Post Market Surveillance

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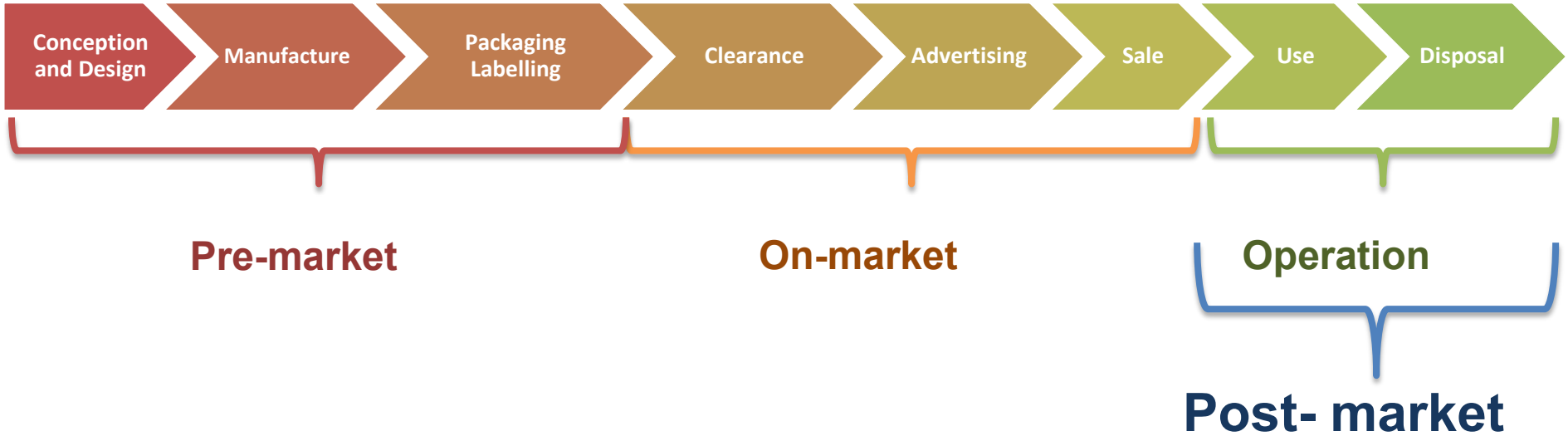
- **Part D:**

Safe use of Medical Devices

Medical Devices Life Cycle



(Post-market Surveillance)

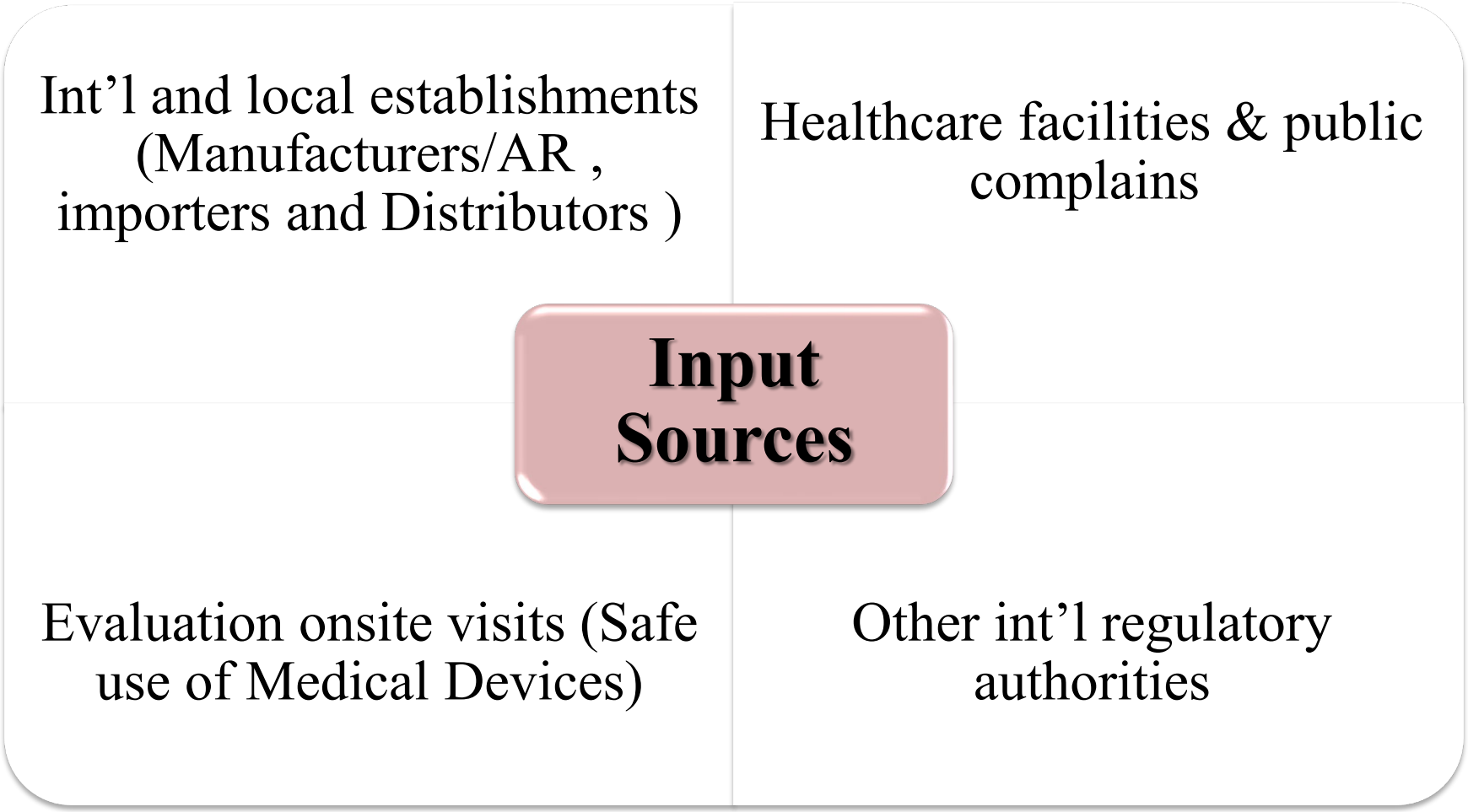
Group of activities carried out by the regulatory authorities and manufacturers to get the necessary data to continuously assess the performance and safety of its medical devices after it has been marketing to ensure the compliance of these medical devices with the regulation requirements of medical devices.

A pictorial view of PMS

Post-Market Surveillance Information is used for:

- Injury prevention
- Product improvement
- Development of standards
- Regulatory refinement

Postmarket Surveillance Inputs



Adverse Events

What is MD Incident (Adverse Event)?

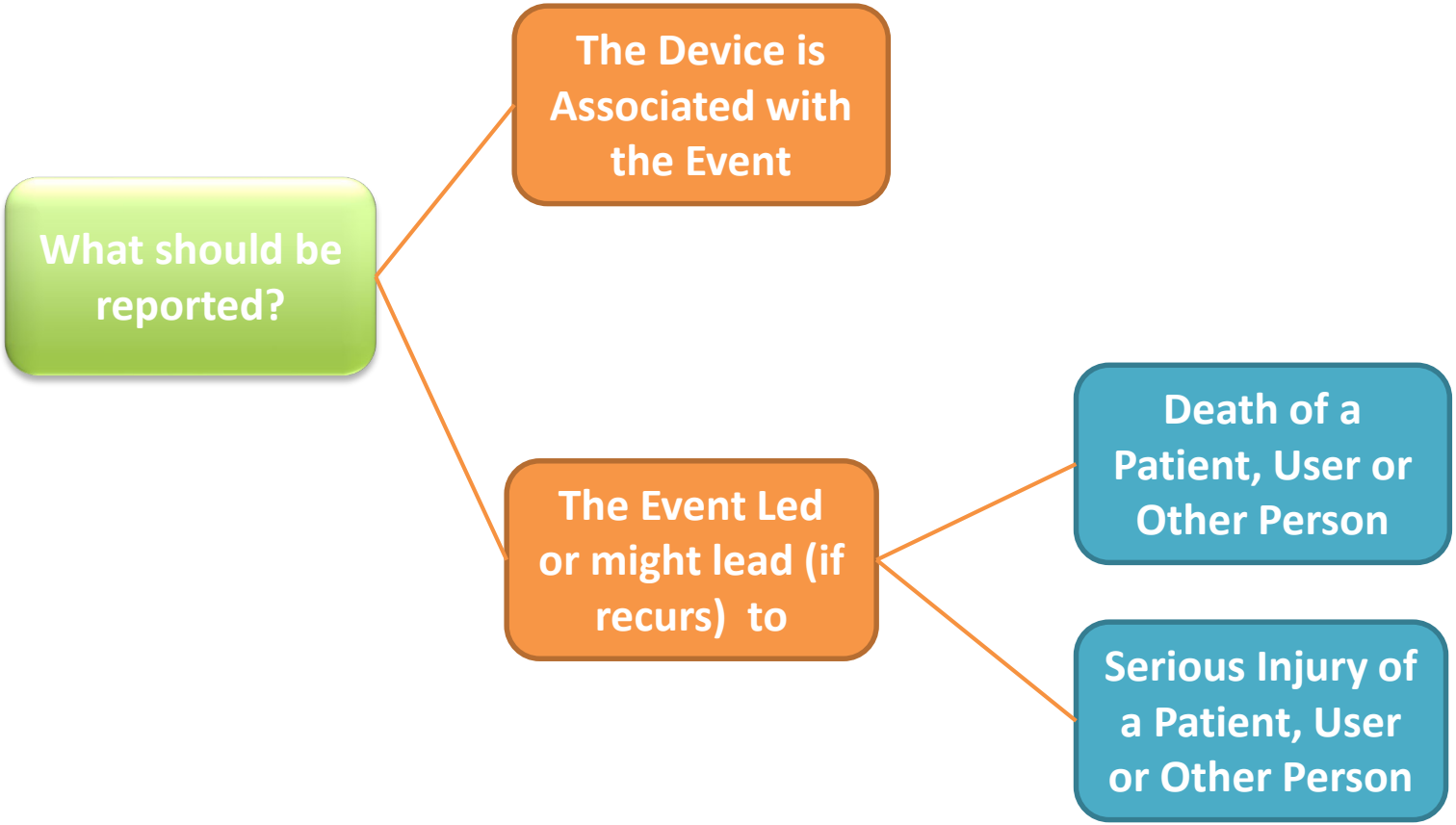
- **Adverse event:** means any malfunction or deterioration in the characteristics and/or performances of a medical device, including any inadequacy in its labeling or the instructions for use which may lead to compromise the health or safety of patients, users or third parties.

- **Reportable Adverse event:** any adverse event or any technical or medical reason leading to a Field Safety Corrective Action, which, directly or indirectly, might lead to or may have led:

  (a) to the death of a patient, a user or another person or

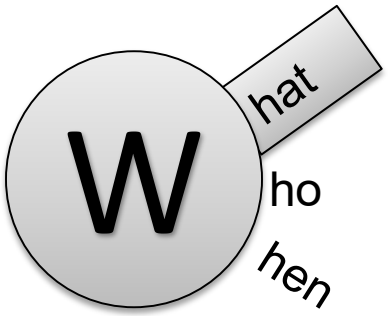
  (b) to a serious deterioration in their state of health.

Reportable Adverse event

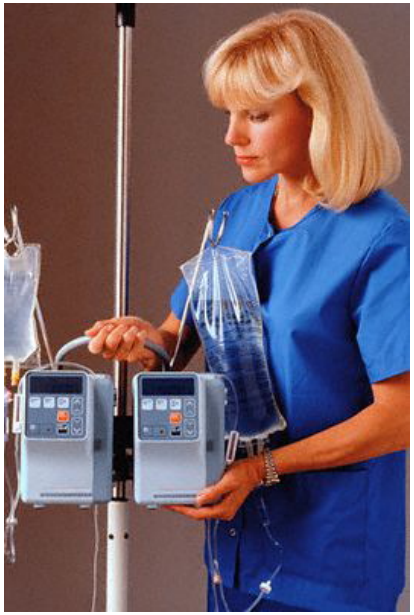


Examples of Adverse Events

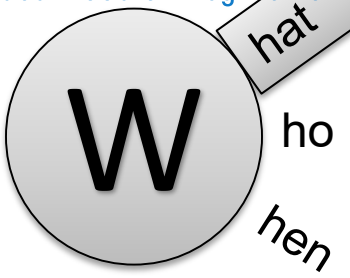
Examples of Medical Devices Problems



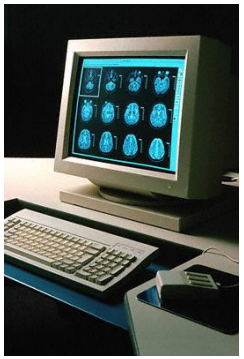
- **Defects :**
  - IV pump bracket found with large crack and sharp edges
  - Surgical gloves found discolored and with holes



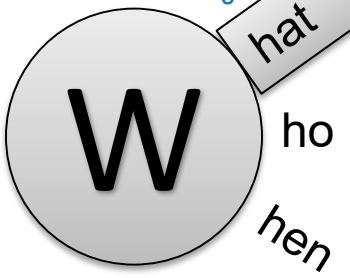
Examples of Medical Devices Problems



- **Software problems**
  - CT scanner found to have a software glitch in new version



  - Virus infects device operating software

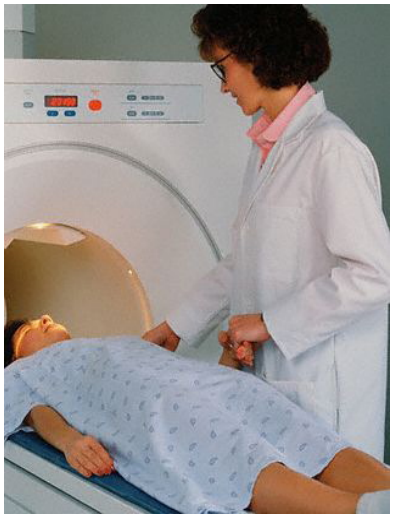


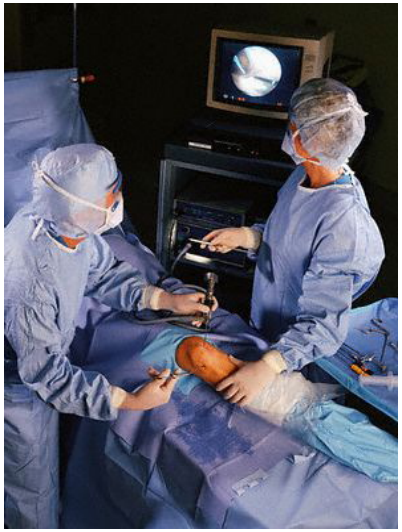
Examples of Medical Devices Problems

- **Failure to work as intended /malfunction:**
  - Electrosurgical fired but did not cut
  - Point-of-care glucose results differ from lab results

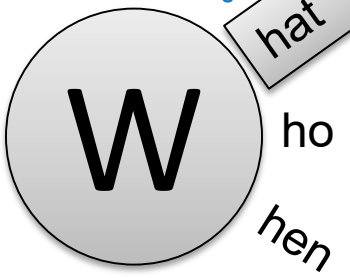
Examples of Medical Devices Problems

- **Interactions with other devices**
  - Burns with use of orthopedic shaver and grounding pad
  - Oxygen cylinder pulled inside MRI machine





Examples of Medical Devices Problems

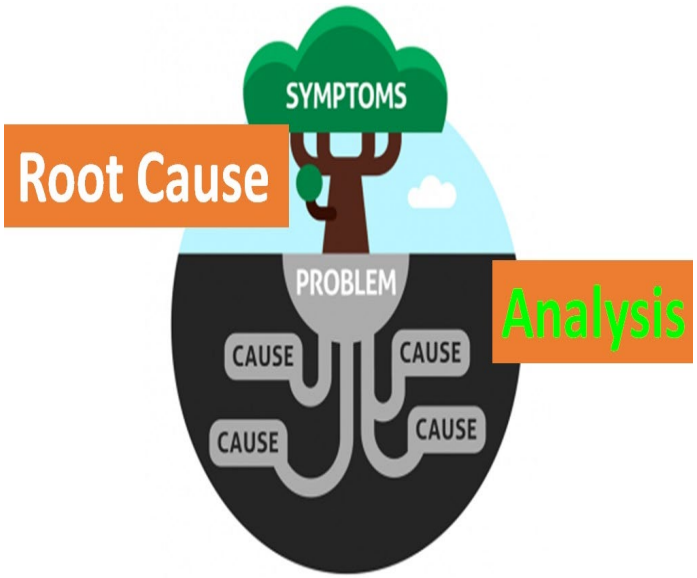


- **Use Errors :**
  - Infusion pumps by the same manufacturer looks similar but operates differently
  - Incorrectly positioned radiant warmer temperature sensor causes overheating

Causes of Device Incident

Causes of Device Incident

- Device related Factors
- External Factors
- Tampering and Sabotage
- Support System Failures
- User Factors



Causes of Device Incident

❑ Device related Factors:

- Device failure
- labeling error
- Manufacturing error
- Packaging error
- Software deficiency
- Component failure
- Accessory Failure
- Device interactions
- Improper maintenance, testing, repair, or lack or failure of pre-use incoming inspection
- Improper modification

Causes of Device Incident

- **External Factors**
  - Power supply failure
  - Medical gas/vacuum systems
  - Electromagnetic EMI or Radio Frequency Interference RFI
  - Environmental conditions
    - Temperature, humidity, light

Causes of Device Incident

❑ Tampering and Sabotage (rare)

1. Family member
2. Patient
3. Healthcare workers (Doctor, Nurse, Aide)
4. Hacking (Cybersecurity)

Causes of Device Incident

- **User Error** – 70% of device accidents
  - Improper connection
  - Incorrect clinical use
  - Incorrect control settings
  - Incorrect programming
  - Failure to monitor
  - Improper Maintenance

Ref: 06 - Human Factors Considerations in Medical Device Accident Investigation - *ECRI 2017.ppt*

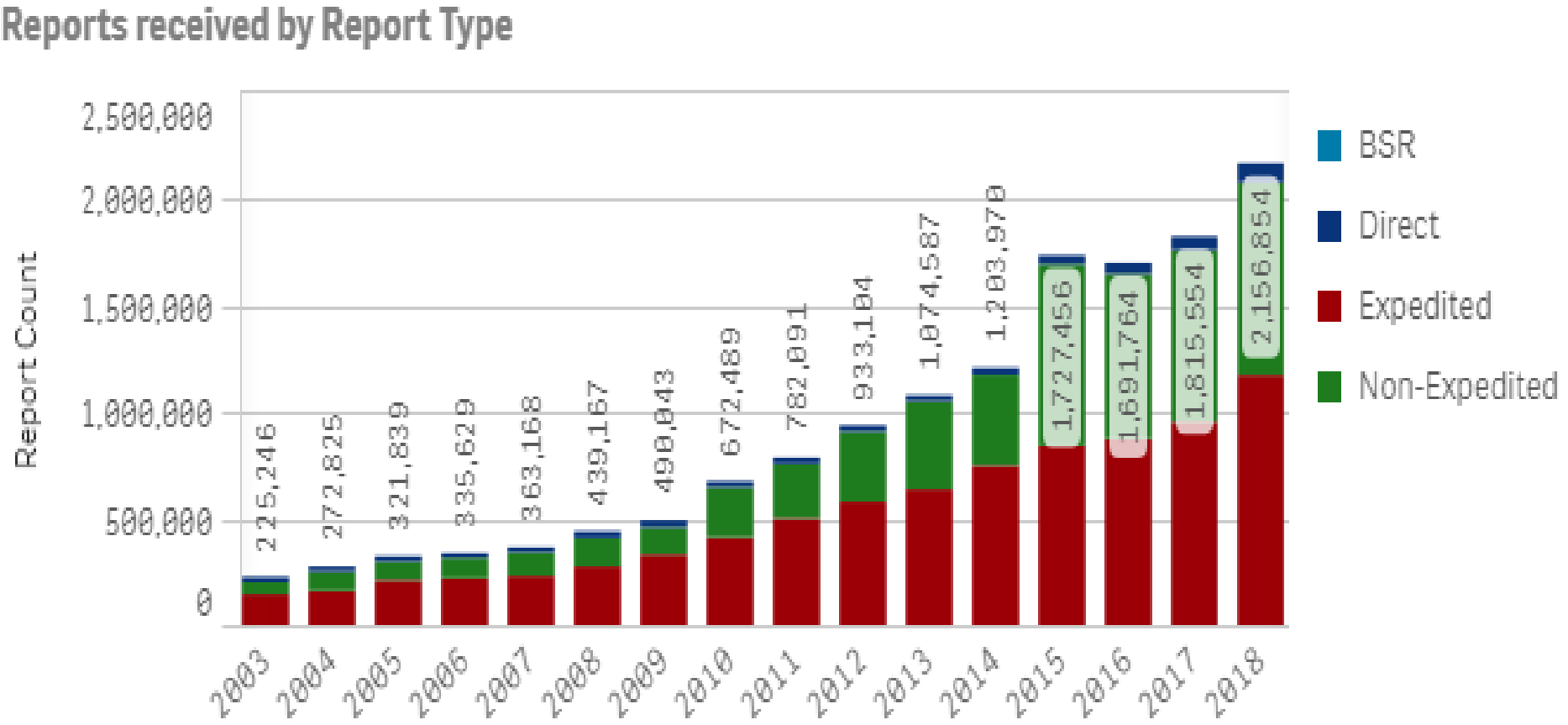
Causes of Device Incident

- **Support System Failures**
  - Using inappropriate devices
  - Improper storage
  - Poor incident/recall reporting system
  - Error in hospital policy

Incident Reports

Global and Local Statistics

MD Incidents Reported in USA



https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/7a47a261-d58b-4203-a8aa-6d3021737452/state/analysis

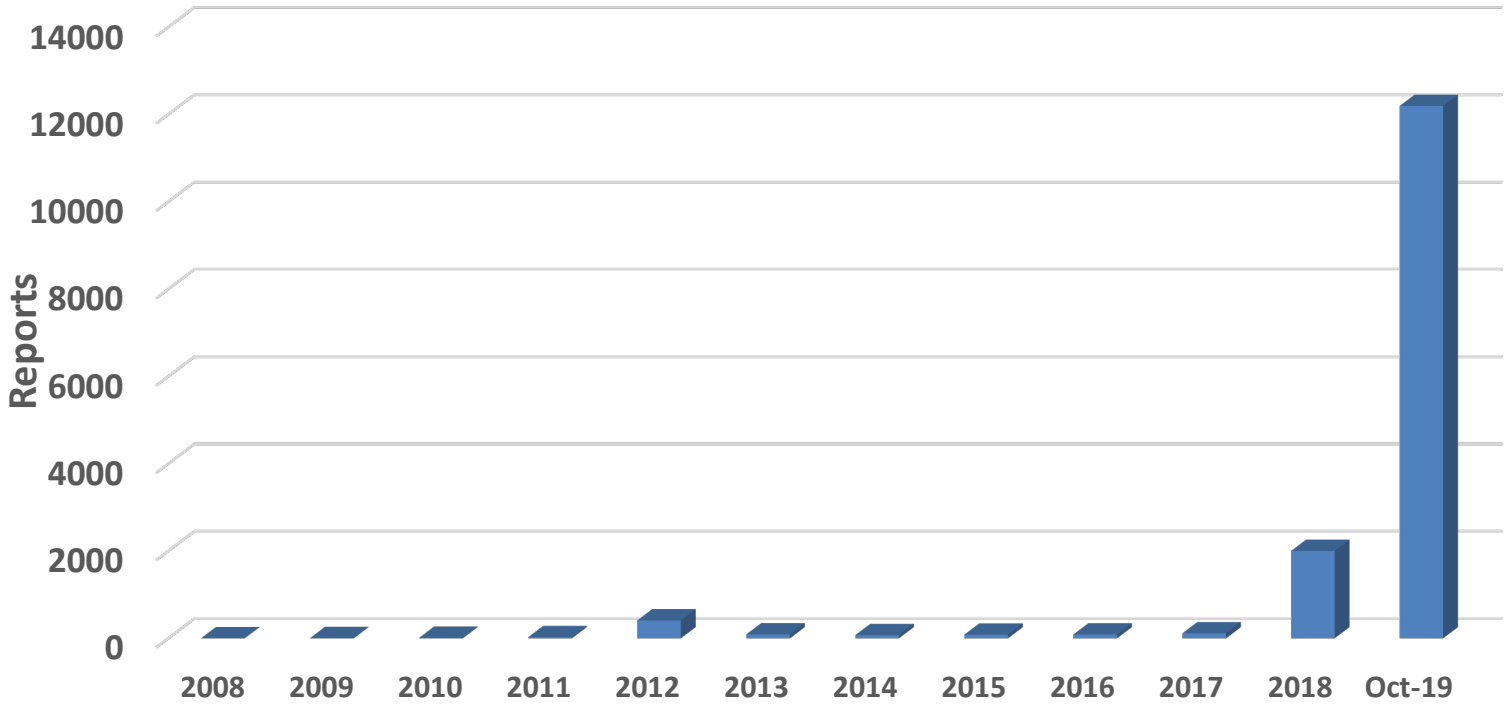
MD Incidents Reported in Australia

This figure illustrates the number of reports in The TGA's Incident Report and Investigation Scheme (IRIS) **by type of reporter** (2015-2017)

Source	2015	2016	2017
Sponsors (AR)	2817	3122	4604
Doctors	45	88	101
Nurses	134	157	109
consumers	88	97	205
Allied health professionals	266	347	351
Total	3359	3841	5370

https://www.tga.gov.au/sites/default/files/medical-devices-post-market-vigilance-statistics-2016.pdf

Medical Devices Incidents Reports in KSA



Incidents vs Adverse Events

Exercises (Reportable or Not)

1. A patient death occurs following the use of external defibrillator. Device shocked appropriately but failed to bring back patient to sinus rhythm and patient expired.

NOT REPORTABLE

2. A patient death occurs following the use of external defibrillator. A malfunction of devices contributed to the patient death.

REPORTABLE

3. An infusion pump delivers the wrong dose because of an incompatibility between the pump and the infusion set used.
   The combination was made against the instructions for use.
   Medical intervention was required to avoid patient injury.

REPORTABLE

Exercises (Reportable or Not)

4. An infusion pump stop due to malfunction of the motor and fails to give an appropriate alarm.
   There is no patient injury.

5. The packaging of a sterile single use device is labeled with the caution: 'do not use if package is opened or damaged'.
   Prior to use, obvious damage to the packaging was observed and the device was not used.

6. The arm of an X-ray vascular system hand uncontrolled motion during patient examination.
   The patient was hit by the image intensifier and injured.

Exercises (Reportable or Not)

8. A catheter fractured during insertion, with no suggestion of inappropriate handling. The fracture occurred in such a position that the broken part could easily be withdrawn. However, this was clearly a fortunate circumstance as if the catheter had fractured in a slightly different position then surgical intervention would have been necessary to retrieve the broken end.

Exercises (Reportable or Not)

9. ISOLATION TRANSPORT BAG

If AE occurred

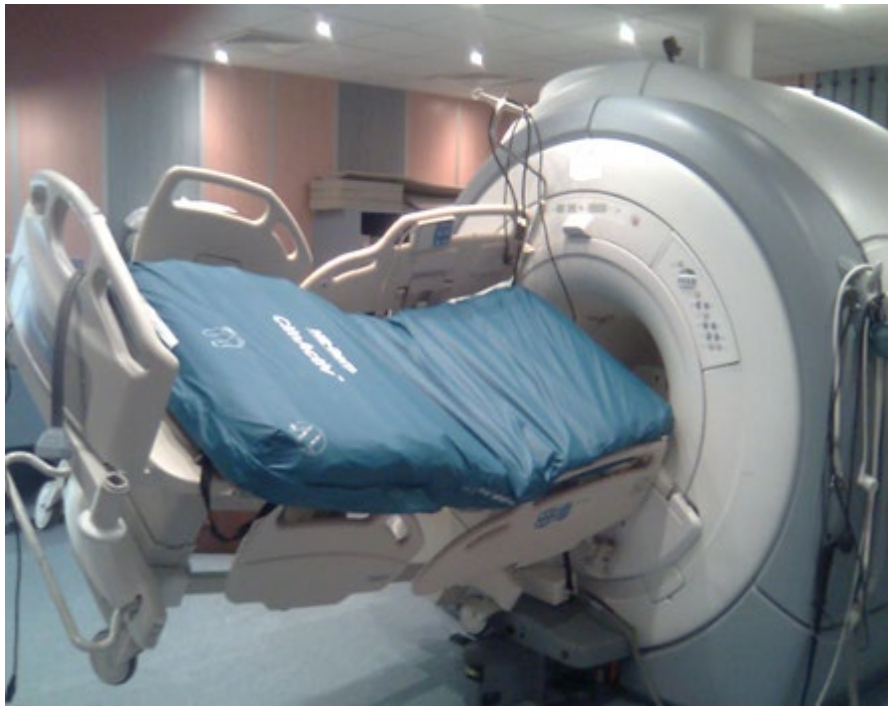
Immediate Actions Plan

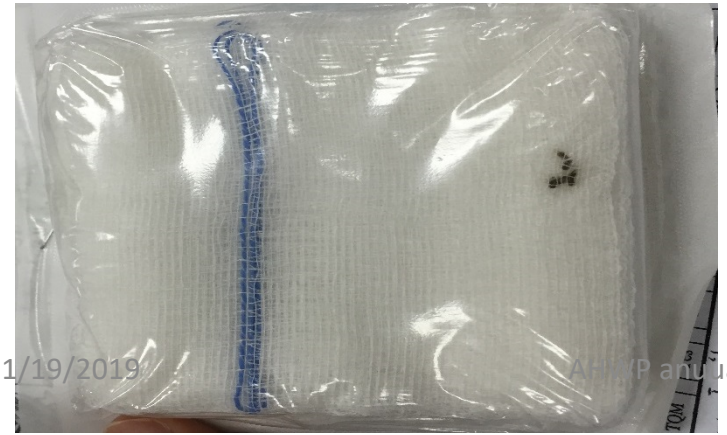
- Protect patient and staff
- Protect equipment / environment
- Isolate equipment (including disposables)
- Record information
- Internal reporting (risk manger. Biomedical engineering)

Preservation of Evidence

- Disposables - Save all!!
- Photographs – Take pictures
- Control Settings – Do not change
- Error codes in device memory!!! (event log) – Do not erase
- Isolating devices and Accessories

Identify, What factors causing these AEs?





Examples on AE Investigation

Water Bag

The result:

- Water bag has exploded on patient.
- A Second degree of burning on Back and Left arm.

The Cause:

- Used High temperature water.
- Fill the bag 95% .
- Lie down top of a hot water bottle.
- There was no instruction for use with device.

The action:

- Device Recall/correction.
- Add instruction for use.
- Safety Communication Notice.

Transport incubator

The result:

- A burn happened with transport incubator while Transport patient from hospital to another hospital.

The Cause:

- The unit is 120V .
- One of the staff nurses changed the power cable from US to UK and plugged it into 220V socket.

The action:

Developing written procedures for handling medical devices

Patient Monitor

The result:

- Suddenly freeze and the image could turn black and there is no more visual representation of the patient data on this monitor.
- Nevertheless, the Patient Monitoring system keeps on working and the audible alarms remain.

The cause:

- electrolytic capacitor on the **invertor board**

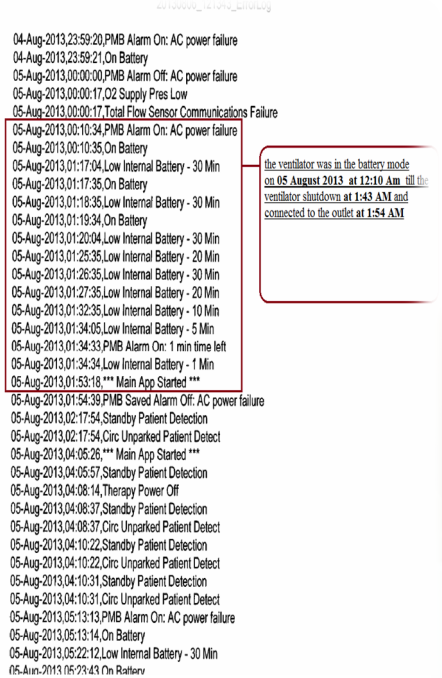
The action:

- SFDA have Request to Manufacturer to Submit a FSN and taking Corrective action.

Ventilator

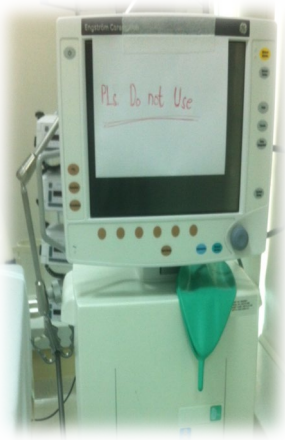
The result:

- Death report
- Investigation team carried out investigations that included checking the device, checking event data stored in the machine's log, and gathering information about the incident.



The cause:

- From the error log , alarm On AC power failure and alarm Off AC power failure are showed many times.
- The device was working on the battery mode.
- Medical staff did not respond to the device alarm and the device stopped working for ten minutes.
- There was a malfunction in the electrical socket



Action:

- Change the electrical socket with new one

Anesthesia

The result:

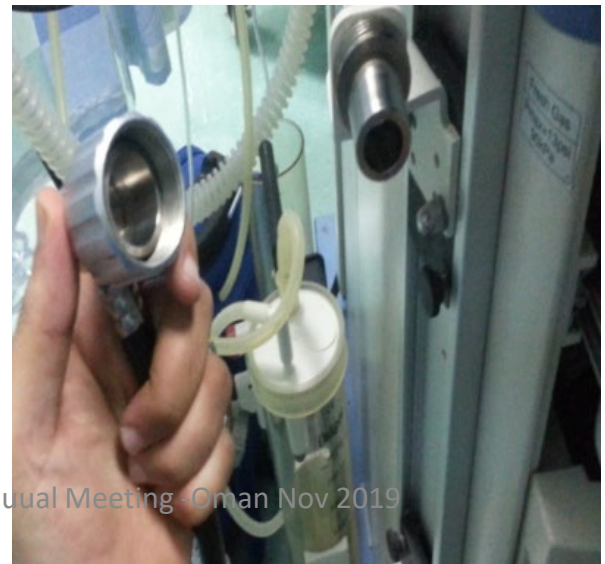
- Death report.

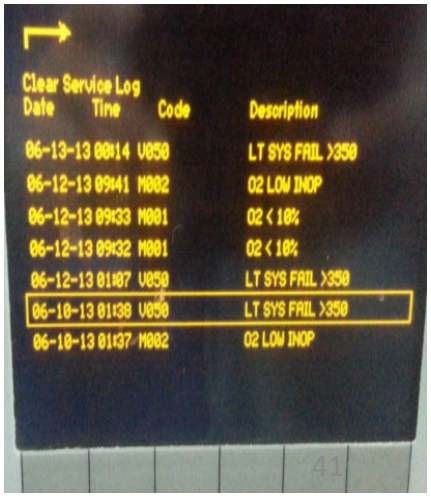
The cause:

- The device works properly and the problem is caused by the user forgetting to reconnect the fresh air hose to the external fresh gas outlet after the previous case.
- Lack of sufficient fresh air reduces the concentration of oxygen in the inhalation, leading to insufficient ventilation for the patient.

The action:

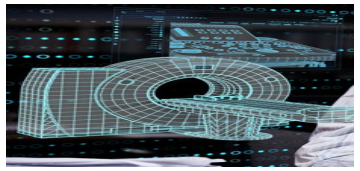
- User training

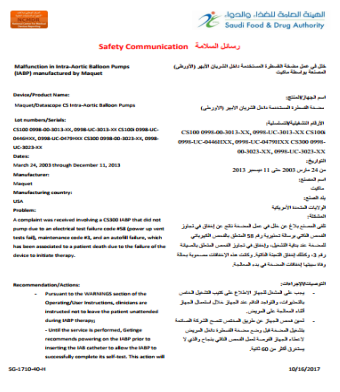




Outcomes of Investigation

- Improved Design
- Improved Instruction/ Labelling /Training
- Device Recall/correction
- Advice to Users /Manufacturers , ..etc
- Suspension license (MDMA, AR,…)
- Safety Communication Notice
- Revised or new guidance





Risk Classification of Adverse Events

Risk Classification of Adverse Events

Calculating risk score using special formula (below). There are four factors influence the risk score:

- A-Severity of injury,
- B-Detectability of occurrence,
- C-Type of incident / likelihood of occurrence
- D-Impact on the Saudi market.

SFDA risk Score = (A+B+C) * D

Risk Classification of Adverse Events

By calculating the SFDA risk score we can determine the risk level

Risk Score	Risk level
3-19	Minor incident (Level1)
20-34	Serious incident (Level 2)
38-48	National crisis (Level3)

Determining the Severity of injury (A)

1. Limited

- ☐ No injury
- ☐ Temporary
- ☐ Self-limiting
- ☐ Minor injury could occur

2. Moderate

- ☐ Prolonged hospitalization
- ☐ Medical intervention required
- ☐ Delay in diagnosis or treatment
- ☐ Incorrect diagnosis or treatment
- ☐ Packaging failure or potential sterility issue
- ☐ Known severe sterility issue

3. Severe

- ☐ Permanent injury and/or impairment
- ☐ Revision of implantable device
- ☐ Surgical intervention required
- ☐ Delay in critical diagnosis, therapy or treatment
- ☐ Incorrect critical diagnosis or treatment

4.Life threatening

- ☐ Life threatening injury
- ☐ Transmission of life threatening infection
- ☐ Death

Determining the Detectability of occurrence (B)

1. **Very likely**

- Fault with the device is very obvious
- The device cannot be used

2. Likely

- Fault with the device is visible

3. Unlikely

- It is not possible to see or detect the fault with the device before use

4. Extremely unlikely

- It is not possible to see or detect the fault with the device at all

Determining the Type of Action / likelihood of occurrence(C)

1. **Trend reporting /User training**

- No similar occurrences
- Occurrence appears isolated
- User error suspected
- Abnormal use

2. Low risk FSCA

- Limited number of similar occurrences
- HCP can intervene / prevent adverse outcome

3. Medium risk FSCA

- High number of similar occurrences
- Single severe occurrence
- HCP may not be able to intervene

4.High risk FSCA

- Multiple severe occurrences
- Occurrence is not obvious to HCP
- Intervention is not be possible to prevent serious adverse outcome

Determining the Impact on Saudi market (D)

1. Limited impact

- Manufacturer trend reports
- Signal reports

2. Low impact

- Low risk FSCA affecting Saudi market
- Low risk Saudi incident
- Local incident directly linked to ongoing FSCA / PSR
- Saudi leads CA (Saudi market not affected)

3. Moderate impact

Medium risk FSCA affecting Saudi market

Medium risk Saudi incident

4. High impact

- High risk FSCA affecting Saudi market
- High risk Saudi incident
- FSCA affecting Saudi market with associated Saudi incident(s)
- Saudi leads CA (Saudi market affected)
- Highly involved issue
- Serious public health issue
- Death directly linked to device

Action taken after calculation:-

After calculating the risk score, there are different action depend on the risk levels as follow:

1- All Minor incidents (Level1) considered as normal tasks “routine”.

2- For Serious incident (Level 2) or National crisis (Level3) will activate the crisis management plan “emergency plan”; and contact Crisis Department.

3- In case of adverse events that meet the below conditions, it will transferred to Biometrics department for further evaluation:

- Adverse Events that are frequently occurring.
- Adverse events that have potential public health impact.
- some cases that the assessment’s team found there is a need to do more clinical trials to ensure safety.

FSN's/ FSCAs Management

What is FSN?

Field Safety Notice (FSN)

A communication to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action (FSCA).

What is a Field Safety Corrective Action ?

Field Safety Corrective Action

An action taken by a manufacturer to reduce or remove a risk of death or serious deterioration in the state of health associated with the use of a medical device that is ALREADY placed on the market. Such actions are notified via a Field Safety Notice.

What type of actions is required?

- **Correction:**

  Addresses a problem with a medical device in the place where it is used or sold.

- **Removal:**

  Addresses a problem with a medical device by removing it from where it is used or sold.

Case studies

Case Study (from AE to FSN)

Affected Product: Ultrasound Probe Cover Kit with Gel Manufactured by YAFHO BIO-TECHNOLOGY CO.

Investigation Summery:

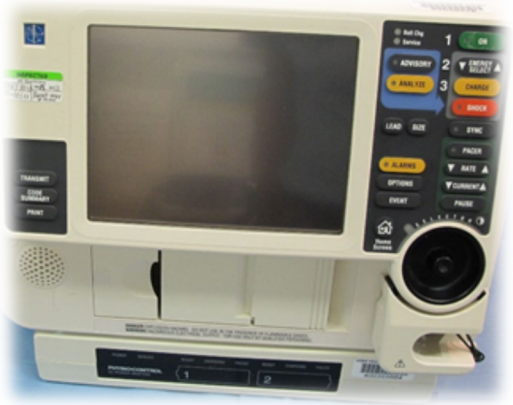
- Start investigation on 8 Jun 2016 and investigator visited the hospital on 9 Jun 2016
- Tests Performed: Sterility test and Organism identification test
- Result showed: Positive contamination of (Burkholderia cepacia) in two lot number.
- Inform POE to stop permeation of device to enter in Saudi market on 14 Jun 2016
- Publish official letter to health care provider officer on 14 Jun 2016.
- Publish safety communication on SFDA web Site on 26 Jun 2016.
- Manufacturer issued a recall about all affected lots

Case Study (Human Factors / Technique of Use)

– Defibrillator Allegedly Malfunctioned during Resuscitation

Brief Overview:

- Patient required synchronized cardioversion
- First sync shock successful
- Second sync shock attempt – defibrillation shock delivered!
- Patient went into ventricular fibrillation
- Patient died
- **Hospital tested the defibrillator and found it to be functioning properly**



Defibrillator Information given by Hospital:

- Sync markers were “temporarily” displayed on the screen
- Electrodes were used (not paddles)
- 1st shock attempt – 200 J, 2nd attempt – 300 J.

Ref:22-2 - Defibrillator - Hypothetical Scenarios – ECRI 2017

Case Study (Human Factors / Technique of Use)

Design Considerations

- Same manufacturer
- Different design

Safety Communications

Safety Communication

- **Safety communication:** a communication provides an important information and recommendations about safety of medical devices, issued by Medical Devices Sector within Saudi-FDA and addressed to public, healthcare providers and/ or health professional.
- These notifications does not necessarily mean a medical device/product is considered to be unsafe
- HealthCare Profissional or Public

Why Reporting is Important

- **Patient safety**
  Prevent future problems and protect our patients, staff, families, and visitors
- **Provide information to manufacturers and/or Saudi Food and Drug Authority**(Build database, monitoring trends)
- **Device Regulation**
  Effect changes in policies and procedures
- **Accrediting agencies** Ex: CBAHI
- **Assist Risk Management with claims or litigation**

Proactive Activities

Definitions

Clinical Investigation

Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety or performance of a medical device. .

Clinical Evaluation

An assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device

Clinical Data

The safety and performance information that is generated from the use of the medical device.

Source of the clinical data:

- Clinical Investigation of the device
- Literature review
- Published or unpublished reports on other clinical experience of either the device or similar device

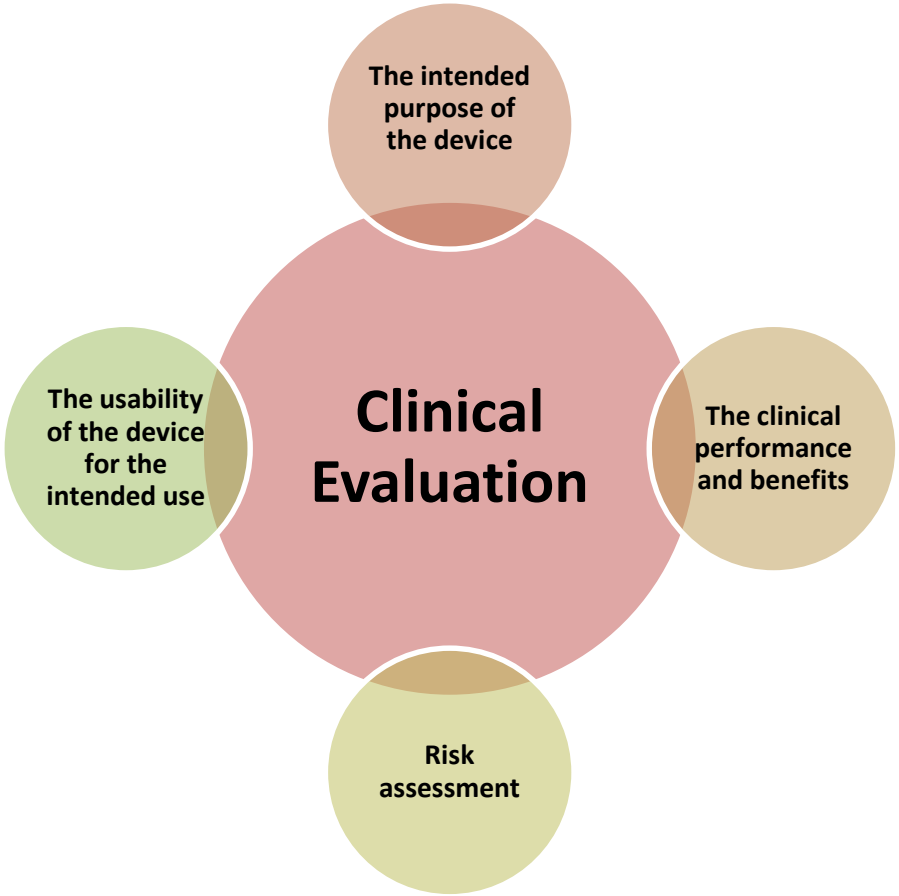
Which medical devices require a clinical evaluation?

All medical devices regardless of their classification

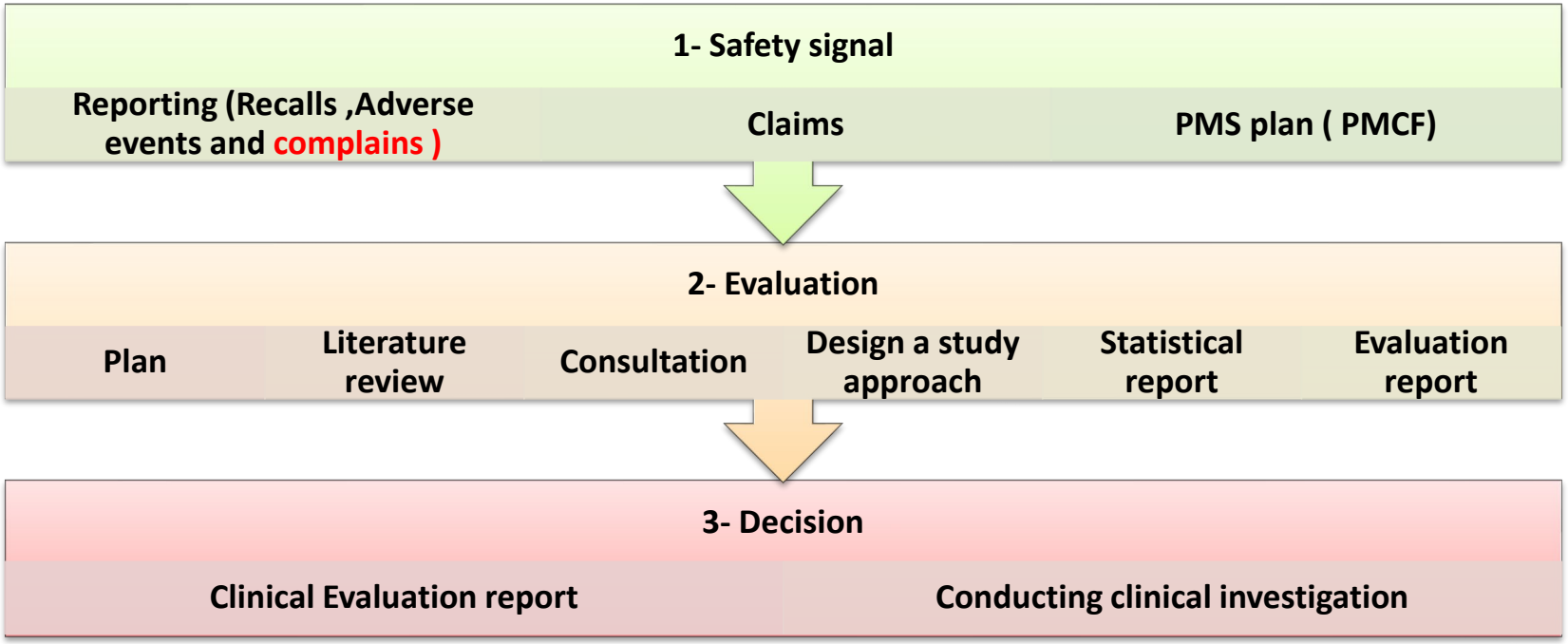
When is the clinical evaluation undertaken?

- An ongoing process, throughout the device's life cycle
- During the conformity assessment process (prior to market the device)
- Mandatory to get CE and must be updated afterwards
- Insufficient clinical evidence. (Approval by equivalent …)

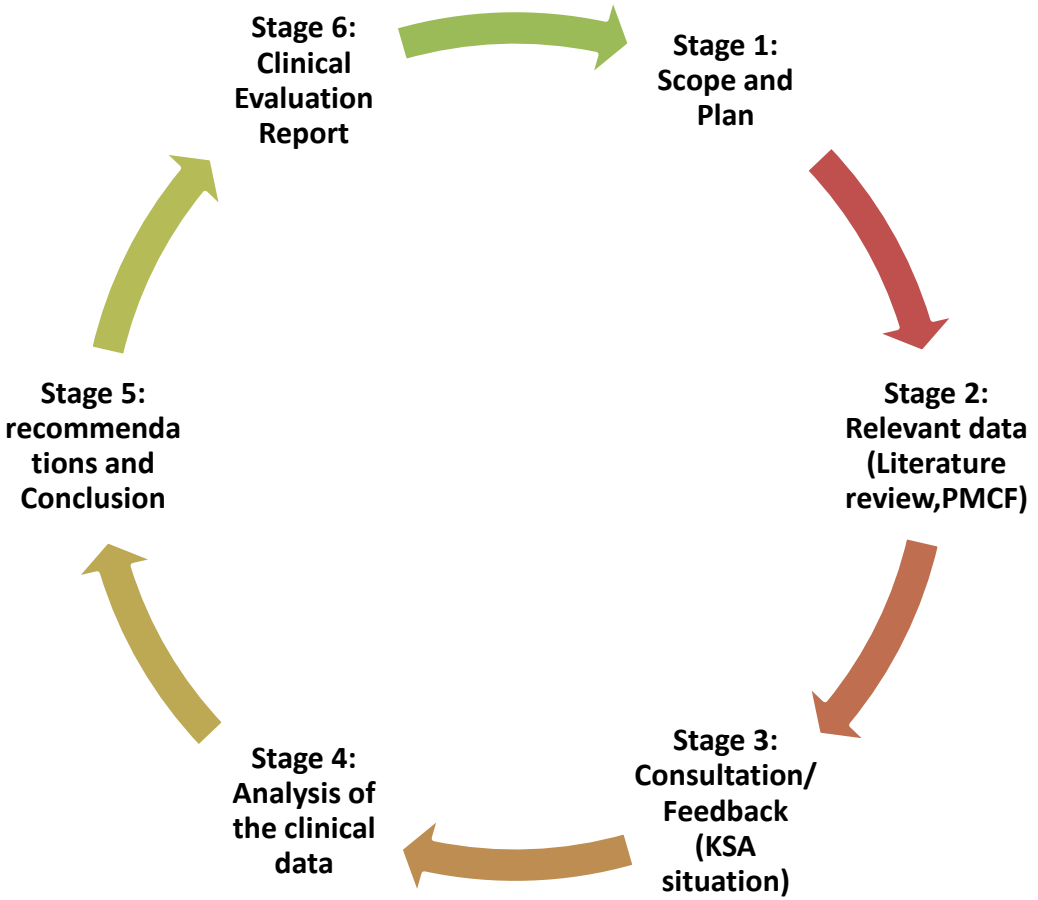
What should the clinical evaluator consider (address) ??



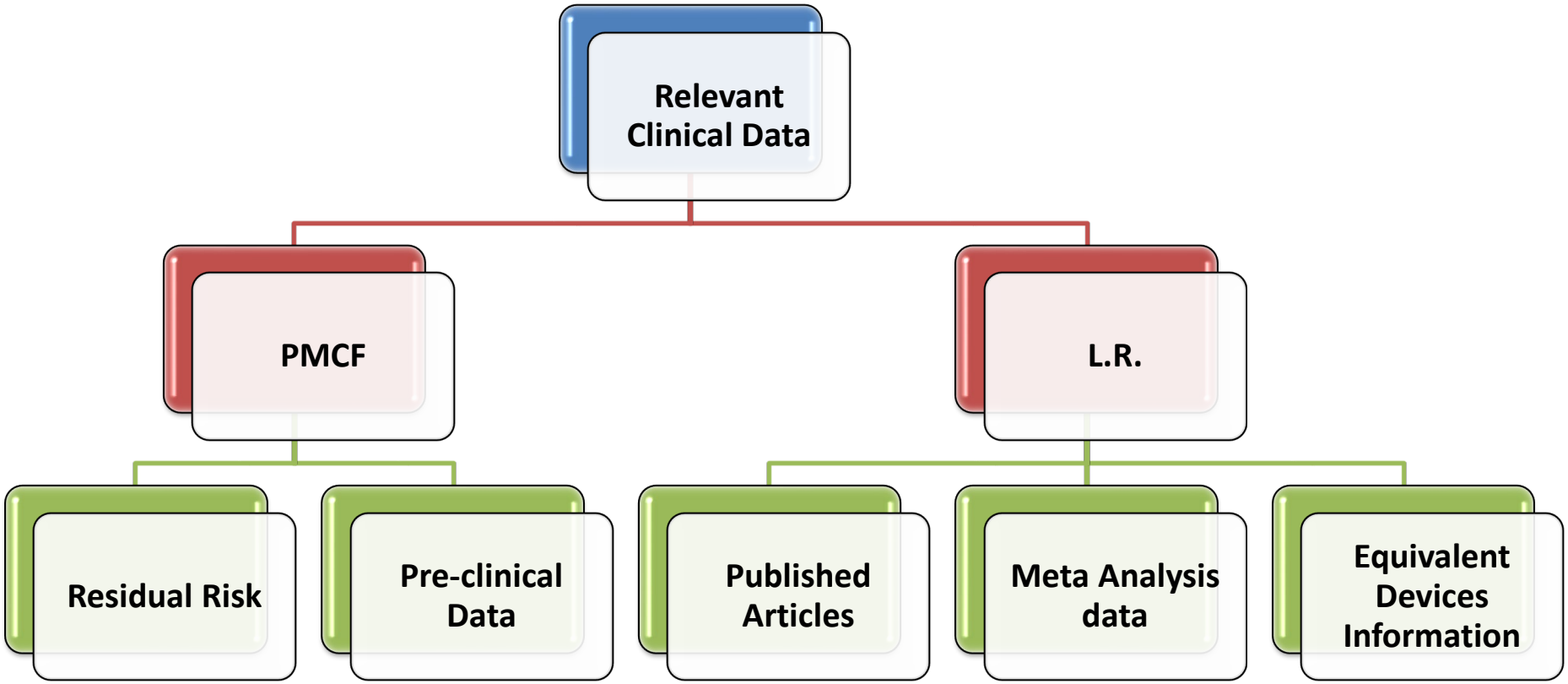
Clinical Evaluation and Investigation routes



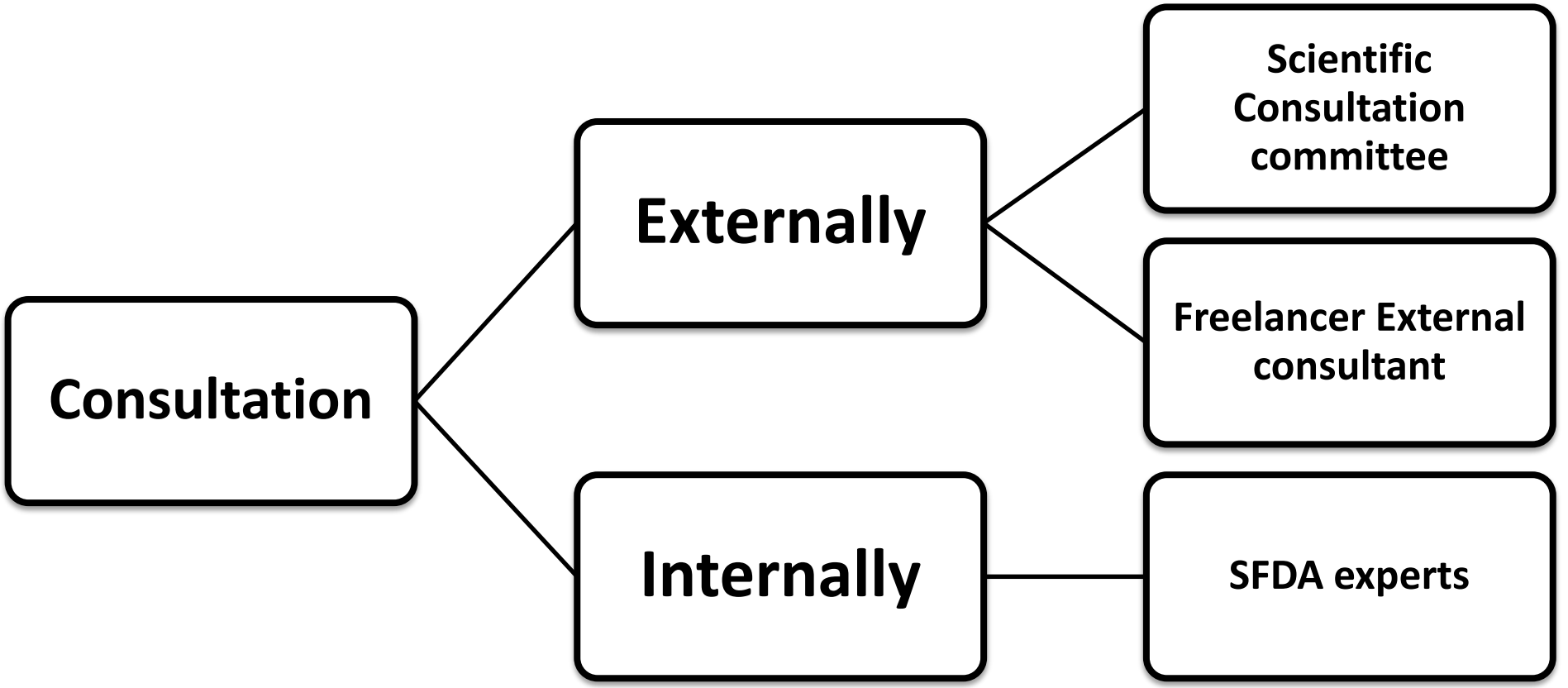
Clinical Evaluation stages



Relevant Clinical Data



Consultation and Feedback



Analysis of the clinical data

The goal of the analysis stage is to determine if the collected clinical data answer the unanswered question regarding the safety and effectiveness of the device

Recommendation and conclusion

- Gather all the deliverable outcomes from the clinical evaluation in the discussion and recommendation section
- Summarize the required action based on the analyzed data in the conclusion section

Safe use of Medical Devices within Healthcare Facilities

Monitoring the Performance of Medical Devices within hospitals

	Current	Future
Monitoring the Performance of Medical Devices within hospitals	• No National requirements for safe use of medical devices within the hospitals in KSA. • There is no effective evaluation process for performance of medical devices during their operation.	• Promote the quality and efficiency of health care through implementing the SFDA Requirements for Quality, safety and effectiveness of medical devices at hospitals • Contribute to reduce the incidents related to calibration, maintenance, poor storage, transportation and disposal medical devices.

Why are we evaluating the use of MDs at healthcare facilities? (Objectives)

- To develop unified national requirements for best practices in medical device management
- To increase the lifetime and reduce the overall cost of health technologies within healthcare facilities.
- To mitigate the risks associated with the usage, transportation and storage of medical devices within healthcare facilities.
- To ensure that medical devices within healthcare facilities:
  - Are utilized appropriately and effectively;
  - Are maintained in a safe and reliable condition;
  - Are operated in accordance with the manufacturer's instructions by trained users and professionals
- To facilitate the periodic monitoring medical devices in relation to the following:
  - Performance and safety inspections;
  - Calibration
  - Reporting and tracking of related adverse events.

Advantages of following the requirements

- Safety
  - patients
  - operators
  - others
- efficiency
  - Enhance the quality of care.
- Economic
  - Extend the life of the device
  - proper management of property
  - Unifying the criteria and procedures of safety and performance.

How are we performing the evaluation?

- Through,
  - Developing a guideline that specifies the SFDA requirements,
  - Delivering the requirements into healthcare facility in a first meeting, and
  - Evaluating the implementation of such requirements in a follow-up evaluation

How are we performing the evaluation?

Policies, Procedures, and implementation in:

- Establishments & Products Approvals
- AEs Reporting
- Follow-up with SFDA Recalls
- Clinical investigation & Ads. Approvals

نظام الترخيص الالكتروني لمنشآت الأجهزة والمنتجات الطبية
MDELS
Medical Device Establishement Lecince

نظام الإذن بتسويق الأجهزة والمنتجات الطبية
MDMA
Medical Devices Marketing Authorisation

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

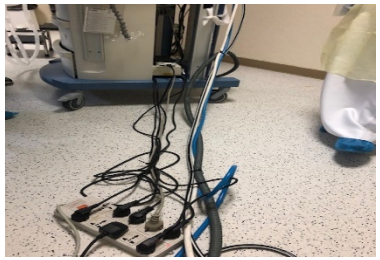
How are we performing the evaluation?

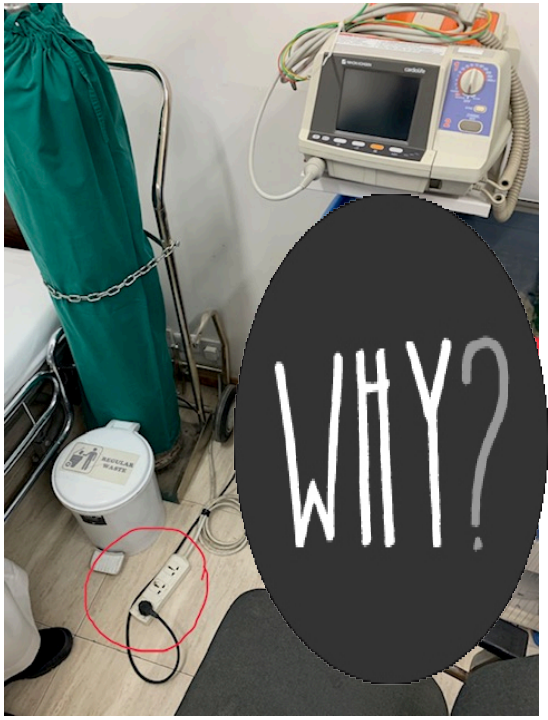
Policies, Procedures, and implementation in:

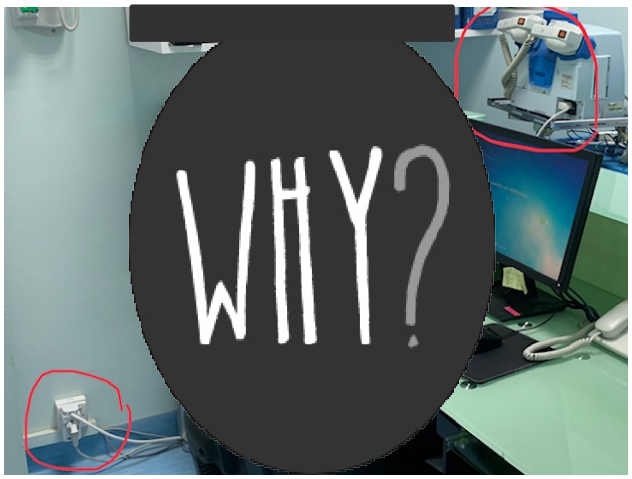
- Asset Management
- BME/BMT Qualifications & Trainings
- Manuals Availability
- Well-Equipped Workshop(s)
- Electrical Safety Tests
- Intended and Proper Use
- Appropriate Spare Parts
- Recommended accessories
- PPM and CM
- Calibration Tests
- Transport & Storage
- Disposal

What are the major outcomes (so far)?

- Most frequent observations:
  - Electricity (plug & socket compatibility)
  - Missing PPM tags
  - Lack of user and service manuals
  - Lack of user and service training

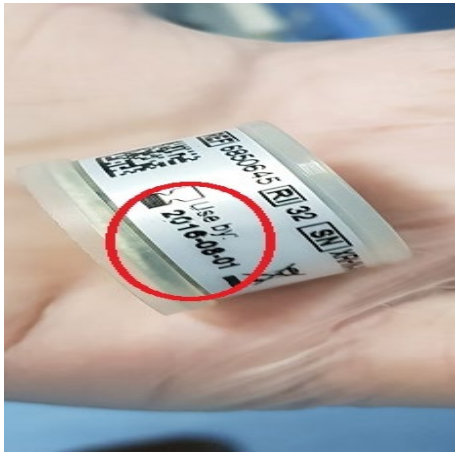






What are the major outcomes (so far)?

- Most frequent observations:
  - Expired oxygen sensors (ventilators)



Postmarket Surveillance

Thank You

Saudi_FDA