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## INTRODUCTION

Implantable Medical Devices (IMD) are subject to **sanitary traceability**:

- defined in R5212-36 to R5212-42 articles of the French Public Health Code, then in decrees of 29/11/2006, 26/01/2007 and 08/09/2021
- evaluated by the contract for the improvement of quality and efficiency of healthcare (CAQES) thanks to regional indicators

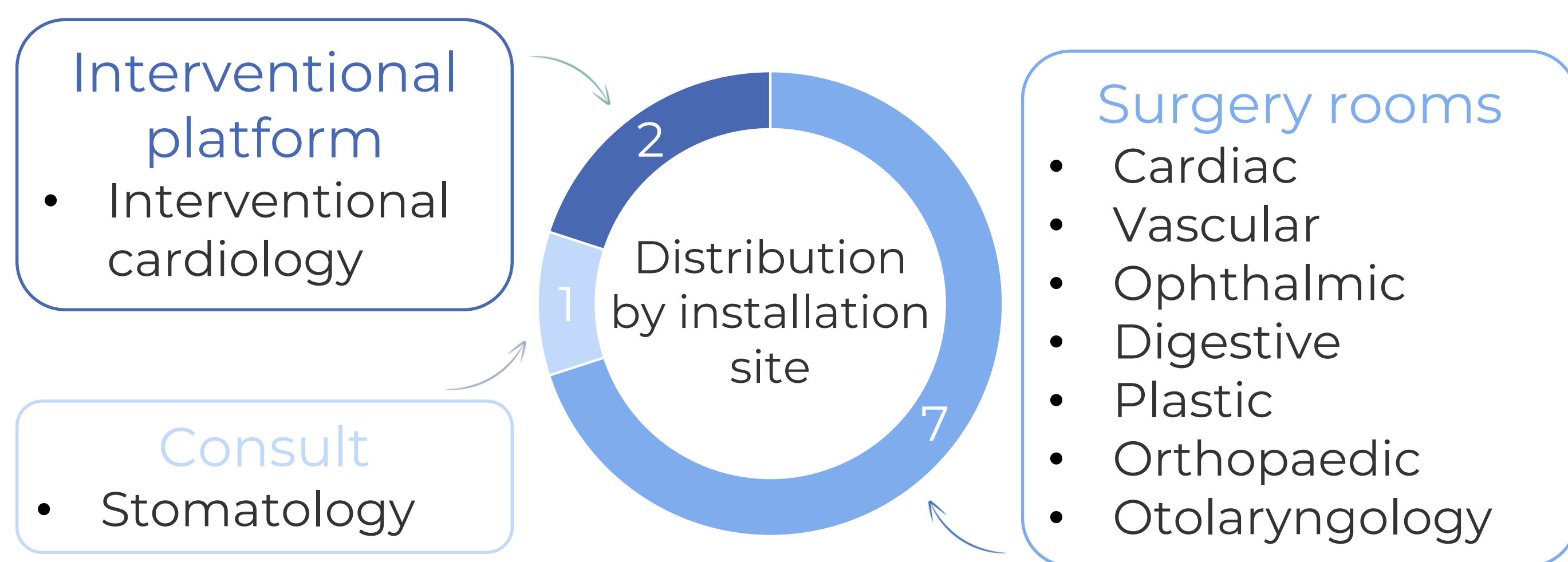
## OBJECTIVE

To evaluate the **quality** of health traceability in our establishment

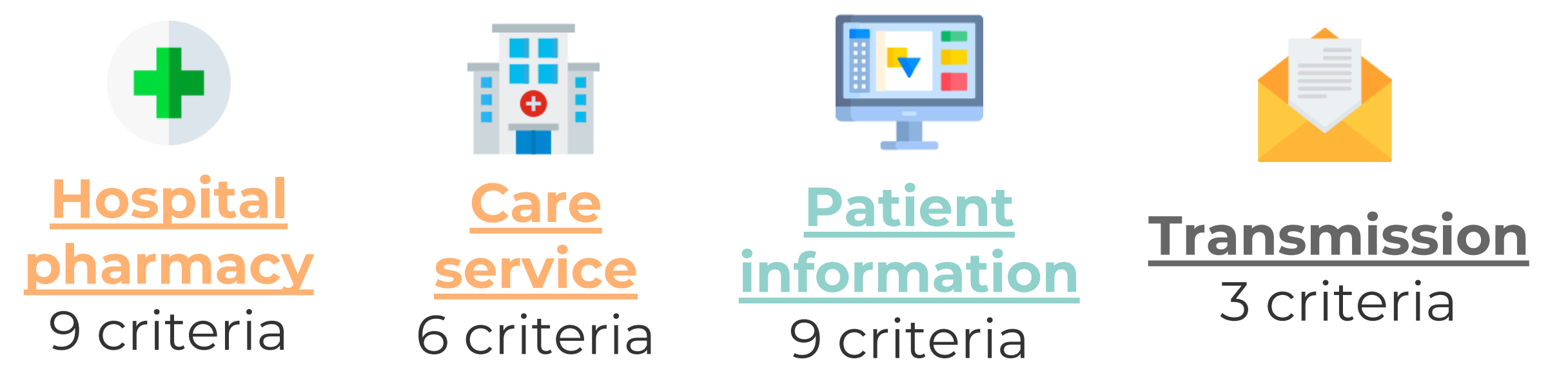
## MATERIALS AND METHODS

Selection of **10 tracer IMD references**, representative of :

- establishment's activity ;
- reimbursement status ("intra-GHS": 3 / "hors-GHS": 7) ;
- management methods (purchase: 4 / deposit: 6).



The evaluation grid consists of **27 criteria** distributed across **4 domains** :



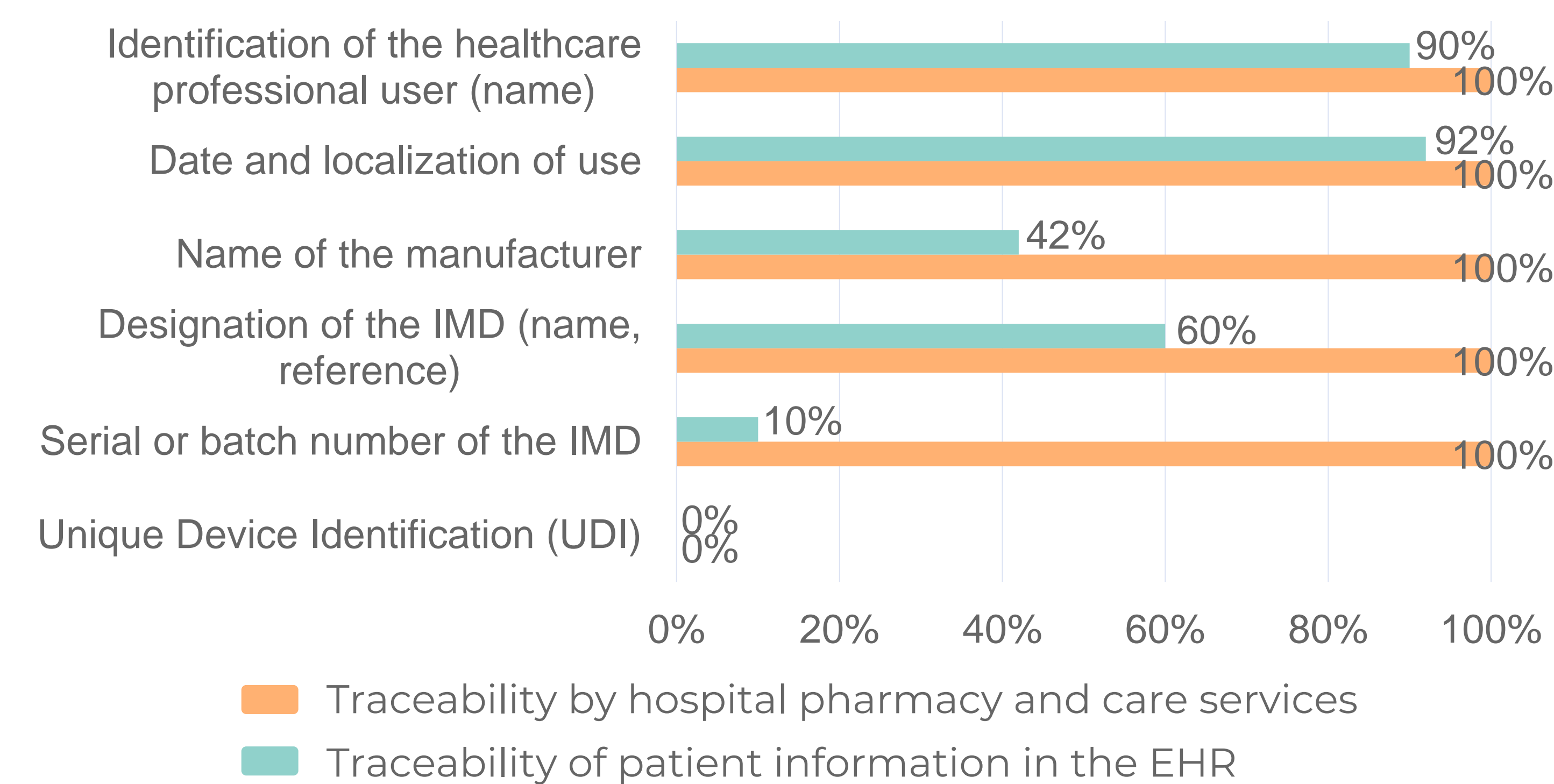
→ **Retrospective analysis of the year 2022 based on 50 implantations of MD** (selected from the 10 tracer IMD references).

→ Comparison with the analysis conducted in 2020 (excluding 8 criteria) – see QRCode –



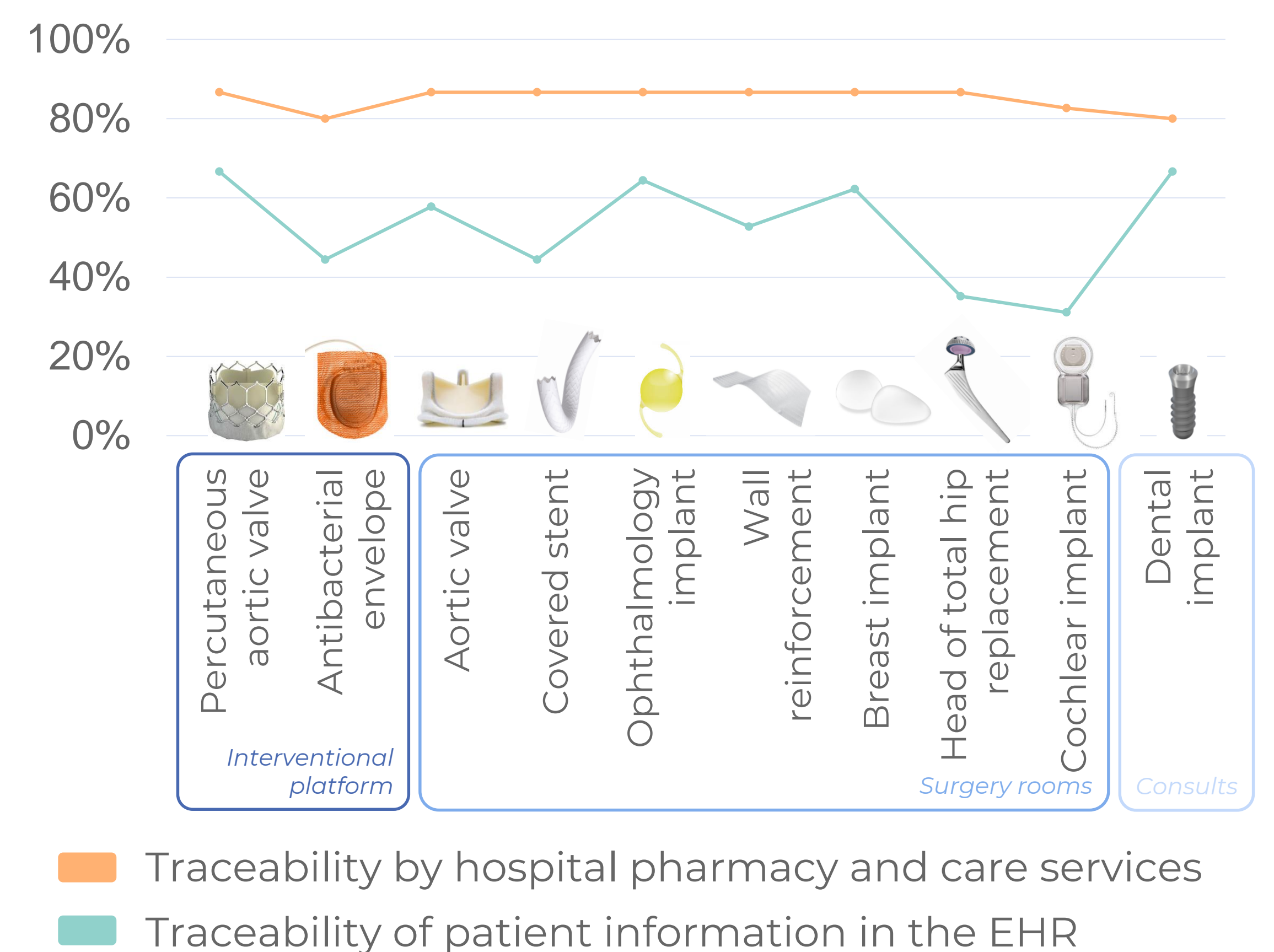
## RESULTS

- Traceability by the hospital pharmacy: **86%**
- Traceability by the care service: **84%**
- Traceability of patient information in the electronic health records (EHR): **52%**  
→ Divergent practices according to surgical specialties
- Communication of information to the patient: **96%**



Loss of information between traceability in professional software and information traced as communicated.

No implant card traced as delivered.



**Improvement** in practices since 2020 (excluding 8 criteria not studied in the previous audit):

	2020	2023
Traceability by the <b>hospital pharmacy</b>	100%	100%
Traceability by the <b>care service</b>	100%	100%
Traceability of <b>patient information in the EHR</b>	6%	49%

## DISCUSSION / CONCLUSION

CAQES 2022-2024 target for all criteria: **> 75%** → **Objective not achieved**

### Improvements in Pharmacy / Services

- Traceability of **UDI**: integrate label scanning throughout the IMD circuit;
- Healthcare professional's **RPPS number**;
- Harmonization of the circuit between surgery rooms.

### Improvements in patient information traceability

- Standardization of follow-up letters;
- Interoperability of professional software: automatic transfer of information traced by the medical/surgical and pharmaceutical services onto the referral letter (especially the UDI);
- Traceability of the surgical report to the patient;
- Implementation of an **implant card** delivering circuit.