

When Pathology and Laboratory Medicine Becomes a Commodity and Health Care Becomes Both Its Customer and Owner

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The purpose of this Op-Ed is to provide readers with an update on the provision of academic pathology and laboratory services in Alberta and across Canada. It builds on an article “Calgary Laboratory Services: a unique Canadian academic model following provincial integration of public, private, and academic laboratories” that was published by *Academic Pathology* in 2015.¹ This Op-Ed documents that the Calgary Laboratory Services’ (CLS) model is presently expanding across Canada, updates and analyzes recent changes in Alberta, and suggests lessons learned from the model’s evolution.

Background Pertaining to the 2015 Publication

The previous paper reported that “regionalization” of health care² was highly disruptive in the mid-1990s after it was initiated by a newly elected provincial government in Alberta committed to balancing the provincial budget at all costs. One result was a 40% province-wide budget cut for laboratory service provision and the exodus of about 40% of the province’s pathologists, all in about 1 year.¹ This turmoil instigated a precipitous merger of all public (hospital-based) and private laboratories in Calgary, including the University of Calgary Department of Pathology and Laboratory Medicine in 1996. This public–private partnership was called CLS with industry holding a 50.1% share and the Calgary Regional Health Authority (CRHA; ie, the provincial health-care service covering Calgary and surrounding towns) owning a 49.9% share. In 2006, CLS became a wholly owned subsidiary of CRHA when the public side bought out the private side. After the 2008 amalgamation of 9 regional health authorities into a single

authority, Alberta Health Services (AHS), CLS became a wholly owned subsidiary of AHS (ie, the government-owned provincial health-care service). Despite the tumultuous 20-year period, academics eventually prevailed—but only after the shock and awe had worn off.¹

The paper also described how the “CLS model” had begun to be implemented elsewhere in Canada, citing 2 locations: Eastern Ontario Regional Laboratory Association (a merger of all hospital laboratories in our nation’s capital and the University of Ottawa’s Pathology Department) and Diagnostic Services Manitoba (a merger of lab services for the Province of Manitoba and the University of Manitoba Pathology Department), which is currently undergoing additional changes of an unknown magnitude as well as a name change to Manitoba Shared Health Services.

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Table 1. Elements of CLS and CLS-Like Models.

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- Merger of academic and nonacademic hospital pathology and laboratory medicine services.
 - Combined service assumes academic duties for a Canadian medical school.
 - Merger was either precipitated by provincial government action or was initiated by the provincial government.
 - Merger results in upgraded and harmonized quality assurance programs.
 - Merger saves provincial health-care dollars through increased efficiency.
 - Enlarged service base and larger test volumes can facilitate research, enhance teaching opportunities, and promote clinical trials.
 - Comprehensiveness of an expanded testing menu results in lessened need to refer out testing.
 - Merger may or may not include community laboratory service provision; if not included, these are likely provided by private laboratories.
 - Merger may or may not result in the provincial health-care service becoming both the owner and customer of the merged laboratory service. If government-owned, the system is at risk for undercapitalization which can stifle innovation.
 - Seamless movement of research and innovation is possible because of inclusion of the academic mandate and the capacity for knowledge translation within the system.
 - Capital planning can be more deliberative and reduce redundancy.
 - Some aspects of the CLS/CLS-like model are variable depending upon how and where it is being implemented.
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Abbreviation: CLS, Calgary Laboratory Services.

Continued Expansion of the Calgary Laboratory Services Model Across Canada

Now, in 2018, 6 more Canadian medical school pathology departments are being assimilated into CLS-like merged laboratory structures, specifically at the University of Alberta (discussed in detail below), the University of Saskatchewan, McGill University, University of Montreal, Sherbrooke University, and Laval University. With roughly half of Canada's medical schools patterning their academic pathology departments to some extent after CLS, the "CLS-like model" (Table 1) is clearly becoming a dominant academic laboratory service model in Canada.

It makes sense that the CLS model is expanding across Canada as such mergers permit simultaneous widespread implementation of quality assurance/improvement initiatives at multiple sites as well as achieving significant cost savings for laboratory service provision. When CLS formed in 1996, immediate efficiencies were gained and annual laboratory operating expenses decreased from Can\$110 million to Can\$60 million at the time of the transition; however, because of the abrupt nature of the merger, there were big-ticket 1-time transition costs which had not been planned for, such as switching to common testing platforms to achieve single reference ranges for the city and implementing a system-wide laboratory information system (personal communication, Fred Swaine, MD,

former CLS Chief Operating Officer, September 28, 2017). While operational savings of this magnitude would be specific to Calgary in 1996-1997, implementation of CLS-like models almost certainly generates real cost savings elsewhere in Canada. Calgary Laboratory Services currently accessions >30 million tests, >160 000 surgical cases, and >210 000 cytology cases per year.

As CLS-like models expand across Canada, the degree of similarity, will of course, vary widely from school to school. Even the approach at the University of Alberta will differ from in Calgary because the CLS model is now poised to become province-wide, and the medical school departments in Calgary and Edmonton, combined with their respective associated zone clinical departments, will become hubs for clinical service provision across all of Alberta.

It is a fascinating time for academic pathology in Canada! It is also timely that the Alberta story be brought up to date and learnings discussed that might benefit transitioning academic pathology and laboratory medicine departments and their clinical laboratory services partners.

An Alberta Review and Update

From the time of health-care regionalization in Alberta in the mid-1990s, the Capital Regional Health Authority (Edmonton)/the University of Alberta took a very different approach than the CRHA/University of Calgary.³ This was likely in large part because merging all hospitals in Edmonton was not politically feasible as 2 of the larger hospitals were under Covenant Health, the largest Catholic health-care provider in Canada. Therefore, true regionalization occurred in Calgary but not in Edmonton. As a result, Edmonton continued with multiple pathology and laboratory service providers including large and small commercial laboratories and laboratories operated by Covenant, the Health Authority, a cancer hospital, and the University of Alberta. A large commercial laboratory was awarded a 15-year contract to provide community laboratory services.

In the early 2010s, it was necessary to develop plans for when this 15-year contract ended, and AHS decided it would contract with a private company to provide a new CLS-like laboratory in Edmonton which would encompass the University of Alberta Department of Laboratory Medicine and Pathology, meet its academic mandates, and would also provide global hospital and community laboratory services for Edmonton and the northern part of the province (geographically 75% of a province which has roughly the same surface area of the state of Texas); the contract was to be for Can\$3 billion over 15 years. A request for proposals (RFP) was issued. Many assumed the current community provider would eventually be hired, but the RFP process would force them to offer competitive pricing. Eventually, 3 multinational laboratory corporations were short-listed. Prior to the 2015 provincial election, Sonic Healthcare of Australia was selected to go forward with a full proposal (<http://www.cbc.ca/news/canada/edmonton/alberta-health-services-privatizing-edmonton-labs-1.2460544>;

<http://www.cbc.ca/news/canada/edmonton/australia-s-sonic-healthcare-nets-3b-contract-for-edmonton-labs-1.2802270>). This unexpected result prompted the current community provider, which was in part owned by one of the 2 multinational corporations which had been unsuccessful in the RFP, to put forward a legal challenge based upon alleged flaws in the bidding process and this prevented further negotiations with Sonic for over 6 months.

In mid-2015, a new provincial party was elected to govern Alberta after a 44-year-long reign of a single political party. On August 14, 2015, the new government of Alberta cancelled the RFP stating that additional privatization was not in the public interest and the whole project was placed on hold. The government announced that it would study laboratory services and then develop a plan to restructure these provincially (<http://www.cbc.ca/news/canada/edmonton/health-minister-cancels-3b-contract-will-not-expand-private-services-in-alberta-1.3190004>). As an interim measure, the contract for the community provider was extended “as a stop-gap measure to March 31, 2017” to assure continued lab services (<http://edmontonjournal.com/news/local-news/alberta-health-services-extends-contract-with-lab-company>). Interestingly, immediately prior to the cancellation, there had been a ruling that AHS had breached its duty of procedural fairness (<http://globalnews.ca/news/2163916/watch-live-albertas-health-minister-discusses-lab-services-in-edmonton/>; https://www.huffingtonpost.ca/2015/08/13/alberta-health-minister-cancels-contract-with-private-lab-company-from-australia_n_7985202.html) and that the bidding process had been compromised which led to additional legal wrangling and Sonic sought to recover its RFP costs; this was settled out of court. Because the original timeline to replace the current community provider was no longer feasible, the contract for the current community provider was extended by 5 years to March 31, 2022, with an agreement that AHS would pay the provider Can\$15 million over the life of the contract to “ensure equipment is upgraded,” as well as Can\$50 million at the end of the contract (<http://www.cbc.ca/news/canada/edmonton/alberta-health-services-to-extend-dynalife-contract-five-more-years-1.3735622>; <http://www.cbc.ca/news/canada/edmonton/alberta-health-services-to-buy-out-dynalife-transfer-services-back-to-province-1.3785100>). In addition to these payments, Dynalife’s parent company (Laboratory Corporation of America Holdings), reported in its 2016 Form 10-K filing with the United States Securities and Exchange Commission that it would amortize the value of Dynalife’s license in Alberta (US\$34.9 million) by 2022 (http://www.annualreports.com/HostedData/AnnualReportArchive/l/NYSE_LH_2016.pdf).

In retrospect, the initial plan would almost certainly have had disastrous consequences for CLS. Although CLS would have continued and would have provided laboratory services for the southern portion of the province in the short term, there were grave concerns that this scenario would not be sustainable as the playing field could not have been more uneven. One of the advantages that existed when CLS was part of a public-private partnership was that the private partner understood the importance of capital expenditures to provide state of the art

services and to remain competitive; unfortunately, this ceased to be a priority once CLS was publicly owned. Specifically, after becoming a wholly owned subsidiary of AHS, the CLS capital budget eventually decreased to 10% of what it had been a decade earlier. If Edmonton had private enterprise funding (with deep pockets) and CLS only public funding, the long-term outcome almost certainly would have resulted in CLS failing to be competitive and being absorbed into Sonic.

Curiously, it never made sense why 3 multinational commercial laboratories would fight over the opportunity to provide laboratory services for a population of less than 2 million people of which roughly three-quarters were residing in the Edmonton area and the rest being spread throughout the remainder of northern Alberta (with a land surface area larger than that of the State of California); furthermore, the contract would have required the successful company to create laboratory infrastructure from scratch, hire the current technical staff and pathologists, provide global academic services for the medical school, and meet many other highly specific conditions. Since this did not appear to be a recipe for profit, most at the time speculated that the business model was a loss leader approach, allowing a foothold in Canada from which Sonic could seek new business all across the country. In addition, with a potential monopoly on all regional clinical, genetic, and laboratory data, they would have had a unique and exploitable informatics asset as well as distinct advantages when competing for pharmaceutical industry dollars and clinical trial business. This model is now defunct with the change in government.

The New and Evolving Plan for Laboratory Services in Alberta

Early signals suggested that the new government planned to reorganize laboratory services for the entire province resulting in a single laboratory service entity as an AHS department, with its workforce under a common union; under this structure, laboratory decisions would have been almost entirely under the control of government health-care providers, and academic pathology leadership would have been largely disenfranchised.

In May 2016, the Health Quality Council of Alberta (<http://www.hqca.ca/>) at the request of the Minister of Health presented a report entitled *Moving Ahead on the Transformation of Laboratory Services in Alberta* (https://d10k7k7mywg42z.cloudfront.net/assets/5728f685d4c961739d073381/HQCA_Moving_ahead_on_transformation_of_laboratory_services_in_Alberta_January_18_2016_FINAL.pdf; <http://edmontonjournal.com/news/local-news/report-recommends-new-public-agency-be-responsible-for-medical-tests-in-the-edmonton-region>) which prompted the government to hire an external consultant, Dr Penny Ballem from Vancouver, who initiated a province-wide consultation. This eventually culminated in a report *Provincial Plan for Integrated Laboratory Services in Alberta* (https://d10k7k7mywg42z.cloudfront.net/assets/59121626a0b5dd209e020b9f/Provincial_Plan_for_Integrated_Laboratory_Services_in_Alberta_FINAL_.pdf) posted online

in May 2017. The report proposed “two conceptual options for a public sector stand-alone organization with the mandate to deliver laboratory services.” One possibility was to dissolve CLS and merge all provincial laboratory services into a single public agency and the other was to have all provincial laboratory services provided by an AHS subsidiary health corporation. Functionally, the second model would keep CLS intact as a wholly owned subsidiary of AHS and as a southern Alberta laboratory hub, form a similar laboratory service in Edmonton to function as the northern Alberta laboratory hub, and then have them share a single board of directors. Because the government recognized the success of CLS, it decided to pursue the latter approach. Technical workforces will share a single union province-wide, but the 2 hubs will maintain some degree of regional and academic autonomy; however, both will report to a single board. If implemented with strong board leadership that is arm’s length from AHS, this could be an ideal model that serves patients and academics alike, resolves current chronic issues on how to implement innovative new tests and rationalize provision of more esoteric laboratory services, and creates economic opportunities for the province. Fortuitously, the province has a once in a lifetime opportunity to get it right. The conditionality of a strong arm’s length board is critical (see below).

What Can Canada Learn From Calgary Laboratory Services and Alberta?

The CLS experience has shown that large city-wide laboratory mergers can work. Calgary Laboratory Services has provided strong, yet economical, high-quality clinical service provision and robust academic support for the University of Calgary; to accomplish the latter, a carefully constructed academic affiliation agreement, as previously described,¹ was necessary. Going forward, AHS is in the process of harmonizing clinical information and laboratory information systems province-wide. With a new merged entity with a monopoly on all laboratory services linked to population data for the entire province, Alberta could become a powerhouse for informatics research and a magnet for pharmaceutical company investment and clinical trial dollars. The merger, which also brings together expertise from 2 medical school departments, creates huge opportunities, which now far exceed those envisioned by the multinational corporations who were vying to serve only 43% of Alberta’s population. This merger creates the right set of circumstances for entrepreneurial opportunities that could never happen in the United States because of its highly fragmented health-care system. The distributed business models of hospitals in large American cities is not conducive to genetic or laboratory-based research attempting to encompass entire populations, as its fragmentation essentially precludes any chance of centralized access to population data and bio-banked patient samples. A visionary board, that is not risk adverse, could spin this merger into gold.

However, the main risk for any CLS-like entity arises when the provincial government health-care service becomes both

the owner (ie, provider) and the customer (purchaser) of laboratory services. While intuitively, a close provider–purchaser relationship should allow the provider to fine-tune their services to meet the needs of the customer, this is only a good thing for patients if the customer fully understands the nuances of its needs, knows what laboratory services best meet these needs, and hopefully wants the state of the art services that the provider naturally wants to provide. While pathology and laboratory medicine are viewed by laboratory physicians and many clinicians as a consultative medical specialty practice, many health-care administrators simply view “lab services” as commodities that are not much different than housekeeping and laundry services, a conundrum that is almost 100 years old.^{4,5}

Realistically, laboratory services are special as they have some elements of both medical practice and commodities. Good, fast, and cheap have been likened to the quest for the Holy Grail in business (also sometime called the “quality triad”). Conventional wisdom suggests that only 2 of the 3 are possible (<https://www.forbes.com/sites/joshlinkner/2015/01/15/pick-only-two-cheaper-faster-or-better/#68a95cc963a3>; <https://www.business.com/articles/fast-good-cheap-pick-three/>); however, for laboratory services, none of the 3 are absolute, all can be viewed as continuums, and the relationship is more of a complex equilibrium state. As such, normally, the “market” determines “good versus fast versus cheap” for any given laboratory service. However, this kind of simplistic analysis does not take into account that sometime efficiencies can be gained through lean processes and that, in high-tech fields like laboratory medicine, implementing newer and more innovative technologies can result in methodologies that are actually better, faster, and cheaper. However, to improve services and achieve operational savings, there may be one-time upfront infrastructure costs. While current laboratory services in Alberta are good and, because of robust quality assurance and a highly skilled and dedicated workforce, will undoubtedly remain so, further progress will require a mechanism for funding for innovation and implementation of newer testing platforms that could make the overall service better but the context, unfortunately, may inhibit such improvements.

Under normal conditions, academic laboratories based on new research should try to drive “good” to be the best, but the market ultimately determines whether better, for any given test, is more valuable than good. Academic commercial laboratories often focus on development of esoteric or niche testing. However, when the government health-care service, which pays globally for laboratory services, owns the provider, is the sole customer of the provider, and naturally wants to minimize the overall costs of providing health-care, incentives can become perverse, and the normal delicate good versus fast versus cheap equilibrium can easily be upset. Cheap can become the primary driving force for government-funded health services, with only lip service paid to making good better. In other words, “competent” laboratory services becomes good enough, and fast becomes defined as fast enough that clinicians ordering tests do not complain very much. When the government owns the provider, nonlaboratory physician administrators with little

content expertise can directly or indirectly play a role in determining whether new and innovative tests will be funded and the public can miss out on opportunities to have better, faster, and cheaper tests. For these reasons, decision-making by providers should be at arm's length from the purchaser.

In Alberta, where there are 2 medical schools competing to provide new and innovative forms of testing, the current service model (soon to become the past service model) has effectively contained costs by slowing the implementation of innovative testing by referring decision-making on implementation of new testing to one or more of 12 laboratory networks (<http://albertahealthservices.ca/lab/Page3285.aspx>), subspecialty-based committees with geographic representation covering the entire province, to adjudicate each proposed new test and make a recommendation to a province-wide committee charged with granting final budgetary approval. Essentially, this form of central decision-making in Alberta was highly political and stifled innovation—especially when one academic laboratory was often able to prevent the other from developing a new test. The new board will need to be able to judge proposals from either hub on merit and avoid regional politics; it should also be possible to retire the 12 laboratory networks, freeing up valuable time for the many laboratory physicians serving on these committees. The new proposed merged structure, with an arm's length board possessing content expertise, could essentially rectify these problems, resulting in esoteric tests being developed and then provided by one of the 2 academic laboratory hubs. Adding advanced modes of testing also creates research, educational, and economic opportunities.

Unfortunately, government agencies are naturally risk averse. And without content expertise and business experience, a board composed of nonlaboratory health-care administrators and government administrators may not be able to recognize unique opportunities that were obvious to multinational corporations and may not be able to correctly assess risk-benefit ratios. For them, it is simpler and much less risky to settle for competent laboratory services.

Success in this new venture will be dependent on a board of directors with vision to support enhanced capital budgets sufficient to facilitate innovation in both hubs. As the centerpiece of the new plan is a state of the art Can\$325 million "super lab" being planned and built from scratch in Edmonton to support northern Alberta (<http://edmontonjournal.com/news/local-news/province-to-announce-new-edmonton-super-lab-for-health-tests>), it is critical not to forget to budget for upgrading equipment and infrastructure in Calgary to support the laboratory needs for the southern and central more populous regions of the province. As a result of decimation of its capital funding for almost a decade, recent press coverage highlighted that 60% of CLS laboratory equipment is considered to be at the end of its life (<http://edmontonjournal.com/news/local-news/report-calls-for-one-lab-services-agency>).

Previous experience has shown that government overseers of the health-care mandate, often insist on direct oversight of decision-making related to laboratory services, providing only a "short leash" to laboratory medical leadership. For example,

in the past, there was resistance to going big and competing for third-party revenue as it was deemed unfair to use publicly funded infrastructure to compete against private laboratories in Alberta. With the new model in which all lab services will be public, this policy, which was previously an anchor preventing CLS from aggressively pursuing entrepreneurial opportunities which could have been used to fund new infrastructure, should no longer be a concern. Hence, the province's new model can be viewed as a grand new experiment which could create economic dividends.

The context has recently moved from hugely promising to worrisome. Several months ago, a new interim board of directors of the new yet-to-be-named provincial laboratory entity was appointed which did not include any medical school representatives, academic pathologists, industry experts, business persons, or academicians with expertise in laboratory medicine. In fact, the only pathologist on the interim board is from a community hospital in Red Deer, Alberta (strategically located exactly halfway between Edmonton and Calgary). The government is approaching a big crossroad as the interim board is to be replaced by a definitive board this fall. These appointments will predict the future of the new Alberta model and the future will be dim if the board is populated primarily by AHS health-care leadership and government administrators. Since at least 70% of important medical decisions are believed to be based upon laboratory results, Albertans could reap huge health benefits from the appointment of a knowledgeable board that recognizes and rewards innovation. Surely, the people of Alberta deserve the best that the combined pathology and laboratory medicine expertise at the University of Alberta and the University of Calgary can provide. Clearly, decisions made in Alberta, since CLS is now a Canadian prototype, will be studied and some will eventually be implemented elsewhere in Canada. What Alberta does next will affect academic pathology one way or the other across the country.

Knowledgeable laboratory physicians need to be inextricably linked to the decision-making process about what laboratory testing should be offered in the province, not health-care administrators focused on cost. Costs can be better controlled by providing the 2 hubs with global annual budgets and holding laboratory medical leadership accountable for these budget targets, rather than by micromanaging individual test implementation. Furthermore, learning from the multinational companies that were formerly vying to provide services to northern Alberta so that they could seize economic opportunities by providing testing outside of Alberta, the new board should reward innovation and allow the 2 hubs to defray some of their operating costs by aggressively seeking third-party revenue.

When CLS was formed in 1996, important decisions were made without considering their effects on academics and, as a result, it took the better part of a decade for research and teaching to fully recover and then thrive under the new system.¹ To the government's credit, academics have not been entirely forgotten in this merger of 2 CLS-like entities, each supporting a different medical school. So what should be the metrics to measure academic success for this new Alberta model? Some

Table 2. Recipes for Success When Implementing a New CLS-Like Laboratory Service.

- Advanced planning—do not implement change precipitously like when CLS formed.¹
- Engagement with “buy in” from laboratory physicians on:
 - Vision and mission statements.
 - Governance structure.
 - Importance of supporting the academic mandate.
- Clinical faculty appointments provided for any medical scientific staff at nonacademic hospitals who are expected to teach.¹
- Leadership must understand and manage town-gown dynamics.¹
- A remunerative structure that values both clinical and academic work.¹
- Explicit academic affiliation agreement outlining responsibilities of all parties.¹
- A mechanism to assure continued capital investment in infrastructure.
- If the potential of owner versus customer conflict of interest exists, a strong arm’s length board of directors is critical.
- If applicable, find a mechanism to avoid regional politics

Abbreviation: CLS, Calgary Laboratory Services.

of the metrics such as departmental publication output, citations, research funding, and growth in the number, scope, and quality of training programs should be the same as those used when evaluating CLS in 2015.¹ However, the 2 academic departments will need to be less competitive and to work together. While a substantial degree of duplication will be necessary so that both departments can provide core academic competencies to their respective medical schools, both will need to accept that sometimes one and other times the other will excel in different research or educational arenas based upon a myriad of factors, including the availability of certain skill sets or infrastructure in one local versus the other. If there is a need to decide upon a single location for an academic program, decisions should be made based upon excellence rather than politics.

The new Alberta model should be extremely well suited for clinical, translational, population-based genetic, and informatics research. Clearly, high clinical test volumes will also create opportunities for test development and validation as well as beta testing with industrial partners. However, the model will also need to support excellent fundamental research into mechanisms of disease, as classic experimental pathology research and discovery-based basic research are the foundations on which translational research is built.

In closing, the prospects for improved academic laboratory services and economic advancement in Alberta look promising if the definitive board has broad arm’s length representation that includes the academy and industry and if there is some distance between the provider and customer interests. For Canadian pathologists engaged in CLS-like reorganizations, vigilance and principled engagement are crucial. The CLS academic model can work exceedingly well in a Canadian environment, but success is dependent upon a workable system of governance and other factors (Table 2). For our American colleagues, perhaps you will find the erratic way decisions are made about our profession in Canada instructive, but, like you, we strive to provide excellent and innovative academic laboratory services.

Authors’ Note

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