

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

June, 2018

Working Group 6 : GCP Training Across Multi-specialties and Countries

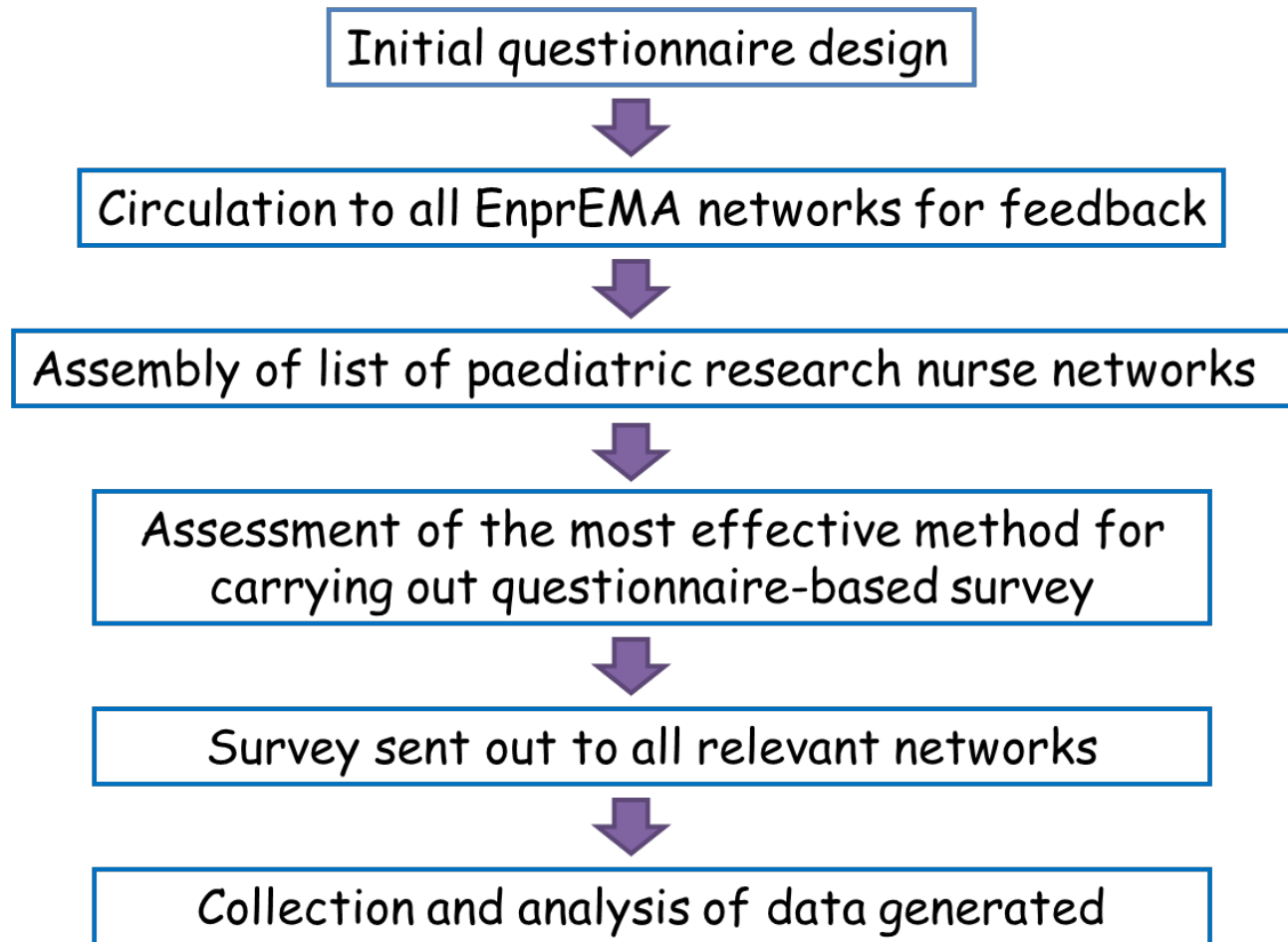
Chair: Gareth Veal

Membership: Pirkko Lepola, Salma Malik, Mary Costello, Susan Macfarlane, Mariangela Lupo

Objectives: Training of research nurses who conduct clinical trials: models, needs and current gaps across different specialties and countries

Task: Coordination and planning of questionnaire-based study on research nurse training

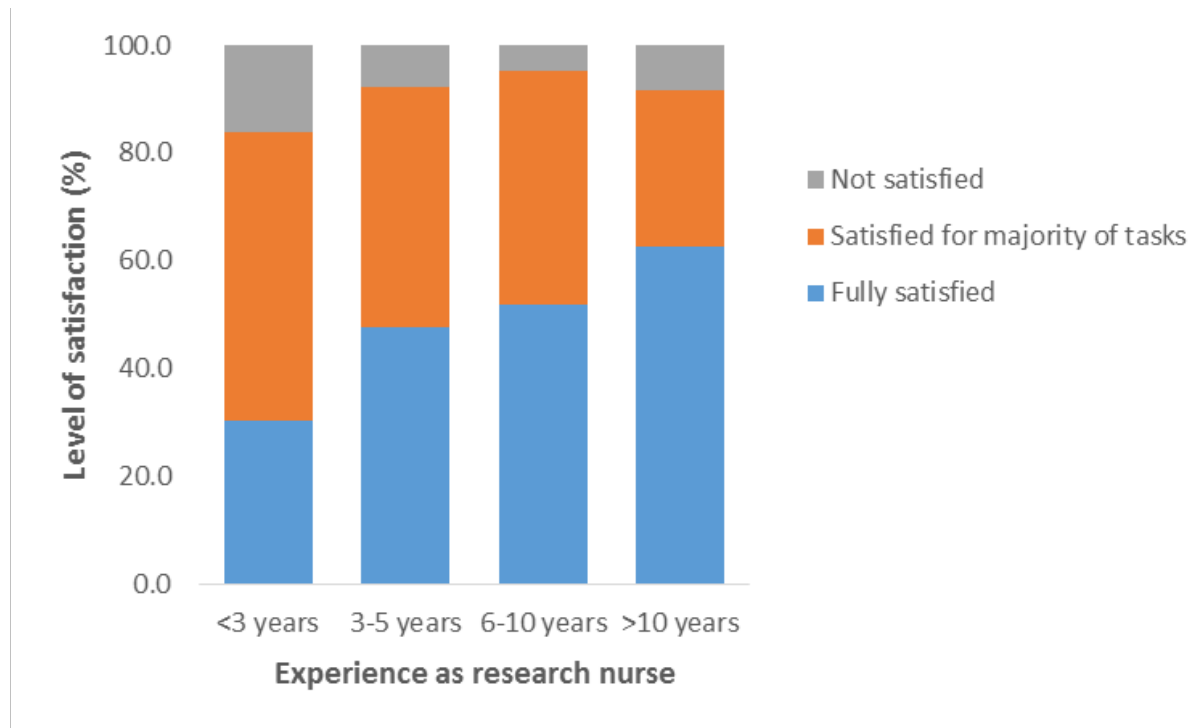
Key tasks and timelines:



Summary of data obtained:

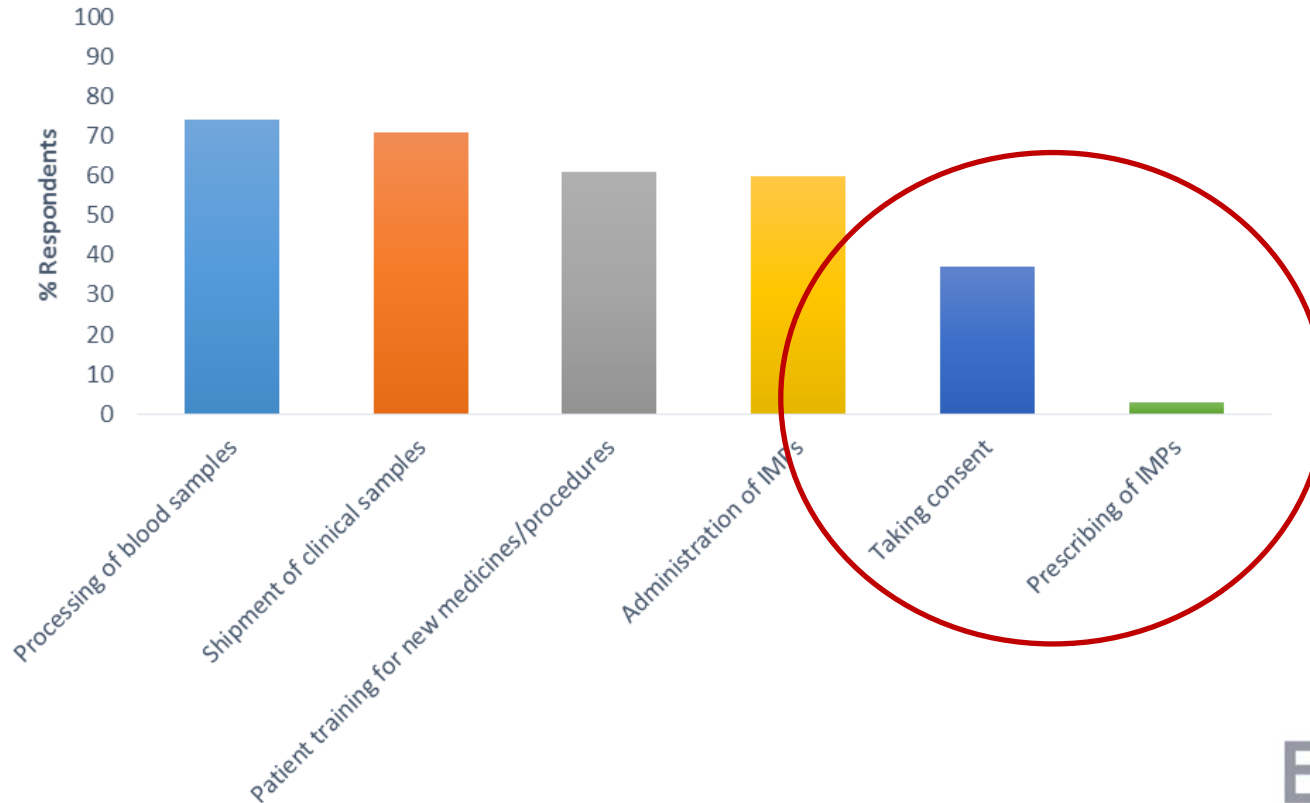
- Total of 75 organisations from 15 countries identified for circulation of questionnaire study
- Countries: UK, Ireland, France, Switzerland, Finland, Norway, Sweden, Denmark, Netherlands, Spain, Germany, Italy, Belgium, Hungary, Albania
- Specialties: Respiratory, oncology, neonatal (majority 'multiple')
- Link to questionnaires sent to points of contact for each organisation within a 9 month window
- Translation of questionnaire into French for organisations in France
- Completed questionnaires received: **343**

Level of Satisfaction vs Experience:



Participation in CTIMPs:

- >80% of research nurses completing questionnaire participate in CTIMPs
- >60% of research nurses participate in Phase I/II trials



Data analysis and publication:

- Analysis of data complete / 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

Original article

Open Access

BMJ Paediatrics Open

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

Gareth J Veal,¹ Salma Malik,² Mariangela Lupo,² Susan MacFarlane,⁴ Pirkko Lepola,⁵ Mary Costello,⁶ Adriana Ceol,⁷ Carine Boux,¹ Charlotte Lecour,¹ Annette Otto,¹ Maryam Raestegan,¹ Philip Berry¹

The other lead GJ, Malik S, Lupo M. et al. Investigating the roles and training of paediatric research nurses working across Europe: a questionnaire-based survey. *BMJ Paediatrics Open* 2017; 1:e001170. doi:10.1136/bmjpo.2017.001170

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ABSTRACT 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 paediatrics from across Europe, to identify potential training needs and compare roles across specialist and countries.

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 specialties in 20 European countries. A higher percentage of research nurses within 3 years of taking up post were dissatisfied with the level of training received (54%), as compared with those in post for 3-6 years (39%) and >6 years (38%). 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 4% 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 role played by research nurses working in paediatric specialties across Europe.

What this study hopes to add?

- 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 required. 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 In order for this role of the research nurse to be developed in line with increasing numbers of often complex research studies consistently built into trial design, to generate as much information

BMJ

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 held in January
- 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.finnedmed.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
- Table to be made available through the EnprEMA website