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Feasibility study of centralizing biotherapy preparations in a hospital center

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Introduction

Biological drugs or biotherapies

No regulatory constraints regarding their hospital preparation



Current circuit issues

- → Consequently pharmacist time
- → Pharmaceutical analyses based on previous and retrospective prescriptions: not optimal
- → Preparation of biotherapies by state-registered nurses (IDE): time-consuming and in non-
- → No management of leftover products in service: significant loss in biotherapy



Objectives of the study

Assessment of the feasibility of centralizing the preparation of non-oncology biotherapies by pharmacies & Medical and economic evaluation of this project

Quality approach and risk management guaranteed by

Recommendation by the HAS: 'promote the centralisation of preparations as far as possible'

Optimisation of pharmacist and nurse timeStreamlining of the processIncrease

Material & Method

Prospective and retrospective data tracking Day hospital service

Six-month period: from 1 January 2024 to 30 June 2024 Extraction of **Pharma®** software from biotherapy prescriptions Analysis in Excel® spreadsheet



Determination of the molecule(s) for centralisation of preparationsData collection: preparation time and quantity of leftovers discarded in the day hospital

Decision tree

Banding doses or standard doses (1) (2)

Proposal for standard dose range + number of advance preparations ADOC tools (3)

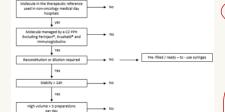
Medical and economic evaluation with an estimate of the savings achieved through the proposed

circuit. Development of a procedure for the proposed circuit.

Results

Choice of molecules

Decision tree for selecting biotherapy molecules for centralized production



Most suitable biotherapy **INFLIXIMAB**

hysical and chemical stabilit after reconstitution and dilution up to 60 days at a temperature between 2°C and 8°C and for an additional 24 hours at 25°C after removal from the refrigerator (4)

Stability of leftovers at least 30 days at +4°C or room temperature at concentrations of 0.7 and 1.6 mg/ml (5) or 35 days at 4°C (4)

Analysis of prescriptions and requirements Number of infliximab preparations: 415 Average number of prescriptions per day: 3.2 (9; 1) Different dosages: 34 (200 mg → 1000 mg)

Projected circuit

Estimates of standard doses, units produced and needs covered over six months

Standard dose (mg)	Interval (mg)		Deviation percentage		Produced	Covered
	Lower	superior	Lower interval	Upper interval	units	needs
220,00	200,00	244,44	10,0 %	10,0 %	21	6,2%
270,00	245,45	300,00	10,0 %	10,0 %	68	20,1%
350,00	318,18	388,89	10,0 %	10,0 %	29	8,6%
435,00	395,45	483,33	10,0 %	10,0 %	72	21,3%
535,00	486,36	594,44	10,0 %	10,0 %	44	13,0%
660,00	600,00	733,33	10,0 %	10,0 %	57	16,9%
810,00	736,36	900,00	10,0 %	10,0 %	43	12,7%
995,00	904,55	1105,56	10,0 %	10,0 %	4	1,2%



Estimation of centralized production of infliximab banding doses available at the pharmacy



Standard dose (mg)	Average number of preparations per month	Maximum number of preparations per day over the study period	Estimated allocation to pharmacy stocks
220 mg	3,5	2	2
270 mg	11,3	3	4
350 mg	4,8	2	2
435 mg	12	3	4
535 mg	7,3	2	3
660 mg	9,5	3	4
810 mg	7,1	3	4
995 mg	0,6	1	1
Overall total	56,1	19	24

Medical-economic evaluation of the proposed circuit

Substitution of Remicade® with Remsima[®]

Annual loss of 92.54 vials of Remsima®

PEC for reimbursements of UCDs for medicines in addition to the GHS and gains per stay associated with the EMI

Centralized production = management of

Average total annual earnings €4,047 incl. tax → Hospital €4.047 incl. tax → Social security

Average annual savings €9,172 incl. tax → Social security Loss of revenue and savings in terms of expenditure > Hospital

IDE time → average annual gain: 278.4 hours

Pharmacist time > optimized

Preparer time → optimized

Management and traceability of remaining stocks Facilitating the use of the biosimilar Remsima®

- → Savings for CHANGE and Social Security
- → Possible removal of infliximab from the Sus list Time savings for PPH
- → Manufacturing sheets
- → Automatic stock movement management between Chimio® and Pharma®

Microbiological safety

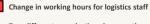
Optimisation of pharmacist time

→ No multiple validation steps

Freeing up nursing time → Prospect of expanding the day hospital

Conclusion

Necessary training for doctors in the Chimio® software



Two different organizations because there are two different sites

- Expansion of the scope of centralized preparations - Integration of molecules outside chemotherapy

- Compliance with Good Preparation Practices and securing the manufacturing process

Context of continuous improvement in patient care Opening up this circuit to the preparation of other non-oncology

Example of Myozyme®

Time-consuming preparation 2 1 hour 20 minutes of preparation in the treatment roomStable for 24 hours between 2 and 8°C after dilutionCan be prepared in advance the day before the patient is admitted to the day hospital



(5) Guirao S, Paul M, Jaccoulet E, Morand K, Astier A. Stabilité de l'infliximab en solutions diluées. Congrès APHIF Paris. 200