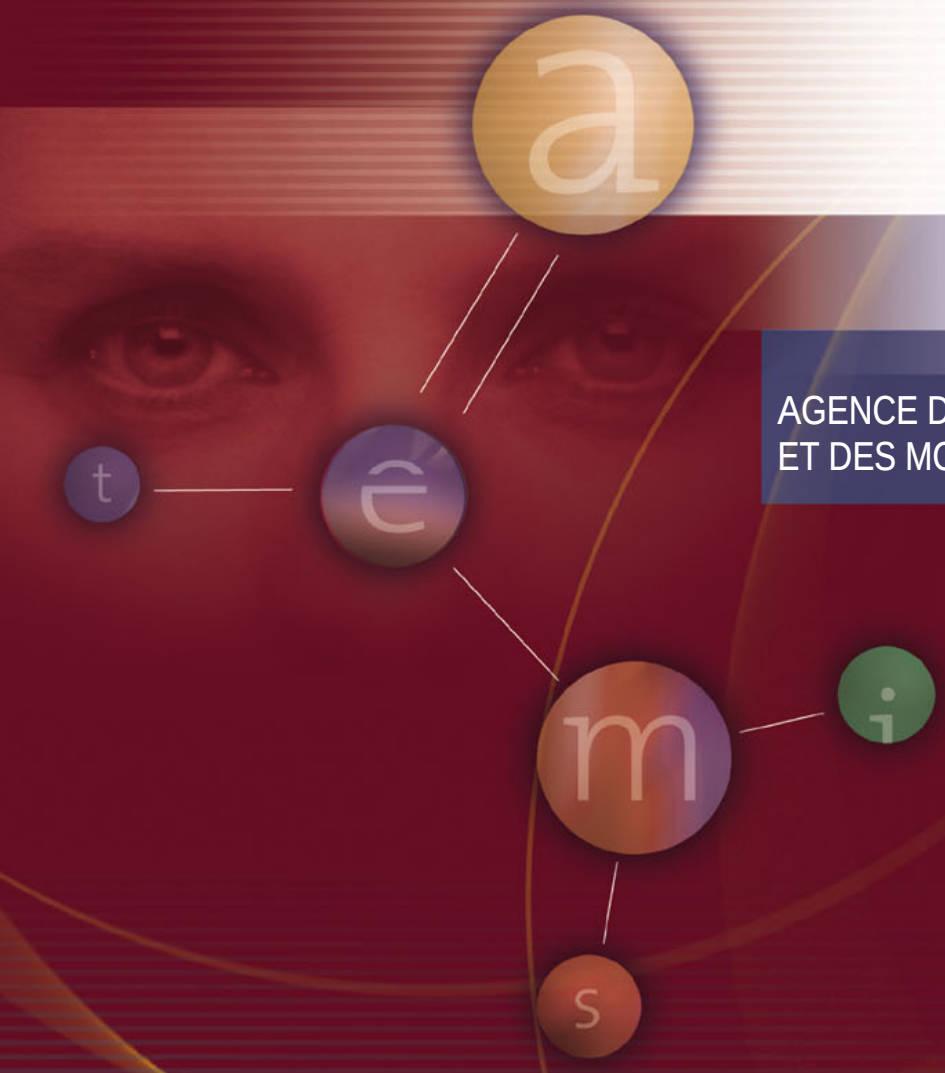
Point-of-Care Testing in the Private Sector

Summary



AGENCE D'ÉVALUATION DES TECHNOLOGIES
ET DES MODES D'INTERVENTION EN SANTÉ

Québec

Point-of-Care Testing in the Private Sector

Summary

Report prepared for AETMIS by

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20 ans AVEC VOUS POUR LA SANTÉ

Agence d'évaluation des technologies et des modes d'intervention en santé
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Mission

The mission of the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) is to help improve the Québec health-care system. To this end, it advises and supports the Minister of Health and Social Services and decision-makers in the health-care system with regard to the assessment of health services and technologies. The Agency makes recommendations based on scientific reports assessing the introduction, diffusion and use of health technologies, including technical aids for the disabled, as well as the methods of providing and organizing services. The assessments examine many different factors, such as efficacy, safety and efficiency, as well as ethical, social, organizational and economic issues.

Preface

Point-of-care testing (POCT) has been on the rise in Québec since the mid-1990s. This refers to analytical tests performed by qualified health professionals outside recognized and accredited public or private laboratories and outside health and social services institutions (as defined by law). This area of activity is not currently regulated.

Faced with the growing reliance on POCT and the need to ensure that these tests are of high quality, safe and technically effective, the Ministère de la Santé et des Services sociaux (MSSS) decided to review the legislation and regulations applicable to POCT and to assess the need for governance oversight in this area.

In that context, the MSSS asked AETMIS to support this review process by performing an exhaustive literature review that would help provide an appropriate definition for POCT, draw up a list of Canada-approved kits and instruments, flag the major issues associated with POCT, and identify the quality-control and quality-assurance measures proposed in Canada and around the world.

This request was also made within the broader context of the reorganization of the health system toward the provision of outpatient health and social services to respond more effectively to the public's growing demands. More specifically, greater demand for laboratory tests has been due in part to the growing number and extended longevity of people with chronic diseases and the urgent need for laboratory test results to be immediately available. Increased demand for short turnaround times raises a number of issues, such as the quality of test results, the appropriateness and frequency of these tests, and the accountability of health professionals in regard to this type of testing. These professionals are in fact being required to take on additional roles and responsibilities. This is especially true for pharmacists in the private sector who not only offer clinical laboratory services but also help patients select testing devices, use them properly and interpret their results.

This report is not an in-depth analysis of each test but a descriptive analysis of the situation characterizing the use of POCT. Given that the MSSS basically wanted background information, this is a factual report based on observations of the POCT situation outside Québec and a literature review on this issue in general. Note that tests self-administered by patients are not included in our analysis.

In submitting this report, AETMIS hopes to contribute to a clearer understanding of the issues related to point-of-care testing that will guide the changes being made to the legislation and regulations surrounding this practice in Québec.

Juan Robert Iglesias, MD, MSc,
President and Chief Executive Officer

Executive summary

Point-of-care testing (POCT), also known as near-patient, bedside or extra-laboratory testing, is defined as testing performed by qualified health professionals outside recognized and accredited public or private laboratories and outside health and social services institutions (as defined by law). These analytical tests are a component of total patient management (including support and follow up). Those in favour of POCT maintain that it improves access to some tests and reduces turnaround time in addition to meeting patient needs more effectively. Those against it draw attention to the risks of unnecessary tests and errors due to inadequate staff training and experience. They also point to the extra work being required of quality-control professionals, including those employed in central laboratories, and the high cost of reagents. Even though the use of POCT is expanding at a rapid pace, it is not yet regulated.

In light of our assessment based on analysis of the major issues raised by POCT and examination of the different measures in place in other provinces and countries to ensure the quality of this practice, AETMIS has identified the principles and conditions that could guide how this practice should be governed in Québec.

As a general rule, POCT should be performed only when justified by the need for a rapid response and in situations requiring immediate test results. This type of testing seems more appropriate for patient monitoring than for disease screening or diagnosis. Point-of-care testing must remain a complementary adjunct to central laboratory services. In an effort to promote high-quality test results and prevent any harm to people's health, the following conditions must be met:

- Point-of-care testing must be performed in a secure setting that meets strict quality standards, including education and training for test operators, periodic audits, internal and external quality controls, and a collaborative relationship with central laboratories.
- Each step in the testing procedure must be accurately recorded in the medical file and the source of errors at the different testing stages must be identified.
- The confidentiality of patients' test results and consultations with the health professionals who order the tests must be safeguarded, whether the information is being reported, stored or transmitted.
- Responsibilities must be clearly defined in policies and procedures on the use of the different tests (which must include standards, guidelines, and accreditation and certification procedures).
- The appropriateness and frequency of the tests must be evaluated.
- Manufacturers' recommendations, maintenance programs, and hygiene and waste-disposal measures must be strictly observed.

Lastly, any decision with regard to prioritizing these tests must be based on a comprehensive analysis of each test, including an economic component to ensure that its benefits outweigh its disadvantages and costs.

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DISCLOSURE OF CONFLICTS OF INTEREST

None to be declared.

Summary

Introduction

Point-of-care testing (POCT), also known as near-patient, bedside or extra-laboratory testing, involves tests performed by qualified health professionals outside recognized and accredited public or private laboratories and outside health and social services institutions (as defined by law), such tests being prescribed by a physician[1] or any other qualified professional. Each of the three elements in this definition—site, operator and prescriber—is key to its understanding and application. Those in favour of POCT maintain that it improves access to some tests, reduces turnaround time, and helps meet patients' needs more effectively. Those who oppose it point to the risks of unnecessary tests, errors due to inadequate staff training and experience, the extra work being required of quality-control professionals, and the high cost of reagents (compared with their cost in central laboratories). A further point that merits consideration is the potentially devastating impact of prematurely releasing test results to patients coping with major health problems without at the same time offering them appropriate professional support.

The use of POCT has been accelerating in Québec without any governance or oversight. This situation has prompted the MSSS to review the legislation and regulations surrounding POCT in order to lay the statutory foundation governing this practice. This is the context in which the MSSS asked AETMIS to support its review process by performing an exhaustive literature review to establish an appropriate definition for POCT, draw up a list of Canada-approved kits and instruments, flag the major issues associated with POCT, and identify the quality-control and quality-assurance measures proposed in Canada and around the world. This report is not an in-depth analysis of each test but a descriptive analysis of the situation characterizing the use of POCT. Note that our mandate excluded analysis of tests self-administered by patients.

Safety, Technical Effectiveness, Ethical Issues and Costs

The literature suggests that the safety of most of the available devices is generally not an issue, summing up the risks as those associated with specimen collection and disposal of some instruments. It does mention adverse incidents due to erroneous results caused more often than not by the interaction of some substances with the reagents used. In addition, the literature consulted indicates that most point-of-care tests are technically effective when performed by health professionals in a proper setting. Ethical issues of concern include providing patients with accurate information so that they can give informed consent to the test and ensuring the confidentiality of patients' test results and consultations with the prescribing health professional. Finally, the cost of reagents, supplies and quality-control material is considerably higher for POCT than for central laboratories. Additional costs include the fees of the professionals responsible for the test-validation process and quality-control measures, which are not negligible.

1. A medical prescription is mandatory for specimen collection and invasive diagnostic tests.

Quality Control and Assurance

Quality control in POCT is largely based on the detection of errors at the different testing stages. It involves various methods and procedures for ensuring quality results. These include manufacturers' recommendations, maintenance programs, hygiene and waste-disposal measures, guidelines for safeguarding confidentiality, training, definition of responsibilities for using POCT devices, along with standards, guidelines, and qualification and accreditation procedures. Australia has defined fourteen standards divided into five categories: clinical governance, analytical requirements, staff training, test implementation and performance, and quality outcomes.

The application of these different measures can be bolstered by legislation and regulations surrounding the use of POCT. These regulatory measures are designed to guarantee that patients receive quality results, test operators work in a safe environment, testing devices and procedures comply with technical requirements through a quality-assurance program, commercially available products are safe, and national legislation is consistent. Regulatory bodies at different levels of government are involved in making sure that these objectives are met. Regulatory requirements apply to such issues as staff accreditation and certification, test complexity, proficiency testing, structures for administering the tests to patients, quality control and site inspections of testing facilities. Lastly, since regulations in other provinces or countries vary considerably, a finer analysis must be performed to verify their applicability to specific contexts.

Discussion and Conclusion

Rapid access to point-of-care tests and their results raises the issue of their appropriateness and frequency. Some believe that POCT should be performed only when justified by the need for a rapid response and in situations requiring immediate test results. These tests seems more appropriate for patient monitoring than for disease detection or diagnosis.

Accountability lines should be clearly identified in policies and procedures on the different tests. Before any test is used, its benefits must be weighed against the disadvantages associated with its result. It must always be kept in mind that the aim of POCT is to contribute to improving patients' care and quality of life and that it must complement, not replace, central laboratory services.

The wide availability of POCT in contexts as varied as superstores raises serious concerns about the trivialization of medical conditions "diagnosed" in this way. There is also the fear that this type of testing might be performed by unqualified staff. To mitigate this problem, some propose that professional laboratory technicians take part in selecting and maintaining the test devices, training operators, and regularly verifying their competence and the accuracy of the documentation provided to patients (in accordance with the requirements issued by regulatory bodies).

Since it has become necessary to develop and adopt statutory measures governing the use of POCT in Québec, the legislator could base them on the regulations in place in other countries in order to adapt and reinforce existing regulatory mechanisms or to provide for new ones. This type of governance oversight could help make point-of-care tests as effective and safe as those performed in central laboratories.

Lastly, any decision with regard to prioritizing these tests must be based on a comprehensive analysis of each test, including an economic component to ensure that its benefits outweigh its disadvantages and costs.

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