Focus on
patient safety

MEASURING
& IMPROVING
QUALITY

Implantable medical devices (IMDs)

7 December 2023

It could happen to you too

Event 1

ERROR IN TYPE OF IMPLANT FITTED REQUIRING ANOTHER PROCEDURE

A Female patient aged over 60 years is hospitalised in a surgery ward for a breast reconstruction following breast carcinoma. The procedure is carried out normally. However, the following day, she is informed that another procedure has been planned to replace the breast implant fitted.

What happened? *Immediate cause*

The surgeon fitted a gluteal implant (buttock implant) instead of a breast implant.

Why did it happen? *Root causes, barriers absent or deficient*

- The healthcare organisation **failed to set up a safeguarded implantable medical device** (IMD) circuit:
  - when the IMD was ordered:
    - the surgeon selected the implant between two appointments and informed their secretary verbally,
    - the pharmacist did not check the implant reference before placing the order;
  - on receipt of the IMD at the operating theatre, no feedback was sent to the pharmacy as to its conformity, or from the pharmacist to the surgeon.
- **There was a failure to comply with best final pre-implantation verification practice by the team:**
  - the surgeon did not check the implant prior to the procedure;
  - during room preparation, the team did not check the implant despite completing the surgery checklist.
- **There was a failure to comply with best IMD traceability practice in accordance with regulations**
  - the healthcare organisation had not purchased IMD traceability software, which prevented them from carrying out **real-time** traceability, **at each stage** and by **each actor**, of the IMD circuit in the healthcare organisation's information system;
  - there is no operating theatre IMD traceability.
- The buttock implant and breast implant references were very similar.
- A warning issued by the French National Agency for Medicines and Health Products Safety and passed on by the healthcare organisation's pharmacy mentioned the difficulty in differentiating between the two types of implants, but the surgeon had not read it and the pharmacist did not make the connection at the time of the order.
- The healthcare professionals present were not familiar with the term “gluteal”.

Event 2

PERCUTANEOUS IMPLANTABLE PORT CATHETER (IPC) INSERTION ERROR LEADING TO PLEURAL EFFUSION

A Female patient aged over 70 years is hospitalised following sigmoid colon adenocarcinoma. A percutaneous implantable port catheter (IPC) is fitted as part of an adjuvant chemotherapy regimen. During the first chemotherapy session, the patient presents with a pulmonary complication (pleurisy) requiring intensive care where she is intubated and her chemotherapy is postponed.

What happened? *Immediate cause*

The implantable port catheter was implanted into the right intra-pleural cavity.

Why did it happen? *Root causes, barriers absent or deficient*

- **The various healthcare professionals failed to comply with best IPC implantation practice:**
  - no venous return was observed immediately after implantation in the perioperative period;
  - no check was conducted that the catheter had been positioned correctly with opacification in the perioperative period;
  - the junior doctor encountered problems during implantation on account of the patient's corpulence. He did not request assistance from a senior doctor while in difficulty.
- **There was a failure to comply with best traceability practices:** the operative report incorrectly mentions the presence of venous return as it was prefilled before the procedure was carried out.
- **Best IPC-related administrative practice was not implemented:**
  - The nurse recorded the lack of venous return in the patient record, but the prescribing physician approved the administration of chemotherapy after the nurse injected "saline solution" without any issues (falsely reassuring practice; the guidelines for an effective flush consist of injecting 10 ml of 0.9% NaCl using a series of pumping actions);
  - despite the fact that reflux had still not been observed, a chest X-ray was not carried out to check that the catheter was positioned correctly before administering the first chemotherapy.
- The implantable port catheter was fitted in a context of stretched human resources and a very busy outpatient chemotherapy department.

Event 3

EYE IMPLANT ERROR LEADING TO IMMEDIATE FURTHER SURGERY

A male patient aged over 70 years undergoes cataract surgery under local anaesthetic. However, when he returns to his room, he is informed that he will need to undergo another corrective procedure, on the same day, on the eye that has just been operated on.

What happened? *Immediate cause*

The patient received an intraocular implant intended for another patient.

Why did it happen? *Root causes, barriers absent or deficient*

- For organisational reasons, while a female patient was already in an operating room with the implant to be fitted, she was transferred to another room. However, the implant intended for her remained in the room. The patient initially scheduled after her was admitted to the operating room, in her place.
- **There was a failure to comply with best final pre-implantation verification practice by the team:** after amending the operating list, the surgeon and the nurse forgot to complete the operating theatre checklist including checking that they had the right implant for the right patient.
- **Best patient identification vigilance practice was not applied:** during the procedure, the nurse took the implant for the initially scheduled patient and called out the type of implant. The surgeon verbally approved the implant without checking the consistency between the prescription, the proposed implant and the patient's identity.
- All the implants from the list had been prepared the previous day and were all stored in the ophthalmology theatre. There was a failure to perceive the purpose of the procedures by the locum surgeon who did not work regularly in this theatre (1 morning per month).

Keywords: *IMD - implant - traceability* - checklist – *patient identification vigilance*

So it doesn't happen again

In France, medical device use is subject to particular regulations (R. 5211-17 of the French Public Health Code). The medical device circuit, from order to use, includes many stages and involves many actors, all representing potential sources of errors. To prevent these errors, **these regulations are applicable to all healthcare organisations, that is to say**:

- **completion of real-time IMD traceability (using the unique device identification [UDI])**[1] in the healthcare organisation's information system, at each stage and by each professional involved:
  - the electronic in-house pharmacy **order** from the manufacturer is prepared based on department requests,
  - **all IMDs entering the HCO must be tracked and safeguarded:** after conducting a consistency check between the order and the delivery, the in-house pharmacy registers the IMD received in the organisation's IS in real time using the UDI,
  - the in-house pharmacy registers the data concerning **the dispensing of the IMD** to users in the IS by scanning the UDI,
  - **receipt** by the user department involves performing a comparison between the request made and the IMDs supplied. It is validated in real time by the user department and is registered.
  - **when the MD is used**, the date of implantation, patient identification, practitioner's name will be tracked in real time in the organisation's IS and in the patient record,
  - **after the procedure**, the patient will be given an implant card indicating the IMD identification, the location and date of implantation and the practitioner's name. The same details will be provided in the discharge letter and letter to the attending physician;
- **implementation of an IMD circuit quality management system in the healthcare organisation,**[2] in order to organise safeguarded, appropriate and tracked use of the implantable medical device in patients, including health professional training and awareness on IMD use, monitoring, and traceability prior to any use;
- **regulations must be accompanied by compliance with best final pre-implantation verification practices:**
  - **one week before the procedure**, check the availability of the IMD and its accessories, its conformity and ensure consistency between the prescription and the IMD received,
  - **on the day of the procedure**, use a materials checklist prior to any scheduled procedure, comply with best patient identification vigilance practice to ensure use of the right IMD for the right patient at the right time.

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
2. Order of 8 September 2021 concerning implantable medical device circuit quality management in healthcare organisations and cosmetic surgery facilities, Reference: SSAH2126932A ELI – French Official Gazette No. 0217 of 17 September 2021.

Focus on patient safety collection

The "Focus on patient safety" collection aims to raise awareness among healthcare professionals as to risk management based on care-related adverse events that they have been confronted with and which are always associated with a series of dysfunctions. Each focus covers a specific and recurrent risk based on care-related adverse events, identified and selected from national care-related serious adverse event reporting databases or doctors' accreditation. This focus on patient safety concerns failures at all stages of the IMD circuit, from supplier orders to use in patients. For this specific focus, the events are not described in their entirety and the analyses reported focused on root causes linked to poor management of this circuit and of the IMD itself.

Find out more

Haute Autorité de santé. Focus on Patient Safety [Online] 2021.

Observatory for Drugs, Medical Devices and Therapeutic Innovations, Eastern Region. Assessment of criteria linked with medical devices in the context of healthcare organisation certification. Nancy: Observatory for Drugs, Medical Devices and Therapeutic Innovations; 2022.

Observatory for Drugs, Medical Devices and Therapeutic Innovations, Brittany. Safeguarding the Implantable Medical Device (IMD) circuit. Process mapping. Quick reference guide. Quimper: Observatory for Drugs, Medical Devices and Therapeutic Innovations; 2023.

Observatory for Drugs, Medical Devices and Therapeutic Innovations, Auvergne-Rhône-Alpes. Guidance for the implementation of the order of 8 September 2021.

Order of 8 September 2021 concerning implantable medical device circuit quality management. Lyon: Observatory for Drugs, Medical Devices and Therapeutic Innovations; 2021.

Haute Autorité de Santé. Equipment checklist 48 hours before any planned procedure. Saint-Denis La Plaine: HAS; 2023.

Haute Autorité de Santé. Drafting a personalised surgical/procedure safety checklist. Saint-Denis La Plaine: HAS; 2022.

Observatory for Drugs, Medical Devices and Therapeutic Innovations, Centre-Val de Loire. Best practice for Implantable Port Catheter (IPC) use. Tours: Observatory for Drugs, Medical Devices and Therapeutic Innovations; 2014.

The HAS would like to extend its thanks to the Observatory for Drugs, Medical Devices and Therapeutic Innovations (OMéDITS) who helped proofread this focus.

HAS
HAUTE AUTORITÉ DE SANTÉ

Advancing quality in the fields of health and social care services