

rivm

National Institute
for Public Health
and the Environment

Report 360020005/2008

J.W.G.A. Pot | C.G.J.C.A. de Vries

Medical devices in intramural settings and patient safety

Availability of incident data and possible solutions to prevent
use problems

RIVM Report 360020005/2008

Medical devices in intramural settings and patient safety
Availability of incident data and possible solutions to prevent use problems

J.W.G.A. Pot
C.G.J.C.A. de Vries

Contact:
Jacqueline Pot
Centre for Biological Medicines and Medical Technology
jacqueline.pot@rivm.nl

This investigation has been performed by order and for the account of The Dutch Ministry of Health, Welfare and Sports, within the framework of Programme 4 the department of Pharmaceutical affairs and Medical Technology of the Dutch Ministry of Health Welfare and Sports, within the framework of Programme 4, Project V/360020 Support for Policy on Medical Technology

© RIVM 2008

Parts of this publication may be reproduced, provided acknowledgement is given to the 'National Institute for Public Health and the Environment', along with the title and year of publication.

Abstract

Medical devices in intramural settings and patient safety

Availability of incident data and possible solutions to prevent use problems

The availability of data on incidents involving medical devices in European health care facilities is not as good as it should be. This is because the countries involved use different methods to collect and present data, making comparisons difficult. This is the result of a study conducted by the National Institute for Public Health and the Environment (RIVM).

The extent to which incidents in health care occur is an important indicator for patient safety. The information on incidents can also act as a guideline for improving medical devices and their use. In 2006, the Netherlands Health Care Inspectorate (IGZ) received 650 reports of incidents involving medical devices. These included, broken catheters , failed fastening mechanisms of patient lifting hoists and a fire in anesthesia equipment.

A European system for incident registration is currently being developed. This system requires compatible regional reporting systems. It is therefore important that the Dutch government collaborates with other countries on how to collect incident data involving medical devices. Data can only be compared if all countries register in the same way. Analysis of the data will also enable any trends to be identified.

Apart from a general inventory of incident data, this report focused specifically on use problems with infusion pumps. For example, an incorrect setting of a pump can lead to an overdosing or underdosing of medication. Health care facilities and manufacturers can help to reduce incidents with infusion pumps by applying more user-friendly designs and developing error prevention plans. Most of the recommendations in this report also apply to other medical devices.

Key words:

medical device, patient safety, incidents, use problems

Rapport in het kort

Medische hulpmiddelen in zorginstellingen en patiëntveiligheid

Beschikbaarheid van incidentgegevens en mogelijke oplossingen om gebruiksproblemen te voorkomen

Gegevens over incidenten met medische hulpmiddelen in Europese zorginstellingen zijn niet optimaal beschikbaar. Dat komt omdat landen deze gegevens op uiteenlopende manieren verzamelen en presenteren, waardoor ze moeilijk zijn te vergelijken. Dit blijkt uit onderzoek van het RIVM.

De mate waarin incidenten in de gezondheidszorg voorkomen is een belangrijke graadmeter voor de patiëntveiligheid. De incidentgegevens bieden ook handvatten om de medische hulpmiddelen en het gebruik ervan te verbeteren. In 2006 zijn in Nederland bij de Inspectie voor de Gezondheidszorg (IGZ) 650 meldingen van incidenten met medische hulpmiddelen binnengekomen. Voorbeelden zijn katheters die afbreken, falende bevestigingsmechanismen van tilliften en brand in anesthesie-apparatuur.

Momenteel is een Europees meldingssysteem in wording. Dat vereist dat de landensystemen op elkaar aansluiten. Het is daarom belangrijk dat de Nederlandse overheid met andere landen uitwisselt op welke manier zij gegevens over incidenten met medische hulpmiddelen willen verzamelen. Alleen als elk land op eenzelfde wijze registreert, kunnen gegevens met elkaar worden vergeleken. Ook kunnen dan eventuele trends zichtbaar worden.

Behalve een algemene inventarisatie van incidentgegevens gaat dit rapport specifiek in op gebruiksproblemen met infuuspompen. Een verkeerde instelling van de pomp bijvoorbeeld kan tot een over- of onderdosering van medicatie leiden. Zorginstellingen en fabrikanten kunnen gebruiksproblemen verminderen door bijvoorbeeld gebruiksvriendelijkere ontwerpen toe te passen en preventieplannen te ontwikkelen. De aanbevelingen in dit rapport zijn grotendeels ook geschikt voor andere medische hulpmiddelen.

Trefwoorden:

medische hulpmiddelen, patiëntveiligheid, incidenten, gebruiksproblemen

Contents

Summary	9
List of abbreviations	11
1 Introduction	13
1.1 Background	13
1.1.1 Quality of care	13
1.1.2 Classifying problems with medical devices	14
1.1.3 Post market surveillance and vigilance	15
1.1.4 Related investigations	15
1.2 Objectives, scope and research questions	16
2 Method	17
3 Results	19
3.1 Published data per country	19
3.2 Use problems with infusion pumps as an example	20
3.2.1 Introduction to infusion pumps	20
3.2.2 Incidents and their causes	21
3.2.3 Lessons learned	25
4 Discussion and conclusions	29
4.1 Availability of data	29
4.2 Possible solutions to prevent use problems	30
4.3 Benefits of collecting data	32
5 Recommendations	33
References	35
Annex I Definitions	39
Annex II Published data per country	41

Summary

The availability of public information about incidents with medical devices has improved a little over the years. Still, the depth of the information varies between countries and there is room for improvements. Optimizing registration systems should facilitate unambiguous interpretation and exchange of data.

In health care, it is impossible to eliminate human errors entirely. When errors do occur, it is necessary to go beyond blaming and to determine how and why accidents happened and to take effective steps to preclude their recurrence.

To determine the availability of public information about incidents with medical devices websites from the competent authorities of the Netherlands, Belgium, Germany, United Kingdom, France, Denmark, Finland, and Ireland, were consulted. Also, a literature study was performed to gain insight into incidents with infusion pumps and their underlying causes. The justification for this choice lies in the fact that infusion pumps are widely used in a great number of settings and the results from three previous RIVM-studies indicated that use problems constitute a major problem with infusion pumps in the Netherlands.

Except for Belgium, the countries investigated provide data on incidents with medical devices on their websites. Information about incidents with medical devices originated from different sources, e.g. manufacturers or authorized representatives, importers, medical professionals, hospitals and patients. The numbers of incidents with medical devices varied from 667 incidents in Denmark to 7,975 incidents in the UK in 2006 and causes of incidents varied from design/construction failure to wrong handling. Use problems, for instance wrong use and insufficient training, were only defined by Germany. Only four countries (Germany, Ireland, the UK and France) had information available about corrective actions (e.g. recall safety warnings). Incidents with implants (active and non-active) appear most frequently in an overview of the investigated countries followed by electro-mechanical equipment. The implementation of a European database, as required in the medical device directive, should play an important role in achieving a uniform reporting system. EUDAMED, the future repository of all registration information on medical devices on the European market, entails potential benefits. The Dutch government should exchange information with other European countries on their methods of collecting data on incidents involving medical devices, because the European reporting system under development requires that the underlying local registries are compatible. Only then it is possible to compare data and identify trends.

The literature study on incidents with infusion pumps showed that most use errors were mistakes made in the set up of the device. The literature provided a considerable number of recommendations to improve the safe use of infusion pump technologies varying from a user friendly design of the equipment to error prevention plans. Most of the recommendations in this report also apply to other medical devices. Stakeholders should assume their responsibility concerning patient safety.

For future research, it would be worthwhile to study the use problems with implants and/or IVDs, because these product groups are in the top five of incidents of different countries. Information on legislation relating to patients safety in other countries could be valuable in bringing solutions to legislative shortcomings as experienced in the Netherlands.

List of abbreviations

AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé (French Health Products Safety Agency)
AIMDD	Active Implantable Medical Device Directive (Europe)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (German National Institute for Medicines and Medical Devices)
CA	Competent Authority
CE	Conformité Européenne
CHC	Copenhagen Hospital Corporation
DKMA	Danish Medicines Agency
EU	European Union
EUDAMED	European Database on Medical Devices
FMEA	Failure modes effects analysis
FSCA	Field Safety Corrective Action
GMDN	Global Medical Device Nomenclature
HFE	Human factors engineering
ICU	Intensive Care Unit
IGZ	Dutch Health Care Inspectorate
IMB	Irish Medicines Board
IVDD	In Vitro Diagnostic Medical Devices Directive (Europe)
IVDs	In Vitro Diagnostics
MAUDE	Manufacturer and User Facility Device Experience Database (FDA, USA)
MDD	Medical Device Directive (Europe)
MDR	Medical Device Reporting
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
NAM	National Agency for Medicines (Finland)
PCA	Patient-controlled analgesia
RIVM	National Institute for Public Health and the Environment
SGZ	State of the Healthcare Report, published by IGZ
SMART	Safe Medication Administration through Technologies
VWS	Dutch Ministry of Health, Welfare and Sport
WHO	World Health Organization

1 Introduction

1.1 Background

1.1.1 Quality of care

A Dutch investigation, published in 2007, focussed on accidental and avoidable damage to patients treated in hospitals. The results indicated that damage was in some situations due to a complication or the risks of the treatment itself, but in other cases due to following the professional standard insufficiently and deficiencies in the care system (1). Quality of care already was an important issue, but this signal strengthened the Dutch Ministry of Health, Welfare and Sport (VWS) in making quality of care a key component of their policy (2). It is their ambition to secure high-quality customer-oriented care, with sufficient choice and with clear rights and obligations for everyone. Patient safety is one of the pillars of this policy.

In health care, it is impossible to eliminate human errors entirely. When errors do occur, it is necessary to go beyond blaming and to determine how and why accidents happened and to take effective steps to preclude their recurrence (3). The need to use a systems approach is evident (3-6). Traditionally, making an error had been viewed as an act of incompetence (4, 7). The systems approach recognizes that there often are a large number of determinants present which may cause an incident and focuses on improving the conditions under which an individual works (6). Reasons' so-called Swiss cheese model (see Figure 1) illustrates how defences, barriers, and safeguards may be penetrated by an accident trajectory.

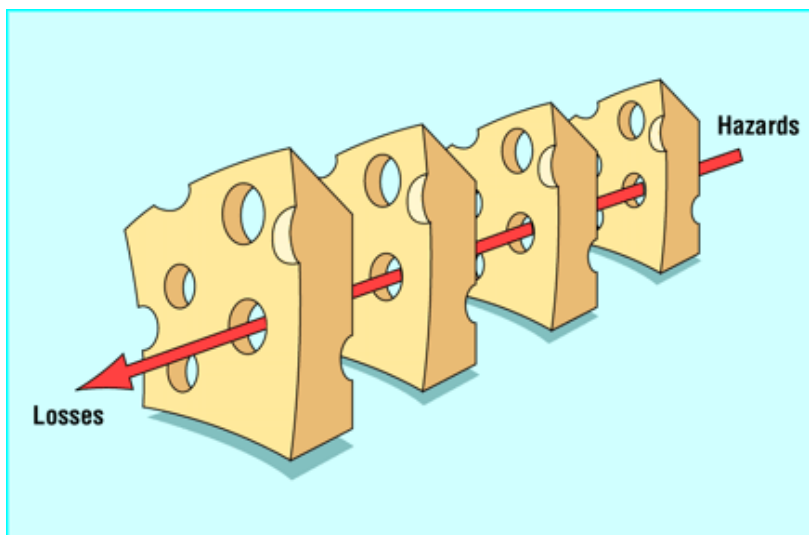


Figure 1: The Swiss cheese model of how defences, barriers, and safeguards may be penetrated by an accident trajectory (6)

‘High technology systems have many defensive layers: some are engineered (alarms, physical barriers, automatic shutdowns, et cetera), others rely on people (surgeons, anaesthetists, pilots, control room operators, et cetera), and yet others depend on procedures and administrative controls. Their function is to protect potential victims and assets from local hazards. Mostly they do this very effectively, but there

are always weaknesses. In an ideal world each defensive layer would be intact. In reality, however, they are more like slices of Swiss cheese, having many holes. Unlike in the cheese, these holes are continually opening, shutting, and shifting their location. The presence of holes in any one 'slice' does not normally cause a bad outcome. Usually, this can happen only when the holes in many layers momentarily line up to permit a trajectory of accident opportunity bringing hazards into damaging contact with victims' (6).

A non punitive environment should encourage clinicians to report errors and system based failures so that complex processes may be examined and inherent error traps may be removed (4, 8, 9).

Since January 2008, each Dutch hospital is obliged to implement a safety management system.

Using such a system, risks within the facility and measures to eliminate or reduce them can be identified and recorded, which is important for improving quality of care.

1.1.2 Classifying problems with medical devices

Medical devices play an important role in the health care process. They cover a wide range of products (ranging from wound dressings to the most advanced therapeutic and diagnostic machinery) and pervade every sphere of care delivery, from prevention and diagnosis through treatment, monitoring and rehabilitation. The number of potential problems is numerous. A complex medical device, for example, can lead to incorrect usage when the user interface is poorly designed. The design of a medical device is critically dependent on the designer's skills and perception of the users of the device. Sometimes it can be questioned if a device is truly fit for its purpose. And even if devices operate correctly and are reliable, they may still contribute to medical error, for example if they operate in a counter-intuitive manner (10). Problems with medical devices generally fall into one of the following three categories (11):

1. Device problems include malfunctions (e.g. mechanical, electrical, or software related) and manufacturing defects in product design or development, or material problems such as product instability.
2. Clinical problems can occur with a patient who is sensitive or allergic to a device, has a pre-existing condition that makes the device difficult or risky to use, or in whom the device would have an inherent risk.
3. Use problems are problems related to human factors, which constitute complex factors in the design of medical devices. Use problems may be caused by:
 - a. inadequate or misleading labelling,
 - b. confusing instructions,
 - c. inadequate packaging,
 - d. problems in hardware design (e.g. an unclear display which results in misreading),
 - e. problems in software design (e.g. extensive multiple functions which can impose an unreasonable cognitive load on the user),
 - f. alarm problems (e.g. false alarm, delayed alarms, too sensitive or insensitive alarms, alarms drowned out by noise, ambiguous meanings, inappropriate silencing, and accidental disabling),
 - g. dimension problems (e.g. forces and angles of workstations, seating, and consoles not fitting the user population) and
 - h. the maintenance of devices.

All of these causes can make the device difficult to use. Use problems (like design errors) can cause or induce user errors.

More relating definitions can be found in Annex I.

1.1.3 Post market surveillance and vigilance

Under the Medical Devices Directives 93/42/EEC, 90/385/EEC (active implantable medical devices), and 98/79/EC (in vitro diagnostic medical devices), European Member States need to ensure that medical devices that are placed on the market and put into service comply with all provisions of the Directives, including the ‘essential requirements’, and that no obstacles are encountered for the free movement of approved devices. As required by the directives, the manufacturer is obliged to institute and keep up to date a systematic procedure (post market surveillance) to review experience gained from devices in the postproduction phase and to implement appropriate means to apply any necessary corrective actions, taking into account the nature and risks in relation to the product. When an incident occurs, the manufacturer or authorized representative is required to notify the competent authority. After notification, the incident must be evaluated and field safety corrective actions (FSCA) involving the medical devices must be taken. This process is called the vigilance procedure. The following types of incidents and recalls should be reported by the manufacturer to the Competent Authority:

- a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health.
- b) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph a) to systematic recall of devices of the same type by the manufacturer.

Suggestions as to the type of incidents to be reported are provided in the European Commission Guidelines MEDDEV 2.12-1 Rev 5 April 2007: Guidelines on the Medical Devices Vigilance System. On certain issues not addressed in the Medical Device Directives, national legislation may be different from these guidelines.

The Directives also require data to be stored in a database in a standardised format. EUDAMED, the European Database on Medical Devices, should be the centralized repository of information for Member States on marketed medical devices. It will also contain a vigilance module which will inform Member States on incidents or near-incidents in relation to certain devices on the market. EUDAMED is still under development.

1.1.4 Related investigations

In 2004, the National Institute for Public Health and the Environment (RIVM) studied, on behalf of the Netherlands Health Care Inspectorate (IGZ), the incident reporting systems for medical devices in eight different countries. The study revealed that there was a considerable lack of information on this subject. The results were published in a State of Health Care Report, SGZ (12). This is a yearly document written by IGZ, which highlights certain aspects of health care. Patient safety and the safe use of medicines and medical devices were the main themes in 2004. Recently, medical technology was the topic again in the SGZ 2008 (13). The Ministry of VWS requested the RIVM to gather information from countries neighbouring the Netherlands to learn from their experiences.

1.2 Objectives, scope and research questions

The objective of this research is to **study use problems with medical devices within clinical settings**. With the risk of getting only superficial data, given previous experience in 2004, it was decided to perform a more in-depth study as well. Since medical devices cover a great diversity of products, it will be impossible to perform an in-depth study for all of them. This research focussed specifically on infusion pumps.

Two main questions (with several sub questions underneath) are to be answered in this report:

1. *Which data are publicly available on patient safety issues related to medical devices in intramural settings?*

The occurrence of incidents can be seen as an indication of the level of patient safety. Therefore, the focus will be on the number of incidents with medical devices and their causes. And if the causes are known, would it be possible to point out the number of incidents related to use problems? And what is known about the corrective actions taken (numbers, types and results)? Are there any improvements in the availability of data since 2004?

2. *What are (possible) solutions to prevent use problems?*

An attempt will be made to answer this question for different stakeholders (device manufacturers, health care facilities and device users) with infusion pumps as a specific example.

2 Method

First, websites from the competent authorities of the Netherlands, Belgium, Germany, United Kingdom, France, Denmark¹, Finland, and Ireland, were consulted for an inventory of:

- the number of incidents with medical devices;
- causes of incidents;
- the number of use errors;
- corrective actions taken.

The search focused on the year 2006. Second, a literature study was performed to gain an insight into incidents with infusion pumps and their underlying causes. The justification for this choice lies in the fact that infusion pumps are widely used in a great number of settings. Moreover, the results from three previous RIVM-studies indicated that use problems constitute a major problem with infusion pumps in the Netherlands (14-17).

During this investigation, literature from the past ten years (1998-2008) was searched with the search engine Scopus to gain an insight into use problems with infusion pumps in other countries as well. The search terms used were: 'incidents,' 'infusion pumps' and 'use error'. The abstracts of the articles were assessed by two researchers to decide on their relevance for this study. Articles assessed as non-relevant for this study (e.g. concerning device use in non clinical settings or not relating directly to infusion pumps) were excluded from the survey and the articles assessed as relevant were used to find more related articles.

Conclusions and recommendations from the SGZ 2008 (13) were included in the discussion of this report to integrate conclusions and formulate suggestions for further research.

¹Danish text was translated with the help of a translation program (<http://translate.google.nl/>).

3 Results

3.1 Published data per country

For an overview of published data about incidents with medical devices, websites of competent authorities of several countries were examined (see Annex II). This paragraph summarizes the results. Data were publicly available in annual reports or in statistical data sheets (Germany) on the websites of nearly all the investigated competent authorities. The incidents reported originated from different sources, e.g. manufacturers or authorised representatives, importers, medical professionals, hospitals and patients. Except for Belgium, the countries investigated provided data on incidents with medical devices on their websites (see Table 1). Numbers of incidents with medical devices varied from 667 incidents in Denmark to 7,975 incidents in the UK in 2006.

Causes of incidents were publicly available for almost every country except Belgium and France.

Causes of incidents varied from design/construction failure to wrong handling. Use problems were only defined by Germany. Approximately 16% of the incidents which occurred in the period 2005-2007 in Germany were defined as use problems. These use problems were for instance wrong use, use of non-compatible components, insufficient training and inadequate maintenance/calibration/cleaning/disinfection.

Corrective action data were available from Germany, the UK, Ireland and France (no exact figures).

For two countries (Germany and Ireland) recalls were the most prominent kind of corrective action.

The UK mentioned MHRA safety warnings and manufacturer notices/letters as the most prominent kind of corrective action. France mentioned additional recommendations for use and modification of the concept as corrective actions taken by the manufacturer.

Table 1: Publicly availability of data on incidents with medical devices

Availability of:	Netherlands	Belgium	Germany	UK	Ireland	France	Finland	Denmark
Number of Incidents	☑	-	☑	☑	☑	☑	☑	☑
Cause of incidents data	☑	-	☑	☑	☑	-	☑	☑
Use problem data	☑	-	☑	-	-	-	-	-
Corrective actions data	-	-	☑	☑	☑	☑	-	-

☑ = yes

- = not found on publicly available websites at the time of the investigation (first half of 2008).

For five of the eight countries, it was possible to determine the top five of medical devices involved in adverse events in 2006. Incidents with implants (active and non-active) appear most frequently in an overview of the investigated countries followed by electro-mechanical equipment (see Table 2).

Table 2: The top five of medical devices involved in adverse incidents (2006)

	The Netherlands	Belgium	Germany	The UK	Ireland	France ^a	Finland	Denmark
1	Disposables	Unknown	Active implants	Active implants/ Non-active implants	Single use devices	Medical consumables	Unknown	Unknown
2	Non-active implants	Unknown	Non-active implants	Life support /incubators/ monitors	Non-Active Implantable devices	Medical implantables	Unknown	Unknown
3	IVD's	Unknown	Electro-mechanical equipment	Electro-mechanical equipment	Electro-mechanical medical devices	Equipment	Unknown	Unknown
4	Electro-mechanical equipment	Unknown	IVD's	Surgical equipment	Hospital Hardware	IVD's	Unknown	Unknown
5	Active implants	Unknown	Dental products	Wheeled mobility equipment	Aneasthetic & Respiratory devices	-	Unknown	Unknown

^a. The AFSAPPS has four product groups described in their annual report. There is no additional information available.

3.2 Use problems with infusion pumps as an example

Apart from the justification of the choice for an in-depth study into infusion pumps (see chapter 2), the prominent place in the top fives of electromechanical equipment also emphasizes the relevance of choosing infusion pumps (as part of electromechanical equipment).

3.2.1 Introduction to infusion pumps

Infusion pumps inject controlled amounts of fluids containing medication or nutrients into a patient's circulatory system. These fluids are generally administered intravenously, although subcutaneous, arterial and epidural administration are other options. Infusion pumps can administer fluids in several ways. For example, they can infuse continuously, or administer injections every minute, or inject repeated boluses requested by the patient, up to a maximum number per hour (e.g. in patient-controlled analgesia, PCA)², or the volumes of fluids may vary, depending on the time of day. The technician or nurse that prepare infusion pumps are usually required to enter details on the type of infusion through the interface of the pump. The available safety features vary with the age of the pump (e.g. an audible error indication, back-up batteries or an 'air-in-line' detector). Smart pumps are intravenous pumps that have software that checks programmed doses against preset limits specific to a drug and clinical location. The clinician may either override an alert (soft limit) or not be allowed to continue at all (hard limit), depending on preset limits (18). 'Smart' is an acronym for Safe Medication Administration through Technologies.

² Patient-controlled analgesia (PCA) refers to patient-controlled infusion of intravenous or epidural analgesic (like opioids) on-demand, usually with a pre-programmed ceiling to avoid intoxication. The rate is controlled by a pressure pad or button that can be activated by the patient.

3.2.2 Incidents and their causes

The infusion pump is a commonly used piece of equipment. An assessment of literature from the past ten years (1998-2008) was performed to find publications on incidents with infusion pumps and their underlying causes. By entering the search terms 'incidents and infusion pumps' the search engine 'Scopus' generated 47 hits. This search was narrowed with the term 'use error'. This resulted in twenty-one hits. Four articles were considered not to be relevant for this study and therefore excluded from the survey, which resulted in seventeen relevant articles. The total number of relevant articles was twenty two, as five additional cross-references were found. Sixteen publications contained data on the number of incidents with infusion pumps and their causes. A summary of information from these articles is shown in Table 3. The most frequently mentioned use errors were mistakes made in the set up of the device, e.g. kinking the infusion line, switching patient to a new device incorrectly, misconnection, administering the wrong dose or drugs to the patient, and wrong programming. In four articles presented in Table 3, corrective actions, such as redesigning the user interface, reviewing the tool kit for briefing the hospital staff and training for each type/model infusion pump, were mentioned. The remaining articles (n=12) did not contain information about corrective actions. In the relevant articles (n=22), there were still a considerable number of lessons to be learned about causes of incidents and possible solutions to prevent problems to occur in the future.

Table 3: Incidents with infusion pumps, a literature survey

Study type	Data source	Number of Incidents	Causes and/or description of incidents	Number of use problems % (n)	Reference
A prospective study	A major teaching hospital in Hong Kong	53 incidents, over a 12-month period	Problems with the delivery circuit, delivery pumps and drug administration. Unfamiliar technique/inexperience, inattention and inadequate communication.	Human factors were involved in 42% (n = 22) of the incidents reported	(19)
A retrospective descriptive quantitative and qualitative analysis	French national vigilance reporting system, 1998	309 reports; 28% concerned infusion pumps and 72% consumables, i.e. catheters, infusion lines, taps, connectors, etc. (6 death and 23 severe incidents).	Infusion pumps; failure of the device, software errors, maintenance omissions or errors, and problems related to obsolescence of the device. Single use devices; manufacturer quality insurance failures, design and utilization errors, problems related to the technique itself rather than device.	Not specified.	(20)
Case report	Unknown	1 case (lethal)	Nurse used a cassette that contained a more concentrated solution of morphine (no other cassette was available). Programming error led to administration of a toxic level of morphine.	100% (n=1)	(21)
A retrospective descriptive quantitative and qualitative analysis	Food and Drug Administration MDR database and other sources	Use programming errors estimated to be a low likelihood event (ranging from 1 in 33,000 to 1 in 338,800), but considerable in absolute terms (ranging from 65-667 deaths).	User programming errors with this device	Nothing mentioned	(21)
Case report	Unknown	1 case	Lack of training/instruction of hospital staff	100% (n=1)	(22)

Table 3 (continued)

Study type	Data source	Number of Incidents	Causes of incidents	Number of use problems % (n)	Reference
Case report	Unknown	1 case	Uncontrolled delivery of drugs by free flowing: misconnection and improper secured device, detection fault of the pump.	100% (n=1)	(23).
Case report	Unknown	1 case	Nurse injected paracetamol using inadvertently the epidural instead of the intravenous pump.	100% (n =1) mistake was repeated after 6 hours	(24)
Case report	Unknown	1 case	Switching patient from old to new device: Incorrect connection, incorrect pump programming, and miscommunication about drug administration	100% (n=1)	(25).
Case report	Unknown	1 case	Nurse mistakenly administrated medication in the wrong line.	100% (n=1)	(26)
A retrospective descriptive quantitative and qualitative analysis	Copenhagen Hospital Corporation (CHC)	Not defined	Incorrect infusion rate/disconnection or kinking of the infusion line	Critical incidents were in 40% of cases caused by user-error.	(27)
Case report	Unknown	A series of use errors occurred with a new model infusion pump.	Switching patient from old to new device: Improper priming/absence of fail-safe mechanism on new model infusion pump.	Not specified.	(28)
Case report	Institute for Safe Medication Practices Canada	7 cases (lethal)	A combination of actions and conditions, each of which on its own would not have caused the event. Together they were causal. Three primary causal chains were identified: <ul style="list-style-type: none"> • An overdose of medication (fluorouracil) • Design of the chemotherapy protocol • Inability to mitigate harm from fluorouracil and cisplatin. 	Not defined.	(29)

Table 3 (continued)

Study type	Data source	Number of Incidents	Causes of incidents	Number of use problems % (n)	Reference
A retrospective descriptive quantitative and qualitative analysis	(30) , a national, Internet-accessible medication error reporting program owned and operated by the USA Pharmacopeia	257 errors were reviewed. 3.9% resulting in harm.	Wrong programming, misinterpretation, switching infusion rate	69% (n= 177) wrong dose errors.	(31)
A retrospective descriptive quantitative and qualitative analysis	Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) reports	2009 intravenous-PCA - related MAUDE medical device events were reported during the 2-year period.	Device malfunction, operator errors, adverse reaction to medication, patient-related events, indeterminate.	Operator error 6.5% (n= 131) and patient-related events 0.6% (n= 12)	(32)
A retrospective quantitative and qualitative analysis of records	Medmarx, a national voluntary medication error-reporting database	From 2000 to 2005, 919,241 medication errors records from 801 facilities were submitted to Medmarx. 9,571 (1%) errors were associated with PCA.	Improper dosage or quantity, omission and unauthorized or wrong drug. Equipment issues, similar drug names, product packaging, distractions inexperienced staff. Incomplete, duplicative, or contradictory orders, adjust dosages, wrong strength, or lack of drug product availability, administration errors due to wrong programming.	Improper dosage or quantity 38% (n=3637), omission 17.4% (n=1665), unauthorized or wrong drug 17.3% (n= 1656), distractions 37.8% (n=3618) and inexperienced staff 26.3% (n=2517).	(33)
Case report	National Hospital for Neurology and Neurosurgery, London	1 case	The pump and catheter were emptied of baclofen 2000 µg/mL, refilled and primed with baclofen 1000 µg/mL. No correction was made for the 'dead space' between the reservoir and catheter access port, which contained baclofen 2000 µg/mL. Failure of the priming bolus to account for the residual baclofen concentration within the dead space resulted in a serious overdose.	100% (n=1)	(34)

Table 4 (continued)

Equipment		
Solution	Short explanation	Reference
User friendly design		
- Human factors approach	- Requirements derived from the Human Factors approach cover contextual aspects of use.	(39)
- Usability tests	- To derive requirements for a specific and operational level usability tests must be conducted on existing equipment and prototypes to understand use problems with existing equipment and to evaluate a redesign and find a satisfying solution. There is an International Standard on application of usability engineering to medical devices. This standard specifies a process for manufacturers to analyze, specify, design, verify and validate usability, as it relates to safety of a medical device.	(39) (40)
o With expert users	- Expert users of the equipment have the experience, competence and confidence to be critical.	(39)
o With novice users	- Novice users, on the other hand, are important test users as they will encounter most of the handling problems and will probably commit most errors. It is important to consider intended user groups when carrying out usability tests, as the nature of the information obtained from the different user groups can differ widely.	(39)
Pre-purchase assessment	It is more economical to buy systems without usability problems than to correct problems after purchase. For example, the user-interface design and user manuals should be evaluated before purchasing infusion pumps. Usability testing prior to procurement decisions is vital; such testing should be performed using validated methods and not by simply testing the in a clinical setting without clear conditions (see usability tests). Requirements, like the usability of a (new) system and the integration of the system into existing systems, form the basis for evaluation criteria to be used in market investigation.	(41) (27) (3)
Standardization	Infusion pumps are produced by different manufacturers and have different handling characteristics. Centralising the decision process for procurement and establishing a central library of standardized equipment might well reduce patient safety risks and prevent equipment not being (fully) used.	(27)
Smart pumps	Smart pump technology can provide an additional layer of protection at the point of care to help avert intravenous drug errors and prevent patient harm. Smart pumps should interface with other systems to generate meaningful improvements in patient safety. Furthermore, technological and nursing behavioural factors must be addressed if these pumps are to achieve their potential for improving medication safety.	(37) (18, 42)

Table 4 (continued)

Procedures		
Solution	Short explanation	Reference
Guideline development	Develop guidelines and examine their effect. Redesign strategies enable clinicians to question the validity of existing systems, and consider ways to improve the quality of care.	(4, 9, 36, 43) (3)
- appropriate for different types of procedures	Guidelines need to be appropriate for the type of action, the complexity of the action and the environment. Guidelines need to be efficient, simple and safe. A highly critical and complex procedure may require more detail and supportive information than a simple and relatively innocuous procedure. Types of procedures include: <ul style="list-style-type: none"> - Administrative procedures - Standard operating procedures - Off-normal operating procedures (such as maintenance and replacement), and - Emergency procedures 	
- medication calculation worksheets	Educational resources should be available for nursing staff in all clinical areas of the hospital to learn and practice complex drug calculations.	(4)
Information campaign	A campaign aimed to highlight the importance of reporting near miss situations is mentioned to be helpful. Reporting near miss situations generates a better understanding of underlying system weaknesses	(4)
An audit programme	An auditing programme to determine a number of measurable parameters as markers of unsafe practice. The audit results should be communicated regularly to nursing and medical staff, together with an achievable goal that reflected the best practice. Engaging medical and nursing staff ensures managerial support for the changes.	(4)
Training		
Solution	Short explanation	Reference
Knowledge of equipment	Training is a key element in promoting full understanding of the characteristics and limitations of the devices in use.	(5)
Determine safety barriers	It is important to determine any safety barriers that minimised or could have minimised the adverse effects of an error. These safety barriers can help to ensure a safer environment for staff and patients, and should be included in training packages.	(5)
Create awareness of medication safety principles	Infusion pump users should be aware of medication safety principles. Therefore, the following critical steps in the use of infusion pumps needs extra attention: drug ordering, preparation, and administration processes, including labelling of drug infusions, checking drug infusion rates at change of shift, complex calculations, and definitions of a valid medical order.	(4)

4 Discussion and conclusions

4.1 Availability of data

Finding relevant information was not easy. There is no uniform format for publishing incident data. Fortunately, the RIVM already had some experience with this kind of research and already knew where to find this type of information. Most of the competent authorities investigated yearly publish general overviews of incidents with medical devices on their websites and/or in their annual reports. There is only limited specific information available to the public. As in 2004 (IGZ, 2004), there still is an important lack of available information on reported incidents in European countries and consequently on the exact nature of incidents. Belgium still has no open access to information on medical devices. However, there are some improvements compared to 2004. The annual report 2006 of Finland was now available in English. Ireland and France published annual reports in 2006 as apposed to before. Germany published more detailed information than before.

Information on the number of incidents is available on Dutch, German, UK, Irish, French, Finnish and Danish websites. Information on the causes of incidents was also available in annual reports on these websites, except for the French website. The causes described varied from design/construction failure to non-product related causes. Also quality issues and software problems were found to be the root causes of many of the vigilance issues relating to electro-mechanical medical devices and in-vitro diagnostic medical devices. Only Germany and the Netherlands reported specific use problems. The characterization of problems is an important step towards the improvement of the quality of care. By characterizing the problem, action can be taken to correct the procedures and improve the equipment, or to prevent reoccurrence of the problem in the future. Germany, the UK, Ireland and France reported corrective actions. France and Germany were the only countries mentioning recommendations or improvements in user information.

In comparison with some of the surrounding countries, there is room for improvement in the public availability of data in the Netherlands. The information was only available in the Dutch language and, unfortunately, there were no data from the year 2006 (only partly upon inquiry).

The top fives of incidents in the different countries seem consistent. This indicates that the problems occurring in different countries are not significantly different, which could substantiate a joint European effort to tackle these problems.

Despite the encouraging improvements in availability of data, there is one major draw back: There is little value in comparing the data from the different countries, because:

- Report sources were not always clear. Data could come from manufacturers, authorised representatives, importers, medical professionals, hospitals and patients.
- The notifications were presented in different categories, which were based on different definitions (e.g. errors defined as those which cause actual harm and errors defined as departures from intended practice).
- The causes of incidents might not always be consistently assigned. Taking into account that several determinants may lead to an error, one person might focus one particular determinant, while another person might conclude that another determinant is the main cause of error.

There are central reporting systems (at a national or international level) and de-central reporting systems (e.g. in hospitals). Central reporting systems can only be meaningful if the underlying local registries are compatible (44).

The implementation of a European database, as required in the MDD, should play an important role in achieving a uniform reporting system. EUDAMED is the future repository of all registration information on medical devices on the European market. It fulfills the obligation under the medical device directives for the development of such a system and entails potential benefits (45):

- It provides for more efficient handling of the notification processes. With data related to devices and incidents in one database, better market surveillance can be achieved.
- Centralization of data on incidents related to medical devices allows for earlier or preventive action at a national or coordinated EU-wide level.
- Devices can be registered in a single country and be applicable for all member states as opposed to registering in each Member State, as is the current process.

But the main problem to finalising EUDAMED implementation relates to the mandatory use of the nomenclature on which the database is dependent: the Global Medical Device Nomenclature (GMDN). There have been discussions on the availability of the GMDN in English only and the licence fees that need to be paid for access to the GMDN (46).

In conclusion, it can be stated that the availability of public information about incidents with medical devices has improved a little over the years. Still, the depth of the information varies between countries and there is room for improvements. Optimizing registration systems should facilitate unambiguous interpretation and exchange of data. One requisite for a useful system is that the definition and classification of incidents are standardized. As long as there is no standardization, it is often hard to identify causes of incidents. The implementation of EUDAMED entails potential improvements.

4.2 Possible solutions to prevent use problems

Regarding the solutions found for use problems with infusion pumps, almost all of the mentioned solutions are probably generally applicable for medical devices. There were only a few solutions specifically for infusion pumps (creating awareness of medication safety principles, smart pumps and medication calculation worksheets). The general measures to solve use problems are summarized below, per stakeholder.

Recommended measures for health care facilities:

- Analyse mission-critical tasks retrospectively (e.g. by root cause analysis) and prospectively (e.g. by Failure Mode and Effect Analysis).
- Perform a pre-purchase assessment and include human factors requirements for equipment purchases. This assessment should be part of the purchasing procedure of health care facilities. The RIVM studied decision processes used by Dutch hospitals to purchase new devices. For complex devices it is advisable to use a multidisciplinary team to establish product requirements (47). Another RIVM-study elaborated the purchase processes for re-usable medical devices and recommended requirements to be specified and evaluated (48).
- Centralize the decision process for procurement and establish a central library of standardized equipment within the facility.
- Use redesign strategies to question the validity of existing systems in order to improve the quality of care.
- Develop (new) guidelines, bearing in mind that they need to be efficient, simple and safe. A highly critical and complex procedure may require more detail and supportive information than a simple and relatively innocuous procedure.
- Establish a non-punitive reporting environment to facilitate employee self-reporting of device use problems or near misses.
- Set up an audit programme to determine the quality of care.

Recommended measures for health care facilities and manufacturers together:

- Conduct device simulation drills upon equipment installation to identify potential problems or user interface flaws. Perform these usability tests with both expert users and novice users.
- Organize a campaign to highlight the importance of reporting near miss situations so that underlying system weaknesses may be better understood.
- Develop a training programme to create understanding of the equipment. Analyse mission critical tasks and determine safety barriers.
- Train people to look for problems as they use equipment, and establish a standing reporting procedure.
- Develop an alert system to quickly relay hazards.
- Optimize/standardize registration systems.

Recommended measure for manufacturers:

- Include human factors requirements in device design.

The solutions found in this study are congruent with the findings in the SGZ 2008 (13). The IGZ stresses that too little is being done in the Netherlands to ensure patient safety. In accordance with the MDD, manufacturers and/or suppliers should actively collect experiences of users to fulfil the statutory post-marketing surveillance requirements (13). Furthermore, the IGZ stresses that manufacturers must supply user manuals in Dutch and written in a style which is appropriate to the knowledge and experience of the intended readers, with due attention for the circumstances in which the technology or equipment is to be used. This refers to article 4 of the MDD: ‘Member States may require the information, which must be made available to the user and the patient in accordance with Annex I, point 13, to be in their national language(s) or in another Community language, when a device reaches the final user, regardless of whether it is for professional or other use.’. It also refers to essential requirement 13.1: ‘Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.’

The medical devices directives can only set requirements for the manufacturers, not for health care users. There is no mandatory requirement to attend training courses. The IGZ is concerned that, with this legislative vacuum, many health care facilities are not sufficiently aware of the risks associated with medical technology. Risk management is essential to the use of technology in hospital care settings. It is not an ‘optional extra’. It is a basic requisite for providing good quality health care and the ability to take timely action in the event of any problems.

The health care facilities management board must ensure that users are demonstrably competent and receive the necessary training within the framework of a clear structure of equipment use and training. The management board must oversee the process of purchasing, implementation, use and maintenance of technology and devices, ensuring that all phases are conducted in a responsible manner. Particular attention should be paid to equipment representing a higher degree of risk. The IGZ proposes that the risk analysis implementation plan and periodic evaluations should be made mandatory for all equipment purchased.

The IGZ calls for action and recommends a series of measures for other stakeholders as well:

- Certification bodies should include requirements for medical technology and equipment in their certification schemes;
- Health care insurers should ensure the quality of the care to be provided. They must approve (and reimburse the cost of) only those technologies which are of demonstrable high quality. Health care insurers should also impose requirements in terms of the competence of health care providers, particularly in connection with the reimbursement of new therapies.

- Those intending to pioneer the use of new and innovative technologies must advise the scientific organizations and professional federations with regard to the procedures, which may not be performed without passing a test of competence. These organisations are jointly responsible for developing professional standards, competence requirements and training opportunities.

The IGZ is of the opinion that there are legislative shortcomings in terms of national and EU laws. The Medical Devices Directive is ‘future proof’ because its risk classes allow for technology developments, though the IVD Directive is not. Its system of classification of listing the high risk devices has been overtaken by technological developments and the classification system should be updated. A risk based classification system is more ‘future proof.’ Also the Dutch Individual Health Care Professions Act (Wet op de beroepen in de individuele gezondheidszorg; Wet BIG) is not future proof, since it does not take account of future developments in medical technology. The Act lists ‘reserved’ medical interventions that may only be performed by certain categories of qualified professionals. The list is limited and the reserved interventions takes neither account of the risks of medical technology which have become available after the Act was implemented, nor of the risks of older technology where those risks have only become apparent during actual use. This means that certain high risk interventions can still be performed by anyone, regardless of professional qualifications, and at any location.

4.3 Benefits of collecting data

Different stakeholders can benefit from an exchange of information. When incidents are analyzed at a company level or at the level of a health care facility (and embedded in their safety management system), people actually can learn from errors. Pre- and post marketing information and vigilance information is useful for device manufacturers, since it is their objective to produce effective and safe systems. Device manufacturers can (re)design medical devices and instrumentation that make errors less likely. Health care facilities are concerned with maintaining the safety of patients and staff and enhancing the efficiency of their operations. Human factors engineering can be effective in realizing the goals of both device manufacturers and health care facilities. Pro-active measures include: evaluations of currently employed systems for efficiency and error potential, evaluation of systems prior to purchase, and design and evaluation of procedures. Health care facilities can establish procedures that take advantage of the strengths of the people who will carry them out and guard against the weaknesses of those same people. Retroactively, accident/incident investigations can help determining what made a human error possible or even inevitable. Device users might recognize errors more easily and can try to ameliorate certain situations. And last but not least: every measure leading to fewer errors is undoubtedly beneficial to patients. The value of incident information can increase when the data are aggregated and analysed at an (inter)national level. A continuous review of databases makes it possible to detect problems, trends and potential hazards.

5 Recommendations

Recommendation 1 Exchange information on methods of data collection

The Dutch government should exchange information with other European countries on their methods of collecting data on incidents involving medical devices, because the European reporting system in development requires that the underlying local registries are compatible. Only then it is possible to compare data and identify trends. Compatibility should be guaranteed before EUDAMED is implemented.

Recommendation 2 Stakeholders should assume their responsibility

All solutions mentioned in this report and the recommendations made by the IGZ are based on the awareness that all stakeholders involved should assume their responsibility concerning patient safety.

Recommendation 3 Perform more in-depth studies in other product groups

Within this investigation, infusion pumps were chosen for an in-depth study. It would be worthwhile to study the use problems with implants and/or IVDs more carefully, because these product groups are in the top five of incidents in each investigated country.

Recommendation 4 Request information on legislation in other countries

Studying other countries' legislation relating to patient safety might bring solutions to legislative shortcomings as mentioned by the IGZ: the IVD Directive and the Dutch Individual Health Care Professions Act are not 'future proof' since they do not take account of future developments in medical technology.

References

1. Wagner C, Bruijne Md. Unintentional Damage in Dutch Hospitals (In Dutch) - Onbedoelde schade in Nederlandse ziekenhuizen EMGO Instituut and Nivel; 2007. Report No.: ISBN-978-90-6905-844-3.
2. VWS. Letter to the Dutch Lower House on the course of quality - 'Koers op kwaliteit' (in Dutch). 2007 July 6th 2007(MC-U-2775877).
3. Welch DL. Human factors in the health care facility. *Biomed Instrum Technol.* 1998 May-Jun;32(3):311-6.
4. Burdeu G, Crawford R, van de Vreede M, McCann J. Taking aim at infusion confusion. *J Nurs Care Qual.* 2006 Apr-Jun;21(2):151-9.
5. Amooore J, Ingram P. Learning from adverse incidents involving medical devices. *Nurs Stand.* 2003 Apr 2-8;17(29):41-6.
6. Reason J. Human error: models and management. *Bmj.* 2000 Mar 18;320(7237):768-70.
7. Shepherd M, Painter, F.R., Dyro, J.F., Baretich, M.F. Identification of human errors during device-related accident investigations. *IEEE Eng Med Biol Mag* 2004 May/June;23(3):66-72.
8. Wilder GL. Medication safety in home infusion care. *J Infus Nurs.* 2003 Sep-Oct;26(5):311-8.
9. Muller T. Typical medication errors in oncology: analysis and prevention strategies. *Onkologie.* 2003 Dec;26(6):539-44.
10. Ward JR, Clarkson PJ. An analysis of medical device-related errors: prevalence and possible solutions. *J Med Eng Technol.* 2004 Jan-Feb;28(1):2-21.
11. White GG, Weick-Brady MD. Improving patient care by reporting problems with medical devices. A medWatch continuing education article. 1997.
12. IGZ. Patient safety: the use of medicines and medical technology in health care settings and at home (in Dutch) - Patiëntveiligheid: de toepassing van geneesmiddelen en medische hulpmiddelen in zorginstellingen en thuis: Inspectie voor de Gezondheidszorg; 2004.
13. IGZ. Risks of medical technology are underestimated (In Dutch) - Risico's van medische technologie onderschat Inspectie voor de Gezondheidszorg; 2008.
14. van Tienhoven EAE, de Boer S. Resultaten RIVM enquête infuuspompen. *VIT Journaal.* 2005 februari 2005(1):5-9.
15. Hollestelle ML, de Bruijn ACP, Hilbers-Modderman ESM. Infuuspompen in de thuissituatie:- Zijn risicoanalyses, gebruiksaanwijzingen, opleidingen en post marketing surveillance hierop afgestemd?-. RIVM-briefrapport 360050015. 2006.
16. Hilbers ESM, Tienhoven, E.A.E. van. An historical overview of the use of infusion pumps and the correlation with incidents (In Dutch: Een historisch overzicht omtrent het gebruik van infuuspompen - een mogelijke correlatie met het ontstaan van incidenten); 2004.
17. Tienhoven EAEv, Boer Sd. Resultaten RIVM enquête infuuspompen. *VIT Journaal.* 2005 februari 2005(1):5-9.
18. Husch M, Sullivan C, Rooney D, Barnard C, Fotis M, Clarke J, et al. Insights from the sharp end of intravenous medication errors: implications for infusion pump technology. *Qual Saf Health Care.* 2005 Apr;14(2):80-6.
19. Chen PP, Ma M, Chan S, Oh TE. Incident reporting in acute pain management. *Anaesthesia.* 1998 Aug;53(8):730-5.
20. Conreux F, Guilleux A, Beydon L, Cazalaa J, Fougere S. Infusion devices postmarketing survey: Analysis of the reports made in 1998 to the French agency for medical devices. . *Annales Francaises d'Anesthesie et de Reanimation* 2000;19(7):523-9.
21. Vicente KJ, Kada-Bekhaled K, Hillel G, Cassano A, Orser BA. Programming errors contribute to death from patient-controlled analgesia: case report and estimate of probability. *Can J Anaesth.* 2003 Apr;50(4):328-32.
22. Draper S, Nielsen GA, Noland M. Using "no problem found" in infusion pump programing as a springboard for learning about human factors engineering. *Jt Comm J Qual Saf.* 2004 Sep;30(9):515-20.

23. Elannaz A, Chaumeron A, Viel E, Ripart J. Morphine overdose due to cumulative errors leading to ACP pump dysfunction. *Annales Francaises d'Anesthesie et de Reanimation*. 2004;23(11):1073-5.
24. Courreges P. Inadvertent epidural infusion of paracetamol in a child. *Paediatr Anaesth*. 2005 Dec;15(12):1128-30.
25. Syed S, Paul JE, Hueftlein M, Kampf M, McLean RF. Morphine overdose from error propagation on an acute pain service. *Can J Anaesth*. 2006 Jun;53(6):586-90.
26. Tiefenthaler W, Tschupik K, Hohlrieder M, Eisner W, Benzer A. Accidental intracerebroventricular injection of anaesthetic drugs during induction of general anaesthesia. *Anaesthesia*. 2006 Dec;61(12):1208-10.
27. Bjorn B, Garde K, Pedersen BL. [Infusion pumps and patient safety]. *Ugeskr Laeger*. 2007 Jan 22;169(4):315-8.
28. Rule AM, Drincic A, Galt KA. New technology, new errors: how to prime an upgrade of an insulin infusion pump. *Jt Comm J Qual Patient Saf*. 2007 Mar;33(3):155-62.
29. Dobish R, Greenall J, Hyland S. Important Findings from an In-depth Analysis of a Medication Incident. *Canadian Journal of Hospital Pharmacy*. 2007 September;60(4):267-70.
30. MEDMARX. MEDMARX database (U.S. Pharmacopeia). available at <http://www.usp.org/hqi/patientSafety/medmarx/>, 16 december 2008. 2007.
31. Hicks RW, Becker SC, Chuo J. A summary of NICU fat emulsion medication errors and nursing services: data from MEDMARX. *Adv Neonatal Care*. 2007 Dec;7(6):299-308; quiz 9-10.
32. Hankin CS, Schein J, Clark JA, Panchal S. Adverse events involving intravenous patient-controlled analgesia. *Am J Health Syst Pharm*. 2007 Jul 15;64(14):1492-9.
33. Hicks RW, Sikirica V, Nelson W, Schein JR, Cousins DD. Medication errors involving patient-controlled analgesia. *Am J Health Syst Pharm*. 2008 Mar 1;65(5):429-40.
34. Dalton C, Keenan E, Stevenson V. A novel cause of intrathecal baclofen overdosage: lessons to be learnt. *Clin Rehabil*. 2008 Feb;22(2):188-90.
35. Chuo J, Lambert G, Hicks RW. Intralipid medication errors in the neonatal intensive care unit. *Jt Comm J Qual Patient Saf*. 2007 Feb;33(2):104-11.
36. Apkon M, Leonard J, Probst L, DeLizio L, Vitale R. Design of a safer approach to intravenous drug infusions: failure mode effects analysis. *Qual Saf Health Care*. 2004 Aug;13(4):265-71.
37. Wilson K, Sullivan M. Preventing medication errors with smart infusion technology. *Am J Health Syst Pharm*. 2004 Jan 15;61(2):177-83.
38. Liljegren E, Osvalder AL, Dahlman S. Setting the requirements for a user-friendly infusion pump Proceedings of the XIVth Triennial Congress of the International Ergonomics Association and 44th Annual Meeting of the Human Factors and Ergonomics Association, 'Ergonomics for the New Millennium'. 2000:132-5.
39. Garmer K, Liljegren E, Osvalder AL, Dahlman S. Arguing for the need of triangulation and iteration when designing medical equipment. *J Clin Monit Comput*. 2002a Feb;17(2):105-14.
40. IEC. NEN-EN-IEC 62366: Medical devices - Application of usability engineering to medical devices. 2008 01-02-2008.
41. Reid MH, Sawyer D. The human factors implications of peritoneal dialysis: cyclor overfill incident reports. *Int J Trauma Nurs*. 1999 Apr-Jun;5(2):68-71.
42. Rothschild JM, Keohane CA, Cook EF, Orav EJ, Burdick E, Thompson S, et al. A controlled trial of smart infusion pumps to improve medication safety in critically ill patients. *Crit Care Med*. 2005 Mar;33(3):533-40.
43. Locock L. Healthcare redesign: meaning, origins and application. *Qual Saf Health Care*. 2003 Feb;12(1):53-7.
44. Legemate J, Christiaans-Dingelhoff, I., Doppegieter, R.M.S., Roode, R.P. de. Incident reporting in health care (in Dutch) - Melden van incidenten in de gezondheidszorg 2006.
45. IADBC. EUDAMED: European database for medical devices. IADBC European eGovernment services. 2007 July 2007.
46. RAJ. Data exchange - Eudamed database unlikely to be mandatory before March 2010. *The Regulatory Affairs Journal Devices*. 2008 May/June 2008;16(8):p. 184.

47. Drongelen AWv, Roszek B, Tienhoven EAEv. Kwaliteitsborging bij aanschaf van medische hulpmiddelen in Nederlandse ziekenhuizen? Inventarisatie van processen en eisen. (In Dutch) 2006. Report No.: RIVM-briefrapport 360050004
48. Drongelen AWv, Bruijn ACPd. Instruction for reuse: beware when buying! . Zentral Sterilization. 2006;14(1):34-60.
49. IGZ. Annual report 2005; 2005.
50. BfArM. Medizinprodukte; Statistische Auswertungen. available at www.bfarm.de, 16 december 2008. 2007.
51. MHRA. Adverse Incident Reports 2007. Device Bulletin DB2008 (02), available at <http://www.mh.gov.uk>, 16 december 2008. 2008.
52. MHRA. Adverse Incident Reports 2006. Device Bulletin DB2007 (02), available at <http://www.mh.gov.uk>, 16 december 2008. 2007.
53. AFSSAPS. Annual Report 2006. available at www.afssaps.santefr.fr, 16 december 2008. 2006.
54. Mazeau V, Grenier-Sennelier C, Paturel DX, Mokhtari M, Vidal-Trecan G. Telephone survey of hospital staff knowledge of medical device surveillance in a Paris hospital. Eval Health Prof. 2004 Dec;27(4):398-409.
55. Laegemiddelstyrelsen. Annual report 2006. available at http://www.laegemiddelstyrelsen.dk/publikationer/netpub/medicinskudstyr/aarsrapport_2006/, 16 december 2008. 2006.
56. NAM. Annual report 2006 from the National Agency for Medicines; 2006.
57. NAM. Annual report 2007. available at http://www.namfi/english/publications/annual_reports/annualreview2007.html, 16 december 2008. 2007.
58. IMB. Annual report 2006 - Protecting public and animal health. available at <http://www.imb.ie/>, 16 december 2008. 2006.

Annex I Definitions

For the purpose of this investigation several definitions were used and described below in alphabetical order.

Abnormal use is an act or omission of an act by the operator or user of a medical device as a result of conduct which is beyond any means of risk control by the manufacturer Meddev 2.12-1 rev 5).

Adverse Medical Device Events (AMDEs): patient experienced harm (Samore et al., 2004)

Corrective action is an action to eliminate the cause of a potential nonconformity or other undesirable situation (EN ISO 9000:2000, 3.6.5).

Hospitals are providers of diagnostic, therapeutic, surgical, and other patient services which include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities.

Human factors is a discipline devoted to studying the interaction of people and equipment and the variables that effect the outcome of the contact. It is rooted in the awareness that the successful performance of the ‘operator’ within large systems depends on an array of complex and interdependent forces. And if those forces are poorly understood and not accommodated in the design of the process or equipment, the stage is set for error and possible disaster: near misses, accidents, or even fatalities.

Incident ‘Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or USER or of other persons or to a serious deterioration in their state of health’. (Article 10 of the MDD).

Intended purpose is the use for which the device is intended according to the data supplied by the manufacturer the labelling, in the instructions and/or in promotional materials (Article 1.2 (h) of the IVDD and Article 1.2 (g) of the MDD).

Medical device-related hazards: no known harm to the patient (Samore et al., 2004).

Use error (1) is an act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user (ISO 14971, IEC 62366).

Use error (2) refers to flawed design – inattention to human factors rather than faulty equipment or incompetent operators (the Institute for Healthcare Improvement (IHI) based in Cambridge, Massachusetts³)

3

<http://www.ihl.org/IHI/Topics/PatientSafety/MedicationSystems/ImprovementStories/ImprovingPatientSafetyByIncorporatingHumanFactors.htm>; last visited September 23, 2008.

Annex II Published data per country

1. THE NETHERLANDS

The Health Care Inspectorate (IGZ) is the competent authority for medical devices in the Netherlands. On their website information on reported incidents with medical devices could be found in the annual report of 2005 (49). The annual report of 2006 did not contain this kind of information. Upon inquiry, information on 2006 was sent to the RIVM by e-mail. Two remarks were made added:

1. These figures relate only to products on the Dutch market 2. No difference is made between intra- and extramural incidents.

Number of incidents

In 2006, 650 incidents with medical devices were reported to the IGZ.

Table A1: Top ten medical devices involved in incidents (2006)

1.	Disposables
2.	Non-active implants
3.	In Vitro Diagnostics
4.	Electro mechanical devices
5.	Active implants
6.	Reusables
7.	Anesthesia equipment
8.	Non-diagnostic devices (e.g. hospital beds)
9.	X-ray and radiotherapy equipment
10.	Devices for handicapped persons

Causes of incidents

The annual report of 2005 contains a Table with information on avoidable and culpable errors with medical devices (see Table A2) Errors are categorized in: personal, organisational, product and application errors. For the year 2006 this kind of information has not been found on the IGZ website.

Table A2: Causes of incidents with medical devices (2005)

Personal errors	14
Organisational errors	4
Product errors	270
Application errors	29
Unforeseen complications	17
Calculated risk	21
No error	63
No conclusion possible	98
Unknown	39

The number of use problems

The ‘personal errors’ and ‘application errors’, as mentioned in Table A2, might be comprehensive to the term ‘use problems’ as defined in this report.

Corrective actions taken

Data of corrective actions taken are not publicly available on the IGZ website or in the annual report (49).

2. BELGIUM

The Belgian federal public service website (federale overheidsdienst, <http://www.portal.health.fgov.be/>) contains no open access to information on medical devices. The English version of the site is under construction. The site refers to the medical device directive and contains incident report forms.

3. GERMANY

The German Federal Institute for Drugs and Medical Devices website (Bundesinstitut für Arzneimittel und Medizinprodukte, (50)) contains statistical data (e.g. risk reports, source reports, cause of incident reports, etc.) on medical devices. The statistical data which are publicly available do not contain information about the location of the incidents (e.g. intramural or extramural setting). Responsibility, regarding incident notification or recall, resides with the following persons:

- The person responsible for bringing the device on the market (manufacturer or authorised representative).
- If the manufacturer does not have his/her registered place of business in the European Economic Area and if an authorised representative has not been designated⁴, or if medical devices are not being imported into the European Economic Area under the responsibility of the authorised representative, the importer is the person responsible.
- Operators or users of medical devices, if the device is operated or used within a professional or commercial framework.
- Persons authorised to practice medicine or dentistry, distributors and traders who sell medical devices to patients or other laypersons for personal use.

Other sources of information used by BfArM are literature and press information.

Number of incidents

Between 2005 and 2007 a total of 11,892 incident reports were collected by the BfArM, of which approximately 80% (n= 9,482) were useful for further risk assessments. A top ten of medical devices involved in incidents has been derived from the vigilance system over the year 2006 and is presented in Table A3.

Table A3: Top ten medical devices involved in incidents (2006) (50)

1. Active implant
2. Non-active implant
3. Injection/infusion/transfusion/dialysis
4. In Vitro Diagnostics
5. Dental products
6. Electronic medical devices
7. Equipment used in the operation room or anaesthesia
8. Medical instruments
9. Products used by orthopedic and rehabilitation techniques
10. General medical equipment

⁴ The current wording of the MDD 93/42/EEC, article 14(2), leaves the possibility that the authorised representative has not been designated, depending on its classification. In the revised MDD 93/42/EEC, as amended by directive 2007/47/EC, which will be effective on 21 March 2010, all manufacturers who do not have a registered place of business in a Member State are obligated to designate a single authorised representative in the European Union for placing their product on the European market.

Problems with medical devices in the period 2005-2007 were in descending order:

1. Mechanical problems
2. Functional error
3. Medical-technical appearance
4. Electronic failure
5. Specific IVD problems (e.g. false positive/negative results, deviations from performance, interaction with other substances, stability problems)
6. Non-sterile products or contaminated products
7. Lack of identification or user instructions
8. High temperatures and inflammable mixtures
9. Alarm failure
10. Other problems (not defined)
11. Software problems
12. Multifunctional appearance

Causes of incidents

Problems (n= 9,482) with medical devices were caused by: design/construction failure, production failure, other product related causes (e.g. obsolescence of components), non-product related causes and unknown causes (e.g. lack of information about problem cause). An overview of the relationship between cause and problem in the period 2005-2007 is presented in Figure A1 (50).

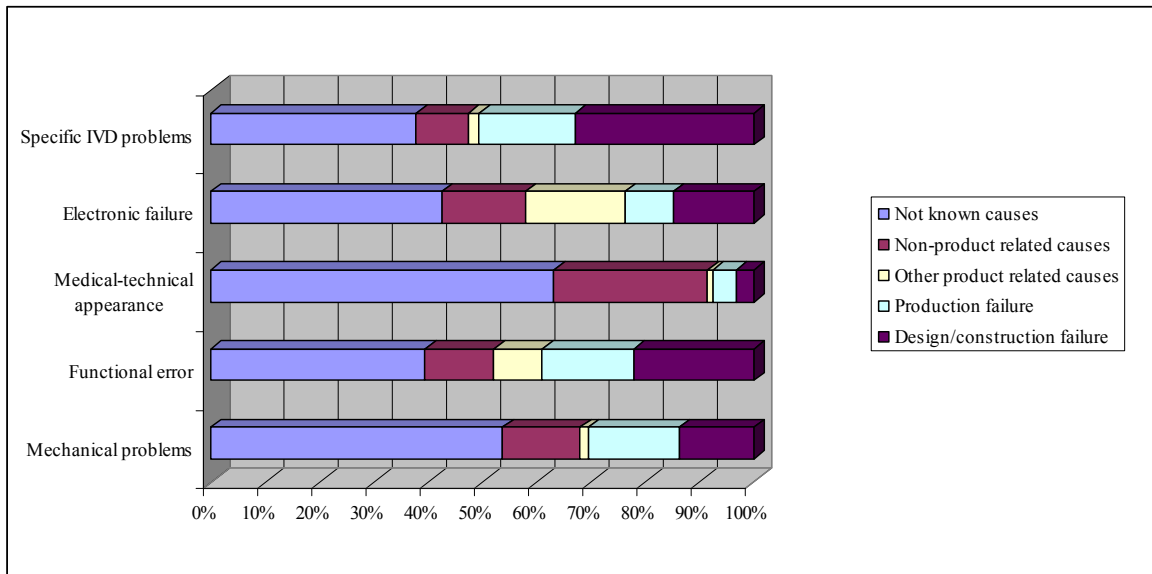


Figure A1: Five most occurred problems combined with causes in the period 2005-2007 (50)

The number of use problems

Approximately 16% (n= 1,477) of these medical device problems were due to non-product related causes, e.g. wrong use, use of non-compatible components, insufficient training/instruction, inadequate maintenance/repair/calibration, inadequate cleaning/disinfection/sterilisation, incorrect storage and/or transportation, product being past shelf life, environmental influence, patient-related causes, and wrong adjustments of the control, and other non-related causes. The majority of these causes are due to use errors. A part of the ‘not known causes’ may in part also be due to ‘use problems.’

Corrective actions taken

There were 9482 reports of corrective measures and measures to rectify causes analysed (50). Approximately 20% (n= 1,867) contained corrective measures and approximately 25% (n=2,404) contained measures to rectify causes.

Corrective measures (in relation to products which are already on the market) were in descending order:

1. Recall
2. Recommended measures for users information
3. Other undefined measures
4. Withdrawal of a product or production stop
5. User training
6. Discontinuation of a product

An overview of the relationship between corrective measures and problems in the period 2005-2007 is presented in Figure A2.

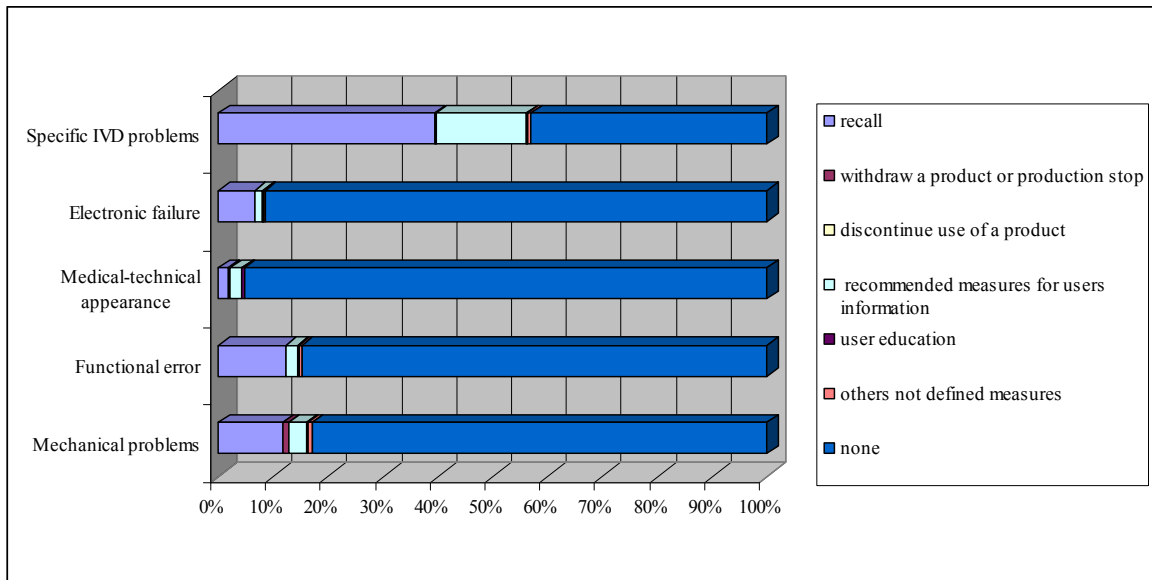


Figure A2: Five most occurred problems combined with corrective measures in the period 2005-2007 (50)

Measures to eliminate causes (in relation to future products) were in descending order:

1. Optimisation of the production process
2. Modification of design and/or construction
3. Changing the product information (users' information, characterization)
4. Software upgrade
5. Improving quality checks
6. Other (not defined)
7. Modification of the material (up to and including change of supplier)
8. Postponement the production
9. User training
10. Changing (e.g. limiting) the target definition respectively use

4. UNITED KINGDOM

In the United Kingdom adverse incident reports are registered by the adverse incident centre (AIC) of the Medicines and Healthcare products Regulatory Agency (MHRA). These reports are imported into the Adverse Incident Tracking system and are available electronically to medical device specialists at the MHRA. The data is summarised in a yearly report, which is published as Device Bulletin on the MHRA website (51). The report data does not contain information about the location of the incidents (e.g. intramural or extramural settings). The MRHA received a total of 24,471 adverse incident reports in the period 2005-2007 (51). Report sources were: National Health Service, other government bodies, non-government bodies, manufacturers, overseas reporting organisations, and private healthcare organisations.

Number of incidents

Since 2001, online reporting has been possible and now also medical device users, members of the public and health professionals can report incidents. In 2007, over 2,500 reports were submitted via this route. In 2006 a total of 7,975 number of incidents reports were received. No exact data per medical device group were presented in the annual report; therefore an estimated top ten of medical devices involved in incidents reports over the year 2006 has been derived from a figure in the annual report. This estimated top ten is presented in Table A4.

Table A4: Estimated top ten medical devices involved in adverse incidents (2006) (52)

<ol style="list-style-type: none"> 1. Active and non-active implant 2. Life support/incubators/monitors 3. Electromechanical devices (e.g. infusion, transfusion, dialysis) 4. Surgical equipment 5. Wheeled mobility equipment 6. In Vitro Diagnostics 7. Surgical consumables 8. Others 9. Diagnostic imaging 10. Syringes/needles
--

Causes of incidents

Causes of adverse incidents are divided into three categories, in descending order:

1. Manufacturer responsibility (before delivery e.g. design, manufacture, quality control and packaging)
2. Healthcare establishment/user responsibility (after delivery e.g. performance and/or maintenance failures and degradation)
3. No established device/use link (device subsequently was found to work as intended or device involved was not available for investigation)

No exact data are available on the frequency of occurrence of the different causes (51, 52).

The number of use problems

Data of use problems are not publicly available on the MHRA website or in the annual report (51, 52).

Corrective actions taken

Corrective measures or other solutions were (in descending order):

1. MHRA safety warning/Manufacturer notice or letter
2. Design change of device, label or packaging
3. Field safety corrective action
4. Manufacturer changed/Improved QA

5. Revised/additional user training/publicity
6. Referred to other organizations
7. Other (e.g. device was taken off the market)
8. Other manufacturer field action
9. Improved maintenance
10. Production ceased

No exact data are publicly available (51, 52).

5. FRANCE

Pursuant to the French Public Health Code, any incident or risk of incident involving a medical device that leads or might have led to the death or serious deterioration of the state of health of a patient, user or third party is to be reported to the Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps) without delay. The report form may be downloaded from the Afssaps website⁵ (53). Medical devices are classified in four groups by the AFSSAPS, namely medical equipment, medical implantables, medical consumables, and In Vitro Diagnostics. In vitro diagnostics is mentioned separately from the medical devices under paragraph “réactovigilance”.

Number of incidents

The only information publicly available is the identification of medical devices involved in adverse incidents over the period 2005-2006 (Table A5). The AFSSAPS received a total of 17,136 incident reports in the period 2005-2006 (53).

Table A5: Medical devices involved in adverse incidents over the period 2005-2006 (53)

1. Medical consumables
2. Medical implants
3. Equipment
4. In Vitro Diagnostics

To get a reliable picture of incidents with medical devices in an intramural setting it is important that the hospital staff knows the procedures for medical device surveillance. Most hospitals in France have local procedures. In 2004, the knowledge of a hospital staff about medical device surveillance was evaluated in a university hospital in Paris (54). A telephone survey was conducted on a sample of the staff (n=327) using a structured questionnaire. The response rate was 66%. Questions varied from, knowledge how to identify a medical device to how to alert the appropriate person if facing an incident with a medical device. The overall result suggested a satisfactory level of the knowledge of the hospital staff on medical device surveillance. Eighty percent gave a correct definition of hospital medical device surveillance. And eighty-seven percent knew who to alert when an incident or near incident occurred. There was a U shaped relationship between rates of correct answers and age. This meant that extreme groups (e.g. experienced old staff and recently qualified staff) gave correct answers more often than the intermediate groups.

Causes of incidents

Causes of incidents are not publicly available on the AFSSAPS website or in the annual report (53).

The number of use problems

Data of use problems are not publicly available on the AFSSAPS website or in the annual report (53).

⁵ www.afssaps.sante.fr

Corrective actions taken

Corrective actions taken or other solutions (n = 1,821) were (in descending order):

1. Corrective action by the manufacturer (e.g. additional recommendations for use, modification of the concept, modification of the manufacturing process, modification of the quality system, restoration of the medical device by adjustments or repairs, taking device off the market)
2. Alerts on the internet site of the AFSSAPS
3. Recall
4. Recommendations or information for use or corrective actions
5. Notification of the European representatives by the AFSSAPS
6. Recommendations or information for use by the AFSSAPS

6. DENMARK

Serious incidents that occur with the use of any medical device must be reported to the Danish Medicines Agency⁶. The report will then be fully investigated with the manufacturer, the authorised representative or the appointed distributor. The purpose is to determine the probable cause of the event and to provide advice or corrective action to prevent further occurrences of a similar nature. In some justified cases, this may require the manufacturer to remove a specific product from the users or marketplace. The obligation of reporting adverse incidents applies to manufacturers, professional users and other healthcare professionals.

All serious incidents or near-incident with medical equipment, in which the equipment plays a role in the incident, should be reported. This is true regardless of whether it is a patient, staff or third parties that have been or could have been injured. A serious incident is an incident that results in death, life-threatening injury or illness, permanent damage to the body or bodily functions or requires medical or surgical treatment to avoid the above. A near-incident is an incident which does not have a serious end, because there is intervened before the incident has evolved.

Number of incidents

The annual report 2006 of the Danish Medicines Agency (55), available in Danish only, mentions 667 reports of incidents with medical equipment that year. The report does not contain detailed information about medical devices.

These reports originate from the Danish users (health professionals), manufacturers (Danish as well as foreign) and foreign authorities. This is an increase of 7% over 2005, which follows the trend since Medicines Agency began to receive notifications. The progress since 2000 is illustrated in Figure A3.

⁶ <http://www.medicaldevices.dk>

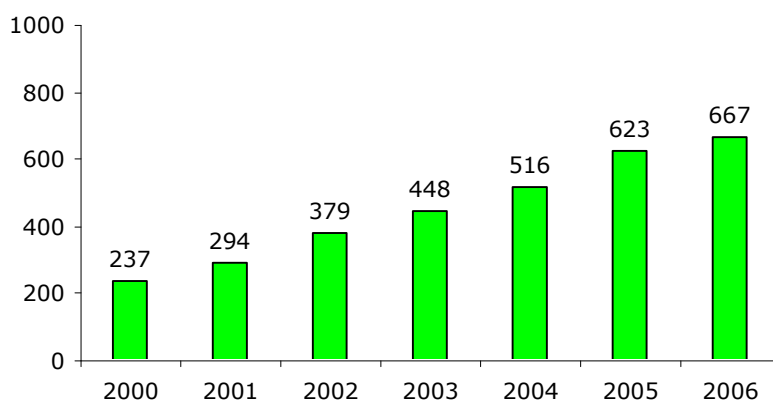


Figure A3: The number of cases relating to incidents in the period 2000-2006 (55)

The increase in the number of cases relating to incidents is not necessarily a sign that the problems with medical devices are increasing. It is probably due to the increased attention for reporting obligations of incidents with medical equipment. Reports from Danish users are based on actual incidents by the use of equipment. Reports from manufacturers are serious incidents or near-incidents on the use of equipment in Denmark as well as information on any preventive measures that are introduced in order to prevent similar incidents and thereby improve patient safety, such as withdrawal or improvement of the product. Reports from foreign authorities cover any preventive measures, which are typically taken as a result of serious incidents or near-incidents abroad in order to prevent similar incidents and thereby improve patient safety. The exchange of information between the authorities ensures that preventive work is carried out anywhere where the equipment is marketed and not only in the country where the incident happened. Figure A4 illustrates the distribution of reporters.

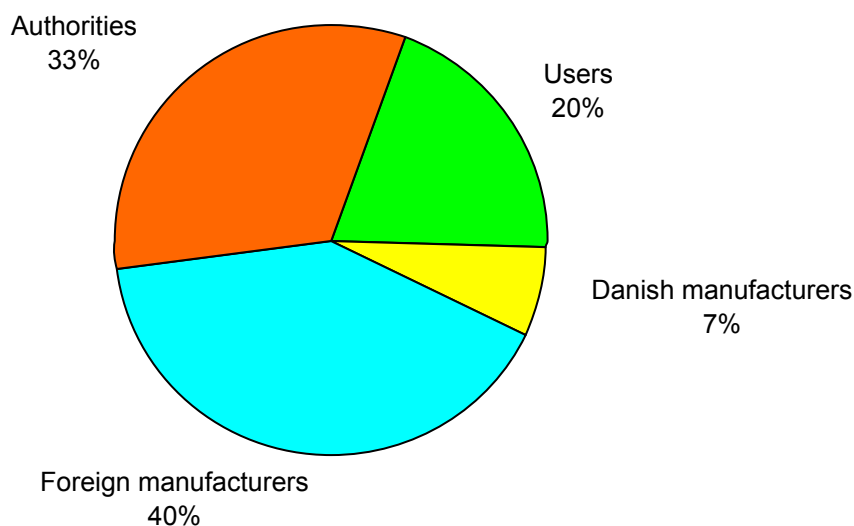


Figure A4: Distribution of reporters (55)

The proportion of cases from foreign manufacturers and the authorities constitute the majority of the reports. This is partly due to the fact that most of the medical equipment used in Denmark is produced by foreign manufacturers, and it is usually the manufacturer who reports.

In addition, it is a natural reflection of events abroad because of the greater population, and that preventive measures in the light of these events will also be implemented in Denmark.

Causes of incidents

The Medicines Agency chose to categorize events in major categories (design, packaging and labelling for use, production, software and handling) and some more broad categories (unresolved, and others).

Figure A5 shows the percentage of causes of incidents of the events that were handled in 2006.

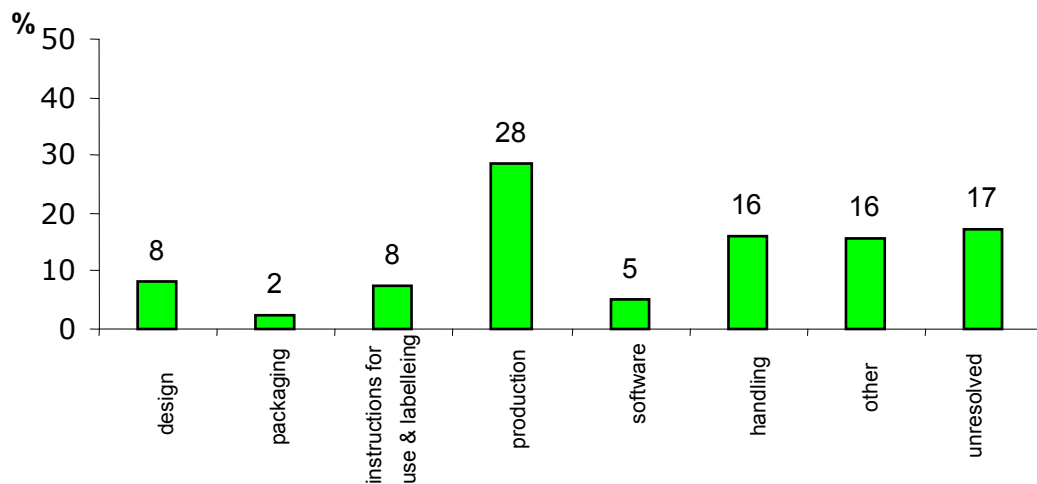


Figure A5: Causes of incidents in 2006 (55)

‘Unresolved’ are incidents where the underlying cause has not been identified. ‘Other’ is a wide variety of cases, including cases where the outcome of the investigation has shown that the device is not the cause of the incident, such as the use of equipment outside the intended use.

In 2006, the Medicines Agency reviewed 467 reports where medical equipment was identified as a possible contributory cause of the incident. Nine of these incidents were identified as being serious incidents with medical equipment.

The number of use problems

Data of use problems are not publicly available on the DKMA website or in the annual report (55).

Corrective actions taken

Corrective actions are not publicly available on the DKMA website or in the annual report (55).

7. FINLAND

The National Agency for Medicines (NAM) promotes the health and safety of the Finnish citizens by regulatory control of medicinal products, medical devices and blood products. Their function regarding medical devices is to monitor the compliance of medical devices with the legislation and regulations and to promote their safe use. The National Agency for Medicines has issued instructions for serious incident reporting by the user and the manufacturer. The instructions are valid from 1.1.2006 - 31.12.2009.

Number of incidents

On the internet⁷ annual reports are available (56, 57). These reports mention the number of adverse events, but these figures do not represent detailed information about the medical devices involved in incidents. In 2007 the NAM received 732 adverse incident reports (57). Figure A6 shows that the total number of adverse incident reports varies per year; only reported incidents by manufacturers show an increase over the years.

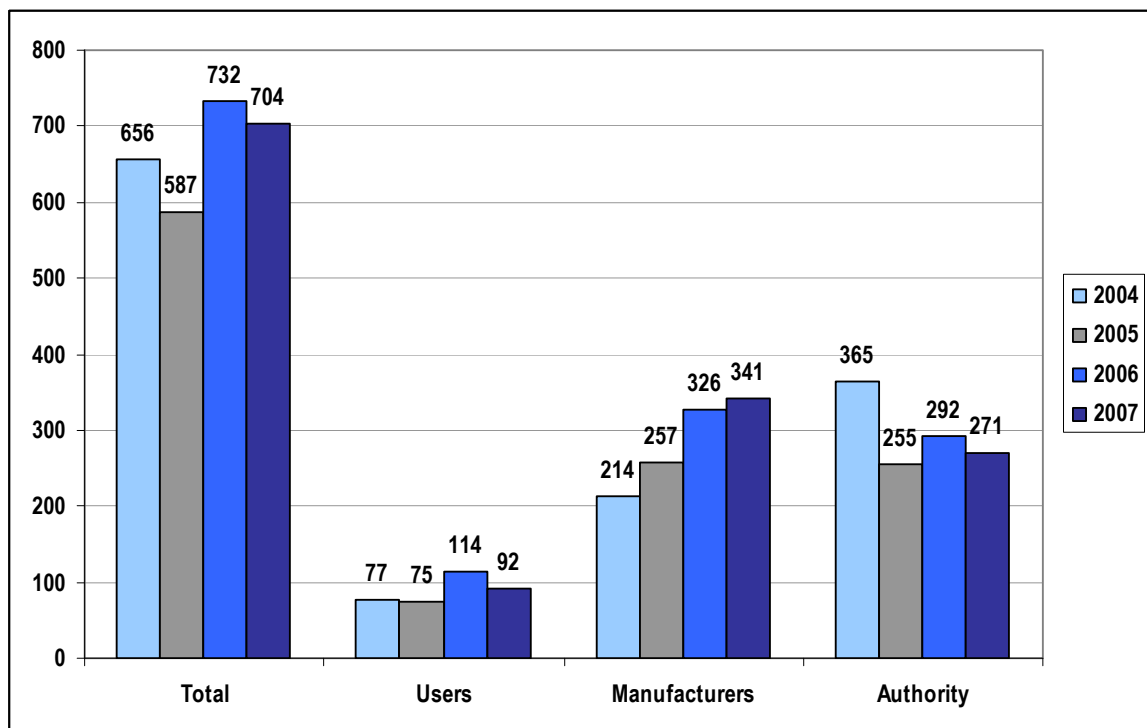


Figure A6: Reported serious adverse incidents 2004-2007 (57)

Causes of incidents

Causes of adverse incidents in Finland in 2007 are not publicly available however the causes of adverse incidents in Finland in 2006 were in descending order (56):

1. Device failure before commissioning
2. Device failure after commissioning
3. Faulty operation
4. Cause unclear
5. Other

⁷ http://www.nam.fi/medical_devices

The number of use problems

The presented information in Figure A6 does not provide information about numbers of use problems; it only gives information how many users reported adverse incidents.

Corrective actions taken

Corrective actions are not publicly available on the NAM website or in the annual report (56)

8. IRELAND

Under the terms of the Irish Medical Devices Regulations, the Irish Medicines Board (IMB), as the Competent Authority, is obliged to institute and coordinate a reporting system for adverse incidents associated with the use of medical devices in Ireland. The system is intended to improve the protection of health and safety of patients, users and others by reducing the likelihood of the same type of adverse incident being repeated in the European Economic area (EEA).

If necessary, notices relating to the safety and/or quality of medicinal products are occasionally published by the Irish Medicines Board. These notices may relate to human and veterinary medicines, or medical devices. The issues covered by these notices will range from quality defect information and medicinal product safety information through to updated information on the appropriate usage of medicines or devices.

Notices are categorized in accordance with their importance at the time of publication.

The four notice categories are outlined as follows:

- Advisory (routine safety information)
- Warning (urgent safety information)
- Recall (urgent safety information relating to a product recall)
- Publications (general safety information provided by the IMB)

Number of incidents

In 2006 IMB received 993 vigilance reports (58). The number of incident reports received for medical devices increase substantially over the years (Figure A7). Unfortunately, the underlying reasons are not described. It is therefore not clear if the number of incidents is increasing over the years or that there is another reason for the larger number of reports each year, e.g. the increase in monitoring activities.

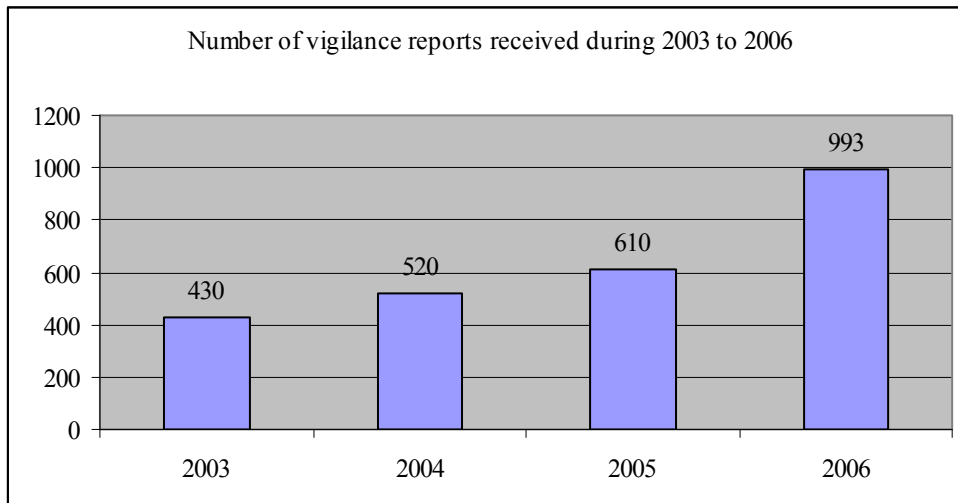


Figure A7: Number of vigilance reports received during 2003-2006 (58)

A top ten of medical devices involved in adverse incidents in 2006 has been derived from the annual report and is presented in Table A6.

Table A6: Top ten medical devices involved in adverse incidents in 2006 (58)

1. Single use devices
2. Non Active Implantable devices
3. Electro-mechanical medical devices
4. Hospital Hardware
5. Anesthetic & Respiratory devices
6. Diagnostic & Therapeutic radiation devices
7. Technical aids for disabled persons
8. Reusable instruments
9. Active Implantable devices
10. Ophthalmic & Optical Devices

Causes of incidents

Quality issues and software problems were found to be the root causes of many of the vigilance issues relating to electro-mechanical medical devices and in-vitro diagnostic medical devices. IVDs are excluded from this Table. Device maintenance and management problems have been identified as important causes of reports in relation to technical aids for disabled people and wheeled mobility.

The number of use problems

Data of use problems is not publicly available on the IBM website or in the annual report.

Corrective actions taken

The annual report only mentions recalls as corrective actions. Other corrective actions are not described in the report (58). The IMB also co-operated closely with other European Competent Authorities, the European Commission and the device manufacturer in relation to a major field safety corrective action associated with an infusion pump (58).

RIVM

National Institute
for Public Health
and the Environment

P.O. Box 1
3720 BA Bilthoven
The Netherlands
www.rivm.com