

Working Group 6: Educational Training of Research Staff Involved in Paediatric Clinical Trials / GCP Training across multispecialty and countries

G. Veal - October, 2019

History of Working Group:

- Initial task of group to carry out a questionnaire-based study to learn about the roles and training of paediatric research nurses across Europe
- In carrying out the study we established a good network of centres and interested parties in this area
- Key challenge in obtaining information with a truly European flavour due to limited/no roles for research nurses in some countries
- Significant amount of work extracting information at a country level and challenging to find the most appropriate contact people
- Further work has been carried out to further establish a more connected European network in this area

Initial study publication:

- Manuscript published in *BMJ Paediatrics Open*
- Interesting points for discussion:
 - *method of obtaining training (67% receive training updates online)*
 - *potential benefits of increased training opportunities when first in post*
 - *availability of training programs? Self-funded training in some countries*
 - *benefits of increasing numbers of nurses able to prescribe IMPs?*
 - *why are <50% research nurses taking patient consent?*
 - *research nurse roles / differences between countries*
- Link to publication through EnprEMA website
- Data presented on behalf of EnprEMA at STTI European nurses conference

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BMJ Paediatrics Open

Investigating the roles and training of paediatric research nurses working across Europe: a questionnaire-based survey

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ABSTRACT
Background The key role played by research nurses in conducting clinical trials in a paediatric setting has developed in line with increasing complexity of trial design. A questionnaire-based survey was conducted to investigate the training of research nurses involved in paediatric trials across Europe, to identify potential training needs and compare roles across specialist and non-specialist centres.
Methods A structured, cross-sectional questionnaire survey was used, with the aim of describing and quantifying research nurse activities. The questionnaire was designed to cover four main areas of interest: demographics, training, clinical trial experience and research nurse responsibilities.
Results The questionnaire was completed by 241 respondents across 41 different paediatric inpatient centres in 20 European countries. A higher percentage of research nurses within 3 years of taking up post were dissatisfied with the level of training (61%), as compared with those in post for 3-6 years (5%) and >6 years (8%). There was a trend towards a higher percentage of respondents receiving self-funded training in mainland Europe, with reported rates of 15%-20%, as compared with 0% in the UK and Ireland. Only 2% of research nurses prescribed investigational medicinal products in clinical trial settings, with contrasting roles observed between countries. **Conclusions** With high levels of training satisfaction were observed, 67% of respondents felt they would benefit from additional training in line with frequently changing practices. Currently, low levels of nurse prescribing are observed in a paediatric clinical trial setting across Europe. Appropriate research nurse training programmes should be promoted through national networks across Europe.

What is already known on this topic?

- Research nurses are increasingly involved in all stages of the development of complex clinical trials conducted across paediatric specialties.
- It is important that research nurses are appropriately trained for the various regulatory, methodological, ethical and administrative aspects of clinical trial design.
- Few studies have been published focusing on the level of training and roles played by research nurses working in paediatric specialties across Europe.

What this study adds to the topic?

- Approximately two thirds of research nurses felt that they would benefit from additional training in specific areas, with a clear need being observed between length of time in post and level of training satisfaction.
- An increased level of nurse prescribing may be beneficial in paediatric specialties, with only 2% of participants prescribed investigational medicinal products in clinical trial settings.
- Sharing of the information generated through national research nurse networks should be used to encourage the development of paediatric research nurse training programmes.

INTRODUCTION
 There is a clear need to accelerate the development of drugs across a wide range of childhood disease specialties. In order for this to be achieved, high-quality clinical research on the safety and efficacy of medicines in children is needed. In this respect, the research nurse plays an increasingly pivotal role in the successful conduct of paediatric clinical trials.¹ Clinical trials in children have an inherent detail level of complexity relating to regulatory, methodological, ethical and administrative issues, with additional burdens commonly introduced for developmental disorders.² The role of the research nurse has developed in line with increasing numbers of often complex research research questions, multi-arm trial designs, to generate as much information as possible from the smallest number of patients.

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Activities in 2018:

- Identification of key research nurse networks in paediatrics across Europe
- 40 networks / clinical centres identified who expressed an interest in working with EnprEMA
- Nearly all networks joined an inaugural teleconference
- Points for discussion:
 - *sharing of experiences from different European centres*
 - *useful exercise in pulling people together with shared interests in this area*
 - *request to provide information to all parties (groups, websites, etc)*
 - *next steps?*
- Agreed that the EnprEMA group could provide a useful central resource for sharing information between interested parties at a European level

Table of European Paediatric Research Nurse Networks and Groups

Provided by the EnprEMA Research Nurse Training Group

| Name of network/group | Country | Specialty | Contact person | Contact email address | Website address |
|---|---------|----------------|------------------|--|---|
| RCN Research in Child Health Network | UK | Multispecialty | Fiona Smith | Fiona.Smith@rcn.org.uk | https://www.rcn.org.uk/get-involved/forums/children-and-young-people-professional-issues-forum/children-and-young-people-professional-issues-forum-forum/home/communities/research-in-child-health |
| TEDDY (European Network of Excellence for Paediatric Clinical Research) | Italy | Multispecialty | Mariangela Lupo | mlupo@teddynetwork.net | https://www.teddynetwork.net/ |
| Children and Young People's Nurse Academics UK | UK | Multispecialty | Debbie Fallon | debbie.fallon@manchester.ac.uk | http://cypnauk.org.uk/ |
| FINPEDMED | Finland | Multispecialty | Pirkko Lepola | pirkko.lepola@hus.fi | http://www.finnpedmed.com |
| DanPedMed (Danish Pediatric Research Network) | Denmark | Multispecialty | Pernille Skovby | perniko@rm.dk | http://www.clinicaltrialsdenmark.com/what-do-we-offer/clinical-research-networks/dannedmed-danish-pediatric-research-network |
| Scottish Children's Research Network | UK | Multispecialty | Pamela Dicks | p.dicks@abdn.ac.uk | http://www.scotcrn.org/ |
| NIHR UK Clinical Research Facility Network | UK | Multispecialty | Jennifer Allison | Jennifer.Allison@uhs.nhs.uk | http://www.ukcrfnetwork.co.uk/the-hub.html |

- >25 networks involved in research nurse training / clinical trials in paediatrics
- Information made available through the EnprEMA website

Activities in 2019:

- Establishment of a EnprEMA Research Nurse Group with nurses from >10 European countries (inaugural TC held in February, 2019)
- Identification of lead research nurse(s) for individual European countries – task carried out in conjunction with c4c network
- 3 topics of mutual interest identified from initial discussions of the group:
 - *Training needs and access to training across Europe*
 - *Standardisation of research nurse practices across Europe*
 - *Further investigation into cultural differences in the role of the research nurse in different European countries*
- Next steps: to instigate working groups within the EnprEMA Research Nurse Group to decide on how best to address the topics above