

# Infusion pumps

## - Identifying risks

### Report from the Medical Products Agency

Date: 22th of August 2014

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# SUMMARY

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The Medical Products Agency is the competent authority that is responsible for surveillance of medical devices available on the Swedish market. The Medical Products Agency's objective with the surveillance is to ensure that users have access to medical devices that are safe and appropriate in respect to their intended use.

Due to the fact that the Medical Products Agency has noted safety issues with infusion pumps, an enquiry was sent out to the public healthcare sector. The purpose was to identify problems and risks that users had observed and experienced using infusion pumps during the period of 1st of January 2011 to 31st of December 2012. Altogether, 35 (50%) of the hospitals that received the enquiry replied to some or all questions.

The report indicates a large number of incidents (approximately 1700) during the time period and that some incidents are judged to be so severe that patient safety could not always be guaranteed. The identified problem areas are software, hardware and user interfaces. The report also shows that many incidents never have been reported to the Medical Products Agency, from either manufacturers or healthcare providers. Less than 50 incidents have been reported by manufacturers during the same time period. Based on the replies in the enquiry there are approximately 18 000 infusion pumps of various types (volume, syringe and portable pumps) used in the 35 hospitals.

The Medical Products Agency concludes that there are insufficiencies in some of the manufacturers' quality management systems and the post-market surveillance of its medical devices. These insufficiencies may lead to field safety corrective actions and reports to authorities not always being carried out to the extent as required. The medical device regulation is the applicable law that has to be followed by manufacturers to guarantee safe medical devices on the market. Due to the findings in this report the Medical Products Agency considers it necessary for manufacturers of infusion pumps:

- To improve their system for acquiring and processing experiences from practical use of its medical devices (Post Market Surveillance System, PMS)
- To improve their reporting to relevant authorities (Vigilance system)
- Review their risk management process to identify problems, assess risks and take appropriate safety measures (Risk Management system and CAPA-system)
- Assess their validation and verification of the software in the infusion pumps

Due to the insufficiencies, the Medical Products Agency also sees a need for the notified bodies of the manufacturers of infusion pumps to further develop the audit of the manufacturers' total quality management systems, including PMS, CAPA and Vigilance system.

On several previous occasions, the Medical Products Agency has provided feedback to some manufacturers and their notified bodies due to insufficiencies in their quality management systems, but the problems seem to remain. For the on-going surveillance within this product area the Medical Products Agency needs to receive reports from both manufacturers, as well as from healthcare providers, to improve the risk assessment of incidents involving infusion pumps. It is also necessary that the relevant authorities continue to cooperate on both a national and an international level to increase patient safety even further.

The Medical Products Agency believes that the benefits of the medical devices currently outweigh the risks and sees no reason why the devices should not be available on the market. However, the Medical Product Agency will continue to focus on this product area with surveillance activities, which may involve actions against certain manufacturers.

# INTRODUCTION

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During the last few years the Medical Products Agency has received numerous reports of incidents where infusion pumps have been involved. Most of the reports are from manufacturers and a few are from healthcare providers. The Medical Products Agency concludes, together with other external factors, that the numbers of the reports as well as the severity of incidents is a serious matter. The Medical Products Agency therefore considers that there is a need to identify safety issues with infusion pumps.

Infusion pumps have contributed to improvements in patient care, allowing for greater levels of control, accuracy and precision of drug delivery. The development of medical device technology combined with advanced drugs and better requirements to control infusion therapy have increased the use of infusion pumps. Today they are used in various clinical applications that can involve both life-sustaining as well as life-saving treatments within clinical areas like anaesthesia, intensive care and oncology. The pumps are also used at wards, within the home care environment and at hospice (palliative care) for fluid therapy, pain relief and other drug treatments. The healthcare sector is nowadays becoming increasingly dependent on the use of advanced infusion pumps which means that interference or problems with the devices will have a direct impact on the delivery of care. From the reported incidents the Medical Products Agency considers that infusion pumps have become more complex and have more complicated user interfaces. Please refer to Appendix 2 for technical background.

The Medical Products Agency has noted that there are problems typically with the software of the infusion pumps. This is why the Medical Products Agency initiated a multidisciplinary seminar for the healthcare sector in 2010 in Uppsala. The purpose was to make an overall assessment of the problems. Clinical engineers, nurses and procurement officers were amongst the participants. The following could be concluded from the meeting:

- That there were software-related problems with infusion pumps.
- That healthcare provider had difficulties knowing how and when to report incidents to the competent authority.
- That there was a low rate of reported incidents, since individuals often postpone or refrain from reporting to the authority.

Apart from the software-related problems for several brands, it was noted that the user interfaces were not optimal and that mechanical and electrical failures occurred to a greater extent, compared to the information the Medical Products Agency had from incident reports. The representatives of the healthcare organisations stressed that the problems had led to an increased work load and greater insecurity amongst users. Many of the problems resulted in interrupted treatments for patients but also caused consequences for delivery of care so that patient safety could not always be guaranteed. Please refer to Appendix 5 for more comments from the seminar.

It was noted, in several reports handed in to the Medical Products Agency after the seminar, that the identified problems still existed. Taking this into account, the Medical Products Agency is doubtful about if the manufacturers properly assess risks when incidents have occurred.

Other international authorities have also noted severe problems with infusion pumps, such as for instance the FDA (Food and Drug Administration) in the US. FDA concluded in a report that the infusion pumps have contributed to improvements in patient care, allowing for a greater level of

control, accuracy and precision in drug delivery, and thereby medication errors. However, the report shows that more than 56 000 adverse events with infusion pumps were reported from 2005 through 2009 in the US (1). FDA has analysed the events and the related corrective actions.

FDA has concluded that many of these problems appear to be related to deficiencies in device design and engineering. In April 2010, FDA launched "Infusion Pump Improvement Initiative" in order to address infusion pump problems and support the safe use of these devices by:

1. Establishing additional requirements for infusion pump manufacturers
2. Proactively facilitate device improvements
3. Increase user awareness

FDA concludes that many of the reported problems are due to software defects, user interface issues and mechanical and electrical failures.

Also the British competent authority MHRA (The Medicines and Healthcare products Regulatory Agency) has observed serious problems with infusion pumps. They receive many reports of incidents involving infusion pumps which in many cases have resulted in patient harm but also death due to over-infusion. From 2005 through 2010 MHRA investigated 1085 events with infusion pumps. MHRA issued the document "Infusion systems" (2) in December 2013. The aim was to raise awareness of the nature of infusion system, their advantages and risks, management and training issues, with a view to reducing the number of adverse incidents that arise from their use.

# AIM

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The aim of this report is to:

- Identify risks and problems with infusion pumps that are observed and encountered by users within healthcare.
- To inform manufacturers, notified bodies and relevant authorities about the problem areas identified by the Medical Products Agency to achieve better and safer infusion pumps in the future.

# METHOD

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In May 2013 the Medical Products Agency sent out an enquiry consisting of 10 questions to medical engineering managers within public healthcare in all counties. The purpose was to gain information about which infusion pump manufacturers that were operating on the Swedish market, the problem areas and the functioning of infusion pumps from a user perspective. All private operators have been excluded from this report due to lack of resources and the problem of finding a proper contact list, such as for the medical engineering managers within public healthcare. The most suitable profession to answer the enquiry was considered to be clinical engineers, due to their knowledge and experience about infusion pumps and their use. It is mainly because they receive information about incidents with infusion pumps and also because they often submit incident reports to the Medical Products Agency.

The scope of the enquiry covers volumetric pumps, syringe pumps and portable/ambulatory pumps with a power source. Target Controlled Infusion (TCI) pumps, used for anaesthesia, is presented separately. The infusion parameters in these infusion pumps are controlled by algorithms and patient data settings. This feature is typically included in the syringe pumps but also some volumetric pumps may have this feature.

The Medical Products Agency has no complete information about which manufacturers or devices that are available on the Swedish market. Swedish manufacturers of devices that are registered with the Medical Products Agency belong to class I, which is not relevant for infusion pumps. The selection of manufacturers and medical devices in the enquiry were based on the incident reports sent to the Medical Products Agency. Most questions also had empty text boxes for additional comments, making it possible for instance to acquire information about other possible manufacturers.

An on-line survey with 10 questions (13) was sent by e-mail to 70 recipients. The questions are presented in Appendix 3. Replies and report results are presented anonymously, both for hospitals as for manufacturers.

## *Delimiters*

The survey does not cover insulin pumps, nutritional pumps, single-use pumps and implantable pumps. Nor does the survey cover single-use devices that are accessories to the infusion pumps involved.

# RESULTS

The response rate was 50 %, and 35 replied to some or all questions. A reminder was sent out once. The presentation below shows the number of replies per question of those who responded to the enquiry. It must be pointed out that it was not mandatory to reply to all questions.

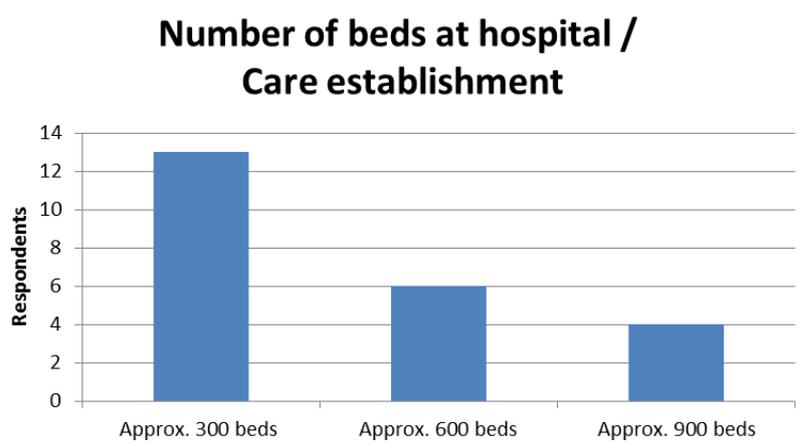
Question	Respondents	No response	Total answers in percent
1	23	12	66%
2	32	3	91%
3	30	5	86%
4	21	14	60%
5	14	21	40%
6	21	14	60%
7	24	11	69%
8	23	12	66%
9	24	11	69%
10	10	25	29%

*Table 1. Response rate*

## Question 1.

*Hospital/healthcare unit. Specify the approximate numbers of beds.*

*Replies: 23(35)*



*Diagram 1. Shows the number of beds at the hospitals who replied to the question.*

The larger hospitals with more advanced care have around 900 beds. Middle sized hospitals have approximately 600 beds and other hospitals around 300 beds.

Out of those who answered the enquiry, 12 did not answer this question.

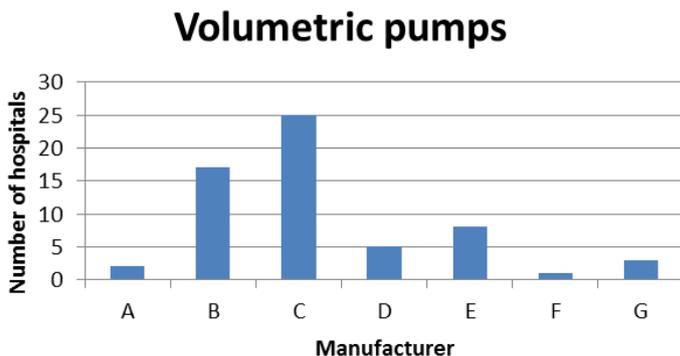
## Question 2.

The Medical Products Agency requests the following information regarding which manufacturers of infusion pumps you have and how many. Please specify an approximate number of infusion pumps for each manufacturer.

Replies: 32(35)

In the enquiry, 11 manufacturers are mentioned whereof 7 replies are presented. The manufacturers in the report are randomly presented as A-G which is used consistently throughout the report.

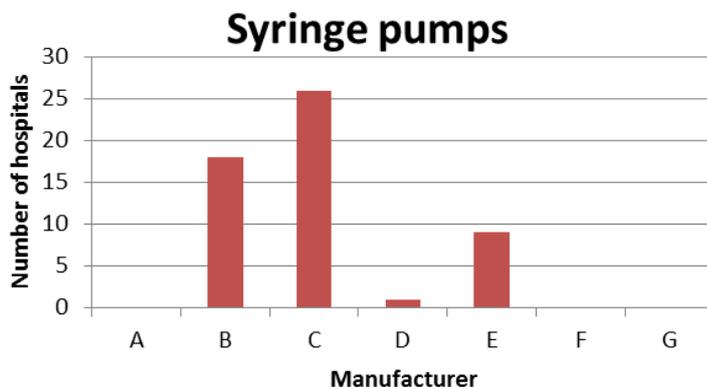
To be able to compare results against other questions the various pump types were presented individually. The diagram below illustrates the distribution of pump types from each manufacturer at the hospitals.



**Diagram 2.** Number of hospitals who replied having volumetric pumps from manufacturer A-G:

The result shows that the hospitals have volumetric pumps from seven manufacturers.

- Five manufacturers have more than 100 volumetric pumps in at least one hospital.
- Three manufacturers have more than 300 volumetric pumps in at least one hospital.

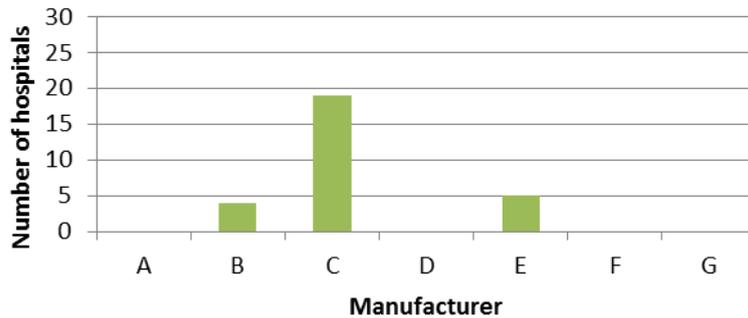


**Diagram 3.** Number of hospitals who replied having syringe pumps from manufacturer A-G:

The result shows that the hospitals have syringe pumps from four manufacturers.

- Three manufacturers have more than 100 syringe pumps in at least two hospitals.
- Two manufacturers have more than 300 syringe pumps in at least one hospital.

## Anaesthesia pumps

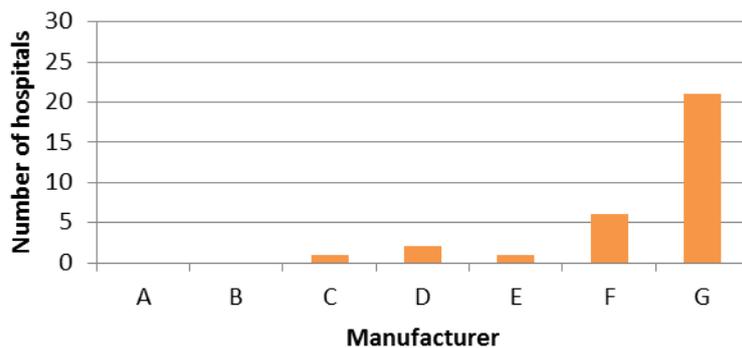


**Diagram 4.** Number of hospitals who replied having pumps with TCI function from manufacturer A-G:

The result shows that the hospitals have TCI pumps from three manufacturers.

- One manufacturer has more than 100 TCI pumps in one hospital.

## Ambulatory pumps



**Diagram 5.** Number of hospitals who replied having portable pumps from manufacturer A-G:

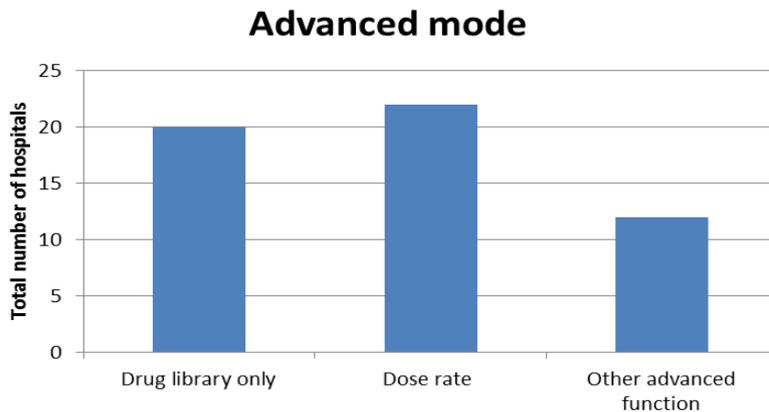
The result shows that the hospitals have portable pumps from four manufacturers.

- Two manufacturers have more than 100 portable pumps in at least three hospitals.
- One manufacturer has more than 300 portable pumps in one hospital.

The result shows that three manufacturers are dominant on the Swedish market both in respect to distribution in various hospitals as well as the overall number of infusion pumps in hospitals. Based on the replies, the overall number of pumps in the hospitals was approximately 18 000 of the types mentioned above.

### Question 3.

*If you use drug protocol (not TCI) at your hospital, please specify how they are used.  
Replies: 30(35)*



**Diagram 6.** Use of advanced mode.

The result shows that the infusion pumps are frequently used in an advanced mode. Only five replied that they didn't use the infusion pumps in an advanced mode. See also Appendix 2. Technical background.

### Question 4.

*Estimate the amount and how many types of incidents you have encountered with infusion pumps during a 2 year period (1st of January 2011 - 31st of December 2012).*

*Replies: 21(35)*

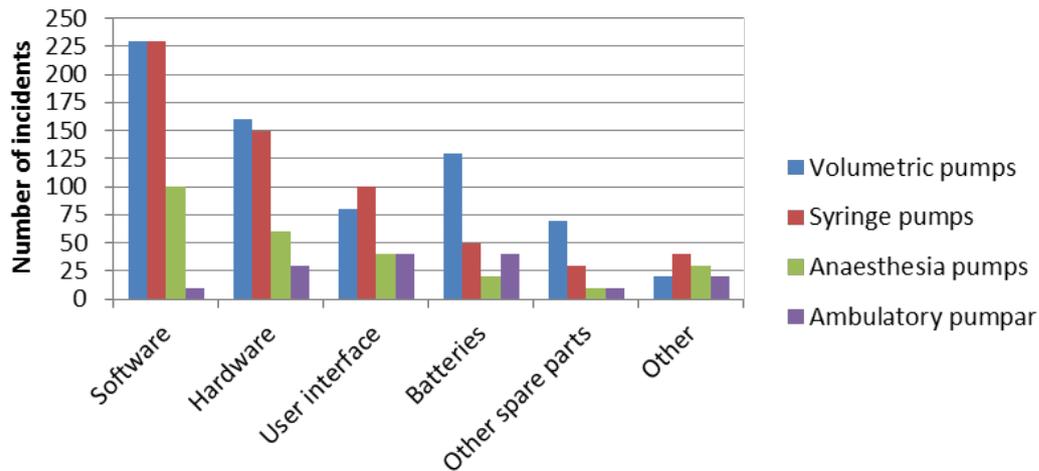
To better illustrate incidents, for all types of pumps at the Swedish hospitals during the two year period, the following approximation was done:

Number of answers	Quantity
1-10 incidents	10 incidents
> 10 incidents	10 incidents
> 20 incidents	20 incidents
> 30 incidents	30 incidents
> 40 incidents	40 incidents
> 50 incidents	50 incidents

**Table 2.** Approximation of the number of incidents.

To calculate the overall number of incidents the response rate table uses the following formula; if one hospital replied that they had 1-10 incidents, two hospitals had more than 10 incidents, 3 hospitals had more than 40 incidents then they were summarised as  $10 + (2 \times 10) + (3 \times 40) = 150$  incidents. The use of the formula may therefore result in a lower estimation of incidents.

## Incidents



**Diagram 7.** Number of incidents per problem area for each infusion pump.

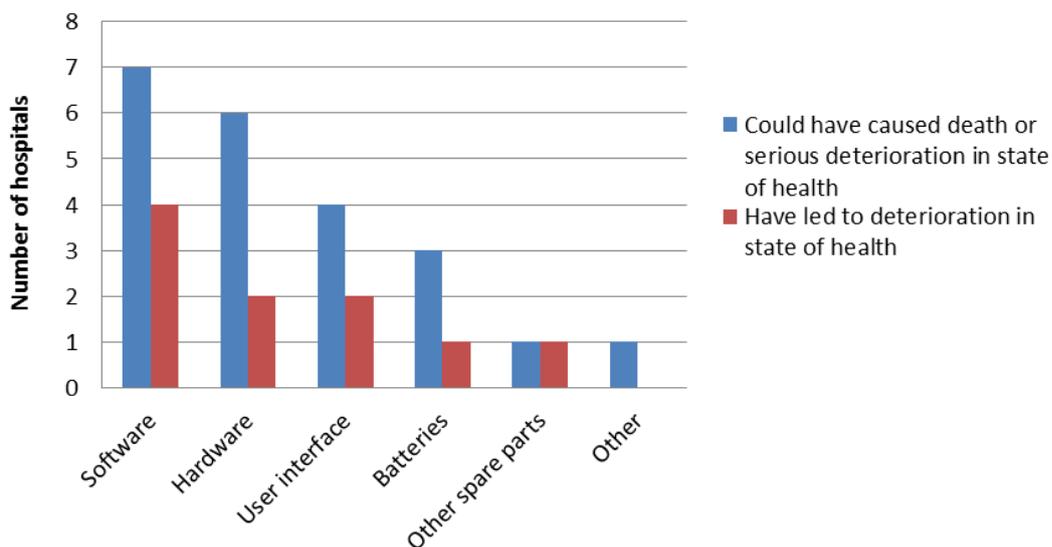
The total number of incidents for all types of problems is estimated to 1700 according to this diagram. The terminology in the question is based on the regulation SOSFS 2008:1(3) from the National Board of Health and Welfare. The result shows a high proportion of software-related problems, especially for volumetric and syringe pumps. Despite the underestimation of the number of incidents in Table 2, the result indicates a large number of incidents during the 2 year period.

### Question 5.

*Out of the incidents that have occurred in your hospital (during the mentioned 2 year period) please specify the severity of those incidents for each problem area. Multiple replies are allowed for each problem area.*

*Replies: 14(35)*

## Severity of incidents



**Diagram 8.** Number of hospitals that have encountered one or more serious incident for each problem area

Even though the response rate was low it is obvious that many hospitals have experienced incidents which also have resulted in deterioration in the patient's health. This applies especially to incidents within the problem area that represents software problems. None of the replies showed incidents with lethal consequences. The terminology in the question is based on the regulation SOSFS 2008:1(3) from the National Board of Health and Welfare.

### Question 6.

*Have you received any feedback, such as written confirmation and/or safety notices, from the manufacturers or their representatives after the occurrence of incidents mentioned above?*

*Replies: 21(35)*

Manufacturer	Yes	No	No answer
<b>A</b>	1	1	4
<b>B</b>	6	1	5
<b>C</b>	14	2	2
<b>D</b>	0	1	4
<b>E</b>	4	3	3
<b>F</b>	3	1	2
<b>G</b>	3	1	2

*Table 3. Manufacturers who have given feedback to healthcare providers.*

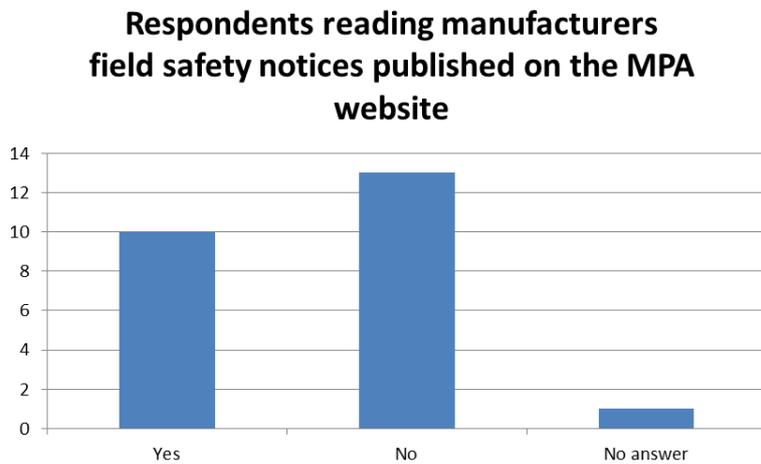
From the replies 14 hospitals out of 21 received feedback from one and the same manufacturer. The other manufacturers had given feedback to 6 hospitals or less.

According to the result from question 2, manufacturers B, C, and E have the majority of infusion pumps on the market. The findings indicate that manufacturer C gives feedback more often than manufacturer B and E. The result is however difficult to evaluate since the staff that receives feedback may be different from those who reply.

### Question 7.

Do you read the manufacturers' safety notices, published on the Medical Products Agency's website? <http://www.lakemedelsverket.se/malgrupp/Halso---sjukvard/Medicinteknisk-sakerhetsinformation/fran-tillverkare/>

Replies: 24(35)



**Diagram 9.** Number of respondents who read the manufacturers' field safety notice, published on the Medical Products Agency's website.

The Medical Products Agency publishes manufacturers' field safety notices on its website to promote the distribution of safety information even further. According to the result the slight majority doesn't read this type of information. The result is difficult to judge when others in the hospital than those who responded to the enquiry may have received the information

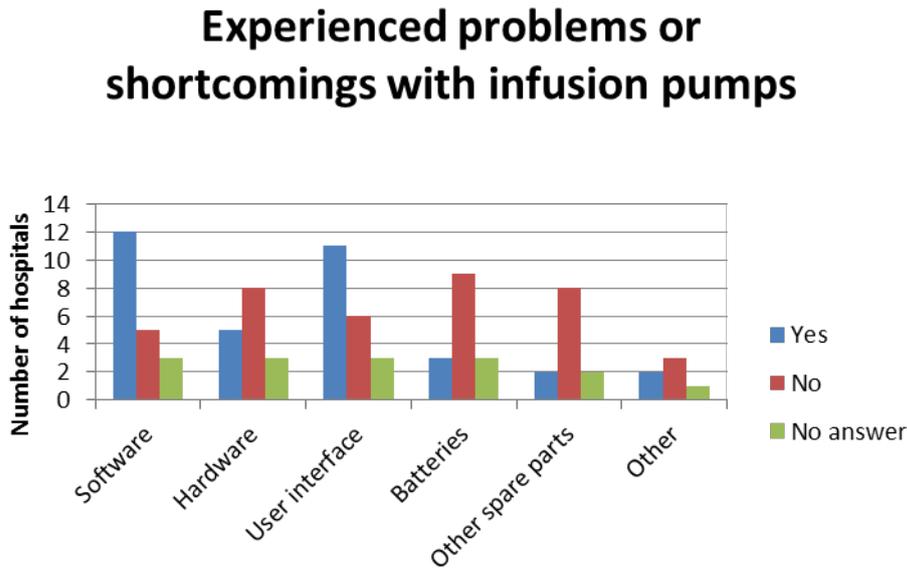
The question also had an informative purpose to emphasize that this type of information is available on the Medical Products Agency's website.

### Question 8.

*Do you believe that there are problems or shortcomings with infusion pumps that have led to or can lead to not always being able to guarantee patient safety?*

*Replies: 23(35)*

The diagram below shows whether hospitals experience problems and shortcomings with infusion pumps where patient safety could not always be guaranteed. The result is presented for the same problem areas as in Question 4 and 5.



**Diagram 10.** *The number of hospitals that experiences problems or shortcomings with infusion pumps.*

The result shows that many hospitals experiences problems and shortcomings in the software and user interface of infusion pumps that can lead to not always being able to guarantee patient safety. The diagram illustrates that there are 12 hospitals that experience software problems compared to 5 hospitals without problems. When it comes to user interfaces, 11 hospitals experience problems compared to 6 who don't. The situation is the opposite for the other problem areas, meaning that less hospitals experiences problems compared to those who don't.

### Question 9.

*Are you satisfied with the way the manufacturers and/or the representatives handle the problems with your infusion pumps?*

*Replies: 24(35)*



**Diagram 11.** *Customer satisfactions with manufacturers' management of infusion pump problems.*

The replies are not related to the number of pumps from the manufacturers at the hospitals. Manufacturer B, C and E are the three largest manufacturers and manufacturer C has all types of infusion pumps represented in most hospitals.

### Question 10.

*Any other comments about infusion pumps, in respect to syringe, volumetric and portable pumps and accessories/single-use devices etc. that you would like to share?*

*Replies: 10(35)*

See Appendix 4.

# DISCUSSION

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## *Incidents*

According to diagram 7 the overall numbers of incidents for all types of problems are estimated to 1700. Question 2 was answered by 21 out of 70 hospitals. The result shows that software problems are by far the biggest contributor to incidents, followed by hardware problems and user interfaces. Volumetric and syringe pumps have the biggest problems but they also represent the largest product types. The Medical Products Agency has not at all received reports of this scale from the manufacturers (Table 4). The opinion of the Medical Products Agency is that the manufacturers have a great potential in revising their routines to improve the post-market surveillance of their medical devices and reporting to the competent authorities.

## *Risk assessment and responsibility*

Since many infusion pumps, according to Question 3, are nowadays used in an advanced way (Diagram 6), patient safety is dependent on stable software when advanced functions are software controlled. This means that the software directly impacts the drug delivery and that the patient is facing risks each time an infusion pump with unstable software is used. The medical device regulation requires the software to be validated and verified prior to placing the devices on the market. This also applies for updating/upgrading software. The findings in this report identify many and severe software related incidents (Diagram 7 and Diagram 10). During the same period the manufacturers have initiated and reported few field safety corrective actions (Table 4). The comments also reflect (Appendix 4) that there are compatibility issues between the different software versions and that the responsibility is unclear when upgrading software and configuring settings for infusion pumps.

## *Severity*

The severity of incidents that have occurred shows that there are significant risks for patients associated with the use of infusion pumps. Several incidents have led to serious deterioration in the state of health (Diagram 8). The biggest contributors are software errors followed by defective hardware. The result also shows that many hospitals have had incidents that may lead to or have led to a deterioration in the patient's health. This confirms that unstable software is a significant risk for patient safety.

## *Feedback*

The communication between manufacturers and healthcare providers is important but is not always working. The Medical Products Agency has observed that the feedback from manufacturers is poor (Table 3). On the other hand, healthcare providers do not always report incidents with infusion pumps. The communication between manufacturer and healthcare providers needs to be improved.

## *Urgent field safety notice*

In Question 7 the Medical Products Agency wanted to gain information about how many who read the "Urgent field safety notices" published on its website (Diagram 9).

According the medical device regulation the manufacturer is obliged to report a field safety corrective action to the competent authority. This action, carried out by the manufacturer, is aimed to reduce risks. Such actions shall be communicated to the relevant users as an "Urgent field safety notice".

### *How problems are perceived*

The result from Question 8 shows that more hospitals experience problems with software and user interfaces compared to those who don't. For the other problem areas, the situation is the other way around. Problems with user interfaces and software are believed to cause larger problems than hardware deficiencies. A possible explanation could be that it is difficult for users to prevent serious situations that are caused by software or user interfaces. Hardware problems may be more obvious and therefore probably simpler to detect and handle by users.

It is a risk that the users believe that they have caused the problem (user error) instead of suspecting that the infusion pump has a poor user interface. This may contribute to a low rate of reports related to usability. It might also be difficult for the user to define whether the problem is due to software or a user interface which may cause these problem areas to be intermixed.

### *The basis for the report*

The enquiry was answered by 50% of which half of the responses came from hospitals with approximately 300 beds. Some of the respondents have commented that the questions were too comprehensive and difficult to answer. The questions were made non-mandatory so that it would be possible to continue answering the questions even though some information was missing. This is the reason why the number of replies varies for different questions. Some questions may have been too comprehensive which may have contributed to a low response rate. Since only 50% participated in the enquiry it is difficult to make definite conclusions. The problem areas are however clearly identified.

### *Reports submitted to the Medical Products Agency*

According to the medical device regulation the manufacturer has the sole responsibility for its medical device placed on the market which includes requirements, as part of the quality management system, to systematically follow up the devices on the market.

During the 2-year period referred to in the enquiry, the Medical Products Agency has received <50 incident reports with infusion pumps where the following problems have been noted:

- Various types of error alarms /fault alarms leading to interrupted infusion.
- Data transmission causing wrong configuration and maltreatment.
- Software versions and upgrades causing compatibility problems.

Incident reports from healthcare providers	Incident reports from manufacturers	Field safety corrective action reports including recalls from manufacturers
<b>&lt; 40</b>	<b>&lt; 50</b>	<b>&lt; 10</b>

**Table 4.** Number of reports submitted to the Medical Products Agency from healthcare providers and manufacturers where infusion pumps have been involved between the years 2011 -2012.

From the submitted incident reports the Medical Products Agency has analysed and concluded that the verification and validation of the manufacturers' infusion pump software is poor. The software-related problems have led to serious incidents such as false alarms with interrupted infusion in critical situations and incorrect settings in the medication protocols. Mechanical failures that have been observed are for instance worn out attachments which have caused pumps to fall down on patients. The Medical Products Agency's analysis and assessment of the manufacturers' reports are also based on information from the healthcare provider reports. There are however relatively few

reports of incidents from the healthcare providers. Therefore the Medical Products Agency strongly recommends the healthcare providers to report all incidents where infusion pumps have been involved.

Taking into account the vast number of incidents that can be assumed from the answers in Question 4, there are remarkably few reports by manufacturers that have been submitted to the Medical Products Agency. The manufacturers' post-market surveillance of devices has only resulted in three corrective actions. Furthermore, the Medical Products Agency has indications of manufacturers who have carried out safety-related corrections at only some hospitals. Many measures have never been reported to other relevant users, neither to the Medical Products Agency.

### *Surveillance by the Medical Products Agency*

The Medical Products Agency is responsible for market surveillance of manufacturers and medical devices to meet the requirements of the medical device regulation. Upon detected deficiencies the Medical Products Agency can demand that the problems be corrected, implement market constrictions and/or demand all medical devices be recalled from the market. The Medical Products Agency may issue any injunctions and prohibitions necessary to comply with the medical device regulation.

In cases where the Medical Products Agency finds insufficiencies with either the devices or the manufacturer's quality management system, such as poor risk management and post-market surveillance, this will be communicated to the manufacturer and its notified body. If the manufacturer has its place of business in a different European country, the competent authority of that country will be contacted. The collaboration between authorities may lead to concerted actions.

The Medical Products Agency has on several occasions had reason to communicate with some infusion pump manufacturers and their notified bodies about insufficient risk management process and post-market surveillance.

### *Harmonised standard*

Manufacturers often use harmonised product standards to fulfil the CE marking requirements for their products. The harmonised product standard SS-EN 60601-2-24 (4) is especially intended for infusion pumps. However, the standard is outdated when it comes to the latest technical developments and some important areas are missing. One example is that manufacturers use the expression "safe mode" in their reports when the pumps stop and give an alarm. This does not however reflect the situation with modern infusion therapy where under-infusion could be fatal. Considering the risks associated with under-infusion this expression needs to be discussed and clarified in the infusion pump standard. The standard is also too general to cover all critical functions of various infusion therapies. More specific standards for various types of infusion pumps need to be developed.

### *Reidar*

The problems identified in this report can also be confirmed by the information found in the adverse event database Reidar (5) used by healthcare organisations. During the same period, 1st of January 2011 to 31st of December 2012, there were 33 registered adverse events with infusion pumps in Reidar. Reidar is an electronic database for the registration of adverse events related to medical devices and their use in the healthcare environment. Reporting is handled by certified staff to promote experience and information about adverse events within the healthcare environment. Reidar is based on voluntary cooperation between different medical engineering departments in Sweden.

*General*

Today, infusion pumps are frequently used within healthcare and are of great importance for the daily treatment of patients. It is therefore not surprising that adverse events happen where infusion pumps are involved. Even so, the Medical Products Agency believes that many adverse events are of serious character and that the report rate is too low. The benefit of infusion pumps must however always be compared to the risk of their use.

# CONCLUSION

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A large number of incidents, approximately 1700, occurred during 1st of January 2011 to December 31st. The biggest problem areas are software and hardware. Many hospitals have had incidents that have been serious for the patients. The healthcare staff mainly experiences problems with software and user interfaces that can lead to not always being able to guarantee patient safety.

During that period few of those incidents, less than 50, have been reported from the manufacturers as incidents to the Medical Products Agency. This indicates that some manufacturers of infusion pumps might have a poor system for acquiring and processing experiences from practical use of their devices and that their reporting system is insufficient. This together with an insufficient risk management process can lead to not always initiating necessary safety-related corrective actions.

The report also proves the fact that problems and shortcomings identified in 2010 still remain, even though the Medical Products Agency have taken actions. It is the opinion of the Medical Products Agency that it is necessary to increase the surveillance even further to achieve improved patient safety.

# DEFINITIONS

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FDA - Food and Drug Administration

LVFS - The regulations of the Medical Products Agency

MDD - Medical Device Directive

MHRA - The Medicines and Healthcare products Regulatory Agency

PCA - Patient Controlled Analgesia

SOSFS - The regulation of National Board of Health and Welfare

TCI - Target Controlled Infusion

TIVA - Total Intravenous Anaesthesia

CAPA – Corrective actions and Preventive actions

# REFERENCES

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2. [www.mhra.gov.uk](http://www.mhra.gov.uk) - Infusion Systems December 2013, Report from MHRA
3. SOSFS 2008:1 National Board of Health and Welfare's regulation on the use of medical devices in health care
4. SS-EN 60601-2-24, Particular requirements for the safety of infusion pumps and controllers
5. [www.reidar.se](http://www.reidar.se)
6. Swedish Medical Devices Act (1993:584)
7. MDD 93/42/EEC European Medical Device Directive
8. Medical Product Agency's regulation (LVFS 2003:11) regarding medical devices
9. [www.vardhandboken.se](http://www.vardhandboken.se)
10. Jacobsons Medicin och teknik (2006) editors Maria Lindén & P. Åke Öberg
11. Handbok i intravenös anestesi (2006) editor Ralph Harlid
12. Anestesi (2005) edited by Matts AB Halldin Sten GE Lindahl
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# Appendix 1

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## *The medical device regulation*

The Medical Products Agency is the competent authority that is responsible for surveillance of medical device available on the Swedish market. A goal for the surveillance of the Medical Products Agency is to ensure that users have access to medical devices that are safe and appropriate in respect to their intended use.

The Swedish Medical Devices Act (1993:584) regulates medical devices in Sweden (6) together with other associated regulation from the Medical Products Agency. The Swedish regulation was transformed in 1993 to meet the safety and performance requirements in the EU Directive 93/42/EEC (7) regarding medical devices (MDD).

All medical devices that are placed on the market must comply with the requirements in the regulation. The device shall bear the CE marking to demonstrate that it complies with the requirements in the regulation. A compliant CE marked device has full access to the entire EEA market. All medical devices, except custom-made devices and devices intended for clinical trial/performance assessment, must bear the CE marking when they are placed on the market.

It is the manufacturer who affixes the CE marking to a device and whose responsibility it is to demonstrate compliance with the requirements. It must be pointed out that CE marking doesn't mean that the device has been approved by an authority.

Medical devices are divided into different classes. The classification reflects the risks associated with the devices and also, among other things, which procedure shall be applied by the manufacturer to demonstrate that the devices comply with the requirements in the regulation. Infusion pumps are risk class IIb. This is according to Annex 9 (8) in the Medical Product Agency's regulation (LVFS 2003:11) regarding medical devices (Annex 9 in MDD 93/42/EEC (7)).

3§ LVFS 2003:11 (8) (Article 3 in MDD 93/42/EEC (7)) states that a device must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned.

According to Annex 1 point 1, the devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients. The risks associated with the use shall be acceptable when weighted against benefits for the patient and shall be compatible with a high level of protection of health and safety.

To affix the CE marking for a class IIb device, the manufacturer must follow some of the declaration of conformity procedures set out in 7 § point 3 LVFS 2003:11 (Article 11 point 3 in MDD 93/42/EEC). The regulation refers to a number of appendices stipulating that manufacturers of class IIb devices must consult with a third party organisation, such as a notified body, to assist and monitor that the manufacturers' routines for verifying their devices placed on the market comply with the medical device regulation. See the Medical Products Agency's website for more information.

The manufacturer shall, according to the regulation, be committed to have an appropriate system in place to acquire and process experiences from practical use concerning its devices placed on the

market. The manufacturer must also have proper routines to identify and carry out corrective actions to prevent unnecessary repetitive incidents.

According to 9a § LVFS 2003:11 (8) the Medical Products Agency shall be contacted immediately in the occurrence of:

1. 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 might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health.
2. Any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in point 1, leading to systematic recall of devices of the same type by the manufacturer.

The surveillance tasks carried out by the Medical Products Agency are to follow up, in various ways, that medical devices placed on the Swedish market comply with the requirements in the medical device regulation and that the manufacturer can guarantee safe medical devices. The surveillance tasks involve handling, analysing and assessing the manufacturers' incidents reports and recalls. To a large extent, the surveillance task is to check that the manufacturer has a proper system for acquiring and processing experiences from practical use concerning its devices placed on the market. The surveillance also involves following up that the manufacturer has a functional system to report any incidents occurring on the market and that they have routines to identify and carry out corrective actions for the devices that have been proved not to fulfil the applicable requirements.

According to the National Board of Health and Welfare's regulation on the use of medical devices in health care (SOSFS 2008:1) (3), the healthcare provider is obliged to report incidents where a medical device has been involved, to the manufacturer and the Medical Products Agency. These reports from the health care providers are used by the Medical Products Agency to better assess the incidents and its root causes.

# Appendix 2

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## *Technical background*

Infusion pumps are used in all types of healthcare, such as for treatment in intensive care units and wards but also in the home care environment. Drug delivery of potent pharmaceuticals in high concentrations creates big demands on the infusion pump's performance. Over-infusion as well as under-infusion is a risk factor for the patient. It is therefore important that drug delivery is carried out in a safe and controlled manner and doesn't cause incorrect dosage. Furthermore, the functionality needs to be adapted to the clinical environment and the pump must be easy to use, such as having an optimal user interface.

The software in infusion pumps offers extended options for configuration and profiles for the various clinical areas. Hence it is possible to configure user interfaces that are tailored to the different clinical treatment methods. The purpose of customized configuration is to aim for a safer usage and mitigate the risk of incorrect settings of the infusion parameters.

Parameters that could be configured are for instance dose rate (drug quantity/bodyweight in kg/time), drug name, medication protocol, preset bolus functions and preset alarm limits. The various protocols can be configured with drug-specific settings with flow limitations and maximum/minimum flow rates. This is to reduce the risk of infusion beyond therapeutic levels and to minimise the risk of incorrect dosage.

Volumetric pumps are often used for continuous drug infusion when larger quantities need to be infused, especially when a higher infusion rate is required. The most common type is a linear peristaltic pump where the fluid gets pushed forward through an infusion device.

Syringe pumps are often used for potent pharmaceuticals and for low flow rate infusions when a more controlled flow is required. The maximum volume is limited to the size of the syringe.

Portable pumps with a power source are often used for patient controlled pain relief, also referred to as "patient controlled analgesia" (PCA). On a PCA pump patients can control the amount of drugs themselves by delivering a bolus dose for optimal pain relief. The software restricts the total amount of drugs infused to the patient.

TCI pumps are infusion pumps specifically for intravenous anaesthesia and they can be divided into two groups; total intravenous anaesthesia (TIVA) and target controlled infusion (TCI). TIVA uses a drug-specific setting with a flow profile for induction dose and maintenance flow. TCI means that the software uses algorithms to infuse the anaesthetic drug with variable speed control, both under the induction and maintenance phase. The algorithm controls the flow rate of the pump to meet the calculated target concentration (target control), for either plasma concentration or the concentration in the effect site (brain). (9,10,11,12)

# Appendix 3

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## *Questions in the enquiry*

The enquiry had the following questions:

Q1 Hospital/healthcare unit. Specify the approximate number of beds.

Q2 The Medical Products Agency requests the following information regarding which manufacturers of infusion pumps you have and how many. Please specify an approximate number of infusion pumps for each manufacturer:

Q3 If you use drug protocols (not TCI) at your hospital, please specify how they are used.

- Pharmaceutical name only
- Dose rate, i.e. quantity/body weight in kg
- Other advanced functions

Q4 Estimate the amount and how many types of incidents you have encountered with infusion pumps during a 2 year period (1st of January 2011 - 31st of December 2012).

Q5 Out of the incidents that have occurred in your hospital, please specify the severity of those incidents for each problem area.

- May have caused death or seriously impaired health
- Seriously impaired health
- Death

Q6 Have you received any feedback, such as written confirmation and/or safety notices, from the manufacturers or their representatives after the occurrence of incidents mentioned above?

Q7 Do you read the manufacturers' safety notices, published on the Medical Products Agency's website?

<http://www.lakemedelsverket.se/malgrupp/Halso---sjukvard/Medicinteknisksakerhetsinformation/fran-tillverkare/>

Q8 Do you believe that there are problems or shortcomings with infusion pumps that have led to or can lead to not always being able to guarantee patient safety?

Q9 Are you happy with the way the manufacturers and/or the representatives handle the problems with your infusion pumps?

Q10 Any other comments about infusion pumps, in respect to syringe, volumetric and portable pumps and accessories/single-use devices etc. that you would like to share?

# Appendix 4

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*Comments in the enquiry (some sentences have been removed and names of manufacturers have been marked with xxx due to confidentiality).*

## Question 3.

### Comments:

- In my opinion the Medial Products Agency should implement regulations, so that Only physicians and anaesthesia nurses that are trained should have the right to configure medication protocols in the pump settings and not medical engineering staff, because we don't have the knowledge of vital parameters such as dose quantity etc. This requirement should be forwarded to all pump manufacturers, because we are sometimes asked to assist the wards in configuring such parameters!
- The functions are used to different extents by different wards. However, in anaesthesia, OR and ICU the advanced functions have been used for more than 10 years.
- Dose rate is possible to use but rarely used in the anaesthesia department.
- Medication protocols are frequently used.
- This varies; different departments have different settings and requirements for medication protocols. As for advanced settings I mean settings such as pressure, air sensitivity and maximum speeds and "normal parameters" that are drug-specific.

## Question 4.

### Comments:

- Almost all problems are solved by replacing the pump with one that functions, so the impact on the delivery of care is minimal. There is often an error code on the display alerting the staff that the pump cannot be used.
- The user interface problems are often related to faulty programming without medication protocols.
- Software problems cause for instance battery problems, false alarms etc. However not directly critical for the patient.
- But each investigation can have several single events that are connected to the same problem. We have for instance big problems with error alarms. We have started 3 investigations but the alarms have occurred 50 times. Other: A number of serious incidents regarding errors in the medication protocol. This proves how difficult it is to have all parameters under control.
- The documentation doesn't get updated. The pump's software doesn't get updated even though the parameters have changed.
- Other spare parts: Problem with defect power cords (cable sets) which even have exploded, causing holes on the hose of the plug where one puts the hand while plugging in it to the wall outlet. One cord had black pins (sparked when the user plugged it in to the wall). When conducting electrical safety tests which includes insulation test (not compulsory in the IEC 60601 standard) many cords proved to be of poor quality. Other: Pumps get dropped on the floor, for instance when putting them into docking stations or when they are attached to or removed from an IV pole. If the pumps are attached to a bed-side IV pole, and the patient shall be moved together with the bed, then the IV pole (the ones I have seen) is at the corner of the headboard, which will cause the pump to hang outside the bed. Then the pump will hit door frames etc. => Broken cases and of course broken on the inside. The volumetric pumps

can break down while closing the door a bit carelessly. The pump cases seem to be of poor quality since they often break down, have small cracks near screw holes and larger cracks at the IV pole attachment.

- Especially software problems - suppliers have not tested the software enough in the clinical environment before releasing the software on the market. Pumps activate "safe mode" due to software bugs – life supporting treatment gets interrupted and all data (infused volume etc.) disappears. "Safe mode" is no longer safe, patients' lives are jeopardised.
- We use a good brand. The events have not been so severe that they needed to be reported.

#### Question 5.

##### Comments:

- We have not experienced any serious incidents in the extent as described above. Regarding syringe pumps and syringe manufacturers, they should have better contact with each other concerning new syringes with bigger resistance; the problems are usually solved by the clinical engineers that have to change the configuration of the pumps to resolve the issues.
- User interfaces are hard to evaluate. There are many problems that never get reported to the medical engineering department.
- Probably a combination of both.
- It is typically software problems that will put the patients in danger.
- We haven't had any cases that have affected patients.
- No incidents.

#### Question 6.

##### Comments:

- Important safety notices are often delivered through mail; this is a very slow system for incidents. Minor or single problems are seldom in writing.
- Sometimes/often one has to nag the suppliers to get the desired answer/information.
- The supplier doesn't believe there is any problem or fault in the pump, even though they have seen how the pump behaves when the problem arises.
- We have received 5 safety notices from xxx that arrived this spring; however they are not consequences from any of our incidents.
- We are awaiting a response from xxx, one incident.
- Xxx always delivers a detailed report within 3 months – Excellent. Other manufacturers need to be reminded or we need to have a verbal dialogue. We get responses sometimes, and sometimes not.

#### Question 8.

##### Comments:

- When "external" suppliers of peripheral equipment (syringes etc.) change their specifications and the pump suppliers don't know about it.
- It is possible to use the wrong syringe in the syringe pump without getting an alarm; may lead to incorrect dosage.
- Sometimes software bugs, which is solved by upgrading, which will cause new bugs... never-ending story.
- Complexity in settings and medication protocols. Difficult to survey and review. It is also difficult with the various users to keep track of which version that should be downloaded

into which pump. Incompatibility between different software versions (in the pump as well as in the editor for setup) is a big problem related to settings and medication protocols.

- Since the pumps can be configured in various ways for customised clinical use, it can lead to problems for staff that change their place of work.
- The problem is probably a combination of both.
- There is always a risk, which may lead to harm. Not all problems are properly addressed or communicated.

#### Question 9.

##### Comments:

- The Swedish distributor of xxx has always had a decent approach and tried to solve situations in the best way possible. The manufacturer doesn't on the other hand seem to understand us at all!
- Generally unhappy with the way manufacturers and their representatives handle problems and inform about them.
- It is negative that it takes a very long time to get answers, but positive that they are investigating problems (to follow up on their errors is also part of their development).

#### Question 10.

##### Comments:

##### Comments related to complications with the pumps:

- For most problems with pumps, an error code is displayed and the pump gets replaced, sent to us and, if we can't repair it, it will be sent to the supplier for service. These cases most often lead to non-documented "incidents".
- The regular infusion pumps have good quality, but there are deficiencies. I think that pumps which are classified as nutrition pumps or PCA/EDA pumps have more severe deficiencies.

##### Comments related to accessories:

- Have a suspicion that problems with supplies, syringes and infusion sets accounts for some of the reported problems we receive. But since administration sets and syringes are disposed 9 times out of 10, this type of problem is hard to find. We cannot provoke these errors to show up on the pumps. This applies to all brands and pump types.

##### Comments related to the manufacturers' performance on the market:

- We are very happy with xxx's pumps and the way the manufacturer supports the client in all aspects.
- Hard to get a good dialogue with the supplier, to be taken seriously. Often it is referred to as user faults. It is desirable that the supplier takes the client's concerns and questions seriously, and sees the client as a resource and collaborative partner to get information about problems and in that way solve the issues quickly. To have the ability to see the potential harm to patients that the behaviour of various pumps can cause. To be committed to solve the problem or at least give an explanation for why it happens (not just show that it happens and how often). If the pump behaves in a certain way (observed by the client) but according to the assessment of the supplier is considered to be harmless, then the supplier must be able to explain and prove why it is harmless.

- The pump manufacturers release new software versions all the time. These new versions include new features that the client sometimes has to pay for to access. This makes the suppliers eager to market the new features (meaning the software versions) at the departments. The software is free, but additional features may cost anything from a few to some thousand Swedish crowns per pump. It feels like the suppliers are getting off the hook too easy after they have released poorly tested software that will lead to drastic consequences for patients and staff. Sometimes it takes several months (up to a year) before a software gets released that corrects the problems. It is not always possible to "downgrade" a pump to an earlier software version. In these cases it all depends on the medical engineering department - we need to test every new software version that is released for clinical use, to be sure that it will work in the healthcare environment. Not all suppliers are willing to explain which changes that have been done or which bug fixes that are corrected from one software version to another (admit mistakes in the previous software version), which makes it even harder for us at the medical engineering department to evaluate if the software "can be trusted". What ought to be a task for the suppliers has become a task for the medical engineering department. It shall also be kept in mind that software to a great extent has an impact on the hardware, for instance the battery function (xxx software) had a bug causing the pump to assume that the battery was flat unless it was connected to power when the pump was turned on. There should be requirements forcing the supplier to demonstrate how a software version has been tested before it is released on the market. Which known faults are there? Software bugs not only have an impact on the patients, but also the staff. Infusion pumps are nowadays a medical device with low status, and it will not get improved due to all the existing problems. We see an increase of user problems due to the fact that the pumps are too advanced. A lot of information is crammed into the small displays requiring numerous key operations to show the desired information. There is more and more stress in healthcare due to lack of staff and cutbacks, which means that medical devices need to be more self-explanatory. Problems may arise because the staff has learned to automatize "push the down-arrow button five times and then push twice to the right" to display a value. There is no longer time for them to reflect on what they do.
- Xxx provides good service in respect to service/maintenance and good communication through technical support. But the company changes the software on all their pumps too often, which complicates things in an unnecessary way.

# Appendix 5

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## *Comments from a seminar at Uppsala University Hospital in 2010 about problems with infusion pumps.*

- Several problems with infusion pump software for several brands that never have been reported to the authority (information from several hospitals).
- The experience from the healthcare sector is that there isn't a single brand that doesn't have software-related problems.
- The healthcare sector has difficulties knowing how to report incidents to the authority.
- Concerns about whether it is obvious that user errors are a contributing factor to the events (both to manufacturers, operational managers and as, in the case in Sweden, that the National Board of Health and Welfare get to know about). The consequences are that manufacturers may never retrieve knowledge about it. Usability problems are never revealed.
- It is a problem that the medical engineering department doesn't handle investigations for all medical devices. Many events related to accessories for pumps are reported directly from the ward. The medical engineering department doesn't get information about insulin pumps and pumps for pain relief either.
- Staff at the wards are not aware that there hasn't been any pre-approval.
- The staff at the wards feel trapped since they have bought a brand and then consequently have to live with the problems during the entire contract period. The manufacturer only solves one customer's problem, "putting out fires". You are then forced to agree to all corrections offered by the manufacturer, and many in a short period of time.
- Pump accessories often get disposed of immediately at the ward.
- The accuracy could not be verified by the users. What is the intended purpose for this pump?
- Reports are sent to the authority only after the situation has become frustrating, i.e. when there is a number of the same type.
- Ignorance in the procurement process about which pharmaceuticals that should be used in the devices.

Typically and most frequently discussed:

- Several hospitals confirm having problems with different brands and a large amount of software problems.