The anticipated compounding of injectable anticancer drugs without physician's prescription : a process study.

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Introduction

- Context of increased production activity at URCC
- Organizational difficulties due to variations in daily activity

Objectives

- Evaluate the feasibility of carrying out advance preparations independently, without physician approval, using a simpler process than dose banding.

→ **Smoothing out activity, reducing preparation provision times**

Materials & methods

1.Define compounds selection criteria

- fixed dose
- physico-chemical stability > 28 days (RCP, Stabilis) / storage conditions
- prescription frequency > 500 bags/year (batch size)
- order of administration within protocols
- manufacturing method

2.Retrospective analysis of 29 weeks prescriptions by extracting data from our Good Chemotherapy Practice software

3.Literature review on early production of anti-cancer drugs

Results

✔ **9 compounds meeting the selection criteria**

↳ **7 antibodies** : atezolizumab, nivolumab, durvalumab, rituximab SC, trastuzumab SC, Phesgo *± daratumumab SC*

↳ **2 cytotoxics** : vincristine 2mg, 5-fluorouracile 4800mg

Production coverage estimated at 10% (or 130 preparations per week)

Specific process points identified (not imagined) :

- edition of non-nominative manufacturing sheets
- manufacturing conditions and labeling
- nominative labeling secondary to medical prescription
- storage conditions and location
- dispensing procedures

Discussion & conclusion

- **Sufficient** volume of anticancer preparations **to initiate the project**
- **The organisation required for efficient anticipated production :**
  - Off-peak production
  - Maximum campaign size to be refined
- **An *a priori* FMEA-type risk analysis is necessary :**
  - Process point distinct from the usual circuit : labeling, storage, dispensing, etc.
  - Risk of financial loss in the event of « non-compliant » campaigns
- Stability studies to be carried out