

TRACEABILITY OF IMPLANTABLE MEDICAL DEVICES (IMDs) IN HOSPITAL :

INDUSTRIAL CODIFICATION SYSTEMS STILL INSUFFICIENT

L Durand¹, S Drouot¹, S Frontini¹, Anne-Marie Taburet¹, S Raspaud¹

¹AP-HP, Hôpital de Bicêtre, Pharmacie, 78 Rue du Général Leclerc, 94275 Le Kremlin-Bicêtre



BACKGROUND

Who requires ?

- French Law 2006-1947 : traceability requirements for IMDs
- European Commission Recommendations 2013/172/UE : unique device identification (UDI)

What for ?

- Identification of patients who received an IMD (e.g. recalls)
- Identification of IMD(s) used for a patient (e.g. adverse events) → Patient safety

IMDS TRACEABILITY

Who is responsible for?

- Pharmacist : IMD registration and transmission to care unit : identification, batch number, manufacturer, date of delivery
- Care unit : further registration in the patient file : date of use, patient identification, name of surgeon/physician

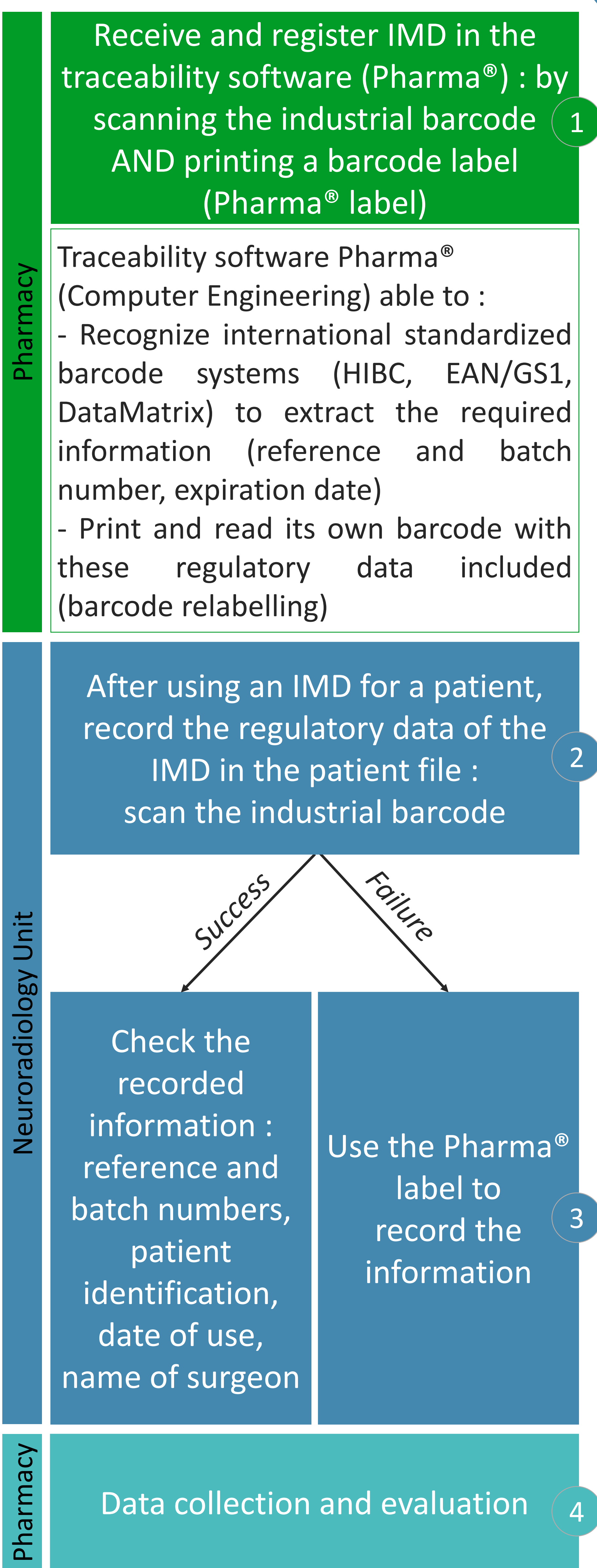
How ?

- Manual registration and barcode relabelling
- OR
- Direct read of information by scanning industrial barcode

OBJECTIVE

Assess the use of the industrial barcodes printed on packaging to avoid a relabelling upon delivery of the devices at the pharmacy.

MATERIAL & METHODES



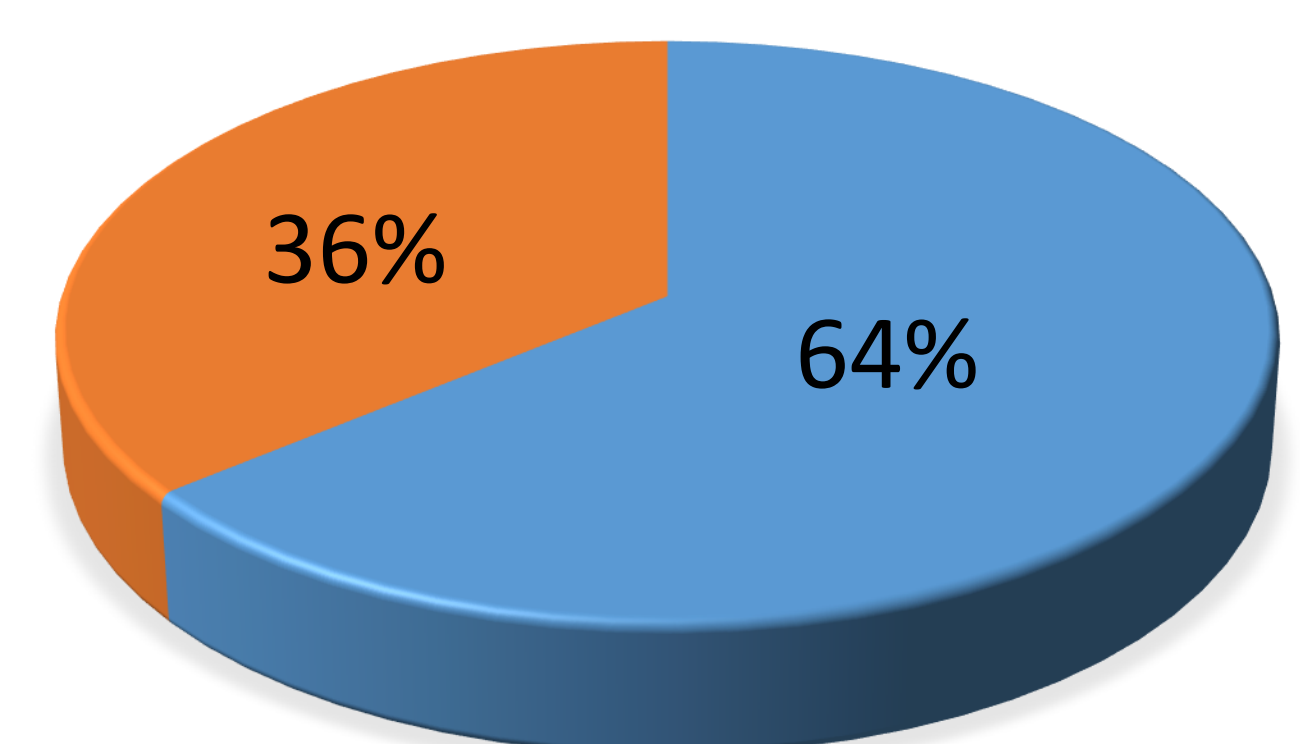
RESULTS

CARACTERISTICS :

- 2-month assessment
- 20 patients
- 89 implanted medical devices
- 19 products from 10 different suppliers

BARCODE USED FOR TRACEABILITY

Industrial barcode (32/89)



Pharma label (57/89)

	Difficulties avoiding the use of industrial barcodes	IMDs Number of units [%]	IMDs Number of different references [%]	Number of concerned supplier	Products Examples (supplier)
Related to the barcode itself	No barcode on the packaging	4 [7%]	1 [5,3%]	1	Vertaplex cement (Stryker)
	Lack of information after scanning	6 [10,5%]	4 (2 brands) [21,05%]	2	Microspheres Embolization particles (Merit Medical), Stent (Boston Scientific)
Software limits	Change of the barcode after supplier modified the packaging	4 [7%]	4 (same brand) [21,05%]	1	Coils (Codman)
	No identification of the IMD after scanning	10 [17,5%]	2 [10,5%]	2	Histoacryl® (Bbraun), Angioseal® (St Jude Medical)
User-related issues	Failure of scanning	13 [22,8%]	7 (3 brands) [36,8%]	3	Angioseal® (St Jude M.), Coils (Codman)
	Several barcodes on internal and external packaging	20 [35,1%]	1 [5,3%]	1	Onyx® (EV3)
		57 [100%]	189 [100%]		

<50% of success → current limits to use the industrial codification systems to identify a IMD at the time of administration

➔ Relabelling still recommended

CONCLUSION : WHAT CAN WE EXPECT ?

- 100% standardized barcodes
- Management of the quality: required information well recorded

Industrial

- Suitable to IMDs traceability (from delivery to administration)
- Able to recognize the standardized barcodes

Software

- Formed to use a traceability software
- Formed to recognize the right barcode to scan on regular IMDs (specific to each care unit)

Care unit

- UDI : from recommendations to obligation
- European arbitration to join the FDA engagement

Regulation