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Incident Management in Recall of Medical Devices: Critical Elements

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Abstract

Recall of medical devices are mechanisms to ensure that device problems that happen do not cause serious harm to the patient population. Corrections are done to address these device problems. The Regulatory authority for medical devices ensures that the post surveillance measures are in place so that the monitoring of device problems, hazards, corrections, recalls and termination of recalls are documented. The Regulatory Authorities maintain databases which provide information on device problems, adverse events and recalls. When analysing the regulatory databases, it is seen that recalls happen during the product lifecycle, only after a certain time period of occurrence of device problems and consequent occurring of adverse events. This study tries to analyse some of the cases to see how the incident management is happening in the case of medical device recalls from the data available under United States Food and Drug Administration. The analysis is done on the basis of recall initiation, termination of recall, the critical adverse events like death reported during the period and the proactive actions that can reduce the harm due to device problems through cases of interest. It is interesting to note that the manufacturers take intermittent measures during the course of recall which is seen to reflect in the adverse event data. The study concludes that tracking the critical elements like Recall- Termination Time, Adverse Events Curve Pattern, Exposure Time would be indications of efficient incident management measures executed by the manufacturers. The study also highlights the fact that all the above critical elements are dependent on the kind of device problem.

Keywords
Medical device recalls, adverse events, device problems, incident management

1. Introduction
Medical devices are subjected to recalls, corrections or removals when it is found that the devices are having device problems which cause serious or temporary health hazards to the patients or users. The adverse events are being monitored by the Regulatory authority and there are self reporting portals maintained for the same. The manufacturer also have other mechanisms like post market clinical follow up studies to monitor the adverse events. Medical devices are varied based on specialty (orthopaedic, neurology, cardiovascular etc) , risk classification (class I, II and III as

per USFDA) and application (diagnostic, therapeutic and so on). Many of these devices are hence life-saving or more pertinent to be available for the patient population. But it becomes detrimental that the devices causing riskier health consequences are to be corrected or removed. Even though the adverse events happen, the recall or corrections are done at a later stage. The corrections depend on the type of device problem like design, labeling, software problem, material integrity and so on.But recall and correction affects not alone the patient safety but also the public trust on the devices and the brand. Hence a rapid response mechanism would create less exposure of the impact of the device problems. The article explores on the imperative role of early intervention by the stakeholders into recall by analyzing critical elementsin the recall process.

1.1 Objectives

Analysis of cases under class I recall under high – risk and moderate risk medical devices to analyse the critical elements of recall process like recall time, termination time, strategies and impact of manufacturer interventions on patient outcomes.

2. Literature Review

USFDA through it's guidelines alerts the manufacturers to be "recall ready". And the guideline specifies on how the manufacturers should have a recall strategy by watching the adverse reactions and identifying the potential risk to the patients/users. The guidance specifies on a recall plan in terms of a recall team, recall communication plans, distribution records and maintaining product codes, The document gives instructions to the manufacturers on initiating the recall on a timely manner (FDA, 2022). Recall strategy of the manufacturer is the major factor that determines the success of recall management(Timothy I Morgenthaler 1,✉, Emily A Linginfelter 2, Peter C Gay 1, Sandra E Anderson 1, Daniel Herold 1, Virginia Brown 1, Joseph M Nienow 3, 2022). The recall management also depends on effective communication with the stakeholders by the manufacturer(Bethany L. Tennant a et al., n.d.)

3. Methods

The USFDA pubkic database contains information on the approvals, device problems, adverse events, recalls, action taken by the manufacturer on dealing with the recall, communication to the physicians, patients or consignees termination of recalls,etc. The article uses case study approach and tries to analyse cases of class I recalls which are the ones that cause severe health consequences due to device problems. Class I recalls belonging to the high-risk and medium -risk are analysed to see the processes involved in the recall management.

4. Data Collection

The data for the cases are collected from the databases of USFDA on recall, Pre Market Approval for high-risk devices, 510K approval for medium-risk devices, Manufacturer and User Facility Device Experience(MAUDE) for the adverse events. Two cases of class I recall from catheter , percutaneous which is a medium risk device, one case from the Implantable Pacemakere Pulse-Generator which is a high-risk device and one case from System, endovascular graft, aortic aneurysm treatment is included for analysis. Each case is analysed in terms of approval, recall, device problem, FDA determined cause, adverse events, communication or actions from the manufacturer, quantity in commerce and recall termination (Table 1- Table 4).

5. Results and Discussion

The cases above give an insight into the recall strategies being followed. In case 1 the product is recalled when the malfunction is found to increase. The recall termination time is around five years. The unused products are to be quarantined or not to be used. Case 2 is a very fast recall soon after the approval. In this case the termination of the recall also is on the same year of recall. In this case also the instruction was to remove the device from the inventory. It is a kind of preventive correction with no adverse events and sudden intervention. Case 3 represents a lifesaving device that is a pulse generator. The original application has around 825 supplementary applications showing that there have been many additions /modifications being done on the original device. It is a typical case of innovation when the product is updated with different kinds of applications/technology advancements. And also, it is evident that the number of recalls is also more. Being a life saving device the recall intimation letter does not give information on the quarantine/return but the letter communicates more on what the physicians are to do and offers supplementary warranty. The last case also gives more guidance to the physicians on managing the recall. In this case it can also be seen that there is an intervention from the part of the FDA in terms of communications and discussions.

Table 1. Case 1

Product	Catheter, Percutaneous (DQY)
Case 1	K042489, K132673 – guiding catheter, 510K- Substantial equivalence
Predicate device	K021256 – with class2 recalls (terminated in 2007)
Application received	14th September 2004, 27th August 2013
Approval	13th December 2004, 22nd October 2013
Recalls	190 out of the 213 – class I recalls under DQY
Date of initiation of recall	15th March 2019
Date posted	1st October 2019
Device problem	There is a potential for extensive loss of primary segment material exposing underlying stainless-steel braid wires on a subset of the product
FDA Determined Cause	Component design/selection
Adverse events	Injury, malfunction (around 227 reported) No deaths
Communication	15th March 2019 Quarantine and/or return unused affected product, and confirmation of the immediate notification was requested. Hand delivery communications in US
Quantity in commerce	1226 units, worldwide distribution
Recall termination	April 2024

Table 2. Case 2

Product	Catheter, Percutaneous (DQY)
Case 2	K121611 - general purpose delivery systems designed to provide a pathway through which devices are introduced within the chambers of the heart.-510K substantial equivalence
Predicate device	K072313, K083214
Application received	1st June 2012
Approval	23rd August 2012
Date of initiation of recall	18th January 2013
Date posted	11th February 2013
Device problem	The distal end of the core wire of the Delivery System could potentially fracture when exposed to a combination of certain cardiac anatomies and usage conditions.
FDA Determined Cause	Device Design
Adverse events	No adverse events reported
Communication	Urgent medical device recall notice to all affected customers. Customers were advised to discontinue use of the device and remove it from inventory.
Quantity in commerce	635 units, US
Recall termination	21st May 2013

Table 3. Case 3

Product	Implantable Pacemakere Pulse-Generator - Product Code DXY
Case 3	P980035S002, Original approval in 1999 with 825 supplements
Supplement reason	Change Design/Components/Specifications/Material
Application received	10th March 1999
Approval	9th August 1999
Date of initiation of recall	May 18, 2009
Date posted	June 11, 2009
Device problem	One or more bond wire pairs will lift or separate from the bonding terminals on the device hybrid. This may present clinically as loss of rate response, premature battery depletion, loss of telemetry, or no output.
FDA Determined Cause	Device Design
Adverse events	More than 1500 deaths reported for P980035
Communication	Important Patient Safety Information letter was hand delivered. The letter describes the issues, provides a predicted failure rate for the 3 populations of devices, and provides Patient Management Recommendations to the physicians. . The letter recommended that physicians should advise their patients to seek medical attention immediately if they experience symptoms (e.g., fainting or lightheadedness). It was also recommended that physicians should consider device replacement for patients who are both pacemaker dependent and who have been implanted with a device in the affected subsets. The company will offer supplemental device warranty if the device is not already at elective replacement time. The last recommendation was that physicians should continue routine follow up in accordance with standard practice for those patients who are not pacemaker dependent. The letter also provides Physician and Patient Support. “
Quantity in commerce	9434-worldwide distribution
Recall termination	March 28, 2012

Table 4. Case 4

Product	System, endovascular graft, aortic aneurysm treatment - Product Code MIH
Case 4	P040002S060 P040002S061
Supplement reason	Labeling Change - Indications/instructions/shelf life/tradename
Application received	2nd April 2018, 10th July 2018
Approval	3rd July 2018, 9th August 2018
Date of initiation of recall	July 31, 2018
Date posted	October 03, 2018
Device problem	Type III endoleaks
FDA Determined Cause	Device design
Adverse events	258 deaths with original PMA no, 92 malfunction, 500+ injury
Communication	“The firm mailed Urgent Important Safety with return delivery confirmation. Physicians were informed about the following: 1) Type III endoleak rates, 2) Refined patient-tailored surveillance recommendations, 3) Sizing recommendations, 4) Recommendations for device interventions/ re-interventions. No product return is required. Customers with questions are encouraged to call Customer service. Because of the ongoing concerns

	regarding Type III endoleaks the FDA has publicly communicated concerns: The FDA Reminds Patients and Health Care Providers of the Importance of At Least Yearly, Lifelong Follow-Up with Use of the product. The FDA convened a public meeting of the CDRH Circulatory System Devices Panel of the Medical Devices Advisory Committee to share information and perspectives from interested parties on the benefit-risk profile of the product focused on the risk of Type III endoleaks."
Quantity in commerce	45304 worldwide
Recall termination	April 09, 2024

The process flow diagram below (Figure 1) represents the flow from approval through recall and finally to the termination of recall. The two very important timelines are the Time to recall and the Time to termination of recall. These two are very relevant as during this period the patient population will be exposed to the adverse events. But cases like 1 and 2 suggests that it is not always the adverse events that decide the decision for recall. But in cases like 3 and 4 , especially for high-risk devices where correction is not that easier it is better to have earlier interventions for solutions/guidance for managing the device problems so that the risk to the patient shall be minimum.

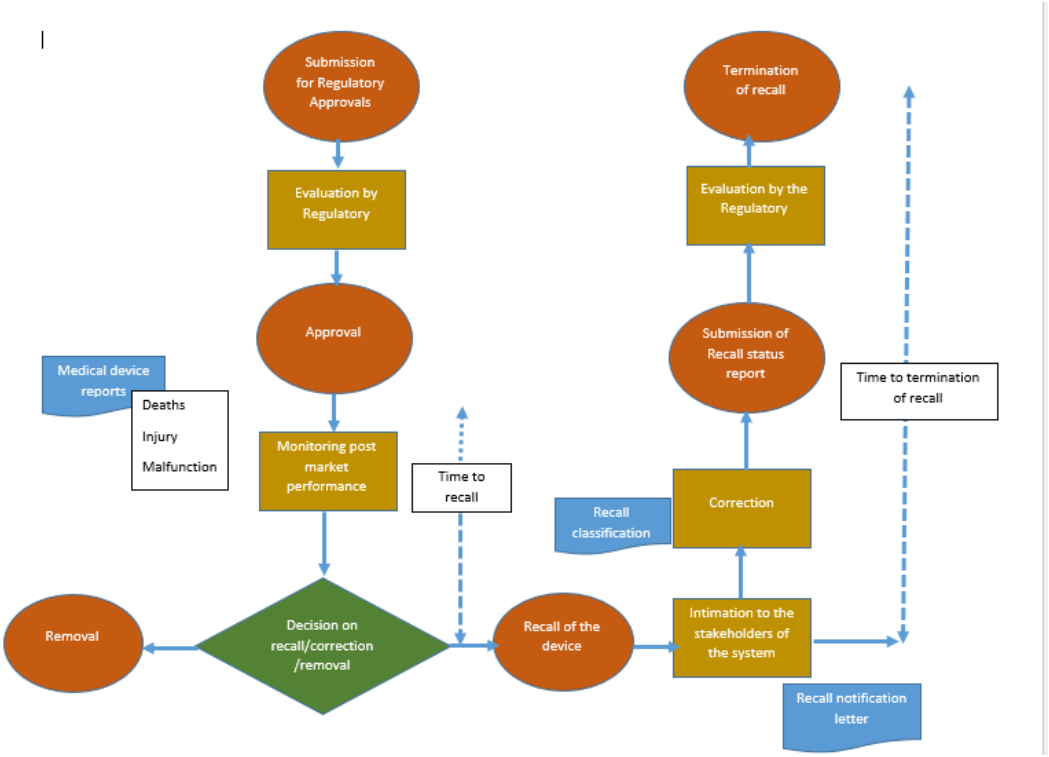

Figure 1. Process flow- Approval – Recall- Termination of recall

6. Conclusion

The analysis of the different cases of Class I recalls for high-risk and medium risk devices signifies that recall strategy of the manufacturer play a major role in recall decisions than the occurrence of adverse events. Especially in high-risk devices it is very evident that the risk-benefit plays a critical role. The Time to recall and Time to termination of recall varies with the category of the device and also based on the device problem. Hence it is not always practical to analyse whether the Time to recall or Time to termination of recall is longer. But earlier intervention into the problem through

communications and corrective measures would add on positively to the situation. To assess the effectiveness of these communications is a study by itself.

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Biographies

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