National System for Incident Reporting

Privacy Impact Assessment

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Canadian Institute for Health Information
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The Canadian Institute for Health Information (CIHI) is pleased to publish the following privacy impact assessment in accordance with its *Privacy Impact Assessment Policy*:

- **National System for Incident Reporting**

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Ottawa, January 2018

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Quick facts about the National System for Incident Reporting

- The National System for Incident Reporting (NSIR) at the Canadian Institute for Health Information (CIHI) is a voluntary reporting system designed to facilitate sharing of and learning from medication and radiation treatment (RT) incidents. It enables analysis at the local and national levels, and helps to identify rare and emerging patient safety occurrences.
- More than 475 health care facilities currently participate in NSIR. Collectively, they have contributed more than 47,000 medication incidents and more than 1,700 RT incidents.
- Through its web-based application, NSIR collects a standardized set of information on incidents. Individual records can be manually entered as single incidents, or facilities can submit data directly from their local risk management systems via batch upload.
- NSIR does not collect any identifiers (patient, provider or facility).
- NSIR provides users with an Analytical Tool to create summary reports or comparison reports, as well as a Communication Tool to enable private, non-identifying discussions with other participating facilities.
- NSIR is CIHI's contribution to the Canadian Medication Incident Reporting and Prevention System (CMIRPS), a collaboration between Health Canada, CIHI, the Institute for Safe Medication Practices Canada and the Canadian Patient Safety Institute. The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.
- The Canadian Partnership for Quality Radiotherapy is a key collaborator for RT incident reporting.

Definitions

For the purposes of this privacy impact assessment, these terms have the following meanings:

Aggregate data means record-level data related to records of incidents that has been compiled to a level of aggregation that ensures that the identity of individuals cannot be determined by reasonably foreseeable methods.

Client means the organization specified in the NSIR Service Agreement, for either data providers or non-submitters, that is binding itself to comply with the terms of the agreement.

Designated user means a client's employee or permitted contractor (e.g., partner organization) that has been authorized by the client to access and use NSIR.

Data provider means any federal/provincial/territorial ministry, department or agency, regional health authority, health care facility, public or private institution, or organization participating in NSIR that provides incident records to CIHI.

Incident record means record-level data related to records of medication or RT incidents provided to CIHI for the purposes of NSIR.

Medication incident means any preventable circumstance or event that may cause or lead to inappropriate medication use or patient harm while the medication/IV fluid is in the control of the health care professional, patient or consumer.

NSIR data means all de-identified record-level incident data contained within NSIR and any aggregate data generated by NSIR.

Own data means medication and/or RT incident records that were originally provided to CIHI by a data provider for the purposes of NSIR.

Partner organization means an organization that has entered into an NSIR Service Agreement for Non-Submitters with CIHI, which permits it to access NSIR for the purposes specified in the agreement.

Radiation treatment incident means any preventable circumstance or event related to patient assessments, imaging, treatment planning and delivery, pre-treatment review and verification, quality management and post-treatment completion that causes harm or has the potential to cause harm.

1 Introduction

The Canadian Institute for Health Information (CIHI) collects and analyzes information on health and health care in Canada. Its mandate is to deliver comparable and actionable information to accelerate improvements in health care, health system performance and population health across the continuum of care. CIHI obtains data from hospitals and other health care facilities, long-term care homes, regional health authorities (RHAs), medical practitioners and governments. This data includes information about health services provided to individuals, the health professionals who provide those services and the cost of the health services.

The purpose of this privacy impact assessment (PIA) is to examine the privacy, confidentiality and security risks associated with the newly implemented radiation treatment (RT) incident reporting module in the National System for Incident Reporting (NSIR). This PIA, which replaces the November 2015 version, includes a review of the 10 privacy principles set out in the Canadian Standards Association's *Model Code for the Protection of Personal Information*, as the principles apply to NSIR, and the application of CIHI's *Privacy and Security Risk Management Framework*.

The primary driver for this PIA is compliance with CIHI's Privacy Impact Assessment Policy.

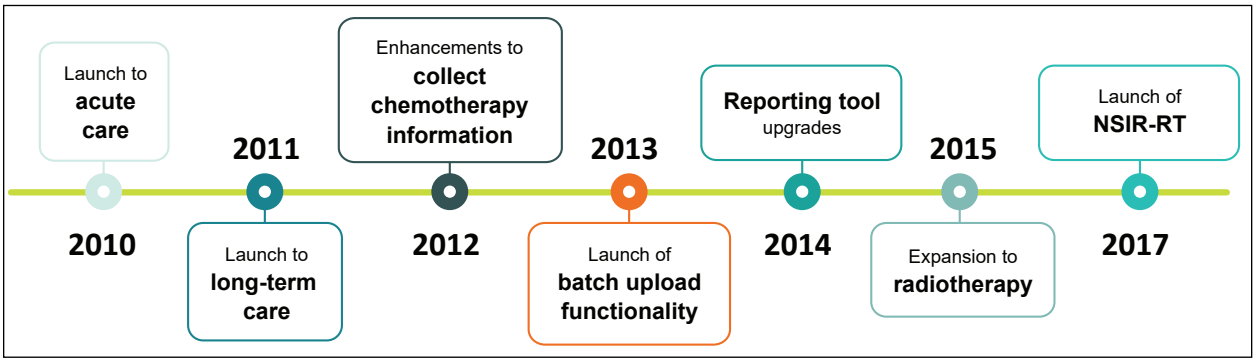
2 Background

Incidents are, by definition, preventable events. Examples include prescribing Lasix for a patient instead of Losec (medication incident) or performing RT on the wrong anatomical site (RT incident). NSIR aims to identify how incidents occur in Canadian health care facilities and how similar incidents may be prevented. NSIR is a voluntary reporting system designed to securely and anonymously support the collection, sharing and analysis of standardized incident data. Anonymized reporting encourages participation and protects the identity of patients, providers and facilities who participate in NSIR. Its data and related analyses inform quality improvement activities at local, regional, provincial, territorial and national levels to foster improvements in health care delivery.

2.1 Introduction to NSIR

NSIR officially launched in 2010. At that time, its focus was to collect medication incident data from acute care health care facilities across Canada. Since then, NSIR has steadily expanded its scope. The collection of medication incident data from long-term care (LTC) facilities was launched in 2011, and the collection of RT incident data was launched in 2017.

Figure 1 NSIR timeline



NSIR is part of the multi-organizational Canadian Medication Incident Reporting and Prevention System (CMIRPS) initiative, which contributes information, tools and expertise to the prevention of harmful medication incidents. CIHI's contribution to CMIRPS is NSIR, which collects medication incident data from Canadian health care facilities. The NSIR system includes the Analytical and Communication tools to support the analysis and sharing of medication incidents and preventive strategies. CIHI produces analytical reports from the NSIR data to support enhancements to the medication use system.

In 2015, CIHI collaborated with the Canadian Partnership for Quality Radiotherapy to develop and implement NSIR-RT, a national system for reporting RT incidents in Canada. NSIR-RT was built as a response to the need for a dedicated, scalable RT incident management system to support not only local quality improvement activities, but also incident learning across programs and jurisdictions.

The 2 types of NSIR users are data providers and partner organizations; they are collectively referred to as clients (see the Definitions section). Data providers include participating organizations that submit and analyze NSIR data according to their signed service agreements. Partner organizations have signed a specific agreement, the NSIR Service Agreement for Non-Submitters, that allows them to access NSIR data for specified analytical purposes.

As of April 2017, clients of NSIR include the following:

Data providers

- Health care facilities (e.g., hospitals, LTC facilities)
- Cancer treatment centres
- RHAs
- Provincial/territorial ministries of health
- Organizations that submit data on behalf of facilities and RHAs (e.g., BC Patient Safety & Learning System)

Partner organizations

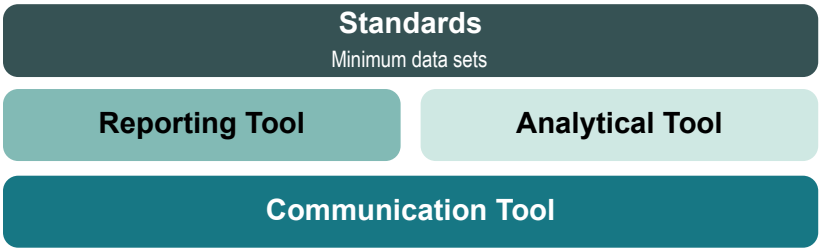
- Institute for Safe Medication Practices Canada
- Health Canada (Marketed Health Products Directorate)
- Saskatchewan Ministry of Health
- Ontario Ministry of Health and Long-Term Care
- Cancer Care Ontario
- Health Quality Ontario

NSIR's objectives for both medication and RT incidents are to

- Collect high-quality standardized incident data;
- Facilitate sharing of and learning from incidents;
- Enable analysis at local, regional and national levels;
- Identify rare and emerging patient safety occurrences; and
- Develop partnerships that create and disseminate strategies, recommendations and solutions to patient safety issues.

2.2 Data collection

NSIR includes a minimum data set (MDS) for each of medication incident records and RT incident records (see Table 1 and appendices A and B) and the following tools:



Reporting Tool

Data providers electronically submit data using the Reporting Tool. It is a secure web-based application designed to accept incident records using 1 of 2 methods: the single-incident submission method or the batch upload method. Individual records can be entered using the single-incident submission method. Facilities can submit multiple incident records that have been extracted and grouped together as a batch file.

Data providers use the Reporting Tool to submit a number of mandatory and optional data elements (see Table 1 and appendices A and B). This includes a text field for a description of the incident, which provides a detailed, factual description of what happened during the incident.

Analytical Tool

De-identified incident records released to the NSIR repository can be accessed via a business intelligence tool that allows designated users of data providers and partner organizations to build template reports that can be customized to some extent. Reports generated by users are anonymous and do not identify the source facilities, except in situations where a data provider is accessing its own data, or where a user has granted another user permission to view data that identifies the health facility. Within any NSIR report, users are able to drill down from aggregate totals to individual de-identified incident records and export results into PDF or Microsoft Excel format. Comparison reports, subject to the service agreement, allow for provincial, regional, corporation, site-level and peer group (i.e., groups of similar facilities) views.

Communication Tool

The Communication Tool is similar to a web-based email application. It allows for non-identifying (private and anonymous) discussion between data providers. Messages sent by data providers are anonymous — email addresses of senders and recipients are replaced with system-generated facility pseudonyms to maintain anonymity. Within NSIR, individual de-identified incident records include a hyperlink to the Communication Tool, where users can also send an anonymous email to the submitting facility.

CIHI and the partner organizations can also send emails via the Communication Tool, but their emails are not anonymous. They are not assigned a pseudonym and are identified by organizational name in their messages to and from other NSIR users.

Table 1 Information domains for the NSIR minimum data sets

Information domain	Medication incident MDS (Appendix A)	RT incident MDS (Appendix B)
Incident Impact	Categorization of the outcomes (actual and/or potential) and effects of the incident	Characterization of the incident (actual/near miss/programmatic hazard) and effects (acute, dosimetric and latent) of the incident
Incident Discovery	The discovery of the incident: time, place and roles of health providers associated with the incident	
Patient/Resident Characteristics	Demographic characteristics of the patient	Demographic and disease characteristics of the patient
Incident Details	Specific medication incident details	Specific RT incident details

Information domain	Medication incident MDS (Appendix A)	RT incident MDS (Appendix B)
Drug Product Information	Information pertaining to drug product(s) reported in the incident, such as drug name, strength, form and route	n/a
Treatment Delivery	n/a	Specific details regarding the treatment delivery, including the RT technique, dose and fraction prescription, technologies and equipment used, site treated and treatment intent
Incident Investigation and Findings	Information pertaining to actions planned or implemented to help prevent a similar incident from occurring in the future	Information pertaining to actions taken to ameliorate the incident outcome, as well as to safety barriers and actions planned to reduce the risk of incident recurrence

Note
n/a: Not applicable.

One of the guiding principles for the development of NSIR was anonymity of patients/residents, health care providers and health care facilities. As a result, the de-identified incident records held in NSIR cannot be used to determine the identity of patients or providers by a reasonably foreseeable method (see Section 3.6).

2.3 Data flow and access to NSIR data

Data flow

This description of NSIR data flow is illustrated in Figure 2.

In NSIR, each record is a single incident. As of October 2017, NSIR contained more than 47,000 medication incidents and 1,700 RT incidents submitted by more than 475 health care facilities.

When an incident occurs (medication or RT), it is reported within the health care facility and reviewed internally. Once the internal review is complete, the incident record is sent from a data provider to CIHI. Data is submitted from data providers to NSIR through the Reporting Tool, either via single-incident or batch upload method. For single-incident submissions, incident data is entered directly into NSIR. For batch submissions, incident data entered in the data provider's incident reporting system is extracted and securely transmitted to NSIR via the batch upload method. Once received in NSIR, all incident records, regardless of whether they were received through the single-incident or batch submission, undergo a 2-step data quality assessment process.

Step 1: Automated data quality processing

The first step is an automated process, where codified data is assessed to be valid and in the proper format.

Single-incident submissions

For single-incident submissions, edit checks are performed automatically by the system as the details of an incident are entered. If the record passes all the edit checks, all data moves on to Step 2, manual data quality processing (see below). If any data quality issues are discovered in Step 1, they are flagged in real time to data providers to be corrected.

Batch submissions

For batch submissions, edit checks are also performed automatically. If the record passes all the edit checks, all data moves on to Step 2 (see below). However, unlike with single-incident submissions, any data quality issues discovered in Step 1 are returned to data providers by way of a submission report via the batch upload method. Corrections made by data providers are resubmitted to NSIR via the batch upload method.

Step 2: Manual data quality processing

The second step is a manual data quality review process that focuses on the text fields of incident records. These are reviewed daily by the NSIR support team for the presence of any personal and geographic identifiers (e.g., actual names, initials, abbreviations) that may be associated with patients/residents, health care providers and health care facilities that may have been submitted inadvertently by the data provider.

If no issues are discovered, the incident record (including both codified and text data fields) is made available within 24 hours for analysis and reporting by all those authorized to access and use NSIR.

If any issues are discovered, the incident records are returned to data providers for correction. The record is suppressed until the data provider makes the correction (i.e., removes the identifier). Once the correction has been confirmed by NSIR staff, these incident records are deemed to be de-identified and are released into the NSIR repository, where they are made available within 24 hours for analysis and reporting by all those authorized to access and use NSIR.

The NSIR team reviews text fields in both single incidents and batch submissions of data. The team works with data providers to establish the level of monitoring required for text fields. This depends in large part on the data provider's level of experience and compliance with data submission requirements, the data quality processes in place at the submitting facility and the

quality of the data received. The degree of scrutiny of CIHI's data quality review process will be determined together with the data provider to balance the risk of an identifier appearing in an NSIR record with the resources needed by both organizations to mitigate these risks. The batch submission of incident data brings unique challenges with the review of text fields due to the potential large volume of data that may be received at a time and the resources required to review and release these records in a timely manner. In contrast, single-incident submissions are received in much smaller numbers and are generally easier to manage.

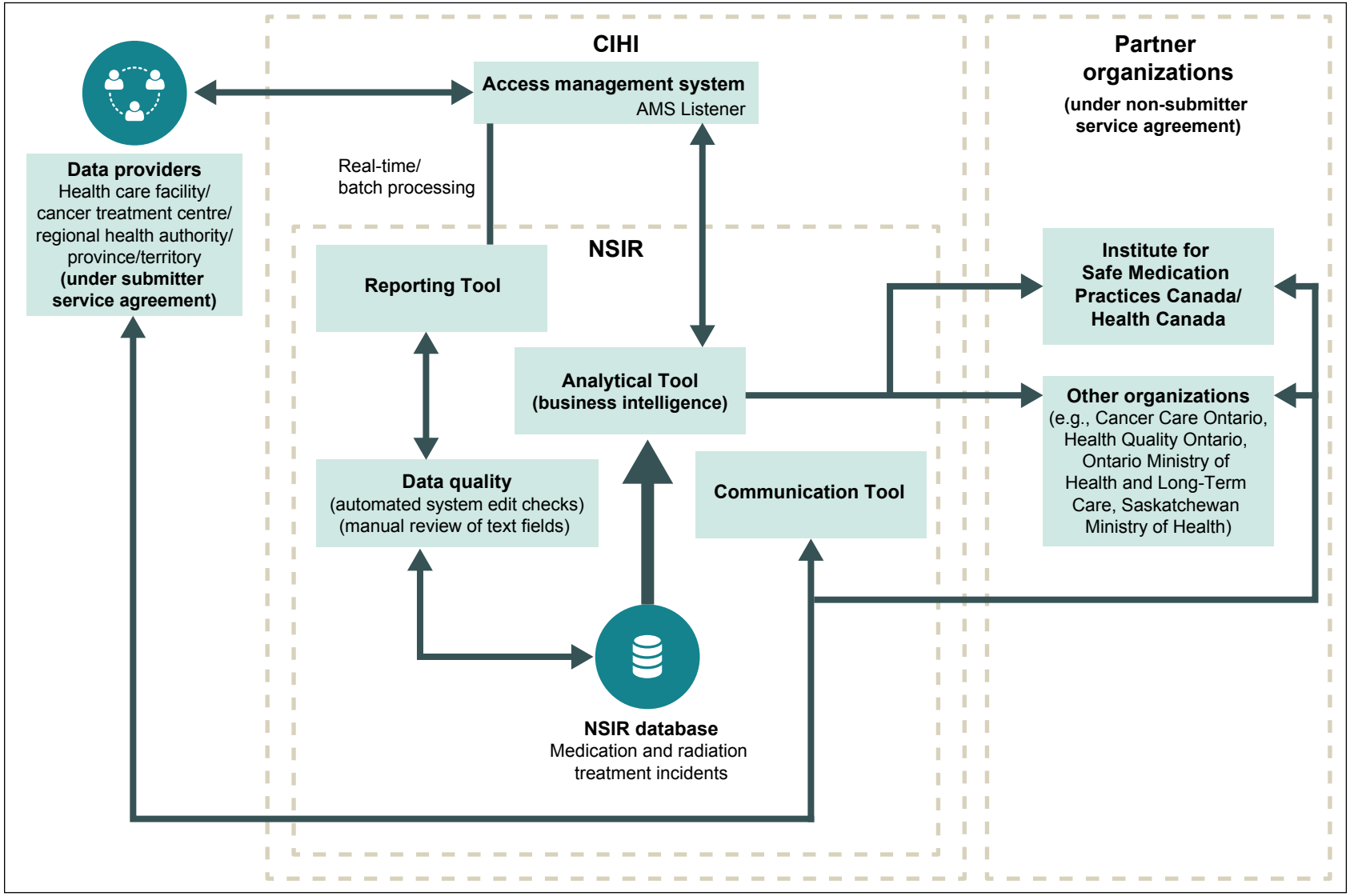
As of December 2017, only the BC Patient Safety & Learning System submits via batch. In order to manage the resources required to review text fields, it currently submits 2 levels of medication incident data to NSIR based on the data element Degree of Harm:

1. Records of critical incidents (incidents that result in severe harm or death of a patient) are submitted with both codified and text field information; whereas

2. Incident records with a lesser Degree of Harm recorded (i.e., reportable circumstance, near miss, none, mild, moderate) are submitted with only codified data and do not contain any text field information.

This process will be re-evaluated in the future.

Figure 2 Overview of NSIR data flow



Access management

The Central Client Services (CCS) department provides first-tier support to data providers who want to access CIHI's electronic products and services. Prior to granting access, CIHI determines whether it needs to enter into an agreement with the client. The criteria for determining whether an agreement is needed are based, in part, on the following:

- The applications themselves that need to be accessed and the nature of the activity;
- The sensitivity of the data being accessed;
- The volume of personal health information being returned; and
- Whether health facility–identifiable information by name is being disclosed.

NSIR clients are required to sign a service agreement that contains a schedule that is specific to each client (see Section 3.2).

All NSIR data flows in and out of CIHI through secure web-based applications. Authorized users are required to set up a CIHI profile. Once authenticated, users can log in to CIHI's Client Services and log in to those applications they are authorized to access.

NSIR is designed to support learning and sharing, and anonymity of data providers is paramount. In addition to the use of pseudonyms, as described in Section 2.2, access management ensures NSIR data is accessible only by those authorized to access and use the NSIR system to submit incidents and analyze data. This includes data providers (medication and RT incidents) and partner organizations.

Access permissions are managed by CCS through established access management system (AMS) processes for granting and revoking access. The process of granting access permissions to NSIR is a coordinated effort between data providers, the NSIR team and CCS. The approach used to provide access to authorized users is role-based access control to either the medication incident or RT modules, or both.

The key components of the AMS process include the following:

Clients

- Enter into a service agreement with CIHI, where appropriate.
- Assign a designated organization contact.
- Identify designated users through the organization contact.

CCS

- Authenticate access requests from designated users by
  - Verifying that designated users are affiliated with the correct organization;
  - Contacting the appropriate organization contact to verify the designated user and to obtain approval from the organization contact for the access request; and
  - Granting the appropriate access privileges following authentication.

NSIR team

- Audit the emails generated by AMS Listener (see below) after CCS has granted access to users.

AMS Listener

AMS Listener is an optional notification feature developed to further reduce the risk of unauthorized access to CIHI's restricted services. Manual audits are triggered when access is granted to a new user of NSIR or when changes are made to an existing user's access privileges. Program area staff monitor the alerting mechanisms within the AMS application. If staff suspect or identify that an incorrect type of access was granted, they immediately alert CCS to disable access and send an email to incident@cihi.ca in compliance with CIHI's *Privacy and Security Incident Management Protocol*.

Access to data within NSIR

A second layer of access management requirements has been implemented for NSIR, based on the stages involved in creating and completing NSIR records. See Table 2 for an overview of who can access what data in NSIR from the time incident records are created to the time they are released into the NSIR repository.

Table 2 User access by affiliation during staging of NSIR records

Stage/condition of records	Access by user's affiliation			
	Data provider (source facility)	Data provider (non-source facility)	CIHI (NSIR team)	Partner organization
Stage 1: Pre-submission (draft) *Single-incident processing:* Incident records are entered in NSIR but not submitted. *Batch submission:* Incident records reside in the data provider's incident reporting system. No records have been extracted via the batch upload method.	Yes	No	No	No
Stage 2: Submitted (under review) Incident records have been submitted via single-incident or batch processing through NSIR's Reporting Tool. Incident records undergo 2-step data quality processing: *Step 1:* Automated review of codified data *Step 2:* Manual review of text fields	Yes	No	Yes	No
Stage 3: Complete (final) 2-step data quality processing is complete and all issues have been corrected. Incident records are de-identified and released into the NSIR repository for analysis and reporting. Users are able to drill down from aggregate totals to individual de-identified incident records.	Yes	Yes Reports are anonymous and do not identify the source facilities	Yes	Yes Reports are anonymous and do not identify the source facilities

3 Privacy analysis

3.1 Privacy and Security Risk Management Program

Privacy and security risk management is a formal, repeatable process for identifying, assessing, treating and monitoring risks in order to minimize the probability of such risks materializing and/or their impact should they occur. In 2015, CIHI approved its *Privacy and Security Risk Management Framework* and implemented the associated *Policy on Privacy and Security Risk Management*. CIHI's chief privacy officer and chief information security officer, in collaboration with senior managers, are responsible for identifying, assessing, treating, monitoring and reviewing privacy and security risks.

Privacy and security risks may be identified from a variety of sources, including PIAs. Once identified, risks are entered into the Privacy and Security Risk Register and categorized as **high**, **medium** or **low** based on the likelihood and impact of a risk event.

- **High:** High probability of risk occurring and/or controls and strategies are not reliable or effective.
- **Medium:** Medium probability of risk occurring and/or controls and strategies are somewhat reliable or effective.
- **Low:** Low probability of risk occurring and/or reliable, effective controls and strategies exist.

The likelihood and impact of the identified risk are used to create a risk score. The risk assessment score of low, medium or high defines how serious a risk is. A higher risk ranking indicates a more serious threat and a greater imperative for treatment. Once an initial risk treatment is applied, the residual risk (the new calculation of the likelihood and impact of the risk given the treatment) is assessed and compared against CIHI's privacy and security risk tolerance statement, which indicates that CIHI's privacy and security risk tolerance is low. If the risk score for the residual risk is still greater than low, additional risk treatment is necessary until the risk is low or the untreated/residual risk is accepted by CIHI's Senior Management Committee on behalf of the corporation.

3.2 Authorities governing NSIR

General

CIHI adheres to its Privacy Policy, 2010 and to any applicable privacy legislation and/or agreement.

Legislation

CIHI is a secondary data collector of health information, specifically for the planning and management of health systems, including statistical analysis and reporting. Data providers are responsible for meeting the statutory requirements in their respective jurisdictions, where applicable, at the time the data is collected.

The following provinces and territories have enacted health information–specific privacy legislation: Newfoundland and Labrador, Prince Edward Island, Nova Scotia, New Brunswick, Ontario, Manitoba, Saskatchewan, Alberta, Yukon and the Northwest Territories. Health information–specific privacy legislation authorizes facilities to disclose personal health information without patient consent for purposes of health system use, provided that certain requirements are met. For example, CIHI is recognized as a prescribed entity under the *Personal Health Information Protection Act* of Ontario, so health information custodians in Ontario may disclose personal health information to CIHI without patient consent pursuant to Section 29 as permitted by Section 45(1) of the act.

For provinces and territories that do not currently have health information–specific privacy legislation in place, facilities are governed by public-sector legislation. This legislation authorizes facilities to disclose personal information for statistical purposes, without an individual's consent.

Agreements

NSIR data is governed by CIHI's Privacy Policy, 2010, legislation in the jurisdictions and existing data-sharing agreements with the provinces and territories. The data-sharing agreements set out the purpose, use, disclosure, retention and disposal requirements of personal health information provided to CIHI, as well as any subsequent disclosures that may be permitted. The agreements also describe the legislative authority under which personal health information is disclosed to CIHI.

As previously indicated in Section 2.1, data providers and participating organizations are required to sign the NSIR Service Agreement, which governs access to and use of NSIR and use and disclosure of NSIR data. It outlines the obligations around access to NSIR data, as well as its security, use and disclosure. The service agreement is signed at a senior level in the organization to ensure that clients are aware of both their organizational responsibilities and the responsibilities of their users.

The service agreement contains a schedule that is specific to each client and sets out the terms and conditions under which de-identified record-level data and/or aggregate data generated by NSIR is accessed, used and disclosed. The terms and conditions set out in the agreement include, in general, the following:

- A prohibition against using NSIR data from data providers to attempt to identify individuals, health care facilities, RHAs, ministries, provinces or territories;
- A requirement to obtain CIHI's written permission prior to publicly reporting information;
- A requirement to immediately notify CIHI of any unauthorized use, access or other breach of confidentiality or security of which the client becomes aware; and
- A requirement to ensure that those authorized to access and use NSIR complete the NSIR training.

Compliance with the terms and conditions of the agreements is mandatory. Failure to uphold the terms and conditions could result in termination of access to NSIR data.

3.3 Principle 1: Accountability for de-identified NSIR data

CIHI's president and chief executive officer is accountable for ensuring compliance with CIHI's Privacy Policy, 2010. CIHI has a chief privacy officer and general counsel, a corporate Privacy, Confidentiality and Security team, a Governance and Privacy Sub-Committee of its Board of Directors and an external chief privacy advisor.

Organization and governance

Table 3 identifies key internal senior positions with responsibilities for NSIR data in terms of privacy and security risk management.

Table 3 Responsibility for NSIR

Position/group	Role/responsibilities
Vice President, Programs	Responsible for the overall operations and strategic direction of NSIR
Director, Pharmaceuticals and Health Workforce Information Services	Accountable for NSIR and responsible for strategic and operational decisions about NSIR, and for ensuring its continued successful development
Manager, Pharmaceuticals	Responsible for ongoing management, development and deployment of NSIR, and chair of the NSIR Advisory Committee
NSIR Advisory Committee	Responsible for providing input and advice to facilitate the ongoing management of and enhancements to NSIR
Vice President and Chief Technology Officer	Responsible for the strategic direction and overall operations and implementation of CIHI's technological and security solutions
Chief Information Security Officer	Responsible for the strategic direction and overall implementation of CIHI's Information Security Program
Chief Privacy Officer and General Counsel	Responsible for the strategic direction and overall implementation of CIHI's Privacy Program
Manager, ITS Product Delivery	Responsible for ensuring that technical requirements for the ongoing development and maintenance of NSIR are met

3.4 Principle 2: Identifying purposes for de-identified NSIR data

NSIR supports the secure and anonymous collection, sharing and analysis of incidents occurring in Canadian health care facilities. The aim is to reduce the occurrence of harmful incidents by helping to identify how incidents occurred and how similar incidents may be prevented. These intended purposes and the scope of NSIR are clearly identified in this PIA (see Section 2.1), in NSIR reports and bulletins, and on CIHI's website (cihi.ca).

3.5 Principle 3: Consent for the collection, use or disclosure of de-identified NSIR data

CIHI is a secondary collector of data and does not have direct contact with patients. CIHI relies on the data providers to abide by and meet their data collection, use and disclosure rules and responsibilities, including those related to consent and notification, as outlined in jurisdiction-applicable laws, regulations and policies.

3.6 Principle 4: Limiting collection of de-identified NSIR data

CIHI is committed to the principle of data minimization. Per sections 1 and 2 of CIHI's Privacy Policy, 2010, CIHI collects from data providers only the information that is reasonably required for health system uses, including statistical analysis and reporting, in support of the management, evaluation or monitoring of health care systems.

CIHI limits the collection of data to that which is necessary to achieve the purposes and goals of NSIR. The NSIR MDS and NSIR-RT MDS (see Table 1 and appendices A and B) were developed in collaboration with an extensive network of experts. For patients/residents, month and year of birth and sex are optional data elements to collect, and they can be used to group incidents by patient/resident demographics. For health care providers, job role (e.g., registered nurse, radiation therapist) is also optional and can be used to group incidents by the role of the individuals involved in the incident.

From a privacy perspective, NSIR is designed to securely and anonymously collect, share, analyze and discuss incidents without disclosing the identity of any individual. It does not include the collection of direct identifiers (e.g., patient/resident-identifiable information such as name, health card number, chart number or date of admission or discharge; provider-identifiable information such as name or registration number).

The only possible source of patient, provider or facility identifiers would be in one of the following NSIR text fields:

Medication incident reporting

- Description of Incident
- Future Strategies/Recommendations
- Actions/Circumstances That Prevented Harm
- Special Drug Product Name
- Drug Product Batch/Lot Number

RT incident reporting

- Description of Incident

Currently, text fields for all incidents submitted to NSIR are manually reviewed daily. The NSIR team searches for any reference to a patient, provider or facility that could identify the source of the incident or those involved. To date, no patient identifiers have been found in the more than 47,000 medication incident records submitted to NSIR, while 39 facility and 46 provider identifiers have been detected; all were identified and removed before the associated records were released into NSIR. During the RT national pilot test, no patient or facility identifiers were found in the incidents submitted.

When the batch upload method was launched in late 2013, the risk of an identifier being included in incident report text fields was revisited. It was determined that the risk would likely increase because there would be

- Variability in data quality activities on the part of the data providers (especially in the case of regional users, where there would be significant growth in the number of registered health care facilities); and
- Increased risk of human error due to an anticipated significant increase in the volume of data submitted and more frequent data submission.

The NSIR team reviews all incidents received via batch submission for identifiers as it does for those submitted as single incidents. As noted in Section 2.3, over time, the NSIR team may choose to conduct a more limited review of text fields on a case-by-case basis. This may depend on the data provider's level of experience and compliance with data submission requirements, the data quality processes in place at the submitting facility and the quality of the data received.

Privacy risk: Patient, provider and facility identifiers inadvertently submitted to NSIR by data providers

Mitigation measures currently in place

- As described in Section 2.3, the text fields in all incident records are manually reviewed for the presence of any identifiers associated with patients/residents, health care providers and health care facilities.
- Agreements with data providers and partner organizations prohibit them from using NSIR data to attempt to identify individuals, health care facilities, RHAs, ministries, provinces or territories.
- Education/training is mandatory for those authorized to access and use the system. Users are informed that NSIR is anonymous and that identifiers are not to be included in the text fields.
- Agreements with data providers and partner organizations include a requirement to notify CIHI if they believe they have access to NSIR data that is identifiable or potentially identifiable that is not specified in their agreement. If this is the case, CIHI may require the records to be securely destroyed.

Risk assessment[i]

Following the application of CIHI's Privacy and Security Risk Assessment Methodology for the above risk, the risk score was assessed to be low. No recommendations were made. However, as new batch submissions are received, the NSIR team will reassess the process for reviewing text fields on a case-by-case basis. Any reassessment of this nature will be included in CIHI's Privacy and Security Risk Register.[ii]

3.7 Principle 5: Limiting use, disclosure and retention of de-identified NSIR data

Limiting use

CIHI limits the use of NSIR data to authorized purposes, as described in sections 2.1 and 3.4. These include comparative analyses within and among jurisdictions; trend analyses to assess/monitor the impact of differences in policy, practices and service delivery; and production of statistics to support planning, management and quality improvement. CIHI staff are permitted to access and use data on a need-to-know basis only, including for data processing and quality management, producing statistics and data files, and conducting analyses. All CIHI staff are required to sign a confidentiality agreement at the commencement of employment, and they are subsequently required to renew their commitment to privacy yearly.

Data linkage

NSIR data is de-identified and does not contain identifiers (e.g., name, health care [card] number) that allow for data linkages to be performed.

Return of own data

In addition to returning data to submitting facilities, Section 34 of CIHI's Privacy Policy, 2010 establishes that CIHI may return records to the relevant ministry of health for data quality purposes and for purposes consistent with its mandate (e.g., health services and population health management, including planning, evaluation and resource allocation). The return of own data is considered a use and not a disclosure.

CIHI may return NSIR data, as authorized, via NSIR, as described in Section 2.3. CIHI routinely makes available to data providers data quality reports (e.g., submission reports) on the outcome of their data submissions to NSIR.

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i. Risk assessment is the establishment of the likelihood and impact of risks to determine the overall potential harm they may cause. Risks are assessed as low, medium or high based on the risk assessment matrix; the score defines the seriousness of a risk. A higher risk ranking indicates a more serious threat and a greater imperative for treatment.

ii. A consolidated list of CIHI's current identified privacy and security risks.

As stipulated in the service agreement, at their sole risk, data providers may disclose their own identifiable data in any manner they choose or otherwise forego the confidentiality of some or all of their data.

Limiting disclosure

Public use

As part of its mandate, CIHI publicly releases aggregate data only in a manner designed to minimize any risk of identification and residual disclosure. This generally requires a minimum of 5 observations per cell. Aggregate statistics and analyses are made available in publications and on CIHI's website (cihi.ca).

For analytical studies and reports, NSIR partner organizations are limited to publishing aggregate data, with no cell sizes less than 5 units of observation, unless they have received express prior written authorization from the data providers to do otherwise.

As described in Section 3.2, clients (data providers and partner organizations) who enter into an NSIR Service Agreement have specified terms and conditions under which they can disclose NSIR data. Clients are prohibited from disclosing incident records in any manner except as otherwise permitted under the agreement, as required by law or where express prior written authorization from the data provider has been obtained.

Third-party data requests

To date, NSIR has not processed any external third-party data requests. Any future requests will be considered on a case-by-case basis in accordance with CIHI's Privacy Policy, 2010. Only CIHI may respond to third-party data requests; under the terms of the service agreements for data providers and non-submitters, those organizations must refer third-party requests to CIHI. If CIHI were to consider responding to a third-party data request, an assessment of the privacy risks would be undertaken and data would be disclosed in accordance with its Privacy Policy, 2010 and through its Third-Party Data Request Program that contains and ensures appropriate privacy and security controls within the recipient organization.

Limiting retention

NSIR data forms part of CIHI's data holdings and, consistent with CIHI's mandate and core functions, CIHI retains such information for as long as necessary to meet the identified purposes. Medication incident data collection began in November 2008 and RT incident data collection began in September 2015 with the NSIR-RT pilot.

Clients are permitted to retain NSIR data and analytical products for as long as their agreement with CIHI is in effect. Data providers can retain their own data in accordance with their organization's own record retention policies.

3.8 Principle 6: Accuracy of de-identified data

CIHI has a comprehensive Information Quality Program. Any known data quality issues are addressed by the data provider or documented in data limitations documentation, which CIHI makes available to all users.

Similar to other CIHI data holdings, NSIR is subject to a data quality assessment on a regular basis, based on *CIHI's Information Quality Framework*. The process of completing the framework includes numerous activities to assess the various dimensions of quality, including the accuracy of the NSIR data. A full data quality assessment was completed in 2017 that included a review of the NSIR medication data, as well as the RT data from the 15-month pilot study. The RT pilot data was further examined in the pilot evaluation report, which identified issues with 3 data elements and recommended changes.

3.9 Principle 7: Safeguards for de-identified data

CIHI's Privacy and Security Framework

CIHI has developed a Privacy and Security Framework to provide a comprehensive approach to privacy and security management. Based on best practices from across the public, private and health sectors, the framework is designed to coordinate CIHI's privacy and security policies and to provide an integrated view of the organization's information management practices. Key aspects of CIHI's system security with respect to NSIR are highlighted below.

System security

CIHI recognizes that information is secure only if it is secure throughout its entire life cycle: creation and collection, access, retention and storage, use, disclosure and disposition. Accordingly, CIHI has a comprehensive suite of policies that specifies the necessary controls for the protection of information in both physical and electronic formats, up to and including robust encryption and secure destruction. This suite of policies and the associated standards, guidelines and operating procedures reflect best practices in privacy, information security and records management for the protection of the confidentiality, integrity and availability of CIHI's information assets.

System control and audit logs are an integral component of CIHI's Information Security Program. CIHI's system control and audit logs are immutable. Analysis at CIHI is generally conducted with the use of de-identified record-level data, where the health care number has been removed or encrypted upon first receipt. In exceptional instances, staff will require access to original health care numbers. CIHI's internal Privacy Policy and Procedures, 2010 sets out strict controls to ensure that access is approved at the appropriate level and in the appropriate circumstances, and that the principle of data minimization is adhered to at all times. CIHI logs the following data:

- Access to health care numbers and patient names (rarely collected) within CIHI's operational production databases;
- Access to data files containing personal health information extracted from CIHI's operational production databases and made available to the internal analytical community on an exceptional basis; and
- Changes to permissions in access to operational production databases.

CIHI's employees are made aware of the importance of maintaining the confidentiality of personal health information and other sensitive information through a mandatory privacy and security training program and through ongoing communications about CIHI's privacy and security policies and procedures. Employees attempting to access a CIHI information system must confirm, prior to each login attempt, their understanding that they may not access or use the computer system without CIHI's express prior authority or in excess of that authority.

CIHI is committed to safeguarding its information technology ecosystem, securing its data holdings and protecting information with administrative, physical and technical security safeguards appropriate to the sensitivity of the information. Audits are an important component of CIHI's overall Information Security Program; they are intended to ensure that best practices are being followed and to assess compliance with all information security policies, procedures and practices implemented by CIHI. Audits are used to assess, among other things, the technical compliance of information-processing systems with best practices and published architectural and security standards; CIHI's ability to safeguard its information and information-processing systems against threats and vulnerabilities; and the overall security posture of CIHI's technical infrastructure, including networks, servers, firewalls, software and applications.

An important component of CIHI's audit program is regular third-party vulnerability assessments and penetration tests of its infrastructure and selected applications. All recommendations resulting from third-party audits are tracked in the Corporate Action Plan Master Log of Recommendations, and action is taken accordingly.

3.10 Principle 8: Openness about the management of personal health information

CIHI makes information available about its privacy policies, data practices and programs relating to the management of personal health information. Specifically, CIHI's Privacy and Security Framework and Privacy Policy, 2010 are available to the public on its corporate website (cihi.ca).

3.11 Principle 9: Individual access to, and amendment of, personal health information

The data in NSIR does not contain any personal identifiers (e.g., name, address, health card number).

3.12 Principle 10: Complaints about CIHI's handling of personal health information

As set out in sections 64 and 65 of CIHI's Privacy Policy, 2010, complaints about CIHI's handling of personal health information are investigated by the chief privacy officer, who may direct an inquiry or complaint to the privacy commissioner of the jurisdiction of the person making the inquiry or complaint.

4 Privacy assessment summary and conclusion

This PIA summarizes CIHI's assessment of the privacy implications of NSIR and the newly launched NSIR-RT module. This assessment focuses on the addition of the RT module, including new data elements and data providers.

The risks associated with the collection of RT incidents are the same as those for the collection of medication incident data and no new risks, specific to RT incidents, were identified. The NSIR team will continue to apply the same rigorous data quality process to review all text fields for identifiers submitted in medication and RT records prior to making them accessible in the NSIR repository. Any changes to process or risk value resulting from reassessments of this nature are to be included in CIHI's Privacy and Security Risk Register.

This PIA will be updated or renewed in compliance with CIHI's Privacy Impact Assessment Policy.

Appendix A: National System for Incident Reporting — Medication Minimum Data Set

Mandatory and optional data elements are specified based on the Degree of Harm of the medication incident.

M = Mandatory O = Optional n/a = Not applicable

Data element number	Data element name	Reportable circumstance	Near miss	None	Mild	Moderate	Severe	Death
1.0	**Incident Impact**							
1.1	Description of the Medication Incident	O	O	O	O	O	O	O
1.2	Degree of Harm	M	M	M	M	M	M	M
1.3	Potentially Severe Medication Incident	M	M	M	M	M	n/a	n/a
2.0	**Incident Discovery**							
2.1	Functional Area(s)	M	M	M	M	M	M	M
2.2	Ward/Unit	O	O	O	O	O	O	O
2.3	Date Incident Was Detected	M	M	M	M	M	M	M
2.4	Time Incident Was Detected	O	M (1)†	M (1)†	M (1)†	M (1)†	M (1)†	M (1)†
2.5	Time Period When Incident Was Detected							
2.6	Date Incident Occurred	n/a	O	O	O	O	O	O
2.7	Time Incident Occurred	n/a	O (1)†	O (1)†	O (1)†	O (1)†	O (1)†	O (1)†
2.8	Time Period When Incident Occurred							
2.9	Health Care Provider(s) and/or Others Who Detected Incident	O	O	O	O	O	O	O
2.10	Health Care Provider(s) and/or Others Who Were Involved in Incident	O	O	O	O	O	O	O

Data element number	Data element name	Reportable circumstance	Near miss	None	Mild	Moderate	Severe	Death
3.0	**Patient/Resident Characteristics**							
3.1	Month and Year of Birth	n/a	O	M	M	M	M	M
3.2	Patient/Resident Sex	n/a	O	M	M	M	M	M
4.0	**Medication Incident Details**							
4.1	Medication/IV Fluid Use Process‡	M	M	M	M	M	M	M
4.2	Medication/IV Fluid Problem‡	M	M	M	M	M	M	M
4.3	Repeated Administrations	n/a	n/a	O	O	O	O	O
4.4	Contributing Factor(s)‡	M	M	M	M	M	M	M
4.5	Chemotherapy Regimen	O	O	O	O	O	O	O
5.0	**Drug Product Information**							
5.1	Type of Drug Product	*	M	M	M	M	M	M
5.2	Drug Identification Number (DIN)	**Note** Only 1 value for data elements 5.2 to 5.5 is required.						
5.3	Generic Name of Drug Product							
5.4	Brand Name of Drug Product							
5.5	Special Drug Product Name							
5.6	Correct or Incorrect Drug Product	*	*	*	*	*	*	*
5.7	Dosage Form	O	O	O	O	O	O	O
5.8	Incorrect Dosage Form	*	*	*	*	*	*	*
5.9	Strength	O	O	O	O	O	O	O
5.10	Route of Administration	O	O	O	O	O	O	O
5.11	Incorrect Route of Administration	*	*	*	*	*	*	*
5.12	Batch Number/ Lot Number	O	O	O	O	O	O	O
6.0	**Investigation and Findings**							
6.1	Patient/Resident Informed of Incident	n/a	O	O	O	O	O	O

Data element number	Data element name	Reportable circumstance	Near miss	None	Mild	Moderate	Severe	Death
6.2	Likelihood of Recurrence	O	O	O	O	O	O	O
6.3	Intervention(s) Required	n/a	n/a	O	O	O	O	O
6.4	Extended Length of Stay	n/a	n/a	n/a	O	O	O	O
6.5	Unplanned Admission/ Readmission	n/a	n/a	n/a	O	O	O	O
6.6	Root Cause Analysis Status	n/a	O	O	O	O	O	O
6.7	Future Strategies/ Recommendations	O	O	O	O	O	O	O
6.8	Actions or Circumstances That Prevented Harm	O	O	O	n/a	n/a	n/a	n/a
7.0	**Unique Identifiers**							
7.1	NSIR Case Identifier	CIHI assigned						
7.2	HCF Case Record Number	O	O	O	O	O	O	O
7.3	HCF Unique Identifier	CIHI assigned						
8.0	**HCF Service Profile**	**NSIR frame information**						
8.1	Principal Type of Health Care Provided	Mandatory						
8.2	Type of Setting	Mandatory						
8.3	Number of Beds Staffed and In Operation	Mandatory						
8.4	Type of Drug Distribution System	Mandatory						
8.5	Computerized Prescriber Order Entry	Mandatory						

Notes

* The requirement of the data elements (mandatory versus n/a or optional) is based on the selection of Medication/IV Fluid Problem.

† Only 1 value is required.

‡ Adapted from MEDMARX®, © 2005 The United States Pharmacopeial Convention, Inc. All rights reserved. Used with permission.

Appendix B: National System for Incident Reporting — Radiation Treatment Minimum Data Set

Mandatory and optional data elements are specified based on whether it is an actual incident, a near miss or a programmatic hazard.

M = Mandatory O = Optional n/a = Not applicable

Data element number	Data element name	Programmatic hazard	Near miss	Actual incident (all known values)
1.0	**Incident Impact**			
1.1	Incident Description	M	M	M
1.2	Type of Radiation Treatment Incident	M	M	M
1.3	Acute Medical Harm	n/a	n/a	M
1.4	Dosimetric Impact	n/a	n/a	M
1.5	Latent Medical Harm	n/a	n/a	M*
2.0	**Incident Discovery**			
2.1	Functional Work Area	M	M	M
2.2	Date Incident Was Detected	M	M	M
2.3	Date Incident Occurred	n/a	O	O
2.4 and 2.5	Time or Time Period Incident Was Detected	M	M	M
2.6 and 2.7	Time or Time Period the Incident Occurred	O	O	O
2.8	Health Care Provider(s) and/or Other Individual(s) Who Detected the Incident	O	O	O
2.9	Health Care Provider(s) and/or Other Individual(s) Involved in the Incident	O	O	O
3.0	**Patient Characteristics**			
3.1	Patient Month of Birth	n/a	O	O
3.2	Patient Year of Birth	n/a	O	O
3.3	Patient Gender	n/a	O	M
3.4	Diagnosis Relevant to Treatment	n/a	M	M
4.0	**Incident Details**			
4.1	Process Step Where Incident Occurred	M	M	M
4.2	Process Step Where Incident Was Detected	M	M	M

Data element number	Data element name	Programmatic hazard	Near miss	Actual incident (all known values)
4.3	Primary Problem Type	M	M	M
4.4	Contributing Factors	M	M	M
4.5	Number of Patients Affected	n/a	n/a	M
5.0	**Treatment Delivery**			
5.1	Radiation Treatment Technique(s)	M	M	M
5.2	Total Dose Prescribed	n/a	M	M
5.3	Number of Fractions Prescribed	n/a	M	M
5.4	Number of Fractions Delivered Incorrectly	n/a	n/a	M
5.5	Hardware Manufacturer and Model Involved	O	O	O
5.6	Software Manufacturer and Model Involved	O	O	O
5.7	Body Region(s) Treated	n/a	O	M
5.8	Treatment Intent	n/a	O	O
6.0	**Incident Investigation**			
6.1	Immediate Ameliorating Actions	O	M	M
6.2	Safety Barrier(s) That Failed to Identify the Incident	O	M	M
6.3	Safety Barrier(s) That Identified the Incident	O	M	n/a
6.4	Actions Taken or Planned to Reduce Risk, and Other Recommendations	O	O	O
7.0	**Unique Identifiers**			
7.1	NSIR Case Identifier	System generated	System generated	System generated
7.2	HCF Case Record Number	O	O	O
7.3	HCF Unique Identifier	n/a	n/a	n/a
8.0	**HCF Service Profile**			
8.1	Principal Type of Health Care Provided	n/a	n/a	n/a
8.2	Type of Setting	n/a	n/a	n/a
8.3	Number of Beds Staffed and in Operation	n/a	n/a	n/a
8.4	Type of Drug Distribution System	n/a	n/a	n/a
8.5	Computerized Prescriber Order Entry	n/a	n/a	n/a

Note

* Not applicable when Acute Medical Harm is death or Dosimetric Impact is none.

Appendix C: Text alternative for images

Figure 1: NSIR timeline

This timeline extends from 2010 to 2017. It highlights key milestones in the development of NSIR and NSIR-RT. In 2010, NSIR launched its system to acute care hospitals to collect medication incidents. In 2011, NSIR expanded its scope to include long-term care facilities. In 2012, NSIR made enhancements to its system and its medication incident minimum data set (MDS) to include the collection of chemotherapy information. In 2013, NSIR met a significant system development milestone with the launch of batch upload functionality. In 2014, the NSIR Reporting Tool was upgraded to incorporate changes to the MDS and to assist in data submissions. In 2015, NSIR expanded its scope of incident collection to radiation treatment with the development of an NSIR-RT MDS and system module. In 2017, the NSIR-RT module was officially launched.

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