RIVM report 318902 012/2002

Wheelchair incidents

AW van Drongelen, B Roszek, ESM Hilbers-Modderman, M Kallewaard, C Wassenaar

This study was performed on request of the Dutch Inspectorate for Health Care on behalf of project V/318902 'Technical support of the Inspectorate'

RIVM, P.O. Box 1, 3720 BA Bilthoven, telephone: +31 30 274 91 11; telefax: +31 30 274 29 71

Abstract

This RIVM study was performed to gain insight into wheelchair-related incidents with powered and manual wheelchairs reported to the USA FDA, the British MDA and the Dutch Center for Quality and Usability Research of Technical Aids (KBOH).

A modified version of the Critical Incident Technique, based on the chain of events from the cause to the consequence of the injury, was used to study the FDA and KBOH data. The chain of events was limited for the analysis of MDA data. The method proved a useful tool for structuring information.

Most of the incidents reported to the FDA and MDA were product-related, whereas the literature reported mostly use-related incidents. Components for operating powered wheelchairs, frames and wheels were most frequently reported in the databases to fail. Although the problems of transportation and comfort or fit were found in the literature, they were only sporadically mentioned in the databases. Falls and tips frequently occurred, often with severe consequences. Fractures were the most frequently observed severe injuries and occurred more frequently among powered-wheelchair users.

The data in the databases do not indicate that incidents with wheelchairs present a major public health problem. However, studies in the literature and Dutch data on fatalities involving wheelchairs suggest that the actual number of serious injuries and fatalities, mostly use-related, is considerably higher than the number found in the databases. This is partially due to the different nature of the sources. In general there seems to be underreporting. The low number of vigilance reports in Europe relative to the USA deserves attention.

Preface

The authors would like to thank Mr. M. Rand of the MDA DTS3 and Mr. B. de Bruin of the KBOH for the information they supplied and for critically reviewing this report. We also thank Mrs. G. Peters-Volleberg and Mr. R. Geertsma for critically reviewing the manuscript.

Contents

Samenvatting **7**

Summary **8**

1. Introduction **9**

1.1 General *9*

1.2 Objectives *10*

2. Methods **11**

2.1 Data collection *11*

2.2 Data abstraction and analysis *11*
2.2.1 Critical Incident Technique 11
2.2.2 FDA and KBOH data 12
2.2.3 MDA data 14

2.3 Literature search *14*

3. Results **17**

3.1 FDA *17*
3.1.1 General 17
3.1.2 Consequences of injury 17
3.1.3 Injuries 18
3.1.4 Effects 19
3.1.5 Problems 21
Causes 23
3.1.7 To whom it happened 24
3.1.8 Device involved 25
3.1.9 Location of incident 26

3.2 MDA *27*
3.2.1 General 27
3.2.2 Outcomes 27
3.2.3 Problems 28
3.2.4 Causes 29
3.2.5 Actions 31

3.3 KBOH *32*
3.3.1 General 32
3.3.2 Reported incidents 32

3.4 Wheelchair standards *33*
3.4.1 ISO standards 33
3.4.2 CEN standards 33

3.5 Quality marks *33*

4. Summary of results **35**

4.1 FDA MAUDE database *35*
4.1.1 Powered wheelchairs 35
4.1.2 Manual wheelchairs 35

4.2 MDA database *36*
4.2.1 Powered wheelchairs 36

4.2.2 Manual wheelchairs 36

5. Discussion and conclusions 39

5.1 Discussion 39
5.1.1 Methodology 39
5.1.2 Number and type of incident reports 40
5.1.3 Causes 40
5.1.4 Problems 41
5.1.5 Effects 42
5.1.6 Injuries, consequences and outcome 42
5.1.7 Actions 43
5.1.8 Wheelchairs involved 43
5.1.9 Considerations 44

5.2 Conclusions 44

Literature 45

Appendix 1: EU marketing of medical devices 47

Appendix 2: USA marketing of medical devices 48

Appendix 3: The GQ mark 49

Appendix 4: FDA Medical Device Reporting 50

Appendix 5: MDA Incident reporting 51

Appendix 6: Description of database for FDA and KBOH 52

Appendix 7: ISO standards on wheelchairs 55

Appendix 8: Recalls and notices 56

Samenvatting

Op verzoek van de Inspectie voor de Gezondheidszorg heeft het RIVM een studie verricht om inzicht te krijgen in incidenten met elektrische en handmatige rolstoelen. Een analyse is uitgevoerd van incidenten die tussen juli 2000 en juni 2001 zijn gemeld in de MAUDE database van de Amerikaanse Food en Drug Administration (FDA) en aan de Britse Medical Devices Agency (MDA) evenals incidenten die tussen juni 1997 en januari 2001 zijn gemeld aan de organisatie voor Kwaliteits- en Bruikbaarheidsonderzoek van Hulpmiddelen voor gehandicapten en ouderen (KBOH). Bovendien is in de literatuur gezocht naar publicaties over rolstoelincidenten.

Een aangepaste versie van de Critical Incident Technique (CIT) werd toegepast voor het samenvatten van incidenten gemeld aan de FDA en KBOH. Deze techniek was gebaseerd op de keten van gebeurtenissen: oorzaak-probleem-effect-verwonding-gevolg van de verwonding. De gegevens van de MDA werden gekarakteriseerd met een beperkte keten van gebeurtenissen (oorzaak-probleem-uitkomst). Hoewel de CIT zeer bruikbaar bleek voor het structureren van de informatie uit de FDA database, konden deze hoofdzakelijk verplichte meldingen niet volledig worden geanalyseerd. De belangrijkste reden hiervoor was dat de data niet de volledige informatie bevatten voor een goede analyse.

In totaal zijn er 814 rolstoelgerelateerde incidenten gevonden in de FDA MAUDE database, 997 incidenten waren gerapporteerd aan de MDA hoofdzakelijk vanuit de National Health Services (NHS) en 17 aan de KBOH door gebruikers, hun familie en verzorgenden. Het aantal rolstoelgebruikers is geschat op 2,2 miljoen voor de VS, 750.000 voor Engeland en 152.400 voor Nederland. De rolstoelincidenten van de FDA en MDA waren hoofdzakelijk productgerelateerd, terwijl in de literatuur meer gebruiksgerelateerde incidenten werden gemeld. Het falen van componenten voor de aandrijving van elektrische rolstoelen en van frames en wielen zijn het meest aangetroffen in de databases. De in de literatuur gemelde problemen tijdens transport en t.a.v. comfort of pasvorm werden zelden aangetroffen in de databases van de FDA en MDA. Het vallen met of uit een rolstoel werd frequent gemeld aan de FDA en MDA en leidde vaak tot ernstige verwondingen voor de gebruikers. Botbreuken waren de meest voorkomende ernstige verwondingen, die relatief vaak voorkwamen onder gebruikers van elektrische rolstoelen. Zowel bij de FDA als de MDA zijn in de onderzoeksperiode vier sterfgevallen als gevolg van het gebruik van rolstoelen gemeld.

Concluderend kan worden gesteld dat, op basis van de bestudeerde databases en rekening houdend met het aantal rolstoelgebruikers en de intensiteit van gebruik, incidenten met rolstoelen geen aanzienlijk probleem vormen voor de volksgezondheid. Uit CBS gegevens bleek echter dat er in 2000 in Nederlandse acht personen stierven als gevolg van een val waarbij een rolstoel betrokken was. Uit de literatuur blijkt bovendien dat het aantal ernstige, vooral gebruiksgerelateerde, incidenten waarbij een rolstoel betrokken is aanzienlijk hoger is dan het aantal dat is aangetroffen in de databases. Er is een discrepantie tussen hetgeen in de literatuur werd gevonden en hetgeen in de databases werd gerapporteerd. Dit wordt ten dele veroorzaakt door de verschillende aard van de gebruikte bronnen. In het algemeen lijkt er sprake te zijn van onderrapportage. Bovendien heeft de MDA gedurende de onderzoeksperiode slechts vijf rolstoelgerelateerde vigilantiemeldingen ontvangen en er zijn geen vigilantiemeldingen van IGZ ontvangen, terwijl de meeste FDA-meldingen vigilantiemeldingen waren. Dit verschil tussen Europa en de VS verdient verdere aandacht.

Om rolstoelgerelateerde incidenten te voorkomen moet niet alleen aandacht worden besteed aan productverbetering maar ook aan het juiste gebruik van rolstoelen. Dit laatste vereist een beter inzicht van gebruiksgerelateerde incidenten dan mogelijk wordt gemaakt door de wettelijk verplichte meldingssystemen en een beter inzicht in de omvang en intensiteit van het gebruik.

Summary

At the request of the Dutch Inspectorate for Healthcare, a study was performed to gain insight into incidents with powered and manual wheelchairs. An analysis was performed of incident reported between July 2000-June 2001 in the MAUDE database of the USA Food and Drug Administration (FDA) and to the British Medical Devices Agency (MDA) and incidents reported between June 1997-January 2001 to the Dutch Center for Quality and Usability Research of Technical Aids (KBOH). In addition, the literature was surveyed for publications on wheelchair-related incidents.

A modified Critical Incident Technique (CIT), based on the chain of events: cause-problem-effect-injury-consequence of injury, was used to abstract the incidents reported to the FDA and KBOH. The data supplied by the MDA were abstracted using a limited chain of events (cause-problem-outcome). Although the CIT was a useful tool to gain an insight in the chain of events of wheelchair-related incidents, the mainly mandatory FDA data itself were less suitable for a complete CIT-analysis, due to the lack of essential information.

In total, 814 wheelchair-related incidents were found in the FDA MAUDE database, 997 were reported to the MDA mainly through the National Health Services (NHS) and only 17 were reported to the KBOH by users, their family and carers. The number of wheelchair users was estimated to be 2.2 million for the USA, 750,000 for England and 152,400 for the Netherlands. The wheelchair incidents in the FDA and MDA databases were found to be mostly product-related, whereas more use-related incidents were reported in the literature. Failures of components for operating powered wheelchairs, of frames and of wheels were most frequently reported in the databases to fail. The problems transportation and comfort or fit were found in the literature, but they were only sporadically mentioned in the databases. Falls and tips were often occurring effects of wheelchair incidents and led to severe injuries for wheelchair users. Fractures were the most frequent severe injuries, occurring more frequently among users of powered wheelchairs. Both FDA and MDA received reports on four fatalities.

Considering the number of wheelchairs used and the intensity of use, it was concluded that the studied databases indicate that wheelchair-related incidents present no major public health problem. However, data from Statistics Netherlands showed that in 2000 eight fatalities were due to falls with wheelchairs. Moreover, studies in the literature indicate that the actual number of serious, mainly use-related, incidents involving wheelchairs will be considerably higher than the number found in these databases. There is a discrepancy between the findings in the literature and the reports in the databases. This is partially due to the different nature of the sources. In general there seems to underreporting. Moreover, during the study period, only five vigilance reports were received from the MDA and no reports were received from the Dutch competent authority, whereas nearly all FDA reports were vigilance reports. This difference between the USA and Europe deserves attention.

Preventing wheelchair-related incidents should be a combination of both product improvement and attention for the correct use of wheelchairs. The latter requires more data on use-related incidents than can be deduced from legally required reporting systems and a better knowledge of the extent and intensity of use.

1. Introduction

1.1 General

Reporting malfunctions of medical devices and harm suffered by users of medical devices to manufacturers and authorities is important, because it can contribute to the safety of the products and thus eventually to the safety of patients and/or users. The manufacturer shall investigate the incidents and, if necessary, improve the medical device or the instructions for use to prevent recurrence (Appendix 1). This is an important part of the continuous cycle of quality improvement. Several authorities and organisations have developed databases to present a structure for collection and review of incidents. This enables them to focus their attention on certain products or aspects in order to guard public health. A previous evaluation of technical files of Class I medical devices (1) included a number of technical files of wheelchairs. None of these files contained references to incidents and/or measures to prevent specific incidents. A limited search was carried out on the websites of the United States Food and Drug Administration (FDA) and Emergency Care Research Institute (ECRI) to gain insight into wheelchair-related incidents. This search revealed several reports on incidents related to problems like fire and broken parts. Consequently, the Dutch Inspectorate for Health Care requested a more extensive review of reported incidents and failures related to the use of wheelchairs.

Another aspect of incident reports is their role in illustrating the effectiveness of regulatory measures that control the safety of products that come onto the market. Outlines of the regulatory systems in Europe and the USA are given in Appendices 1 and 2. Standards can be used to show compliance with the European regulatory requirements, allowing the CE-mark to be affixed. During the evaluation of the technical files of Class I medical devices, it became apparent that in the Netherlands another quality mark exists for wheelchairs (GQ-mark, Appendix 3). Information about incidents occurring with medical devices with or without regulatory or quality marks can give an impression of the value of these marks.

The total number of wheelchairs in England, supplied by the National Health Services (NHS), is about 750,000 (personal communication M. Rand, MDA). The number of wheelchair users in the USA is 2.2 million (2). The total number of wheelchairs supplied under the Supplies for the Disabled Act (Wet Voorzieningen Gehandicapten, WVG) in the Netherlands was 119,000 ultimo 1999 (3). Moreover, it is estimated that 20 % of the residents of nursing homes and homes for the elderly use a wheelchair (personal communication P. Vreeswijk, The Dutch Council of the Chronically Ill and the Disabled). These wheelchairs are provided under the General Act on Exceptional Medical Expenses (AWBZ). The number of residents of both types of homes was approximately 167,000 in 2000 (4;5). The total number of wheelchair users in the Netherlands is therefore estimated to be 152,400. The number of powered wheelchair users in the USA was 155,000 in 1995 (personal communication J.F. Todd, FDA), whereas the number of powered wheelchairs supplied by the NHS in England is about 85,000 (personal communication M. Rand, MDA). The latter is an underestimation, because there is a considerable private market in England, especially for powered wheelchairs, about which little is known. There are no data on the number of powered wheelchairs in the Netherlands.

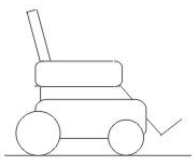
1.2 Objectives

The objectives of the study were:

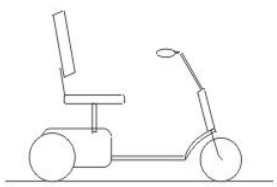
- to gain insight into incidents related to the use of wheelchairs;
- to list the applicable standards for wheelchairs;
- to list the regulatory and quality marks used for wheelchairs and to relate the absence or presence of quality marks to incidents with wheelchairs.

Both manually propelled wheelchairs and electric powered wheelchairs[1] were investigated during this study. Scooters[2] were excluded.

[1] An electric powered wheelchair has the same basic design as a manually propelled wheelchair, but it is propelled by an electric motor. The movement of the wheelchair is controlled by a panel and/or a joystick (see below).
[2] A scooter is considered to be a three or four-wheel electrically powered 'platform-wheelchair'. At the rear of the platform it has the two driven wheels with the seat on top of the motor and one or two wheels in the front connected to a steering mechanism (see below).



Powered wheelchair



Scooter

(These pictures are used with permission of TNO Automotive)

2. Methods

To gain insight into wheelchair-related incidents, an analysis was performed of incidents reported between July 2000-June 2001 in the MAUDE database of the USA Food and Drug Administration (FDA) and to the British Medical Devices Agency (MDA) and incidents reported between June 1997-January 2001 to the Dutch Center for Quality and Usability Research of Technical Aids (KBOH). In addition, the literature was surveyed for publications on wheelchair-related incidents.

2.1 Data collection

FDA data
A search was performed in the FDA MAUDE[3] database for powered wheelchairs (using the device code 'iti') and manual wheelchairs (using the device code 'ior') over the period July 1st, 2000 until June 28th, 2001. The MAUDE database represents reports of adverse events involving medical devices (Appendix 4).

MDA data
The MDA supplied a database on wheelchair failures and incidents for the period July 1st, 2000 until June 30th, 2001. The data concerned failures and incidents for which the investigation by the MDA was completed. Information on MDA incident reporting procedures is given in Appendix 5.

KBOH data
From the KBOH we received reports of wheelchair incidents over the period June 1997 – January 2001, which have been voluntary submitted by users, their family or carers.

2.2 Data abstraction and analysis

2.2.1 Critical Incident Technique

A modified Critical Incident Technique (CIT) (6) was used to interpret and analyse information about the incidents in the MAUDE database and the data received from the KBOH. Each incident was categorised to identify factors that were associated with the incident. The intent was to identify why critical incidents occurred. This approach was used in the Australian Incident Monitoring Study (7), which served as a basis for the method described in this report. Critical incidents with wheelchairs were defined as those occurrences that might have led (if not discovered in time) or did lead, to an undesirable outcome. In this study, wheelchair malfunction and/or harm suffered by the user of the wheelchair were considered to be undesirable outcomes. The subsequent taxonomy was used to interpret the information about the incidents:

- *To whom did it happen?*
  This aspect contained information on the user and the operator (e.g. age). The user is the occupant of the chair and the operator is the person propelling the chair or performing other operations (e.g. maintenance).
- *Which device was involved?*
  This aspect contained information on the device (e.g. brand name, type and age of the wheelchair).

[3] MAUDE: Manufacturer And User facility Device Expertise.

- *Where did it happen?*
  For instance indoors or outdoors.
- *Why did it happen?*
  This aspect dealt with the problem and the cause. The problem could be related to a part of the product (e.g. electric drive). The cause could be related to e.g. a product failure.
- *What happened?*
  This aspect dealt with the *effect* of the incident on the user or operator (e.g. collision).
- *What was the consequence of the injury?*
  This aspect contained information on the *injury* and the *consequence of the injury* (e.g. required medical intervention).

Shortly, a *cause* resulted in a *problem* having an *effect* on the user or operator, leading to *injury* with a certain *consequence*. This is schematically shown in the following chart:

Chain of events

It should be noted that a critical incident could occur without every item of the chain being applicable (e.g. a wheel detaching from a chair without causing an effect or an injury).

2.2.2 FDA and KBOH data

Data from the FDA MAUDE database and from KBOH were entered in a database. Table 1 summarises the items chosen for abstraction. A record in the database contained data for a single incident with a single wheelchair. If several incidents were stated in a single report, a separate record was created for each incident. Reports that did not mention an incident as defined in § 2.2.1 were not entered into the database. For example, a complaint of a user about a dealer who needed a week to repair a flat tire would have been excluded. A complete overview of all fields in the database is given in Appendix 6.

Reports can be subjected to different interpretations if different persons perform the abstraction of reports into database records. The following steps were taken to limit these differences, to increase the consistency of the database, and to improve the reproducibility of this study.

- A manual was written to facilitate the abstraction of information. The manual contained a general description of the method, descriptions of items to be abstracted and the corresponding fields in the database, and additional information and agreements for most fields.
- All reports were abstracted independently by two of the authors blinded to each others work and double entered into the study database. Both entries were compared and inconsistencies were checked and resolved. If necessary data were re-abstracted and inconsistencies in the database corrected. If required the manual was amended.

Table 1. Summary of items for abstraction of incident information (continued on next page).

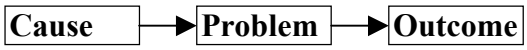
Factor	Description	Options
Report source	Source of report	Manufacturer, distributor, voluntary, other, unknown
Wheelchair	Type of wheelchair	Powered wheelchair Manual wheelchair
Consequence of injury	Consequence of injury	Death Injury requiring medical treatment Injury without medical treatment No injury Unknown
Injury	Type of injury resulting from an incident	Fracture Burn Bruise Cut Concussion Decubitus Multiple injuries Other None Unknown
Effect	Effect of problem	Fall with or out of wheelchair Entrapment Collision with other object or person Fire wheelchair without someone in wheelchair Fire wheelchair with someone in wheelchair Involuntary standstill Uncontrolled movement (without any other effect) Exploding rim and/or tire Other None Unknown
Problem	Malfunction and/or failure (more than one per incident possible)	Stability: wheelchair tipped without apparent technical failure Electric drive, including motor and user interface Power supply, including batteries and charger Wheels, including casters Frame, including attached parts Seat, excluding its frame Brakes, including (electro)mechanical and dynamic brakes Transportation of wheelchair in car or public transport Medical devices used in combination with wheelchair Comfort and/or fit of wheelchair leading to disorder Electromagnetic interference affecting wheelchair Other Unknown problem, i.e. problem not specified in report
Cause	Cause of problem as identified in report	Product User Use-related (mainly maintenance and assembly) Combination with other devices Information and/or education Other Unknown

Table 1. (continued)

Factor	Description	Options
Operator	Operator of the wheelchair	User (occupant) Family member/carer/other Unknown
Pre-existing condition	Condition of user	Text field
Where did it happen		Indoors (no institution) Outdoors Institution During transport Unknown

2.2.3 MDA data

The MDA data on incidents with wheelchairs were already entered in a database by the MDA. The database, a summary of the complete MDA database on wheelchairs, contained a limited number of items relating to problems, causes, effects and actions taken. The information in the MDA database was not suited for analysis using CIT, as essential information was often missing (e.g. type of injury and consequence). Some of this information was available in a non-structured way in narratives in text fields. Due to time restrictions, it was not possible to read through the text fields and abstract that data for all the incidents reported to the MDA. We categorised the information in the MDA database as shown in Table 2. Effect of the problem, injury and consequence of injury were not separated in the MDA-database. The chain of events used to describe the incidents reported to the MDA is given in the following chart:



Chain of events

2.3 Literature search

A scientific literature search was performed for wheelchair-related incidents. The search strategy covered the period January 1990 up to January 2002 using the electronic database PubMed and focused on relevant biomedical papers and reviews. The query was formed using the term ‘wheelchairs/adverse effects[MESH]'. The number of retrieved references during this period was 32.

Table 2. Summary of items of MDA incident information.

Description of factors	Categories	Included options
Type of wheelchair	Powered wheelchair	-
	Manual wheelchair	-
Problem [1]	Brakes	Brake assembly and linkage
	Electrical not specified	-
	Frame	Arm-, back-, foot-, head-, leg rest, battery carrier, seat support, side frame
	Other	Problem not allocated
	Electric drive	Connector, controller, gear, harness, motor
	Power supply	Battery, charger
	Seat	Upholstery
	Stability	-
	Wheels	Casters, fork, hand rim, spokes, tyres
Cause [2]	Labelling / instructions	-
	Other	Contaminated, incident reported in error, tampering
	Packaging / storage / transit	-
	Product	Damage, design, end of normal life, mechanical failure, performance
	Quality assurance	-
	Unknown	Cause not established
	User	Device performed as intended, user error
	Use-related	Maintenance, device degradation
Outcome [2]	Actual injury	Serious injury and fatality
	Actual minor injury	-
	No effect	-
	Chair no longer used	-
	Other	Adverse reaction, burn, electric shock, fire, explosion, inadequate treatment, overheating
	Potential injury	Minor and serious injury
	Unknown	-
Action taken [2]	Additional user training	-
	Alternative manufacture method	-
	Design modified	-
	Device-related action	Device exchange, recall, repair
	Field correction	-
	Improved maintenance	-
	Improved quality assurance	-
	Labelling / instructions	-
	Manufacturer advisory notice	-
	None	-
	Production ceased	-
	Safety warning issued	-
	Unknown	-

1. One problem per incident
2. Three or less per incident

3. Results

3.1 FDA

3.1.1 General

For powered wheelchairs 176 MAUDE reports were collected over the one-year period. Two reports were not entered into the database: one report only mentioned the anxiety of a patient about the safety of the wheelchair and the second report involved a walker. Thus, 174 reports were abstracted. A single incident was mentioned in 171 reports and three reports mentioned three incidents. Eventually, 180 incidents with powered wheelchairs were entered into the database. Of these incidents 167 (93%) were found in reports by the manufacturer, 11 (6%) in 'voluntary' reports and two (1%) were reported by a distributor.

For manual wheelchairs 626 MAUDE reports were collected over the same one-year period. One report was not abstracted, because the incident was not wheelchair-related. Three reports mentioned two incidents, one report mentioned three incidents and another report mentioned five incidents. In total, 634 incidents were abstracted. Of these incidents 618 (97%) were found in reports by the manufacturer, 15 (2%) in 'voluntary' reports and one incident was reported by the 'user facility'.

3.1.2 Consequences of injury

No injuries were reported in 49% of the incidents with powered wheelchairs and in 91% of the incidents with manual wheelchairs (Figure 1). Injuries requiring medical intervention were mentioned in 40% of the reports on powered wheelchairs and in only 5% of reports on manual wheelchairs. In total, 4 deaths were reported due to incidents with wheelchairs: three with manual wheelchairs and one with a powered wheelchair.

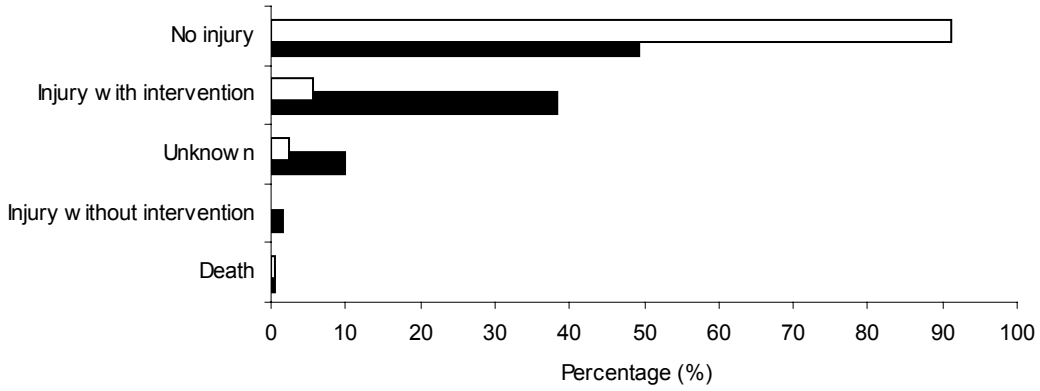


Figure 1. Wheelchair-related consequences of injuries. Consequences of injuries reported in incidents for powered wheelchairs (solid bars, n=180) and manual wheelchairs (open bars, n=634) are shown as percentage.

A dealer reported the death of a user. He alleged that the wheelchair caught fire and the user died as a result of the incident. The incident was investigated and a candle was identified as the cause of the fire.

3.1.3 Injuries

The majority of injuries for incidents with powered wheelchairs were fractures (Figure 2). Only few fractures were reported for manual wheelchairs. The remainder of injuries, i.e. cut, multiple injuries, concussion, burn, decubitus, bruise and other injuries, occurred in a relatively small number of incidents.

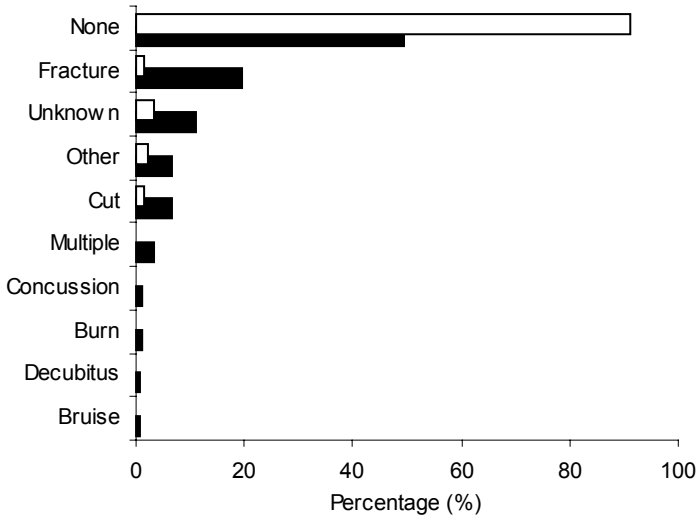


Figure 2. Wheelchair-related types of injuries. Injuries reported in incidents for powered wheelchairs (solid bars, n=180) and manual wheelchairs (open bars, n=634) are shown as percentage.

Table 3 shows that for powered wheelchairs nearly all injuries lead to a medical treatment. Burns caused the only death reported.

Table 3. Injuries vs. consequences of injuries for powered wheelchair [*].

	Consequence of injury										
	Death		Intervention		No intervention		None		Unknown		Total
Injury	n	%	n	%	n	%	n	%	n	%	n
None	-	-	-	-	-	-	89	*100*	-	-	89
Fracture	-	-	35	*100*	-	-	-	-	-	-	35
Unknown	-	-	3	*15*	1	*5*	-	-	16	*80*	20
Other	-	-	9	*75*	2	*17*	-	-	1	*8*	12
Cut	-	-	12	*100*	-	-	-	-	-	-	12
Multiple injury	-	-	5	*83*	-	-	-	-	1	*17*	6
Concussion	-	-	2	*100*	-	-	-	-	-	-	2
Burn	1	*50*	1	*50*	-	-	-	-	-	-	2
Decubitus	-	-	1	*100*	-	-	-	-	-	-	1
Bruise	-	-	1	*100*	-	-	-	-	-	-	1
Total	1		69		3		89		18		180

[*] *Note that the percentages are given for the injuries in the rows.*

If an injury was reported for manual wheelchairs, intervention was frequently needed (Table 4). The three fatal incidents were caused by:

- The wheelchair tipping during transportation in a van. The user sustained a broken leg and subsequently died.
- A malfunctioning seat belt. The user became trapped under the belt.
- A push handle coming off a wheelchair. The patient fell on the ground and hit his/her head.

Table 4. Injury vs. consequence of injury for manual wheelchairs [*].

	Consequence of injury										
	Death		Intervention		No intervention		None		Unknown		Total
Injury	n	%	n	%	n	%	n	%	n	%	n
None	-	-	-	-	-	-	578	*100*	-	-	578
Unknown	-	-	6	*29*	1	*5*	-	-	14	*67*	21
Other	2	*15*	9	*69*	1	*8*	-	-	1	*8*	13
Fracture	1	*10*	9	*90*	-	-	-	-	-	-	10
Cut	-	-	9	*90*	-	-	-	-	1	*10*	10
Multiple injury	-	-	2	*100*	-	-	-	-	-	-	2
Total	3		35		2		578		16		634

[*] *Note that the percentages for the injuries are given in the rows.*

3.1.4 Effects

Figure 3 shows the effects of problems with powered and manual wheelchairs. Falls and tips were found to be the most common effect of problems for powered wheelchairs (23%). No distinction was made between users falling from a wheelchair and users tipping over with a wheelchair. For manual wheelchairs, the effects of problems were mostly 'unknown' (90%).

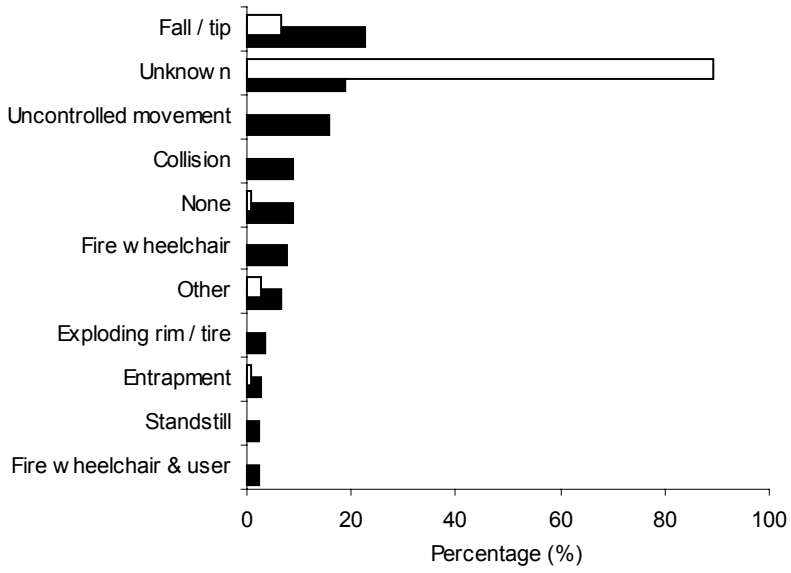


Figure 3. Effects of problems with wheelchairs. Effects for powered wheelchairs (solid bars, n=180) and for manual wheelchairs (open bars, n=634) are shown as percentage.

The most frequently mentioned effect for powered wheelchairs, 'falls and tips', often led to fractures (39%, Table 5). The effect 'uncontrolled movement' did not often lead to an injury.

Table 5. Injury vs. most frequently occurring effect for powered wheelchairs.

	Most frequently occurring effect*									
	Fall/tip		Unknown		Uncontrolled movement		Collision		None	
Injury	n	%	n	%	n	%	n	%	n	%
Fracture	16	*39*	1	*3*	-	-	6	*38*	-	-
Bruising	1	*2*	-	-	-	-	-	-	-	-
Cut	8	*20*	-	-	-	-	2	*13*	-	-
Concussion	2	*5*	-	-	-	-	-	-	-	-
Multiple injury	2	*5*	1	*3*	-	-	2	*13*	-	-
Other	3	*7*	2	*6*	-	-	1	*6*	-	-
None	5	*12*	22	*65*	28	*100*	2	*13*	16	*100*
Unknown	4	*10*	8	*24*	-	-	3	*19*	-	-
Total	41		34		28		16		16	

* Effects ‘fire wheelchair’ (n=14), ‘other’ (n=12), ‘exploding rim/tire’ (n=6), ‘entrapment’ (n=5), ‘standstill’ (n=4), and ‘fire wheelchair and user’ (n=4) are not shown.

For powered wheelchairs the category ‘other’ comprised the following effects:

- wheelchair ran over foot (4x),
- user tripped over wheelchair (2x),
- user got trapped due to a wrong transfer,
- push handle touched boiling pot of water,
- chair useless,
- discomfort,
- user slid forward in seat,
- spouse fell from footplate.

The collision leading to an ‘other’ injury (Table 5) was the only incident in which a bystander (no user or operator) was injured. The report stated that “while the user was learning how to drive the chair, user accidentally changed from drive 1 to drive 2. This caused the chair to take off and hit a bystander in the stomach. As a result, the bystander received an intestinal injury”.

For manual wheelchairs the effects were mostly ‘unknown’, nearly always resulting in no injury. Falls and tips as well as effects categorised as ‘other’ were responsible for the majority (71%) of the few specified injuries.

Table 6. Injury vs. effect for manual wheelchairs.

	Effect									
	Unknown		Fall/tip		Other		None		Entrapment	
Injury	n	%	n	%	n	%	n	%	n	%
Fracture	-	-	6	*15*	1	*6*	-	-	3	*60*
Cut	1	*0*	2	*5*	7	*44*	-	-	-	-
Multiple injury	-	-	2	*5*	-	-	-	-	-	-
Other	-	-	9	*22*	2	*13*	6	*100*	2	*40*
None	557	*98*	11	*27*	4	*25*	-	-	-	-
Unknown	8	*1*	11	*27*	2	*13*	-	-	-	-
Total	566		41		16		6		5	

For manual wheelchairs the category ‘other’ included:

- pusher caught chair when wheel broke,
- user cut himself on wheelchair (6x),
- shopping basket fell on user’s knee,
- armrest broke,
- fingers got caught between spokes,

- user was lowered in chair (2x),
- chair collapsed,
- wobbling chair,
- near fall,
- chair folded under user.

3.1.5 Problems

Electronic problems involving electric drive (controllers, drive systems) and power supply (batteries, charger) were unique to powered wheelchairs and were mentioned in many reports (Figure 4). Problems occurring for both types of wheelchairs were related to frame, wheels, and brakes. The majority of manual wheelchair problems were reported to be failures of these mechanical components. Instability and problems during transportation were only reported for powered wheelchairs. Electromagnetic interference (EMI) was not reported for powered wheelchairs.

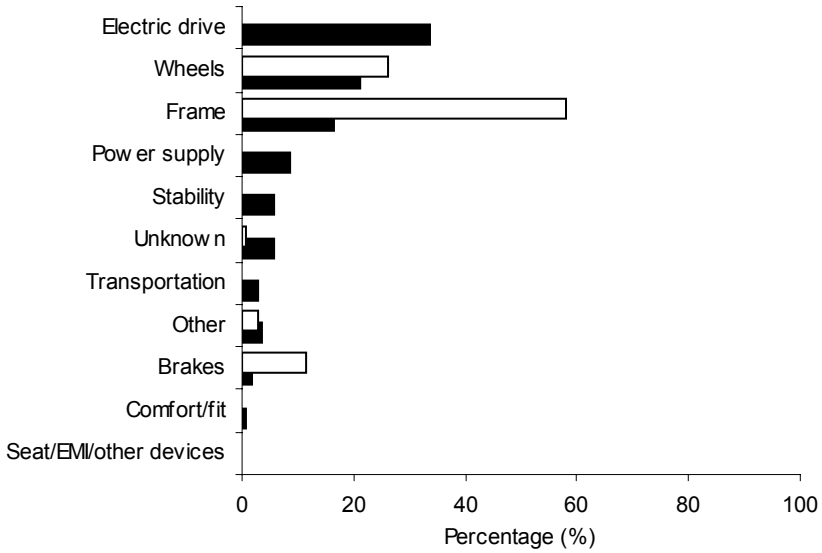


Figure 4. Wheelchair-related problems. Problems are shown as percentages for powered wheelchairs (solid bars, n=175) and manual wheelchairs (open bars, n=632).

It should be noted that the total number of problems for powered wheelchairs (n=175, Table 7) is lower than the number of reports (n=180). Of the 180 reports on powered wheelchairs, 16 reports mentioned no problem, 153 reports mentioned one problem and 11 reports mentioned two problems. The number of problems mentioned for manual wheelchairs (n=632, Table 8) is lower than the number of reports for manual wheelchairs (n=634). In four reports, no problems were mentioned, In 628 reports one problem was mentioned and in two reports two problems were mentioned.

Problems with the 'electric drive' of powered wheelchairs often led to uncontrolled movement (28 of 59 cases) or collisions (10 of 59 cases) as shown in Table 7. Power supply led to fire in 10 of 15 problems reported. Falls and tips were the result of problems with frame, stability, electric drive or wheels.

A unique example of a problem with the power supply is the report about a wheelchair that caught fire at the wire harness. A review of the incident by the engineering department revealed that a nickel and a dime, found in the returned charger, shorted the wire leads.

Table 7. Effect vs. most frequently occurring problem for powered wheelchairs.

	Most frequently occurring problem*											
	Electric drive		Wheels		Frame		Power supply		Stability		Unknown	
Effect	n	%	n	%	n	%	n	%	n	%	n	%
Fall and tip	9	*15*	6	*16*	11	*38*	-	-	10	*100*	-	-
Entrapment	4	*7*	-	-	-	-	-	-	-	-	-	-
Collision	10	*17*	-	-	-	-	-	-	-	-	3	*30*
Fire, no user	1	*2*	-	-	-	-	10	*67*	-	-	2	*20*
Fire, user	1	*2*	-	-	1	*3*	-	-	-	-	2	*20*
Standstill	2	*3*	-	-	-	-	2	*13*	-	-	-	-
Other	1	*2*	1	*3*	-	-	-	-	-	-	1	*10*
None	-	-	9	*24*	7	*24*	-	-	-	-	-	-
Uncontrolled movement	28	*47*	-	-	-	-	-	-	-	-	-	-
Exploding rim/tire	-	-	6	*16*	-	-	-	-	-	-	-	-
Unknown	3	*5*	15	*41*	10	*34*	3	*20*	-	-	2	*20*
Total	59		37		29		15		10		10	

* The problems ‘transportation’ (n=5), ‘other’ (n=6), ‘brakes’ (n=3) and ‘comfort or fit’ (n=1) are not shown.

Problems categorised as ‘other’ were:
- ”sip-n-puff straw” (used to control chair by mouth),
- backrests fell back due to failing actuator,
- cable from chair got caught and was torn off,
- unspecified pin broke,
- protruding part,
- melted parts.

For manual wheelchairs, effects of the problems ‘frame’, ‘wheels’ and ‘brakes’ were mostly unknown (Table 8). Falls and tips were mostly caused by problems with wheels, frame and brakes.

Table 8. Effect vs. most frequently occurring problem for manual wheelchairs.

	Most frequently occurring problem*											
	Frame		Wheels		Brakes		Other		Unknown		Seat	
Effect	n	%	n	%	n	%	n	%	n	%	n	%
Fall and tip	12	*3*	14	*8*	6	*8*	3	*16*	1	*25*	1	*33*
Entrapment	1	-	-	-	-	-	3	*16*	-	-	-	-
Other	3	*1*	2	*1*	-	-	9	*47*	1	*25*	2	*67*
None	4	*1*	2	*1*	-	-	-	-	-	-	-	-
Unknown	346	*95*	148	*89*	67	*92*	4	*21*	2	*50*	-	-
Total	366		166		73		19		4		3	

* The problem ’transportation’ (n=1) is not given.

The category ‘other’ included:
- detent button spring came out,
- protruding part (7x),
- combination chair / shopping basket,
- adjustment left little space between arm rest and wheel,
- user lost balance,
- retrofit kit was not installed,
- safety belt,
- pin is stuck in housing leaving it non-functional,
- anti tips (2x),
- release pin stuck,
- push handle came off,

- unidentified part cracked.

The incident with the safety belt led to the death of the user. The report stated that it was a custom made wheelchair. The report further stated "The chair had a h-strap attached to a lap seat belt. The latch mechanism malfunctioned at the waist allowing the patient to slide forward at the hips and their throat became trapped on top of the h-strap."

3.1.6 Causes

Figure 5 depicts the causes of wheelchair incidents. For powered wheelchairs, the product is the major cause, whereas the major causes for manual wheelchairs are 'product' and 'other'.

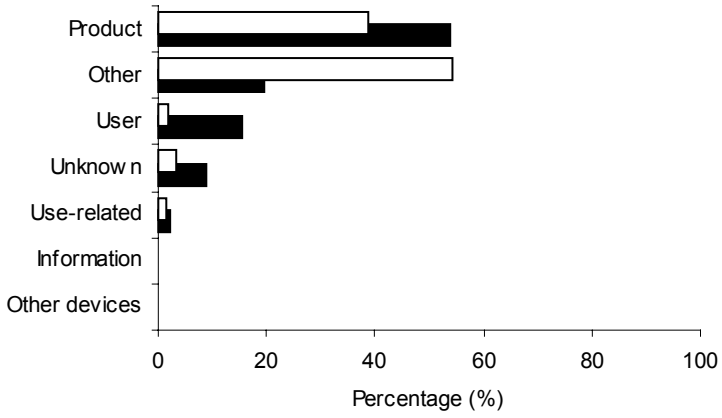


Figure 5. Causes of wheelchair incidents. Causes are shown as percentages for powered wheelchairs (solid bars, n=180) and manual wheelchairs (open bars, n=634) obtained from the MAUDE database.

The relation between problems and their causes is shown in Table 9 for powered wheelchairs. It should be noted that the number of causes (n=175, see 3.1.5) is lower than the number of causes mentioned in Figure 5 (n=180). If the cause was 'product', the problems mentioned were most often related to the electrical systems ('electric drive' and 'power supply').

Table 9. Cause vs. problem for powered wheelchairs.

	Cause									
	Product		Other		Unknown		User		Use-related	
Problem	n	*%*	n	*%*	n	*%*	n	*%*	n	*%*
Stability	-	-	2	*6*	1	*6*	6	*40*	1	*17*
Electric drive	52	*51*	1	*3*	2	*12*	2	*13*	2	*33*
Power supply	13	*13*	1	*3*	-	-	1	*7*	-	-
Wheels	4	*4*	22	*63*	7	*41*	2	*13*	2	*33*
Frame	20	*20*	7	*20*	1	*6*	-	-	1	*17*
Brakes	3	*3*	-	-	-	-	-	-	-	-
Transportation	1	*1*	-	-	-	-	4	*27*	-	-
Comfort	1	*1*	-	-	-	-	-	-	-	-
Other	4	*4*	1	*3*	1	*6*	-	-	-	-
Unknown	4	*4*	1	*3*	5	*29*	-	-	-	-
Total	102		35		17		15		6	

The cause 'other' (n=35) for powered wheelchairs comprised the following causes:
- high stresses/excessive loading (n=31);
- combination user and product;
- wrong chair supplied;
- inattention of user and carer;
- short circuit due to coins.

Causes of problems with manual wheelchairs were most often categorised as 'other'. These 'other' causes led to the problem 'frame' in 99% of all incidents. It should be noted that the number of causes (n=632) is lower than the number of causes in Figure 5 (n=634), because for two incidents no problems were identified (see 3.1.5).

Table 10. Cause vs. problem for manual wheelchairs.

	Cause											
	Product		Other		Unknown		User		Use-related		Information	
Problem	n	*%*	n	*%*	n	*%*	n	*%*	n	*%*	n	*%*
Wheels	152	*62*	3	*1*	-	-	3	*30*	7	*70*	1	*50*
Frame	10	*4*	340	*99*	14	*67*	1	*10*	-	-	1	*50*
Seat	2	*1*	-	-	-	-	1	*10*	-	-	-	-
Brakes	72	*29*	-	-	1	*5*	-	-	-	-	-	-
Transportation	-	-	-	-	-	-	1	*10*	-	-	-	-
Other	10	*4*	-	-	2	*10*	4	*40*	3	*30*	-	-
Unknown	-	-	-	-	4	*19*	-	-	-	-	-	-
Total	246		343		21		10		10		2	

For manual wheelchairs causes categorised as 'other' (n = 344) included:
- awkward transfer;
- high stresses/excessive loading (n=343).

An example of a report for a manual wheelchair mentioning high stresses is: "Reporter states the X-tube cracked while the chair was in use. No injuries reported." Additional manufacturers narrative stated: "High stress factor at centre and ends of X-tube."

3.1.7 To whom it happened

For powered wheelchairs the occupant operated the wheelchair in 172 of the 180 cases (96%). In the other 8 cases, the operator was someone else, e.g. a family member or a carer. For manual wheelchairs, in 615 of the 634 incidents (97%) the occupant operated the wheelchair. In 11 cases the operator was someone else, e.g. a family member or a carer, and in 8 cases it was unknown who operated the wheelchair. The age of the user was never mentioned and hardly any information was offered on the pre-existing condition of the user.

3.1.8 Device involved

3.1.8.1 Brand name

The brand 'Quickie' was involved in half of the incidents with powered wheelchairs (Table 11). The brand names 'Action Storm', 'Pride' and 'Ranger' were also mentioned frequently.

Table 11. Brand names for powered wheelchairs

Brand name	Occurrence	
	n	*%*
Quickie	90	*50*
Action storm	23	*13*
Pride	21	*12*
Ranger	18	*10*
Other	10	*6*
Rascal	8	*4*
Power 9000	5	*3*
Tiger	3	*2*
Unknown	2	*1*
Total	180	

For manual wheelchairs the brands 'Quickie' and 'Breezy' occur most frequently and together they are mentioned in 92% of all incidents (Table 12). Both brand names are marketed by Sunrise.

Table 12. Brand names for manual wheelchairs

Brand name	Occurrence	
	n	*%*
Quickie	500	*79*
Breezy	85	*13*
Other	16	*3*
Tracer	9	*1*
Rolls	8	*1*
Excel	6	*1*
Medline	5	*1*
Unknown	5	*1*
Total	634	

3.1.8.2 Wheelchair age

For powered as well as manual wheelchairs the first bulge of wheelchair-related incidents was reported within the 7-12 months wheelchair age group (Figure 6). After one year the number of reported incidents for powered wheelchairs decreased, whereas manual wheelchairs showed repetitive bulges of increased reported incidents at 25-30 months, 61-66 months, and 85-90 months.

3.1.8.3 Device usage

In incident reports for powered wheelchairs, reuse was mentioned 12 times, initial device usage was mentioned 141 times, and no information was given in 27 cases. In the reports for manual wheelchairs, reuse was mentioned 6 times, initial device usage was mentioned 610 times, and no information was given in 18 cases.

3.1.8.4 510 (k) number

A 510 (k) number for the wheelchairs (see Appendix 2) was indicated in 129 out of 180 reported incidents with powered wheelchairs. For manual wheelchairs a 510 (k) number was mentioned in 578 out of 634 reported incidents.

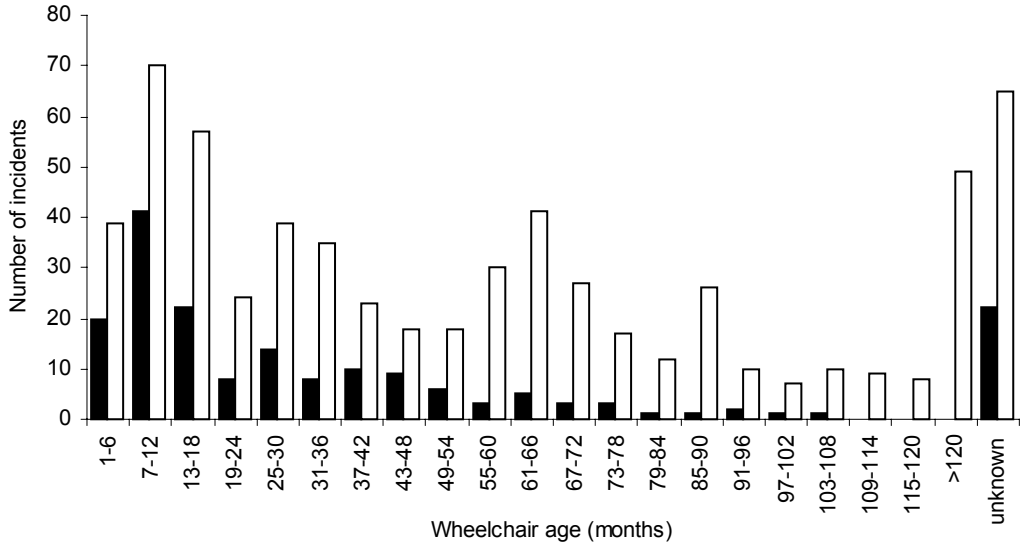


Figure 6. Distribution of wheelchairs involved in reported incidents by age. Incidents for powered wheelchairs (solid bars, n=180) and manual wheelchairs (open bars, n=634) are shown. The >120 months age group consisted of manual wheelchairs up to 16 years old.

3.1.9 Location of incident

Table 13 and 14 indicate that the location was not mentioned in most of the reports in the MAUDE database. For powered wheelchairs (Table 13), the location was specified in only 68 of the 180 cases. For falls and tips the location outdoors was more frequently mentioned than the location indoors.

Table 13. Location vs. effect for powered wheelchairs.

	Location									
	Indoors[1]		Outdoors		Institution		Transportation		Unknown	
Effect	n	*%*	n	*%*	n	*%*	n	*%*	n	*%*
Falls and tips	3	*10*	20	*61*	1	*50*	4	*100*	13	*12*
Entrapment	2	*7*	1	*3*	-	-	-	-	2	*2*
Collision	7	*24*	3	*9*	-	-	-	-	6	*5*
Fire, no user	7	*24*	1	*3*	1	*50*	-	-	5	*5*
Fire with user	-	-	1	*3*	-	-	-	-	3	*3*
Standstill	-	-	-	-	-	-	-	-	4	*4*
Other	4	*14*	2	*6*	-	-	-	-	6	*5*
None	1	*3*	1	*3*	-	-	-	-	14	*13*
Uncontrolled movement	2	*7*	2	*6*	-	-	-	-	24	*21*
Exploding tire	-	-	1	*3*	-	-	-	-	5	*4*
Unknown	3	*10*	1	*3*	-	-	-	-	30	*27*
Total	29		33		2		4		112	

[1] Not in an institution

For manual wheelchairs, the location was not specified in 591 of 634 cases (94%, Table 14).

Table 14. Location vs. effects for manual wheelchairs.

	Location									
	Inside		Outside		Institution		Transportation		Unknown	
Effect	n	%	n	%	n	%	n	%	n	%
Falls and tips	10	*48*	6	*50*	2	*22*	1	*100*	22	*4*
Entrapment	-	-	-	-	3	*33*	-	-	2	*0*
Other	5	*24*	1	*8*	4	*44*	-	-	6	*1*
None	-	-	-	-	-	-	-	-	6	*1*
Unknown	6	*29*	5	*42*	-	-	-	-	555	*94*
Total	21		12		9		1		591	

3.2 MDA

3.2.1 General

The MDA received 463 reports for powered wheelchairs and 600 reports for manual wheelchairs. The investigation of the reported incidents was completed for 436 reports on powered wheelchairs and for 561 reports on manual wheelchairs. Information on these incident reports was supplied by the MDA. The MDA supplied a database containing information on the closed reports (Table 15). The number of mandatory vigilance reports by the manufacturer were three for powered wheelchairs and two for manual wheelchairs (personal communication M. Rand, MDA).

Table 15. Items per wheelchair incident of the MDA database.

Category	Number of items	Powered wheelchair		Manual wheelchair	
		n	%	n	%
Outcome	1	372	*85*	521	*93*
	2	61	*14*	34	*6*
	3	3	*1*	6	*1*
Problem	1	436	*100*	561	*100*
Cause	1	344	*79*	480	*86*
	2	76	*17*	74	*13*
	3	16	*4*	7	*1*
Action taken	1	372	*85*	500	*89*
	2	58	*13*	48	*9*
	3	6	*1*	13	*2*

3.2.2 Outcomes

In a minority of the incidents actual injury was mentioned as an outcome: 6 incidents with serious injuries and 1 fatal incident for powered wheelchairs; 1 incident with serious injury and 3 fatal incidents for manual wheelchairs (Figure 7). The type of injury was infrequently reported. ‘Actual minor injuries’ were reported more often than actual injuries (5.6 vs. 1.4% for powered wheelchairs, 5.8 vs. 0.7% for manual wheelchairs). The majority of manual wheelchair incidents resulted in an ‘unknown’ outcome (28%) or ‘no effect’ (27%). The most common outcome for powered wheelchairs was potential injury (27%), which indicates that many incidents could have led to injuries.

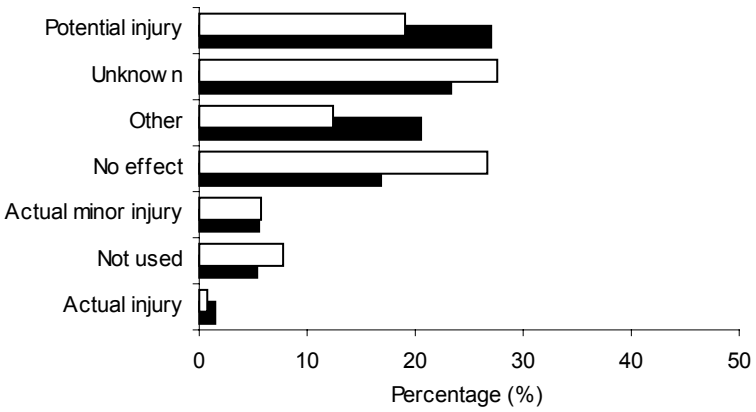


Figure 7. Outcomes of wheelchair incidents. Outcomes are shown as percentages for powered wheelchairs (solid bars, n=503) and manual wheelchairs (open bars, n=607) obtained from the MDA database.

3.2.3 Problems

The majority of wheelchair problems were related to frame and wheels for powered as well as for manual wheelchairs (Figure 8). Electronic/electrical components for powered wheelchairs (electrical, power supply, and electric drive) were affected by failure to a slightly lesser extent. For 'other' problems the failures were not allocated by the MDA (n=49 and n=43 for powered and manual wheelchairs, respectively) and not specified 'wheelchair' problems (n=10 and n=9 for powered and manual wheelchairs, respectively).

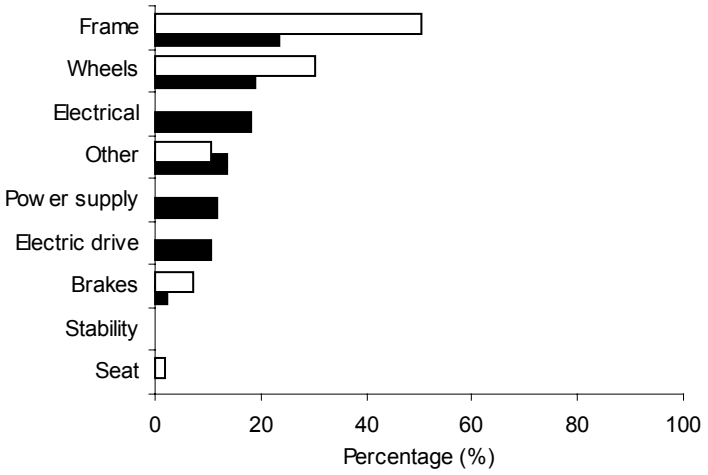


Figure 8. Wheelchair-related problems. Problems are shown as percentages for powered wheelchairs (solid bars, n=436) and manual wheelchairs (open bars, n=561) obtained from the MDA database.

For powered wheelchairs actual or potential injury was mentioned in 27% of the cases, evenly distributed over all categories of problems (Table 16).

Table 16. Outcome vs. most frequently occurring problem for powered wheelchairs MDA.

	Most frequently occurring problem											
	Electrical		Frame		Other [§]		Electric drive		Power supply		Wheels	
Outcome	n	%	n	%	n	%	n	%	n	%	n	%
Actual injury	-	-	-	-	1	*1*	-	-	-	-	6	*7*
Actual minor injury	2	*2*	6	*6*	6	*8*	2	*3*	3	*4*	9	*10*
No effect	13	*14*	24	*22*	9	*12*	16	*27*	13	*16*	10	*11*
Chair not used	2	*2*	7	*7*	7	*9*	9	*15*	-	-	2	*2*
Other	29	*31*	14	*13*	3	*4*	13	*22*	28	*35*	16	*18*
Potential injury	20	*22*	36	*34*	18	*24*	7	*12*	27	*34*	28	*31*
Unknown	27	*29*	20	*19*	32	*42*	12	*20*	8	*10*	18	*20*
Total	93		107		76		59		79		89	

[§] Including: problem not allocated, brakes, seat and stability.

Also for manual wheelchairs no single problem seemed to contribute excessively to the (few) reported actual or the potential injuries (Table 17).

Table 17. Outcome vs. problem for manual wheelchairs MDA.

	Problem									
	Brakes		Frame		Other		Seat		Wheels	
Outcome	n	%	n	%	n	%	n	%	n	%
Actual injury	-	-	2	*1*	2	*3*	-	-	-	-
Actual minor injury	3	*7*	11	*4*	9	*14*	1	*9*	11	*6*
No effect	9	*21*	83	*28*	10	*15*	2	*18*	58	*30*
Chair not used	5	*12*	21	*7*	2	*3*	1	*9*	18	*9*
Other	8	*19*	44	*15*	4	*6*	-	-	19	*10*
Potential injury	5	*12*	48	*16*	10	*15*	4	*36*	49	*25*
Unknown	12	*29*	86	*29*	29	*44*	3	*27*	38	*20*
Total	42		295		66		11		193	

3.2.4 Causes

Figure 9 depicts the causes of wheelchair incidents. Over one third of the causes for powered wheelchairs were product-related and nearly one fourth for manual wheelchairs. A remarkable fact is that no causes could be established for about 30% of the powered wheelchair incidents and 40% of the manual wheelchair incidents. User and use-related causes were less common, whereas quality assurance was the third cause of problems with manual wheelchairs.

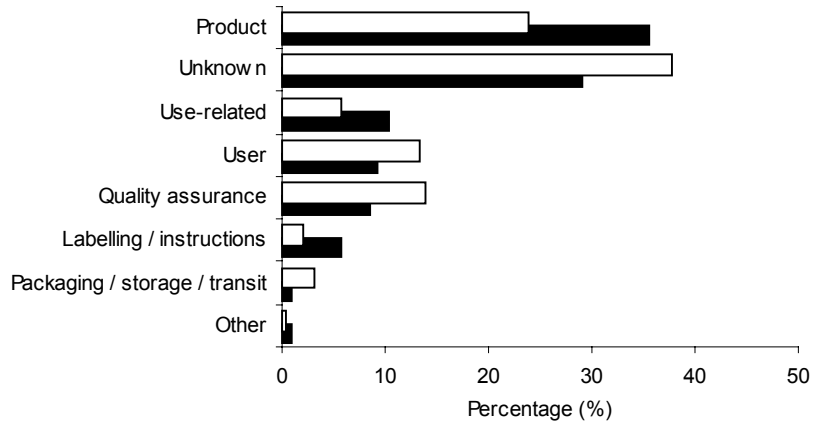


Figure 9. Causes of wheelchair incidents. Causes are shown as percentage for powered wheelchairs (solid bars, n=544) and manual wheelchairs (open bars, n=649) obtained from the MDA database.

Table 18 shows the relation between cause and problem for powered wheelchairs. Powered wheelchair incidents mentioned a product failure as the major cause. The cause 'product failure' was related to problems of the electrical system (electric drive, power supply, and not specified electrical components: 37%), frame components (29%), and wheels (23%).

Table 18. Cause vs. most frequently occurring problem for powered wheelchairs MDA.*

	Most frequently occurring problem												
	Electrical		Frame		Other [§]		Electric drive		Power supply		Wheels		Total
Cause	n	%	n	%	n	%	n	%	n	%	n	%	n
LI[#]	7	*23*	1	*3*	5	*16*	3	*10*	12	*39*	3	*10*	31
Other	4	*80*	-	-	1	*20*	-	-	-	-	-	-	5
PST[#]	-	-	-	-	2	*40*	1	*20*	-	-	2	*40*	5
Product	27	*14*	55	*29*	22	*11*	22	*11*	23	*12*	44	*23*	193
QA[#]	4	*9*	7	*15*	9	*20*	6	*13*	5	*11*	15	*33*	46
Unknown	38	*24*	29	*18*	35	*22*	18	*11*	13	*8*	25	*16*	158
User	5	*10*	14	*28*	14	*28*	2	*4*	4	*8*	11	*22*	50
Use-related	10	*18*	6	*11*	4	*7*	5	*9*	15	*27*	16	*29*	56

* Note that the percentages for the causes are given in the rows.
[§] Including: problem not allocated, brakes, seat and stability.
[#] LI = labelling / instructions; PST= packaging / storage / transit; QA= quality assurance

The majority of manual wheelchair reports mentioned an unknown cause attributing to frame problems (52%) for the major part of the incidents (Table 19). Product failure was the second major cause and was related to frame problems (48%) and wheel problems (36%) as well.

Table 19. Cause vs. problem for manual wheelchairs MDA.*

	Problem										
	Brakes		Frame		Other		Seat		Wheels		Total
Cause	n	%	n	%	n	%	n	%	n	%	n
LI	2	*15*	4	*31*	5	*39*	1	*8*	1	*8*	13
Other	-	-	2	*100*	-	-	-	-	-	-	2
PST	-	-	12	*60*	1	*5*	-	-	7	*35*	20
Product	12	*8*	75	*48*	10	*7*	2	*1*	56	*36*	155
QA	8	*9*	37	*41*	2	*2*	4	*4*	39	*43*	90
Unknown	19	*8*	128	*52*	32	*13*	4	*2*	62	*25*	245
User	8	*9*	43	*49*	11	*13*	3	*3*	22	*25*	87
Use-related	2	*5*	16	*43*	4	*11*	-	-	15	*41*	37

* Note that the percentages for the causes are given in the rows.
LI = labelling / instructions; PST= packaging / storage / transit; QA= quality assurance

3.2.5 Actions

The majority of actions were device-related and consisted of device exchange, recall, and/or repair (Figure 10). 'Unknown' and 'none' were frequently reported and 'design modified' was ranked fourth.

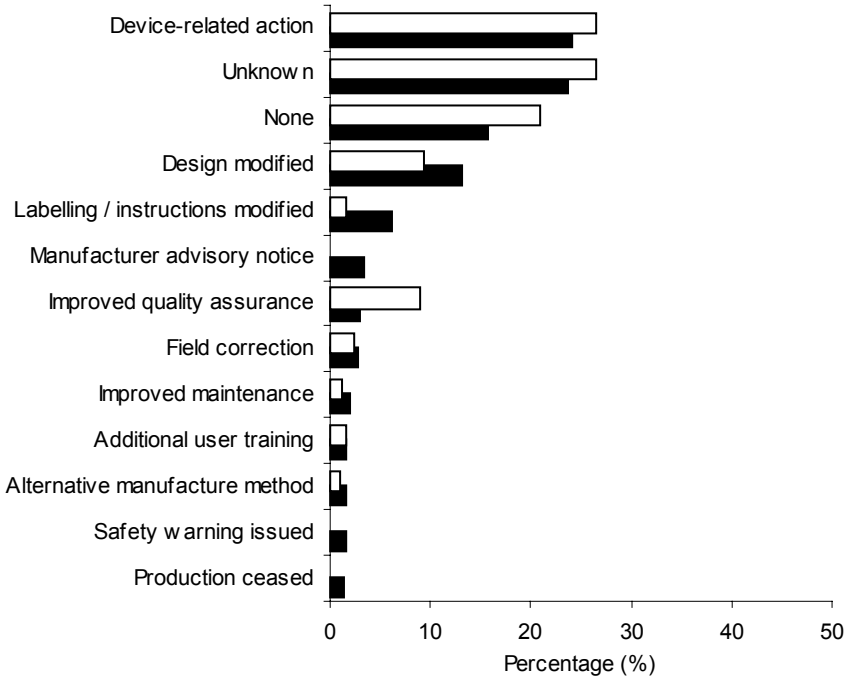


Figure 10. Actions taken due to wheelchair incidents. Actions are shown as percentage for powered wheelchairs (solid bars, n=506) and manual wheelchairs (open bars, n=635) obtained from the MDA database.

For powered wheelchairs product failure was most frequently related to a modification of the wheelchair design (32%) followed by device-related actions (21%) (Table 20).

Table 20. Action taken vs. most frequently occurring cause for powered wheelchairs MDA.

	Most frequently occurring cause											
	Other [§]		Product		QA		Unknown		User		Use-related	
Action taken	n	%	n	%	n	%	n	%	n	%	n	%
Additional user training	1	*11*	1	*1*	1	*2*	-	-	5	*9*	-	-
Alt. manufact. method	-	-	-	-	5	*9*	1	*1*	1	*2*	1	*1*
Design modified	-	-	49	*32*	-	-	-	-	8	*15*	9	*12*
Device-related action	1	*11*	32	*21*	25	*45*	22	*14*	9	*17*	33	*42*
Field correction	-	-	8	*5*	1	*2*	-	-	3	*6*	2	*3*
Improved maintenance	-	-	-	-	-	-	-	-	-	-	10	*13*
Improved QA	-	-	1	*1*	13	*24*	-	-	-	-	1	*1*
LI	4	*44*	13	*8*	1	*2*	-	-	5	*9*	8	*10*
Manufacturer advice notice	-	-	13	*8*	1	*2*	-	-	-	-	3	*4*
None	3	*33*	24	*16*	5	*9*	18	*11*	22	*42*	7	*9*
Production ceased	-	-	6	*4*	-	-	-	-	-	-	1	*1*
Safety warning issued	-	-	2	*1*	3	*5*	-	-	-	-	3	*4*
Unknown	-	-	4	*3*	-	-	117	*74*	-	-	-	-
Total	9		153		55		158		53		78	

[§] Including: other cause, labelling / instructions, and packaging / storage / transit
LI = labelling / instructions; QA = quality assurance

For manual wheelchairs product failure was firstly related to device-related actions (42%) and secondly to a modification of wheelchair design (24%) (Table 21).

Table 21. Action taken vs. most frequently occurring cause for manual wheelchairs MDA.

	Most frequently occurring cause											
	Other [§]		Product		QA		Unknown		User		Use-related	
Action taken	n	%	n	%	n	%	n	%	n	%	n	%
Additional user training	-	-	2	*2*	1	*1*	-	-	7	*7*	-	-
Alt. manufact. method	1	*6*	2	*2*	1	*1*	-	-	1	*1*	1	*2*
Design modified	-	-	30	*24*	5	*5*	1	*0*	16	*16*	7	*16*
Device-related action	11	*65*	52	*42*	46	*44*	25	*10*	23	*23*	11	*24*
Field correction	-	-	6	*5*	1	*1*	2	*1*	6	*6*	-	-
Improved maintenance	-	-	-	-	-	-	-	-	-	-	7	*16*
Improved QA	-	-	5	*4*	40	*38*	8	*3*	2	*2*	2	*4*
LI	3	*18*	2	*2*	1	*1*	-	-	3	*3*	1	*2*
Manufacturer advice notice	-	*12*	-	-	-	-	-	-	-	-	1	*2*
None	2	-	25	*20*	9	*9*	40	*16*	42	*42*	15	*33*
Production ceased	-	-	-	-	-	-	-	-	-	-	-	-
Safety warning issued	-	-	1	*1*	-	-	-	-	-	-	-	-
Unknown	-	-	-	-	-	-	168	*69*	-	-	-	-
Total	17		125		104		244		100		45	

[§] Including: other cause, labelling / instructions, and packaging / storage / transit
LI = labelling / instructions; QA = quality assurance

3.3 KBOH

3.3.1 General

Fourteen reports were received from KBOH over the period June 1997 - January 2001. One report mentioned four incidents, whereas all other reports mentioned one incident. The CE mark and the GQ-mark (see Appendix 1 and 3) were both mentioned three times.

3.3.2 Reported incidents

Table 22. Summary of KBOH data

No.	Type of wheelchair	Consequence	Injury	Effect	Problem	Cause
1	Manual	Unknown	Unknown	Entrapment	Other	Product
2	Manual	Unknown	Unknown	Unknown	Frame	Product
2	Manual	None	None	Uncontrolled movement	Electric drive	Product
4*	Manual	Unknown	Unknown	Other	Frame	Product
5	Manual	Treatment	Multiple	Entrapment	Other	Unknown
6*	Manual	Unknown	Unknown	Entrapment	Instability	Unknown
7*	Manual	Unknown	Unknown	Entrapment	Instability	Unknown
8*	Manual	Unknown	Pain	Other	Other	Unknown
9	Powered	None	None	Standstill	Electric drive, wheels	Information
10	Powered	None	None	Unknown	Electric drive	Product
11	Powered	Treatment	Unknown	Entrapment	Electric drive, wheels	Product
12	Powered	Unknown	Unknown	Collision	EMI	Product
13	Powered	Unknown	Other	Standstill	Electric drive	Product
14	Powered	Treatment	Unknown	Entrapment	Electric drive	Product
15	Powered	Unknown	Unknown	Entrapment	Wheels	Product
16	Powered	None	None	Other	Electric drive	Unknown
17	Powered	None	None	Standstill	Electric drive	Use-related

* Four incidents from one report.

3.4 Wheelchair standards

3.4.1 ISO standards

The ISO 7176-serie contains a number of standards dealing with several aspects of both manual and powered wheelchairs (see Appendix 7).

3.4.2 CEN standards

There are two European standards on wheelchairs:

- EN 12183 “Manually propelled wheelchairs – Requirements and test methods” and
- EN 12184 “Electrically powered wheelchairs, scooters and their chargers – Requirements and test methods”.

EN 12183 refers to all parts of the ISO 7176-series that specify requirements for manual wheelchairs. EN 12184 refers to all published standards from the ISO 7176-series, except for part 7 and part 22. If the ISO standards do not give requirements, the EN standards state these requirements and refer to the ISO standard for the test method.

3.5 Quality marks

In the FDA-MAUDE database, information was given on the 510 (k) approval (see 3.1.8.4 and Appendix 2). For the MDA, the percentage of wheelchairs bearing a CE mark involved in incidents was 63% for powered wheelchairs and 72% for manual wheelchairs (personal communication M. Rand, MDA). For the KBOH, a CE mark and GQ mark on the device were only mentioned three times.

4. Summary of results

4.1 FDA MAUDE database

4.1.1 Powered wheelchairs

During the period July 2000-June 2001 the number of reported incidents was 180. The major cause of the incidents was product-related (54%), whereas user or use-related causes were less common (18%). Product-related causes resulted in problems concerning electric drive (51%), frame (20%), and power supply (13%). Other and unknown causes were frequently related to wheel failures in 63% and 41% of the cases, respectively. User-related causes often led to instability (40%).

Problems with the electric drive were the most frequently occurring problems (34%). Twenty-one percent of the problems were due to wheel failures, 17% to frame failures, 9% to power supply, and 6% to stability. Problems with the electric drive led to uncontrolled movements (47%), collisions (17%) and falls and tips (15%). Wheel problems led to unknown effects (41%), no effect (24%), exploding rims/tires (16%) and falls and tips (16%). Frame failures led to falls and tips (38%), but also to unknown effects (34%) and no effects (24%). Problems with the power supply led frequently to a wheelchair fire without user (67%) and instability of the wheelchair always led to falls and tips.

Falls and tips (23%), unknown effects (19%), uncontrolled movements (16%) and collisions (9%) were the most frequently mentioned effects of problems, whereas no effect was reported in 9% of the incidents. Falls and tips resulted mainly in fractures (39%) and cuts (20%). Wheelchair incidents with unknown effect often did not cause any injury (65%). Uncontrolled movement, often a consequence of electric drive problems, never led to an injury. Collision resulted mainly in fractures (38%) and to a lesser extent in cuts, multiple injuries and no injuries (all 13% of the cases of collisions), whereas the injury was unknown in 19% of these cases. In a small number of the incidents (9%) no effect was reported and therefore no injury was given.

In 49% of all incidents no injury was reported, whereas fractures and unknown injuries were mentioned in 19% and 11% of the incidents, respectively. Other injuries and cuts were both mentioned in 7% of the cases. Medical intervention was always required for fractures and cuts, whereas ‘other’ injuries frequently resulted in medical intervention (75%). If the injury was unknown, the consequence of injury was often unknown (80%). In other cases, the MAUDE report mentioned that medical intervention was required. A burn was only mentioned once, but this particular incident caused the only death reported for powered wheelchairs.

4.1.2 Manual wheelchairs

During the period July 2000-June 2001 the number of reported incidents was 634. Most incidents were attributed to ‘other’ causes (54%) leading to a frame failure in 99% of the cases. The product was the second frequently mentioned cause (39%) resulting in failures of wheels (62%) and brakes (29%).

Frame failures were a major problem (58%), but wheels (26%) and brakes (12%) were also frequently mentioned. Frame failures led to an unknown effect in 95% of the cases, whereas it led to falls and tips in only 3% of the cases. Wheel failures led to an unknown effect in 89% of the cases and falls and tips in 8% of the cases. Problems with the brakes led to unknown effect in most instances (92%) and only led to falls and tips in 8% of the cases.

In 89% of the incidents the effect was unknown. In 6% of the incidents falls and tips were given as the effect. If the effect was unknown, the injury was unknown in 98% of the incidents. Falls and tips led to no injuries or an unknown injury both in 27% of the incidents. An 'other' injury was mentioned in 27% of the falls and tips, whereas fractures were only mentioned in 15% of these incidents.

In 91% of the incidents no injury was reported. Unknown injuries were reported in 3% of the incidents and 'other' injuries were mentioned in 2% of the incidents. Fractures, cuts and multiple injuries together were only mentioned in 3% of the incidents. Unknown injuries often led to an unknown consequence (67%), whereas it led to medical intervention in 29% of the cases. If there was an 'other' injury, medical intervention was required in 69% of the cases, but it led to death in two cases (15%). Fractures and cuts both led to medical intervention in 90% of the cases, but one fracture resulted in the third death for manual wheelchairs.

4.2 MDA database

4.2.1 Powered wheelchairs

The number of powered wheelchair incidents was 436 during the period July 2000-June 2001. The most frequently reported cause was the product (36%). Use-related (10%), user (9%), quality assurance (8%), and labelling and instructions (6%) were less common causes, whereas the cause was unknown in 29% of the incidents.

Product- and user-related causes often led to problems concerning electrical/electronic components (37% vs. 22%), frame (29% vs. 28%), and wheels (23% vs. 22%). Use-related causes often resulted in problems with electrical/electronic components (54%), wheels (29%), and frame (11%). Unknown causes led to failure of electrical/electronic wheelchair components (44%), 'other' failures (22%), frame (18%) and wheel failures (16%). Overall, major problems concerned frame (23%), wheels (19%), non-specified electrical components (18%), other (14%), power supply (12%), and electric drive (11%). Hence, problems involving electrical/electronic wheelchair components including electric drive/supply and non-specified electrical problems added up to 41%.

Frame as well as wheel failures frequently resulted in potential injury (34% and 31%, respectively). Failure of power supply and non-specified electrical problems often led to other non-specified injuries (35% and 31%, respectively), whereas electric drive failure had often no effect (27%). Overall, outcomes were potential injury (27%), actual minor injury (6%), and actual injury (1%). One fatality was reported for powered wheelchairs. Unknown outcome (23%), other outcome (21%), and no outcome (17%) were frequently mentioned.

Product-related causes often resulted in a modified design (32%). User-related causes resulted more often in no action (42%) than in additional training of the wheelchair user (9%). Use-related causes frequently led to device-related action (42%). Overall, actions taken by MDA often were device-related (i.e., device exchange, recall, and repair; 24%) and design modification (13%), although unknown actions and no action were frequently reported (24% and 16%, respectively).

4.2.2 Manual wheelchairs

The number of manual wheelchair incidents was 561 during the period July 2000-June 2001. The major cause in these incidents was unknown (38%), whereas a product-related cause was reported in 24% of the incidents. Quality assurance (14%), user (13%), and use-related causes (6%) were less common.

Quality assurance, product-related, user, and use-related causes often led to problems involving frame (41, 48, 49, and 43%, respectively), and wheels (43, 36, 25, and 41%,

respectively). Unknown causes led frequently to frame failure (52%). Overall, major wheelchair problems were failures of frame (50%) and wheels (30%). Less frequent problems concerned brakes (7%) and seats (2%), whereas other problems were reported in 11% of the incidents.

Overall, outcomes were potential injury (19%), actual minor injury (6%), and actual injury (1%). Frame as well as wheel failures frequently resulted in no outcome (28% and 30%, respectively), although frame failure showed more often unknown outcome (29%). Three fatalities were reported for manual wheelchairs Unknown outcome (28%), other outcome (12%), and no outcome (27%) were often mentioned.

Product-related causes often led to device-related action (42%). No action taken was more often the result of user and use-related causes (42 and 33%, respectively). Quality assurance frequently resulted in device-related action (44%). Overall, actions taken often were device-related (i.e., device exchange, recall, and repair; 27%) and design modification (9%). Although unknown actions and no actions taken were frequently reported (27% and 21%, respectively).

5. Discussion and conclusions

5.1 Discussion

The identification and investigation of problems is an essential component of quality management. In response to identified problems corrective and preventive actions can be taken which will eventually lead to product or process improvement. However, during a review of technical files of wheelchairs no reference was found to incidents with wheelchairs during the post-marketing phase, although it is known that incidents do occur. Therefore the Dutch Inspectorate for Healthcare requested a study into the incidence, severity and causes of problems with wheelchairs during their use. In this study we examined incidents with powered and manual wheelchairs reported to FDA (Food and Drug Administration) in the USA, the MDA (Medical Devices Agency) in the UK, and the KBOH (Centre for Quality and Usability Research of Technical Aids) in the Netherlands.

5.1.1 Methodology

Before discussing the results of our study we need to discuss the applied methodology, especially the suitability of the Critical Incident Technique (CIT) for the purposes of our study. The CIT has primarily been used to evaluate systems in functioning work-environments, thereby offering options for improvement. Although the CIT has especially proven its usability in studying the human component during and around critical incidents over a specific period, its use is not restricted to it. An important example of a successful application of the CIT in health care is the Australian Incident Monitoring Study (7).

We modified the CIT as used in the Australian Incident Monitoring Study for application to data from the FDA MAUDE database and data obtained from the KBOH. The taxonomy applied proved extremely useful in structuring the information. Applying the modified CIT we were able to gain insight in the chain of events for incidents with wheelchairs (cause-problem-effect-injury-consequence). However, missing information on key issues prohibited us to analyse the chain of events for all incidents obtained from the FDA database. In particular, this problem was encountered with manual wheelchairs. Furthermore, most narratives with the incident reports did not contain sufficient contextual detail to gain insight into the influence of contributing factors like environmental factors (e.g. stairs or kerb cuts), human error or control measures (e.g. anti-tips, quality and regulatory marks) on the chain of events. With hindsight this is probably a result of the fact that the reports in the MAUDE database are not first-hand incident reports, but FDA summaries of legally mandated reports by manufacturers, distributors and user facilities on incidents reported to them by users. Moreover, because most of the reports in the FDA database were mandatory reports, while there is no legal obligation to report on use-related incidents, we found relatively few use-related incidents. Therefore, no clear understanding of use-related incidents could be gained.

Another point of concern is the influence of reporting bias. The CIT is intended to be applied to incident reports obtained from subjects present during the incident. It can thereby provide rich information and understanding of users and products in functioning environments. However, the reliance on the memory of reporters, their accuracy and truthfulness is also a disadvantage of the technique. The reviewer must be attentive of the fact that each incident report reflects the personal perspective of the person or organisation submitting it. Moreover, memory is fallible and hearsay may influence the accuracy of the contents of incident reports. We relied on the FDA to have at least checked the accuracy and truthfulness of the information provided to them. The limited information in a large number of reports on frame failures for manual wheelchairs made us wonder whether the information was indeed checked for all incident reports on wheelchairs submitted to the FDA. Finally, it

may well be that our interpretation of the FDA information deviates from the actual facts. Thus, although the data itself proved to be less suitable for complete CIT analysis, the CIT provided a very useful tool for structuring the information.

We did not use the CIT to analyse the incident reports obtained from the MDA. Like the FDA data the analysis of the MDA data was at times hampered by missing information. Due to the different format of the MDA data and due to time constraints, the narratives with the incident reports were not abstracted and the chain of events was limited to 'cause-problem-outcome'. This restricted the possibilities for comparison of the results from the FDA and MDA databases.

5.1.2 Number and type of incident reports

The MDA received more incidents on powered wheelchairs than the FDA, although the number of powered wheelchair users is lower in the UK than in the USA (see paragraph 1.1). This difference may be caused by the fact that the FDA-MAUDE database contained nearly exclusively mandatory reports from manufacturers and distributors, whereas the MDA data mainly contained reports from health professionals of the National Health Service (NHS, see Appendix 5) with a broader scope. For manual wheelchairs the FDA received more reports than the MDA (634 vs. 561). However, a single manufacturer reporting a single type of incident, namely frame failures due to high stresses, submitted 54% of the reports in the MAUDE database. This manufacturer is not the largest manufacturer of wheelchairs in the USA. Therefore, the question arises whether all manufacturers report incidents to the same extent.

In the period 1975-1993 the FDA received 154 reports on powered wheelchairs and 142 reports on manual wheelchairs (8). During this period of eighteen years the yearly number of reports increased but never exceeded 50 (in 1993). Comparison of this number with our findings (some 800 reports for a one-year period) indicates that the number of reports on wheelchair-related incidents submitted yearly to the FDA has increased considerably over the last years. This increase is probably attributable to the introduction of legal obligations to report incidents (see Appendix 4). Less than 1% of the reports submitted to the MDA were received from manufacturers and most reports were received through the NHS. No incident reports were obtained from the Dutch Inspectorate of Health Care and only a few from KBOH. It should be noted that there is no large wheelchair manufacturer based in the Netherlands and that both MDA and FDA are able to invest many resources in the collection of incident reports. Due to the limited number of reports from KBOH, these results will not be discussed here. On the other hand Statistics Netherlands reported eight deaths involving wheelchairs in 2000 (see 5.1.6).

5.1.3 Causes

The product was most frequently mentioned as the cause for powered wheelchair incidents in both the FDA and MDA database (54% and 36%, respectively). The higher percentage for the FDA is probably because the FDA reports are mainly mandatory. User and use-related causes were described in 18% and 19% of the FDA and MDA reports, respectively. Because the MDA database mainly contained reports from health care professionals, user and use-related causes were expected to appear more often in the MDA database. This effect was probably countered by the fact that the MDA added quality assurance and labelling/instructions as causes. Incidents caused by these two factors might otherwise have been attributed partly to user or use-related factors. It should be noted that many chairs are customised (personal communication B. de Bruin, KBOH). This might affect the quality of the original product or the chair could even become a custom-made medical device according to the MDD (9). The latter does not require a CE-marking.

In the MDA database the cause was often unknown for manual wheelchair-related incidents. For manual wheelchairs in the MAUDE database the cause was most often 'other', because a single manufacturer stated in 54% of the reported incidents that high stresses were the cause for frame failures. If these incidents would be attributed to the product, the contribution of the product as a cause would increase from 39% to 93%.

For FDA reports over the period 1975-1993 (8), engineering factors (e.g. frame, motor) were the cause for approximately 80% of the manual wheelchair incidents and approximately 60% of the powered wheelchair incidents. A study based on personal interviews of active wheelchair users, who were involved in an incident (10), showed that 'component failures' caused only 24% of the incidents with manual wheelchairs and 42% of the incidents with powered wheelchairs. This indicates that in practice product failures are less often the cause of an incident than what appears from the databases studied. This confirms practical experience in England, which indicates that many incidents stem from a lack of understanding by the user or insufficient training (personal communication M. Rand, MDA).

It can be concluded that reports of FDA as well as MDA on wheelchair incidents are mostly product-related, whereas more use-related incidents are reported in the literature.

5.1.4 Problems

For the incidents on powered wheelchairs reported to the FDA, the product often caused a problem with the electric drive and the electrical system (64%), whereas this was only 37% for the MDA reports. Frame and wheel failures were ranked second and third, whereas these failures were the most frequently reported problems for manual wheelchairs in the FDA and MDA databases.

Our results are in accordance with a study among users recently provided with a new powered wheelchair in the UK, mentioning electric drive and control system-related problems in 43 % of the incidents (11). Moreover, incidents experienced by wheelchair users indicated that 35% of all engineering factors could be assigned to the drive train or the control system (10), although only 53% of all incidents reported in this study were related to powered wheelchairs. This illustrates the relative vulnerability of the components used for powering a wheelchair. Several studies also indicated that, apart from the electric drive and electrical systems, failures of frame and wheels are the most frequently occurring problems (8;10;11). Several FDA recalls and MDA notices on failures of wheels and frames substantiate these apparent problems (see Appendix 8).

Transportation problems were only reported a few times (n=6) in the MAUDE database and were not specifically mentioned in MDA and KBOH incidents. Safety of transportation is currently being studied by the Netherlands Organisation for Applied Research (TNO). The MDA has published a safety notice and a device bulletin on transportation (Appendix 8) and a standard on the transport of wheelchairs in motor vehicles is being developed (ISO 7176 part 19, see Appendix 7). This indicates the importance of this issue in the daily use of wheelchairs. Transportation-related problems are infrequently reported to the FDA and the MDA because in most cases the wheelchair itself will not be the cause of the incident. However, two of the deaths for manual wheelchairs reported to the MDA were related to transportation in the narrative (personal communication M. Rand, MDA).

The problem comfort or fit, which could lead to decubitus, was only mentioned once in the MAUDE database for powered wheelchairs, mainly because there is no legal obligation to report this problem. However, several studies deal with the problem of pressure sores and ulcers (12-14), indicating that decubitus is a significant problem in daily wheelchair use. Spending more time in a wheelchair than the wheelchair is actually designed for, an incorrect posture or incorrectly prescribed wheelchairs might cause this problem.

No problems with electromagnetic interference (EMI) were found, although this was a topic several years ago (15). A recent study revealed that the effect of EMI on wheelchairs is limited (16).

It can be concluded that failures of components for operating powered wheelchairs, and of frames and wheels are most frequently reported in the databases we studied. The literature indicates that there are other problems associated with the use of wheelchairs, which are only infrequently found in the FDA and MDA databases.

5.1.5 Effects

The FDA data on powered wheelchairs showed a considerable percentage of 'falls and tips': 23% leading to severe injuries (see 5.1.6). This is nearly four times higher than the percentage for manual wheelchairs. The low percentage for manual wheelchairs is again partially due to the high number of frame failures being reported by one manufacturer without any effect being specified. However, it seems unlikely that a failing frame will not cause any effect, e.g. a fall or a tip. If these incidents with frame failures are excluded, the contribution of all other effects, including falls and tips, will approximately double for manual wheelchairs. Other studies mentioned rates for falls and tips ranging from 42% among active users who had a wheelchair incident (10), up to 73% among wheelchair users seeking assistance in emergency rooms (17).

Uncontrolled movement was mentioned in 16% of the incidents with powered wheelchairs in the FDA database, mostly as a result of a problem with the electric drive. This problem was never associated with an injury, but uncontrolled movement is certainly a potentially dangerous effect (15).

It may be stated that falls and tips are found to be occurring frequently and lead to severe consequences for wheelchair users. Probably due to their inability to stop an initial fall or tip or to compensate for instability of the wheelchair, powered wheelchair users are more likely to experience a fall or a tip. Moreover, the speed of powered wheelchairs is likely to be higher. Practical experience indicates that falls and tips without any injuries are a major effect for manual wheelchairs (personal communication B. de Bruin, KBOH).

5.1.6 Injuries, consequences and outcome

Of the powered wheelchair-related incidents in the FDA database, 40% resulted in a known injury of which 49% were fractures. Falls and tips and collisions, which account for 32% of all effects, often caused fractures (39% and 38%, respectively). For manual wheelchairs injuries were reported in only 9% of the incidents, 18% of which were fractures. Excluding the large number of reports on frame failures not specifying any effect or injury, the contribution of specified injuries for manual wheelchairs approximately doubles. However, the contribution of injuries for manual wheelchairs is still considerably lower than for powered wheelchairs. The MDA only reported actual injuries in 6% of the incidents with both powered and manual wheelchairs. The differences in the number of injuries for powered wheelchairs between the MDA and FDA is probably due to the different scopes of the reporting systems.

A review of FDA data over the period 1975-1993 for all types of wheelchairs, including scooters, indicated that 39% of the injuries were fractures (8). A study into falls and tips by manual wheelchair users indicated that fractures made up only 11% of the injuries (18), which is even less than the number found for manual wheelchairs in the MAUDE database. However, this study also included partial falls and tips. Despite any bias, powered wheelchair users seem to be more likely to sustain an injury than manual wheelchair users. This might be due to powered wheelchair users being more vulnerable and/or the speed of powered wheelchairs.

A study into fatal wheelchair incidents in the USA (19) showed that in the period 1973-1987 the yearly number of wheelchair-related fatalities was 51. This number is much lower than the number of fatalities found in the MAUDE database and the MDA database (both n=4). Moreover, a study was undertaken to establish the number of wheelchair users admitted to emergency rooms over the period 1986-1990 in the USA. The estimated number of serious wheelchair-related injuries, causing the injured person to seek attention at an emergency department (ER), was 55514 for 1992 (17). Although we realise that there are several fallacies in the following simple approach, we calculated the incidence of serious wheelchair-related incidents in the USA by dividing the number of ER visits (55514) by the number of wheelchair users (2.2 million, see 1.1). This indicates that the incidence of serious injuries related to the use of wheelchairs in the USA is 2.5%. Statistics Netherlands collects data on the causes of death in the Netherlands. For 2000 eight deaths were attributed to a fall involving a wheelchair. During the period 1996-1999, this number varied between three and seven (20). Although most of the aforementioned figures are dated, they indicate that use-related incidents, for which there is no legal obligation to report, are responsible for the majority of serious injuries and fatalities. Another explanation is that there is serious underreporting.

Fractures are the most frequently occurring and severe injuries for wheelchair users, occurring more frequently among powered wheelchair users. The number of serious injuries and fatalities in the FDA and MDA databases seem to underestimate the actual numbers of serious injuries and fatalities.

5.1.7 Actions

Design modification and device-related actions are the most frequently reported actions in the MDA database. It is remarkable that user-related incidents are not often related to additional user training for powered and manual wheelchairs (9% and 7%, respectively), but more often to design modification and device-related actions. However, practical experience within the MDA indicates that lack of understanding by the user or insufficient training are often associated with incidents (personal communication M. Rand, MDA).

5.1.8 Wheelchairs involved

A histogram relating wheelchair age to the number of incidents reported to the FDA showed several peaks. Because we have no information on the warranty period, maintenance requirements, or time limits for replacement in the USA, no relation between these periods and the peaks in incidents can be made. Because it was often unknown whether a 510 (k) number was present, the absence or presence of the 510 (k) mark could not be associated with the occurrence of incidents.

Because the CE and GQ marks were only mentioned three time in KBOH reports and not in the FDA database, no conclusions on the influence of these marks could be drawn. No data on CE marking were given in the database supplied by the MDA. Several fatalities reported to the MDA involved a non-CE marked product, but in only one case the design of the product contributed to the incident. In most cases it was a lack of awareness of the risk that probably contributed most to the incident (personal communication M. Rand, MDA). These risks are to be dealt with by the instructions for use, which are required to be supplied with a CE marked product.

The extensive series of standards for wheelchairs indicate that, starting in the late 1980’s, strict requirements for wheelchairs are present. Some examples of the subjects covered by the standards are static and dynamic stability and resistance to ignition. The stability is related to falls and tips, whereas ignition of upholstery is related to a fatality in the MAUDE database. It is not clear if all types of wheelchairs on the market fulfil these requirements.

5.1.9 Considerations

Comparing the data from the FDA, MDA and the literature is hampered by the different scopes of interest for collecting the data, the reporting mechanisms and the reporters. Nevertheless, several conclusions can be drawn. The MAUDE database and the MDA database reported a considerable number of wheelchair-related incidents, but considering the number of wheelchairs in use (US: 2.2 million, England 750,000) and the intensity of use, this would not indicate a major problem. On the other hand, studies in the literature indicate that the actual numbers of serious injuries and fatalities are considerably higher. Moreover, the actual use of wheelchairs gives rise to other, mostly use-related, incidents than those reported in the databases we studied (e.g. transportation, decubitus). Thus, there is a discrepancy between the data in the literature and the data reported to both FDA and MDA. Moreover, there might be underreporting of wheelchair-related incidents. Preventing wheelchair-related incidents should be a combination of both product improvement and attention for the correct use of wheelchairs. The low number of vigilance reports in Europe relative to the USA deserves attention to gain insight into the causes of this difference.

5.2 Conclusions

- Although the use of a ‘chain of events’ proved to be a useful tool for structuring information, it was not possible to use the CIT for the analysis of information which is not designed for CIT, e.g. the FDA MAUDE database.
- The databases studied do not indicate that wheelchairs present a major public health problem.
- Data from the literature show that the actual number of serious injuries and fatalities is considerably higher than can be deduced from the MDA and FDA databases.
- Most of the reported incidents are product-related, whereas the literature indicates a considerable number of use-related incidents.
- There is probably underreporting of wheelchair-related incidents to the FDA and MDA.
- The low number of vigilance reports in Europe relative to the USA deserves attention.
- The components used to power electrical wheelchairs give rise to a relatively high number of problems, whereas failures of frames and wheels are common for both powered and manual wheelchairs.
- Falls and tips are frequently occurring and lead to severe consequences for wheelchair users.
- Fractures are the most frequent and severe injuries for wheelchair users.
- Users of powered wheelchairs are more likely to sustain serious injuries.
- Preventing wheelchair-related incidents should not only be based on product improvement but also on the correct use of wheelchairs, including the instructions for use.
- A study of use-related wheelchair incidents could be a worthwhile exercise to gain an understanding of those incidents.

Literature

(1) Inspectie voor de Gezondheidszorg. Klasse I medische hulpmiddelen: dossier laagste risicoklasse niet in orde. In: IGZ, editor. Jaarrapportage 2001. Den Haag: 2002 p. 75.

(2) US Census Bureau. Americans with Disabilities: 1997 - Table A. 15-5-2002. http://www.census.gov/hhes/www/disable/sipp/disab97/ds97ta.html.

(3) Ipso Facto, SGBO. Kwaliteitseisen van voorzieningen. Een verstrekkende wet 3: einrapport; Evaluatie van de Wet voorzieningen gehandicapen derde meting. Doetinchem: Elsevier bedrijfsinformatie, 2001.p. 159.

(4) FDA. Manufacturer and User Facility Device Experience Database (MAUDE). 19-10-2001. http://www.fda.gov/cdrh/maude.html.

(5) Centraaal Bureau voor de Statistiek. Intramurale personeels,- inversterings en algemene gegevens; instellingen en plaatsen/bedden, from Statline database. Voorburg/Heerlen: 2002.

(6) Flanagan JC. The critical incident technique. Psychol Bull 1954; 51:327-358.

(7) Webb RK, Currie M, Morgan CA, Williamson JA, Mackay P, Russell WJ et al. The Australian Incident Monitoring Study: an analysis of 2000 incident reports. Anaesth Intensive Care 1993; 21(5):520-528.

(8) Kirby RL, Ackroyd-Stolarz SA. Wheelchair safety - adverse reports to the United States Food and Drug Administration. Am J Phys Med Rehabil 1995; 74(4):308-312.

(9) Council of the European Communities. Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. Offical Journal of the European Communities 1993; L 169/1.

(10) Gaal RP, Reholtz N, Hotchkiss RD. Wheelchair rider injuries: causes and consequences for wheelchair design and selection. J Rehabil Res Dev 1997; 34(1):58-71.

(11) Frank A, Ward J, Orwell N, McCullagh C, Belcher M. Introduction of a new NHS powered indoor/outdoor chair (EPIOC) service: benefits, risks and implications for prescribers. Clin-Rehabil 2000; 14(6):665-673.

(12) Brienza DM, Karg PE, Geyer MJ, Kelsey S, Trefler E. The relationship between pressure ulcer incidence and buttock-seat cushion interface pressure in at-risk elderly wheelchair users. Arch Phys Med Rehabil 2001; 82(4):529-533.

(13) Wall J. Preventing pressure sores among wheelchair users. Prof Nurse 2000; 15(5):321-324.

(14) Batavia M, Batavia AI. Pressure ulcer in a man with tetraplegia and a poorly fitting wheelchair: a case report with clinical and policy implications. Spinal Cord 1999; 37(2):140-141.

(15) Radiofrequency interference with medical devices. A technical information statement. IEEE Eng Med Biol Mag 1998; 17(3):111-114.

(16) TNO. "Storing op medische apparatuur thuis door zaktelefoons e.d. - een praktijkonderzoek" Report TNO/PG/TG/00.050. Leiden: 2000.

(17) Ummat S, Kirby RL. Nonfatal wheelchair-related accidents reported to the National Electronic Injury Surveillance System. Am J Phys Med Rehabil 1994; 73(3):163-167.

(18) Kirby RL, Brown MG, Kirkland SA, Ackroyd-Stolarz SA. Tipping accidents among noninstitutionalized users of manually propelled wheelchairs in Nova Scotia. Am J Phys Med Rehabil 1994; 73:319-330.

(19) Calder CJ, Kirby RL. Fatal wheelchair-related accidents in the United States. Am J Phys Med Rehabil 1990; 69(4):184-190.

(20) Centraaal Bureau voor de Statistiek. Overledenen op landelijk niveau naar primaire doodsoorzaak, leeftijd (op de laatste verjaardag) en geslacht in de periode 1996-2000, val waarbij rolstoel betrokken is, from Statline database. Voorburg/Heerlen: 2002.

(21) FDA. Premarket Notification [510(k)]. 23-10-2001. http://www.fda.gov/cdrh/devadvice/314.html#link_1.

(22) FDA. Reporting problems with medical devices. 26-4-2002. http://www.fda.gov/cdrh/mdr.html.

(23) MDA. MDA Corporate. 25-7-2002. http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwSectionsMDA/About+MDA?Open.

(24) MDA. Reporting adverse events. 25-7-2002. http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/webvwSectionsMDA/Reporting+adverse+incidents?Open.

Appendix 1: EU marketing of medical devices

Medical devices to be marketed in the European Union are subject to council directive 93/42/EEC of 14 June 1993 concerning medical devices (9). They must meet the essential requirements in this directive to ensure that devices do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose. These requirements include the design and construction as well as labelling and instructions for use. Applying harmonised European standards (CEN- and CENELEC-standards) facilitates the demonstration of conformity with the essential requirements.

Devices are divided into Classes I, IIa, IIb or III, where Class I are the low risk and Class III the high-risk devices. The procedure for the assessment of conformity with the essential requirements becomes more complicated from Class I going to Class III devices. Wheelchairs are in Class I. The conformity assessment procedures for Class I devices is carried out, as a general rule, under the sole responsibility of the manufacturer. For Class IIa devices the intervention of a Notified Body is compulsory. For devices classified as Class IIb or III inspection by a Notified Body is required with regard to the design and the manufacture of the devices. For Class III devices explicit prior authorisation with regard to conformity is required for them to be placed on the market.

Devices for which compliance with the requirements of the Directive is confirmed bear the CE-marking (Conformitée Européenne), and can be marketed freely within the European Union.

Member States must have a medical vigilance system to record and evaluate:

a. 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 may lead to or might have led to the death of a patient or user or to serious deterioration in his state of health.
b. any technical or medical reason in relation to the characteristics or performance of a device for reasons referred to in a.), leading to systematic recall of devices of the same type by the manufacturer.

Manufacturers are required to “institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action, taking account of the nature and risks in relation to the product.”.

After carrying out an assessment the Member State shall inform the European Commission and the other Member States of those incidents for which relevant measures have been taken or are contemplated.

Appendix 2: USA marketing of medical devices

Medical devices are subject to the general controls of the Federal Food Drug & Cosmetic Act (FD&C Act). These controls are the baseline requirements that apply to all medical devices necessary for marketing, proper labelling and monitoring its performance once the device is on the market. Medical devices must obtain marketing clearance from the Centre for Devices and Radiological Health (CDRH), a component of the FDA (21).
If the product meets the definition of a medical device in de FFD&C Act it must be classified in one of three classes:
Class I : minimal potential for harm to the user
Class II : low-to-intermediate risk
Class III : life supporting, life-sustaining or implanted

Most Class III devices require Premarket Approval (PMA), a process of scientific review to ensure safety and effectiveness. In most cases this includes well-controlled clinical studies, full reports of safety and effectiveness and data regarding the manufacture of the device.

Class I, II and some Class III devices require submission of a Premarket Notification or 510(k)[4] to FDA-CDRH at least 90 days before marketing unless the device is exempt from 510(k) requirements.
The performance and effectiveness of medical devices marketed through the 510(k) process must only be demonstrated to the extent of substantial equivalence (SE). That is, the device is substantially equivalent to a legally marketed device that is not subject to premarket approval. Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalence claims. The legally marketed device(s) to which equivalence is shown are known as the “predicate” device(s).
A new device that is as safe and effective as the predicate device(s) is called “SE”.
A device is SE if, in comparison to the predicate device it:

- has the same intended use, and
- has the same technological characteristics, or has different technological characteristics that do not raise new questions of safety and effectiveness and the applicant demonstrates that the new device is as safe and effective as the legally marketed device.

The SE determination is usually made by CDRH within 90 days.
A 510(k) must be submitted by:

- domestic manufacturers introducing a device to the U.S. market
- specification developers introducing a device to the U.S. market
- repackers or relabelers who make labelling changes or whose operations significantly effect the device
- foreign manufacturers/exporters introducing a device to the U.S. market.

A mechanical wheelchair is a medical device of Class I; a powered wheelchair is a medical device of Class II.

[4] According to section 510(k) of the FD&C Act.

Appendix 3: The GQ mark

In the Netherlands the KBOH is an independent non-profit centre for Quality and Usability Research of Technical Aids. KBOH issues the GQ (Guaranteed Quality) mark since 1989 for devices that bear the CE marking and fulfil additional requirements on quality, efficiency, ergonomics and durability. These requirements are drafted consulting users, assessors, providers and manufacturers/distributors.

Manufacturers can have their products tested for the GQ mark on a voluntary basis. Recognised testing institutes carry out the tests. New series of approved types are checked randomly to see if they still satisfy the approval requirements.

Technical aids are always approved on the basis of suitability for specific users with their own specific requirements and capabilities in a specific situation. Therefore KBOH has subdivided categories of technical aids into so-called clusters. Within a category different sets of testing requirements can exist for different clusters. For example, a wheelchair, which is intended for short periods of use, does not require a seat with an adjustable posture. In that case, for the purposes of GQ, that wheelchair does not need to satisfy this requirement. There are also different requirements for wheelchairs to be used indoors and outdoors, or only indoors, but the requirements in the European Standards for wheelchairs (EN 12183 and EN 12184, see 3.4) always have to be fulfilled.

For wheelchairs conformity with the requirements is hitherto only tested by TNO.

Appendix 4: FDA Medical Device Reporting

Medical Device Reporting (MDR) is the mechanism for the FDA to receive significant medical device adverse events from manufacturers, importers and user facilities, so they can be detected and corrected quickly (22).
Since 1984 manufacturers and importers have been required to report to FDA all device-related deaths, serious injuries [5] and certain malfunctions.
Under the Safe Medical Devices Act (SMDA) of 1990, device user facilities are legally required to report (suspected) device-related deaths to the FDA and the manufacturer, if known. Device user facilities must also report device-related serious injuries to the manufacturer, or to the FDA if the manufacturer is not known. These reports must be made on the MedWatch 3500 A Mandatory Reporting Form.
FDA's MedWatch program allows healthcare professionals and consumers to voluntary report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use. These problems include serious adverse reactions, product quality problems, and medical errors. Reporting can be done on-line, by phone, or by submitting the MedWatch 3500 Voluntary Reporting Form.

MedWatch Voluntary Reporting:

Consumers
Health Professionals

MedWatch Mandatory Reporting:

Medical Device Manufacturers
Distributors
User Facilities

Reports of adverse events involving medical devices are entered in MAUDE, the Manufacturer and User facility Device Experience Database. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August, 1996 (4).

[5] Serious injury necessitates medical or surgical intervention.

Appendix 5: MDA Incident reporting

The Medical Devices Agency (MDA) is an Executive Agency of the UK Department of Health. A main activity is investigating adverse incidents associated with medical devices and their use, and helping to prevent further incidents by communicating findings to those who make or use the devices. The Adverse Incident Centre is within the business area Device Technology and Safety (23). The Agency's business plan states: "The Agency's aim is to take all reasonable steps to protect the public health and safeguard the interests of patients and users by ensuring that medical devices and equipment meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.". Therefore, other issues than safety are also dealt with within the MDA. Reporters also inform the MDA of quality issues and when products do not perform to the expected level (personal communication M. Rand, MDA).

All adverse incidents involving medical devices should be reported to the MDA as soon as possible, even if user error is suspected. (24).

Reporting Adverse Incidents can be done on-line, by e-mail, by mail, or by fax. For reporting by e-mail, mail or fax the form can be downloaded from the MDA internet site. Apart from the general form there are special forms for some categories of devices (e.g. for wheelchairs, pacemakers). Telephone reports are taken only for incidents involving death, serious injury or serious public health concern and should be followed up as soon as possible by a written report.

All adverse incident reports received by MDA are entered into a database.

Appendix 6: Description of database for FDA and KBOH

Field	Description	Values
General		
ID-number	Unique identification number of record	-
Date input	Date of entering record in database	dd/mm/yy
Staff member	Member of staff entering record into database	avd, ehm, br
Source	Source where the report originated from.	fe = FDA MAUDE, powered fm = FDA MAUDE, manual kb = KBOH
Reference number	Serial number of report	-
Report source	Reporting source of report	1 = manufacturer 2 = voluntary 3 = distributor 4 = other 99 = unknown
What happened		
Effect on user	Effect of the problem	1 = fall with/from wheelchair 2 = entrapment 3 = collision 4 = fire wheelchair without user 5 = fire wheelchair with user 6 = (coming to a) standstill 7 = other 8 = none 9 = uncontrolled movement of chair 10 = exploding rim and/or tire 99 = unknown
Text effect other	Specification of other effect	-
Why it happened		
Problem stability	Wheelchair tipped or fell without a technical problem.	1 = yes 2 = no
Problem electric drive	Failure of the electric drive and/or controls	1 = yes 2 = no
Problem power supply	Failure of the power supply (including batteries and charging batteries)	1 = yes 2 = no
Problem (mechanical) failure wheels	Failure of one or more wheels (including casters becoming detached)	1 = yes 2 = no
Problem (mechanical) failure frame	Failure of the frame (including parts becoming detached)	1 = yes 2 = no
Problem (mechanical) failure seat	Failure of the seat (excluding its frame)	1 = yes 2 = no
Problem brakes	Failure of the brakes	1 = yes 2 = no
Problem during transportation	Problem during transportation of the wheelchair in a car or public transport	1 = yes 2 = no
Problem combination with other medical devices	Failure caused by the combination of the wheelchair with other devices (excluding transport devices)	1 = yes 2 = no
Problem comfort or fit	Problem with fit or comfort of wheelchair, leading to e.g. pressure sores	1 = yes 2 = no

Problem EMI	Electromagnetic interference influencing wheelchair	1 = yes 2 = no
Problem other	A problem which is not specified in the report	1 = yes 2 = no
Text problem other	Specification of problem other	-
Problem unknown	Occurrence of a problem which is not specified in the report	1 = yes 2 = no
Obviousness cause	Is the cause given in the report obvious?	1 = obvious 2 = not obvious
Cause	Cause of the problem	1= product 2 = user 3 = use-related (maintenance/assembly) 4 = other devices 5 = information/education 6 = other 99 = unknown
Text cause other	Specification of cause other	-

Wheelchair involved

Type of wheelchair	Manual or powered wheelchair	1= powered 2 = manual 99 = unknown
Brand name	Brand name as given in the report	99 = unknown
Model	Model as given in the report	99 = unknown
Age	Age of wheelchair in months	999 = unknown
Reuse	Does the report state that the wheelchair is re-used?	1 = yes 2 = no 99 = unknown
CE mark	Does the wheelchair have a CE-mark?	1 = yes 2 = no 99 = unknown
Quality mark KBOH	Does the wheelchair have a Dutch KBOH (GQ)-mark?	1 = yes 2 = no 99 = unknown
510 (k)	Does the report state a 510 (k) number?	1 = yes 2 = no 99 = unknown

Where and when

Month report	Month of the report (FDA received)	mm, 99 = unknown
Day report	Day of the report (FDA received)	dd, 99 = unknown
Year report	Year of the report (FDA received)	yyyy, 99 = unknown
Location	Location of the incident or problem	1 = indoors (not an institution) 2 = outdoors 3 = institution 4 = during transport 99 = unknown

To whom it happened

User	Type of user	1 = patient 2 = family member/carer/other 99 = unknown
Age user	Age of the user	999 = unknown
Pre-existing condition	Condition of the patient causing the wheelchair use	99 = unknown

Consequence

Consequence	Type of consequence	1 = injury requiring medical treatment 2 = injury without medical treatment 3 = death 4 = none 99 = unknown
Type of injury	Type of injury	1 = fracture 2 = burn 3 = bruising 4 = cut 5 = concussion 6 = decubitus 7 = multiple injuries 8 = other 9 = none 99 = unknown
Text other injury	Specification of other injury	-

Appendix 7: ISO standards on wheelchairs

ISO standards on wheelchairs

Standard	Date	Subject of standard
ISO 7176-1	1999	Determination of static stability
ISO 7176-2	2001	Determination of dynamic stability of electric wheelchairs
ISO 7176-3	1988	Determination of efficiency of brakes (under revision)
ISO 7176-4	1997	Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
ISO 7176-5	1986	Determination of overall dimensions, mass and turning space
ISO 7176-6	1988	Determination of maximum speed, acceleration and retardation of electric wheelchairs (under revision)
ISO 7176-7	1998	Measurement of seating and wheel dimensions
ISO 7176-8	1998	Requirements and test methods for static, impact and fatigue strengths
ISO 7176-9	1988	Climatic tests for electric wheelchairs (under revision)
ISO 7176-10	1988	Determination of obstacle-climbing ability of electric wheelchairs
ISO 7176-11	1992	Test dummies (under revision)
ISO 7176-13	1989	Determination of coefficient of friction of test surfaces
ISO 7176-14	1997	Power and control systems for electric wheelchairs -- Requirements and test methods (under revision)
ISO 7176-15	1996	Requirements for information disclosure, documentation and labelling
ISO 7176-16	1997	Resistance to ignition of upholstered parts – Requirements and test methods
ISO/FDIS 7176-19	-	Wheeled mobility devices for use in motor vehicles (in preparation)
ISO/FDIS 7176-21	-	Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorised scooters (in preparation)
ISO 7176-22	2000	Set-up procedures
ISO/FDIS 7176-23	-	Requirements and test methods for attendant-operated stair-climbing devices
ISO/WD 7176-24	-	User-operated stair-climbing devices – Requirements and test methods (in preparation)
ISO/AWI 7176-25	-	Requirements and test methods for batteries and their chargers for powered wheelchairs and motorised scooters (in preparation)

Appendix 8: Recalls and notices

Several FDA recalls on wheelchairs

Date	Type of chair	Problem
02/94	Permobil Super-90	Motor and gearbox are defective
11/95	Redman type 107/07	Joystick circuitry can cause unintended starting and stopping
04/96	Quickie P300	Front castor forks may collapse
05/96	Several Invacare powered wheelchairs	Fuse holder may cause wheelchair to lose power
05/96	Rolls 2000 & 9000	Steel caster forks can buckle under stress
10/96	Permobil Chairman	Backrest welds may crack and fracture
01/97	Several powered and manual wheelchairs	Rear wheel axle bolt may break when bending stress exceeds the carrying capacity
08/97	Quickie revolution	Caster hinge and bolt may detach
08/97	Chief 107 SR	Frame may fracture
02/98	Several Invacare powered wheelchairs	Brushes in motor may fail prematurely
09/98	Breezy 501	Excess weight placed on folded chair may damage the lock which hold the back in upright position
01/02	Several Quickie models	Armrest receiver may collapse

MDA notices on wheelchairs (1996-2001)

Notice	Device	Problem
DA 2000(04)	Scandinavian mobility powered wheelchairs	Charger/controller connection may overheat leading to burns to users' hand
DB 2001(03)	General	Guidance on the Safe Transportation of Wheelchairs.
HN 2000 (13)	Several battery chargers	Overheating may lead to fire
HN 1999(03)	Newton Badger powered wheelchairs	Corrosion of fuse may lead to overheating and can potentially cause fire
SN 2001(31)	Invacare powered wheelchairs	Drive wheels becoming detached during use
SN 2001(21)	Ferno MkI chair	Partial frame collapse due to failing pivot pin
SN 2001 (24)	Battery chargers for powered wheelchairs	Plug of battery chargers may split apart exposing bare terminals
SN 2000(03)	Unwin wheelchair clamps	Incorrect clamping of chair in vehicle allow it to tip backwards
SN 2000(06)	Invacare Celt and Zipper 1	Reduced fire retardancy of upholstery
SN 2000(08)	Bohle side panels for armrests	Reduced fire retardancy
SN 2000(11)	MBL single hand use propelling wheel system	During removal, parts can separate and cause harm
SN 2000(20)	Lomax powered chairs	Castor stems may fail
SN 1999(14)	Phoenix powered chair	"Pram type" handle may suddenly detach if not correctly secured
SN 1999(15)	Electrical powered wheelchairs and scooters	Freewheel devices on most powered wheelchairs and scooters also disengage braking system. Not all users may be aware of this, leading to potentially serious situations.
SN 1999(33)	Wheelchairs, seating and accessories	Injuries and incidents continue to happen due to inadequate inspection, maintenance and repair
SN 1999(34)	Wheelchair seating and wheelchair accessories	Failure to follow instructions of use result in injuries
SN 1999(35)	Safety of wheelchair passengers in vehicles	Injuries and fatalities during transportation of occupants of wheelchairs in road vehicles
SN 1999(37)	Unwin wheelchair headrest	Headrest is attached to push handles. Headrest, used to push the chair, can become detached.
SN 1998(03)	Quicklok wheelchair clamp	Quicklok clamps, designed for securing manual wheelchairs, are incorrectly used to secure powered wheelchairs
SN 1998(37)	Invacare Action 2000	Failure of hinges in backrest tubes
SN 1997(19)	Ross and Bonnyman powered wheelchairs	High incidence of castor assemblies failing
SN 1996(05)	Wheelchairs fitted with Framco motors	Problems with missing brake drive hub, insufficient tightened screw and wrong brakes being fitted
SN 1996(23)	Newton Avon wheelchair	When chair is used to transport the occupant in a vehicle (against instructions), the bolts in the backrest reclining mechanism can fail

DA: Device alert
DB: Device bulletin
HN: Hazard notice
SN: Safety notice