

ORIGINAL RESEARCH

Factors that may influence the implementation and adoption of point-of-care diagnostic tests to detect antimicrobial resistance in Quebec, Canada – A qualitative study

Armelle Lorcy, PhD¹, Antoine Garnier, MA¹, Ève Dubé, PhD^{1,2*}

¹ Axe Maladies infectieuses et immunitaires, Centre de recherche du CHU de Québec – Université Laval, Québec, Canada

² Département d'anthropologie, Faculté des Sciences sociales, Université Laval, Québec, Canada

*Corresponding author

Ève Dubé

Département d'anthropologie

Faculté des Sciences sociales

Université Laval – Pavillon Charles-De Koninck

1030 Avenue des Sciences Humaines

bureau 3433, Québec (Québec)

G1V 0A6, Canada

Email: eve.dube@ant.ulaval.ca

ABSTRACT

Background: Antimicrobial resistance (AMR) represents a major public health concern worldwide. To effectively combat AMR, the use of point-of-care (POC) diagnostic tests is recommended by the World Health Organization (WHO). In this qualitative study, we investigated the drivers that influence the implementation and adoption of POC diagnostic tests in healthcare settings in Quebec, Canada, to help fight against AMR.

Methods: Interviews were conducted with experts on AMR and/or diagnostic tests at the federal and provincial (Quebec) levels. Applying Greenhalgh and colleagues' non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework as a theoretical basis, we examined the complexities involved in implementing diagnostic innovations aimed at reducing AMR.

Results: A total of 42 participants were interviewed. We identified multiple drivers across the development, assessment and implementation stages of new POC tests: the complexities associated with evolving AMR and POC technology development; issues related to trust in test results; challenges of cost-benefit analyses; considerations regarding user impact; local organizational aspects related to POC tests; the regulatory, political, and economic contexts; and the impact of the COVID-19 pandemic on public health priorities.

Conclusion: The implementation of diagnostic tests that deliver rapid results to inform antibiotic prescription is a priority in Canada and globally. However, our study underscores the complexity and challenges involved in adopting new POC tests. Despite presenting challenges, the COVID-19 pandemic has also facilitated the development and assessment of diagnostic innovation in healthcare settings. Our study further emphasizes the need for AMR to be elevated as a political priority for effective management.

KEYWORDS

Canada, Quebec, antimicrobial resistance, point-of-care diagnostics, implementation, qualitative research

INTRODUCTION

In 2021, the World Health Organization (WHO) declared that “antimicrobial resistance (AMR) is one of the top 10 global public health threats facing humanity” (<https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>). In Canada, AMR resulted in more than 14,000 deaths in 2018, imposing a cost of approximately \$1.4 billion on the healthcare system (CCA, 2019). Health and social services in Canada's federation are primarily under the jurisdiction of provinces

and territories. Specific to AMR, priorities for surveillance and action vary among provinces, and despite the former federal action plan (PHAC, 2015), government policies adopted to combat AMR in Canada between 2008 and 2018 were deemed “inadequate” (Rogers Van Katwyk *et al.*, 2020).

Rapid diagnosis of pathogens to guide treatment and avoid unnecessary antibiotic use is crucial for reducing AMR. WHO, in its Global Action Plan (2015), recommended the development and use of rapid, effective, and accessible diagnostic tools,

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including POC tests, to address the global threat of AMR. POC tests are designed to deliver diagnostic results closer to the bedside, significantly reducing turnaround times compared to traditional microbial culture methods, thus enabling healthcare workers (HCWs) to make timely treatment decisions (Köchling *et al.*, 2018).

Despite their benefits, several authors have highlighted challenges in the implementation and uptake of POC diagnostic tests by HCWs (Engel *et al.*, 2022; Huddy *et al.*, 2016; Kierkegaard *et al.*, 2021; Pandolfo *et al.*, 2021). Our qualitative study aimed to explore the multiple drivers influencing the implementation and adoption of POC diagnostic tests in healthcare settings in Quebec. Rapid diagnosis of pathogens not only informs treatment, but also enhances infection prevention and control (IPC) practices, such as isolation protocols and the use of personal protective equipment.

METHODS

Recruitment

Experts involved in combatting AMR and/or in various stages of POC diagnostic test development or use were invited via email. Participants were primarily identified through an environmental scan of expert committees and governmental groups focused on AMR. Current and past members were contacted using publicly available contact information. Additionally, some participants were identified through previous collaborations with the research team. The snowballing technique, where participants recommend potential recruits from their own networks, was also employed to identify other potential participants (Creswell & Poth, 2018)).

Data collection

Semi-structured interviews were conducted virtually in French or English, based on participants' preferences. The interview guide was tailored to participants' expertise. Key themes and

questions guiding data collection for this study are detailed in Appendix A (see online edition). Out of 75 potential participants invited, 33 declined participation. All interviews were audio recorded and subsequently transcribed for analysis.

Data analysis

The transcribed interviews underwent thematic coding using an inductive approach with Nvivo qualitative analysis software. Following the initial inductive analysis, data were synthesized to produce a coherent multi-level analysis using an adaptation of the non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) framework (Greenhalgh *et al.*, 2017) (Figure 1). Despite limited implementation of POC diagnostic tests in Quebec to address AMR, the NASSS framework remains relevant for evaluating early-stage technology adoption.

As shown in Figure 2, our analysis also incorporated the innovation process framework for health technology in Canada (MacNeil *et al.*, 2019) (Figure b). In Canada, diagnostic tools must undergo certification by Health Canada to meet quality and safety standards before they can be marketed. In Quebec, the implementation and use of diagnostic tests within the healthcare system are overseen by the Quebec Ministry of Health (QMH). Diagnostic tests require both medical and economic assessments to be used in Quebec. To register a new diagnostic test into the Quebecois inventory of medical biology procedures, a request must be submitted by a doctor or a PhD in a laboratory affiliated with a healthcare facility and approved by the QMH.

In Quebec, the implementation and use of POC diagnostic tests in healthcare facilities falls under the jurisdiction of a centralized network of 12 laboratory clusters governed by the QMH. Once registered in the Quebecois inventory, the decision to implement a POC test is made locally. Participants from the Canadian and Quebec governments noted that Health Canada allows the Public Health Laboratory in Quebec

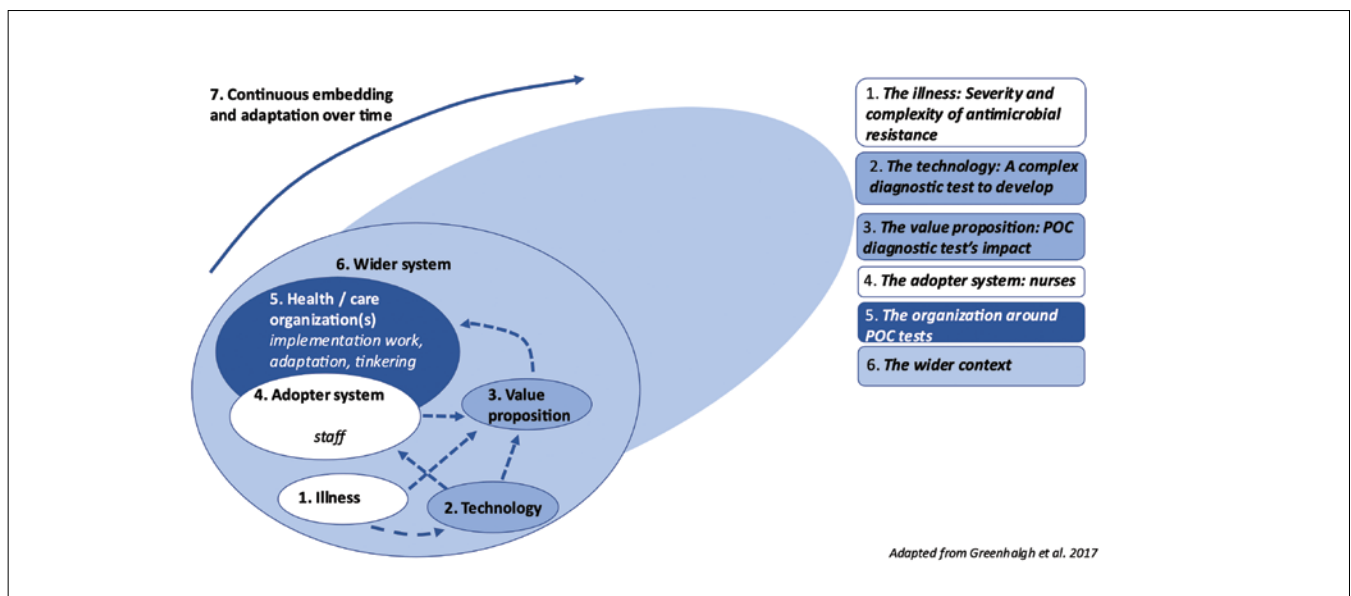


Figure 1: NASSS framework adapted to POC diagnostic tests implementation in Quebec

and university hospital laboratories to develop their own tests (without Health Canada's approval) as long as they are not marketed, and comply with ISO (International Organization for Standardization) standards.

RESULTS

From October 2021 to September 2022, 37 semi-structured interviews were conducted with 42 participants, which included 32 individual interviews, and five interviews with two participants each. The participants were affiliated with various organizations at the federal or provincial (Quebec) level (see Table 1).

IPC: infection prevention and control

Interviews revealed that the implementation of POC diagnostic tests in Canada and Quebec is highly complex, with most participants having only a partial understanding of the full process, which varied according to their professional

responsibilities and experiences. Illustrative quotes for each theme can be found in Appendix B (see online edition).

The illness: Severity and complexity of antimicrobial resistance

Participants regarded AMR as an emergency, but within the context of COVID-19, they described AMR as a "silent pandemic". Most participants identified (multi)resistant, gram-negative bacteria, as one of the most alarming AMR organisms, referring to it as "a nuclear bomb" and "the biggest Canadian problem".

Manufacturers and microbiologists considered AMR as a "complex" issue for four main reasons: it involves a wide range of organisms; the resistance of these organisms' is constantly changing due to new variants and gene mutations; resistance to multiple antibiotics; and, geographical variations across Canada.

The technology: A complex diagnostic test to develop

Given the complexity of AMR, the development of rapid diagnostic tests presents significant challenges. Some

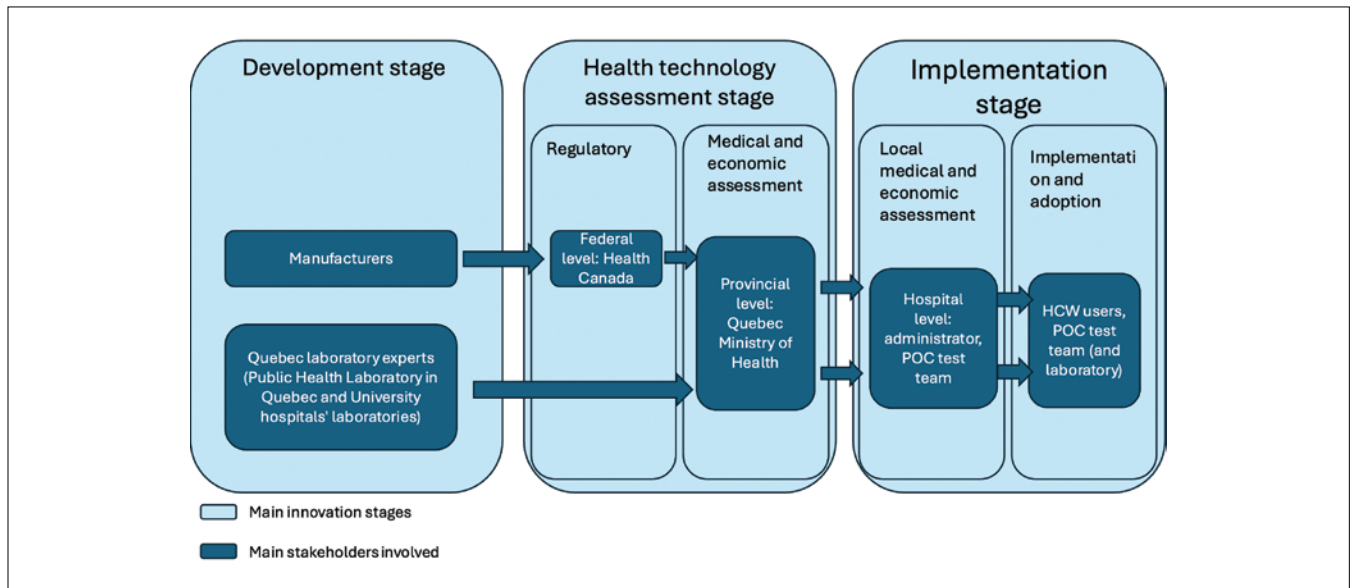


Figure 2: POC diagnostic test innovation process in Canada and Quebec

Professions	Federal government	Federal public organizations	Pharmaceutical companies	Academia and research	Provincial government	Provincial public health institutions	Hospitals	Total by profession
Biochemists					1		1	2
Epidemiologists		2		1		1	1	5
Microbiologists/infectious diseases specialists				1		2	5	8
IPC nurse managers						1	2	3
Pharmacists				1			2	3
Analysts		1					2	1
Laboratory managers						1		3
Directors	4	1	6					11
Managers	1	1	2					4
Advisers			1		1			2
Total by organizations	5	5	9	3	2	5	13	42

microbiologists and manufacturers believe it would be easier to develop a POC diagnostic test for “more stable” organisms, such as those resistant to only one antibiotic. The primary challenge in developing new diagnostic tests lies in identifying the type of resistance and ensuring the test is available before new mutations emerge.

Many laboratory experts emphasized the need for multiparametric molecular diagnostic tests capable of discriminating between different targets, such as viruses and bacteria. They further called for the development of rapid, compact, highly sensitive and highly specific tests to deliver accurate results, and technologies capable of testing large-volume samples. According to these experts, the reliability of POC diagnostic tests is crucial in the context of AMR. They also expressed a desire for POC tests with robust computer connectivity to quickly share results with laboratories, doctors, and electronic patient files, as well as to send early warnings to laboratory managers in the case of technical issues.

All participants agreed that POC diagnostic tests should be user-friendly, featuring simple steps and clear interpretation. Laboratory experts emphasized that users should possess the necessary skills to ensure the quality of results, comparable to those obtained in a laboratory setting.

Some solutions, such as rapid antigen detection tests, were considered less reliable than polymerase chain reaction (PCR) or culture methods. These tests may require confirmation by culture methods or PCR in a laboratory. Due to these reliability issues, HCWs do not always trust every diagnostic test result, which is crucial for influencing antibiotic prescription behaviours.

The value proposition: POC diagnostic test's impact

Most participants considered cost an essential factor, including the cost of the technology, operation, and implementation. Rapid antigen detection tests were generally viewed as less expensive than PCR. For implementation, a diagnostic test must meet a clinical need and be cost-effective.

Participants emphasized the need for a cost-benefit analysis comparing the new POC test with existing tests available on site, including those in laboratories. Various aspects should be considered, such as hospitalization costs and the impact on the patient, HCWs, and their workflow. Many microbiologists raised concerns about the challenges in demonstrating the economic and overall benefits of a POC diagnostic test due to the lack of evidence in the literature and the siloed management of budgets in hospitals.

According to participants working for Quebec public health organizations, assessing the overall costs and benefits of diagnostic tests is challenging for three main reasons: the scarcity of literature on the efficiency of diagnostic tests; the need for recommendations that account for the complexity of local contexts; and, the limited availability of experts to provide guidance. Biochemists and microbiologists highlighted several enabling conditions to

demonstrate benefits, including conducting pilot projects before implementation, and fostering collaboration among hospital services to better understand the broader impact.

The adopter system: nurses

Laboratory and ICP experts recommended nurses as the main POC diagnostic test users for three reasons: to expedite test results and facilitate prompt treatment; nurses already use various tests, such as glucometers, at the bedside; and, collective prescribing could enable nurses to administer the tests. Biochemists added that HCWs with advanced technical skills would be optimal users of POC tests.

However, many participants expressed concerns that nurses may be reluctant to take on new responsibilities amidst work overload and increased stress and fatigue as a result of the pandemic. Some laboratory experts doubted whether HCWs could perform tests and maintain quality control without adequate training. The situation was described as “a cultural misunderstanding” between laboratory and clinical staff, highlighting errors and inaccuracies in tests conducted by clinicians. This raised questions about legal liability in the event of an incorrect diagnosis.

The organization around POC tests

In Quebec, the biochemists interviewed explained that they established a POC test team to oversee the processing, implementation support, training, follow-up, and device maintenance for POC applications. The team ensures the tests adhere to standards and collaborates with local super users to promote proper usage. However, staff turnover during the pandemic led some super users to resign their positions without transferring their expertise, potentially jeopardizing proper implementation and use.

Many microbiologists and infectious diseases specialists interviewed in Quebec explained that POC tests, which provide results more quickly than with laboratory tests, would require clinical organization and workflow changes, including ensuring that doctors are available at all times.

The final decision regarding healthcare facilities is generally made by the administrators and the POC test team in collaboration with the laboratory. Administrators must make cost-effective decisions regarding the adoption of new tests, and many participants emphasized the need to prioritize AMR.

The wider context

Manufacturers and participants from the federal government explained that Health Canada's quality and safety requirements are demanding, complex, and often unfamiliar to manufacturers. For example, tests must demonstrate efficiency across diverse populations, and results must consistently align with the information in their applications, accompanied by clear and user-friendly instructions. Manufacturers are also responsible for bearing the costs of approval, translation, and renewal, which are considered quite expensive.

Participants from the federal government explained that Health Canada has implemented different strategies to facilitate

regulations for manufacturers, especially during the pandemic. Participants mentioned that the COVID-19 Interim Order helped expedite the process by accepting the applications submitted to the U.S. Food and Drug Administration (FDA), proactively communicating certification requirements, and implementing priority reviews for devices considered “urgent medical needs”, such as diagnostic tests for detecting AMR.

Many participants expressed concern over the lack of priority given to AMR at the federal, provincial, and territorial levels, emphasizing the need for political pressure from citizens to address AMR effectively. In a federal system such as Canada’s, the relationship between the federal, provincial and territorial governments is crucial for the implementation of new tests. Cooperation can either pose a challenge or facilitate the process. Even if diagnostic tests are approved and available at the federal level, it is at the discretion of a provincial government to decide whether to adopt them, depending on priorities, strategies, and confidence in the test results.

Furthermore, microbiologists and manufacturers interviewed generally perceived the federal system with its two-level decision process (federal government approving diagnostic tests and provincial governments deciding whether to use them) as having “too many rules and people to convince”, thereby doubling the work between federal and provincial bodies.

Microbiologists and manufacturers generally perceived the centralization in Quebec as a barrier to the implementation of diagnostic tests. Some manufacturers and participants from provincial public health organizations criticized the system’s focus on economic efficiency, questioning the cost-benefit analysis of centralization, especially in terms of patient impact.

According to some participants at the federal level, the production of POC diagnostic tests faced several challenges in Canada: it was not a priority before the COVID-19 pandemic; the Canadian government was considered inefficient at supporting and incentivizing domestic production; there was a lack of private-public partnerships; and a “Canadian inferiority complex” regarding the innovation quality compared with the United States or European Union production. Further, there was weaker demand due to Canada’s smaller population size. Canada’s universal healthcare coverage also means every expenditure needs to be justified, as opposed to the U.S. system where tests are paid for by the patients and/or their insurance. However, the pandemic has influenced domestic production by highlighting the need for greater self-sufficiency to address health crises. The COVID-19 diagnostic tests became a priority globally, including in Canada.

DISCUSSION

In this study, we applied the NASSS framework (Greenhalgh *et al.*, 2017) alongside the health innovation process (MacNeil *et al.*, 2019) to highlight the multiple, interconnected factors affecting POC test implementation in Quebec. Our findings demonstrated that most barriers occurred during the first (design and development) and last (implementation and adoption) stages of the process.

In the initial stage, significant barriers to diagnostic test innovation include the complexity of evolving AMR microorganisms, the development of POC technology, and the lack of priority and funding. According to participants in our study and other authors, the production and use of POC diagnostic tests would be facilitated if they became a political priority, received more funding and more public-private partnerships (Engel *et al.*, 2022; MacNeil *et al.*, 2019). As highlighted in this study and others, successful innovation also depends on market attractiveness, profitability, and the reimbursement system (MacNeil *et al.*, 2019; Quinn *et al.*, 2016; Ukuhor, 2021).

In the final stage of implementation, key drivers identified in this study included ease of use, user confidence in the results, staff resources, impact on users’ workflow and workload, support for implementation, and political and economic contexts, as corroborated by other studies (Engel *et al.*, 2022; Huddy *et al.*, 2016; Kierkegaard *et al.*, 2021; Quinn *et al.*, 2016).

Between the development and implementation stages, our findings illustrate that regulatory and political contexts can act as barriers to the implementation of POC diagnostic tests. Similarly, MacNeil and colleagues (2019) have argued that regulatory and political contexts hinder health innovation in Canada. Firstly, Canada’s federal system means that each province or territory has its own organizations, priorities, and strategies (MacNeil *et al.*, 2019), underscoring the need for better coordination between both levels of government (Alami *et al.*, 2021). Secondly, a complex and poorly-known regulation process was identified as an impediment to health innovation, although Health Canada is working to improve implementation (MacNeil *et al.*, 2019; Quinn *et al.*, 2016; Ukuhor, 2021). Thirdly, assessing the cost-benefits of POC tests was perceived as difficult due to a lack of literature (Quinn *et al.*, 2016).

Provincial centralized governance was perceived as a barrier to POC diagnostic test implementation at the Health Technology Assessment and implementation stages. However, Scarffe and his colleagues (2022) noted that centralization mainly has a negative impact on the development phase.

In our study, as well as in others, nurses were identified as the primary users of POC diagnostic tests, with recommendations to further involve them in stewardship programs aimed at tackling AMR (Broom A. *et al.*, 2017; Danielis *et al.*, 2022). However, POC test use presents organizational challenges for nurses in Quebec, exacerbated by staff shortages and increased workload, even before the COVID-19 pandemic (Lorcy & Dubé, 2018). These factors must be carefully considered (Broom A. *et al.*, 2017; Danielis *et al.*, 2022; Lorcy & Dubé, 2018).

Another significant barrier to POC test implementation identified in our study and others was HCWs’ lack of trust in test results and technology uptake in general (Gille *et al.*, 2020). This lack of confidence is often attributed to insufficient evidence and knowledge, which creates uncertainty about its effectiveness (Huddy *et al.*, 2016; Pandolfo *et al.*, 2021). To address this barrier, participants in our study and other research emphasized training (Kierkegaard *et al.*, 2021), clear and concise guidelines, and selecting appropriate settings for use. These measures can help to build or reinforce confidence in diagnosis (*et al.*, 2022), enhance

patient relationships (Kierkegaard et al., 2021), and support prescribing decisions (Pandolfo et al., 2021).

This qualitative research highlights the complexity of implementing a diagnostic strategy to tackle AMR in Canada. However, our findings should be assessed within the context of certain limitations. Firstly, the results cannot be generalized to the entire country as they only consider perspectives from the federal and provincial levels in Quebec. Secondly, we interviewed a limited number of participants, which may not capture the full spectrum of expertise and viewpoints. Thirdly, there is the possibility that interviewees provided socially desirable answers. Fourthly, while data saturation was achieved for the main objective of identifying key drivers of POC diagnostic test adoption and implementation, the diverse profiles of participants meant that data saturation was not necessarily reached for all participant groups and secondary objectives.

CONCLUSION

AMR is increasingly becoming a major concern in Canada and globally. The implementation of diagnostic tests that provide faster results to inform antibiotic prescription is crucial for controlling AMR. However, with challenges at the developmental, approval and implementation stages, our study has highlighted that the implementation of new POC tests is complex and should not be underestimated. Success is contingent upon coordination between different levels of governments, manufacturers, and other stakeholders. To effectively tackle AMR, a broad and systemic approach is needed alongside making AMR a political priority.

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