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Adverse Event Report Impacting QMS

Quality Management System

MDV-QMS Intersection

2020 AHC-SCH Medical Device CoE Pilot Training.

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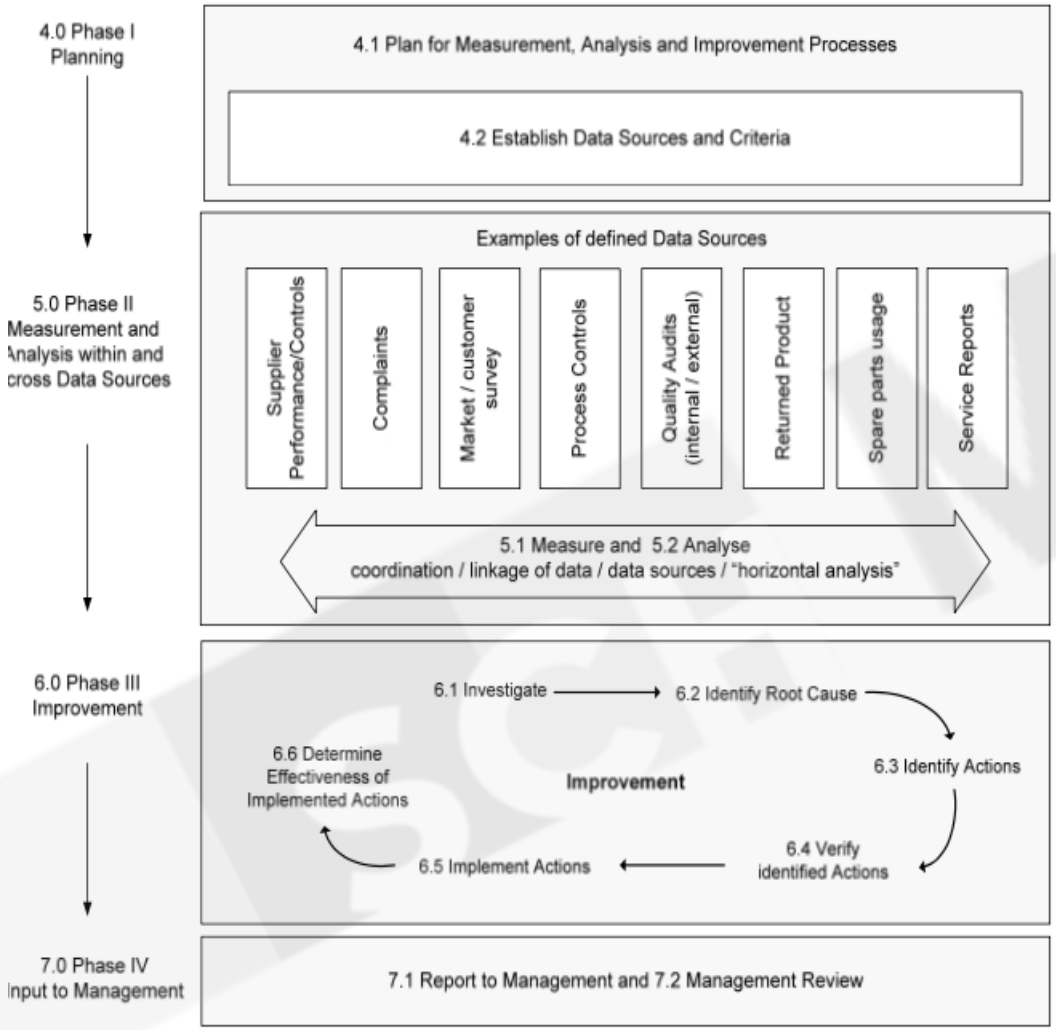
Learning Objectives

In this program, we shall review a scientific possibility to corelate learnings and findings from AE reports of medical devices to potentially improve QMS initiatives/activities (Corrective Action, Preventive Action). A few cases are selected to demonstrate this possibility.

Outlines

- QMS – Medical Device Corrective action and preventive action (GHTF/SG3/N18:2010)
- Example cases
- Review and analyze example incident cases
- Impact on QMS program.

QMS – Processes for measurement, analysis and improvement



Adverse Event Analysis/Finding/ Statistics

Figure 1: Processes for measurement, analysis and improvement

Source : GHTF/SG3/N18:2010

Incident Case Study 1: Surgical Robot

A 66-year-old man was seen by a urologist for difficulty urinating and diagnosed by biopsy with localized prostate cancer. The urologist recommended a radical prostatectomy (removal of the prostate). The urologist stated that the best and safest way to remove the prostate was with a minimally invasive robotic surgery. The robotic surgery, he explained, would involve a few small incisions, performed by a surgeon seated at a computer console in the operating room. The procedure would be carried out using robotic arms and surgical instruments. The urologist went on to say that the robotic technology would allow for smaller incisions, better control of the instruments, lower risk of complications, and faster return of erectile function.

During the procedure, there were mechanical problems as the robotic arms were not responding as expected. The urologist persisted in using the robotic technology and ultimately was able to complete the procedure. The operation took twice as long as expected, but the urologist felt it had been successful.

Postoperatively, the patient developed serious bleeding requiring multiple blood transfusions. He was taken back to the operating room where it was noted the inferior epigastric artery (a key artery in the pelvis) had been damaged during the original procedure. The injury was repaired but this second operation was prolonged and complicated due to the degree of bleeding. The patient ultimately required several additional surgeries and a prolonged hospital stay.

Analysis (example)

People

- Lack of training for surgeon on proper usage and troubleshooting.
- Surgeon persisted using the robot despite malfunction.

Process

- No universal standard guidelines on training or credentialing for robotic surgery.
- Hospitals do not have a specific policy on the amount of training for a medical devices

Technology

- Malfunction of the robotic arms (related to pressure sensors) causing it to not immediately respond to a user's command.
- Consistency of consumable arm supplies
- Consistency in maintenance services

Lesson's learnt (examples)

- Ensure well design training program is developed for Users
  - This may involve certification for use on medical device that are highly dependent of user skills
  - Ensure records of Users understanding of potential risk to surgical outcome and its liability
- Review medical device maintenance requirement
  - Scope of maintenance are well defined to minimize risk of malfunction
  - Comprehensive maintenance record
- Consumable arm supplies are required to undergo more robust testing before releasing into inventory
  - Increase factory testing program
  - Potentially tested by independent organization.

Impact on QMS Activites (example)

Planning

- Product Realisation - Design & Development parameters
- Risk Management - Risk acceptability criteria
- Quality Audits – observation initiatives, effectiveness of device
- Service reports – frequency, personnel, type of repairs

Incident Case Study 2: Surgical Stapler

- A patient underwent laparoscopic right hemicolectomy surgery to remove potentially malignant tissue from her colon. The procedure involved the use of a Endo GIA 60 mm stapler, which has been linked to reports of malfunction and misfires, although she was unaware of the problems. Just days after her surgery, the patient returned to the hospital suffering progressive fatigue and anorexia. Following additional procedures and surgery, her doctors discovered she was suffering an anastomotic leak near the staple line, due to a 0.5-1 cm opening where the staples were placed and appeared to have been disrupted. As a result of the Endo GIA surgical stapler malfunction, patient is required to undergo long-term antibiotic treatment, intraabdominal drains, the placement of an enteral tube, and underwent a failed colonscopic attempt to clip the leak site, as well as further procedures.

Case Report Analysis (example)

People

- Surgeon and the surgical team not familiar with the risks of using incorrect staple size and risk of misfiring and malfunction.
- Incident reports submitted by manufacturers were not well communicated among relevant stakeholders.
- Surgeon did not recognize the complication cause by procedural failure.

Process

- FDA initially classified surgical stapler as low risk devices before it was reclassified as moderate risk medical device.
- Before April 2019, there weren't any rules and guidelines designed to make surgical staplers safer.

Technology

- Endo GIA staplers were subject of many recalls.
- Reported surgical stapler problems involve opening of the staple line, malformation of staples, staplers misfiring, staplers being too difficult to fire, staplers failing to fire and staplers that were misapplied.

Lesson's learnt (examples)

- User awareness program on risk associated to wrong stapler size selection
  - Lesson from other reported incident, shared with users could reduce risk of incident recurrence
- Regulatory guideline review is required for all type of interventional medical device. US FDA has only recognized the need after reviewing many reported cases.
- The continuous case increase should warrant manufacturer and regulator to dive deep in nonconformity of QMS design and compliance of manufacturing processes. Intensity and depth of audit parameters requires additional review

Impact on QMS Activites (example)

Measurement and Analysis

- Non conformity statistics should be produce
- Identify device failure statistics vs Corrective action issued/performed
- Review design and development parameters ensure changes were realised
- Periodical review and report must be produced justifying actions vs complaints
- Analysis on recurring incident and failure mode of the device and its corrective action plan (initiative and monitoring)
- Marketing material, product labelling, and all communication resources provides adequate information on Benefit and Risk

Incident Case Study 3:
Implants that left some women with 'rotting pelvises'

Watson had a **pelvic mesh implant** to treat complications from childbirth that resulted in her **bowel and bladder prolapsing**. Her right leg went numb almost immediately after the procedure, and after a few weeks the mesh was like a knife constantly cutting her up from the inside. Watson's pain was so severe that she tried to take her own life after being hospitalized multiple times. Doctors didn't believe her, she said, referring her to psychiatrists instead.

After giving birth to two boys, both weighing more than 8 pounds, Watson struggled with incontinence. But within three months of the procedure, Watson was incontinent again and after suffering multiple medical problems, such as fibromyalgia, chronic pain and fatigue, **she had the mesh removed**. At 47, the procedure left her with the body of an 80-year-old: unwell, overweight and unable to walk more than 100 meters.

Other women with the mesh had similar complications.

Case Report Analysis (example)

People

- Inadequate communication on the possible risk of using the mesh.

Process

- Inadequate verification on the biocompatibility properties.
- Inadequate review and understanding on the manufacturer recommended surgical technique.

Technology

- Polypropylene mesh is not inert and shrinks substantially after implantation, it degrade and migrate inside the body after implantation.
- Mesh was not proven safe and effective for treating pelvic organ prolapse

Lesson's learnt (examples)

- User awareness program on risk associated to wrong stapler size selection
  - Lesson from other reported incident, shared with users could reduce risk of incident recurrence
- Regulatory guideline review on Usability test ; material properties and user technique should be reviewed and/or tested independently as a verification process
- Review Scientific publications and finding, secondary research may support additional clarity to risk associated with the mesh.
- Review of all Marketing Communication resources should be part of QMS initiatives.
- The continuous case increase should warrant manufacturer and regulator to dive deep in nonconformity of QMS design and compliance of manufacturing processes. Intensity and depth of audit parameters requires additional review

Impact on QMS Activites (example)

Planning

- Product Realisation - Design & Development parameters
- Risk Management - Risk acceptability criteria
- Quality Audits – observation initiatives, effectiveness of device
- Adding Marketing Communication resource into QMS activities

Impact on QMS Activites (example)

Measurement and Analysis

- Non conformity statistics should be produce and reviewed
- Identify device failure statistics vs Corrective action issued/performed
- Review design and development parameters ensure changes were realised
- Periodical review and report must be produced justifying actions vs complaints
- Analysis on recurring incident and failure mode of the device and its corrective action plan (initiative and monitoring)
- Marketing material, product labelling, and all communication resources provides adequate information on Benefit and Risk

Summary

- Reported cases are evidence to take a serious look into details of QMS activities.
- Potentially a significant initiative to support product improvement
- The key source to evidently dive into greater depth of QMS parameters
- Require consolidated effort
  - Manufacturer with the intend to improve product outcome and minimize incident risk
  - Regulators to be more engaged in reviewing and auditing the required intensity and depth of medical device type with consistent incident reported.

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Questions ?

Thank you .

Eric Woo.