Special Articles

Anaesthesia equipment safety in Canada: the role of government regulation

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Medical device problems as detected by the Health Protection Branch (HPB) of Health and Welfare Canada were studied in order to examine the frequency and safety priority of problems in the subgroup of anaesthesia devices. Data pertaining to the time period from April 1, 1987 to November 30, 1992 were gathered from the Medical Devices Notification Database and the DAFFY Reporting System. The Medical Devices Notification Database contains all notifications for newly marketed medical devices in Canada and the DAFFY Reporting System keeps record of all submitted problem reports and manufacturer recalls along with their designated safety priority status. When an important safety hazard is associated with a medical device as determined from information submitted to HPB, an Alert—Medical Devices may be issued to inform hospitals and health care professionals of the problem. During the studied time period, the percentages of problem reports and recalls as well as Alerts were compared with the percentage of newly marketed anaesthesia devices. It was found that although only 2.3% of the newly marketed medical devices were classified as anaesthesia devices, 8.6% of all problem reports/recalls and 37.5% of all Alerts originated from the field of anaesthesia devices. Comparison of the percentages of problem reports/recalls (8.6%) and Alerts (37.5%) with the percentage of marketed devices for anaesthesia (2.3%) showed differences ($P < 0.05$). As well, the percentage of class I priority (the highest safety priority) problem reports/recalls for anaesthesia devices was 10.2% compared with 4.9% for non-anaesthesia devices ($P < 0.05$). A recent HPB survey on who reports medical device problems indicated that only 1% of all problem reports received by HPB

were from anaesthetists which raises the possibility of under-reporting by this group. The findings of this report demonstrate a considerable overrepresentation of device safety problems with anaesthesia equipment. The role of the anaesthetist in post-marketing surveillance of anaesthesia equipment may become more important in the future with the possibility of mandatory problem reporting by health professionals.

Les problèmes décelés sur les appareils médicaux par la Direction générale de la protection de la santé de Santé et bien-être social Canada sont étudiés dans le but d'examiner la fréquence et la priorité accordée au sous-groupe de l'équipement anesthésique. Les données pour la période s'étendant du premier avril 1987 au trente novembre 1992 ont été recueillies à partir du Système de base de données des déclarations d'instruments médicaux et du Système de rapport Daffy. Le premier système contient toutes les déclarations sur les déficiences des appareils médicaux nouvellement commercialisés au Canada. Le deuxième garde en filière tous les rapports de problèmes soumis de même qu'une classification de leur priorité sous l'aspect sécurité. Quand une déficience mettant en cause la sécurité est découverte sur un appareil médical d'après les renseignements fournis à Santé et bien-être social Canada, une Alerte Instrument médical est émise pour avertir les professionnels hospitaliers et sanitaires du danger. Pendant la période étudiée, le pourcentage des rapports et rappels ainsi que des alertes est comparé au pourcentage des nouveaux instruments d'anesthésie mis en service. On constate que bien que seulement 2,3% de tous les nouveaux instruments commercialisés soient classés anesthésiques, 8,6% de tous les rapports et rappels pour déficiences et 37,5% de toutes les alertes avaient pour origine l'instrumentation anesthésique. Cette différence est significative ($P < 0,05$). Le pourcentage des problèmes de priorité de classe I (la plus élevée des priorités quant à la sécurité) pour l'anesthésie est de 10,2% comparativement à 4,95% pour les autres instruments médicaux ($P < 0,05$). Une enquête récente de Santé et bien-être social Canada sur l'identité de ceux qui rapportent ces problèmes montre que seulement 1% de ces rapports sont produits par des anesthésistes, ce qui laisse présumer une

Key words

EQUIPMENT.

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carence de leur part. Les données de cette étude montrent aussi que les problèmes de sécurité propres à l'appareillage anesthésique occupent une très grande place. Le rôle des anesthésistes dans la surveillance de leur équipement après achat grandira si jamais il devient obligatoire pour les médecins de rapporter les déficiences de l'instrumentation.

The role of government regulation and post-marketing surveillance of medical devices in the maintenance of safety in anaesthesia has received limited exposure in the anaesthesia literature.¹⁻³ There has been some discussion in the Canadian medical literature regarding the federal government's role in the surveillance of medical devices safety.⁴⁻⁶ Most recently, the Report of the Medical Devices Review Committee evaluated the Canadian medical devices regulatory programme and made recommendations.

The Health Protection Branch (HPB) of Health and Welfare Canada is responsible for regulating medical devices which currently include approximately 450,000 different device products.⁷ According to the Medical Devices Regulations (of the Canada Food and Drugs Act), only certain classes of medical devices are required to undergo scrupulous premarketing review of device safety and efficacy (e.g., "any device designed to be implanted into the tissues or body cavities of a person for 30 days or more").⁸ This pertains to approximately 5% of all medical devices, few of which are related directly to anaesthesia use.⁷ Thus, the majority of anaesthesia devices are not regulated in that they do not undergo preclinical evaluation before sale in Canada. Thus, anaesthesia equipment safety in Canada is monitored through post-marketing surveillance. Within ten days of marketing a medical device, the manufacturer is required to provide HPB with a notification (referred to as post-marketing notification) indicating the identity, directions for use and purpose of the device as well as the name and address of the Canadian distributors. The HPB may request evidence of device safety from the manufacturer and has the authority to instruct the manufacturer to stop selling the device if this evidence is considered insufficient. The recall or correction of a device that is defective or inadequate is a voluntary action which may be initiated by the manufacturer but details of the recall must be provided to HPB.⁸ It should be noted that the Canadian Standards Association of the Standards Council of Canada has specific voluntary standards which exist for anaesthesia equipment. The Health Protection Branch advises health professionals to use equipment that complies with CSA standards; however, these standards are not mandatory under the Medical Devices Regulations.⁷ Since April 1, 1987 the *Adverse Devices Experience Network*

TABLE Medical device priority system

Class	I	II	III
Criteria	Probability of death or permanent injury 1-100%*	Probability of death or permanent injury <1%* Probability of temporary injury 1-100%*	Probability of temporary injury <1%* Probability of inconvenience or economic cost 0-100%*

*Probability that given incident reported will occur at least once per annum.

of HPB has maintained a *Medical Devices Hot Line* (Tel.: 1-800-267-9675) which health care professionals anywhere in Canada may call to report voluntarily device problems encountered.⁹ Device safety is monitored by HPB through the evaluation of information from: (i) health professionals reporting through the *Medical Devices Hotline*, (ii) problem reports and recalls received from device manufacturers and (iii) reports from the U.S. Food and Drug Administration. The Field Operations Directorate of HPB also provides information on adverse device-related incidents which are investigated by inspectors directly in the field (i.e., in plants and factories). The *Medical Device Priority System* designates a *class level* (from I to III in decreasing level of priority) to each recall or problem report according to specified criteria (see Table). Problem prioritization is a complex task which involves assessment of the device, user and patient population characteristics as well as likelihood, consequence and risk/benefit evaluation. This task is multidisciplinary and multifactorial. A computer-based potential risk index decision support system (PRIEST) that would facilitate this task is currently being developed.⁷ Based on the above assessment of device safety problems, HPB may issue an *Alert-Medical Devices* to inform hospitals and health care professionals of important concerns and, in more serious cases, the device may be removed from the Canadian market.⁸

The purpose of this study is to compare the percentages of problem reports and recalls (with their corresponding priority designations) and *Alerts* with the percentage of newly marketed anaesthesia devices in order to determine the frequency and safety priority of these events in the field of anaesthesia.

Methods

Data collection

All notifications of newly marketed medical devices submitted to HPB from device manufacturers are recorded in the *Medical Devices Notification Database*. Among

FIGURE 1 Anaesthesia devices, reports and alerts.

the different codes which identify these notifications is the usage code which indicates the clinical field or specialty in which the device will most frequently be used (e.g., anaesthesia). The usage code designation is made according to information provided by the manufacturer and may not always truly reflect clinical utility (e.g., all types of ventilators are classified under anaesthesia). All problem reports and recalls received by HPB, subsequent to problem prioritization, are recorded in the *DAFFY* (Device Action Form by Fiscal Year) *Reporting System* along with their priority assessment status. The time period studied in this report spanned from April 1, 1987 to November 30, 1992. This period is important as it marked the first five years of the existence of the *Medical Devices Hotline*. The number of newly marketed medical devices and the number of newly marketed anaesthesia devices were tabulated from the *Medical Devices Notification Database*. The numbers of total and anaesthesia-related problem reports and recalls along with their respective priority designations were retrieved from the *DAFFY Reporting System*. Finally, the number of anaesthesia *Alerts* were tabulated from the list of all *Alerts* released during the studied period (see Appendix). The specific nature of the incidents or reports leading to the issuance of these *Alerts* were not available for analysis or public disclosure.

Statistical analysis

Analysis of the data was performed using Chi-square to compare: (i) the observed frequency of problem reports/recalls and *Alerts* in the anaesthesia device group with the expected frequency of newly marketed anaesthesia devices and (ii) the frequency of priority class I reports/recalls in the anaesthesia group with that of the non-anaesthesia group. Statistical analyses were performed

FIGURE 2 Comparison of problem priority distribution.

using the computer program Statview[™] v 1.03 (Abacus Concepts Inc., Berkley, CA).

Results

Problem reports and alerts

Anaesthesia devices made up 2.3% (585) of all devices (25,404) newly marketed in Canada from April 1, 1987 to November 30, 1992. A total of 5,499 problem reports and recalls were received by HPB, 471 (8.6%) of which involved anaesthesia devices. Over the same time period, six (37.5%) out of the 16 *Alerts* issued by HPB were anaesthesia related (see Figure 1). Chi-square analyses showed a significant difference between: (i) the number of newly marketed anaesthesia devices and the number of anaesthesia reports/recalls ($\chi^2 = 5.800$, $P < 0.05$) and (ii) the number of anaesthesia devices and anaesthesia *Alerts* ($\chi^2 = 34.341$, $P < 0.05$). The Appendix lists the titles of the specific *Alert-Medical Devices* that were issues for anaesthesia devices over the studied time period and their respective outcomes.¹⁰⁻¹⁵

Problem priority status

The priority classes for non-anaesthesia device problem reports/recalls are compared with those of anaesthesia reports/recalls received during the study period (Figure 2). Specifically, the percentages of non-anaesthesia versus the anaesthesia device problem reports/recalls were 4.9% versus 10.2% for class I, 74.1% versus 76.9% for class II and 12.4% versus 12.9% for class III. The incidence of class I reports/recalls for anaesthesia devices (10.2%) was different from that for non-anaesthesia devices (4.9%) ($\chi^2 = 10.031$, $P < 0.05$).

Discussion

This data review revealed that (for the time period examined) there are differences between the percentage of newly marketed anaesthesia devices (2.3%) and both the percentages of anaesthesia problem reports/recalls (8.6%) and anaesthesia Alerts (37.5%). As well, the percentage of class I priority problem reports/recalls for anaesthesia devices was 10.2% compared with 4.9% for non-anaesthesia devices ($P < 0.05$). A recent internal HPB data survey from April 1, 1992 to September 30, 1992 reported only 1% of all device problem reports to HPB were received from anaesthetists (Figure 3).

An accurate interpretation of the findings of this study requires evaluation of the process by which the studied data set was developed. Firstly, the method of designation of the anaesthesia usage code to a device notification is not clearly defined and, as previously mentioned, may not appropriately reflect the clinical use of the device. Given the possible misclassifications that may occur (e.g., all types of ventilators are classified under anaesthesia) the subgroup of anaesthesia devices obtained from the *Notification Database* may in fact provide an overestimation of the number of devices actually used in anaesthesia practice. It is unlikely that devices used in anaesthesia practice would be inappropriately omitted from the anaesthesia usage classification. It is thus possible that the numbers of problem reports/recalls for anaesthesia equipment are overestimated, as well. Of interest, the six anaesthesia Alerts from the studied time period pertain almost exclusively to anaesthesia practice. If the percentage of newly marketed devices exclusively used in anaesthesia practice were smaller (i.e., $< 2.3\%$), its comparison with the percentage of anaesthesia Alerts (37.5%) would be more dramatic. Another factor that may contribute to an inflated number of anaesthesia problem reports/recalls is a lower level of tolerance for reporting in the area of anaesthesia equipment. Likely, it is the clinical impact of device problems in anaesthesia that gives rise to a higher frequency of reporting and not that anaesthesia devices malfunction more often than other devices. The process of problem prioritization, as previously mentioned, is quite complex and the current level of clinical input into this process is not apparent. Lastly, the nature of the decision process leading to the issuance of an *Alert* is not clearly delineated and may not involve purely objective evaluation.

The issue of who reports device problems is of interest in considering the role of the anaesthetist in post-marketing surveillance of anaesthesia equipment. Given the five-year problem rate for anaesthesia devices of 8.6%, the recent rate of reporting by anaesthetists of 1% is small. This may be explained by several factors: (i) some devices being reported were not exclusively anaesthesia related

FIGURE 3 Device problem reporting.

and were thus reported by other groups, (ii) some reporting to HPB by anaesthetists was done indirectly via hospital biomedical engineers, hospital administrators or the device manufacturer and (iii) there may have existed the possibility of underreporting by the anaesthetist. The latter is of most concern and should prompt further evaluation.

Among the several recommendations for future change made in the recent Report of the Medical Devices Review Committee, considerable attention was paid to the area of post-marketing surveillance. Through regulatory harmonization with other countries such as the United States, it was recommended that the present post-market notification requirement (i.e., notification within ten days of marketing) be converted to pre-market notification to allow for the screening of devices to determine their risk classification. As well, the committee recommended the establishment of mandatory reporting "where devices may have caused or contributed to death or serious injury or serious illness." It was proposed that this be implemented in a phased manner starting with mandatory re-

porting by device manufacturers and importers. Following impact analysis, this would extend to mandatory reporting by health care professionals and institutions.⁷ Thus, post-marketing surveillance in addition to being an important activity for the maintenance of safety in anaesthesia may in the near future become a legal requirement.

In conclusion, the results of this study demonstrate a considerable overrepresentation of device safety problems with anaesthesia equipment. It should be emphasized that it is the nature of the clinical use of these devices and not the devices themselves which elicit more safety concern than is seen in other fields. A brief review of the anaesthesia equipment *Alerts* in Appendix 1 illustrates the importance of product design and the clinical impact of device problems in anaesthesia practice. From previous studies, the contribution of equipment failure to adverse outcomes in anaesthesia is small.¹⁶⁻¹⁸ It would therefore be difficult to ascertain the degree of improvement of safety in anaesthesia that could be achieved through tighter regulation of medical devices. Harmonization of medical devices regulation will likely benefit Canadian device experience and will require the implementation of more stringent regulations currently being enforced by other agencies (e.g., U.S. FDA). The possibility of mandatory reporting by health professionals warrants further evaluation and emphasis of the anaesthetist's role in post-marketing surveillance.

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Appendix

Alert – Medical devices for anaesthesia equipment

Date	Title of alert
January 18, 1990	<i>Misconnection of anaesthesia scavenging system</i> ³ OUTCOME: "Retrofit kit" provided by manufacturer to known device users to eliminate possibility of inadvertent misconnection of exhaust hose to pressure relief valve.
June 6, 1990	<i>Potential for failure of the vapour exclusion system on the Narkomed 2A, 2B and 3 anaesthetic machines</i> ⁴ OUTCOME: Specific recommendations regarding use and test procedures for such systems were distributed to known device users.
March 8, 1991	<i>Penlon IDP ventilator pressure failure alarm</i> ⁵ OUTCOME: Upgrade kit which provides positive indication of correct alarm function was distributed by manufacturer to known device users.
June 14, 1991	<i>Air flowmeters incorporating an oxygen outlet connector</i> ⁶ OUTCOME: Users advised of the possibility of attachment of an oxygen outlet connector to an air source.
January 24, 1992	<i>Leakage and breakage of anaesthetic bottles of forane and possible damage of metal filling adaptors</i> ⁷ OUTCOME: Users advised of the possibility of damage to metal filling adaptors due to a lot of oversized liquid anaesthetic bottles and the subsequent potential for vaporizer overfilling.
July 20, 1992	<i>Cauda equina syndrome associated with use of small-bore catheters in continuous spinal anaesthesia</i> ⁸ OUTCOME: All such spinal catheters subsequently discontinued from the Canadian market.

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- 10 Health Protection Branch Alert—Medical Devices: No. 91; January 18, 1990.
- 11 Health Protection Branch Alert—Medical Devices; No. 93; June 6, 1990.

- 12 Health Protection Branch Alert—Medical Devices: No. 96; March 8, 1991.
- 13 Health Protection Branch Alert—Medical Devices: No. 98; June 14, 1991.
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