Paediatric clinical research from the perspective of hospital pharmacists from France and Canada

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Objectives

- To compare pharmacy practice for pediatric clinical research in hospitals in France and Canada
- To identify issues related to pediatric clinical research, as perceived by hospital pharmacists
- To rate the relative importance of factors that may influence the conduct of pediatric clinical research

Methods

- Cross-sectional survey of 11 pharmacy departments from France and 12 from Canada
- Online 50-questions survey (June-September 2012)
- The median [minimum-maximum] was calculated for each country and compared with a Mann-Whitney or Fisher's exact-test.
- Respondents were asked to rank, in order of importance from 1-10 (1 being the most important), factors that influence pediatric clinical research.

Results

Table 1. Profile of the French and Canadian Respondents

Variables	France Median [min;max](n)	Canada Median [min;max](n)	P Value
Number of Beds	2000[493;3000]	438[129;1197] (n=10)	0.001
Number of Pediatric Beds	193[89;400] (n=10)	174[79; 396]	0.833
Overall number of pharmacists (including all titles) in full-time equivalents (FTE)	17 [11.5;35]	45[18.9;76.8]	0.009
Number of pharmacists specifically assigned to clinical trial support (FTE)	1.5 [1;3]	1,9[0.2;17.4]	0.921

Table 2. Profile of French and Canadian Pharmacy Practices in Pediatric Drug Research

Variables	France	Canada	P Value
Volume of activity	**Median [min;max](n)**		
Overall Number of Active Protocols on June 6, 2012	268 [50;550]	102 [13;200]	0.004[w]
Number of Pediatric Active Protocols on June 6, 2012	38 [10 ;81]	20[4 ; 178]	0.205[w]
Number of industrial pediatric protocols	39%[0;86]	75% [0;100] (n = 9)	0.239[w]
Number of institutional pediatric protocols	61%[14;100]	25% [0;100] (n = 9)	
Pharmaceutical Services Offered during the Day	**Proportion (n)**		
Help in writing and developing institutional protocols	91%	50% (n = 10)	0.063 [f]
Help in steps leading up to obtaining ANSM/Health Canada authorization	45%	60% (n = 10)	0.670 [f]
Member of a Research ethics board	36%	91% (n = 10)	0.395[f]
Preparation of a binder for a protocol	36%	100% (n =10)	0.004[f]
Entering information about participation in the protocol in the computerized pharmacological record	18%	80% (n = 10)	0.009 [f]
Preparation of research drugs	91%	80% (n = 10)	0.586 [f]
Nominative research drug dispensing	100%	80% (n = 10)	0.214 [f]
Patient education and counseling	91%	70% (n = 10)	0.311 [f]
Other Considerations			
Are there additional costs that are billed to the investigator for services offered outside the pharmacy's normal hours?	55%	82%	0,303 [f]
Is there a mandatory standard billing scale for the support of clinical trials in your country/province?	90% (n=10)	20% (n=10)	0,003 [k]
Is the rate scale used in your center different for industry and institutional trials?	91%	60% (n=10)	0,149 [k]
Do you use clinical trial management software in your department?	73%	10% (n=10)	0,008 [f]
Do you enter pediatric research drug prescriptions into a computerized pharmacological record ?	9%	70% (n=10)	0,024[f]
Are the global revenues from the support of clinical trial enough to cover 100% of your operating costs?	18%	0% (n=10)	0,476[f]
Do you require authorization from an authority for the preparation of research drugs?	82%	67% (n=9)	0,361 [f]
Have you already used subcontracting (e.g., other hospitals, manu-facturers) to conduct pediatric clinical trials?	27%	0% (n=10)	0,214[f]
Have you already acted as a multicenter coordinator for a pediatric research protocol?	73%	50% (n=10)	0,387 [f]

Table 3. Respondents perceptions of issues related to pediatric research

Variables	France Median	Canada Median	P Value
The pharmaceutical services offered in our hospital fully comply with good clinical practices.	100%	100% (n = 10)	NA
The manufacturers of commercial drugs collaborate easily when it comes to OBTAINING the RECIPE to prepare a placebo	14% (n = 7)	43% (n = 7)	0.559[f]
The manufacturers of commercial drugs collaborate easily when it comes to PROVIDING excipients to prepare a placebo	17% (n = 6)	33% (n = 6)	1 [f]
The devices provided by sponsors for the administration of research drugs to children are safe and have been adapted	70% (n = 10)	100% (n = 7)	0.603 [f]
The industry sponsors' clinical research assistants (CRAs) are able to answer the questions asked should a problem arise	73%	80% (n = 10)	1 [f]
The institutional investigator (physicians) budget is adequate to ensure the funding of the pharmaceutical services	40% (n = 10)	40% (n = 10)	1 [f]
The dispensing regulations required by the pediatric research protocols comply with standard operating procedures	82%	90% (n = 10)	1 [f]
The administration of a research drug is documented in the patient's medical record.	78% (n = 9)	100% (n = 10)	0.211 [f]
Healthcare professionals and patients are able to understand research drug labels (language, font size, vocabulary, etc.)	60% (n = 10)	90% (n = 10)	0.303 [f]
An understanding of the content (volume, type package is acquired before the first patient is recruited.	36%	50% (n = 8)	0.658 [f]
Research protocols are adapted to the child's life (daycare, school, etc.)	50% (n = 10)	13% (n = 8)	0.152 [f]

Table 4. Relative importance of factors that can influence pediatric investigational drug trials in hospital settings

Variables	France Median min;max](n)	Canada Median [min;max](n)	P Value
The pharmaceutical industry's lack of financial interest in the pediatric population	2 [1; 6]	4[1 ; 10] (n = 10)	0.232[W]
The pharmaceutical industry's fear of legal suits related to the pediatric population	5 [1; 9]	5,5 [2; 10] (n = 10)	0.391 [W]
Prohibitive cost of doing clinical research with a pediatric population in terms of the expected benefit (e.g., recruitment costs, weight-based formulation)	2 [1; 3]	3 [2; 9] (n = 10)	0.007 [W]
Potential patient cohort to be recruited is too small per institution	3 [1 ; 7]	4,5 [1 ; 10] (n = 10)	0.476 [W]
Lack of flexibility on the part of the Research ethics board when it comes to pediatric studies	5 [2 ; 8]	8,5 [2 ; 10] (n = 10)	0.055 [W]
High risk of peadiatric non-compliance, given the age and number of third parties involved in managing the drug at home	5 [2 ;10]	5,5 [1 ; 10] (n = 10)	0.567 [W]
Lack of available appropriate galenic forms for weight-based dose titration	3 [1 ; 9]	5 [1 ; 10] (n = 10)	0.143 [W]
The MEDICAL teams' lack of interest in PARTICIPATING in pediatric clinical research (e.g., child exposition to investigational drug, limited expertise)	9[2; 10]	7,5 [4; 10] (n = 10)	0.669 [W]
The MEDICAL teams' lack of interest in CONDUCTING pediatric clinical research studies (e.g., limited, limited contacts with sponsors)	9 [3 ; 10]	7,5 [4 ; 10] (n = 10)	0.453 [W]
The PHARMACEUTICAL teams' lack of interest in PARTICIPATING in pediatric clinical research (e.g., child exposition to investigational drug, limited expertise)	9 [3; 10]	7,5 [1; 10] (n = 10)	0.154 [W]
The 6-month patent extension for pediatric studies (Regulation 1901/2006, Article C.08.004.1 of the Food and Drug Regulations) has played a major role in increasing the number of clinical trials conducted IN MY COUNTRY.	4,5 [2; 9] (n = 8)	8 [4; 10] (n = 9)	0.015 [W]
The 6-month patent extension for pediatric studies (Regulation 1901/2006, Article C.08.004.1 of the Food and Drug Regulations) has played a major role in increasing the number of clinical trials conducted IN MY HOSPITAL.	8,5 [3; 10] (n = 8)	8 [3; 10] (n = 9)	0.921 [W]

n = 11 unless otherwise noted
W – Mann-Whitney ; F – Fisher test ; K : Khi^2

Discussion/Conclusion

- This study is the first to explore the issues involved in pediatric clinical research.
- A better understanding of the favorable and unfavorable practices may facilitate pediatric clinical research
- The findings of this study may also make it possible to reinforce our potentialities and find practical solutions to the difficulties encountered when setting up such trials.

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