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Recruitment in pediatric clinical research was influenced by study characteristics and pediatricians' perceptions: a multicenter survey

Florentia Kaguelidou[a,b,c,d,*], Philippe Amiel[e], Audrey Blachier[c,d], Catalina Iliescu[f], Jean-Christophe Rozé[g], Michel Tsimaratos[h], Christian Brandt[i], Behrouz Kassai-Koupai[j], Evelyne Jacqz-Aigrain[b,c,d], Claude Gaultier[b,c], Corinne Alberti[a,c,k]

[a]*AP-HP, Hôpital Robert Debré, Unité d'Épidémiologie Clinique, 48 boulevard Sérurier, 75019, Paris, France*
[b]*Inserm, CIC 9202, 75019 Paris, France*
[c]*Université Paris Diderot, Sorbonne Paris Cité, 75013, Paris, France*
[d]*AP-HP, Hôpital Robert Debré, Unité de Pharmacologie Pédiatrique et Pharmacogénétique, 48 boulevard Sérurier, 75019, Paris, France*
[e]*Institut de cancérologie Gustave-Roussy, Unité de recherche en sciences humaines et sociales, 114 rue Edouard Vaillant, 94800, Villejuif, France*
[f]*Inserm CIC 9301, CHRU Lille, Université Nord de France, boulevard du Professeur Jules Leclercq, 59037, Lille, France*
[g]*Inserm CIC 004, Hôpital Mère Enfant, CHU de Nantes, Université de Nantes−INRA, UMR 1280, 38 boulevard Jean Monet, 44000, Nantes, France*
[h]*Inserm CIC9502, AP-HM Timone Enfants, Université de la Méditerranée, 264 rue Saint-Pierre, 13385, Marseille, France*
[i]*Inserm CIC-P2, CHRU Strasbourg, 1 rue de l'Hôpital, 67091, Strasbourg, France*
[j]*Inserm, CIC201, EPICIME, CHU Lyon, Service de Pharmacologie Clinique, Université Lyon, UMR 5558, 52 boulevard Pinel, 63003, Lyon, France*
[k]*Inserm, CIE 5, 75019 Paris, France*

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Abstract

Objectives: The aim of this survey was to quantify refusal rates and identify factors of refusal pertaining to studies and recruiting pediatricians in the research recruitment process.

Study Design and Setting: We performed a cross-sectional survey on all clinical studies conducted in six pediatric Clinical Investigation Centers in France over an 18-month period. Data were retrieved using a data collection form for the characteristics of each of the studies included in the survey and a questionnaire addressed to recruiting pediatricians. Multilevel models were used for the statistical analysis.

Results: Overall, 145 pediatricians approached the families of 999 children and adolescents for participation in 44 studies. In the 36 of the 44 studies that enrolled subjects, median refusal rate was 12.5% (Q1−Q3, 0−28%). Lower refusal rates were associated with therapeutic drug use as the focus of the study [odds ratio (OR), 0.51; 95% CI: 0.25, 1.05], additional hospital stays required for the study (OR, 0.53; 95% CI: 0.28, 0.99), longer duration of the inclusion visit (OR, 0.93/10 min; 95% CI: 0.87, 1), and recruitment by a pediatrician with university teaching responsibilities (OR, 0.26; 95% CI: 0.10, 0.68). Refusal rate was higher when the recruiting pediatrician perceived the study as generating heavy practical burden for the subject and/or its family (OR, 1.3; 95% CI: 1.17, 1.45).

Conclusion: Refusal to participate in clinical research was low and was influenced by factors associated to the objectives and conduct of the studies and factors related to the characteristics and perceptions of the recruiting pediatricians.

Keywords: Recruitment; Pediatrics; Participation; Refusal rate; Clinical research; Pediatrician perception

1. Introduction

One of the main challenges in clinical research is the recruitment of eligible participants [1,2], and children are generally considered more difficult to recruit than adults [3,4]. Reasons for this include the low prevalence of some pediatric diseases and the need to obtain written informed consent from both parents while respecting the child's autonomy [5]. However, recent studies suggest that many pediatricians may be reluctant to invite families to participate

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* Corresponding author. Tel.: +33-1-40-03-41-42; fax: +33-1-40-03-24-24.

E-mail address: florentia.kaguelidou@rdb.aphp.fr (F. Kaguelidou).

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What is new?

Key findings

- Median refusal to participate in pediatric clinical research was 12.5% (Q1−Q3, 0−28%).
- Therapeutic drug use as the focus of the study, longer duration of the inclusion visit, and recruitment by a pediatrician with university teaching responsibilities were associated with a lower probability of refusal to participate.
- Refusal rate was higher when the recruiting pediatrician perceived the study as generating heavy practical burden for subjects and/or families.

What this adds to what was known?

- Survey findings contradict the common suggestion that children and their parents may be reluctant to participate in research.
- Use of multilevel models allowed assessment of relationships between refusal to participate and several explanatory variables while accounting for interindividual correlations within the same study.

What is the implication and what should change now?

- Implementation of pediatric studies should not be discouraged by concerns about subject refusals.
- Recruitment in pediatric clinical research can be improved by
  - enhancing the involvement of pediatricians with university teaching responsibilities in the recruitment process,
  - raising awareness among pediatricians about the importance of dedicating time to the research inclusion process, and
  - promoting the involvement of recruiting pediatricians in the early stages of study conception.

in research and that several aspects of the design and conduct of research may influence their referral behavior [6−9]. In a previous qualitative study, recruiting pediatricians reported failing to invite eligible participants because of ethical concerns or anticipated subject refusal [10]. Pediatricians' input to the recruiting process is of great concern as most families and children consent to take part in clinical research when invited to participate [11,12], and their decision is strongly dependent on the recommendations of their physician [13−16].

Evaluation of parents' and children's perspectives on research participation has been extensively addressed in the literature, and parents' psychology or personal perception of research is potentially difficult to change. Conversely, little attention has been granted on quantifying the impact of study characteristics and recruiting pediatricians' views on participation rates. Moreover, to our knowledge, participation rates have never been quantified across a large spectrum of research fields and age groups in pediatrics. Thus, the principal aim of this survey was to determine refusal rates in pediatric clinical research. We also sought to examine the relationship between study and recruiting pediatricians' characteristics and participation decisions.

2. Methods

2.1. Participants and procedures

We performed a cross-sectional survey on clinical research studies conducted in six pediatric Clinical Investigation Centers (CICs) in France (Paris, Lille, Nantes, Strasbourg, Lyon, and Marseille) between February 2006 and August 2007. The CICs are academic departments that conduct most of the pediatric clinical research performed in university-affiliated hospitals in France [17]. All studies ongoing in the six CICs during the survey period were included, regardless of study objectives and design. The recruiting physicians were pediatricians and pediatric subspecialists who practiced in university-affiliated hospitals. Subjects and families were given consent information and were invited to participate by one of the recruiting pediatricians according to a predefined study-specific procedure. Those who agreed to participate signed a written consent specific to each study.

When families were given consent information for each included study, they were also given oral information about the survey by the research team. In accordance with French laws, no written form was required for the survey. The survey was approved by the Institutional Review Board of the Paris North Hospitals, Paris 7 University, APHP (Comité d'Evaluation de l'Ethique des projets de Recherche Biomédicale du GHU Nord, n° IRB00006477, decision n° 10072).

2.2. Measures

A data collection form was used to retrieve the characteristics of the potential participants and those of the study, and this form was completed by a clinical research assistant. Also, a questionnaire was directly addressed and completed by recruiting pediatricians to assess their personal characteristics and perceptions.

When families and subjects were invited to participate in one of the included studies and were informed about our survey, the data collection forms were completed based on medical records and study protocols. Information on subjects and families included age and sex of the subject, date of the invitation to participate, participation decision (consent or refusal),