Leading POCT networks: operating POCT programs across multiple sites involving vast geographical areas and rural communities

Edward W. Randell¹,², Vinita Thakur¹,²

¹ Laboratory Medicine, Eastern Health Authority, St. John’s, Newfoundland and Labrador, Canada
² Faculty of Medicine, Memorial University, St. John’s, Newfoundland and Labrador, Canada

ARTICLE INFO

Corresponding author:
Prof. Edward W. Randell
Lab. Medicine, Eastern Health Authority & Faculty of Medicine, Memorial University
Rm 1J442 Laboratory Medicine
Eastern Health
St. John’s, NL
Canada
Phone: 709-777-6375
Fax: 709-777-2442
E-mail: erandell@mun.ca

Key words:
point of care testing, leadership, rural, remote, service delivery model

ARTICLE

Few peer-reviewed publications provide laboratory leaders with useful strategies on which to develop and implement point of care testing (POCT) programs to support delivery of acute care services to remote rural communities, with or without trained laboratory staff on site. This mini review discusses common challenges faced by laboratory leaders poised to implement and operate POCT programs at multiple remote and rural sites. It identifies areas for consideration during the initial program planning phases and provides areas for focus during evaluation and for continued improvement of POCT services at remote locations. Finally, it discusses a potential oversight framework for governance and leadership of multisite POCT programs servicing remote and rural communities.
INTRODUCTION

Providing leadership for Point of Care Testing (POCT) programs across large geographical areas presents unique challenges whether in low and medium income regions of Africa or in remote locations of developed countries such as in some of the Canadian provinces and territories (1,2). There are few published reports in peer reviewed literature that laboratory leaders can draw on when contemplating laboratory service delivery by POCT to remote rural communities. Many published reports in this area focus on the provision of new services to such communities in order to address public health concerns and/or to support the needs of acute care and chronic disease management services not supported by on-site laboratories. Other major areas for focus of POCT research related to service delivery involve delivery of diagnostic testings at facilities that are located in relatively close geographic proximity to centralized clinical laboratories. These studies often compare outcomes and benefits of POCT service delivery models with centralized laboratory services, but yield conflicting results depending on the setting (3). An area left relatively unexplored from a research perspective is the delivery of laboratory services using POCT devices, to replace small on-site clinical laboratories. Many jurisdictions are exploring how POCT technologies can be leveraged to support acute care service needs but as an alternative to maintaining small core laboratories equipped with small to moderately sized autoanalyzers operated by laboratory staff. Potential POCT service delivery models in these instances can involve sole operation of POCT devices by non-laboratory operators or sharing models where both on-site laboratory and non-laboratory staff share use of devices. Drivers for both of these POCT service delivery models arise from difficulties with recruitment of medical laboratory technologists, excessive costs incurred through call-back, and difficulty with sustainability of small laboratories in rural communities from both financial and human resource perspectives. Clinical laboratories in these health centers generally serve small communities, and do not operate twenty-four hours per day, nor on all days. This leaves urgent and emergent testing needs arising during late evenings, nights and weekends to be done by call-back of laboratory staff and/or by arranging urgent transport of samples, or the patient to another center.

BENEFITS AND CHALLENGES

Benefits

For a review on the clinical benefit for POCT overall, the reader is directed to Florkowski et al. (3). Here we focus on use of POCT in remote settings, and Wong et al. (4) has published a recent review of economic and efficacy of POCT in remote settings in Australia. Possibly the greatest amount of published work examining benefits and challenges facing POCT service delivery to such populations were from studies done in Australia, which hosts possibly the largest POCT programs to remote rural communities (5,6). A wide variety of tests are available for use at the point of care and by a variety of different POCT technologies (7). Apart from blood glucose monitoring, some of the long standing POCT programs in rural settings involve testing for HbA1c (8) and urinary albumin testing (9) for chronic disease; cardiac troponin (10,11) and NT-proBNP (12,13,14), basic metabolic panels (11,13,14), blood gases (11,13,14), complete blood counts with differential (15,16), creatinine (8), urine test strips (17), or INR (11,13,14) for acute disease management; and others for infections disease screening and monitoring. These have brought about benefits including decreased mortality for acute coronary syndromes (10,12); improved diagnostic accuracy and patient triage, decreased patient transfers...
to other hospitals, more rapid turn around time, and economic benefits (4,6,13,14,15,16,18); improved antibiotic stewardship (15); and improved availability, assessibility and affordability of health care, especially to patients living in low and middle-income countries (19). Albiet in many of these instances the comparator for benefit was to be remotely available and no on-site laboratory.

**Challenges**

Providing clinical laboratory services by POCT to remote rural communities requires overcoming geographical and infrastructure challenges. Healthcare centers servicing these populations can be hours in travel time from the next laboratory (4). At times, transportation modes can be unreliable because of need to travel over ocean, by air, or over difficult terrain especially during severe weather and adverse climatic conditions. The dependability of the power grid and local infrastructure can be inadequate. Implementing new POCT technologies can present challenges for supply chains to deliver a continued supply of reagents, consumables and quality assurance materials to support services, and laboratory specimens for other tests from rural sites to testing centers outside (20). Providing a robust and safe system, especially if replacing an on-site laboratory, requires due consideration of the costs required to maintain supply chains, for travel and transportation, and for storage of supplies and consumables following delivery and waste disposal after use. These costs depend on the transportation mode used, and how consumables and supplies must be stored to assure stability and for convenient availability, and how wastes will be disposed of. Robust contingency is also required to address unexpected events, infrastructure failure, and equipment malfunction.

Each remote rural location has its unique workplace and community cultures. Furthermore, the burden of chronic and acute disease can be greater in these areas compared with urban areas and vary with ethnicity (4, 21, 22). Adding to this complexity is the more frequent need for patient transport to a larger facility. Such sites are also challenged by high staff turnover (11). Some sites may be more vulnerable to data breach, operate under inferior or inadequate quality standards, or encounter difficulty with integrating new technology (19). Prior to set up, consideration must be given to training systems to build and maintain local testing capacity by preparing on-site POCT operators (11).

Addressing increased staff turnover may require flexible and convenient solutions for ongoing and non-disruptive training of new operators. Consideration must also be given to the hidden burdens and costs of POCT (20, 15) created by how tests are used and reported locally, the distances patients need to travel for testing, the requirements for training and maintenance of competency of POCT operators, and to provide quality management and monitoring in compliance with local regulation and accreditation standards (23). Other burdens include increased workload for clinical staff and especially POCT operators (14), and increased use and possibly misuse of tests (11). Furthermore, there can be lack of trust in results (19); and challenges with quality assurance (15). Trustworthiness and ease of use improve the acceptance of POCT devices by healthcare workers. Consideration must be given to how local testing will be supported for reporting, interpretation of results, troubleshooting, and resolving issues related to quality assurance including identifying who will participate, how samples will be distributed and results reported back, and how corrective actions will take place (11, 23). These can be addressed by developing robust quality management systems to function within the diverse local operational contexts (24). Development of a robust system for management of POCT results
and quality assurance data involves accurate recording and transfer between the testing device and the several different electronic health records and laboratory information systems (25). Information technologies including web-based resources (on the internet or intranets depending on local connectivity challenges) can be applied to providing information on test interpretation and limitations, for tracking and communicating quality assurance activities, and for simple troubleshooting (23). Use of webinars for instruction and telephone hotlines for assistance are other approaches that can be helpful in supporting the needs of remote rural community POCT programs. Utilization management surveillance is an important part of demonstrating financial stewardship for use of testing materials. These challenges highlight the need for comprehensive oversight, a collaborative approach to change management, and implementation of a robust quality management system. A proactive approach is required to identify challenges such that robust solutions are available early.

**MULTI-SITE POCT NETWORKS**

Constructing multi-site networked POCT systems for servicing remote rural communities requires attention to the service delivery challenges outlined above but also through offering an organized framework for leadership and governance (26). Moreover, is the need to bring all components of materials management, human resources, finances, and quality management together with a focus on people and the way people interact with technologies and the supporting infrastructure (20, 27) within local cultural contexts. The main goal for high-quality POCT programs is providing reliable testing information to inform evidence-based decisions and to support improved patient outcomes. Strategic planning towards achieving this end depends on prospective consideration of local factors at each site. This includes taking stock of the specific testing needs of local clinicians, the local environment, including the community and workplace cultures, in which testing will take place; patient triage and treatment processes influenced by laboratory tests; determining the frequency and type of clinical conditions commonly encountered and requiring prompt testing; and evaluating the competency and availability of those performing testing using POCT devices (27). Critical to the sustainability of a multicentre POCT network is the provision of appropriate technologies that are affordable, rapid, and easily used by non-laboratory healthcare professionals (4, 28). Maintaining the safety of POCT programs over networks requires robust quality management systems to support POCT device use. This includes robust routine quality assurance systems including regular internal quality control, external proficiency testing, and where required sporadic comparison against larger reference laboratories associated with the network, and internal audits to confirm compliance with standards and then externally by accreditation agencies. This review process is often conducted centrally.

Some jurisdictions have considered leveraging POCT technologies to address financial and human resource challenges as an alternative service delivery model to small on-site laboratories yet using excess capacity of the broader diagnostic testing network to address other testing needs. An example is the Hub and Spoke network models (29), and with test menus at specific sites determined based on the right test at the right time principle. In other words, developing local POCT testing menus and focusing on tests that provide benefit when results are available early, but leveraging centralized testing at large laboratories to meet other testing needs. In these situations the value of each test is evaluated with the care setting in mind and
considering the overall clinical and operational benefits to be delivered.

Much planning is required to effectively integrate POCT service delivery models into multiple and diverse local settings in a fair, resource-conscious and standardized manner. For example, the Canadian province of Newfoundland and Labrador improved the efficiency and effectiveness of laboratory services delivery to its 23 rural community health centres by establishing a standard test menu after consulting with many rural physician groups (Table 1). This menu addressed urgent testing needs and defined the minimal level of testing that would be available to all, and provide a list of elective tests to address specific local needs. Some of these health centers were located at great distances from larger hospitals that had full service laboratories, and required in excess of two hours of travel by road and/or over open ocean. Consistent with the right test at the right time principle, the rural on-site STAT menu was developed to meet the needs for urgent acute care decision making, while most routine laboratory samples were stabilized for transport and testing at larger full service laboratories. This standardized approach to test menu development but allowing local customization has been safely operating for over 5 years, and the entire test menu can be supported by POCT technologies. It is a false notion that POCT can replace the need for continued investment of resources to developing centralized laboratories (20). In networked systems broader infrastructure at large centers facilitate operation of quality management programs, and other functions for maintaining the system’s integrity. In its second list of essential in vitro diagnostic tests (30), World Health Organization established 46 tests for use in routine patient care and 69 others for

| Category 1 tests                                      | Category 2 tests                        |
|------------------------------------------------------|-----------------------------------------|
| Electrolytes (Sodium, Potassium, Chloride)           | Amylase                                 |
| Creatinine                                           | Blood gases                             |
| Glucose                                              | Urea                                    |
| Cardiac Troponin                                     | PT/INR                                  |
| Urinalysis                                           | D-dimer                                 |
| Pregnancy Screen (urine)                             | Liver tests (Albumin, ALT, ALP, Total Bilirubin) |
| Complete Blood Count with differential               | Ethanol (Breath samples)                |

Test menus were available to rural community health centers provided that STAT turn around time is not provided by a nearby larger site with a central lab; the test ordering frequency justified on-site testing over transport; and there is on-site expertise for specimen collection and interpretations of the test results.

All sites with emergency rooms that were staffed by a physician receive Category 1 test menus. Category 2 tests are allocated based on other conditions being met.
Leading POCT networks: operating POCT programs across multiple sites

Edward W. Randell, Vinita Thakur

Detection, diagnosis and monitoring of specific diseases. These can also be used to inform decisions on local test menu scope to remote rural areas.

Several factors contribute to success of multi-site testing networks involving POCT (31). First is having the support of administrators and decision makers across the network. This requires that the benefits of POCT are understood by all. Secondly is the support from laboratorians within the network. Thirdly is use of a horizontal collaborative approach to developing and maintaining a cooperative network. It is reasonable to expect considerable cultural differences across different health care centers providing POCT. Moreover, meeting the needs of diverse groups requires leaders that are skilled in working collaboratively with individuals from diverse backgrounds. Collaborative leaders establish relationships of mutual trust; gain commitment from network participants by providing a clear rationale and communicating the benefit and vision for the network; maintain transparency in decision making; involve participants of the network, in planning and decision making for the network and thereby establishing the group identity; clearly expresses expectations up front and establishes accountabilities; and provides a clear and fair appeal mechanism for decisions such that individual participant rights are protected (31, 32).

LEADING POCT NETWORKS

A supportive governance structure is important to the success of a POCT network. It requires a leadership team taking a collaborative approach. Kremitske et al. (33) described a system to drive practice improvement and innovation through use of co-led leadership teams. These dedicated teams, led by an operational leader and doctoral director, focuses on the improvement and standardization of practices, working with each site to establish cultures of excellence and collaboration (27, 34), and discovering new ideas and emerging leaders from within the workforce, and by engaging other laboratory professionals system-wide. This best practice team approach helps support a common best practice focused culture. Clinical governance in the POCT network is provided by the doctoral/medical lead who has oversight for continuous improvement of services, improving assessability, making evidence-based clinical decisions, and through fostering local environment where service excellence flourishes and the wellbeing of the patient is protected (35). Key objectives of the leadership team include developing, implementing and promoting POCT policy, standards, training programs, and building and nurturing partnerships with clinicians and other healthcare providers at networked sites. This also includes communicating and coordinating activities across sites, establishing and monitoring outcomes for the network, maintaining multidisciplinary local groups for decision making, and maintaining a robust risk management process for the protection of POCT operators and patients (35).

A common organizational framework for support of POCT services that can be applied across remote and rural laboratory networks is made up of a POCT network leadership team, POCT coordinators, and various POCT committees. Figure 1 shows a possible operational framework. The willingness to work collaboratively with a diverse group of stakeholders is important to the quality and effectiveness of POCT programs. Horton et al. (26), identified 5 stakeholder groups to consider for large laboratory networks. This included laboratory professionals, physicians, policy makers, politicians, and the public. Not to be understated is the importance of serving the interests of the
The POCT Services Advisory Committee is comprised of the POCT leadership team and multidisciplinary stakeholders from different geographical regions. This is the main decision-making body. Regional POCT Operations Teams coordinate routine operation of POCT programs for sites within a region. These teams are comprised of regional POCT coordinators (for quality management oversight and local program coordination), regional laboratory leaders, and other POCT support staff. Rural community health centers are small hospitals with emergency rooms. Regional POCT programs consist of local POCT stakeholders and rural site POCT operators and are assisted by regional POCT operations teams.
patient and the public by open communication and involvement when implementing new service systems (26) and by gauging their satisfaction with the services provided. Furthermore, leaders must demonstrate cultural sensitivity when working across diverse workplace cultures and for building trust. Licher et al. (19) indicated that to improve the acceptability to healthcare workers required that POCT and its related processes be compatible and a good fit for the local setting. Arriving to this point requires collaboration with local stakeholders. Healthcare stakeholders must be trained and familiarized with the interpretation and application of test results, and with limitations of technologies that can restrict the scope for use in patients and for specific clinical indications. It is important that clear information on interpretation and limitations of POCT be presented in written documents to assure roles are established and understood. A clear set of accountabilities should be communicated to participant sites up front, and supported by monitoring to confirm that expectations are met and reported back to participants (27). Furthermore, clear statements concerning courses of action when expectations are not met. There should be regular meetings at a frequency of at least quarterly for sharing of information and group decision making that involve participation by local stakeholders (31). This collaborative interaction can be done through POCT committees (11). (Figure 1)

EVALUATION AND PROCESS IMPROVEMENT

The widely accepted Donabedian model for quality in health care involves sub-grouping under areas of structure, process, and outcomes (36). This model extends quality focus beyond process to more subtle components of the interplay between structure, process, and outcome. The Donabedian model called on the consideration of ethical dimensions of participants in quality systems, was rooted in compassion, and was determined by attitudes to the patient, the profession, and higher spiritual elements, as essential contributors to a quality systems success (37). Structural metrics address how and by whom services are delivered and is covered by certification of individuals, accreditation of organizations, and whether there was adequate supporting infrastructure like special facilities and technologies in place to support service delivery. The contribution of process to quality is rooted in the specific evidence-based activities that occur during service, and these should be linked to an outcome metric, or will otherwise risk unintentional wastage of resources and effort. Outcome is the ultimate measure of healthcare performance and has traditionally focused on mortality and care-related morbidities, but recently expanded to include counts of readmissions, improvements in functional status, degree of improved accessibility, quality of life, and patient satisfaction. Hence, the patient satisfaction survey has become a common means for assessing the outcome of a service and assessing accountability of organizations and programs to the public. However, there is little evidence of an association between high patient satisfaction scores and improved outcomes (38, 39). Patient surveys reflect patient perception about services they receive - this does not necessarily align with appropriate or evidence-based practice.

Establishing a robust system to develop, monitor and manage outcomes requires a clear statement of goals and objectives and then establishing metrics accordingly. Evaluations to support quality management and continuous improvement activities (6, 31, 34) should be system-imbeded as part of a standardized POCT quality management system applied across the testing network. When viewing the
Donabedian model through a contemporary lens at least one area seems unresolved, that is a prospective consideration of the potential for negative impacts (risks) by the system. The organization of a quality management system according to international standards including a risk management framework, carefully monitored, and continuously improving the system helps fill this gap.

CONCLUSIONS

Delivery of high quality and safe POCT programs across vast geographical areas to remote rural settings presents many challenges. Nevertheless, many jurisdictions are considering POCT as part of a more cost-effective service delivery model for servicing such populations. Establishing and maintaining multiple POCT programs in these settings is facilitated by a standardized approach but with customized consideration of each location and then by working collaboratively with local health care workers at each site. Leadership can be provided by a POCT team consisting of operational service leads and clinical doctoral leaders to provide oversight for the programs overall, and as resources for local sites participating in the POCT network. Sensitivity to local cultural norms is important to a collaborative approach by leadership, and to gaining stakeholder trust and support when establishing standardized systems for quality management and operational efficiency.

REFERENCES

1. Mashamba-Thompson, T. P., Sartorius, B., & Drain, P. K. (2018). Operational assessment of point-of-care diagnostics in rural primary healthcare clinics of KwaZulu-Natal, South Africa: a cross-sectional survey. BMC health services research, 18(1), 380-8.

2. James, M. (2008). An analysis of the use of a point-of-care system for international normalized ratio testing in remote areas of Canada: A literature review. Point of Care, 7(1), 34-37.

3. Florkowski, C., Don-Wauchope, A., Gimenez, N., Rodriguez-Capote, K., Wils, J., & Zemlin, A. (2017). Point-of-care testing (POCT) and evidence-based laboratory medicine (EBLM)—does it leverage any advantage in clinical decision making? Critical reviews in clinical laboratory sciences, 54(7-8), 471-494.

4. Wong, H. Y., Marcu, L. G., Bezak, E., & Parange, N. A. (2020). Review of Health Economics of Point-of-Care Testing Worldwide and Its Efficacy of Implementation in the Primary Health Care Setting in Remote Australia. Risk Management and Healthcare Policy, 13, 379-86.

5. Shephard, M. (2013). Point-of-Care Testing in Australia. Point of Care 12.1: 41-45.

6. Dahm, M. R., McCaughey, E., Li, L., Westbrook, J., Mumford, V., Iles-Mann, J., ... & Georgiou, A. (2017). Point-of-Care Testing Across Rural and Remote Emergency Departments in Australia: Staff Perceptions of Operational Impact. Studies in health technology and informatics, 239, 28.

7. Luppa, P. B., Bietenbeck, A., Beaudoin, C., & Giannetti, A. (2016). Clinically relevant analytical techniques, organizational concepts for application and future perspectives of point-of-care testing. Biotechnology Advances, 34(7-8), 139-160.

8. Malcolm, S., Cadet, J., Crompton, L., & DeGennaro, V. (2019). A model for point of care testing for non-communicable disease diagnosis in resource-limited countries. Global health, epidemiology and genomics, 4.

9. Shephard, M. D. S., & Gill, J. P. (2005). An innovative australian point-of-care model for urine albumin: Creatinine ratio testing that supports diabetes management in indigenous medical services and has international application. Annals of Clinical Biochemistry, 42, 208-15.

10. Tirimacco, R., Tideman, P., & Simpson, P. (2009). Design, implementation, and outcomes for point-of-care pathological testing in a cardiac clinical network. Point of Care, 8(2), 56-60.

11. Shephard, M. D., Spaeth, B., Mazzachi, B. C., Auld, M., Schatz, S., Loudon, J., ... & Daniel, V. (2012). Design, implementation and initial assessment of the Northern Territory Point-of-Care Testing Program. Australian Journal of Rural Health, 20(1), 16-21.

12. Tideman, P., Simpson, P., & Tirimacco, R. (2010). Integrating PoCT into clinical care. The Clinical Biochemist Reviews, 31(3), 99-104. PMID: 24150513; PMCID: PMC2924130.

13. Blattner, K., Nixon, G., Dovey, S., Jaye, C., & Wigglesworth, J. (2010). Changes in clinical practice and patient disposition following the introduction of point-of-care testing in a rural hospital. Health Policy, 96(1), 7-12.
14. Blattner, K., Nixon, G., Jaye, C., & Dovey, S. (2010). Introducing point-of-care testing into a rural hospital setting: Thematic analysis of interviews with providers. Journal of primary health care, 2(1), 54-60.

15. Blattner, K., Beazley, C. J., Nixon, G., Herd, G., Wigglesworth, J., & Rogers-Korokehe, M. G. (2019). The impact of the introduction of a point-of-care haematology analyzer in a New Zealand rural hospital with no onsite laboratory. Rural & Remote Health, 19(2).

16. Spaeth, B., Shephard, M., Kokcinar, R., Duckworth, L., & Omond, R. (2019). Impact of point-of-care testing for white blood cell count on triage of patients with infection in the remote Northern Territory of Australia. Pathology, 51(5), 512-517.

17. Chalmers, L., Cross, J., Chu, C. S., Phyto, A. P., Trip, M., Ling, C., ... & Nosten, F. (2015). The role of point-of-care tests in antibiotic stewardship for urinary tract infections in a resource-limited setting on the Thailand–Myanmar border. Tropical Medicine & International Health, 20(10), 1281-1289.

18. Spaeth, B. A., Kaambwa, B., Shephard, M. D., & Omond, R. (2018). Economic evaluation of point-of-care testing in the remote primary health care setting of Australia’s Northern Territory. ClinicoEconomics and Outcomes Research: CEOR, 10, 269.

19. Licher, Y. J. M., Visser, J. S., Van, G. Y., & Diehl, J. C. (2019, July). Formulating Design Recommendations for the Acceptance of the Use and Results of Point-of-Care Testing in Low-and-Middle-Income Countries: A Literature Review. In Proceedings of the Design Society: International Conference on Engineering Design (Vol. 1, No. 1, pp. 2795-2804). Cambridge University Press.

20. Ansumana, R., Bah, F., Biao, K., Harding, D., Jalloh, M. B., Kelly, A. H., ... & Rogers, J. (2020). Building diagnostic systems in Sierra Leone: The role of point-of-care devices in laboratory strengthening. African Journal of Laboratory Medicine, 9(2), 1-5.

21. Couzos, S., & Murray, R. (2008). Aboriginal primary health care: an evidence-based approach. Oxford University Press.

22. Tu, J. V., Chu, A., Maclagan, L., Austin, P. C., Johnston, S., Ko, D. T., ... & Lee, D. S. (2017). Regional variations in ambulatory care and incidence of cardiovascular events. Cmaj, 189(13), E494-E501.

23. St John, A., Tirrimacco, R., Badrick, T., Siew, L., Simpson, P., Cowley, P., ... & Tideman, P. (2015). Internet support for point-of-care testing in primary care. Australian family physician, 44(1/2), 10.

24. St John, A. (2010) The Evidence to Support Point-of-Care Testing.” Clinical Biochemist Reviews 31(3): 111-19. Web.
37. Berwick, D., & Fox, D. M. (2016). “Evaluating the Quality of Medical Care”: Donabedian’s Classic Article 50 Years Later. The Milbank quarterly, 94(2), 237–241.

38. Fenton JJ, Jerant AF, Bertakis KD, Franks P (2012). The cost of satisfaction: a national study of patient satisfaction, health care utilization, expenditures, and mortality. Arch Intern Med. 2012;172(5):405–411

39. Marin, J. R., & Quinonez, R. A. (2019). A (Not So) Perfectly Designed System: The Paradox of Medical Stewardship and Quality Measurement. Hospital pediatrics, 9(1), 64-66.