



Importance of Risk Communication and Risk Analysis in Medical Device Industry

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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ABSTRACT

In medical device industry the risk management plays a very vital role. There should be proper communication from each and every stakeholder related to risk management of each respective department, it can be Production, Design and Development or Quality Control and all other departments. In this current research work the role of risk analysis which had been done accordingly ISO 14971 for risk management of medical device using FMEA is implemented. FMEA (Failure Mode and Effects Analysis) plays important role in risk analysis by having several steps for mitigation of risk. Also it had been used for identifying hazard of each risk throughout the lifecycle of the medical device. Risk communication should be advanced so, that the risk identified can be easily controlled by taking appropriate risk control measures. In any medical device industry risk analysis should be done properly and as well the risk communication channel should be strong for proper and immediate action. In this research paper practically the role of Risk communication and risk analysis is covered. Risk management of any of the organization can only be effective if the risk analysis is done strongly and the communication related to risk is proper. In this research FMEA analysis for risk analysis is done on a medical device and also the communication from risk manager to the other entire stakeholders of the risk management from various departments are fully taken into the consideration.

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1. INTRODUCTION

Risk Management is the process of identifying, assessing, mitigating, monitoring, controlling, and reporting risks. This Risk Management Plan defines how risks associated with the various medical devices manufactured by KAULMED are primarily identified for the various risk and then the risk associated with different medical devices produced are fully analyzed with the point of view of all risk hazards, that can take place during the designing phase as well production and post production. Then these identified associated risks with that product are mitigated to its possible range, the risk is controlled throughout the process of manufacturing of the medical device. Risk management process outlines how risk management activities will be performed, recorded, and monitored throughout the lifecycle of the product. Risk management comprises of combined process as shown in Fig.1. Risk is defined as per ISO 14971:2019 that it is a combined probability of occurrence of the harm and the severity level of that harm and harm is defined as the physical impact on the health of the people or damage to the property or the environment [1,2,3].

There are several key terminologies which together forms the Risk management system these are Harm, Hazard, Risk, Risk analysis, Risk evaluation, Risk control, Residual risk, Risk assessment, Severity(Consequences), Safety, Risk Management etc. as per ISO 14971:2019 [2].

Risk management in medical devices are considered as the vital part through which the risk is first predicted and analyzed and then by applying certain risk control measures the risk is mitigated from the whole loop. Risk management is the process in which there is a proper loop in which the raw material intake to post processing and even customer feedback is included for mitigating the risk from the whole system. Risk management in medical device industry is now a days mandatory by the government, without controlling the risk associated with medical device, no industry can supply any of the medical device without identifying the hazards and controlling them and documenting the same in the risk management file. Medical device should not affect human body and do not have any adverse impact on human

for that proper risk management should be done [4,5].

Risk management is having certain measures only if the risk of any device is under control or having very less severity and occurrence then only it is accepted and the process is further proceeded else the whole process thoroughly checked for the hazards which are having adverse impact on human life.

2. METHODOLOGY

In this research work the methodology used for risk management is FMEA (Failure Mode Effect Analyses) through which the assessment of the hazards is identified and analyzed for its impact controls are applied and as well monitored. In medical devices many of the standard reference documents are used for identifying the risk present throughout associated with medical devices either it is during production or might be during post production. The below given are the few standard documents whose methodology is used in this paper for identifying the risk. FMEA (failure Mode Effect Analysis) method is used for mitigating all the risks by applying several risk controls throughout the lifecycle of the medical device. The all risks associated are either reduced to the acceptable limit or it can also be transferred by introducing third party for that specific device [6,7].

Risks related to device must be identified and documented based on the methodology in:

1. EN ISO 14971:2019, Medical Devices- Application of Risk Management to Medical Devices,
2. MDD 93/42/EEC amended by 2007/47/EC
3. EN 62366:2008, Medical Device - Application of Usability Engineering to Medical Devices.
4. Device Design and Quality Management System

3. FMEA (FAILURE MODE EFFECT ANALYSIS)

Failure mode and effects analysis is the process of studying as many components, assemblies, and subsystems as probable to identify potential failure modes in an organization and their causes and effects. Failure mode effect analysis is a

process through which the risk throughout the lifecycle of the medical device is analyzed and accordingly certain risk control measures are taken to mitigate those risks. For each constituent, the failure modes and their resulting effects on the rest of the system are detailed in an explicit FMEA worksheet as shown below in Table 2. [2,8,9,10]

Accordingly, all the below mentioned stages are to be covered in the whole risk management FMEA process. FMEA analysis will cover all the prospective of the analysis and will result in identifying the root cause of the identified hazard. The risk which is analyzed through this FMEA analysis is mitigated by applying certain risk controls to mitigate the risk associated with the medical device i.e.

orthopaedic implant manufactured at KAULMED Pvt. Ltd. In KAULMED Pvt. Ltd. Risk Manager looks over the whole process of risk management and all the concerned staff associated is allocated individual task to identify

the risks in their expertise field and after that it is department wise summarized and then analyzed as well mitigated to its lower possible level. The process chart of FMEA process which takes place is given below in Fig. 2. [2].

Risk Management will cover the following stages of lifecycle for Orthopaedic Implants. Following are the identifications of the hazards and reasonably foreseeable sequences associated with the medical devices manufactured by KAULMED Pvt. Ltd. [11,10]

1. Design and Development
2. Procurement
3. Production and Testing
4. Storage and Handling
5. Labeling
6. Packaging and Shipping
7. Shelf Life
8. Distribution
9. Product Use
10. Potential Removal (if required)



Fig. 1. Framework for risk management of medical devices

S. No	Hazard	Hazardous situation	Severity Level	Possibility of Occurrence	Risk	Risk Evaluation/Acceptability Decision	Risk Control Option	Implementation of Risk Control	Residual Risk Severity	Occurrence after Risk	Residual Risk Acceptance	Risk acceptance after risk control measure	Information supplied to user/patient	Risk arising from risk control measure
1a	Dimensional variations in predicate and subject device	Inadequate Measurement Improper dimensional input	S4	O3	Not Acceptable	Dimensional variation with predicate device is not acceptable as it may lead to device failure or revision surgery	Design review Drawing is to be control and approval before transfer to production	Design review Procedure for Design Review A3-DND-QP-xxx Controlling & Approval of drawing covered under A3-DND-QP-xxx Procedure for 3D, 2D Model & Drawing preparation.	S4	O1	AFAP	With strict compliance with Design and Development controlling all D&D stages: input, output, review, verification, validation and design transfer, current risk is acceptable	Not Applicable	No

Fig. 2. Detailed example of FMEA (Failure Mode Effect Analysis) sheet



Fig. 3. The process chart of FMEA process

4. PROCEDURE

- Establish Risk Management plan.
- Establish PHA (Process Hazard Analysis) team.
- Identify all hazards covering each stage in lifecycle of the implants.
- Report the results of PHA by using a PHA worksheet as described in Risk Management File.
- Estimate the severity of the consequence and probability of occurrence.
- An accidental event may lead to wide range of consequences ranging from negligible to catastrophic; hence we need to consider several possible consequences, including the worst foreseeable consequence of the accidental event.
- When estimating the frequency of an event we have to bear in mind which consequences we consider.
- The risk is established as a combination of a given event/ consequence and the severity of same event/consequence.
- Identify control options used to minimize the risk and record the same in risk management file.
- Verify the effectiveness of the control options.
- Determine any risk arising from control options and try to mitigate the same.
- Determine any residual risk remaining after implementation of the control option. Accordingly identify measures to manage the residual risk within the limits.
- Perform overall risk benefit analysis.
- Also perform overall residual risk benefit analysis.

Following table will be used for determining the probability of occurrence and severity of harm:

Table 1. Probability of occurrence and severity of harm with description

No.	Probability of occurrence		Severity	
	Terms	Description	Terms	Description
1	Negligible/ Improbable	$< 10^{-6}$	Negligible	Inconvenience or temporary discomfort
2	Remote	$< 10^{-5}$ and $\geq 10^{-6}$	Marginal	Results in temporary Injury or impairment not requiring professional medical intervention
3	Occasional	$< 10^{-4}$ and $\geq 10^{-5}$	Critical	Results in Injury or impairment requiring professional medical intervention
4	Probable	$< 10^{-3}$ and $\geq 10^{-4}$	Serious	Results in permanent impairment or life threatening injury
5	Frequent	$\geq 10^{-3}$	Catastrophic	Results in Patient Death

5. ACCEPTABILITY OF THE RISK

Based upon the Severity level and Probability of Occurrence risk will be categorized in different zones which are Red, Yellow and Green zones. These three different zone specifies that the risk is acceptable or unacceptable for the medical device [2].

1. In Red zone the risk is unacceptable but the risk can be mitigated risk by using several control measures due to which the risk is mitigated and the risk is brought to the yellow zone and then the risk lies in AFAP (As Far as Possible).
2. In Yellow zone the risk is reduced to as far as possible, however, if risk control measures further can ensure keeping the same level over a period of time with further investigation into the existence of risk, then risk may be considered to be acceptable, being as far as possible. The risk in this yellow region is acceptable by continuously monitoring throughout the lifecycle of the medical device.
3. In Green zone the risk is broadly accepted and also there is no need of mitigating the risk.

6. RISK COMMUNICATION

Risk coordination entails the two-way exchange of information between all risk stakeholders from all agencies in order to make the right risk management decisions possible.

It includes several communications on the essence of risk as well as non-risk messages that convey concerns, views, or responses to risk messages or legal and administrative arrangements for risk management.

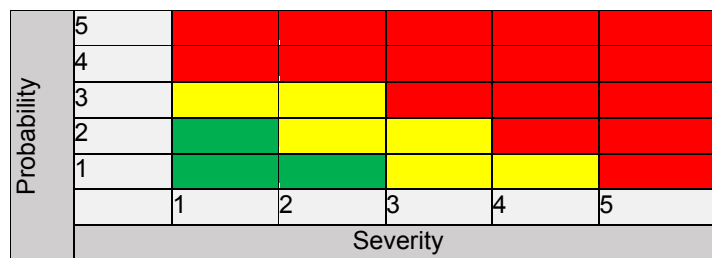
While risk communication originated as a separate phenomenon within the risk science community in the early 1970s, the term was first used in the scholarly literature in 1984, as a result of the growing interest in risk perception theory, which used psychological analysis to understand how individuals and groups formed and held differing opinions regarding risk acceptability. Until the middle of the year 1980, Risk communication aimed to provide reliable information about risks by describing risk probabilities as objectively and specifically as possible using empirical analysis and risk assessments. With increased public interest in risk communication, the area of risk communication has evolved to include the explanation of technical knowledge and technical risk evaluations. The development of risk communication continued in the 1990s, with an emphasis on increasing public trust through relationship building, open dialogue, and collaborative decision-making [1,2,4].

A main goal of the study was to determine the gaps in risk assessments conducted by experts and no experts (the general public). Unlike risk assessment research, which focused on identifying gaps between experts and the general population, risk communication research was more realistic. These variations were acknowledged by risk communication researchers, and they may be the product of strong beliefs or deep-seated habits.

Attempts at risk dialogue aimed to bridge the expertise gap between professionals and no experts. Furthermore, risk communication aimed to increase risk communication in order to direct and improve the handling of contentious issues [2].

Table 2. Acceptability of risk

Red Zone	Unacceptable	Cannot be accepted, however if risk control measures lead to either AFAP or Broadly acceptable, then risk is acceptable
YellowZone	As far as possible(AFAP)	The risk reduced to as far as possible, however, if risk control measures further can ensure keeping the same level over a period of time with further investigation into the existence of risk, then risk may be considered to be acceptable, being as far as possible. The risk is Acceptable with continuous monitoring of the residualrisk through PMS Activities
Green Zone	Broadly Acceptable	The risk has been reduced to as far as possible



	Broadly Accepted
	AFAP (As far as possible)
	Not accepted

Fig. 4. Different zones for acceptability of the risk

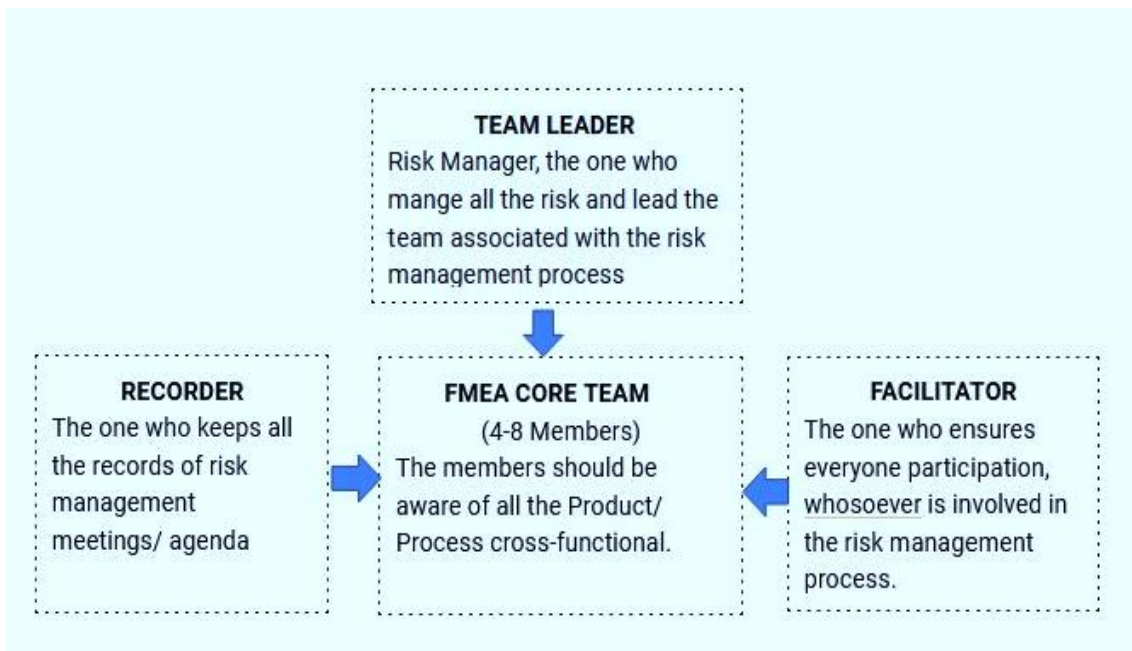


Fig. 5. Communication of risk throughout the organization

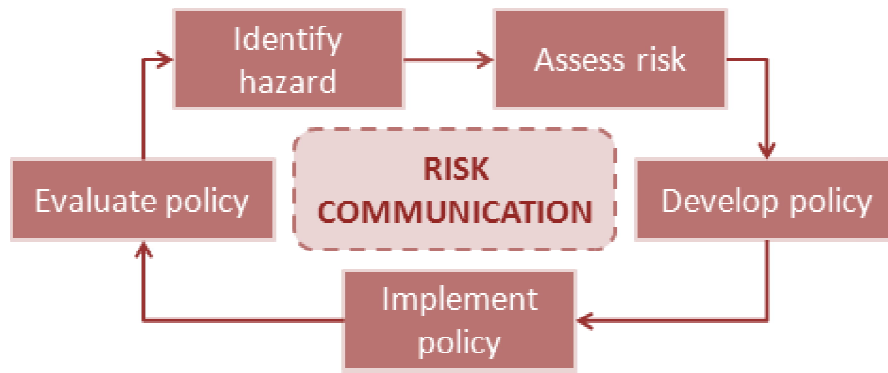


Fig. 6. Risk communication process chart

Risk factors and coping styles have been divided into three categories.

Routine risk scenarios, for starters, have risks that have been thoroughly characterized by risk scientists.

There are few unknowns when it comes to routine risk problems, and those in charge of risk management are well aware of the consequences of disclosure. The confirmation that the risk is still normal and that all management agencies are well-prepared to execute the requisite activities for public safety is needed for risk coordination for this sort of risk (such as ongoing monitoring, testing, evaluation, and reporting).

Second, threats will have a lot of confusion attached to them. The implications and experiences that could lead to new threats are not well known in this situation. Risk contact is needed in these situations to overcome concerns of the unknown and possible threats. Maintaining public interest necessitates the use of a precautionary strategy and accountability.

Third, threats with a high likelihood of causing controversy can arise. These threats can or may not bear a high level of confusion, but they elicit extremely divisive or emotional reactions due to their feared consequences. Moral or legal questions regarding the risk issue or its treatment are often the source of controversy. Risk contact in the event of a widely feared, potentially disastrous event or deeply contentious risk questions, a wider framing that includes societal values, lifestyles, and worldviews is needed. For increasingly contentious risks, incorporating stakeholder and public participation into the risk communication effort is critical [9].

Failures in risk disclosure that lead to skewed public opinion are the product of an intelligence gap, in which those in charge of experimental risk management make little particular attempt to disclose conclusions to the public on a daily basis. Instead, other sources fill the information void, and could be skewed or fail to correctly convey the threats. The good management of unpredictable and contentious risk problems requires entering into and retaining risk coordination at a pre-emptive or early level. Any mind-set formed without a fair degree of understanding about a risk can be difficult to alter once formed.

7. RESULTS AND DISCUSSION

Risk management plays a very vital role in medical device industry for mitigation of associated risk with the device. Risk strategy used in this Research paper can help to mitigate the risk to AFAP. Risk communication is always required for communication of risk to the Risk Manager. Risk communication can play a vital role to mitigate risk by taking proper risk control measures due to .

Risk analysis can lead towards producing safe device by using several risk control measures. Risk communication with proper stakeholders from every department is required for identification of risk hazards. Risk can be eliminated or reduced to AFAP by taking proper risk control measures against the identified hazards.

8. CONCLUSION

Risk communication and risk analysis are well-known as important assets in medical device industry which implies important contributions in

supporting decision-making and ensuring the safety of the human being from the medical device produced by KAULMED Pvt. Ltd. In this research paper the method for developing the risk assessment is made by using the FMEA process which will cover the total lifecycle of the medical device which is going to be manufactured or already in market. This research paper has placed its focus on recent work and advances covering the essential ideas and thinking on which the risks assessment and risk communication can be based. Having evaluated a considerable number of risk assessments in this area of risk management, the following main conclusions are drawn:

1. The Risk assessment can enhance the safety factor due to any medical device.
2. Risk is mitigated to its lowest limit which will not affect the human body due to the implant in his/her body.
3. All the hazards and hazardous situations are taken into consideration for the mitigation of risk which directly reduces the risk and the residual risk is now in the acceptable region.
4. Table signifies the severity and probability of occurrences for any of the risk which will arise during the manufacturing, production or design and development phase for any of the medical device. According to the table the severity and probability is defined.
5. Acceptability limits are set as per the different zones described in the table acceptability of the risk. The acceptability is divided into the further three colour zone in which the risk arising in red zone are not accepted, Yellow Zone known as AFAP (As far as possible) zone those risks which arise in this particular zone are broadly accepted but can be just considered for acceptance and the last one is Green Zone (Broadly Accepted) those risk which are arising in this green zone are broadly accepted.
6. Example of FMEA is described in the figure in which the whole process from identification of hazard, hazardous situation, risk control measures, residual risk and many more are
7. Importance of the risk communication is shown in this research work in a flowchart.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our

area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was funded by the producing company KAULMED PVT. LTD., INDIA.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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