



21ST WORLD STERILIZATION CONGRESS



Interest in setting up a platform for dematerialized reservation and management of medical device loans

Name: Laura Delassus

Affiliation: University Hospitals of Strasbourg,
Pharmacy & Sterilization Department

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CICG, GENEVA, SWITZERLAND



Organisation at the University Hospitals of Strasbourg (HUS)



Logistics unit

- **Pharmacy:** purchase and supply of medicines, sterile medical devices (**SMDs**) and implantable medical devices (**IMDs**)



Hautepierre
Hospital (HP)

Nouvel Hôpital
Civil (NHC)



- **CSSD**
- Average daily production of **350 sets** and **300 units**
- **Operating theatres:** 1 technical platform with 32 operating theatres + 8 additional rooms
- Surgical specialties: ortho-traumatology, maxillofacial, spine, hand, neurosurgery, ENT, gynecology, senology, digestive, hepatic, pediatric surgery
- **2nd CSSD site**
- Average daily production of **130 sets** and **160 units**
- **Operating theatres:** technical platform of 16 operating rooms + 3 extra rooms
- Surgical specialties: cardiac, vascular, thoracic, ophthalmology, urology, digestive



IT traceability deployed in CSSD

- **Production traceability software** (Sterigest®, SPS): traceability to the operating platform
- **Database :**
 - All the sets of the hospital and all loan sets + single MDs
 - Generic code for medical devices on loan
- **Traceability labels**
 - Affixed to packaging objects, or attached to container seals via label holders
 - Information: functional unit, name, sterilization date, expiry date, traceability number
- **Interface** between sterilization traceability software and operating room software (Qbloc®)





Medical devices on loan

- **IMD +/- ancillary equipment provided by a supplier** for one or more surgical procedures
- Ancillary: instrument(s) necessary for the installation of an IMD, non-sterile when supplied
- **No pre-purchase**, billing of the implant afterwards

- Examples:

- Breast implants
- Aortic stents

Several sizes of implants ordered and loaned by the supplier for the procedure, billing only for what was implanted



GORE® EXCLUDER stent®

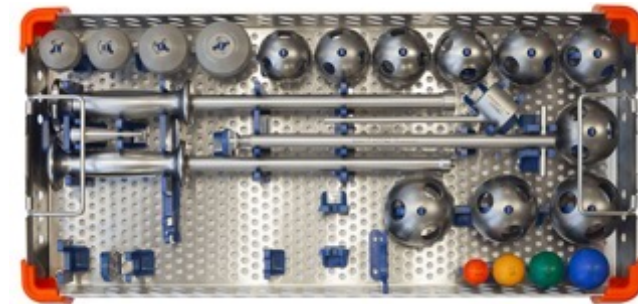
- Acetabular implant + ancillary



Cotyle HYPE® SERF®



SEBBIN® Breast Implant



- In France, **mandatory traceability of upstream and downstream processing**
(Instruction DGS/R13/2011/449 on the risk of transmission of non-conventional transmissible agents)



Circulation of medical devices on loan to the HUS

Pre-booking by the
OR



The OR sends a
request for supply to
the pharmacy



The pharmacy orders
IMD and/or ancillary
equipment from the
supplier



Delivery to the
pharmacy or OR /
inspection



Sterilization of the
ancillary before use

Use



Sterilization of the
ancillary after use



Preparation of
unused ancillaries
and IMDs for return
to supplier



Return to supplier



Financial settlement
of the installation of
the IMD by the
pharmacy



Multi-stakeholder circuit

- Operating theatres
- Pharmacy: MD unit, CSSD
- Suppliers



Complex and time-consuming process

No common communication tool, malfunctions and emergency management

What is the solution

Online booking and surgical
equipment loan management
platform



Evaluate the interest of setting up a platform for
managing medical devices on loan

Specify volume and scope

Present the project to the institution's Information
Systems Steering Committee (COPIL SI)

1

A priori risk analysis of the loan circuit according to the FMECA method with evaluation of the platform as an element of risk control

2

Mapping of HUS loan orders in 2019 to determine volume and scope

3

Implementation in November 2020 by the MD sector of a **daily request for loan orders** in progress and creation of a **support system to track ancillaries in CSSD**

4

Prospective follow-up
Tracking support and traceability software



Loan MD management platform: Ascaly®



- Online platform for booking and tracking MDs on loan
 - Operating theatres book MDs and ancillaries through a single form
 - The MD section of the pharmacy validates requests
 - Transmission of orders to suppliers
- Dashboard for real-time display of reservations and orders in progress by all circuit participants
- Logistical follow-up of the equipment
- Access to MD data sheets
- Sterilization tab: confirmation of sterilization before/after use, indication of the number of sets

1 Risk analysis of the loan circuit

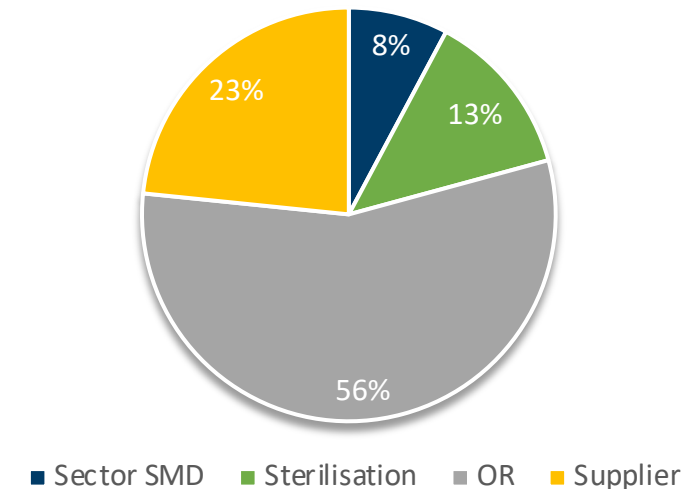
- FMECA (Failure Modes, Effects and Criticality Analysis) analysis, evaluation of the platform as an element of risk control

Steps	Number of risks identified	Number of risks controlled	Number of residual risks
Pre-booking by the block	4	3	1
Request from the OR to the pharmacy	7	4	3
Order by the pharmacy from the supplier	6	6	0
Delivery / control	8	2	6
Sterilization before use	13	2	11
Use	3	1	2
Sterilization after use	5	1	4
Preparation of non-implanted IMD +/- ancillary equipment for return to the supplier	5	2	3
Return of MDs to supplier	4	4	0
Regularization of the installation of the IDM	3	2	1

- 58 risks identified
- 31 residual risks

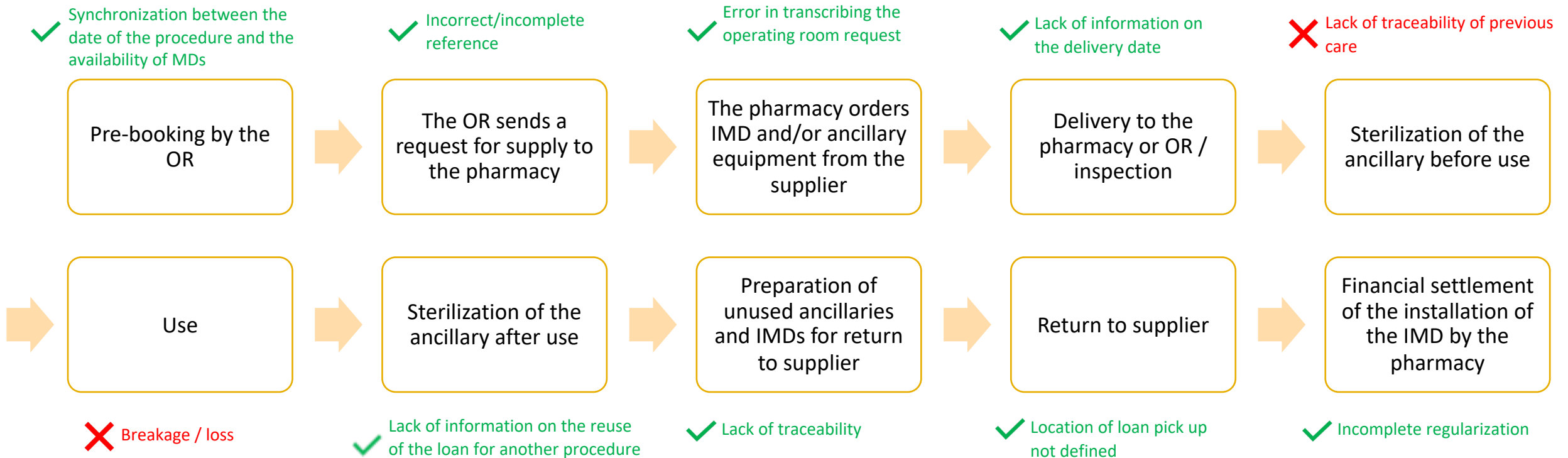
→ Control of 47% of risks via the platform

Actors identified in the risk analysis of the loan circuit



1 Risk analysis of the loan circuit

- Examples of risks controlled or not with the loan management platform:



2

Mapping of medical devices on loan

- Data from the query of loan orders made by the MD unit of the pharmacy from the Economic and Financial Management software (GEF) over the year 2019

- **1 229 orders**, $\bar{x} = 3,4$ orders/day

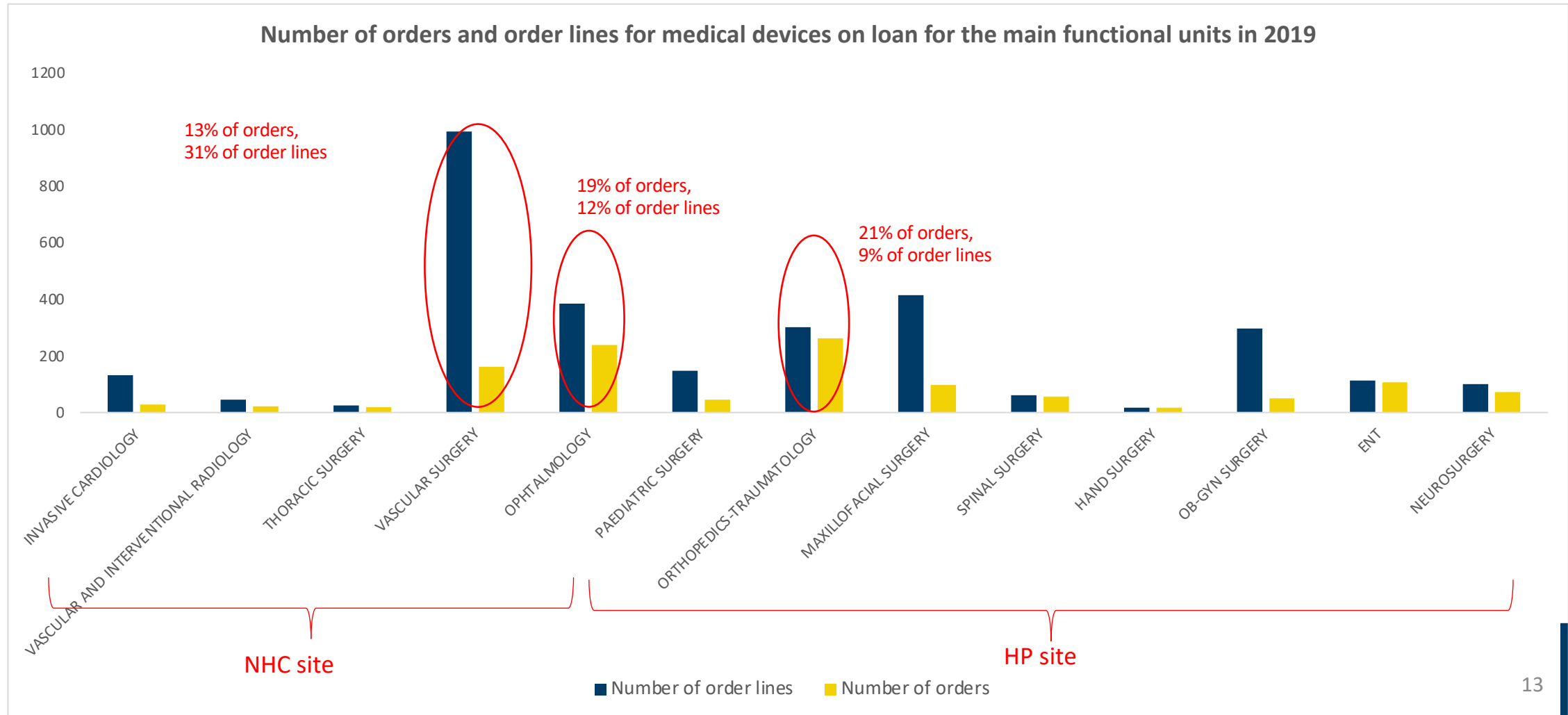
1 order = 1 or more order lines = 1 intervention

- **3 172 lines**, $\bar{x} = 2,5$ lines/order

1 order line = 1 IMD +/- ancillaries

2

Mapping of medical devices on loan

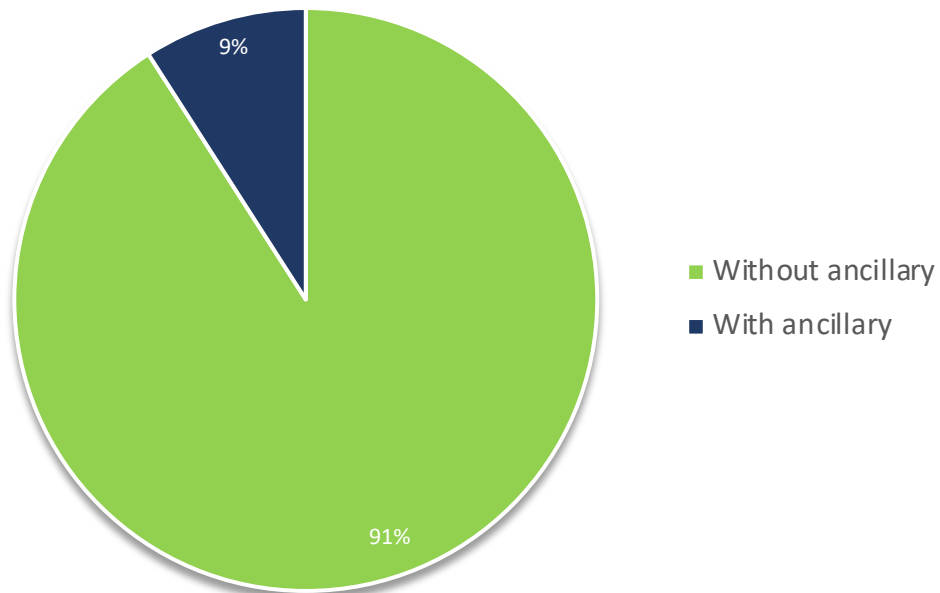


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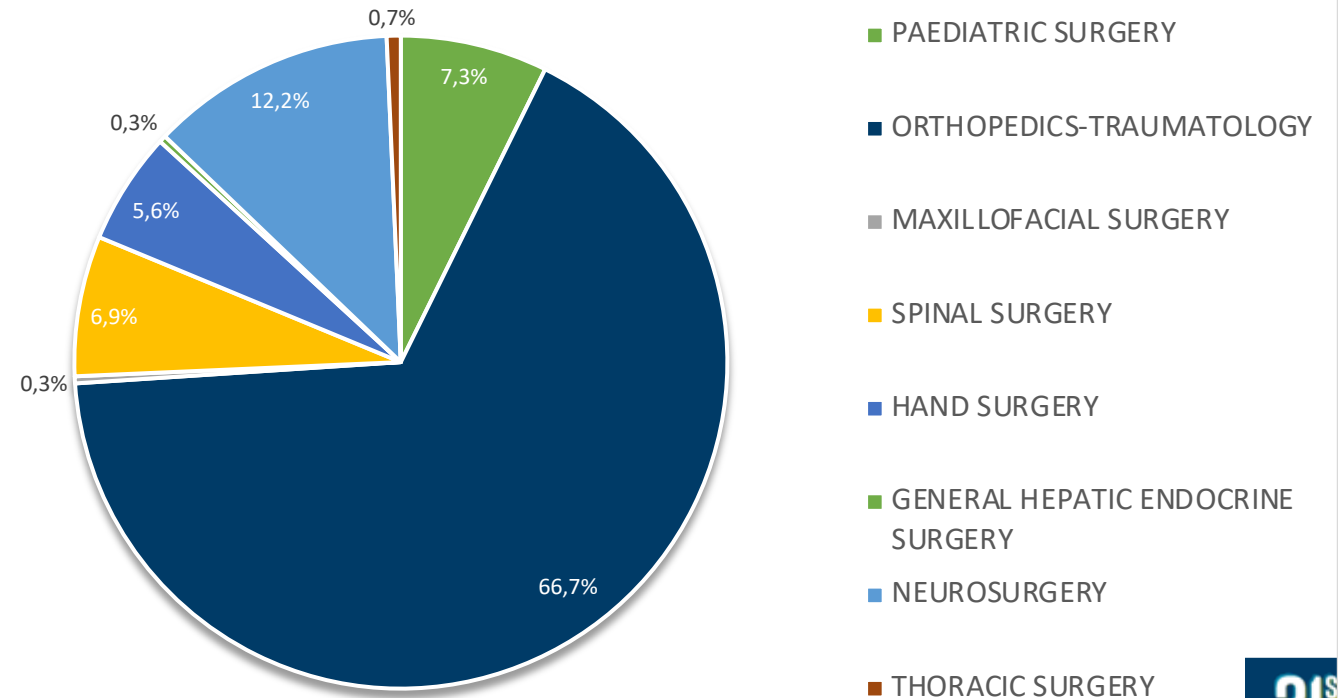
Mapping of medical devices on loan in 2019

- 288 order lines with ancillaries

Order lines for MDs on loan with and without ancillary equipment in 2019



Order lines for MDs on loan with ancillary equipment by functional unit in 2019



3

Support for the tracking of ancillaries in CSSD

- From November 2020, development of a daily query of orders made by the pharmacy on D-1
- Filling of a dashboard specifying: functional unit, supplier, designation of the ancillary, date of procedure, surgeon, estimated date of delivery
- Email sent once a week on Friday to the CSSD team with the loans expected for the next 15 days
- Update in case of add-ins

UF code	Specialty	Sterilization site	Supplier	Full designation	Expected Delivery Date	Date of procedure	Operator	Week
7381	ORTHO MI OR	HAUTEPIERRE	MATHYS ORTHOPEDIE SAS	ANCILLARY EQUIPMENT AND IMPLANTS RM PRESSFIT ACETABULUM	09/02/2021	16/02/2021	PR. B	Week 6
7381	ORTHO MI OR	HAUTEPIERRE	SERF	ANCILLARY PUC UNIKROMA + UNIKROMA IMPLANTS + TEST KITS ON THE RIGHT (2 UNIKROMA ON THE SAME DAY	10/02/2021	17/02/2021	PR. B	Week 6
7381	ORTHO MI OR	HAUTEPIERRE	SERF EXTREMITY	ANCILLARY + FAST FOREFOOT IMPLANTS	10/02/2021	17/02/2021	DR. N	Week 6
7381	ORTHO MI OR	HAUTEPIERRE	MATHYS ORTHOPEDIE SAS	ANCILLARY EQUIPMENT AND IMPLANTS RM PRESSFIT ACETABULUM	10/02/2021	17/02/2021	PR. B	Week 6
7384	SPINAL OR	HAUTEPIERRE	SI BONE FRANCE	IFUSE ANCILLARY + IMPLANTS	15/02/2021	25/02/2021	DR. T	Week 7
7381	ORTHO MI OR	HAUTEPIERRE	PROTHEOS	ANCILLARY + RIGHT PRIMARY ACS PTG IMPLANTS + OPERATING ASSISTANCE	16/02/2021	23/02/2021	PR. B	Week 7
7583	NEUROCHIR. OR	HAUTEPIERRE	SPINEART SA	SCARLET AL-T TITANIUM ANCILLARY AND IMPLANTS	17/02/2021	24/02/2021	DR. T	Week 7
7381	ORTHO MI OR	HAUTEPIERRE	ORTHOFIX SA	EMERGENCY CASE TL HEX TRAUMA RINGS 240 MM 5/8 AND 3/8 + IMPLANTS	18/02/2021	25/02/2021	DR. B	Week 7

4 Prospective follow-up

- Monitoring using the dashboard and traceability data from the sterilization software
- Data collected between November 2020 and March 2021
- Dashboard monitoring:

Number of loans with ancillaries identified from the query	Number of loans processed in CSSD
106	90 (85%)

→ $\bar{x} = 5$ loans/week

- Discrepancies: procedures postponed or canceled, notably due to the COVID-19 pandemic

4

Prospective follow-up

- Follow-up of the traceability with the sterilization software:
 - Traceability with a generic code "LOAN" for each functional unit
 - Additional information entered in the software: name of the loan, number of sets constituting the loan
 - Procedure date and surgeon name written by hand

H.U. Strasbourg

Liste des séries de production

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Stérilisation: du 08/02/2021 au 26/02/2021 | Produit 162895 - Etablissement :

N° de fabrication	Désignation	Clé	Date (stér.)	Id. stér.	Cycle	Agent	Quant.
2021101628953533	PRET ORTHO-TRAUMATO LD <i>Initiale revision amplitude 1/3</i>	PRET	09/02/2021	033	42	VCHA	1
2021101628953534	PRET ORTHO-TRAUMATO LD <i>Initiale revision amplitude 2/3</i>	PRET	09/02/2021	033	42	VCHA	1
2021101628953535	PRET ORTHO-TRAUMATO LD <i>Initiale revision amplitude 3/3</i>	PRET	09/02/2021	033	42	VCHA	1
2021101628953536	PRET ORTHO-TRAUMATO LD <i>FAST AVANT PIED SERF 1/1</i>	PRET	09/02/2021	033	44	TSCH	1
2021101628953537	PRET ORTHO-TRAUMATO LD <i>Xnov kaps 1/2</i>	PRET	10/02/2021	034	29	FJAC	1
2021101628953538	PRET ORTHO-TRAUMATO LD <i>Xnov kaps 2/2</i>	PRET	10/02/2021	034	29	FJAC	1
2021101628953539	PRET ORTHO-TRAUMATO LD <i>TRIATHLON TS 1/9</i>	PRET	10/02/2021	034	31	TSCH	1
2021101628953540	PRET ORTHO-TRAUMATO LD <i>TRIATHLON TS 2/9</i>	PRET	10/02/2021	034	31	TSCH	1
2021101628953541	PRET ORTHO-TRAUMATO LD <i>TRIATHLON TS 3/9</i>	PRET	10/02/2021	034	31	TSCH	1

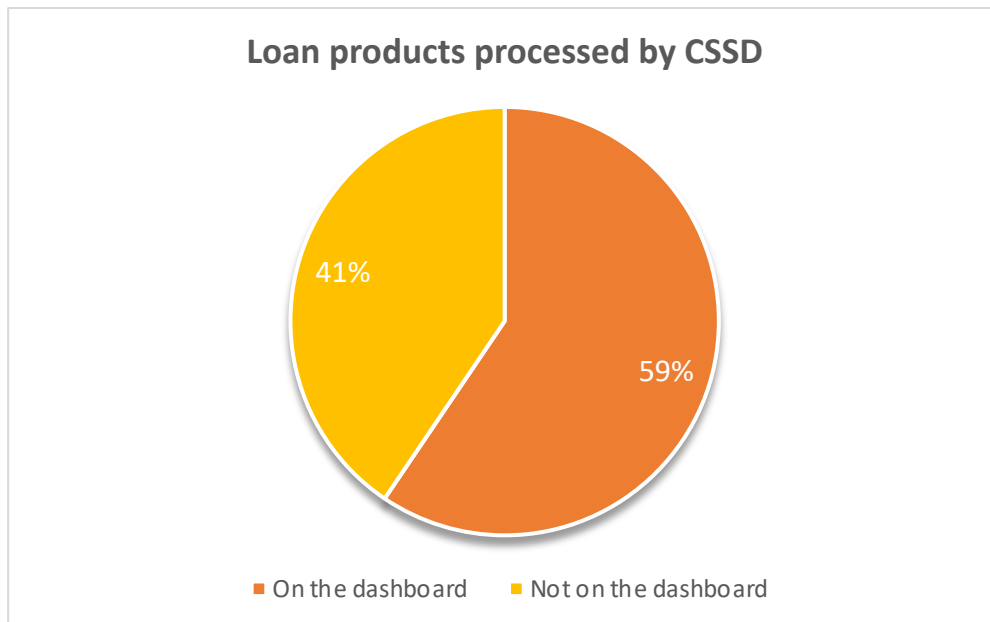
4 Prospective follow-up

- Data extraction from the traceability software

Number of products supported traced under the LOAN code	Number of corresponding loans
861	209

$$\bar{x} = 4 \text{ compositions/loan } [1;10]$$

Note that 1 loan = 1 or more products, reprocessed twice (before/after use)



- Differences between the dashboard and the software:
 - Traceability errors: MD wrongly traced as loans
 - MDs in testing
 - Courtesy instruments made available during the repair of a biomedical instrument
 - Instruments to be reintroduced into an OR box
 - Unscheduled processing

- Loans = significant activity for the Pharmacy-Sterilization department:
 - More than 3 loan orders placed by the MD unit every day
 - 5 prêts, soit 20 compositions en moyenne, par semaine pris en charge en stérilisation
 - Traceability to be implemented
 - Time-consuming activity and risk of errors
- Today: management and monitoring support for sterilization loans
 - Better visibility on future loans / processes more secure
 - Raises sterilization operators awareness concerning traceability
 - Dissociation of loans and tests
 - Raising awareness in other sectors: pharmacy MD unit, biomedical, ORs
 - More comprehensive dashboard

- Benefits of a dematerialized and shared tool:
 - About 50% reduction in risk
 - Feedback from other health care institutions* :

Advantages	Expected points of improvement
<ul style="list-style-type: none"> • No more retranscription of information • No more manual tracking • Common communication tool • Real-time visibility over reservations • Optimization of delivery times • Traceability of logistics flows 	<ul style="list-style-type: none"> • Lack of information for re-composition in sterilization: no detailed listing, no information in case instruments go missing • Previous procedures traceability sheet digitized

- Pilot scope :
 - Vascular surgery and ophthalmology: large volume of IMDs
 - Orthopaedics and traumatology: large volume of ancillary equipment

*Hattat et al. Gestion dématérialisée des dépôts provisoires. Congrès CEFH; 2018.

Kalfon et al. Plateforme Arsenal Chirurgical de réservation et de gestion des prêts de matériel chirurgical : Bilan à 9 mois d'utilisation. 3ème Congrès de la SF2S; 2019



Implementing the tool would allow:

- **To harmonize** loan management
- **To secure** information and logistics flows



Presentation of the project to the COPIL SI in January 2021

- Appointment of an IS project lead
- **Deployment** planned for the **4th quarter of 2021**



Before deployment :

- Continuation of the **daily query**
- Filling of the **CSSD dashboard**, and investigation of discrepancies with traceability data

Thank you for your attention

Laura Delassus, interne en pharmacie
laura.delassus@chru-strasbourg.fr

Sandra Wisniewski, pharmacist in charge of
sterile and implantable medical devices
sandra.wisniewski@chru-strasbourg.fr



Julie Scholler, CSSD pharmacist
julie.scholler@chru-strasbourg.fr

Bénédicte Gourieux, Head Pharmacist
benedicte.gourieux@chru-strasbourg.fr

