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Failure Mode, Effects and Criticality Analysis (FMECA) for medical devices: Does standardization foster improvements in the practice?

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Abstract

Risk analysis techniques received increasing attention in the health care sector in the last 30 years. These techniques are diffused for health care processes, and less for devices. In fact, risk management for medical devices was introduced only recently (ISO 14971 in 2000 and GHTF/SG3/N15R8 in 2005) [1,2]. The goal of this study is twofold. First, we aim at evaluating the state of the art of the diffusion of standards for the risk assessment of medical devices (with a focus on FMECA). Second, we evaluate the impact of risk assessment techniques on the practice. To pursue the first goal, a literature review has been performed through the investigation of medical and non-medical databases. To reach the second objective, we selected a leading Company in the development of medical devices and we investigated the process enacted to evaluate the risk connected to the design of new devices. The literature search confirmed the widespread application of the FMECA, the scant number of contributions about its applications on medical devices, and the main limitations related to the use of this technique. The empirical investigation showed that the Company spends a surprising amount of time and resources to set and deploy the FMEA rigorously, and it follows the passages envisioned by the literature carefully, with the unique intent to respect the standards. A gap emerges among the practitioners and academic words, with two possible explanations. First, the academics are not addressing the managerial and practical implications of their contributions; in so doing they deepen the "theory versus practice" chasm. Second, the presence of standards actually discourages the practitioners to push over and find new solutions.

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Keywords: Risk assessment; Medical device; FMECA

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1. Introduction

In the last 10 years, several techniques applied to industrial risk management[1] have been adapted to clinical contexts. These techniques have been extensively applied in healthcare settings to answer to an intrinsic need for higher control of adverse events, but over and above to respond to the pressures of external agents (i.e. legislations and standards). In fact, periodical risk analysis is required both by the U.S. Joint Commission on Accreditation of Healthcare Organisation (JCAHO), and by the International Organization for Standardization (ISO) normative [1]. As for the specific technique to be applied, the standards do not require the exclusive use of Failure Mode and Effects Analysis (i.e. FMEA), although much of the terminology of FMEA is built on the intent of the standards. As a consequence, nowadays the FMEA is the most widespread technique in healthcare facilities and healthcare industry to identify risks related to specific processes [3]. Despite its unquestionable diffusion, the FMEA applications have disregarded the evaluation of risk connected to medical devices. Nevertheless, the urgency of extending risk assessment techniques to medical device is evident. On the one hand, a specific normative has been developed in this view (ISO 14971)[1]. On the other hand, unsafe design and manufacturing of medical devices can significantly affect the patients' safety [4,5,6]. The goal of this paper is to assess the state of the art of the application of FMEA on risk assessment of medical device and to provide an example of its application. The results of this study might be relevant to clarify the state of the art of the FMEA applications on medical device, and to discuss the implications of its practical implementation.

2. FMEA on medical device: State of the art

As previously disclosed, the review addresses the application of a specific methodology, the FMEA, on medical device [3]. FMEA is an inductive, bottom-up technique to evaluate processes, by determining potential sources of failure and how these failures affect the performance of the process. The FMEA implementation steps are: (a) choosing a process to be studied; (b) assembling a multidisciplinary risk management team; (c) collecting and organizing information on the process studied; (d) conducting a hazard analysis; (e) developing and implementing actions and outcomes measures. The main measures to be computed are: Severity (S), i.e. the worst potential consequence of a failure, determined by the degree of injury, property damage, or system damage that could ultimately occur; Occurrence (O), i.e. the probability of occurrence of a failure mode; Detection (D), i.e. the possibility to inspect the potential causes of a failure mode. Usually, S, O and D are quantified in a scale ranging from 1 to 10, or 1 to 5. The risk management team according to its experience and process capability assigns the score. The application of FMEA is often the result of two sub-analyses, the first being the Failure Modes and Effects Analysis (FMEA), and the second, the Criticality Analysis (CA). This is the reason why FMEA is often extended to FMECA, to indicate that criticality analysis is performed too. For the sake of completeness, we take into account both the terminologies in the literature search.

The aim of the literature search is to analyze the contributions about the application of FMEA/FMECA on the development of medical devices, and to highlight potential limitations or points of interest. Since the contributions about FMEA/FMECA fall at the intersection between the medical and broader industrial/scientific literatures, we explored both medical and non-medical databases were explored, namely Pubmed and Web of Science. We limited the search from 2000 (the date of the first version of the standard ISO 14971) and we used the following keywords: "FMECA"; "FMECA" AND device* in title/abstract; "FMECA" in title/abstract AND device* in full text; "FMECA" in full text AND device* in title/abstract; "FMECA" AND device* in full text; "failure mode and effects analysis" AND device*; Keywords for non-medical databases were: "failure mode and effects analysis" AND "medical device*" in topic. The analysis was performed in 3 steps: first, the results of the search in the two databases were matched to eliminate the duplicates; second, a screening process was enacted by the three authors separately, to identify relevant articles and commentaries. Divergences were discussed in the face-to-face meetings, to find convergence; third, the screening process was repeated to define the final list of papers. The results of this

[1]Both retrospective (e.g. Root Cause Analysis, Ishikawa diagram analysis, TRIPOD beta analysis) and prospective analysis (e.g. Failure Mode and Effect Analysis, Healthcare Failure Mode and Effect Analysis).

literature search included a total of 54 references; 35 articles were selected for first step review, while 25 papers were removed since they focused on healthcare processes and not on device. 10 references have been finally selected for full review.

2.1. Results of the literature review: Risk analysis and management in medical devices

Risk analysis techniques received increasing attention in health care sector in the last 15 years. This is due to the increased attention on safety of both users and patients [7,8] and to the development and diffusion of risk assessment standards [1,2]. The analysis of risk associated with the device can be accomplished in different ways [9]. Failure Modes and Effects Analysis (FMEA), fault tree analysis (FTA), and HAZOP technique are the most relevant, as described in ISO 14971 [1]. We focus our analysis on the FMEA, since it is the most widespread technique [3].

FMEA is applied inductively, to evaluate the components of a device and to determine the way in which each component could fail and how the failure would affect the performance of the component itself, and potentially the device as a complete unit. When applied on medical device, FMEA identifies and removes defects, enhancing safety, and increasing customer satisfaction. It can also be applied to the design of medical device in order to prevent errors, accidents and adverse reactions. Healthcare organisations may use FMEA to determine failure mode that could be obviated with technology software and hardware solutions and work with device vendors to achieve these changes [10]. The terminologies and concepts related to FMEA are maintained in its application on medical device (e.g. *S, O, D*; 1 to 10 or 1 to 5 scores). FMEA documents are prepared by device manufacturers during product development and are generally part of the overall document submission package to regulatory agencies (e.g. the United States Food and Drug Administration (FDA), Centre for Devices and Radiological Health) and recommended as best practices by the Global Harmonization Task Force (GHTF) [2] and the International Organization for Standardization (PTC, 2012) [11]. The FMEA is also a communication medium between device developers and device users, medical experts and system developers [12], which make it a "living document" that changes with the device use, in an effort to provide the most accurate risk profile.

Although contributions about FMEA/FMECA underline the usefulness of this method to evaluate risks in medical devices, some recent contributions identify some limitations [3,4], especially when it comes to the reliability and validity of the FMEA process and its output. Some authors highlight the mathematical limitations of FMEA output, the risk priority number (RPN), and the different modes of FMEA application in practice. In fact, there is considerable variation within the process steps, e.g. in team composition, frequency of meeting, duration, how the probabilities are quantified. The main fault of FMEA therefore deals with subjectivity, although the use of numerical scores gives an impression of mathematical impartiality. This research stream is confirmed by Liu et al. (2012) - who proposed an improved FMEA based on Mathematics and Grey Relational Analysis to better carry out use-related risk analysis for medical devices, by limiting the uncertainties related to experts' subjective analysis [4] – and by Lin et al. (2014) – who developed a FMEA procedure, based on experts fuzzy linguistic evaluation of RPN [13].

2.2. Concluding remarks

According to the results of the literature review, we confirm that the FMEA technique is actually one of the most used for failure analysis in risk management in medical devices design. Nevertheless, two aspects deserve a comment. First, the scant number of contributions retrieved on this topic, shows that, despite the wide consensus about the need of improvement of FMEA techniques in healthcare, the academic interest in FMEA theory and applications to medical devices is still limited. Second, several limitations of the FMEA applications emerged from the contributions on healthcare device. In our view, the expedient proposed by the authors to overcome the methodological limitations in this field are unmanageable in the practice.

Hence, how do practitioners deal with the FMEA limitations? We attempt to answer this question in the following section, by describing an application of the FMEA on the design of a medical device, according to the approach followed by a leading Company in the field of medical devices design and production.

3. FMECA in practice: Problem and case study

In the last two decades, Diabetes, especially type 2, has increased its incidence in world population [14]. Chronic Critical Limb Ischemia (CLI) represents the major outcome of significant atherosclerotic diabetes-related disease of the lower-extremity vessels. This pathology is associated with a loss of quality of life (QoL), significant lifestyle-limiting symptoms, potential major limb loss (amputation), and death. Patients with CLI require a multidisciplinary, multimodality approach targeting their atherosclerotic risk; however, less invasive approaches are often tardive and unsatisfactory and CLI *sequelae* of rest pain and claudication translate in tissue loss, representing an urgent to emergent care matter. These patients require immediate and aggressive modification of their risk factors and endoluminal or open intervention to restore circulation to the endangered limb. Endoluminal intervention consisting in Percutaneous Transluminal Angioplasty (PTA) is a key revascularization therapy in these patients since re-establishing an adequate blood supply to the wound is essential for avoiding a major amputation [15]. PTA is an endovascular technique based on the use of balloon catheters: a device consisting of a shaft connected to an inflatable "balloon" is used during a catheterization procedure to enlarge an atherosclerotic plaque within the body. Peregrin et al. (2010) analysed the clinical success of PTA in diabetic patients with CLI taking into account the number of vessels successfully treated (increasing from 56% to, respectively, 73%, 80% and 83% with 0, 1, 2 or 3 lower limb vessels open) [16]. The development and production process of PTA catheters requires a sophisticated approach in terms of design and manufacturing. Overall risk management is a major concern, since the implications of the poor performances of the device on the patients' quality of life are apparent and appalling.

Provided the relevance and implications of this kind of medical device, an angioplasty balloon catheter (hereafter called "PTA catheter") has been selected as a case study to be investigated in the second part of this paper. More specifically, we looked at how a leading Company in the field of healthcare devices development (i.e. Medtronic Inc.) applied the FMEA technique in the design process of this device.

3.1. Medical device functioning and description

The PTA catheter acts dilating the plaque obstructing the artery, inflating a balloon via contrast media. The catheter consists of two plastic tubes: guide wire (gw) and shaft tube. Gw tube is inserted coaxially into the shaft for the whole catheter length, and exits from the shaft tube for additional few cm. In the distal part of the catheter, a balloon is bonded proximally to the distal end of the shaft, and distally to the distal end of the guidewire tube. In the proximal part of the catheter, a hub is connected to the proximal end of the shaft and of the gw tube, emerging from the shaft tube. Gw tube lumen allows the passage of guide wires (i.e. ancillary device to navigate the vasculature) to facilitate advancement of the catheter to and through the stenosis to be dilated. The gap between Gw tube and the shaft tube allow passage of contrast media solution to inflate the balloon when it is in the target anatomical site.

3.2. PTA balloon catheter risk assessment

The observation of how the Company applies FMECA confirms and strengthens the FMECA implementation steps already discussed in Section 2.1. The standard approach followed by the Company is as follows: (1) *Choosing a process to be studied* - the selected process in this case is the PTA angioplasty balloon design and construction. (2) *Assembling a multi-disciplinary team; a*ccording to the procedure of Medtronic, the members of the team should necessarily belong to defined product development areas. At least an R&D engineer, a Quality Assurance (QA) engineer, a Process engineer, a Clinical Specialist, and a Regulatory (RA) Specialist must be involved in the analysis. Each member brings different expertise: R&D and Process engineers provides the information on product design and components and manufacturing processes; Clinical specialists expertise provide the knowledge of the clinical field and operating conditions of the device; QA expertise is functional to link product design to operating field; RA specialist is in charge of ensuring compliance with Standards and Regulations. (3) *Collecting and organizing information on the process studied* - Information collection and organization: recursive meetings are set, initially involving R&D, Process engineers and QA for product/processes analysis, then extending to Clinical and finally to RA to have a complete work review. (4) *Conducting a hazard analysis* - Hazard Analysis is performed under the leadership of QA and Clinical expertise, since knowledge of the clinical/operating field is necessary to

understand impact of product failure on patient. (5) *Developing and implementing actions and outcomes measures* - As a last stage, it is mandatory to address each risk with actions aimed at Design/Process controls – each control will have a detection rate of the related failure mode, whose value is chosen on the team judgment basis.

At points (3) and (4), the team faces the key topics of: (a) potential failure modes and functional effects of the product having potential impact on the product safety; (b) potential hazards related to the product – also called *clinical harms*, that may affect the product user (patient undergoing PTA procedure).

Once all relevant hazards and failure modes/functional effects are listed, risk estimation is conducted on the basis of team's experience, knowledge and web/literature data, assigning Severity and Occurrence (Table 1).

Table 1. Risk analysis workflow drawn onto the considered company approach, from part to functional effects and clinical harms.

Product	Part Name	Function	Potential Failure Mode (FM)	Functional Effects (related to the FM)	Clinical Harms (related to the FM)	Causes (of failure mode)
Name of the product	Name of the part under consideration	Function performed by the part	Failure associated with the function	Assigned occurrence rating (1 to 10)	Assigned occurrence rating (1 to 10)	When this cell contains "x", the Cause is considered a potential cause of the FM

3.3. PTA balloon catheter: Potential failure modes and functional effects

Considering the described PTA catheter design, the question is "which potential failure modes are related to this product?". This depends on the device structure, materials, geometry and overall design and consists in the information that are usually collected during step *(3)* (information collection and organization) of the FMECA workflow. Possible failure modes identified for device components are: A. Inability to inflate / being pressurized (device part: balloon); B. Inability to maintain bonding to catheter shaft tube (device part: balloon); C. Inability to transmit fluid during injection (device part: guidewire tube); D. Inability to allow access for the Guidewire (device part: gw tube); E. Loss of connection/bond to the hub (device part: gw tube); F. Inability to transmit fluid from the Luer to the balloon (device part: shaft); G. Inability to bend and track in the vasculature (device part: shaft); H. Inability to transmit load from and to physician (device part: shaft); I. Inability to transmit inflation fluid to shaft (and then to balloon) (device part: hub); L. Inability to confine gw tube and shaft tube radially (device part: hub).

Once failure modes are identified, the following question arises: which are the functional effects of the selected failure modes? There are different ways to answer this question in industry practice: (1) Medical Device manufacturers have complaints data base, collecting complaints coming from the *clinical* field: these usually provide a wide range of possible failure modes related to previous marketed and similar products. Thus, that is used as a basis for collecting and populating the list of failure modes during risk analysis in product development. (2) Regulatory agencies (e.g. FDA with MAUDE – Manufacturers and Users Facility Device Experience) [17] collect and report suspected device-associated deaths, serious injuries and malfunctions in the MAUDE, monitoring device performance, detecting potential device-related safety issues, and contributing to benefit-risk assessments of products. Accordingly, these regulatory agencies sources are often used as a basis for initial risk analysis. (3) Guidance, Standards are intended as reference and aid for manufacturers to identify possible failure modes according to different devices class/type. (4) Engineering and clinical experience is an additional tool always involved in the potential failure modes determining.

The team has investigated all the potential failure modes related to PTA catheters starting from device potential issues. Data for this analysis came from each of the above-mentioned sources: medical device company complaints data base was considered; MAUDE website was referenced; FDA guidance was followed (i.e. "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters", issued on September 8, 2010 *and* ISO 10555-1: 2013(E) -Intravascular catheters – sterile and single-use catheters; Team members engineering and clinics background).

3.4. PTA balloon catheter: Clinical harms

Clinical harms section is usually completed according to the same sources listed above, especially complaints data base, MAUDE data and Engineering/Clinical experience. In this phase of the risk analysis, the team member from Clinical Department is usually responsible for collecting these data. Literature is definitely an additional valuable source for this research. The working team has approached the research of clinical harms starting from the MAUDE and company's complaints data base (Table 2).

Table 2. Clinical harms and related severity, assigned on a basis of MAUDE analysis, team discussion and company historical data.

Clinical Harm	Severity	Explanation
Delayed Procedure	6	Time needed to accomplish the procedure is increased due to the device fail
Vessel Rupture	8	Blood vessel wall rupture
Secondary intervention	8	Need of a second device
Embolism	7	Particle loss in the downstream blood districts
Dissection	7	Tear within blood vessel wall
Ischemia	8	Blood supply lack
Blood Loss	7	Blood loss within the tissues or from the puncture location
Vasospasm	6	Blood vessel spasm leading to vasoconstriction
Amputation	9	Limb/body extremity removal
Death	10	

3.5. PTA balloon catheter: Overall FMECA

Finally, working team has organized the collected info in a table that connects failure modes, functional effects and clinical harms. An occurrence (1-10) has been assigned to each functional effect and related clinical harm.

Occurrence of each functional effect and clinical harms has been established according to the same principles followed by company working team. Occurrence Ranks are assigned starting from the complaint and sales analysis, by considering: the number of sales in a significant time-frame (e.g. last three years) of a device similar to the one selected (i.e. PTA catheter) in a significant geography (e.g. US market); the number of complaints related to a selected failure mode is considered; the ratio of number of complaints due to a selected failure mode over the number of sales is calculated and then normalized on a 1-10 scale; the same occurrence calculation is performed for clinical harms; Team members – based on product knowledge, literature data and engineering judgment – discuss the given ratings, (if needed) increasing or decreasing the ranks with proper rationales. A set of possible detection methods has been provided (according to point *(5)* in section in 3.3). In particular, the design choice consists in a combination of dimensions/material choice able to guarantee that the product addresses the potential failure mode; the test represents the method used to verify that designed product is able to meet design specifications, thus ensuring product safety. It is worth deepening this last step, being the key one in the FMECA workflow: assigning occurrence, and previously severities, is indeed a delicate issue. We have seen that the different stages of FMECA are led by project team members, often supported by experts belonging to the departments responsible for the risk analysis. This is the typical approach that, as we have seen, characterizes practitioners. The authors of the present paper applied the same approach in the risk analysis performed: inspired by the medical company approach, each step of the analysis was debated and discussed – since the authors had different knowledge degree of the topic, this was ultimately useful to facilitate the debate. From this exercise, the authors have noticed that, when discussing severities, occurrences and potential failure modes, the debate strongly depended on team members' perspective: there is room of discussion around each topic, even if ratings (e.g. occurrence) and values (e.g. severity) rise from robust assumptions (e.g. review of similar products, database, etc…).

Thus, the potential limitations that occur when a project team performs risk analysis within an industry have been experienced: even if the overall FMECA structure is well defined and strictly constrained by overall Company

Quality systems, subjectivity of ratings has still a meaningful role in the analysis. Experience and team members knowledge represent the most important drivers; moreover, teams usually leverage on database and similar product analysis as useful tools to limit subjectivity, however without reducing it at all. Responsibility of each team member is aimed at providing the best risk classification, severity and occurrence allocation: moreover, technical rationales are always at the base of key choices that ultimately represent the mostly shared opinions.

4. Discussion and conclusions

This study takes roots from the consideration that, despite its unquestionable diffusion, the FMEA contributions in healthcare tend to polarize over the evaluation of the risk connected to medical processes, neglecting the urgency of extending risk assessment techniques to medical devices.

Coherently, the goal of this essay was twofold. On the one hand, we evaluated the state of the art of the application of FMEA on the assessment of the risk connected to medical devices. The literature search confirmed the widespread application of the FMEA, the scant number of contributions about its applications on medical devices, and the main limitations related to the use of this technique in this field. Second, once collected the potential solutions proposed in the industrial field to overcome the FMEA limitations, we looked within the practitioners' worlds, to see how they deal with this methodology and its faults in the practice. To do so, we selected a leading Company in the development of medical devices (Medtronic Inc.) and we investigated the process enacted to evaluate the risk connected to the desing of new devices.

The empirical investigation showed that the Company spends a surprising amount of time and resources to set and deploy the FMEA rigorously, and it follows the passages envisioned by the literature carefully. Despite the unquestionable usefulness and diffusion of the FMEA in the Company practice, some limitations emerge. In concert with the literature findings, the issues of reliability and subjectivity of scores came out pretty evidently. The Company tries to overcome these limitations through the use of historical data (e.g. complaint database) and of the multidisciplinary competencies of the team. While team members competencies, experience and knowledge of the field are ultimately subjective items, complaint database and online reports made by governative or recognized institutions (e.g FDA) represent a more objective source. Thus the effort of Company is constantly aimed at keeping the most documented and objective approach, trying to limit all the potential sources of subjectivity and newness in the workflow. This definitely affects the relation with the solutions envisioned by the academic words: even if potentially innovative or less time consuming, these are often not even considered. In fact, it seems more well-advised to maintain a strengthened approach employed through the years, than to introduce changes that could make issues emerge from certification bodies and auditors.

It is however worth to underline that, despite the FMECA is necessary for a project to be accomplished, the final document remains "alive" during the product lifecycle: indeed, product monitoring after launch and complaints analysis are constantly controlled by the quality members of the project. If needed, so, FMECA can be revised, well supported by rationales or justifications for each action that is taken in this perspective. Thus, the possibility to maintain the document monitored and, eventually, to revise it on a rationale basis might be preferable than a change in the document form or, more drastically, in the risk analysis approach.

To conclude, an evident gap is therefore retrieved among the practitioners and academic words. This consideration brings with it two possible explanations. First, the academics are not addressing the managerial and pratical implications of their contributions; in so doing, they deepen the theory versus practice chasm. Second, the presence of standards actually disincentivizes the practitioners to push over and find new solutions: in fact, the quality of the process of risk assessement applied by Medtronic is coherent with the requests of the ISO 14971 and there is no reason why the Company should modify a well-rooted process. This study is useful to shed light on a still under-debated phenomenon. Nevertheless, it has several limitations. Above all, more generalizable conclusions might be taken by applying the research on other leading Companies in the Industry of healthcare device development. Moreover, the attempt to bridge the academic and practitioners' worlds by developing a more manageable technique to overcome the FMEA limitations, might represent a ambituous though needed contribution.

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