Review article

Development of a Robust Point of Care Testing Program in Newfoundland and Labrador Using Lean Method of Rapid Process Improvement Workshop (RPIW)

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Abstract

The implementation of a provincial Point-of-Care Testing (POCT) program across Newfoundland and Labrador (NL), Canada, is designed to standardize verification processes and ensure consistent analytical performance of POCT analysers across diverse healthcare settings. The program is developed using a "Test and Treat" model to support both remote rural communities and urban populations. Many provincial locations operate as standalone POCT sites hence vendors are required to provide site-specific support services. Selection of analytically robust and cost-effective POCT devices is prioritized to support sustainability and quality patient care. Extensive project planning include Lean Six Sigma methodologies, including Rapid Process Improvement Workshop (RPIW), to standardize workflows and improve operational efficiency. Carefully selected Six Sigma team members participate in collaborative brainstorming sessions to develop streamlined verification and installation strategies across 23 provincial POCT sites. Each analyzer is assigned a Provincial Equipment Unit Identification Number (PEUIN) to enhance traceability and inventory management. Primary verification is conducted centrally at St. Clare's Mercy Hospital, St. John's, while secondary verification is completed at individual installation sites to ensure site-specific performance validation. Harmonized installation of identical analysers support a standardized and quality-driven approach to provincial POCT expansion. Structured utilization management processes are not yet fully established within NL Health Services. Development of utilization monitoring tools to evaluate financial implications and cost-effectiveness is ongoing. Quality improvement initiatives are continuously monitored using key performance indicators. Additionally, the implementation of the EPIC hospital information system in April 2026 provides opportunities for further standardization and integration of POCT processes across the province.

Introduction

Point-of-Care Testing (POCT) refers to diagnostic testing conducted near the patient's bedside, enabling faster turnaround times compared to traditional laboratory services [1]. Traditional laboratory testing follows a multi-step process that begins with sample collection at the bedside or clinic, followed by transportation to a centralized laboratory, often located at a significant distance. Once there, samples undergo multiple stages of processing. This extended timeline can delay diagnosis and treatment, ultimately hindering timely clinical decision-making. By delivering rapid results at the site of care, POCT supports immediate clinical decision making and timely patient management, reducing delays and improving outcomes and overall satisfaction with healthcare services [2]. The practical challenges of managing POCT compared to centralized laboratory testing, and its impact on improving healthcare outcomes have been debated [3]. However, POCT has demonstrated clear clinical benefits of facilitating expedited diagnoses, faster treatment initiation, and enhanced patient care in acute care settings [4].

The COVID-19 pandemic underscored the critical value of having a robust POCT infrastructure in the healthcare system [5]. The global health crisis highlighted the urgent need for rapid, decentralized testing capabilities, particularly in settings with limited access to centralized laboratories. The experience of the pandemic validated the importance of well-equipped POCT programs with modern instrumentation and appropriately trained personnel to help mitigate community transmission. As such, many diagnostics companies continue to invest significantly in developing advanced POCT technologies.

The province of Newfoundland and Labrador (NL) has one healthcare authority, Newfoundland and Labrador Health Services (NLHS), tasked with the administration & delivery of healthcare services across the province. NLHS is divided into 5 zones to balance centralized province-wide efficient healthcare delivery. These zones are named Eastern (Urban, and Rural), Central, Western, and Labrador & Grenfell zones. Laboratory services within NLHS are provided across the province through major hospitals and regional health centers.

NL is characterized by its rugged North Atlantic coastline and harsh winter conditions. NL is home to many remote and rural communities, often located 200 to 300 kilometers away from major hospitals. This realization led the provincial government to recognize the urgent need for a strong POCT network in the province. In response to these geographical and demographic challenges, and in alignment with provincial directives, Department of Pathology and Laboratory Medicine initiated a strategic transition from a centralized laboratory model to a province-wide POCT-based service delivery model. This approach aims to provide timely and uninterrupted diagnostic services to even the most remote communities across NL. More so, the provision of a timely, robust, and standardized province-wide medical care for the aging and widely dispersed population aligns with the quality improvement initiatives across all healthcare zones within NLHS. Central to building this system was the implementation of a cost-effective lean process, designed to streamline operations and enhance efficiency.

As the demand for POCT continued to evolve in the province, the division of Pathology and Laboratory Medicine (PLM) services initiated the process of phasing out routine laboratory testing from smaller rural facilities and replacing it with a POCT-centric model. This transition includes regionalizing routine testing and centralizing specialized diagnostics services at hub sites. Under this framework, outpatient samples such as blood and urine are transported to central laboratories for routine analysis, while POCT is used to rapidly deliver test results for immediate intervention directly at the point of care. To further support this initiative, the POCT team members undertook the responsibility of developing unified policies, procedures, and workflows. NLHS POCT covered mainly 23 rural sites in addition to other isolated coastal community sites. Each project for installation of various POCT analysers across 23 provincial rural sites constituted five phases of DMADV (Define, Measure, Analyze, Design and Verify) framework guided by Lean Six Sigma principles.

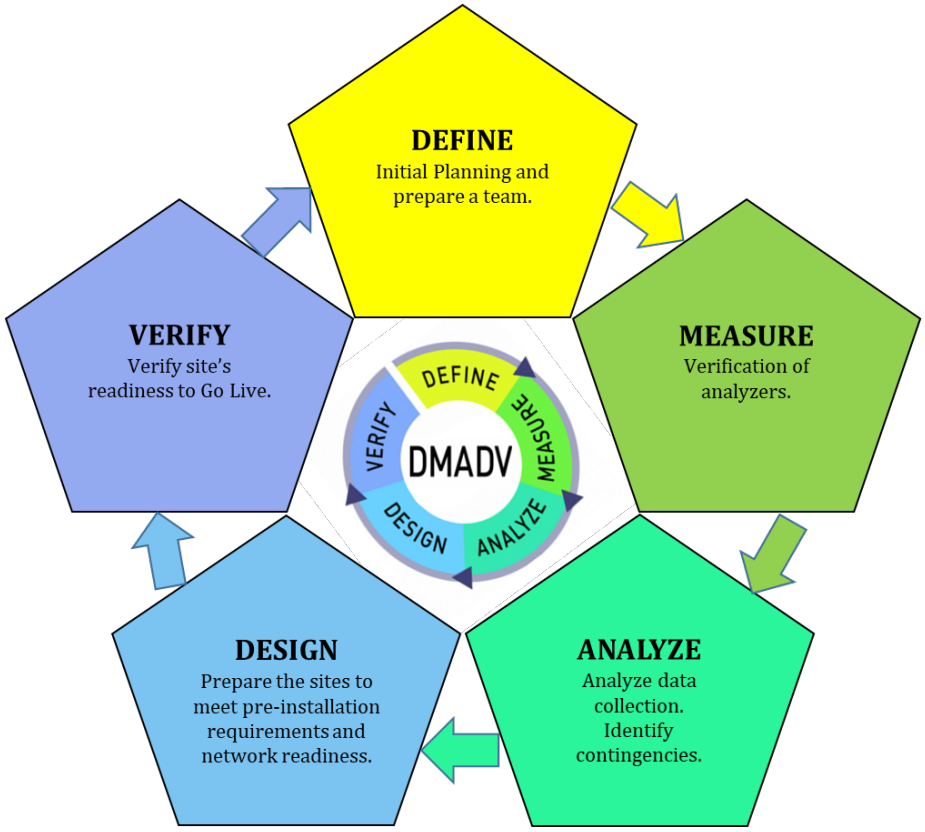
The Lean Six Sigma is a quality improvement methodology designed to systematically reduce defects and minimize variation in processes. Originally developed for the automotive and manufacturing industries, it's application in healthcare is relatively recent but increasingly impactful [7]. Today, Lean Six Sigma has established a strong presence in healthcare systems, driving operational excellence across various domains. Recent literature underscores its effectiveness in addressing operational challenges in emergency departments, cardiology, surgery, intensive care units, pediatrics, pharmacy, radiology, and laboratory services [6 – 11]. In addition to the standard DMADV framework, we employed another Lean Six Sigma tool; the Rapid Process Improvement Workshop (RPIW), to establish a strong foundation for our POCT program [12].

Description of sigma tools

Pentagon Model of DMADV

Each project plan was broadly based on pentagon model, DMADV, a Lean Six Sigma planning strategy for smooth execution of project activities. Each phase describes the activities involved as shown in Figure 1 below. "Pentagon model" term has been used by us for the first time due to the design of this framework.

Figure 1: A Pentagon model of DMADV process of NL-POCT program.



Description of Rapid Process Improvement Workshop (RPIW) Sigma tool

A RPIW is a Lean Six Sigma tool designed to assess and improve utilization management and existing workflows before launching a new program. It begins with the collection of baseline data on current practices, followed by a focused five-day workshop involving key stakeholders. During the workshop, participants collaboratively analyze current processes, identify inefficiencies, and develop a future-state model along with a detailed action plan that includes measurable outcomes and evaluation strategies [12-14]. Key activities in this framework include pre-workshop planning, data collection, project charter development, volunteer or team member selection, defect identification, and iterative planning to remove process inefficiencies (Muda) [14]. Typically, a 6–10 weeks pre-work phase precedes the workshop to define waste and establish improvement goals. On Day 1, participants receive RPIW training and review collected data. Day 2 involves process mapping (current and future state), gap analysis, and identification of challenges. The remaining days are used for action planning, implementation trials, and evaluation, guided by the Plan-Do-Study-Act (PDSA) cycle [15]. Follow-up assessments are conducted at 30, 60, and 90 days to monitor and sustain progress. The U.S. Veterans Health Administration (VHA) used RPIW to implement its eScreening program, a mobile, automated health screening platform for veterans [12].

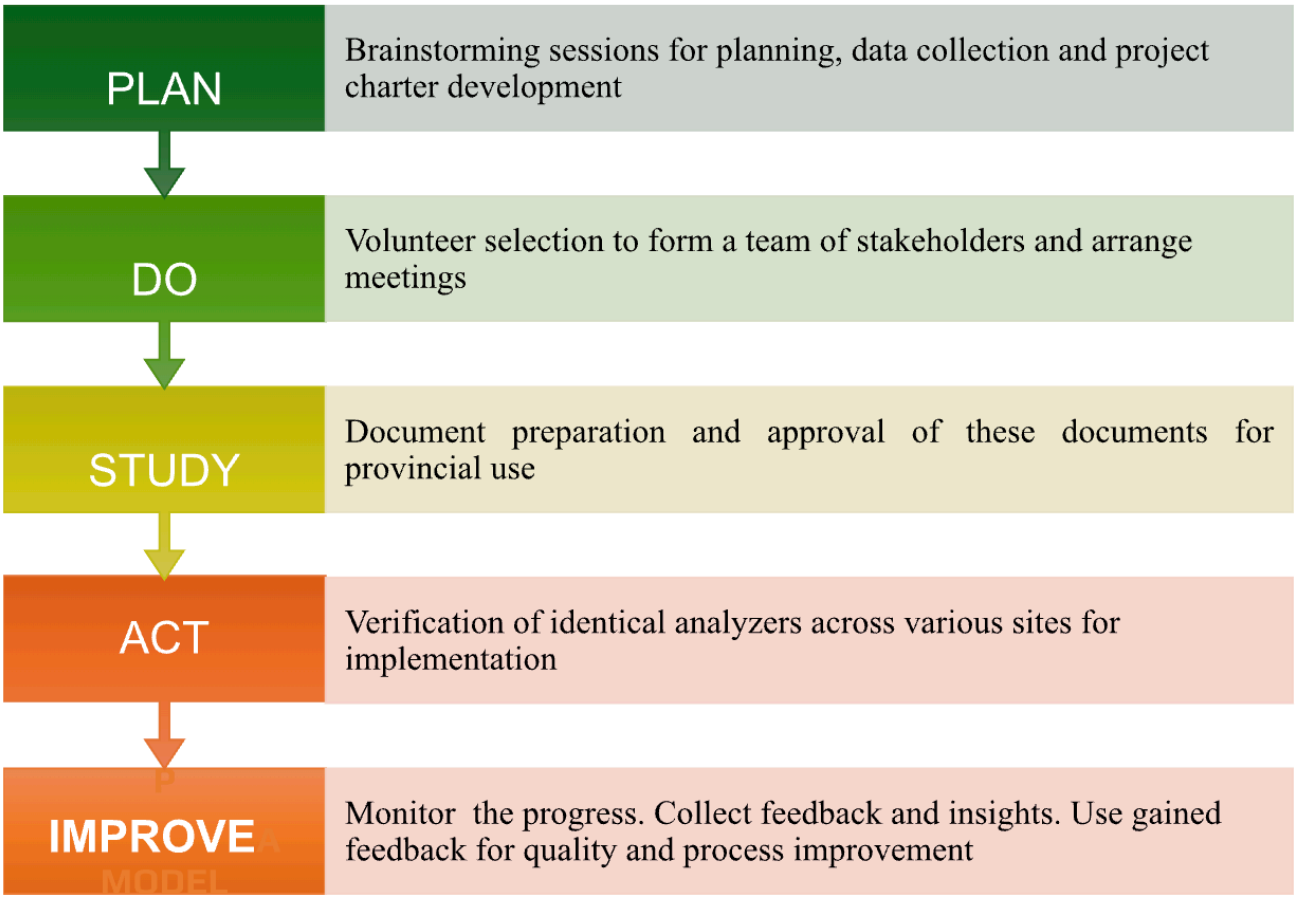
Development of RPIW framework for NLHS-POCT

A typical RPIW plan was framed for developing our process. The Eastern Urban zone POCT center at St Clare's Mercy Hospital (SCH) served as the primary referral center supporting multiple POCT sites (n=23) across the province. Project initiation and implementation within the division closely followed the RPIW framework to ensure structured and effective execution. Project charter was developed and signed. The POCT team was constituted which includes committed members who volunteered for various project assignments, contributing to collaborative progress. This initiative was strongly supported by the Medical Scientific leadership, including the Division Head of POCT and the Clinical Chief of the Pathology and Laboratory Medicine Program, who actively oversaw and guided project milestones. Regular team meetings were held to develop and refine strategies aimed at implementing a streamlined and standardized verification process across all provincial POCT sites.

PDSAI structure to portray RPIW

The utilization improvement plan, a typical PDSAI (Plan, Do, Study, Act and Improve) framework, was structured into five key steps as illustrated in Figure 2. We added an "Improve" step in typical PDSA framework to make this model more efficient for monitoring quality improvement.

Figure 2: A typical PDSAI model to mirror the RPIW plan for developing NLHS-POCT program.



A detailed description of PDSAI framework is given below.

1. **Initial Brainstorming Sessions (P):** Collaborative meetings were held with provincial POCT staff, the IT team, quality assurance personnel, and other relevant stakeholders to establish a unified direction. Project charter was developed and signed.
2. **Requirement Identification and Task Delegation (D):** The team identified the verification requirements for each POCT instrument and outlined the steps necessary for deployment. Specific responsibilities were assigned to team members, each with a defined timeline for completion.
3. **Document Preparation and Approval (S):** Essential documentation was prepared, including the new equipment accession form, equipment transfer policy, pre-move checklist, master inventory list, verification protocols, and standard operating procedures (SOPs). These documents were studied, reviewed and approved by designated signatories prior to implementation.
4. **Verification Phases (A):** Primary verification was conducted by the POCT team at central sites such as St. Clare's Mercy Hospital (SCH) or the Health Sciences Centre (HSC) St. John's. Secondary verification was carried out at the final site of installation and were compared with site specific analysers before the device's approval for clinical use.
5. **Continuous Improvement (I):** Feedback and insights gained for the implementation process were used to generate ideas for quality and process improvement. These adaptations ensured the model remains responsive and effective throughout the project lifecycle.

Project Model of NLHS-POCT Program

A project charter was developed to guide all provincial POCT analyzer installations, accompanied by a Gantt chart outlining the overall process plan and implementation timeline. Regular scheduled meetings were conducted to monitor progress and ensure timely execution of each project phase. Analysers were deployed to designated sites either in acute care and community hospitals or at remote standalone POCT sites. These instruments were introduced either as replacements for outdated equipment as the backup for main Chemistry analysers or as new additions to expand the POCT services. In adherence to Good Laboratory Practices (GLP), all necessary documentation was meticulously completed for each installation. This included the master inventory list, equipment accession forms,

equipment transfer policy, pre-move checklist, SOPs and quick reference guide. Each analyzer was assigned a unique PEUIN to facilitate standardized tracking and management.
Initially, installations of analysers took place within laboratory settings and were operated by laboratory technologists until the program matured into a fully integrated point-of-care model.

Provincial Equipment Unique Identification Number (PEUIN)
Each newly installed analyzer was assigned a unique PEUIN in addition to the existing inventory asset number generated by the Biomedical Engineering Department of each health zone. The PEUIN was developed specifically for the standardized identification, verification, and inventory management of POCT equipment across the province. This helped in timely identification of sites and type of equipment if any failure or interruption in services occurred.
The PEUIN was systematically structured using the following format:

- The first three letters of the site name (e.g., SCH for St. Clare's Mercy Hospital)
- The division code (POC for Point of Care)
- The analyzer trade name or model (e.g., ABL)
- A sequential number (e.g., 1, 2, 3…)
- The two-letter code for the device type (e.g., BG for Blood Gas Analyzer)

For example: SCH-POC-ABL1BG represents the first ABL blood gas analyzer installed at St. Clare's Mercy Hospital within the POCT division. This unique identifier (PEUIN) was incorporated into the verification protocol for each instrument to ensure proper alignment between the analyzer and its corresponding documentation. It served as an additional reference point, complementing the quality division's protocol numbering system.
A Provincial POCT Equipment Master Inventory List was prepared and regularly updated by the Eastern Zone POCT Coordinator. This centralized inventory included comprehensive details for all POCT equipment installations across the province, supporting ongoing standardization and quality assurance efforts.

Documentation
Accession form and Pre-Move Check List
The Accession form and Pre-Move Check List were completed if analysers were shipped from Eastern-Urban zone to other zones, and records were maintained by POCT coordinator.

Equipment Transfer policy
A robust policy was developed to align with the equipment shipment from one site to another including indemnity clause for vendors to bear the losses if there is any damage to the equipment during shipment of analysers.

Verification Protocol
Protocols for Primary device verification and secondary verification were prepared and signed off before starting verification processes.

Standard Operating Procedure and Quick Reference Document
These documents were prepared, reviewed and signed off before the placement of equipment at the final site.

Verification of analysers
Verification of these devices was completed in two phases.

Primary Verification
Operator training was conducted for all team members involved in the primary verification process. A comprehensive primary verification protocol was developed to guide the procedure. Two reference analysers were selected for in-depth validation at the primary verification site at SCH. The lab-based analysers, already in use at the site, were designated as the reference instrument for comparison. The primary verification process included a series of critical performance evaluations such as:

- Precision (Repeatability and Reproducibility)
- Linearity or accuracy studies
- Clinical correlation or method comparison
- Reference range verification, including pediatric populations
- Interference studies, wherever applicable

Once the analysers demonstrated acceptable performance, these were designated as the reference analysers for all subsequent secondary verification procedures conducted at the final installation sites e.g. Piccolo Chemistry analysers at 23 remotes sites were compared with primary validated Piccolo analyzer installed at St Clare's Mercy Hospital, the primary site of verification. Alternatively, if specific site was previously equipped with any other lab-based analyzer, then the oncoming device was compared with that site specific device e.g. Coaguchek devices were compared to site specific coagulation analysers for PT-INR testing. Process adjustments were made as necessary depending on the instrument model and sample type requirements, ensuring flexibility while maintaining scientific rigor.

Secondary verification Phase
Instruments were shipped to final sites. Operator's training was provided. Secondary verification studies were designed according to the site and analyzer requirement. Reproducibility was checked for all analysers and accuracy of these secondary devices was tested either using linearity material or clinical samples. Analysers were put into use once verification was accepted.

Connectivity
The implementation of POCT technologies included connectivity solutions that standardize data management (e.g.

through common middleware) across all provincial sites of NL to reduce the costs of infrastructure, upgrades, and ongoing operational expenses.

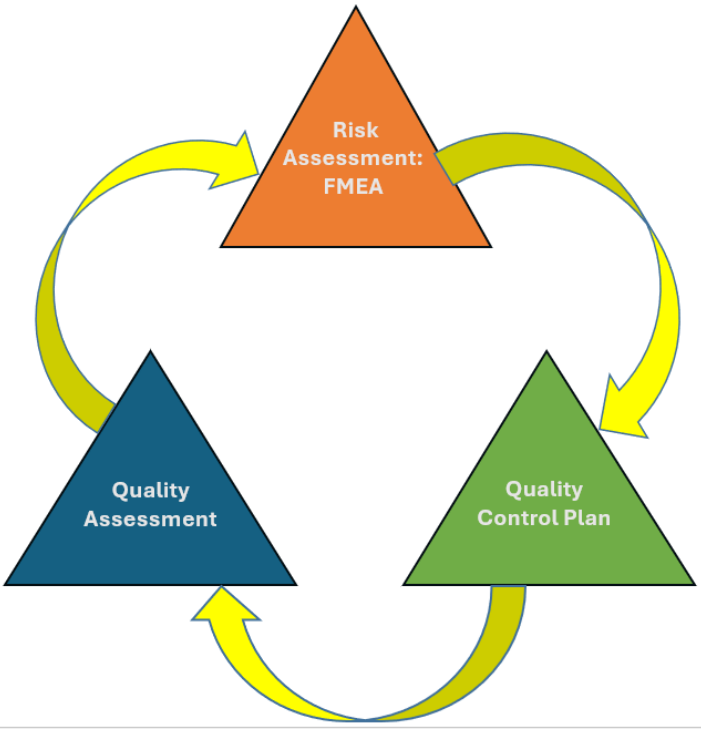
Electronic Tracking of Inventory of reagents and equipment
Due to nonavailability of centralized electronic tracking system for POCT reagent and equipment, tracking of calibrators, validated reagent lot numbers, cartridges and control material was done through shared Microsoft excel folder and information regarding availability of validated stock was transferred to the provincial users through a common group email. Master Inventory List was saved on this shared folder, and access was provided to all authorized users. Shared database and common email are helpful to track lot numbers of validated POCT reagents, calibrators, cartridges and controls and reduce the cost of validating same lot number of reagents multiple times and at multiple locations.

Instrument connectivity for patient result tracking
POCT results were electronically transmitted to the medical record to improve data quality and to support safe patient care. It is important that POCT results were reported in a manner which clearly distinguishes them from tests done using traditional central laboratory equipment e.g. prefix POC was added with name of each test for easy differentiation. Instruments are currently connected to the hospital information system network of EPIC. The EPIC system is connected to Navify, the POCT middleware.

Developing the IQCP for NLHS-POCT program
The Individualized Quality Control Plan (IQCP) is an inherent part of the quality improvement initiative. The traditional quality control (QC) processes have largely been replaced by IQCP [16]. CLSI in its recent guideline EP-23 A, advocated inclusion of individualized quality control plan [17]. According to this guideline, IQCP processes should be divided into 3 phases: pre-analytical, analytical and post-analytical. Each phase should contain appropriate control processes at the points where there is a possibility of error, to either prevent or monitor them and to take corrective action.
Keeping these requirements in view, we developed individualized plan for our POCT program where 3 key steps of IQCP were included (Figure 3).

1. **Risk assessment:** Risk assessment using failure mode and effects analysis (FMEA) tool was used to identify weaknesses of quality assurance process of every phase and plan mitigation.
2. **Quality Control Plan:** The plan was prepared to identify the processes where there was a maximum possibility of committing errors e.g. in analytical phase.
3. **Quality Assessment:** The monitoring of the IQCP included performance of testing personnel, testing environment, specimens, reagents, and test system [18].

Figure 3: Individualized Quality Control Plan for NLHS-POCT program.



IQCP for NLHS POCT Program

IQCP included following key points:

1. It was important to understand all aspects related to development of procedure, policy, procurement, accreditation, evaluation and validation, personnel education and training, quality assurance, and utilization management of POCT technologies.
2. The program collaborates with other provincial Pathology and Laboratory Medicine divisions for implementing and maintaining POCT service delivery models. We used cutting edge POCT technologies across all hospitals, long term care, and rural health facilities.
3. The multidisciplinary committee, named "POCT advisory council" was established mainly to authorize and approve implementation of POC tests across the province. Members of committee are from various disciplines of NLHS and carry expertise in their field. Selection of tests are done through voting on application submitted by clinical program. Members vote in favor or against, largely depends on appropriate requirements of clinical program, quality of the tests, competency and commitment of users to follow policies and maintain quality management system set up by the program.
4. The Division developed standardized policies, procedures, quality assurance protocols, and processes for the province and ensured that appropriate information is collected to assess the clinical justification, desired patient outcomes, financial impacts, infrastructure support and educational/ competency requirements of the specific point of care test.
5. Risk assessment for each project implementation was done by members of quality division. Risk assessment was carried out using FMEA technique to calculate the high-risk priority number of each process and analyze improvement strategy for weak processes.
6. It is mandatory for each POCT operator to comply with established policies and procedures regarding appropriate sample collection, quality control and reagent checks, basic maintenance (if applicable) and cleaning protocols for equipment, test performance, reporting, follow-up of all critical results, documentation and performance of proficiency testing. These professionals must perform POCT only after getting trained, and completion of subsequent recertification at prescribed intervals.
7. Only certified users who demonstrated competence in specimen collection and performing a specific POC test were permitted to operate the devices and report the results.
8. Appropriate internal QC, electronic QC or external QC procedures were designed.
9. Related proficiency test scheme was selected for each test. If appropriate commercial proficiency test scheme was not available, then alternate methods like inter-lab comparison or split sampling procedures were introduced.

Setting up internal quality control frequency

A designated QC procedure was developed for each POCT analyzer. The QC frequency for each system was developed based on recommendations given by Norwegian Quality Improvement of Laboratory Examination (NOKLUS) QC scoring system for POC tests as depicted in figure 4 [19]. POC analysers were of different types e.g. multi-test cartridge, single strip test, bench top analyzer etc.

The Scoring System

QC was used each time if

a) A new batch of reagent or test was used,

b) After unexpected test results, and

c) After maintenance and instrument repair.

In addition to this mandatory QC performance, the frequency of QC was established based on a scoring system.

The general principle of the scoring system was to mitigate any high risk of harm to the patients; therefore, QC was performed at an appropriate frequency.

Frequency Calculation

For each POCT device, factors A, B, and C were given points as depicted in scheme (Figure 4) to calculate the total score by adding each individual factor score. The total score determines QC frequency for each POC test. For example, if for ALT, total score (A+B+C) is between 7 - 9, then QC frequency should be weekly.

In addition to this score, frequency is tweaked depending on the number of patient samples analyzed over a specific period (Factor D). We adopted this scoring system to decide performance of QC at various intervals for each point of care device (19).

Scoring was given as below:

Analyte Score: was given based on the risk of harm caused to the patient if any error occurred. There were two categories:

Moderate risk: 2

High risk: 4

Device Score: Device score was given depending on multiple types of POC device which could be scored as follows:

Strip test: 1

Strip test with automated readers like Glucometer: 2

Single Cartridge based analyzer: 3

Small Bench top models like blood cell counter: 4

Ease of Use: User Friendliness of a device was scored as follows

Easy: 1

Moderate: 2

Difficult A1C reader: 3

Blood cell counter: 4

Changes in QC frequency depending on the work volume: number of samples tested over a specific time.

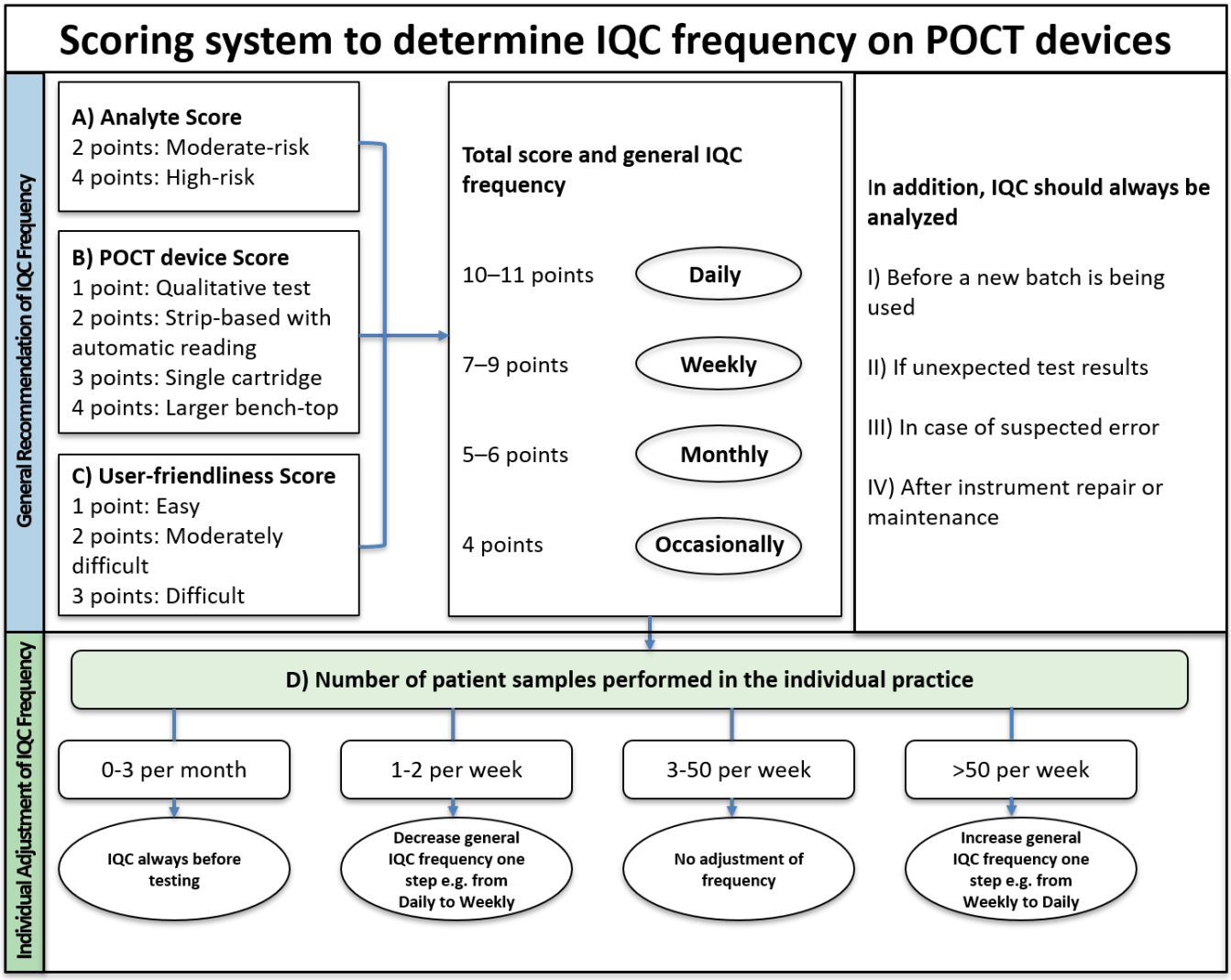
If total score was between

- 11 points; QC was performed daily, every day that the test was in use

- 9 points; QC should be performed weekly
- 6 points; QC should be performed Monthly
- 4 points; QC should be performed occasionally

Depending on the work volume, this frequency was modified (Figure 4).

Figure 4: Quality control frequency for all Point of Care devices was developed based on NOKLUS recommendation of Daily Quality Control Frequency scoring scheme. (Reused with permission from authors and journal editors, Gidske G, Sandberg S, Fossum AL, et al. Point-of-care testing in primary healthcare: a scoring system to determine the frequency of performing internal quality control. Clin Chem Lab Med. 2022; 60(5):740-747 [19]).



Program effectiveness evaluation

Utilization management and cost effectiveness

Utilization management interventions to evaluate the medical necessity, efficiency, and appropriateness of usage of POCT is an important step towards increasing work efficiency and cost effectivity. Scope of POCT is expanding beyond the clinics today. Tests are being carried out deep in sea and at the heights of Mount Everest [20]. Usage of POCT especially by non-laboratory users outside the central laboratory, in acute care settings, physician's offices, pharmacies, ambulances, and outpatient clinics presents a unique challenge for any POCT program to assess the utilization [21].

Currently, there are no established structured processes that will routinely monitor and manage utilization of POCT within our health system i.e. Newfoundland and Labrador health services. The preparation of structured utilization monitoring tools to assess financial implications and cost effectiveness is under development. To develop a map of cost effectiveness for our program, intervention techniques like prior authorization, concurrent review, control costs, ensured quality care, audit and manage resource utilization need to be included [22]. These techniques will act as a bridge between users and the providers. We expect that the developed metrics will be helpful in analyzing the cost effectiveness of the project against rising cost, inflation, supply chain bottlenecks, overutilization and underutilization of tests due to poor understanding of caregivers.

Developing structured metrics for any program beyond laboratory is a daunting task. The biggest challenge is to enforce accountability for users who are repeated offenders for overutilizing or underutilizing POCT resources to obtain quick patient results. The users are in large number and have different qualifications and skillsets. Each user works for a different clinical program and reaching out to them individually is impossible hence we have developed a standardized process of sending out memos and opted to include updated information on the intranet and pulse web. However, surprisingly not many users spend time reading the required essential information on these platforms.

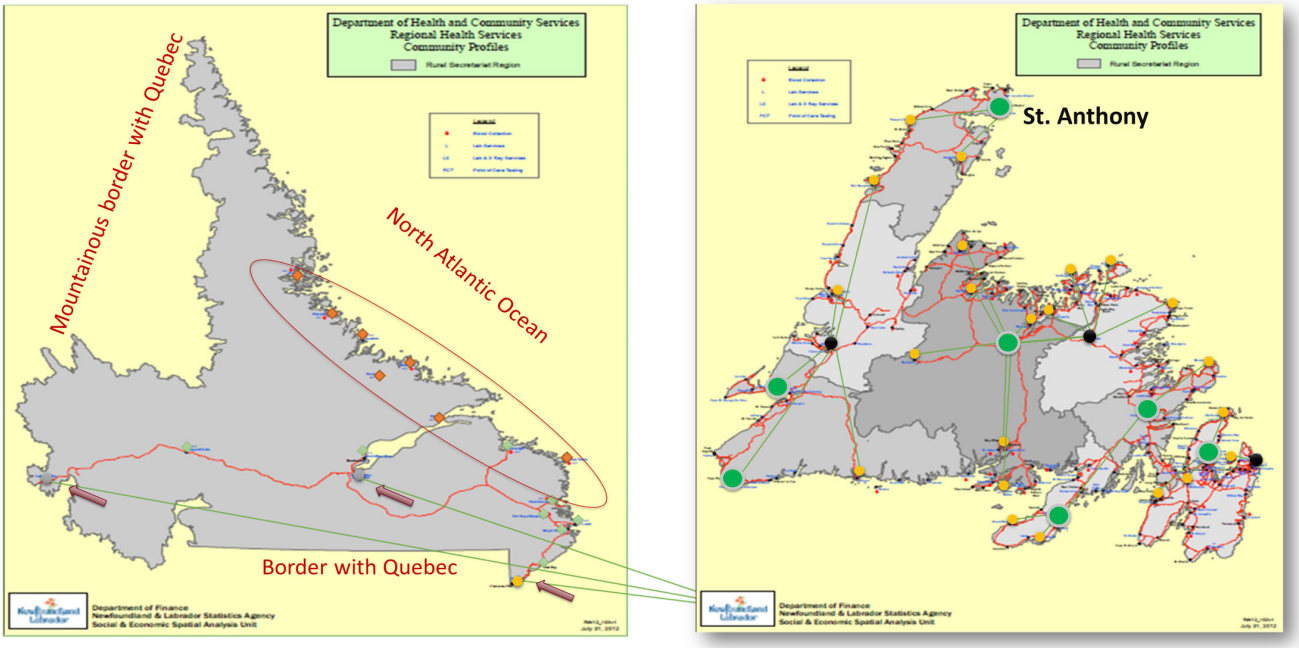
Audit is an integral part of a healthcare system to monitor utilization of resources. Auditing any hospital unit, to reduce the overutilization involves systematic approach of reviewing test orders against clinical necessity, focusing on reducing unnecessary, repetitive, or low-value testing, which is estimated to account for 20% to 40% of laboratory tests [23]. Use of evidence-based clinical guidelines is a helpful tool in determining if multiple and repeated test requests are necessary for clinical interpretation and diagnosis of diseases or not. The audits are planned to be carried out by some authorized and certified auditors working within NLHS. Quality Officers and Operation Managers having provincial POCT responsibilities will be designated with the jobs of reviewing and auditing POCT utilization on a regular basis. Utilization audits will be conducted at defined intervals to assess the cost efficiency of the program.

Effectiveness and sustainability of any healthcare project is primarily affected by the increasing financial burden. Overutilization or underutilization greatly affects expenditure. The cost of consumables (test kits, QC materials, etc.) is significantly higher for POC tests compared to traditional laboratory tests [24]. Simeon et al. [24] also reported that costs per POC test vary substantially, depending on the number of tests performed on an instrument.

Removing inefficiencies and equipment sharing between clinics appears to help decrease costs in smaller and more remote clinics. These clinics are unable to absorb the costs of equipment individually.

There is an additional cost of transportation of samples from remote clinics to centralized labs. NLHS POCT program covers a vast majority of remote locations separated from one another by a greater distance (Figure 5) with no immediate laboratory support, therefore, assessment of factors responsible for sustainability of these remote POCT sites becomes mandatory. Simeon et al did not evaluate costs related to increasing distance from centralized laboratories which include an important cost factor of transportation of samples from remote clinics to lab [24].

Figure 5: Location of POCT and laboratory sites operated by Newfoundland and Labrador Health Services. Yellow Circles: Location of small community health centers transitioned to become POCT sites. Orange Circles: Isolated coastal community sites changed to POCT. Green and Grey Circles: Larger community hospitals with limited-service in-house laboratories. Black Circles: Indicate sites with larger full service (Pathology, Microbiology, Clinical Chemistry, and Hematology) laboratories.



Another important aspect of cost saving is to choose the tests wisely and appropriate to the clinical need to reduce burden on any healthcare program. Our recent article on "Choosing Wisely Canada for POCT" describes recommendations on choosing wisely using POCT in Acute care settings. This guidance document is a useful tool for POCT users working in emergency and acute care hospitals for improved patient care through strong diagnostic integrity, augmented safeguards to patients, and optimization of related healthcare resources [25].

Key Performance Indicators or Quality Indicators

Our POCT program is still emerging. Quality improvement processes are continually assessed for their effectiveness through the key performance indicators or quality indicators. These quality indicators help in improving the processes. These are designed to identify the criteria to monitor, measure and analyze the processes [26]. NLHS POCT program has established a strong provincial quality indicator special interest group named as "Newfoundland & Labrador Quality Indicator Interest Group (NLPQIIG)". Function of this group is to develop standardized provincial POCT QIs. The group, which is chaired by Medical Scientific Lead for POCT, includes all key staff members of POC and quality division. The group holds monthly brainstorming meetings and is working towards developing quality indicators to standardize the processes across 23 POCT sites.

Two most effective quality indicators have been selected and implemented to monitor CQI and CPI. Choice of these two indicators aligns with recommendations given by our Canadian POCT QI special interest group of CSCC, which is coauthored by lead author of this manuscript [27]. These indicators are,

1. Percentage of invalid patient identification or generic ID use for performing tests on glucose meters

and

2. Critical glucose results follow up.

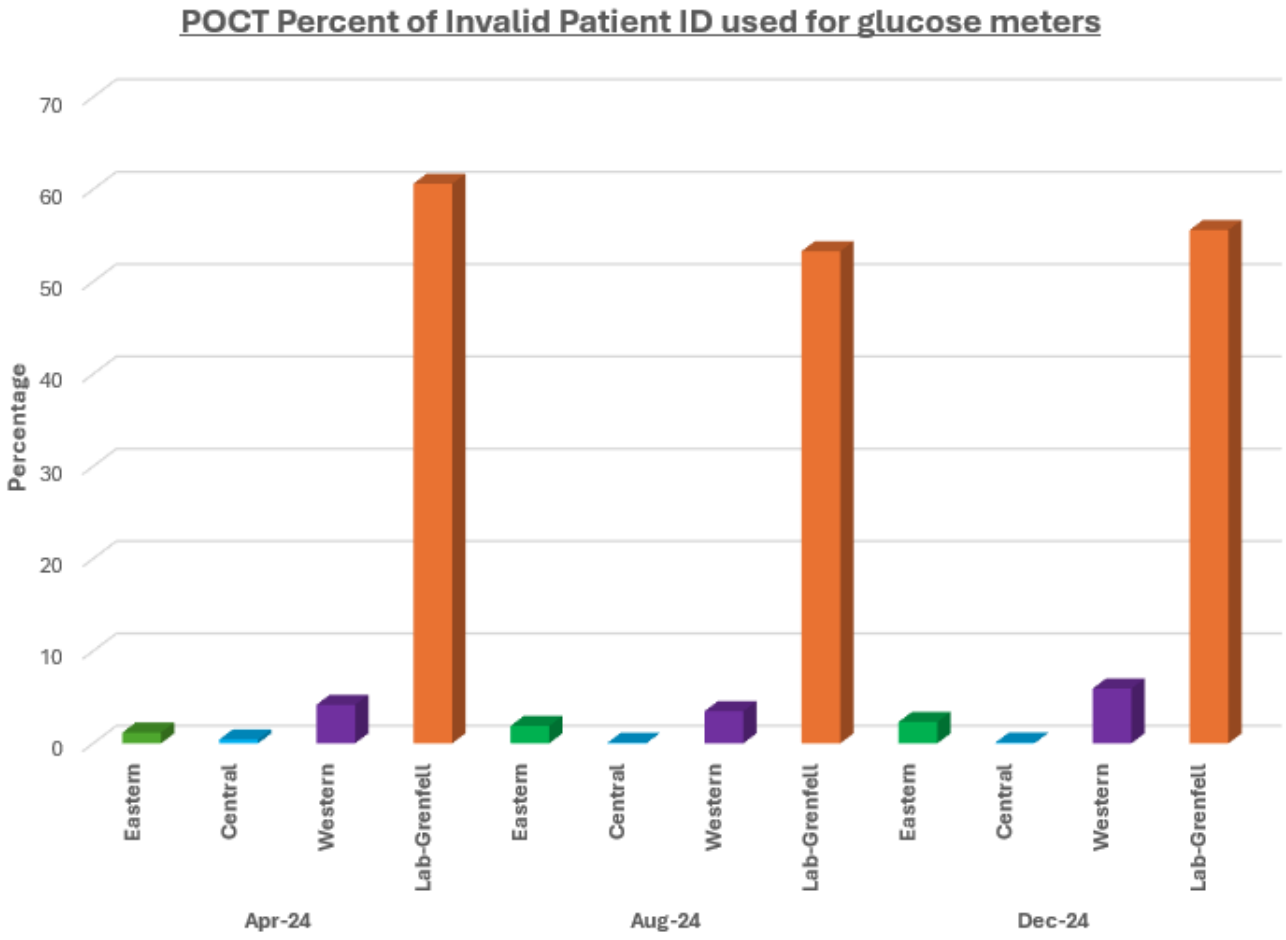
The standardization of process of quality indicator data collection across our program, including 23 sites is in initial stages. Implementation of one process across these many sites is difficult due to several factors like limited available resources, staffing challenges, different information system across all zones (Meditech) which has recently been replaced by new EPIC system, multiple certified glucometer users, and different laboratory levels of their competency and commitment towards following recommended guidelines. Continuous quality and process improvement (CQI and CPI) procedures will be used across the province after full implementation of EPIC hospital information system replacing meditech.

Percentage of invalid patient identification or generic ID use for performing tests on glucose meters

Figure 6 shows comparative data (expressed in percent) for the use of Invalid Patient ID (e.g.999999) for testing glucose on glucose meters across all 4 zones. Data collected is from the three quarters of year 2024. Eastern zone data includes both rural and urban eastern zone sites. The highest use of generic ids was seen in Labrador-Grenfell health zone. The health

zone is catering to multiple remote indigenous communities and has the highest number of isolated remote POCT clinics. These clinics are located at greater distances from major acute care centres and operated by locum nurses and physicians. These staff members are not available for follow up calls to get the valid patient identification number against used generic identification numbers. The users did not complete the required documentation to match the generic ids with actual patient identification numbers.

Figure 6: Percent use of invalid patient ID for glucose meters across four different healthcare zones (Eastern, Central, Western and Labrador-Grenfell), NLHS in 3rd quarter of year 2024. Labrador-Grenfell (Lab-Grenfell) healthcare zone had highest number of invalid or generic id usage for testing patient samples on glucose meters. POC program did not receive completed documentation for actual patient identification number for the generic numbers used (e.g.999999) even after repeated requests. Lowest use was in central healthcare zone.



Critical Glucose Result follow up

"Critical glucose results follow up" is an important quality indicator for POCT. This indicator is focused on reducing patient safety risks. The extremely high (> 25 mmols /L) or very low (<2.5 mmols /L) blood glucose results must be rechecked for confirmation before releasing the results on patient's medical records. Our POCT program has a policy for "Retesting Critical Glucose" results within 10 minutes of first result, either on another POCT meter or by sending a venous blood draw to the central laboratory. The confirmatory patient results must be documented in patient charts. Nonlaboratory users, mainly nurses, are required to complete the task. The process has been developed to reduce the patient risk.

We do not have recent data on this QI from all 4 zones. Only two sites provided us the data on critical glucose retesting which showed 75-80% compliance on policy implementation (data not presented).

It is planned to collect more robust and reliable annual data by the end of April 2027 (post EPIC) from all 4 zones. This data will clarify and effectively assess implementation of Lean processes across NLHS POCT program.

Turn Around Time (TAT)

TAT calculation is not a useful indicator as POCT uses a "test and treat" model and these devices are used only to perform stat and urgent tests. The results obtained from these devices

are auto verified in the EPIC and immediately available for clinical use.
Collection of TAT data for the samples sent from these clinics to hub lab for analysis is not possible as several sites are located as standalone and remote clinics. Transportation of samples from these clinics to hub labs is affected by multiple variables like adverse weather conditions, difficult terrains and accessibility for sample pickups, different transportation modes, bad road conditions, nonavailability of 24/7 transportation as some sites are only connected by sea route.
Quality indicator data collection previously used did not provide any reliable data as these procedures were not uniform and were different for each regional healthcare authority. NLHS was divided into 4 separate healthcare authorities until 2025. These authorities worked as independent entities and had customized processes suitable for them. Challenges were encountered in implementation of uniform procedures of QI data collection due to lack of a single robust hospital information system (Meditech) throughout these 4 authorities. The old Meditech builds were customized as per each authority's requirements. Staff members like POCT coordinators and other quality team members working for these authorities were more focused on collecting QI data only to fulfil the ACD regulatory requirements and to present the data to auditors during annual audits. They did not work towards provincial standardization of QI collection.
There is a great scope post EPIC for implementation of continuous quality and process improvement procedures in future. The standardization will be much easier and robust after full implementation of EPIC Hospital Information System across the province.

Discussion

POCT has emerged a transformative approach in rural and remote healthcare delivery, offering significant advantages over conventional laboratory testing, particularly because it eliminates the need for dedicated laboratory infrastructure. It enhances mobility for both staff and patients, provides portability across remote and community-based locations, and ensures faster turnaround times for diagnostic results. Clinicians desire a rapid, reliable and efficient service delivered at low cost; of these characteristics, timeliness is perhaps the most important. Timeliness remains a critical determinant of clinical utility, as clinicians often prioritize rapid availability of results to guide immediate decision-making. The integration of Lean Six Sigma methodologies into healthcare system has further enhanced operational efficiency across several clinical environments, including emergency departments, cardiology, surgery, intensive care units, pediatrics, pharmacy, radiology, and laboratories [6-10]. The application of these methodologies within POCT program development represents a strategic advancement toward standardized, efficient, and scalable diagnostic services. Over years several regulatory changes have been implemented in the building of POCT devices by diagnostic companies, to ensure compliance with quality assurance processes like the centralized laboratory service. In Canada, all near-patient, In Vitro Diagnostic Devices (IVDDs), including most POCT devices, are classified as Class III and must undergo pre-market evaluation by Health Canada to obtain a Medical Device License [28]. All POCT equipment/ devices require regular quality control testing to be performed at defined intervals to ensure that the results are accurate and reliable and the device's technical performance is within the expected performance checks [29].
More so, POCT represents a "Test and Treat" model, which has successfully been used in Cervical Cancer Prevention Program of Papua New Guinea [5]. This use of Xpert HPV assay on self-collected vaginal specimens with same-day curative cervical ablation had proved best 'Test and Treat' tool for these patients. Any visual inspection of the cervix with acetic acid (VIA) had shown poor performance when used as part of screen and treat strategies for cervical cancer prevention [5].
In our previous review [30], we highlighted the unique leadership and logistical challenges associated with implementing POCT programs across large geographic areas. These difficulties were evident not only in low- and middle-income regions of Africa but also in remote parts of developed countries like Canada. In rural locations of NL, challenges included the lack of trained personnel, limited infrastructure, and poor transportation access, all of which contributed to inefficiencies, increased waste, and delayed test results. To address these challenges, we employed RPIW, a Lean Six Sigma tool, designed to eliminate operational waste, streamline workflows, enhanced team collaboration, standardized procedures, and reduced turnaround times [12-13, 31]. RPIW has been extensively used in several sectors of healthcare system. For instance, RPIW was used to develop and implement a playbook employed for automated patient-facing assessment with efficient collection and communication of patient information in Veteran Health Administration [12]. RPIW has also been used in optimizing hierarchical condition category-risk adjustment factor management in population health [32].
The primary objective of adopting the RPIW framework was to lay the foundation for a strong, standardized POCT program across rural and remote communities in Newfoundland and Labrador. As a foundational step, a multidisciplinary team was assembled to assess and guide the implementation of key Lean Six Sigma components within the provincial POCT initiative. The RPIW model proved adaptable to NL's needs, with structured planning phases allowing diverse stakeholders to align on shared objectives. The initial intensive workshop enabled real-time problem-solving, process mapping, and future-state modeling, ensuring that waste (Muda) was minimized and workflows streamlined. This structured approach provided a repeatable model for future initiatives within the POCT division and potentially other laboratory units. The creation of standardized documentation, particularly

the PEUIN system, brought much-needed transparency and traceability to analyzer installations. This supported improved regulatory compliance and audit readiness, while facilitating centralized inventory control. The use of unique identifiers, in conjunction with verification protocols, allows clear documentation alignment and performance tracking, mitigating risks related to manual data entry and fragmented tracking systems.

The two-phase verification process adopted in this program represents a robust approach ensuring high analytical integrity. Conducting primary verification centrally, allowed for thorough analytical assessments using reference instruments, while secondary verification at local sites ensured reproducibility in real-world conditions. This dual-step model enhanced the reliability and comparability of POCT results across sites, contributing to better clinical decision-making.

The incorporation of the IQCP as a core part of the quality framework signified a shift from traditional QC practices to a more risk-based, device-specific approach. This approach is consistent with international models such as the Norwegian Quality Improvement of Laboratory Examination (NOKLUS). The integration of a scoring system based on NOKLUS recommendations allowed POCT teams to adjust QC frequency dynamically, ensuring appropriate balance between patient safety and operational efficiency [19]. This system emphasized patient-centered care by recognizing higher-risk analytes and devices and ensuring more frequent QC as needed. For example, analysers used for high-risk tests such as blood gases or glucose in critical care settings received daily QC, whereas low-risk tests on stable populations could be monitored less frequently without compromising safety. For almost two and half decades, NOKLUS had focused on POCT in primary healthcare laboratories. The NOKLUS quality system used different tools to obtain harmonization and improvement like external quality assessment for the pre-examination, examination and post examination phase to monitor the harmonization process and to identify areas that need improvement and harmonization. This program also included manufacturer-independent evaluations of the analytical quality and user-friendliness of POC instruments. Close interactions and follow-up of the participants through site visits, courses, training and guidance is a part of NOKLUS program [33]. NOKLUS was established in 1992 as the Norwegian Quality Improvement of Primary Care Laboratories, with the purpose of improving analytical quality of the POC laboratory examinations. This is now re-named as Norwegian Quality Improvement of Laboratory Examination and has more than 3100 voluntary participants [34-35].

An earlier review article [31] from our group on setting up the provincial POCT network for rural communities of Newfoundland and Labrador described expected benefits and challenges for setting up this program in remote locations. Another review article from an Australian group has described advantages for setting up POCT program for largely replacing conventional laboratory setup due to large investments and capital funds required [36].These authors described POCT as a beneficial approach over conventional design of laboratory to avoid delays in clinical decision making due to late availability of the results from lab, increased costs for purchase and maintenance of equipment, staff training, connectivity to the laboratory information system (LIS), quality control (QC) and external quality assurance (EQA) procedures, some essential steps needed to fulfil the regulatory compliance requirements of ISO 15189: 2022 [36].

An important aspect of POCT, which has always received very little attention, is utilization management. POCT usage is vulnerable to the same risks for overuse and underuse as other laboratory tests. The cost of consumables (test kits, QC materials, etc.) tend to be significantly higher for POCT compared to traditional laboratory tests. It is a common belief that the cost of point of care tests is significantly higher than the traditional laboratory testing, however, we did not come across any peer reviewed journal article describing the overall cost effectiveness of the POCT over traditional laboratory testing. However, there are a few reports available in the literature evaluating cost effectiveness of different POC tests compared to traditional laboratory settings. The data from a study which was completed in the year 1999 has shown that by replacing central laboratory testing of blood samples both at an accident and emergency (A&E) department and at an intensive therapy unit (ITU) by POCT decreased total hospital cost from £132,630 to £93,050 [37]. El-Osta et al have developed a mathematical model of cost-minimization analysis to investigate the potential cost-saving use of POCT in delivering NHS Health Check in the primary care setting [38]. The National Health Service (NHS) Health Check program is England's national CVD primary prevention program launched by the Department of Health in April 2009 and people aged 40–74 years and free of vascular disease diagnosis were registered for an NHS Health Check. The program used information from the Health Check to calculate a CVD risk score. The score is based on results of blood sugar (glucose or HbA1c) and total cholesterol levels. These samples are tested either by laboratory or POCT equipment. GPs relying on laboratories first schedule phlebotomy tests and afterwards conduct the full NHS Health Check using glucose and cholesterol readings to calculate and communicate CVD risk. Lab based pathways require patients to book several appointments to get their CVD score and complete the NHS Health Check. The NHS Health Check program delivered using POCT equipment obtains immediate total cholesterol and glucose/HbA1c results using blood samples taken from 'finger pricking' patients. The use of POCT facilitates communication of CVD risk scores to patients on a single visit. According to the results of their mathematical model, the cost savings to the NHS associated with POCT were estimated at £29 per 100 patients.

In 2020, Wong et al [39] published a review on health economics of point of care testing worldwide. According to

these investigators, POCT could potentially reduce costs, enhance workflow efficiency and improve patient care by enabling more prompt diagnosis and treatment decisions, cost-saving technology solutions and wireless connectivity. They did find some studies who have reported higher rates for implementation and sustainability of POCT [40]. According to these investigators, POCT design, outcomes and economics are strongly linked to economic status. Ultrasound-based POCT is the most implemented type of POCT in developing countries, while biomarker/lab test-based POCT is prevalent in developed countries. Biegler et al have published a report on use of POC system in emergency departments for rapid analysis of blood samples resulting in a substantial saving of $111 per patient, with total savings from Canada of $7,350,000 per year in the health care setting [41].

POCT instruments are used at various locations in hospitals, health care institutions, ambulances, at physician offices, in flights and ships. Providing connectivity for hundreds of POC devices with thousands of users become a difficult task for any provincial program. Network middleware serves as a critical digital bridge between these POC analysers like glucose meters, blood gas analysers, chemistry or CBC analysers and the centralized information systems like the Laboratory Information System (LIS) or Electronic Medical Record (EMR).The use of information systems directly interfaced to the point of care devices through a middleware ensure that results obtained from these analysers are being transmitted without manual interventions. This helps in reducing the transcription error [42].

There are multiple network providers available in the market to make POCT middleware available to the users. These networks are all HL7 compatible which is used for communication between the middleware and the Laboratory Information System, enabling the integration of data from multiple devices into a single Electronic Health Record system [42]

Limitations and future directions

Although the RPIW framework is successfully implemented, certain limitations remain. The full transition to the Employees Participating in Change (EPIC) information system introduced temporary workflow disruptions. Training provided by the EPIC team to POCT staff members is adequate just to introduce the staff to the new system, however, familiarization of users to the new HIS will take months. A robust structured framework to evaluate utilization of POCT and implement uniform processes of pulling key performance indicator data is currently under development. The proposed provincial materials management system for reagent lot tracking represents a significant advancement, its development and adoption is currently in progress. Continuous monitoring, stakeholder engagement, and responsiveness to evolving clinical and technological needs will be essential to sustain the gains achieved through this initiative.

Abbreviations

ACD: Accreditation Canada Diagnostics
ALT: Alanine Transaminase
CBC: Complete Blood Counts
CLSI: Clinical & Laboratory Standards Institute
CPI: Continuous Process Improvement
CQI: Continuous Quality Improvement
CSCC: Canadian Society of Clinical Chemistry
CVD: Cardiovascular Disease
DMADV: Define, Measure, Analyze, Design and Verify
EPIC: Employees Participating in Change
FMEA: Failure Mode and Effects Analysis
GLP: Good Laboratory Practice
GPs: General Physicians
HIS: Hospital Information System
HL7: Health Level 7
H Sc: Health Sciences Centre
HPV: Human Papilloma Virus
Ids: Identification numbers
IQCP: Individualized Quality Control Plan
KPI: Key Performance Indicator
NHS: National Health Service
NLHS: Newfoundland and Labrador Health Services
NLHS-POCT: Newfoundland and Labrador Health Services-Point of Care Testing
NOKLUS: Norwegian Quality Improvement of Laboratory Examinations
PDSAI: Plan, Do, Study, Act and Improve
PEUIN: Provincial Equipment Unique Identification Number
POCT: Point of Care Testing
PT-INR: Prothrombin Time-International Normalized Ratio
QC: Quality Control
QI: Quality Indicator
RPIW: Rapid Process Improvement Workshop
SCH: St. Clare's Mercy Hospital
SOP: Standard Operating Procedure
TAT: Turn Around Time

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