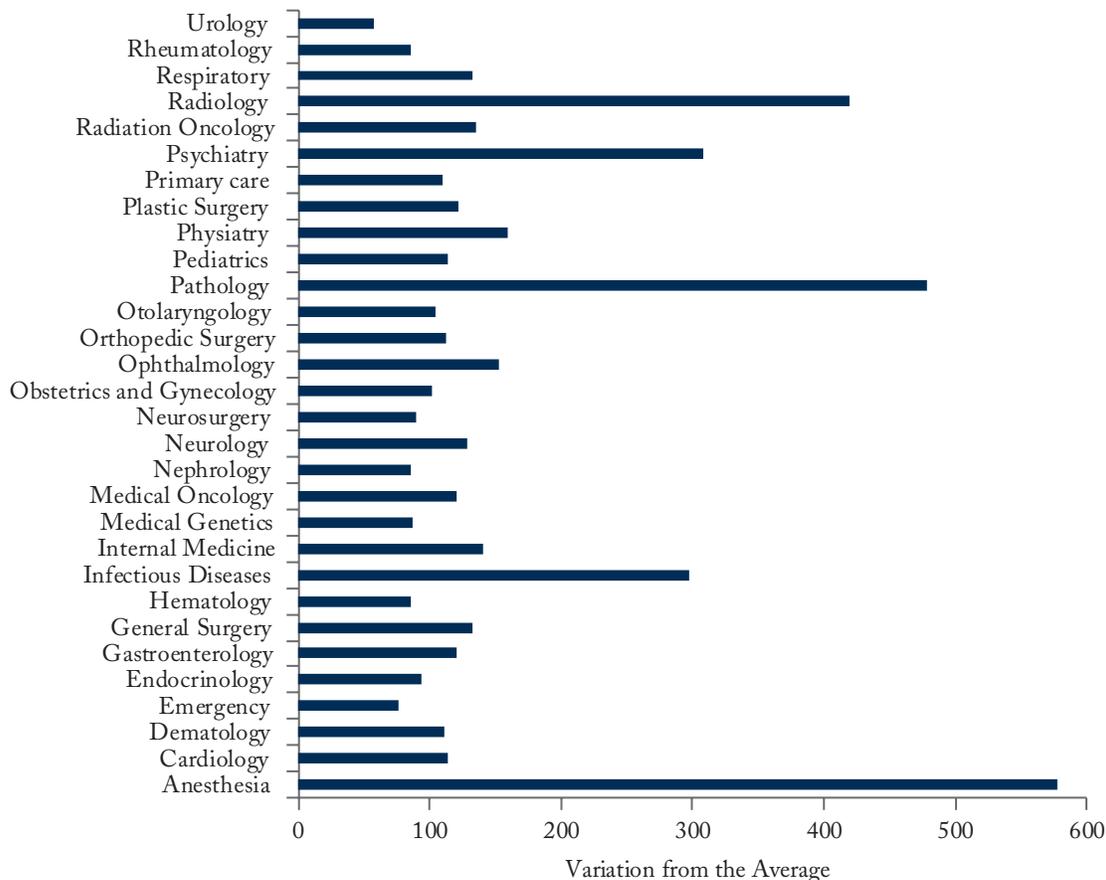
Another approach to detecting inappropriate laboratory tests is to look for repeat testing outside of recommended minimum retest intervals.<sup>7</sup> The Royal College of Pathologists in the United Kingdom has published guidelines on minimum retest intervals for a number of tests and clinical scenarios. For example, tests of total cholesterol should not be repeated within 12 weeks since serum cholesterol changes slowly and repeat testing won't provide new information (Lang and Croal 2015). A recent audit of repeat testing in Calgary showed that 16 percent of sampled tests were repeated inappropriately (Morgen and Naugler 2015).<sup>8</sup> Similarly, an Ontario study concluded that 6 percent to 20 percent of tests associated with nine analytes were inappropriate repeat testing (Chami et al. 2017). However, as with compliance with clinical practice guidelines, this approach is limited by the fact that most tests do not have defined minimal retest intervals. As well, establishing retest intervals does nothing to address tests ordered inappropriately only a single time or performed repeatedly by different facilities and/or physicians.

Given the limitations of these approaches in detecting inappropriate utilization, new ways of

7 The minimum test interval is the minimum time before a test should be repeated, based on the properties of the test and the clinical situation in which it is being used (Lang and Croal).

8 This result is similar to those found in other jurisdictions. For example, a study of tests for immunoglobulin measurement, common autoantibodies and tumour markers showed that inappropriate repeat requests (within 12 weeks) accounted for 17 percent of tests (Kwok and Jones 2005).

Figure 5: Variation of Average Clinical Laboratory Test Expenditures per Physician



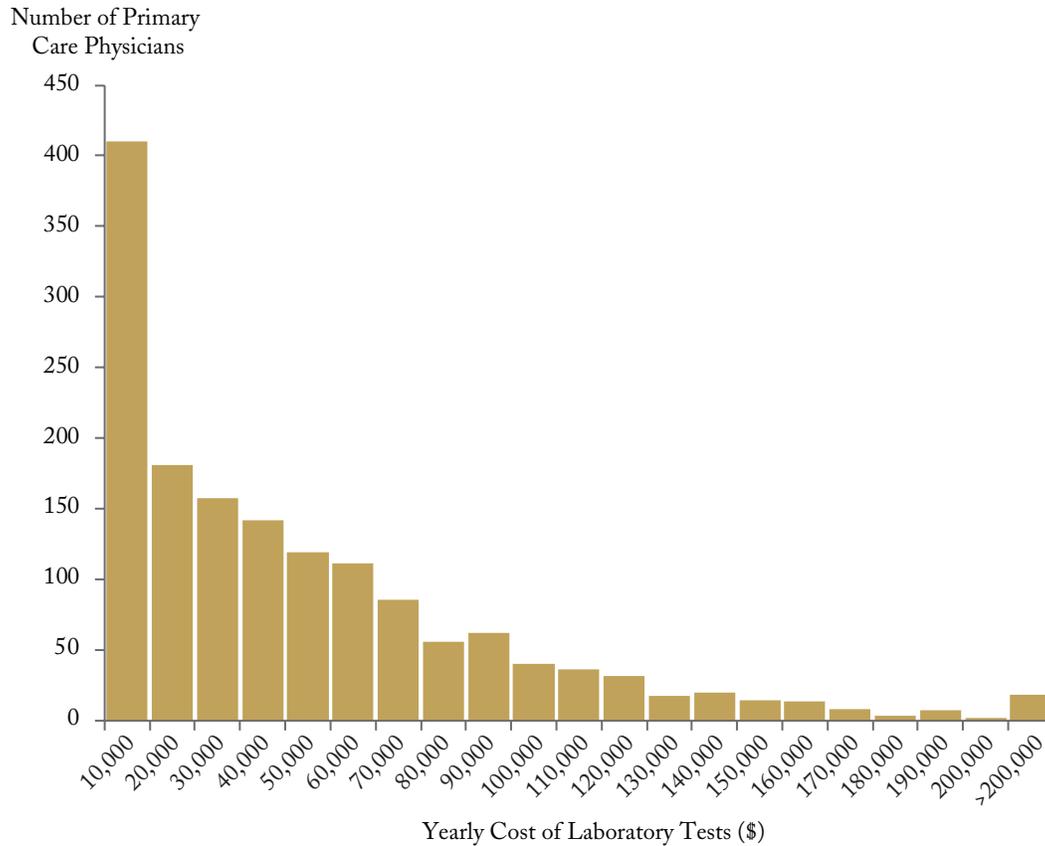
Note: Coefficient of Variation = (mean/standard deviation) x 100 .

Source: American Journal of Clinical Pathology 2015: 144 97-102.

addressing the problem are needed. One promising approach is to benchmark the ordering patterns of individual physicians against one another and publish this information through an audit and feedback exercise where individual doctors can see how they compare to others in the profession. Audit and feedback is already being used to provide information on guideline compliance (Kobewka et al. 2015), so extending it to overall test-ordering patterns should not be a great leap. The idea here is to identify unexplained practice variation and provide this information to practitioners as an intrinsic motivator to change their practice patterns.

Indeed, the identification and reduction of unexplained practice variation is a major goal in healthcare quality improvement initiatives and is based on the belief that unexplained variation is a major cause of financial inefficiency and medical error. For example, a recent systematic review of 836 studies examining medical practices across OECD countries showed large practice variations for almost every studied condition and corresponding procedure (Corallo et al. 2014). Inter-practitioner variation in the total volume and value of ordered laboratory tests is well documented and occurs in all medical specialty groups (Figure 5, Naugler et

**Figure 6: Variation in Yearly Laboratory Test Expenditures by 1,400 Family Physicians in Calgary, Alberta**



Source: Authors' unpublished data.

al. 2015). Some variation in ordering is, of course, attributable to variation in patient characteristics (Barber et al. 2017), but the majority is attributable to physician factors. Indeed, a study examining laboratory test orders by Calgary family physicians found that the associated costs varied by as much as 40 times between them (Figure 6). Work in other jurisdictions has suggested that this variation may be associated with physician age, being in solo practice or being a foreign medical graduate (O'Neill and Kuder 2005, Landon et al. 2001).

Three metrics have been proposed as potentially useful in identifying variation in overall test-ordering patterns: peer-to-peer variations in test volumes, the mix of tests ordered and rates of abnormal results (Naugler and Guo 2016).<sup>9</sup> The primary limitation with using total test volume as a benchmark is that it fails to take into account the size and scope of individual practices. This could be corrected for by factoring in practice size and individual practice characteristics. But this information is generally not readily available.

9 An abnormal test result is one that is either positive or false-positive.

A second approach to identifying test-ordering differences, which at least partly controls for this limitation, looks at the variation in the mix of tests ordered by individual physicians. This is not widely used in practice, but a method for the calculation of inter-practitioner variation has recently been proposed (Mohammed et al. 2015). In brief, this approach involves obtaining test volumes for individual tests from the group of practitioners to be compared, converting these volumes into a standardized score that measures deviation from the average (z-scores) and then plotting the means against the standard deviations of z-scores for each practitioner. In following this approach, practitioners can be separated into high volume + high variance, high volume + low variance, low volume + high variance and low volume + low variance groups. It is suggested that the high volume + high variance group is the one that may represent the lowest value-ordering practices. This approach could be useful in detecting idiosyncratic ordering patterns but does not address the issue of total test volumes.

The third approach attempts to measure the value of laboratory tests by looking at the proportion of abnormal or “positive” test results (Naugler and Gao 2016, Brack et al. 2017). For many laboratory tests, the range for results is determined by performing the test in question on healthy volunteers and defining the middle 95 percent of test results as “normal” and the remaining 5 percent as lying at the upper and lower tails as “abnormal” (Naugler 2014). Therefore, by definition, most lab tests performed on a population of healthy individuals will have an expected abnormal rate of 5 percent, all of which will represent false results.

The actual/observed abnormal rate of testing performed by family doctors in Calgary was about 9 percent in 2015 (Brack et al. 2017). An expected false-positive rate of 5 percent and an observed positive rate of about 9 percent suggest that approximately half of reported abnormal results

for community patients are actually false-positive results (Ma and Naugler 2018). This is further supported empirically by the observation that as more tests are ordered on an individual patient, the proportion of positive results decreases to close to 5 percent (Figure 7, Naugler and Gao 2016). This strongly suggests that ordering large numbers of tests on patients without clinical justification serves primarily to generate false-positive test results.

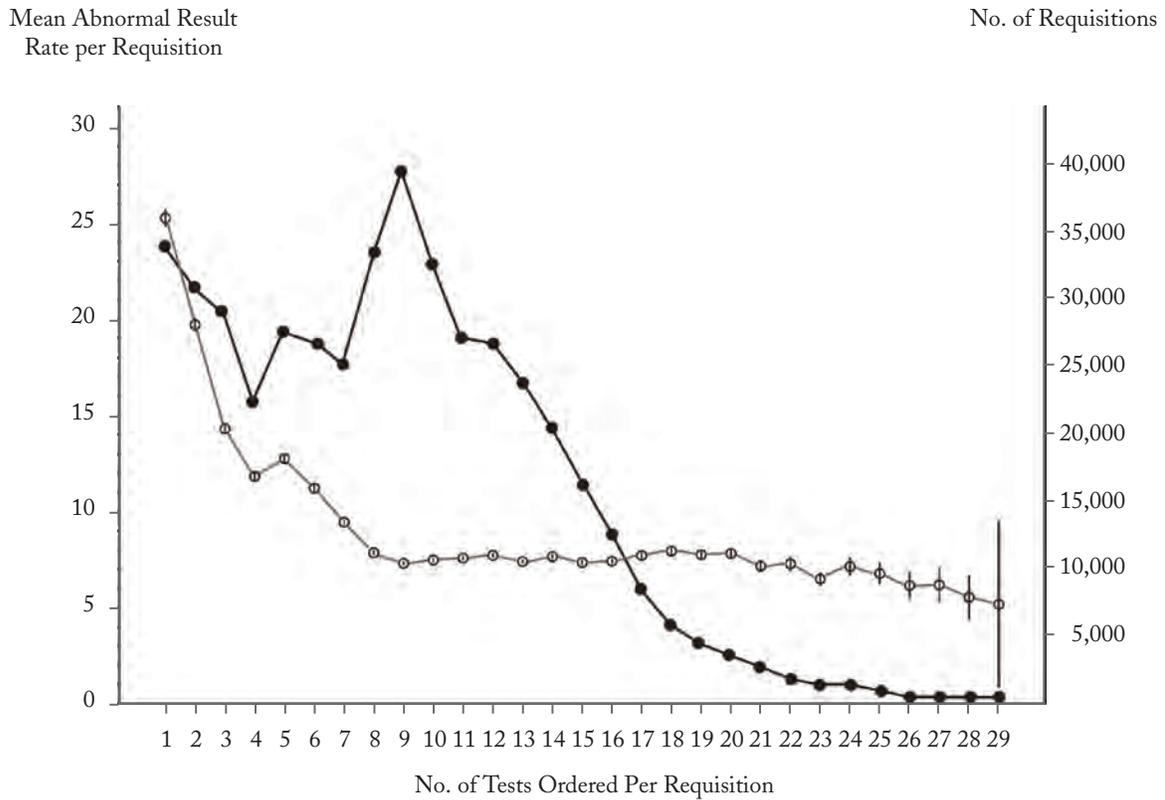
### **The Trade-off between Effectiveness and Acceptability**

There is a trade-off between the effectiveness of utilization management interventions and their acceptability to end-users. For example, a recent survey of family physicians showed that nearly all (98 percent) were accepting of educational utilization management interventions (Thommasen et al. 2016). However, a high-quality randomized controlled trial of such education showed no effect on utilization (Thomas et al. 2016).

Likewise, audit and feedback interventions are acceptable to 85 percent of family physicians (Thommasen et al. 2016) but produce only modest changes in utilization (Thomas et al. 2016). Evidence suggests that physicians’ beliefs about appropriate levels of testing are correlated with ordering practices suggesting that those who order more tests than average may be self-aware of their variation from their peers, even without audit and feedback mechanisms (Epstein and McNeil 1986). A randomized control trial showed that audit and feedback information had no effect on physician laboratory-ordering practices in the hospital setting. One potential reason for the lack of effectiveness is that physicians did not meaningfully engage with the information – only about two-thirds opened relevant emails and fewer than 20 percent accessed the personalized dashboard during the study (Ryskina et al. 2018).

In contrast, interventions that restrict access to tests or impose barriers to their use are much

**Figure 7: Number of Tests Ordered per Requisition Related to Abnormal Results**



Mean Abnormal Result Rate (test value outside of the reference range) for requisitions requesting up to 29 tests (open circles). Vertical lines are the 95% error bars. Also shown on the Y-axis is the total number of requisitions with a given number of tests re-quested (closed circles). The data represent all tests ordered by 1,340 family physicians in Calgary on outpatient (community) patients over a one-year period. Requisitions requesting more than 9 tests had low overall average abnormal result rates, suggesting that these tests were being requested less selectively.

Source: American Journal of Clinical Pathology 2016; 145:568-573 Naugler and Guo.

more effective. These so-called administrative interventions showed an average reduction of 35 percent in a recent systematic review (Thomas et al. 2015). One such administrative intervention to reduce vitamin-D testing in Alberta, as noted above, showed a reduction of more than 90 percent (Naugler et al. 2017). A similar intervention in Manitoba reduced vitamin-D testing by about 86 percent (Rodd et al. 2018). Predictably, however, these more effective interventions are deemed much less acceptable to physicians – only about

half of family physicians deemed them acceptable (Thommasen et al. 2016).

## POLICY IMPLICATIONS

Inappropriate use of laboratory and other diagnostic services is associated with significant costs to patients, physicians and the healthcare system. The reasons for continuing inappropriate use are complex, involving individual patient factors as well as physician ordering habits and beliefs.

With complex causes, it is unlikely that any one solution will effectively address inappropriate use of laboratory tests on its own. The tension between effectiveness of an intervention to reduce inappropriate care and its acceptability to patients and physicians shows that a heavy-handed approach could result in negative unintended consequences. In this section, we detail a number of options that policymakers could employ to reduce inappropriate use.

### **Option 1: Physician Education with Mandatory Audit and Feedback of Laboratory Usage**

The first step in reducing inappropriate use of laboratory and other diagnostics is to make physicians aware of the problem. While educational interventions may not have a strong effect on utilization of mid-career physicians, an argument can be made for improving the teaching of pathology and laboratory medicine during medical school and residency. A survey of training physicians in a UK hospital found that confidence in ordering tests was higher than confidence in interpreting them. Indeed, 70 percent of these physicians requested specific training related to appropriate test ordering practices and interpretation of results (Khromova and Gray 2008). Improving education for new physicians about the appropriate use of lab tests would reduce inappropriate usage over time, as the level of knowledge grows with each new cohort of graduates.

For practising physicians, comparing their ordering practices to their peers can facilitate learning and help to reduce practice variation. This could be achieved by implementing a mandatory audit and feedback policy on lab-ordering practices. To be effective, all physicians should be obliged to participate in order to include very high- or low-volume users and ensure accurate representation of the ordering practices of all physicians. To date, personalized audit and feedback has had only modest effect on the total volume of tests ordered,

but evidence suggests that it is more effective in reducing practice variation and reducing usage by the most high-volume users (Ryskina et al. 2018).

In Ontario, a combination of audit and feedback with education has been effective in addressing high-volume users. Physicians were visited by a laboratory representative up to three times in a two-year period where they discussed personal laboratory test utilization and were provided with additional educational material. This resulted in an 8 percent reduction in utilization that persisted for at least two years after the consultations (Bunting and van Walraven 2004).

Neither audit and feedback nor educational interventions are particularly effective on their own. A combination of the two, where doctors receive meaningful information through consultation with peers or laboratory representatives along with feedback on their ordering practices, would likely be more effective at addressing inappropriate use.

### **Option #2: Adjusting Incentives in Primary Care**

To decrease the amount of unnecessary laboratory testing and associated downstream medical costs, the trade-off between effectiveness and acceptability of utilization management must be managed. One way of doing this is to introduce different ways of remunerating physicians that align incentives to the ordering of laboratory tests or other procedures only when they are medically useful. Generally, family physicians in Canada are remunerated on a “Fee-for-Service” basis, where they are paid a specified rate for each service performed though there are some alternative payment models. This system incentivizes physicians to perform as many services as possible.

An alternative remuneration method is “capitation,” where physicians’ pay is pre-determined, based on defined population and patient parameters. The amount of remuneration is based on the average expected healthcare utilization of individual patients (meaning doctors are paid more for patients that are likely to require more

medical care). In this model, physicians are paid to deliver a basket of services and are paid per patient, not per service. If laboratory testing is included in the capitation basket of services, then doctors would only order tests that they deem to be medically useful in diagnosis.

Another alternative would be to pay bonuses or commissions based on rates of laboratory tests across physicians' patient rosters and reward physicians near or at the average. This would address abnormally high- and low-volume users and should serve to reduce practice variation.

The current fee-for-service model does not incentivize physicians to reduce laboratory testing, since they do not pay for it and are paid directly for consultation and assessment services. Changing primary care physicians' remuneration to incentivize them not to order laboratory tests excessively would be a way to make physicians aware of the costs of unnecessary testing and share in the benefits of reducing them through unrealized good-practice bonuses.

To avoid such an incentive structure leading to under-utilization of laboratory testing, it would have to be carefully structured to reward physicians whose utilization aligns with their peers and does not reward physicians with very high or very low relative testing volumes. This could be done by evaluating the proportion of abnormal test results as the utilization management metric (Naugler and Gao 2016).

Overall, family physicians order 58 percent of all laboratory tests. The next largest orders among specialty groups comes from internal medicine at less than 10 percent (Naugler et al. 2015). Since primary care physicians order the majority of tests and there is large variation among their ordering practices, including laboratory services in capitation formulas or aligning incentives via bonus structures would be an effective tool to reduce variation and discourage unnecessary lab tests. In a study of simulated clinical scenarios, physicians were less likely to perform discretionary care under a capitated payment structure as compared to fee-

for-service (Shen et al. 2004). An older systematic review suggested that fee-for-service was associated with a higher number of diagnostic services (Gosden et al. 2000).

### **Option #3: Technology and Targeted Administrative Intervention**

For laboratory tests that have well-defined clinical applications, ordering could be restricted to patients that fall within the guidelines. If physicians are obliged to provide the reason for ordering a particular test, they are much less likely to inappropriately order it, as evidenced by the successful interventions to reduce inappropriate vitamin-D testing in Canada. This option would not address the underlying causes of inappropriate testing, but would be an effective tool to reduce inappropriate use of specific tests.

There is also the option of adapting ordering procedures and requisition forms to make them more restrictive in their "default" options. For example, providing family physicians with a modified basic shortcut test menu where some tests were not included, showed significant decreases in the volume of test orders (14.0 versus 29.3 tests per 100 consultations) (Martins et al. 2017). This intervention does not actually restrict a doctor's ability to order a particular test; it simply changes the default options shown to physicians. If the doctor thought a particular test was necessary, they would still be able to order it.

Similarly, if physicians had access to better information about minimum retest intervals and a patient's most recent test result, they would be much less likely to inappropriately reorder a test. This would be most beneficial if physicians had access to test results that the patient may have received at a different facility via comprehensive electronic medical records. There would still be reductions in inappropriate test reordering if such an intervention, likely a software application, were individual to each medical practice. Indeed, results from Ontario show that 60 percent to 85 percent

of tests reordered inappropriately were ordered by the same physician that requested the initial testing (Chami et al. 2017). More generally, electronic health records would be an important feature of potential implementation more generally. A more restrictive approach to address inappropriate repeat testing would structure laboratory ordering procedures to reject test orders repeated before the minimum retest interval in clinical guidelines.

#### **Option # 4: Develop Provincial Formularies**

Develop clearly defined provincial laboratory formularies based on collaboration among funders, laboratory physicians/scientists and clinical subject matter experts. This formulary would define which tests are paid for through public insurance schemes, for which purposes and, particularly, how often. Standing multidisciplinary groups in each province would consider requests for adding new tests and/or clinical indications to the formulary. In the setting of stable laboratory budgets, addition of new tests or indications would need to be linked with the removal of older- or lower-value tests from defined provincial laboratory formularies. Tests not on the formulary could still be ordered but would be paid for by the patient or supplementary insurance. This provides an economic incentive for higher-value testing but at the same time maintains patient and physician autonomy and control over medical procedures.

To ensure high-quality care, the formulary should be inclusive of most diagnostic procedures and specify the appropriate use of the results. To ensure it doesn't reduce medically valuable patient access, it should not be overly restrictive in appropriate uses, as long as health professionals and clinicians support the procedures. The frequency of testing, on the other hand, should be relatively restricted. As discussed above, ordering repeat tests generally serves little medical value and primarily serves to generate false-positive test results.

Diagnostic tests on the provincial formulary should be given minimum retest limits. For

example, a routine cervical cancer screening is recommended once every three years for women aged 21 to 70. On the proposed provincial formulary, the test would be covered by insurance plans only if the patient is female, over 21 years of age and had not billed a negative cervical screening in the last 2.5 years. Imposing such limitations would improve the likelihood that a patient will not receive unnecessary or inappropriate tests.

The implementation of a formulary would be a complex process, and its benefits would have to be weighed relative to the cost of implementing and then continuously administering such a system.

#### **CONCLUSION**

Growth in Canada's healthcare spending has outpaced economic growth, as measured by GDP, generating ongoing debate about the sustainability of publicly funded healthcare. In addition, aging, new treatments and rising patients' expectations continue to exert pressure on the healthcare system.

The frequency of laboratory testing and its critical role in diagnosis makes it a prime target for improving the appropriateness of care. Inappropriate use of laboratory diagnostics serves no medical value and results in costs to patients, physicians and the healthcare system overall. Reducing inappropriate use, however, requires careful considerations of the trade-off between the effectiveness of utilization management interventions and their acceptability to end users. Incorporating laboratory services in capitation/physician compensation formulas would be an effective tool to reduce variation between physicians and discourage unnecessary lab tests.

Generally, practice-variation feedback is an acceptable utilization management tool to physicians, but it has relatively small impacts on total use. Incorporating feedback with incentives for individual physicians to order only tests useful in diagnosis would likely improve the effectiveness of utilization management and would serve to reduce practice variation without resorting to restrictive

regulatory barriers. Similarly, combining feedback information with education about appropriate test-ordering practices is likely to be more effective than audit and feedback information alone.

In contrast, interventions that restrict access to tests or impose barriers to their use are much more effective but are generally less acceptable to physicians. Developing clearly defined provincial laboratory formularies of which tests are paid through public insurance schemes, for which purposes and particularly how often would limit inappropriate lab use. This solution, though effective at reducing inappropriate diagnostic treatments billed to provincial governments, may shift these costs to patients or limit the accessibility of diagnostics. Provincial formularies would need

to be frequently reviewed and adjusted to ensure appropriate coverage.

The reduction of inappropriate care is a prime target for policymakers to improve the fiscal sustainability of Canada's healthcare systems without reducing the standard of care. Laboratory testing is widely used and critically important to diagnosis and subsequent treatment. In addition, laboratory testing is relatively well documented in administrative data, making progress on reducing inappropriate use easier to monitor than in some other areas of healthcare. While inappropriate use is not limited to diagnostic activities, they are a prime target for improving efficiency in Canada's healthcare system.

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