SAFETY FRAMEWORK FOR THE FOLLOW-UP OF DIAGNOSTIC AND SCREENING TEST RESULTS
Working Committee

Marc Billard, acting director and secretary of the professional inspection committee and secretary of the transplantation subcommittee, Collège des médecins du Québec

Dominique Derome, former CEO, Association des conseils des médecins, dentistes et pharmaciens

Louis-André Lacasse, physician advisor, AQESSS

Annie Léger, director of professional services, CSSS de Rouyn-Noranda

Lucie Raymond, service organization advisor, AQESSS

Publication

Writing: Louis-André Lacasse, physician advisor, AQESSS

Layout: Aurore Dobbeleer, executive secretary

Editing: Chantal Gosselin

Distribution

Association québécoise d’établissements de santé et de services sociaux
505 de Maisonneuve Boul. West, Suite 400, Montréal, QC H3A 3C2
Telephone: 514 842-4861

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For over 25 years now, Quebeckers have benefited from spectacular advances in medical laboratory, medical imaging and other diagnostic and screening modalities (electrophysiology, respiratory physiology, etc.).

Clinical care processes have thus evolved over time, due to the widespread availability of these procedures. Nowadays, few clinicians rely solely on the clinical history or the physical exam for making a definitive diagnosis, or initiating or modifying a treatment plan.

Moreover, specialized nurse practitioners (SNPs), midwives, pharmacists and all other healthcare professionals covered by the Act to amend the Professional Code and other legislative provisions as regards the health sector\(^1\) now can prescribe certain investigations as members of the healthcare team, particularly through the application of collective prescriptions or medical directives.

In 2010-2011, 171 million procedures were carried out in Quebec at medical laboratories, as well as 7.5 million medical imaging procedures.

Over the years, the reliability of the process for communicating test results to ordering healthcare providers (HCP) has not changed much, and the harms due to failures in this process are well recognized. Every day, critical test results go astray or are ignored. Consequently, patients experience harm from erratic follow-up, either because the results did not reach the right person at the right time, or because the ordering HCP did not attend to the results in a timely manner.

In 2011, the Association québécoise d’établissements de santé et de services sociaux (AQESSS) and the Association des conseils de médecins, dentistes et pharmaciens du Québec (ACMDPQ) accepted an invitation from the Collège des médecins du Québec (CMQ) and formed a working committee to address the issue and propose the way forward.

During their work, members of the working committee for the safe follow-up of diagnostic and screening test results, assisted by clinicians and administrators from the healthcare and social services network, identified the most significant areas of weakness in the process for communicating test results to ordering HCPs. They also suggested a series of actions for strengthening this process by implementing better practices and more robust safety nets.

Committee members also concluded that organizations need to carry out periodic audits of key processes for following up diagnostic and screening test results. All of these recommendations appear in a 3-step summary table produced by the team.

This document accompanies that table. We believe that it will help clinical and administrative leaders to more systematically evaluate the follow-up process for diagnostic and screening test results at their facilities, and quickly identify opportunities to improve safety.

\(^1\) Bill 90.
# Table of Contents

- **Glossary** ...................................................................................................................................... 5
- **Highlights** .................................................................................................................................... 6
- **Audience** ..................................................................................................................................... 7

## General Context .......................................................................................................................... 8
- Responsibilities and obligations of the various stakeholders ......................................................... 8
- Ordering HCPs’ obligations ............................................................................................................. 8
- Patient responsibilities ...................................................................................................................... 8
- Institutional responsibilities ............................................................................................................. 8

## Step 1: Managing diagnostic and screening test results ................................................................. 9
- Objectives ........................................................................................................................................ 9
- Physicians and HCPs working out-of-hospital .............................................................................. 9
- Physicians and HCPs working in hospitals .................................................................................... 10
  - Council of Physicians, Dentists and Pharmacists/Medical Advisory Committee
  - Committee and Director of Professional Services/Chief of Medical Staff ................................. 10
  - Operational procedures for hospital services and departments ................................................. 10
  - Appointing a backup for other HCPs involved ........................................................................... 11
- Diagnostic services .......................................................................................................................... 11

## Step 2: Managing critical test results ............................................................................................ 12
- Requirements in the institution’s services or departments ............................................................. 12
- Ordering HCP (or backup) ................................................................................................................ 12
- Requirement for the institution ....................................................................................................... 13
- Alert systems for critical values ....................................................................................................... 13
- Ordering HCP (or backup) not contacted ....................................................................................... 13

## Step 3: Continuous improvement process .................................................................................... 14
- Collaboration within the local service network .............................................................................. 14
- Independent organizations .............................................................................................................. 14

**Conclusion** ................................................................................................................................... 15
GLOSSARY

Here is a brief description of terms used in this safety framework.

ORDERING HCP
A healthcare professional (HCP) authorized to order diagnostic or screening tests based on the individual’s scope of practice.

BACKUP
The healthcare professional to contact if the ordering HCP is not available to provide appropriate follow-up for diagnostic or screening test results in a timely manner.

CRITICAL VALUE
An unexpected quantitative or qualitative result of a diagnostic or screening test, with a large enough difference from the reference values that it signifies a critical risk to life, functioning or an organ if the ordering HCP is not informed within the specified timeframe.

NON-COMPLIANCE
Ordering HCP or backup not reached when there is a result with a critical value.

DESIGNATED PRACTITIONER
An HCP who must follow up with the patient if neither the ordering HCP nor the backup can be reached when there is a critical result.
The working committee has highlighted the main points from the Safety Framework for the Follow-Up of Diagnostic and Screening Test Results:

- Every ordering HCP (physician or other HCP authorized to order diagnostic or screening tests based on their scope of practice) is responsible for following up on the results of diagnostic or screening tests;
- Every ordering HCP should identify a backup before ordering any diagnostic or screening test;
- For every diagnostic service, the ordering HCP should be clearly noted on the request and on the report, in order to identify the person responsible for following up the result;
- Critical values should be defined, for both qualitative and quantitative investigations, and a systematic plan to manage critical values should be implemented;
- There must be a systematic plan to manage cases of non-compliance and action taken when the request for intervention by the ordering HCP or backup does not yield results;
- A rigorous audit process should be carried out periodically to assess the reliability of follow-up of diagnostic and screening test results from any diagnostic service as part of a continuous quality improvement process.
The Safety Framework for the Follow-up of Diagnostic and Screening Test Results is intended for institutional leaders, directors of professional services, chiefs of medical staff, CPDP, executive committee members, Medical Advisory Committee members, diagnostic service teams, department and service heads, managers of family medicine groups (FMG), quality managers and all other clinical and administrative leaders.

This document may also be of interest to any ordering HCPs who wish to assess and improve the safety of their process for following up on diagnostic and screening test results.

The results of the working committee’s work are presented in a quick reference guide, i.e., the Safety Framework for the Follow-up of Diagnostic and Screening Test Results Table. HCPs can use it as a starting point for assessing and improving the processes in their work environments. Although this document is not intended to be prescriptive, HCPs are invited to share their experiences in order to enhance its impact on healthcare safety.
Responsibilities and obligations of the various stakeholders

Faced with the problem of “orphan” diagnostic or screening test results, it would have been easy to dream up new regulatory or ethical obligations for both organizations and ordering HCPs. However, the team members believe that all regulations and ethical obligations are already in place. We are reminded of this at the top of the table by the premise of the Safety Framework for the Follow-up of Diagnostic and Screening Test Results.

Ordering HCPs’ obligations

Ordering HCPs have an ethical obligation to provide follow-up care as dictated by the patient’s condition, an ethical obligation to transfer care to a colleague if they cannot provide it themselves and an obligation, when ordering an investigation, to follow up appropriately and in a timely manner. These obligations should extend to all HCPs ordering diagnostic or screening tests.

Patient responsibilities

Patients, whose involvement as partners has become vital, must have the opportunity and means to participate actively at all times in their treatment plan and in decisions regarding their care. This is clearly stated in Article 10 of the Act respecting health services and social services (LSSSS). At a minimum, they are responsible for ensuring that the institution and ordering HCP have up-to-date contact information, and for following the recommendations of their various HCPs.

Institutional obligations

Lastly, institutions have a strict obligation, under Article 100 of the LSSSS, to provide safe, continuous and accessible quality health and social services that respect individuals’ rights and needs.

To that end, institutions must integrate and operationalize these obligations into each of their functions, particularly within diagnostic services.

2. RSQ, c. S-4.2
3. RSQ, c. S-4.2
**Objectives**

The safety framework proposes various methods for safe management and follow-up of all diagnostic and screening tests. The objectives are to:

- Ensure the follow-up of diagnostic and screening test results, particularly critical values;
- Ensure the safety of care and services by involving physicians, other HCPs and institutions;
- Make sure the concept of backup is understood, as well as the need for this concept to be put into practice by all HCPs ordering a diagnostic or screening test.

It is important to establish fulsome procedures for follow-up of all results and rapid action in the event of a critical value.

**Physicians and HCPs working out-of-hospital**

All ordering HCPs should designate a backup to follow up on diagnostic or screening test results when they are unavailable to do so. They should also establish a mechanism for communicating that information to the diagnostic services carrying out the investigations. In the case of a critical value, the diagnostic service should be able to rely on having up-to-date information for contacting the backup, if necessary.

This applies particularly to:

- Physicians in solo practice;
- Physicians in a group practice (FMG or other group clinic);
- Nurse practitioners specialized in primary care;
- HCPs implementing a collective prescription or medical directive.

Therefore, during any periodic review of the process for communicating diagnostic and screening test results, particular attention should be paid to HCPs working alone. Coverage arrangements for diagnostic and screening test results, within an FMG or any group clinic, should be defined, explicit and formal. Similarly, nurse practitioners should identify a backup, as should the various HCPs implementing a collective prescription or medical directive.
Physicians and HCPs working in hospitals

**Council of Physicians, Dentists and Pharmacists/Medical Advisory Committee and Director of Professional Services/Chief of Medical Staff**

A hospital’s Council of Physicians, Dentists and Pharmacists (CPDP) or Medical Advisory Committee should have rules that include the individual obligation for every member to appoint a backup for follow-up of diagnostic and screening test results. Moreover, procedures should be established for physicians involved in temporary coverage arrangements.

Periodically, the CPDP or Medical Advisory Committee should make sure that these rules are being applied within departments and services, for both inpatients and outpatients.

The CPDP or Medical Advisory Committee should maintain and distribute the list of backups of each member for their hospital-related practice. An update mechanism should also be established. That might be done when granting and renewing privileges, and be updated periodically in the event of a change (e.g. annually). Notice should be sent to HCPs whose information is missing or obsolete.

**Operational procedures for hospital services and departments**

The CPDP or Medical Advisory Committee’s rules regarding a member’s individual obligation to appoint a backup can be applied with consideration to the particular features of individual departments and services. Operational procedures within the hospital’s services and departments should be reviewed regularly. For example, when a test is ordered for a hospitalized patient, it should be clearly established from the time the result becomes available who, between the ordering HCP and the clinician on duty for the service or department where the patient was cared for, is responsible for following up on the result once the patient is discharged. This type of situation arises every day, and the accountability for following up on an abnormal test should be clearly stated in the service or department rules and rigorously applied.

Hospitals that rely on physicians for coverage should pay particular attention to the responsibility for tests ordered by these physicians during their coverage period. When assigning temporary privileges to a physician working in such a situation, it is important to establish who will be responsible for safe follow-up of diagnostic and screening test results that will only become available after the ordering HCP’s departure. Such temporary privileges should not be granted unless an explicit, formal agreement for follow-up has been established in advance.
Appointing a backup for other HCPs involved

The increasing number of collective prescriptions or medical directives in hospitals raises the risk that diagnostic or screening test results will not be followed up. Many HCPs can now order investigations as part of collective prescriptions or medical directives. Therefore, the hospital must ensure that the ordering HCPs have legitimate ordering privileges under the protocols and that the ordering HCPs’ backups are clearly identified, in the event that a critical result is obtained and the initial ordering HCP is unavailable.

Identifying a backup is also necessary for nurse practitioners and midwives, who likewise order diagnostic and screening tests.

Diagnostic services

Diagnostic services must perform the diagnostic and screening tests and communicate the results in a diligent manner, ensuring that all measures are in place so the ordering HCP can provide appropriate follow-up in a timely manner. In order to do so, the following elements should be considered:

- Requisition forms and reports of investigations should clearly identify the HCP responsible for follow-up, so as to avoid any confusion (HCP orders a test with the intention that the family physician will ensure follow-up, while at the same time, the family physician receiving a copy of the result might believe that the other HCP is handling it!);
  - Use explicit wording, for example, “HCP responsible for follow-up” or “HCP informed of results”;
  - Suggest removing terms such as “requesting”, “attending” or “CC”, which can create ambiguity;
- Clear visual presentation of results in the report using various tactics to draw the ordering HCP’s attention to abnormalities (font size, underlining of key words, avoidance of distracting superfluous content, addition of a note stating “ATTENTION”, etc.);
- Communication of results to the right ordering HCP, including taking all appropriate measures to avoid errors in transmission and corrective actions when required;
- Access to the different collective prescriptions or medical directives in effect and to up-to-date lists of people authorized to implement them, ensuring that they are updated periodically;
- Access to the list of backups for all HCPs authorized to order diagnostic or screening tests;
  - Single centralized computerized database is desirable to prevent the risk related to circulation of outdated versions;
  - If necessary, sending a notice to HCPs whose information is missing or obsolete.
A critical value is an unexpected quantitative or qualitative result of a diagnostic or screening test with a large enough difference from the reference values that it signifies a critical risk to life, functioning or an organ if the ordering HCP is not informed within the specified timeframe. Therefore, a critical value requires immediate intervention by the ordering HCP.

The concept of a critical value is not limited to medical laboratory exams alone. The incidental finding of an aneurysm of the abdominal aorta larger than 5.5 cm on imaging or atrial flutter during an elective electrocardiogram are also critical values that should set off a chain reaction, of which timely reporting to the ordering HCP is the cornerstone.

Unfortunately, many of these abnormalities are not communicated in time. For example, a radiologist attempting to verbally report such a finding may sometimes find that the ordering HCP is unavailable and that there is no backup. Moreover, recording the event in the patient’s file is not yet a widespread practice.

Requirements in the institution’s services or departments

There is now abundant scientific literature defining critical values and the timeframes within which ordering HCPs should be notified. Every service or department should make use of the literature and adapt it to its specific context, with collaboration from ordering HCPs. The heads of services or departments producing reports of diagnostic or screening tests should undertake this work and standardize practices among all their members to ensure the reliability, reproducibility and continuous improvement of their process.

Ordering HCP (or backup)

When critical values are rigorously defined, they do not occur as often as might be expected. For every critical value, a precise pathway should be prepared, with a feedback loop to confirm that information has been communicated.

Once notified, the ordering HCP should give serious attention to a reported critical value and acknowledge its receipt to the diagnostic service, thereby preventing any delay in the actions to be taken. Any ordering HCP who receives notification of a critical value should take immediate measures and explicitly document the actions taken in the patient’s file.

The ordering HCP will also take appropriate corrective action to ensure follow-up when non-compliance is reported (appointing another backup, communicating to the institution any change in contact information, etc.).
Requirement for the institution

Every institution should have an established safety net if neither the ordering HCP nor the backup can be reached. A clinical practitioner (most often, an experienced nurse) should be appointed to take over and direct the patient to the most appropriate resource for an urgent condition. However, this situation should be considered an exception, rather than the rule.

Alert systems for critical values

Triggering an alert, when a critical value is identified, should be choreographed with the greatest detail. The Safety Framework summary table systematically lists the series of actions necessary when an alert is reported, distinguishing a quantitative critical value from a medical laboratory (e.g. an INR of 7) from a qualitative critical value from another diagnostic or screening procedure (e.g. tension pneumothorax on a chest x-ray).

Every diagnostic service should set up a system for identifying critical results, communicating them to the ordering HCPs or their backup and writing a follow-up note in the patient’s file. In addition, it should report instances of non-compliance (ordering HCP or backup not reached) and notify the ordering HCP involved. The latter should participate actively in the subsequent analysis of the non-compliance, as it is the best way to improve the system and prevent future catastrophes.

Moreover, in the absence of a confirmation of receipt from the ordering HCPs or their backup, the institution should have a callback system for the diagnostic service for any critical value. The logic underlying this strategy is the very low likelihood that a critical result would be unintentionally lost or ignored twice.

With an eye on continuous improvement, all notifications of non-compliance issued by the diagnostic services should be reviewed periodically by the DPS or chief of medical staff and the relevant professional bodies. In the case of repeated non-compliance, the ordering HCPs involved should have their practice reviewed by the appropriate authorities, given the potential danger to patients.

Ordering HCP (or backup) not reached

When neither the ordering HCP nor backup are reached, the diagnostic service involved should communicate the critical value result to the designated clinical practitioner who will contact the patient to ensure appropriate follow-up for the condition and critical results. Once the situation is under control, a notice of non-compliance should be reported to the ordering HCP and authorities (CEO, DPS or chief of medical staff, professional council).
How can this kind of safety framework be quickly implemented at an institution and within a local service network? How can we be sure it is sustainable despite the many competing crises in the health and social services system, and periodic changeovers in clinical and administrative leadership?

This question is related to the problem of managing change in healthcare organizations. First of all, it is important to shine a light within the organization on the urgency for action necessitated by the gravity of the situation. A strong coalition, with credible clinical and administrative leadership, supported by the organization’s highest body, will be able to get the transformation off to a strong start and ensure in follow-up that changes have been implemented.

Collaboration within the local service network

With a vision focused on continuous quality improvement and safe provision of care, the institution is encouraged to set up a committee—composed of, for example, the CEO, deputy CEO, director of professional services, chief of medical staff, a CPDP or Medical Advisory Committee representative and the director of nursing—that is mandated to develop, establish and provide follow-up for the application of the safety framework. The initiative should be promoted through a sustained information campaign with backing from all bodies supporting quality improvement and the safety of healthcare.

Once the process has started, periodic audits should be conducted to consolidate achievements and smooth any rough edges. A systematic approach to managing failures will facilitate any necessary adjustments from a perspective of integrated risk management. It would be appropriate to publicize the work team’s success, as proof of change impregnating the organizational culture.

It is also useful to establish performance targets and indicators to measure how well the targets have been achieved. A process does not become truly integrated until it is regularly measured and monitored closely.

Independent organizations

Accreditation organizations will pay more attention to the reliability of processes for following up on diagnostic and screening test results now that it is more widely recognized as a determining factor in the quality and safety of care.

We might also expect that the Collège des médecins du Québec, along with all other professional bodies that periodically assess the quality of professional practice, implement the Safety Framework for the Follow-Up of Diagnostic and Screening Test Results in its evaluation mechanisms.
A safety framework of this kind cannot implement itself. Although its rollout should not represent an insurmountable task for any organization that can approach it as a team effort, assigning timelines and resources and tackling it as a continuous improvement project, it will nonetheless constitute, for some, a change in their habits and, as a result, might generate resistance.

That is why strong clinical and administrative leadership is crucial for launching the project and for longer-term follow-up of the framework’s implementation. The success of the process hinges on the participation of many stakeholders in a global, integrated approach. The framework suggests establishing clear, explicit rules which must, however, be adapted to the reality of each facility. Unconditional support from leaders for the periodic audit process will ensure improvement and sustainability.

Regulatory and professional bodies, along with accreditation organizations, will soon be able to expect a framework of this kind to be established and completely functional. Within increasingly complex clinical processes, diagnostic services will reach their full potential for safely improving patient health, one patient at a time.