TCH012 - BATCH OR NAMED-PATIENT PREPARATION: INTRODUCTION OF A DECISION ALGORITHM

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BACKGROUND

One of the missions of the Pharmacy Department of the CHUV (Centre Hospitalier Universitaire Vaudois) is to secure the supply of the hospital in pharmaceuticals. Medicines not publicly available must be manufactured by the Pharmacy. This can be done batchwise or through a nominal preparation for a specific patient

OBJECTIVES

Batch manufacturing implies a number of principles and constraints such as planning, delays to be taken into account, number of items per batch, final control by the Quality Control Unit, and storage and supplying by the Pharmaceutical Logistics Unit. Because these are often incompatible with personalized medicine, it was necessary to define criteria allowing the Manufacturing Unit to decide between batchwise and individual preparation.

MATERIALS ANS METHODS

Three pharmacists collaborated to conceive and develop a decision algorithm meeting the above objective. This algorithm was then implemented and is being applied to all preparations manufactured by the Pharmacy Department.

RESULTS

The first step was to define a batch-wise preparation *versus* a nominal preparation. The Table below offers a definition of both types of preparations.

Batchwise series	Individualized preparations
➢Quality control ➢Supplying by the logistics unit ➢Planning possible (longer delays) ➢Standard doses ➢Validated protocols ➢ Qualified equipment	➢Quality insurance ➢Nominal dispensing by the manufacturing unit (labels bearing the patient's name) ➢Order with individual prescription issued to manufacturing unit by the medical departments ➢No planning possible (short delays) ➢Large variability in doses ➢New protocols: OPM (operating modes) to be created according to requests ➢Personal qualification ➢New requests
Adequate premises, Resources	

The following criteria were subsequently taken into account when conceiving the algorithm: standardized doses, stability, frequency and number of prescriptions, urgency and costs (figure 1):

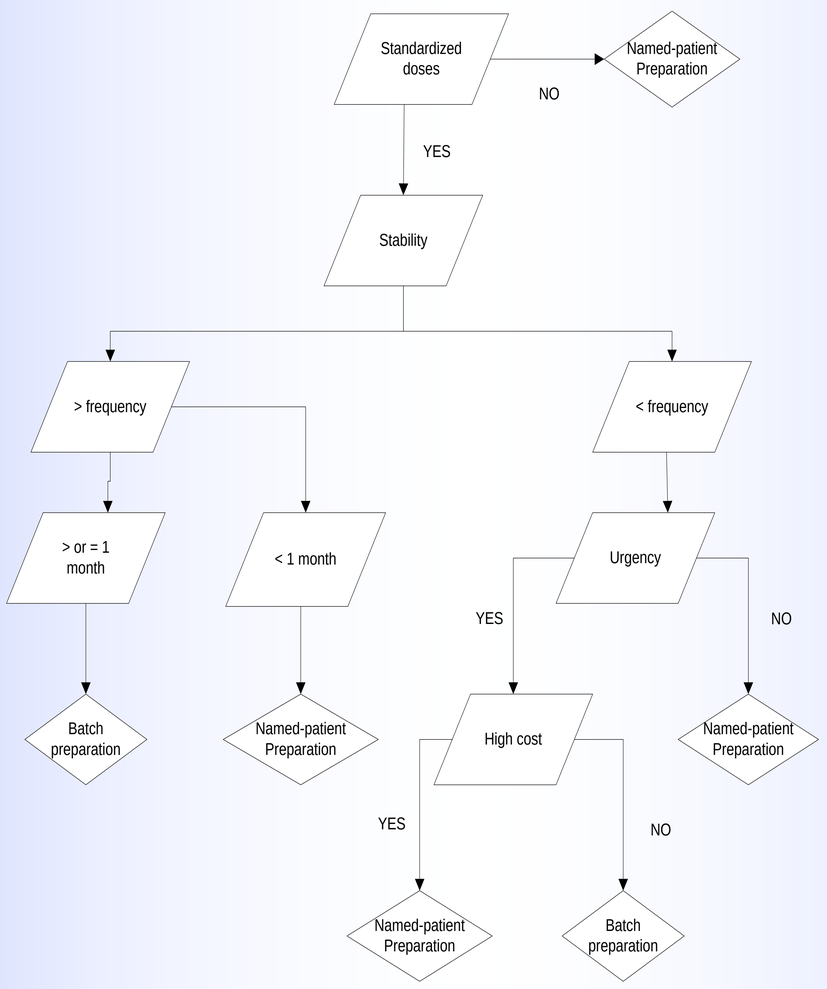

Figure 1: Decision Algorithm

A total of 440 formulations were analyzed according to the algorithm; 174 were earmarked for batchwise and 266 for nominal preparation (figure 2):

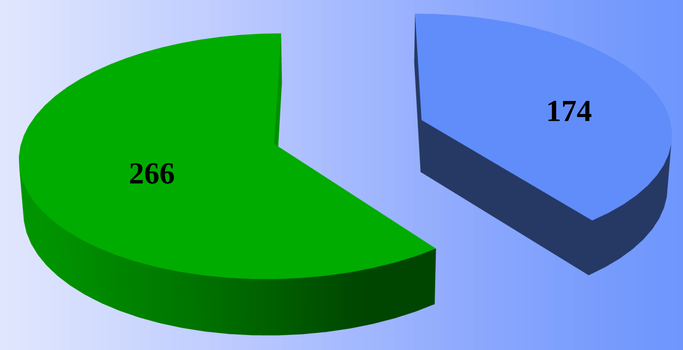

Figure 2: Number of batchwise preparations versus nominal preparations

Three examples are presented below:

1. Phenobarbital suspension 10 mg/ml
2. Quetiapine suspension 10 mg/ml
3. Dexamethasone suspension 2 mg/ml

In these examples, we considered that a suspension allows a clear YES reply to the question of standardized doses, even for pediatric suspensions which must meet highly variables posologies.

	Phenobarbital suspension	Quetiapine suspension	Dexamethasone suspension
Standardized doses	YES	YES	YES
Stability	115 days	5 days	60 days
Frequency	high	low	< 60 days
Urgency		No	Yes
High cost			No
	Batchwise preparation	Named-patient preparation	Batchwise preparation

CONCLUSIONS

The implementation of this algorithm now provides the Manufacturing Unit with an objective tool to decide between a batch-wise or a nominal classification for new preparations and for the annual review of the status of preparations.