Clinical Studies Groups
Supporting the clinical research community
Welcome

Welcome to this report of the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Children’s Clinical Studies Groups (CSGs).

The overarching mission of CRN: Children is to support the development and delivery of the highest quality research involving children and families. The CSGs are a fundamental part of achieving this mission. This report highlights the ways in which the CSGs work closely with all elements of the research community, and parents and families, to ensure that the research undertaken within their specialties is robust, relevant to children and the NHS, and addresses important clinical questions. CSGs also have a key role in making sure that studies on the UK CRN portfolio are feasible and are designed appropriately to ensure that they deliver effectively.

We very much hope that you enjoy reading this report, and that it is helpful in outlining the wide range of ways in which the CRN: Children CSGs can enhance and support paediatric research within the UK, to ensure that children everywhere receive the best available clinical care.

Michael W Beresford - Joint Director
NIHR CRN: Children.

William van’t Hoff - Joint Director
NIHR CRN: Children.

Since 2005, the NIHR has established an integrated health research system giving researchers from the private and public sectors access to all NHS patients in all UK healthcare settings. The underlying principal of equity of access to research and best treatments is now embedded in both the NHS constitution and recent changes to the NHS organisation.

The NIHR itself encompasses a range of infrastructure including clinical research facilities for experimental medicine and early phase trials, and for delivery of later phase research across larger patient populations; researchers themselves (people); funding streams for different types of research; and systems such as the globally unique “Integrated Research Application System (IRAS)” which lets study Sponsors and Researchers complete just one regulatory application for all UK sites in a multicentre trial at the same time.

The NIHR CRN: Children CSGs provide unique, joined-up access to the paediatric academic and clinical expertise in the UK health research system. Linking with the UK Royal College of Paediatrics and Child Health Speciality Groups research committees, the CSGs can support studies at a variety of levels, from feasibility and site identification through child, young person and parent engagement, to developing and supporting national project applications.

This report outlines some of the ways in which the CSGs achieve this, and we hope it will be of interest to those involved in paediatric research, whether from within the research community, the life-sciences industry or charitable and funding organisations.

Please don’t hesitate to get in touch if you would like to discuss how the NIHR CRN: Children CSGs can help you plan or deliver your project in the UK.

Saul Faust on behalf of the Chairs of the CRN: Children CSGs

Introduction

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An introduction to CSGs

Within CRN: Children we have developed Clinical Studies Groups (CSGs) to cover the different specialty areas within child health. The CSGs provide, free of charge, expert advice to help researchers develop high quality research proposals.

What we do

The CSGs help to direct and develop the future research portfolio within their specialty to ensure it is balanced and meaningful by supporting those who are designing study proposals (reactive role) or developing our own research to run across the network (proactive role):

• **Proactive role** - in prioritising and developing new study proposals in collaboration with clinical investigators
• **Reactive/advisory role** - by guiding and supporting investigators and the pharmaceutical industry in the planning, development and delivery of new studies

The members of the CSGs meet regularly to provide the following service:

• Focusing ideas and refining the research question
• Facilitating patient and parent input
• Overall study design
• Formulations and pharmacy advice
• Feasibility of study recruitment
• Linking up with Clinical Trials Units who can contribute expertise in statistics and trial management
• Signposting to funding opportunities and NIHR CRN support
• Providing connections with other relevant researchers
• Disseminating and publicising research

Our CSGs

Our 14 CSGs are listed below alongside the number of studies they support within the CRN: Children’s research portfolio (as of December 2014).

1. Allergy, Infection and Immunity - 114
2. Anaesthesia, Intensive Care and Cardiology - 39
3. Cleft and Craniofacial Conditions - 6
4. Diabetes and Endocrine - 60
5. Gastroenterology, Hepatology and Nutrition - 64
6. General Paediatric - 140
7. Inherited Metabolic Disorders - 51
8. Neonatal - 97
9. Nephrology - 47
10. Neurosciences - 139
11. Pain and Palliative Care - 11
12. Pharmacy and Pharmacology - 9
13. Respiratory and Cystic Fibrosis - 72
14. Paediatric Rheumatology - 58

Who we are

CSGs include active researchers (clinical and other health professions including nurses, pharmacists and physiotherapists), parents, charity representatives and paediatric drug formulation experts.
Supporting the research community

The Royal College of Paediatrics and Child Health (RCPCH) has worked in partnership with CRN: Children and its CSGs for many years. The linkage with the CSGs was forged from the outset when they were set up to mirror and complement the RCPCH specialty groups. Since then the CSGs have collaborated closely with their specialty group counterparts and the College as a whole to take forward child health research in the UK.

The CRN: Children CSGs share a number of common aims with the College, for example the development of and support for research trainees and strengthening links with children’s charities and funders of paediatric research. The latter will be facilitated by the recent development of the United Kingdom Child Health Research Collaboration hosted by the College. This section of the report highlights some specific examples of how the CSGs are working to achieve these aims. Building on this strong history of collaboration, we very much look forward to continuing to work together with the CRN: Children CSGs to further progress child health research.

Supporting the research community

Anne Greenough, Vice-President for Research and Education, Royal College of Paediatrics and Child Health

The CRN: Children CSGs support the paediatric research community in a variety of ways, including:

- Advise on feasibility/deliverability of proposed research
- Support development of Research Trainees
- Work with researchers to develop study protocols
- Link to clinical specialty groups & professional associations
- Work in partnership with Clinical Trials Units and academic units
- Collaborate with Royal Colleges on key initiatives
- Contribute to relevant consultations on behalf of the paediatric research community

Working with the Neonatal Community

The Neonatal CSG has a long established partnership with the National Perinatal Epidemiology Unit (NPEU) and together have set up a Network of researchers and clinicians who develop and deliver research into new and existing treatments for infants and babies.

This Neonatal Network has helped to facilitate the successful delivery of a number of large trials involving infants and premature babies, and the linkage between the NPEU, the Neonatal Network and Neonatal CSG, alongside the partnerships the CSG has with funders of neonatal research and representation from neonatal professional societies, means that the lessons learned from delivering these studies are incorporated into the development of new trials involving infants and babies.
Supporting strategic coordination of multicentre research

The Diabetes and Endocrine CSG has established a sub-group to facilitate the strategic placement of new multicentre diabetes studies based on where eligible children are located and which sites are best able to recruit them into studies.

This joined-up approach is achieved by bringing together members of the CSG with those involved in delivering research within the NHS. This has allowed the paediatric diabetes community to work together to support the entire research pathway from identification of research priorities and questions, through to development of study protocols and delivery of studies once on the portfolio. By doing so, the pipeline of future studies can be informed by awareness of ongoing research, thereby allowing the strategic introduction and appropriate geographical distribution of new studies which improves the ability of sites to deliver studies to time and target.

Developing the new generation of paediatric researchers

A key role of the CSGs is to work with and support researchers in developing studies which are feasible and will successfully recruit the required number of participants within a specified timeframe (to time and target). A number of CSGs are paying particular attention to support the paediatric trainee community in order to increase the number of investigators available to undertake research, and have established mechanisms to involve and mentor trainees in the development and delivery of their own research protocols. This not only allows the further development of the CSGs portfolio, but also provides a cadre of young researchers with the necessary skills and experience which they will carry with them throughout their clinical careers.

For example, the Nephrology CSG is setting up a Trainee Development Scheme which will involve a series of subgroups focused on designing protocols to address key clinical questions in a range of areas, with a trainee paediatric nephrologist actively involved in each of these. This model is based on that of the other CSGs which have a long-standing, highly effective system of involving and supporting trainees to develop their own research alongside contributing to studies led by more experienced research leaders.

“The CRN: Children CSGs share a number of common aims with the College, for example the development of and support for research trainees and strengthening links with children’s charities and funders of paediatric research.”

Support snap-shots

CSGs have a key role in engaging, involving and representing their clinical and research community, and do so by forging strong links with the clinical and professional societies associated with their specialism.

The Gastroenterology, Hepatology and Nutrition CSG works closely with the British Society of Paediatric Gastroenterology, Hepatology and Nutrition and regularly holds joint national meetings with this organisation and collaborates with them on key initiatives associated with their field.

Within Neonatal Medicine, the British Association of Perinatal Medicine has delegated research activity and leadership to the Neonatal CSG, and similar arrangements are in place between other CSGs and their clinical and professional organisations.

Many of the CSGs are fully integrated with both National and European / American professional societies and clinical research networks within respective specialisms, ensuring that the CSG is aware of and involved in the latest international developments within paediatric research.
Working in partnership with funders and charities

CSG’s have worked hard to build strong links and partnerships with research funders, charities and professional societies over the years.

We would like to thank the following organisations for their support:

- British Paediatric Allergy Immunology and Infection Group
- The Healing Foundation/Craniofacial Society of Great Britain and Ireland
- British Society for Paediatric Endocrinology and Diabetes
- British Society of Paediatric Gastroenterology, Hepatology and Nutrition
- Action Medical Research Collaboration
- Louis Dundas Development Fund
- Arthritis Research UK
- Paediatric Intensive Care Study Group

The CRN: Children CSGs have worked closely with the Association of Medical Research Charities (AMRC) over a number of years on key initiatives to facilitate the design and delivery of paediatric research. For example, the CSG Chairs led a joint meeting with AMRC in 2010 focused on “Supporting the development and delivery of the very best paediatric research across the UK”.

The aim of the meeting was to facilitate partnerships with charities and funding bodies to identify and address priorities in children’s research. A key output was the development of a joint guidance document entitled “Points to consider when assessing the feasibility of research” which was subsequently adopted by several funders, including NETSCC who included a link to the guidance document on their website.

“The CSG has been successful in developing research priorities in pain and Palliative care, increasing the number of studies in this area in the NIHR portfolio and raising awareness of the need for more work in this area within the research and research funding communities.”

Dr Richard Howard
Chair of Pain and Palliative Care CSG

More recently, the CRN: Children CSGs helped support the AMRC’s All Party Parliamentary Group meeting focused on the involvement of children and young people in research which was held in the House of Commons in November 2013.

All the CSGs have been working with the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) to identify research priorities to feed into the NETSCC funding programmes. Over 30 research questions, prioritised following consultation with the broader specialist clinical communities and parents, have been submitted to NETSCC and more will be developed in this on-going relationship with the funding body.

Case study 1 - Cleft and Craniofacial

Following an approach from the Craniofacial Society and the Healing Foundation, the Cleft and Craniofacial Conditions CSG was established with financial support from both organisations. The group is now well established and functioning effectively, with patient representative members recently appointed. The CSG has been working with its membership and a wider group of expertise from within the specialty, alongside funders of cleft and craniofacial research, to identify key research questions to prioritise within future funding calls.

Case study 2

Pain & Palliative Care

Initially, treatment of pain in childhood was included within the remit of the Anaesthesia, Intensive Care and Cardiology CSG, which somewhat diluted the focus on pain due to the diverse group of specialties within the one CSG. Fortunately following generous support from the Louis Dundas Development Fund, which is administered through Great Ormond Street Hospital, the Pain and Palliative Care CSG was established which has allowed much greater focus on this vital area of paediatric care.
**Neonatal**

The Neonatal CSG received financial support from Action Medical Research, which has enabled the CSG to set up a number of sub-groups to focus on sub-specialty topics, and to increase the number and frequency of meetings undertaken by the CSG. This has led to an increase in activity and outputs from the CSG. More recently, the Neonatal CSG has been working with a number of the Royal College of Obstetrics and Gynaecology CSGs to focus on development of studies associated with the perinatal period. In addition, the CSG has for a number of years led an annual Neonatal Nurse Delivery meeting, to bring together and support nurses involved in recruiting babies to Neonatal studies. This meeting will be extended to involve research midwives and will address issues relating to the recruitment of women in pregnancy to studies in which outcomes are assessed in the newborn.

**Working with Asthma UK to improve access to Asthma patients**

The Respiratory CSG has established valuable links with the charity organisation Asthma UK. These strong links have enabled the CSG to establish a system for researchers to access Asthma UK and their large patient population (approx. 160 Research and Policy Volunteers) to enable patient and public involvement in research.

A system has been agreed for finding parents of children with asthma to comment on applications, sit on steering groups and also to disseminate the results of research. This important work will provide value to researchers in paediatric respiratory medicine, and help improve research outcomes for patients.

**Working with Bliss to ensure parents views help shape neonatal research**

Bliss is a UK Charity working to provide the best possible care and support for all premature and sick babies and their families. The Neonatal CSG has developed a close partnership with the Charity Bliss to ensure parents have a voice in the development and delivery of neonatal research.

Zoe Chivers is Innovations Manager at Bliss, and is a valued member of the Neonatal CSG. Zoe’s membership on the CSG has enabled closer working and partnerships with Bliss to develop an initiative for the CSG and researchers to engage with parents of premature babies, to support study development and promote open studies.

Bliss members on the Neonatal CSG also feed into Neonatal Research by providing research prioritisation updates at each meeting, enabling a national steer on the priorities for neonatal research.

For more information about Bliss visit: www.bliss.org.uk

"My role on the CSG is to make sure that the voice of the parent is heard and wider representation on the research projects the group looks at.

As more and more research is for patient benefit we need to seek ways to involve parents in research at the design and application stage. Our role therefore is to be a channel for helping researchers find parents who can sit on research teams ensuring the view of the parent and family is addressed.

We have helped find parents for focus groups for views on research as well as to sit on steering groups. This has all been done through contacts via the CSG. Our role is to influence research particularly in the area of the top 15 priorities for preterm birth."

Zoe Chivers - Innovations Manager, Bliss and Neonatal CSG member
Working in partnership with children and families

NIHR CRN: Children has strived to involve children, young people and families in all elements of its activity since it was established. Each of the CSGs has appointed a number of parent members to their groups to ensure that the views and perspectives of families are incorporated into CSG activity and the design of new research proposals. These parent members receive training to support their involvement and actively contribute to the business of the CSGs, with some taking a leading role in developing study proposals and driving the research agenda.

"Much proposed research relates to work in clinical settings. The home is often the therapeutic environment for children, and experience of this is absolutely essential to ensure that funding is balanced between clinical and home settings."

Hazel Greig, Anaesthesia, Intensive Care and Cardiology Parent Representative

Parent voices: shaping research in Paediatric Rheumatology

Sharon Douglas is a parent representative on the Paediatric Rheumatology CSG, and is also a consumer champion for NIHR CRN: Children. She has provided invaluable advice and input to the CSG over a number of years.

Through her involvement in the Paediatric Rheumatology CSG and the Scottish Network for Arthritis in Children (SNAC), Sharon sees many families affected by JIA and has a good understanding of their experiences of chronic illness. This enables her to bring this unique perspective to the work of the Paediatric Rheumatology CSG, providing invaluable insight into patients’ experiences and ensuring that the views of children with these conditions, and their families, are considered and have influence in the activity of the CSG.

“Patients and their representatives should be involved in evaluating services, and what matters to them should be collected and fed back to the paediatric rheumatology community ensuring that improving care is integral to improving satisfaction and outcomes.”

Sharon Douglas - CSG parent representative
Defining consumer priorities in research

Simon Stones is a consumer representative on the one of our CSGs, and has been part of the group for two years. Simon has had juvenile arthritis from the age of three, and over the past eighteen years, has experienced the ups and downs of living with a long-term condition as a child and young person.

He joined the group wishing to make a difference to other young people and their families, but was unsure how to do this beforehand. Since joining the CSG, Simon has actively participated in a variety of discussions, consultations and events, and is now actively researching consumer priorities with fellow consumer representatives, is a co-applicant on a project developing mobile app technology as well as a co-applicant on a health technology assessment led by researchers in the North West.

“Since joining the CSG, I have actively participated in a variety of discussions, consultations and events, and am now actively researching consumer priorities with fellow consumer representatives...the support, friendship and sharing of knowledge with the CSG has been so rewarding”

Building partnerships in Cleft and Craniofacial research

A collaboration with the Healing Foundation Centre for Cleft and Craniofacial Conditions research is being developed to include a public and patient involvement project, which will ensure representation from young people and parents is at the forefront of Cleft and Craniofacial research, helping to widen participation and improve outcomes.

Facilitating engagement with schools and community

The Pharmacy & Formulations group has been engaging with consumers through interaction with CRN: Children Young Persons Advisory Groups (YPAG), local schools and community events to explore children’s views on medicines. These events are particularly valuable as children learnt about the different medicine dosage forms, safety of medicines and the importance of clinical research in developing appropriate medicines for children. These opportunities are useful as they allow children, parents and carers to interact with researchers, and thus help inform future research questions. The information gleaned from these events is extremely valuable and some of the work has helped to inform the development of European guidelines (for example the European Medicines Agency Guideline on pharmaceutical development of medicines for paediatric use), which in turn informs the development of new medicines, bringing further benefits to children.

“The data generated from these events are extremely valuable and some of the work has helped to inform the development of European guidelines.”
Mandy Wan, CRN: Children, Paediatric Clinical Trials Pharmacist
Supporting industry

The CSGs interact with the global pharmaceutical industry across all paediatric specialties to maximise the likelihood that studies are robust and feasible, relevant to clinical practice in the U.K. and benefit children and families.

There are a diverse range of services and functions that are undertaken by the CSG that are of value to the pharmaceutical industry:

- Advice on drug development strategies
- Preparation of PIPs
- Development of study protocols
- Advice on pharmacy and formulations
- Identification of participating sites
- Supporting the delivery of studies to time and target

### Case study 1

**Problem** - A feasibility assessment undertaken for a commercial paediatric liver study, and associated evaluation of availability of the investigational drug in question, identified that there was limited active drug available in the U.K. In addition, the requirement for the dosage of the drug to be based on the weight of each individual participant had implications for the storage, preparation and administration of the drug which was considered a significant barrier to trial recruitment in England.

**Solution** - Members of the Pharmacy and Formulations CSG working together with members of the Gastroenterology, Hepatology and Nutrition CSG, initiated an early discussion with the company to explore different supply options and logistical aspects of delivering the study. With an understanding of UK pharmacy capability and knowledge of the trial design, the CSG recommended that support from a contract investigational drug manufacturer in Europe would facilitate the running of the study in England.

**Impact/Result** - The trial was set up based on CSG recommendations and feedback facilitated the sponsor’s decision to place the study in England. Two further studies investigating the same drug have since opened in England.

### Case study 2

**Problem** - Significant complexity associated with a novel agent for paediatric bone and joint infections, including the need for an unblinded pharmacy team, technical blinding issues, out-of-hours pharmacy support, and potential unblinding of the study due to the choice of comparator, meant that this commercial study would be difficult to deliver in the U.K.

**Solution** - Pharmacy and Formulations CSG, in collaboration with members of the Allergy, Infection and Immunity CSG:

- engaged with the UK investigators, and clinical research organisation and sponsor
- explored options to allow the study to run in UK ensuring the research question is being answered
- suggested the use of an alternative comparator
- worked through with the sponsor the logistics of delivering the study in an NHS environment.

**Impact/Result** - The study was able to go ahead within the UK once these significant barriers to uptake and delivery had been addressed.
**Case study** - Supporting the pharmaceutical Industry with protocol design

**Action** - Extended expertise from across a number of CSGs including General Paediatrics, Gastroenterology Hepatology & Nutrition, and Allergy, Infection and Immunity CSGs enabled collaboration with the pharmaceutical company Nutricia to develop an infant formula research protocol compatible with UK practice.

**Result** - The study is now being delivered in 7 sites in U.K., and has recruited 19 babies to date.

“We are a busy grouping incorporating dermatology as well as general paediatrics. 80% of paediatrics in the UK is general and thus we are privileged to comment on and indeed encourage engagement with many studies both industry and publically funded.

“We have representatives from Emergency medicine and generalists in addition to dermatologist, and nurses, and meet twice a year. Of all the groups we have the largest portfolio of studies and I am greatly privileged to chair the group.”

Professor Alastair Sutcliffe
Chair of the General Paediatrics CSG

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**Delivering clinical trials effectively**

**Case Study 1 – Supporting the identification of new study sites**

The Allergy Infection Immunity CSG engaged and actively collaborated with a pharmaceutical company on the design of a complex phase 1 single and multiple ascending dosing trial in infants hospitalized with Respiratory Syncytial Virus Infection. Excellent links between the CSG and their wider clinical community ensured the rapid and accurate identification and selection of study sites at an early stage, and establishing strong links with company has resulted in the possibility of the U.K. being selected for future phase 3 trials of the same drug.

**Case Study 2 – Overcoming barriers to site involvement in complex studies**

Gastroenterology Hepatology & Nutrition advised a company on a drug trial in the treatment of cholestatic liver disease in paediatric patients with alagille syndrome. Good collaboration at site level facilitated by CSG members resulted in overcoming significant initial complexities with screening patients and ensured the study achieved its 1st global recruit in the UK as well as completing to time and target.

**Supporting development of new initiatives to develop provision of treatments for children**

The CSGs all regularly contribute to national and international consultations, enabling the perspectives of children and paediatricians to be incorporated into the development and refinement of services, legislation and policy. A key example of this was the contribution the members of the Inherited Metabolic Disease CSG made to the recent consultation led jointly by the European Medicines Agency and the US Food and Drug Administration to ascertain views on the proposal to encourage a collaborative approach within the pharmaceutical industry to investigate novel treatment for the rare condition, Gauchers Disease.

**Case study - Supporting the recruitment of Global firsts within the UK**

The support of the Inherited Metabolic Diseases CSG has meant that U.K. can effectively undertake and deliver on complex clinical trials in rare conditions. Two specific examples of studies in which UK sites achieved first global recruits are; in patients with Hunter Syndrome and early cognitive impairment; and in 4 to 5 year-olds with phenylketonuria. The latter was also the top recruiting site in the UK and exceeded the company target.

Willemien Sinke
Clinical Study Manager, Paediatric Care and Metabolics at Danone Nutricia Research

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Diversity and collaboration

The General Paediatrics CSG covers a wide range of conditions from burns to adverse drug reactions, and dermatology to sleep disorders. As such, this CSG works particularly close with general paediatricians within the NHS, and supports a large portfolio covering a broad spectrum of commercial and publicly-funded studies.
International collaboration

Whilst CRN: Children works to support children’s studies across all of England, with strong links to equivalent networks within the Devolved Administrations, many of the studies on our portfolio are multinational. The CSGs have therefore fostered strong links with relevant international agencies, specialty organisations and research networks, particularly across Europe and the US. These links allow the CSGs to be aware of, involved in and influence international developments in paediatric research which enhances the work they do in the UK.

Helping to improve the health of children globally

The Pharmacy and Pharmacology CSG and Neonatal CSG both have strong links with European-funded Global Research in Paediatrics (GRiP) initiative which aims to stimulate and facilitate the safe use and development of medicines in children, and to improve the health of children globally.

GRiP partners, including members of the Pharmacy and Pharmacology CSG, are working to build and maintain an infrastructure matrix, which has the core aim of reducing the current fragmentation of the efforts to study and develop the use of medicine in children.

Supporting the development of international webinars about paediatric formulations

As part of a broad remit, GRiP also provides a programme of international webinars, to share global expertise and knowledge in topics relevant to paediatric medicines. The Pharmacy and Pharmacology CSG have been involved in leading on a recent webinar to encourage a global dialogue with Investigators and Scientists, including the 5th webinar of the “Meet the Experts in Paediatric Formulations” series, which was entitled “In-vitro biopharmaceutic methods in the development of oral dosage forms for children”.

“...GRiP also provides a programme of international webinars, to share global expertise and knowledge in topics relevant to paediatric medicines.”

Supporting the development of a globally recognised paediatric research qualification

The Pharmacy and Pharmacology CSG members have played an integral part in the development of a formal Masters-level qualification funded by GRiP. The ‘Master in Paediatric Medicines Research Programme’ involves 10 modules and the Pharmacy and Pharmacology CSG has worked closely with the GRiP education team to develop two modules, one in Paediatric Drug Formulations and the other in Paediatric Clinical Trial Management.