Management of experimental health products in hospital pharmacies: a national survey

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Background and importance
- Management of investigational health products (IHPs) = major part of conducting clinical trials (CTs)
- Specific risks all along the circuit, with data integrity and patient safety issues
- But few standardised tools available and no national inventory has been conducted in hospital pharmacies

Aim and objectives
- Make an inventory of the current situation in French hospital pharmacies → prioritise risk reduction standardised tools to develop

Materials and methods

Regional working group:
- 4 clinical research pharmacists
- 1 pharmacist of the regional drug observatory
- 1 pharmacy resident

National survey
- 76 questions
- Quality approach
- Proposal of new tools

Dissemination
- Online anonymous survey
- Emailed to clinical research pharmacists in health facilities
- Activated from 11 December 2019 to 31 January 2020

Results

94 participating pharmacists
- 70% Response rate

Tools: expectations and needs

Examples of standardised tools
- Documentary base model
- Risk self-assessment grid (cartography)
- Internal audit grid
- Patient information support
- Training support for professionals
- Common list of monitoring indicators
- Internal/external satisfaction survey
- List of requirements for the pharmacy
- List of requirements for the sponsor

Overall score of quality approach
- Score II is the most frequent (38/94)
- The score:
  - depends on the type of health facility (p<0.0005)
  - increases with the number of active CTs (p<0.0005)

Features of quality approach
- Yes
- No

Distribution of the utility scores attributed by the 94 pharmacists to each standardised tool proposed

Conclusion and relevance
- All types of facilities conducting CTs represented → overall interest in this topic of IHPs’ management
- Quality approach = heterogeneous in hospital pharmacies, more implemented in the university hospital centres and cancer centres, with a high activity level
- Needs identified → 2 tools prioritised: self-assessment and traceability audit grids, soon to be validated and disseminated
- Such tools will help to upgrade practices in hospital pharmacies by identifying the specific risks and improving the IHPs’ circuit

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