Evidence *in* Context

Issue: Troponin Point-of-Care Testing
Released: December 2014

Health research – synthesized and contextualized for use in Newfoundland & Labrador

Synthesis Topic

Troponin Point-of-Care Testing in Smaller Hospital and Health Centre Emergency Departments in NL

Newfoundland and Labrador's Department of Health and Community Services and its four Regional Health Authorities asked the Contextualized Health Research Synthesis Program (CHRSP) to identify and evaluate the best available research-based evidence on the use of Point-of-Care Testing (POCT) in emergency departments (EDs) in smaller hospitals and health clinics without 24/7 central lab facilities. In Newfoundland & Labrador, these emergency departments are called Category B EDs. They are usually located in rural or remote parts of the province, although some are within an hour's drive from a larger hospital. Achieving adequate medical testing in the emergency departments of smaller health centres involves both medical laboratory services and departments of emergency medicine. Our health system partners are interested in point-of-care testing as a potential alternative to 24/7 lab services.

To address this research question, CHRSP put together a project team that included people from the clinical and medical testing sectors of the health system, including administrators from Regional Health Authorities and the Department of Health and Community Services, as well as emergency department physicians from Eastern and Western Health. The team was led by Dr. Nitika Pant Pai, Assistant Professor of Clinical Epidemiology at McGill University. Dr. Michel Grignon, a health economist at McMaster University, was recruited to assess health economics for the project. Ms Vickie Kaminsky, who was then CEO of Eastern Health, served as the Health System Leader for the project team.

Initially, the scope of the project included a range of clinical biochemical and hematologic tests that are commonly requested in the province's emergency departments and are potential candidates for POCT. The project team narrowed the focus of the study based on:

- the time course of the presenting conditions that would require the test;
- the effects of related treatment decisions;
- potential economic and process outcome impacts.

The project team ultimately selected cardiac troponin point-of-care testing for suspected acute coronary syndrome as the focus of the study. No exclusion criteria were set for the outcomes studied; however, the following outcomes were prioritized for inclusion in the report: health service process variables, such as turn-around time and length of stay in the ED, the cost of implementation and operation, feasibility (including accreditation), and any evidence related to quality control and forward compatibility of any POCT systems. The full report is now available for review online at www.nlcahr.mun.ca/chrsp.

The Research Question:

"What do the scientific literature and local knowledge tell us about the clinical effectiveness, feasibility and acceptability of cardiac troponin point-of-care testing for emergency departments in smaller hospitals and health centres in Newfoundland and Labrador?"

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Read the full report here: http://www.nlcahr.mun.ca/CHRSP/

Emergency Care in Newfoundland & Labrador

In Newfoundland and Labrador, emergency care is provided in three types of facilities:

- Category A EDs are in larger hospitals with 24/7 lab services, have at least on physician on site, and are within a half hour drive of 70% of the population (~350,000).
- Category B EDs are in smaller facilities and are the closest ED for 22% of the island's population (~104,000). They have lab services during working hours, and may or may not have the ability to call back lab staff after hours.
- Community Clinics in Labrador are staffed by nurses who consult with one of three Category A EDs in Labrador Grenfell Health, and serve roughly one fifth of the Labrador population (~6,000).

> ***Health system administrators prioritize equitable access to health services but the costs of maintaining around-the-clock labs for all emergency departments in the province would be very high.***

Attending physicians in Category B emergency departments are faced with a problematic situation when they see patients at night or on weekends who present with conditions that require lab testing. If lab staff cannot be called back and a potential medical emergency is suspected, physicians must make patient management decisions with incomplete information. Physicians may wait until lab staff is available: they can admit patients overnight or send them back home to schedule testing at a later time. They may refer patients to the nearest hospital with an open lab; however, referrals are often not convenient for patients living in rural areas, since a significant number of these patients are older and a referral can require driving more than an hour.

Summary *of* Findings

Our literature search focused on high-level research: systematic reviews, meta-analyses, health technology assessments, as well as on very recent high-quality primary research not captured in the review literature. Our search identified five systematic reviews, eight recent primary research studies and an additional seven health economic articles.

Troponin POCT Test Performance

Point-of-care testing, in general, is a medical technology that is developing very quickly. The pace of advancement in POCT is such that significant improvements may not be adequately captured by the most recent review literature. In the case of cardiac troponin POCT in particular, there has been a rapid improvement in the threshold sensitivity of testing. New technologies are able to detect cardiac troponin with increasing accuracy at ever lower detection thresholds. Recent primary research has demonstrated that, as *a screening test*, cardiac troponin POCT is a comparable and reliable alternative to lab testing. A new class of 'high-sensitivity' cardiac troponin POCT has recently been shown to be even more sensitive and also more accurate.

Clinical Health Outcomes

Available evidence indicates that ED patients screened with cardiac troponin POCT had similarly low rates of adverse coronary events compared to patients tested by central laboratories, including rates of death, rates of readmission and the need for revascularization within three months of the test.

Emergency Department Process Outcomes

The literature demonstrates conclusively that cardiac troponin POCT reduces turnaround time compared to central lab testing by up to 75%. However, the evidence related to downstream process outcomes, including the time to [clinical] decision about the patient and the time to disposition (i.e., decision to admit or discharge the patient) is inconsistent, with conflicting evidence from three systematic reviews. What these findings imply is that factors other than test turnaround time influence how long it takes to decide on the course of action for patients suspected of Acute Coronary Syndrome (ACS).

Length of Stay/Time to Discharge

The evidence on whether cardiac troponin POCT reduces length of stay and time to discharge outcomes is inconsistent and weighted toward finding no difference. Inconsistent reductions in the downstream process outcomes described above are likely to contribute to this absence of improvement. The review literature proposes that cardiac troponin testing methods are not the determining factor for ED process outcomes. Instead, site-specific variables such as the facilities themselves, local protocols, existing and implemented guidelines for ACS and related symptoms, existing POCT and central lab cardiac troponin tests, and staffing variables, appear to explain the variability of the evidence.

Cardiac Troponin in Small Hospitals

There is little available research comparing the relative benefits of ED cardiac troponin POCT in hospitals with and without 24/7 lab services. We identified one primary research study that made such a comparison. Not surprisingly, it found that POCT had the greatest impact on length of stay at those centres without 24/7 lab services, and concluded that it was those centres that had the most to gain from POCT.

Health Economic Evidence

Several studies have found that cardiac troponin POCT is more expensive, overall, per patient or per patient-hour outcome than central lab testing. The differences in overall costs are quite variable between the studies because of differences in methodology and setting.

POCT generally costs more than central lab testing. The main reason the POCT approach is more expensive is the increased cost of the reagent slides or cartridges for POCT compared to the lower cost for central laboratory tests. This cost factor is compounded by the fact that each POCT quality-control measurement will consume a new slide or cartridge. Another expenditure that must be considered is the cost of training emergency department clinicians in how to administer the test and read the results.

However, one author points out that the health economic research-based evidence for difference in overall costs between central laboratory tests and POCT has neglected to take into account the costs associated with the longer timeframe between collecting the sample and receiving the test results for central laboratory tests. This author implies that the health economic literature, in general, has underestimated the true cost of central lab testing.

Economic Benefits

Despite the overall increase in cost, the research evidence points to some economic benefits of cardiac troponin POCT. One comprehensive health technology assessment found that POCT in hospitals without 24/7 lab services was more cost-effective. A single primary research study found cardiac troponin POCT improved 'throughput', i.e., the rate of processing patients in the ED, and, as a result, improved costs related to length-of-stay. However, a larger study could not find such clear and consistent effects and concluded that 'throughput' is setting-dependent.

The Newfoundland & Labrador Context

Patient Population: The population of NL has higher rates of risk factors for ACS and these are higher still in rural and remote areas where health facilities would be more likely to lack 24/7 lab services. This patient-level factor would be expected to enhance cost-effectiveness of cardiac troponin POCT in NL.

Patient Transfer/Monitoring: A POCT cardiac troponin screening test delivered on site would be able to differentiate between patients who require closer monitoring (and possible transfer) and those with angina who could potentially go home safely for the night, thereby decreasing the chances of a patient in the higher-risk group being released inappropriately. The quicker turnaround time for POCT could help to prevent delays in treatment and their resulting negative health consequences.

Effective Monitoring and Data Collection: The most effective implementation of cardiac troponin and other POCT will depend, in part, on effective monitoring and data collection, consolidation and analysis. Any challenges to integrating and analysing data from multiple hospitals could reduce the effectiveness of any POCT program.

Risk of Misuse: The effectiveness of troponin POCT could be undermined if the device is misused as *diagnostic* test and not for its intended use as a *screening test*. Staff must be careful not to substitute the more convenient POCT for the more sensitive and time-consuming lab test. There may also be confusion in distinguishing between the results of a POCT screening test and those of a central lab diagnostic test. These risks, while not specific to this province, are cause for concern. The new accreditation requirements for the province and quality assurance measures, including protocols for use, are designed to help prevent testing misuse/misinterpretation.

Organizational Concerns: Recent increases in turnover rates among lab technician staff, as well as recent and broad policy changes in point-of-care testing in general, could pose a risk to establishing the organizational and procedural conditions needed to support cardiac troponin POCT, as well as other types of POCT.

Health Human Resource/ Political Factors: The risk to successful implementation of cardiac troponin POCT is compounded if the POCT is not accepted by clinical and/or lab technician staff. While the public is likely to be accepting of an ED troponin POCT, it will be important to maintain that trust as well as resolving any potential difficulties arising from within the healthcare system itself.

In order for any POCT to be implemented successfully in Newfoundland and Labrador, both laboratory and clinical healthcare workers will need to accept and support the new tests and the quality assurance measures required by accreditation.

Implications for Decision Makers

In addition to the following considerations, which are based on the available research-based evidence and the Newfoundland and Labrador context, decision makers may wish to consider the continuing advances in technology for point-of-care testing. Advances in miniaturization, bioassays, biosensors and health informatics are occurring at a rapid pace, while the costs of these technologies continue to decrease. In this technological context, the number and variety of point-of-care testing devices can be expected to proliferate and to extend into emergency departments and other healthcare settings including acute care, primary care, long-term care and, increasingly, into patients' homes.

1. Cardiac troponin point-of-care testing technology is sufficiently accurate and reliable to be used as a screening test for acute coronary syndrome in emergency departments in Newfoundland and Labrador.

2. When implemented properly and used appropriately, cardiac troponin POCT, used as a screening test, does not increase the risk of adverse events or readmission rates compared to central lab testing; furthermore, this POCT significantly reduces the turnaround time for test results, and has the potential to reduce other emergency department time outcomes and to improve patient throughput.

3. When implemented properly, cardiac troponin POCT, used as a screening test, can reduce time to anti-ischemic therapy for high-risk patients and time to a negative diagnosis among low-risk patients, especially in hospitals and health centres without an operating central lab.

4. Hospital and regional level supports for POCT in the emergency department will strongly influence the effectiveness, efficiency and cost-effectiveness of cardiac troponin POCT. In particular, adherence to quality control measures and clinical protocols is required for POCT to realize its potential benefits. Emergency department physicians and nurses, and central lab technicians, will need to accept any proposed POCT on order to sustain quality control measures and protocols.

5. The requirement for accreditation for POCT in the province will help ensure that the appropriate quality control measures and protocols are implemented and sustained. However, health human resource challenges are potentially significant, particularly for smaller hospitals in Newfoundland and Labrador; these challenges could have an impact on sustaining those measures and protocols.

6. Tracking and monitoring are crucial requirements of POCT quality control. In order to properly implement POCT, the RHAs will need to be able to compile and analyze data from multiple sites in a timely and effective manner.

7. The evidence does not provide a clear indication of the economic impacts of ED cardiac troponin POCT in Newfoundland and Labrador, though it does suggest that POCT will be the most cost-effective in hospitals without 24/7 central lab services.

For the complete CHRSP report, including details on the evidence reviewed by the project team, and for more information about the CHRSP process, please visit the NLCAHR website: http://www.nlcahr.mun.ca/CHRSP/

Newfoundland and Labrador Centre for Applied Health Research
www.nlcahr.mun.ca | nlcahr@mun.ca | 1.709.777.6993