

## Paediatric clinical pharmacology in Europe

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**Maurizio Bonati<sup>1</sup>, Joerg Breitzkreutz<sup>2</sup>, Imti Choonara<sup>3</sup>, Kalle Hoppu<sup>4</sup>,  
Evelyne Jacqz-Aigrain<sup>5</sup>, Jean-Paul Langhendries<sup>6</sup>, Gerard Pons<sup>7</sup>,  
Anders Rane<sup>8</sup>, Hannsjörg Seyberth<sup>9</sup>, John van den Anker<sup>10</sup> on behalf of the  
European Network for Drug Investigation in Children (ENDIC)**

<sup>1</sup>Mario Negri Institute, Milan, Italy

<sup>2</sup>Institute of Pharmaceutics and Biopharmaceutics, Heinrich Heine University, Duesseldorf, Germany

<sup>3</sup>Academic Division of Child Health, University of Nottingham, Derbyshire Children's Hospital, UK

<sup>4</sup>Hospital for Children and Adolescents, and Department of Clinical Pharmacology, University of Helsinki, Helsinki, Finland

<sup>5</sup>Department of Paediatrics and Pharmacology, Robert Debré Hospital, Paris, France

<sup>6</sup>CHC-St Vincent NICU, Liège, Belgium

<sup>7</sup>Clinical Pharmacology, Hospital St Vincent de Paul, Université René Descartes, Paris, France

<sup>8</sup>Karolinska Institute, Stockholm, Sweden

<sup>9</sup>Department of Paediatrics, Philipps University, Marburg, Germany

<sup>10</sup>Department of Paediatrics, Erasmus MC, Sophia Children's Hospital, Rotterdam, the Netherlands

### Corresponding author

Professor Imti Choonara, Academic Division of Child Health, University of Nottingham, Derbyshire Children's Hospital, Uttoxeter Road, Derby, DE22 3DT, UK. Email: imti.choonara@nottingham.ac.uk

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Paediatric clinical pharmacology involves the scientific study of medicines in children. It is a relatively new sub-specialty of paediatrics and/or clinical pharmacology. A survey of members of the European Society for Developmental, Perinatal and Paediatric Pharmacology was performed in October 2005. This demonstrated the presence of 18 paediatric clinical pharmacologists

and 23 trainees in Europe. The majority of the trainees are based in five countries (Finland, France, Germany, the Netherlands and the UK). Only Finland, France, Germany and the UK had more than one paediatric clinical pharmacologist. In order to strengthen expertise in this area, greater collaboration is required.

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### Introduction

Many medicines used in infants and children have neither been licensed for such use nor

scientifically evaluated. Studies carried out by the European Network for Drug Investigation in Children (ENDIC), a working group of the European Society for Developmental, Perinatal

and Paediatric Pharmacology (ESDP), indicate that two thirds of paediatric patients admitted to hospital receive at least one unlicensed or off-label drug during their stay in hospital<sup>1</sup>. The scientific study of medicines in children is known as paediatric clinical pharmacology.

Historically paediatric clinical pharmacologists have been self-taught. Such individuals have managed to provide scientific information which has been crucial in preparing consultation documents such as the "Better Medicines for Children" document as well as the proposed European regulation on children's medicines<sup>2</sup>. It is only recently, however, that paediatric clinical pharmacology has been recognised as a sub-specialty<sup>3</sup>. The developments in paediatric clinical pharmacology are in contrast to the situation in adult clinical pharmacology, where unfortunately there has been a fall in numbers recently<sup>4</sup>.

## Methods

In order to establish the number of paediatric clinical pharmacologists and trainees in this area in Europe a survey was performed. This was done by email through the ESDP. For the purposes of the survey a paediatric clinical pharmacologist was defined as a medical graduate (MD) who had training in both paediatrics and clinical pharmacology. A trainee in paediatric clinical pharmacology was defined as a medical graduate who was receiving training in both paediatrics and clinical pharmacology.

Three questions were asked to all members of the ESDP in October 2005. They were as follows:

1. Are you a paediatric clinical pharmacologist?
2. Do you currently have a trainee in paediatric clinical pharmacology and if so how many?
3. How many trainees in paediatric clinical pharmacology have you had in the last 5 years?

Members of the ESDP were asked to forward on the email to other relevant individuals within their own country to ensure that the census was complete.

## Results

Replies were received from the majority of members of the ESDP. There were 18 paediatric clinical pharmacologists in Europe (Table 1). Only four countries (Finland, France, Germany and the UK) had more than one paediatric clinical pharmacologist. These four countries and the

**Table 1** Number and centres for paediatric clinical pharmacologists

Country	<i>n</i>	Location
Belgium	1	Liège
Finland	2	Helsinki, Turku
France	5	Paris, Tours
Germany	3	Erlangen, Marburg, Muenster
Italy	1	Milan
Netherlands	1	Rotterdam
Spain	1	Barcelona
Sweden	1	Stockholm
UK	3	Derby, Newcastle

Netherlands accounted for all but two of the trainees in Europe. There were 23 trainees in Europe in total (Table 2). Four trainees were training in centres where there is no paediatric clinical pharmacologist. There were an additional 11 trainees who had received training in the last 5 years (six of them in France). It was unclear how many of these individuals had completed their training and whether they were still active in the field of paediatric clinical pharmacology.

Replies were also received from outside of Europe. These included Israel, Canada and Australia. Each of these three countries had at least two paediatric clinical pharmacologists and at least two trainees currently.

## Discussion

Paediatric clinical pharmacologists have played a crucial role in both clinical trials<sup>5,6</sup> and the scientific study of medicines in children<sup>7-11</sup>. A weakness of the survey is that paediatric clinical pharmacologists were defined as paediatricians. This therefore excluded some other paediatric specialties that work exclusively with children and may also have training in clinical pharmacology. In addition the definition limited paediatric pharmacologists to medical graduates. This excluded paediatric pharmacists who have shown themselves to be capable of scientific research of major importance in this area<sup>1,12,13</sup>. It is to be hoped that in the future, multidisciplinary training in paediatric clinical pharmacology can be developed.

**Table 2** Trainees in paediatric clinical pharmacology

Country	<i>n</i>	Location
Finland	2	Helsinki
France	5	Paris, Lyon
Germany	7	Marburg, Muenster
Italy	1	Milan
Netherlands	3	Rotterdam
Sweden	1	Stockholm
UK	4	Derby, Aberdeen, London

In Europe, comparison of paediatricians trained and working in different countries is inherently very difficult. Many countries do not allow medical graduates to sub-specialise in two sub-specialties, i.e. clinical pharmacology and paediatrics, although it is possible in Finland, France, Germany and the UK. This is an area where discussion needs to take place within national paediatric professional organisations in order to ensure that paediatric clinical pharmacology develops. Paediatric clinical pharmacologists have different clinical commitments in different European countries. In Belgium, Germany, Hungary, the Netherlands, Switzerland and the UK, paediatric clinical pharmacologists have direct clinical responsibilities for patients as paediatricians. In many other European countries, however, they do not have such direct clinical responsibilities. It is important that within each European country an appropriate training protocol is developed. Currently only Finland and the UK have a formal training programme with accreditation. Accreditation needs to be independent and thus one requires a minimum of two centres.

There are very few paediatric clinical pharmacologists in Europe and it is of concern that only four countries have more than one paediatric clinical pharmacologist and five countries more than one trainee. Groups such as the ESDP and ENDIC can play a significant role in both training and increasing the number of paediatric clinical pharmacologists by providing the facilities for such training. ENDIC members have trained research fellows from other centres<sup>14-16</sup>. Additionally, ESDP and ENDIC have established three regular scientific forums for teaching and training in Europe. These include the biannual congress of the ESDP<sup>17</sup>, currently the largest international meeting of paediatric clinical pharmacologists worldwide. An annual European training course (ESDP-Eudipharm) is held in Brussels. There is also an international workshop on paediatric clinical trials held in Derby each summer in the year that the ESDP Congress does not take place<sup>18</sup>. These meetings are of value not only to trainees in paediatric clinical pharmacology but to also to others interested in research in this area such as paediatric clinical pharmacists, paediatricians with an interest in medicine, the regulatory authorities and the pharmaceutical industry.

The European Commission's proposed regulation on developing and investigating medicines in children will hopefully stimulate research in different aspects of paediatric therapeutics. Such research would be enhanced by an increase in the number of paediatric clinical pharmacologists in Europe. In conclusion, there is an urgent need to develop paediatric clinical pharmacology in Europe in order to improve the evidence basis

for the treatment of children with medicines. In such a context, paediatric clinical pharmacology needs to be evolving in relation to approaches, practice and methods to ensure that the children of Europe receive safe and effective drug therapy in a rational manner.

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