Safety problems with the use of medical equipment/devices

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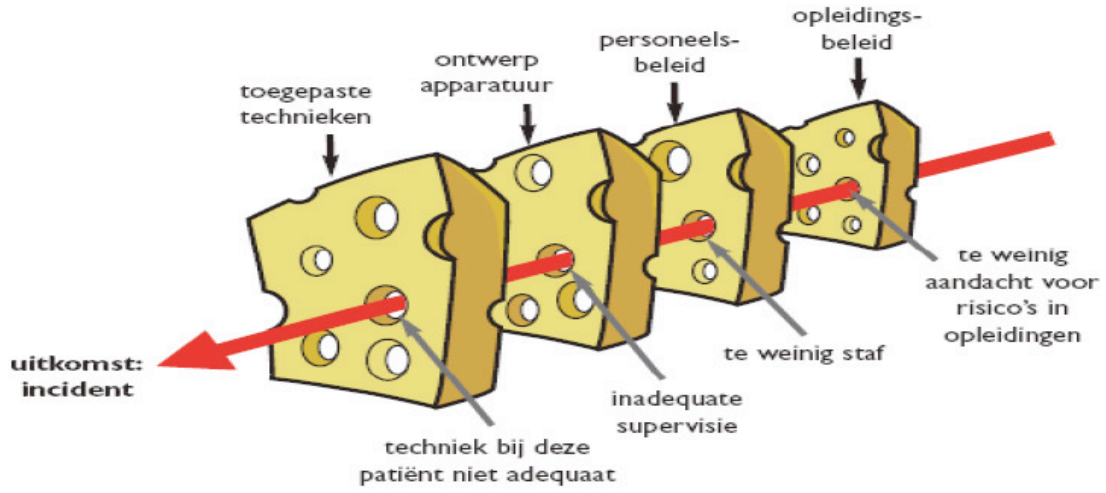
Abstract

In the past decennia medical technology has rapidly developed. Nowadays it plays an important role in all medical fields. It introduced technologic solutions for many medical problems and it definitely increased the possibilities in the medical field to increase the quality of life. However with this rapid development also new problems came up. Only since the last decennium the government developed and is still developing a policy for this technology. Therefore the risk and safety aspects of these medical devices are still under development. This study aims to point out the current safety problems with medical devices. Therefore accidents reports of two important agencies, The Netherlands Health Care Inspectorate (IGZ) and the Dutch Safety board, have been studied. From this reports several problems with medical devices become clear. The current safety problems with medical devices are based on three main problems. The internal communication in the hospitals, the responsibility aspect. The external communication between hospital and manufacturer and the knowledge and skills of the different actors involved with the medical device.

The IGZ expects a safety management plan from the hospitals. However hospitals cannot create a quality plan, without receiving the correct technical files from the manufacturer. Also the incidents signals from the users about medical devices do not get a good follow up. If the signals come to the manufacturer, it is up to the manufacturer to decide what the nature of the incident is. Finally the manual does not provides the user with useful information about errors that can occur and what will happen when the device is incorrectly used.

Introduction

In the last decades there have been tremendous technical advancements in de medical sector. Consequently hospitals in the Netherlands faced the ‘Kwaliteitswet zorginstellingen’ (Quality Act for institutions of care). In this act general quality standards are imposed on the institutions of care while the specific instantiations of these standards were left to the institutions themselves. The Ministry of Health assumed that the hospitals would take care of implementing quality control policies themselves, which would improve overall safety [1]. However, in 2004 two new reports, by IGZ [2] and Shell Nederland, showed an increase in incidents per year at hospitals. Shell Nederland estimates the number of preventable deaths due to medical errors between 1500 and 6000 per year. They estimate the total damage as a consequence of this at about 4 billion euro per year [3]. Research by Nivel showed that in 2008 in the department of surgery on average 15.6% of the incidents happened following the use of materials and the use of medical devices [4]. According to the report cause of such incidents can be traced to the failure of multiple barriers following Reason’s Swiss Cheese Model.



Figuur 1: Reasonmodel Nivel

According to Gert de Vries, quality coordinator in several hospitals, this is caused by medical devices entering the marketplace. Devices whose safety cannot be guaranteed by the manufacturer. Hospitals assume, often wrongly, that medical devices entering the marketplace are safe. Manufacturers need to show the safety of devices they bring to the market in a technical report. Research by the RIVM (Rijksinstituut voor Volksgezondheid en Milieu) shows, however, that such reports are often incorrect. Hospitals oftentimes do not have access to these reports because they concern trade secrets [5].

It is up to the Inspectie voor de Gezondheidszorg (IGZ) to supervise the quality of care and medical equipment used in institutions of care [6]. When serious incidents happen it is up to them to conduct research into how these incidents happened and take actions to prevent this from happening again. Another institution that investigates medical incidents is the Onderzoeksraad van Veiligheid. They investigate causes of incident in several sectors with the goal of preventing future incidents and suggest policy recommendations [7]. This study will investigate the lessons these two research institutions draw from their respective research.

Method

This research focuses on the current problems with medical equipment using the reports of the Inspectie voor de Volksgezondheid and the Onderzoeksraad voor veiligheid. The following questions will be addressed.

What problems in the use of medical equipment are found by both institutions following investigations into medical incidents?
Do schooling and knowledge of the handling of medical equipment come to the fore in the research by both institutions?
Do the investigations address the roles of the different actors in the life cycle of the equipment? Do they look into manufacturing, acquisition, use and maintenance?

The reports that are considered in this study describe the fire in the operation room of the Twenteborg Hospital [8.9] and the faulty use of disinfectants for endoscopes at the Bernhoven Hospital [10]. Furthermore this study looks at reports by the IGZ made in 2005 concerning the quality assurance of medical devices in hospitals [11].

In studying the reports the main focus will be on the examination and assessment of the actions of different actors connected to the incident. The conclusions and recommendations presented in the reports and whom they are targeting will be addressed as well. In this study special attention will be given to the various aspects of the research focusing on medical devices, in particular the life cycle of the device. What attention is focused on the manufacturer, merchant, maintenance person and user, who bears responsibility for the device and to what extent are the competences of the involved actors paid attention to.

Results

IGZ and the Onderzoeksraad come to the following conclusions concerning the use of medical equipment in their reports about the Twenteborg and Bernhoven.

In the case of the fire at Twenteborg the IGZ concludes that the maintenance technician of the hospital did not have adequate understanding of the safety regulations and functioning of the anesthesia device. The hospital did not have contact with the manufacturer concerning the modifications they implemented. This modification was implemented without the hospital informing themselves about the standards. Neither was the maintenance, performed by the hospital, coordinated with the manufacturer. The hospital did not have adequate knowledge about the anesthesia device in house to perform good maintenance.

Concerning safety management they conclude there was inadequate safety management by the hospital with regard to the anesthesia device. Maintenance was overdue and the hospital did not inform themselves of maintenance protocols by contacting the manufacturers. The maintenance schedule as drawn up by the hospital did not adequately address all aspects of the device according to the IGZ. Also the hospital refrained from creating a risk analysis for the modification of the device given that doing so was not customary. The board of Twenteborg relied mistakenly on the technical and safety proficiencies of the department of Vastgoed en Instandhouding. Furthermore the board fell short in providing managers in charge with ‘state-of-the-art’ instructions concerning safety and quality control of the anesthesia devices. It was unclear within the involved departments who was responsible for the safety aspects of the equipment. For example the head of the OR could decide whether equipment needed to be replaced without informing him/herself about the state of the equipment and the questions of safety involved with this decision. The technical maintenance staff would accept these decisions without involving the board of the hospital following their own expertise in the matter. The medical specialist who use the equipment assume that the devices are safe and function well. They do not inform themselves about the devices.

Concerning the manufacturer IGZ draws the following conclusions. The manufacturer did not follow their own safety instructions. They did not provide the hospital with essential information concerning the safety of the equipment. The ‘Besluit Medische Hulpmiddelen’ requires manufacturers to provide hospitals with important safety information as soon as they find out about such information. Because the devices were older than the BMH the manufacturer was not required to do so in this case. Economic considerations have likely been the reason for the manufacturer no to share safety information in this case.

The Onderzoeksraad also concludes that the IGZ mainly focuses on medical safety of patients over the physical safety. Also the IGZ does not supervise the design of medical equipment, they put their confidence in the CE quality control. Neither do they supervise the quality of the maintenance of the equipment. Finally the Onderzoeksraad points out that there are ambiguities concerning the monitoring of dangerous substances used in medical equipment in hospitals. The central government and the IGZ both assume the other party is in charge of the monitoring. The Onderzoeksraad recommends that the ministry of Health should appoint a single institution for monitoring high-risk medical equipment.

In the report about equipment for disinfection of endoscopes the IGZ describes the complete procedure spanning from acquisition of the devise till its first use. They conclude that the board of the hospital had false expectations about the safety aspects of the devices. Furthermore they used the quality control plan for the older machines. They did not decide to make a new plan following the acquisition of the new disinfection equipment. And there was insufficient coordination between the hospital and the specialist who tested the technical functioning of the device and subsequently had to release it. Following this release a work instruction was created by the endoscopy assistant of the hospital. This work instruction, however, is not based on the user manual by the manufacturer neither is it based on the quality control plan.

At the beginning of the use of the device by the hospital an employee replaced a coupling because the previously used coupling was too stiff according to other employees. This increased the risk of decoupling of a tube. The IGZ argued that this risk was inherent to the device and that the manufacturer's user manual should include a warning to check coupling following replacements because there is no technical solution to the problem available. They base their argument on the Besluit Medische Hulpstukken. It is also unclear what kind of couplings can be used.

According to the reports the following problems can be seen with medical devices. In the reports this comes down to three problems. The first problem is to let hospitals make modifications to the medical devices on their own. Both at the Twenteborg and in Bernhoven no contact was made with the manufacturer to get informed about potential safety risks. Also in both cases it was assumed that the technical staff at the hospital had enough competence to make the modifications. The second problem follows the first and concerns responsibility. Within the hospitals it is unclear who bears responsibility for what. In the Twenteborg case the hospital did not consider a certain part (the 'pendel') of the anesthesia device to be a high-risk device. As such no risk analysis was made of the device and the responsibility for the device was put in the hands of departments with an inadequate understanding of the technical functioning of the device. As a result certain parts of the device were not replaced because the necessity to replace these parts was not known by the responsible parties. There was a lack of internal communication concerning the safety aspects of the medical equipment. There was also a lack of safety plans with risk analyses, because there was no communication with the Board who bears primary responsibility for the safety policy at the hospital. And finally it appears that the communication between the manufacturer and the hospital is poor.
Because of trade secrets the manufacturer is not willing to provide much information to the hospital and manuals are at times incomplete and inadequate. The safety reports of the manufacturer are at times incomplete as well. Research by the RIVM shows that all of the technical reports of Class I equipment are incomplete [12]. Another research shows how 95% of equipment that has not reached the market yet and is meant for clinical research lacks adequate technical documentation [13]. With Annex II medical equipment on the other hand 45% come with a correct technical report because these reports are verified by a notified body [14]. The shortcomings concern mainly labeling, risk analyses and manuals. Since the reports can not be viewed completely by the hospitals because of compete clauses they lack insight into the technical functioning of the medical devices and should be contacting the manufacturers concerning modifications to the equipment. Here it is important that modifications should lead to

new research by a notified body to re-evaluate the device. On the other hand the manufacturer does not adequately inform the hospitals about the condition (for maintenance) of the device. It is noteworthy that all reports lack a discussion on the competences of the user. The medical specialists using the devices assume that they are safe and function correctly. The reports do not discuss the knowledge of the users needed to operate the devices. Instruction and training are important to be able to safely use newer equipment. Both the report about the Twenteborg incident and the report about the cardiology department at the Radboud [15] did not look at instruction and training. Minimal attention is paid to the relation between the medical doctor and the technician. Here the reports only look whether the technician provided instructions to the medical personnel. Whether the technician is competent to provide such instructions or whether years of use lead to new insights and to new instructions is not studied in the reports. It is very likely that this is again a consequence of bad internal communication and a lack of a regular renewal of risk analyses.

Quality control at hospitals

The IGZ published two reports in 2002 and 2005 concerning quality assurance of medical equipment. In 2002 the IGZ concluded that is it was necessary to improve quality assurance for several product phases of medical equipment in hospitals. The report outlined measures that needed to be implemented to realize such improvements. These measures focused on the quality control policy, risk management, responsibilities, the procedures around acceptance and release, the introduction at the department including the manuals, the prevention of infection, the control system, preventive maintenance and spatial provisions [11]. Examples of practical implementations of these measures are change of protocols or providing instructions to users following updates to the equipment.

In 2005 the IGZ checked whether the hospitals had implemented the mentioned, binding, measures. The majority of hospitals aspired to reach the quality assurance standards of the NIAZ. The NIAZ model outlines five areas for safety management. The first area is ‘leadership’. This area points out the responsibility and mission of several managers. In this chapter it should become clear how the managers want to achieve their missions and visions. The second area is ‘strategy and policy’ and follows from the aims set in ‘leadership’. This area concerns the translation of the mission and vision to concrete policies and subsequently the plans and budgets that come with these policies. The third area focuses on ‘management and employees’. This chapter concerns how managers and specialists are hired to achieve the set aims and visions. It should also include how the institution determines the knowledge and know-how of the employees and how they will assure this in the future. Finally this chapter includes how employees can raise problems within the institution. The fourth chapter in the NIAZ-standard focuses on ‘management of means’. This chapter considers the management of financial means as well as knowledge & technology and materials & services. The institutions need to show how they acquire information and technology and how these are distributed, applied, maintained and assured. Furthermore they need to write out the use and the collaborations. Finally, in the fifth chapter, the institution has to pay attention to the ‘management of processes’. Of importance here is how patients flow through the care-process and how the relations between different departments the patient encounters are accounted for. The hospital takes into account the preferred results and the safety of patients in case of incidents of negative results of the treatment

process [16]. However, the IGZ argues that the directive comes short. “The needed cohesion between the responsibilities of the user and the responsibilities of the ‘instrumentele dienst’ (instrument department) when accepting and releasing medical equipment with an eye on (renewed) use is not paid attention to well enough. This also goes for prevention of infection in relation to medical equipment and communication with manufacturers concerning incidents” [11].

The same research revealed that a third of the hospitals lacked an operational quality control policy regarding medical equipment. Especially the cohesion between the responsibilities between the user and the ‘instrumentele dienst’ (instrument department) was not paid attention to well enough. On top of that most hospitals considered the quality assurance of medical equipment to be the sole responsibility of the instrument department. The responsibilities of the user with regard to maintenance and release are rarely taken into account. And the performed maintenance cannot be checked by the user.

It is also remarkable that only 25% of the hospitals made a release procedure for external maintenance, while most hospitals do outsource part of the maintenance. Such a procedure is very important given this level of outsourcing, since the hospitals have the final responsibility for the results.

Another problem mentioned in the report is that only a few of the plans include communication about incidents with the manufacturers.
In part this is caused by the way the registration of reporting is set up. 25% of hospitals does not register medical equipment as a separate category. As a result only one in six hospitals has a policy to inform manufacturers of incidents with medical equipment. This makes it hard to hold manufacturers responsible. Manufacturers are required to report incidents with the IGZ and they need to take the necessary actions to prevent such incidents from happening again.

A third problem concerns the expertise of the different actors. At 60% of the hospitals, the composition of the instrument department is not evaluated. Nevertheless almost all hospitals provide the required training for the instrument department. A third of the hospitals lacks a policy for introducing new equipment to the users. As a result they cannot guarantee that the users are able and authorized to use the equipment. Half of the hospitals does not have the manufacturer’s manual with the relevant warnings available for the users. The IGZ comes to a similar conclusion in 2008: “The inspection concludes that hospitals are not enough aware of the risks that come with the use of medical equipment. Not enough is done to structurally assure the safety of the patients. There are tens of deaths resulting from errors in use. Users can use advanced devices without being trained and without passing an exam” [17].

Discussion

In the studied research reports and the report “Kwaliteitsborging medische apparatuur” (Quality assurance medical equipment) the focus is on the following problems concerning medical equipment in hospitals.

The internal communication in the different hospitals is insufficient. In the communication between different actors, like the user, the technical department and the Board of the hospital, with regard to the use of medical equipment, not all concerned parties are informed. A lack of clarity about the different responsibilities of different departments forms clearly a base for this way of approaching the situation. This problem is caused by insufficient attention to creating risk analyses and the lack of a clear safety protocol in many hospitals. Although most hospitals follow the NIAZ-standard, this standard has its own clear shortcomings. There is insufficient attention for the relation between the technician and the specialist and the quality assurance plan is not updated enough. In the years following the initial use of the equipment new problems regarding safety might become known or there might be new instructions regarding use and maintenance.

The second problem that arises is the communication between the hospital and the manufacturer of the medical devices. The hospital makes modifications to the equipment without checking with the manufacturer whether such modifications are safe. Furthermore the hospitals do not report incidents originating from the medical equipment to the manufacturer because such a policy doe not exist in the safety standards used.

The manufacturer does not release all technical documentation to the hospital for reasons regarding trade secrets and the documentation is often incomplete. The hospital cannot make a good risk analysis as a result, while they are expected to do so. Hospitals should have more access to the technical documentation so they can make a good risk analysis.

The manufacturer does not sufficiently inform the hospital about the condition of the equipment and the possible consequences of not replacing it. Furthermore the manuals as they are provided by the manufacturer only mention how the equipment should be used. The manuals do not address possible errors that can occur or the consequences of certain actions.

The requirements for safety management by the IGZ do not address the consequences of modification. Hospitals should report modified equipment to the IGZ, the manufacturer and the notified body who classified and approved the equipment for use. All equipment should be officially (re-)released following modifications.

Finally there is insufficient expertise by certain actors to use the equipment to be able to guarantee safe use. There is especially a lack of training of the user with regard to the use of new equipment. The expertise of the instrument department and the user is not discussed in the studied reports concerning the incidents. In a report concerning the problems at the department of cardiology at the Radboud there is no mention at all of the medical equipment, despite its eminent importance at this department.

Remarkably, however, the IGZ argues that the medical specialists should make sure that the technology they use is safe, they should no longer consider it a black box and they should be able to solve problems. The IGZ argues that this can be resolved by adding a technical component to the training to be a specialist. It will be clear that it is impossible for specialist to view every medical device he encounters as a ‘white box’. It is therefore not reasonable to give this responsibility to the specialist. A responsibility that specialist should have is to report errors in a correct manner and to make sure that these signals arrive at the right departments within the hospital.

Another problems that occurs after this is the solving of problems. A hospital encountering a problem with medical equipment can report this to the manufacturer. At that moment the manufacturer will investigate the incident. The manufacturer can decide whether this is a structural problem or a use error. If it is a structural problem they need to report this to the IGZ. Even if all hospitals would report problems to the manufacturer, it is still up to the manufacturer to judge the origins of the error, without informing the IGZ. This will make it very easy to declare problems errors in usage. Even if it is a use error, this should still raise the question whether this might be the result of a bad interface design. Furthermore it is increasingly hard to discover errors since most of the equipment contains a large software element. This makes it harder to reproduce errors or find hidden circuits in the software. Also the disappearance of bits is an error that can occur which is impossible to trace back. This will quickly lead to the manufacturer concluding that it was human error. Hospitals, therefore, should also report their problems to the IGZ. This way there are more checks on the manufacturer. And hospitals should discuss the errors they encounter amongst each other to be able to find errors faster because of the combined use experience they have. After this they can report the errors to IGZ and the manufacturer, so they cannot filter the signals first. Then the manufacturer can be enforced to make mend the new equipment to the experiences of the users.

The Onderzoeksraad also concludes that the IGZ mainly focuses on medical safety of patients over the physical safety. The IGZ does not supervise the design of medical equipment and they put their confidence in the CE quality control despite the fact that hospitals make modifications to the equipment themselves on a regular basis. This way the classification as used in the ‘Besluit medische apparatuur’ (Decision medical equipment) comes under pressure if devices are combined. When the two devices that are combined are independently approved it could be possible that because of a modification or combination the safety class is too low. This could result in the approval of a device for a lower risk category than it actually should be in. The hospitals should therefore ask permission from the notified body for every modification or combination of medical equipment. There also need to be regulations for such combinations of devices.
The notified body should come with criteria for checking the device. At the moment they look if the criteria as set by the manufacturer are met by the device. Two approved devices can have a different level of reliability without the hospitals being aware of this difference. Because they do not have access to the technical documentation.

While in case of incidents with medical equipment all actors in the life cycle are reviewed, it would be a good development to also review the design of high-risk medical equipment. The IGZ should get access to the complete technical documentation. Using the final design the IGZ

will de able to review which combination of components could lead to possible incidents. Using the technical documentation they can also better judge whether the maintenance plans for medical equipment is sufficient, whether certain aspects need more attention during maintenance. At the moment the IGZ focuses too much on the legal requirements and will only spring to action if these are not met, while a more active approach is desirable.

The introduction and fast development of medical technology led, without a doubt, to improvements in health care. However, it also led to new problems as laid out in this report. These problems affect all involved parties, the manufacturer, user and supervisor, and because of this it is important for all of them to be included in drafting safety management for medical equipment and especially the manufacturer should bear more responsibility for the functioning of the equipment.

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