

CONTEXT

Implantable medical devices (IMD) traceability is managed in two ways at our hospital :

Cardiology



= Digital traceability process (DTP) using the unique device identifier (UDI)

VS.

Operating theatre



= Manual traceability process (MTP) with retrospective adjustment by the hospital pharmacy

OBJECTIVE



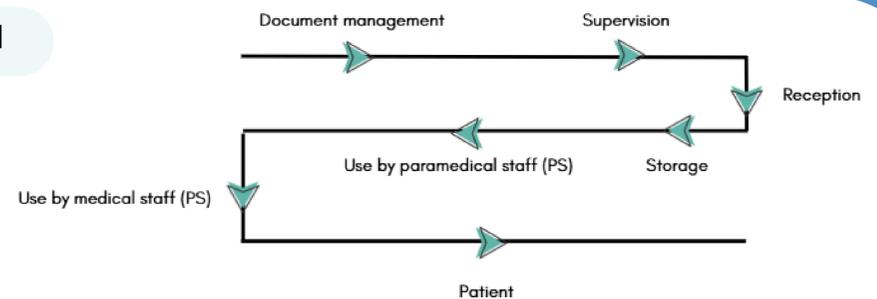
The objective is to assess the actual implementation of the IMD process according to the traceability method used.

METHODS

Use of an audit grid proposed by OMEDIT Ile-de-France¹



- Period : 4 months (June 2025 to September 2025)
- 30 min for each audit
- Team: 1 pharmacist and 2 residents

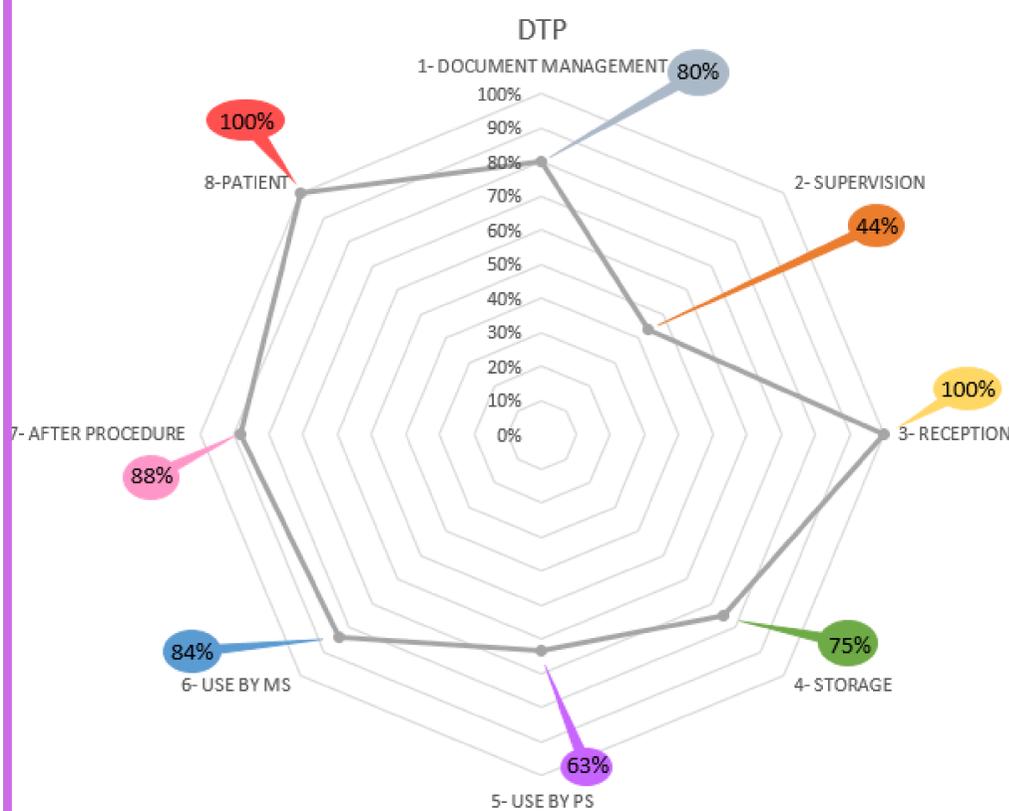


The patient-tracer methodology was applied to evaluate the entire process, including document management (processes), supervision (health executives), reception and storage (logistic agents), and the use of devices by medical staff (MS) and paramedical staff (PS), as well as patient information and traceability

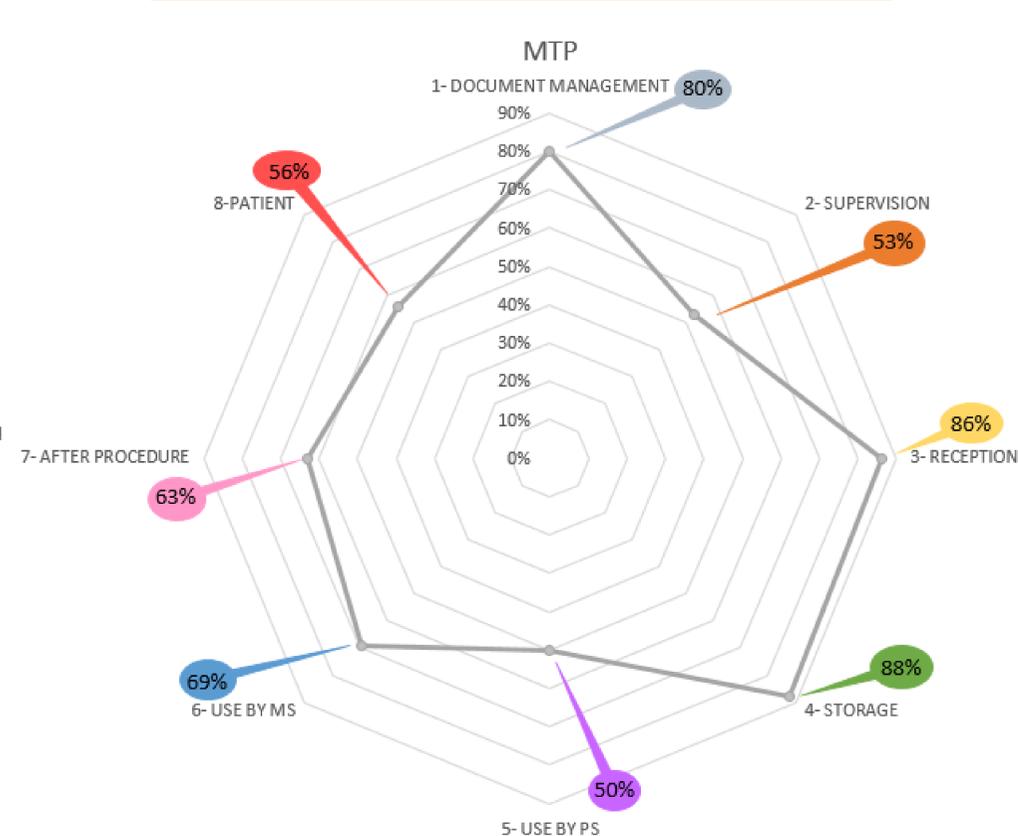
RESULTS

Digital traceability process (DTP) (Cardiology)

Manual traceability process (MTP) (Operating theatre)



14 individuals audited including 2 patients



42 individuals audited including 6 patients

REVELANCE

Digitalisation of the traceability process using the UDI :

- allows better control of the IMD process
- improves patient information
- has no impact on the quality of management and supervision

- Storage is managed by rigorous pharmaceutical staff in the MTP, which improves results
- Both processes share common improvement areas, including staff training and proficiency in adverse event reporting and medical device vigilance



Discharge documents are not always explained to patients:
Only 3 out of 8 patients remember being informed about the implant card before discharge.

CONCLUSION

- This project provided an opportunity to engage with all staff involved in the IMD process.
- Creation of training for MS and PS on the shortcomings observed with a Wooclap® of 20 multiple-choice questions.
- Digitalisation of the IMD process for the operating theatre is planned for 2026.
- A project of pharmaceutical consultations on the implant card for patients leaving surgery is born.

