HIROC

Multi-Patient Lookback and Notification Guide

For Health Alerts, Advisories and Recalls

PARTNERING TO CREATE THE SAFEST HEALTHCARE SYSTEM

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Healthcare Insurance Reciprocal of Canada
www.hiroc.com

4711 Yonge St., Suite 1600
Toronto, Ontario M2N 6K8
Tel: 1-800-465-7357
riskmanagement@hiroc.com

1200 Rothesay St.
Winnipeg, Manitoba R2G 1T7
Tel: 1-800-442-7751
westernregion@hiroc.com

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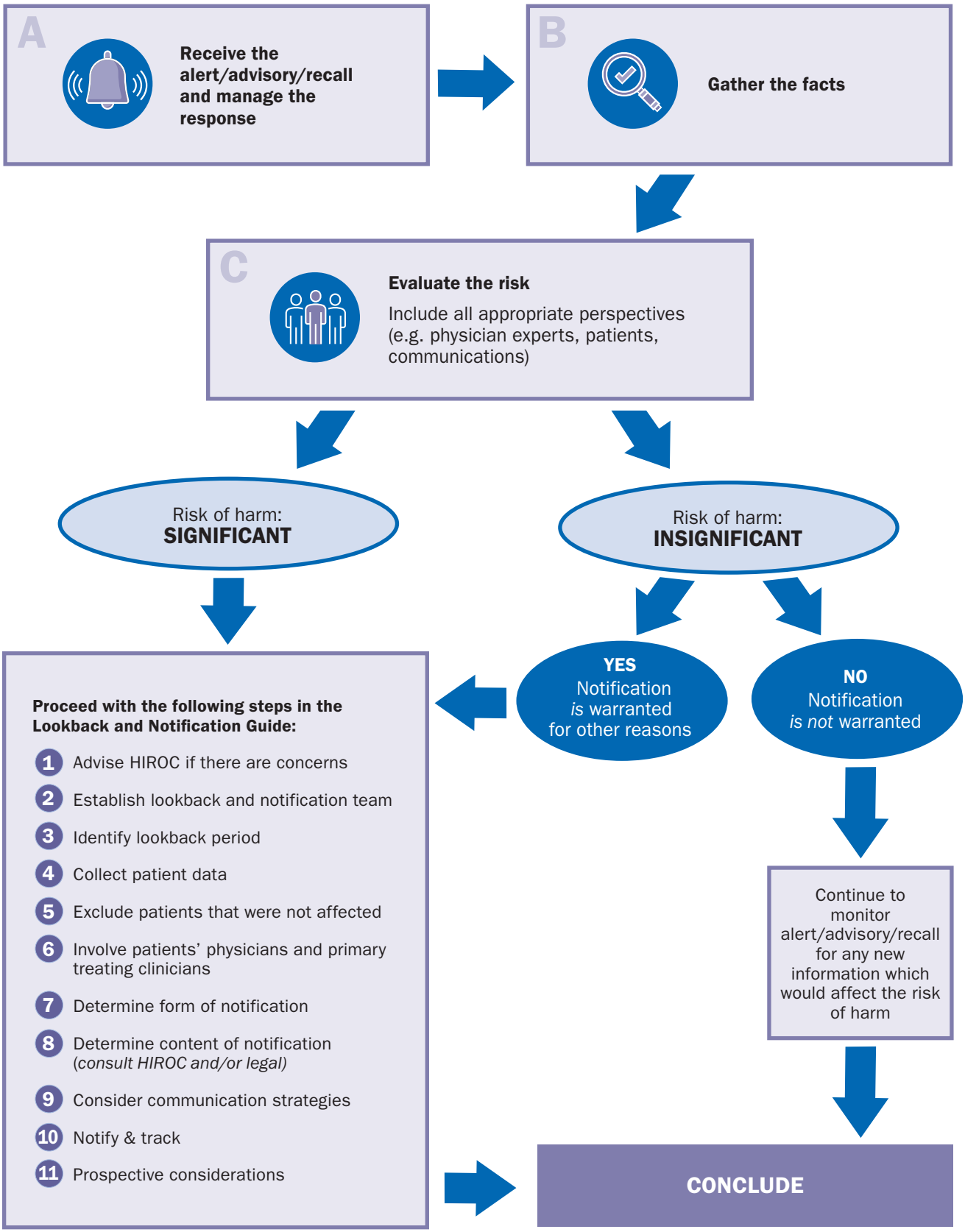
Introduction

The following Lookback and Notification Guide is designed to assist healthcare organizations with assessing whether a third party alert, advisory or recall warrants a multi-patient lookback and notification. It also provides a step-by-step process to be followed if a lookback and notification is required. This guide is intended to provide a uniform approach to managing alerts, advisories and recalls and to ensure risks to patients, healthcare providers and organizations are minimized.

Although the guide notes several times where a subscriber may be more likely to reach out to HIROC, subscribers should know that HIROC is always available to provide specific advice and assistance throughout this process.

Note: This guide does not deal with lookbacks required when investigating other multi-patient events, such as those involving infection control, sterilization, diagnostic imaging or privacy matters. If a subscriber is considering a lookback or notification for a multi-patient event, we recommend advising HIROC at the earliest opportunity. HIROC is available to provide specific advice and assistance for these events as well. Organizations may also refer to HIROC's Critical Incidents & Multi-Patient Events Risk Resource Guide.

Multi-Patient Lookback and Notification Guide
For Health Alerts, Advisories and Recalls*



*This guide does not deal with lookbacks required when investigating other multi-patient events, such as those involving infection control, sterilization, diagnostic imaging or privacy matters. Contact HIROC to discuss these types of matters.

A. Receive the alert/advisory/recall and manage the response

Every alert/advisory/recall should flow to a designated person or department at the organization, e.g. the risk manager or procurement department, to ensure consistency in evaluating whether a multi-patient lookback and notification is warranted. This person/department's role is responsible for managing the response to the alert/advisory/recall and ensuring that all actions taken, and the rationale for decisions made, are documented.

Every healthcare organization should have a process for managing alerts/advisories/recalls. The process should include:

- Who will be responsible for managing the response
- How decisions will be made regarding the response
- The process for flow of information to all affected parties
- How all related actions will be documented

B. Gather the facts

The designated person or department needs to ensure all relevant facts related to the alert/advisory/recall are gathered. This will usually require input from a number of sources. Be sure that you are canvassing the appropriate sources, e.g. operating room tracking system, cardiac cath lab tracking system.

Relevant facts include:

- Who issued the alert/advisory/recall, e.g. Health Canada, professional network, manufacturer or distributor
- What is the applicable timeframe included in the alert/advisory/recall
- When the alert/advisory/recall was received and method of notification
- Whether the alert/advisory/recall included a response form to be returned to the vendor
- Whether the recalled product/device was in circulation and what remains in inventory
- How many patients have received the affected product/device and if these patients can be identified
- Whether this is a matter which can have clinical impact, e.g. harm, subsequent procedure needed
- What clinical expertise is required to evaluate the potential risk

- Whether the alert/advisory/recall has instructed the healthcare organization to notify its patients and provided a sample letter
- Whether the alert/advisory/recall affects multiple organizations
- Whether other organizations are also affected and if possible whether peer organization(s) has/have notified patients or intend(s) to

Once the facts are known, you will be able to determine if and how the alert/advisory/recall applies to you. The person or department managing the recall will need to establish with the team how decisions are going to be made regarding the organizational response, including potential disclosure to patients. The team will also need to consider whether escalation to senior leadership is appropriate.

If it is unclear if the alert/advisory/recall affects more than one organization, it is advisable to consider reaching out to peers, HIROC, or the applicable ministry/department of health. A frequent issue is lack of a coordinated response with inconsistent approaches.

C. Evaluate the risk

A significant challenge of multi-patient lookbacks and notifications is deciding which, if any, patients are at "risk" and require disclosure. The designated person or department is responsible for ensuring the risk has been evaluated by a team. This team may include the same individuals as those involved in gathering the facts in addition to others who may be required based on their expertise, e.g. an infectious disease physician. In essence, the designated person or department acts as a project manager who:

- Takes responsibility for assembling the team
- Takes the lead in discussions
- Documents the process of arriving at the team decision
- Takes next steps following the decision whether or not to notify

The evaluation team

The evaluation team should be pulled together quickly to minimize the potential for harm or loss. Where consequences to a patient are probable, serious and/or imminent, the team meeting and evaluation of risk should take place as soon as possible after receipt of the alert/advisory/recall. Keep the team small but representative of stakeholders that have responsibility for the potential lookback. In situations where the risk to patients is obvious or very time-sensitive, the evaluation of the risk may occur in a faster and less formal fashion though it is important to document the process and decisions reached.

Depending on the type of alert/advisory/recall, potential team members include representatives from:

- Clinical/Biomedical Engineering
- Clinical Leadership
- Materials Management/Procurement
- Pharmacy
- Food Services
- Blood Services
- Physicians
- Infection Control
- Legal Counsel
- Ethics
- Communications
- Risk Management

The patient perspective should be included. For example, this could be done by including a patient experience specialist or patient representative on the team.

Deciding whether to notify

Generally speaking, where the risk to patients is significant, there is an obligation to notify patients. In making the determination as to whether the risk is "significant" and to therefore notify patients, the probability of the risk materializing and its seriousness are relevant factors. This frequently involves questions as to the degree of risk (e.g. is it infinitesimal?) and expert assistance will be required. An unusual or improbable risk should be disclosed if its effects are serious, i.e. life threatening or capable of having very serious health consequences.

Where there is a consensus that the risk to patients is not significant, there is no legal obligation to notify patients, however this does not end the inquiry. A healthcare organization may still decide to notify patients if that is considered warranted for other reasons, such as input from a patient representative, public relations considerations, or a consensus about what would be most beneficial to patients. Alternatively, after all appropriate perspectives are considered, you may decide not to notify patients, as the notification itself may cause distress to patients and their families without providing a benefit to those patients.

Typically, a healthcare organization has the right internal expertise to evaluate the risk if a variety of lenses are considered. The key is to ensure that all appropriate perspectives are part of the discussion about notification.

In evaluating the risk, the team should consider the following questions:

- What is the view of internal expert physicians?
- Is an external expert physician required to evaluate the risk?
- How is the risk quantified, e.g. evidence based, theoretical, perceived with best-estimate percentages?
- What do the authoritative bodies estimate the risk to be?
- Can we obtain additional information from the manufacturer/distributor about the estimated risk?
- Will the manufacturer/distributor be conducting any form of notification?
- What is the view of other organizations of the assessed risk?
- Is the applicable ministry/department of health, HIROC or other central body involved?

It may be beneficial to seek consensus from fellow experts and clinicians in the medical community and/or from other organizations, especially if a coordinated response would be beneficial.

If the conclusion is that the risk is not so great that notification is required on the basis of patient safety, then the evaluation team should also consider:

- Are other healthcare organizations notifying patients?
- Would patients want to know about this issue?
- How distressing would receiving notification be for patients? Would the notification create more harm than benefit? A patient might ask why, if the risk is so minimal, are they receiving a letter from senior leadership at the hospital about this.
- Are there treatment options that could be presented to patients?
- Is there an organizational consensus about whether disclosure is the ethical thing to do?
- Is disclosure important for public relations reasons?

Following the team meeting, to the extent possible consensus should be reached as to whether or not notification is warranted and whether a recommendation should be made to senior leadership for their decision. Regardless of the decision, the rationale and process in arriving at the recommendation and the decision should be documented and retained.

Where notification is warranted, the designated person will assist in coordinating the steps below to facilitate notification.

Steps to consider if notification is warranted

1 Advise HIROC if there are concerns

Advise HIROC of the circumstances giving rise to the lookback and notification if there are concerns about exposure to the organization or if assistance from HIROC is desired.

2 Decide whether the existing team will function as the "lookback and notification team" and if not, establish a lookback and notification team

The lookback and notification team is responsible for delivery of the notification and tracking the notification and may be comprised of the individuals responsible for gathering the facts, including:

- Health Records
- Clinical Programs
- Patient Relations
- Clinical experts as required to assist in preparing the accurate information for disclosure and act as the clinical resource for questions arising from the team, other clinical leaders and patients
- Quality, Risk, Patient Safety
- In-House Counsel (if applicable) or external legal advisor
- VP Medical Affairs/Physician in Chief, Chief of Department/Medical Lead of Associated Program
- Other senior leaders
- Procurement
- Communications
- CEO

3 Identify lookback period

- The lookback period is the specific period of time in which the alert/advisory/recall event has affected or will potentially affect patients. Each situation is unique and will have its own lookback period.
- If a coordinated response is occurring, the lookback period should be consistent among all involved healthcare organizations.

4 Collect patient data

Data to be collected

- Medical Record Number ("MRN" or equivalent)
- Patient name
- Patient address and telephone number
- Current Most Responsible Physician ("MRP") at the time if no longer a current patient
- Family physician
- Family physician address and telephone number

Where patient's last known contact information or status is not available

- Reach out to applicable ministry/department of health where reasonable
- Family physician, if known
- Applicable health insurance plans, e.g. OHIP may be able to assist

5 Exclude patients that were not affected

- Patients who are deceased
- Patients to whom the alert/advisory/recall does not apply
- Patients outside the lookback timeframe

6 Involve patients' physicians and other primary treating clinicians (OPTC)

- Physicians/OPTCs whose patients are affected by the lookback and notification should be advised.
- It may be appropriate to notify the patient's family physician (if outside of the healthcare organization) of the lookback and notification.
- Other healthcare organization physicians/OPTCs who may see patients affected by the notification or the alert/advisory/recall should be advised, e.g. Emergency Department physicians.

7 Determine form of notification

- Letter
- In-person
- By telephone
- Website
- Proactive press release
- Multiple methods where necessary

The form of notification will often be dictated by the number of patients involved. For example, if a very large group of patients is to be notified this may make contacting individuals by telephone or in person impractical. If the issue is widespread and/or affecting multiple institutions, all involved healthcare organizations should embark on the same lookback process, and ideally, work from the same template letter or other form of communication.

8 Determine content of notification

- Should be:
    - Accurate
    - Clear and concise
    - Consistent with consensus in the community and/or expert views
    - Consistent with authoritative alerts and/or advisories
- Should include what the alert/advisory/recall is, where it came from and clinical recommendations if appropriate. Authoritative bodies often make clinical recommendations.
- Should distinguish the healthcare organization from the manufacturer/distributor.
- Should provide a mechanism where the patient can obtain further information directly from the healthcare organization or direct care-provider.

HIROC and/or legal counsel should be consulted prior to releasing the notification.

9 Consider communication strategies in parallel with notification

- FAQs
- Hotline
- Website postings
- Proactive press releases

With some alerts/advisories/recalls, information continues to evolve. Website postings allows for information to be regularly updated. Assume the notification letter and all email and other written communications will become public.

10 Notify & track

- Track, document and keep a record of all notifications, patient responses, and returned mail in a centralized manner.
- Notification letters should be delivered by registered mail.
- As necessary, attempt to identify an alternative address.
- Consider placing the notification letter in the health record where appropriate.

11 Prospective considerations

- Continue to monitor the alert/advisory/recall for changes and/or new information.
- Consider what authoritative bodies recommend as prospective clinical management steps.
- Consider whether an informed consent process requires review and revision, if applicable.
- Consider if specific discharge instructions are applicable.
- Consider whether the organization can recover costs of the lookback and notification from the manufacturer/distributor.
- Track costs.
- Consider what information, if any, ought to be stored in a central database.
- Consider the impact of the response to the notification on resources.
- Evaluate the entire lookback and notification process.

Case study

Health Canada issued an alert regarding inferior vena cava (IVC) filters and advised of serious complications occurring in patients implanted with a retrievable IVC filter that had not been removed, including complications of thrombosis and death. The risk was assessed as significant enough to warrant patient notification by the internal evaluation team. In collaboration with other subscribers, there was an agreement that notification should occur. The first subscriber together with BLG and HIROC developed a template letter for notification to patients which was then shared with all HIROC subscribers to enable a uniform and consistent approach. The notification was delivered to hundreds of patients provincially.

Acknowledgements

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4711 Yonge Street, Suite 1600
Toronto, ON M2N 6K8
416-733-2773
Toll Free: 1-800-465-7357

1200 Rothesay Street
Winnipeg, MB R2G 1T7
204-943-4125
Toll Free: 1-800-442-7751

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