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

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

- 35 Non-university hospital
- 28 University hospital centre
- 11 Private clinic
- 11 Cancer centre
- 7 Not-for-profit private hospital
- 5 Academic cancer institute

Features of quality approach

- Documentation system: Yes 74, No 20
- Adverse drug event reporting system: Yes 77, No 17
- Prior risk assessment: Yes 73, No 21
- Training and empowering staff: Yes 72, No 22
- Means of evaluation and monitoring: Yes 70, No 24
- ISO 9001 certification: Yes 72, No 22

Overall results of the 94 participating hospital pharmacies on the components investigated by the survey

Tools: expectations and needs

88/94 pharmacists interested

- 0: useless
- 1: not very useful
- 2: quite useful
- 3: very useful

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)

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