Terms of use, privacy statement, and interpretation of data to use the Medical Devices System incident and recall data extract

Note: Read the following terms of use, privacy statement and interpretation of data; and then select the link at the bottom of this page to access the data extract.

Terms of use

This information relates to information taken from medical device problem reports that are submitted to Health Canada by health professionals and consumers, either directly to Health Canada or via market authorization holders (manufacturers and importers). Each report represents the suspicion, opinion, or observation of the individual making the report. Also included in this extract is information about recall reports, submitted by manufacturers and importers. Health Canada's post market surveillance of medical devices includes the Canada Vigilance - Medical Device Problem Reporting Program and medical devices compliance and enforcement staff within Health Canada's Regulatory Operations and Regions Branch, and is designed to detect signals of potential health product safety issues during the post-market period. The data is collected primarily by a spontaneous surveillance system in which device problems and adverse events are reported on a voluntary basis. However, Health Canada is aware that medical device incidents are often underreported to both voluntary and mandatory spontaneous surveillance systems.

The number of incidents in the Medical Devices System incident and recall data extract is not suitable for inferring the incidence or prevalence of a problem or for estimating risk associated with a particular medical device, as neither the total number of problems occurring, nor the number of patients exposed to the medical device, is known. Because of the multiple factors that influence reporting, quantitative comparisons of medical device safety should not be made from the data. Some of these factors include the length of time a device is marketed, the market share, publicity about problems with a device or class of devices, and regulatory actions. In some cases, the reported clinical data is incomplete and there is uncertainty that the device(s) caused the reported health effects. A given health effect may be due to an underlying disease process or to another coincidental factor.

Recall information included in this extract is submitted by manufacturers and importers to the Medical Devices Compliance program within the Regulatory Operations and Regions Branch of Health Canada. Recall data is limited to those recalls that are verified as acceptable by a Health Canada Inspector. Recalls are not limited to removal of product from the market, a recall can mean any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device

(a) may be hazardous to health;
(b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or

(c) may not meet the requirements of the Food and Drugs Act or the Medical Devices Regulations.

This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this Terms of Use statement.

Privacy Statement

Information related to the identity of the patient and/or the reporter of an incident is protected as per the Privacy Act and in the case of an access to information request. Suspected device-related problem information is submitted on a voluntary basis, and is maintained in a computerized database. These data are used for the monitoring of medical devices, and may contribute to the detection of potential product-related safety issues as well as to the benefit-risk assessments of these devices.

More details regarding personal information collected under the Medical Device Problem Reporting Program can be found in InfoSource's Personal Information Bank
Health Canada;
Health Products and Food Branch;
Medical Devices - Medical Device Problem Reporting Program;
PIB, HC PPU 415.

More details regarding personal information collected under the Medical Device Compliance Program can be found in InfoSource's Personal Information BankHealth Canada;
Regulatory Operations and Regions Branch;
Compliance and Enforcement - Medical Devices;
PIB, HC PPU 405.

Interpretation of Medical Devices System Incident and Recall Data

The following limitations should be taken into account when interpreting the suspected medical device incident data:

1. Incident data has been collected primarily by a spontaneous surveillance system in which incidents involving medical devices are reported to industry (manufacturers and importers) and Health Canada on a voluntary basis.
2. Recall data has been collected from industry (manufacturers and importers) who are required to report recalls to Health Canada once a recall has been initiated, as well as recalls that have been ordered by Health Canada.
3. There is underreporting of incidents with both voluntary and mandatory surveillance systems.
4. Medical device problem reports are suspected associations which reflect the opinion or observation of the individual reporter. The data presented reflects, as much as possible, the reporter's observations and opinions, and does not reflect any Health Canada assessment of association between the device and the patient health effects or outcomes.

5. Medical device recalls data presented reflects, as much as possible, the submitter's information, and does not reflect any Health Canada Assessment of association between the device and the patient health effects or outcomes.
6. Inclusion of a particular health effect in an incident does not necessarily mean that it was caused by the medical device(s). The purpose of medical devices post market surveillance within the Canada Vigilance Program and the Regulatory Operations and Regions Branch is to detect possible signals of adverse events or problems associated with medical devices. Additional scientific investigations are required to validate signals from these areas and to establish a cause and effect relationship between a device and a reported health effect. Assessment of causality must include other factors such as temporal associations, the possible contribution of concomitant medication or therapies, the underlying disease, and the previous medical history.
7. The number of incidents should not be used as a basis for determining the incidence of a problem or health effect as neither the total number of incidents occurring, nor the number of people exposed to the device is known.
8. Numerical comparisons should not be made between problems associated with different devices on the basis of the data.
9. Where an incident may involve multiple devices, it may not be possible to determine which, if any, of the devices involved in the incident were responsible for a particular health effect.
10. In order to be entered into the database, information from mandatory problem reports are coded using adverse event terminology terms and codes (device problems and health effects) which represent the incident described in the report. The coding of reports is subject to limitations of coding terminology.
11. The data provided do not represent all known safety information concerning the device(s) and should not be used in isolation to make decisions regarding the use of these devices; other sources of information should be consulted.
12. The assistance of a health care professional should be sought to aid in the interpretation of the information contained herein.
13. The database is routinely checked for duplicate reports. Duplicate reports are reports related to the same incident received from more than one source (e.g., industry and consumer). It is not always possible to detect duplicate reports, often because the documentation in the original report may be variable or incomplete. When duplicates are detected, the incidents are merged in the system.
14. Recalls listed by Health Canada may not be found in the databases of other jurisdictions, and vice versa, due to differing regulatory reporting requirements and differing definitions of what constitutes a recall

Information from the Medical Devices System incident and recall data extract is provided with the understanding that it will be appropriately referenced and used in conjunction with the terms of use.