

Turning the tide: five years on



5-11 Theobalds Road, London, WC1X 8SH

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Turning the tide: five years on

Lindsey Hunter

Anne Greenough

Neena Modi

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Foreword

Paediatrics and child health can only advance by research. The stunning improvements in global child health over the last 15 years have all been based on research, some quite old. Child health has also improved in the UK over this period, and research leading to better practice has driven many of these changes. Several fields of paediatrics and child health have recently progressed very fast, others depressingly slowly. In general these mirror the rate of scientific advance. In all fields patients who are enrolled in clinical research tend to do better than those who are not. It is therefore a moral as well as a scientific responsibility to maximise the strength of research for children in the NHS, and to ensure children have the opportunity to be involved in research if they have health problems for which optimal treatment has not yet been determined.

The initial RCPCH report in 2012, *Turning the Tide*, was extremely influential in highlighting the opportunities but also the limitations of neonatal, paediatric and child health in the UK, and galvanised funders to look again at their models. This report follows up on that analysis 5 years later, and again examines the state of UK research and the academic base to see what has changed. Some things have improved, including several new funding streams for research in and with children. Several objective metrics, such as publications by paediatric specialists have increased. There are however some worrying trends, and in particular the decrease in academic paediatricians at senior lecturer grade, and the limited amount of time (often zero) that paediatricians of all grades have for research in their job plans. Arguably too little research is taking place relative to other areas of medicine. A discipline that chooses not to prioritise research is choosing not to advance, and it is therefore strongly in the interests of children in the UK that the RCPCH, and its outgoing President Professor Modi, have highlighted this issue so clearly.

There are clear data-driven messages for many groups in this report: for funders of research; for scientists and clinical researchers; for practicing paediatricians and their employers. We all need to take the messages from the data presented here seriously, and act on it.

Professor Chris Whitty

Chief Scientific Adviser

Department of Health and Social Care

Executive summary

In December 2012, the Royal College of Paediatrics and Child Health (RCPCH) launched *“Turning the Tide”*, a report that shone a spotlight on the importance and relevance of biomedical and life sciences research focussed on the needs of infants, children and young people. Over the ensuing five years there have been many developments that highlight a national commitment to sustaining and strengthening UK basic science and clinical research, and the life sciences industries. These include the 100,000 Genomes Project, and the establishment of UK Research and Innovation, Innovate UK, and Health Data Research UK. Paediatricians continue to advance the evidence-base for practice, the National Institute for Health Research provides a globally unparalleled framework for the delivery of clinical trials involving children, and the UK Research Councils and charities have provided sustained funding opportunities. We welcome these developments and these commitments.

There are however, areas that must not be forgotten. A poor evidence-base for practice is a patient safety issue. Strong basic science and clinical research are essential to driving improvement, testing treatments, reducing uncertainties in patient care and evaluating the effectiveness of innovations. The uncertainties of the planned departure of the UK from the European Union and the severe pressures currently facing UK health services may limit opportunities for trainees and the involvement of clinicians in research. The paediatric academic workforce remains small. There is inadequate representation of children’s interests in the UK life sciences strategy and few paediatricians on national research boards and committees. Reliable paediatric and related data sources are growing in number and improving in quality, as is child centred research infrastructure, but more could be done to integrate development and advance the pace of change. Research in crucial areas such as public health continues to be limited.

The RCPCH is committed to strengthening basic science and clinical research, and the development of devices, medicines and technologies that address the needs of children. We wish to see paediatric practice driven by the excitement of discovery science, and the curiosity and questioning that are at the heart of good medicine. We will sustain and improve education and training in research skills for all clinicians caring for children, and support paediatricians who wish to pursue an academic career. We will continue to advocate for child health expertise and the perspectives of the paediatric population to be represented on national research boards and committees. We aim to grow our engagement with industry and promote opportunity for the involvement of paediatricians to contribute their expertise to the development and evaluation of products. Good science does not stand still, so we will track progress over time to ensure

that infants, children and young people, and so too, UK population wellbeing and prosperity, benefit from a sustained focus on strengthening child health research.

Abbreviations

ACF	Academic Clinical Fellowship
BRC	Biomedical Research Centre
BRU	Biomedical Research Unit
CCT	Certificate of Completion of Training
CL	Clinical Lecturer
COiN	Core Outcomes in Neonatology
CRF	Clinical Research Facility
CRN	Clinical Research Network
EU	European Union
HDR-UK	Health Data Research UK
HRA	Health Research Authority
IPF	In-Practice Fellowship
MCRN	Medicines for Children Research Network
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute for Health Research
OOPR	Out of Programme (Research)
PA	Programmed Activity
PPI	Public Patient Involvement
RCPCH	Royal College of Paediatrics and Child Health
RCT	Randomised Controlled Trial
SASS	Staff, Associate Specialist and Specialty
StaR	Standards for Research
TITCH	Technology Innovation Transforming Child Health
UKCHRC	UK Child Health Research Collaboration
UKRI	UK Research and Innovation

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1 Introduction

In 2012, the Royal College of Paediatrics and Child Health (RCPCH) published *Turning the Tide* [1, 2], a report on children's clinical and biomedical research. This covered training, capacity, infrastructure and outputs, and brought a spotlight to bear on the importance of clinical and biomedical research in improving the health and wellbeing of children. In *Turning the Tide* the RCPCH made several recommendations aimed at improving early-years research, and raised the need for strengthened:

- **Education, training and guidance**, to assist the child health workforce in supporting, delivering and leading clinical research
- **Engagement with children, young people and families**, to hear their voices and how they want to be involved in and benefit from research
- **Collaboration**, between organisations to coordinate efforts to fund high cost projects, programmes, infrastructure and training, and raise the profile of child health research
- **Capacity**, by increasing the number of clinical and non-clinical child health researchers and establishing child-appropriate infrastructure
- **Integration**, of children's research with preclinical science and clinical practice

Five years on from *Turning the Tide*, we evaluate progress, reflect on our own actions, and identify next steps.

2 Changes in the UK biomedical research landscape

Since the publication of *Turning the Tide* [1, 2], several changes have taken place within UK healthcare research systems, and the country is currently planning for a future outside the European Union (EU). The full implications of leaving the EU are unknown and may have a challenging impact on child health research. In this changeable environment, it is a priority of the RCPCH to continue to promote the rights of the child to high quality, evidence-based healthcare and to strengthen the underpinning scientific basis of paediatric practice.

2.1 NIHR Clinical Research Networks

The Medicines for Children Research Network (MCRN) was established in 2005, funded by the Department of Health as part of the National Institute of Health Research (NIHR) Clinical Research Network (CRN). The “Paediatrics (non-medicines) Specialty Group” was subsequently formed in 2007 and together with the MCRN helped drive improvements in paediatric clinical research in the UK. In 2014, changes to the structure of the CRN led to the amalgamation of these two elements to form the National Children’s Speciality [3]. This is one of 30 CRN groupings bringing together communities of clinical practice in national networks of research expertise. The Children’s Specialty leads, manages and supports a portfolio of research studies related to children.

These initiatives have been very successful, resulting for example in a large number of children recruited to clinical trials and the UK participating in the highest number of pan-European clinical trials for childhood diseases, facilitated by harmonised frameworks for conducting studies [4]. In the future, developments in precision medicine and more targeted treatments will mean that many trials will increasingly be applicable to smaller national patient cohorts and hence rely even further on coordinated networks [5].

2.2 The UK Life Sciences Industrial Strategy

The UK continues to prioritise the development of the life sciences sector as a major component of the national economic base. The life sciences industries involve the application of biology and technology to health improvement, and include biopharmaceuticals, medical technologies, genomics, diagnostics and digital health. The life sciences industrial strategy published in August 2017 [6] set out a vision of how the UK might exploit existing strengths to increase the pace of economic growth in this sector, emphasising the necessity for sustained effort over a long period if the UK is to maintain a competitive edge. The strategy is based around nine core recommendations i) creating a “Health Advanced Research Programme” to undertake large research projects

and create new high-risk healthcare industries; ii) increasing funding for basic science; iii) continuing to improve UK clinical trial capabilities; iv) a tax environment that supports growth; v) creating “Life Sciences” clusters, a ‘single front door’ to the UK for research collaboration, partnership and investment; vi) attracting investment; vii) adopting and advancing the Accelerated Access Review to speed the delivery of new products to patients; viii) establishing Digital Innovation Hubs; ix) developing and delivering an action plan based on a gap analysis of key science skills.

The UK Life Sciences Industrial Strategy provides no specific reference to infants, children and young people. However, research targeting these groups is essential to improve understanding of childhood disease as well as the developmental origins of adult health and disease. The growing burden of long-term conditions such as obesity, cardiovascular disease, vascular dementia and diabetes have a substantial component of their origins in early life and are adversely affecting the health and economic wellbeing of the nation [7]. A focus by the life sciences sector upon life-course research has substantial potential to benefit patient and population health, and hence reduce NHS costs and improve adult productivity and the UK economy. The UK has undoubted strengths to support life-course research, including a unified health system, ability to link whole population datasets, and mature clinical networks.

The RCPCH considers it important that the UK recognise the benefits of the involvement of child perspectives in strategic plans for the life sciences. The development by the RCPCH of a framework for interaction with industry will facilitate the development of stronger links and promote transparent collaborations with the aim of benefiting child and population health [8]. The RCPCH are also pleased to note the launch in 2017 of the UK Prevention Research Partnership, an alliance of UK charities, Research Councils and the Health Departments to support research that targets population-level health, especially the physical and social antecedents of non-communicable diseases.

2.3 A UK-wide framework for Health and Social Care Research

In October 2017, the Health Research Authority (HRA) published the UK policy framework for Health and Social Care Research [9], replacing the separate Research Governance Frameworks previously in place for each nation. The framework sets out principles of good practice for the management and conduct of health and social care research in the UK, bringing together the Health Research Authority and the health departments in Northern Ireland, Scotland and Wales, and facilitating the conduct of research across all UK nations.

The new framework outlines the responsibilities of organisations undertaking health and social care research, aims to streamline management and conduct across the UK, and

promotes the interests of patients. Recent changes include the assessment of Wales-only non-commercial studies through the NIHR Clinical Research Network non-commercial adoption process, emulating existing arrangements in place for Scotland-only studies. The principal justification for adoption is that a study is of clear value in meeting the priorities, needs and realities of the NHS.

The RCPCH welcomes this framework, as alignment of operational processes across the UK nations is an important facilitator of research. The RCPCH would also welcome the inclusion of infants, children and young people as the default in research studies unless this can clearly be shown to be unnecessary or inappropriate, and has made representations to this effect to the HRA through the National Research Advisory Panel.

2.4 UK Research and Innovation

There is high level recognition of the need for the UK to keep research and innovation at the forefront of national endeavour. A component of the Higher Education and Research Bill (part 3) proposed the establishment of UK Research and Innovation (UKRI) [10]. UKRI will launch in April 2018 and operate across the UK with a budget of £6 Billion. UKRI will bring together the seven research councils, Innovate UK and a new organisation, Research England, in partnership with equivalent organisations in the devolved nations, to provide a strong voice for research and innovation to government and internationally, to ensure the UK maintains its position as a world leader.

UKRI will be measured by the impact delivered in relation to three elements, i) extending the frontiers of human knowledge and understanding; ii) delivering economic impact and social prosperity; and iii) supporting society to become enriched, healthier, more resilient and sustainable. UKRI will address science and technology as well as the social sciences, arts and humanities and will be responsible for allocating £4.7 Billion from the 2016 Autumn Statement. The RCPCH will continue to reiterate the importance to population health and the national economy of a strong focus on research to improve child health and wellbeing.

2.5 Innovate UK

Innovate UK is the operating name of the Technology Strategy Board, an arm's length body reporting to the Department for Business, Energy and Industrial Strategy. The name Innovate UK was adopted in August 2014. Innovate UK [11] drives productivity and growth by supporting businesses to realise the potential of new technologies, develop ideas and make them a commercial success. Innovate UK promotes growth by funding science and technology development, linking innovators to partners and helping them launch and grow successful businesses. In the coming years, as Innovate UK becomes the business-

facing part of UKRI, the aim is to lead on delivering economic impact and creating jobs. Innovate UK will invest around £500 Million in the financial year 2017/18 in competitions supporting business-led innovation and in innovation infrastructure that allows businesses to access leading-edge expertise, equipment and facilities. The RCPCH is involved in discussions with Innovate UK around mechanisms to connect child health expertise and knowledge with industry partners.

2.6 Health Data Research UK

Informatics provides a powerful approach to improving the monitoring of population health and prevention, providing novel insights into disease pathways and patient care, and increasing the efficiency and effectiveness of health and biomedical research. Health Data Research UK (HDR-UK) is a multi-funder UK institute for health and biomedical informatics research [12]. This national, interdisciplinary research institute will capitalise on the renowned data resources and research strengths of the UK, developing the capacity and methods to accelerate the pace and scale of health and biomedical data science to deliver a step change in UK capabilities. The institute will be delivered in partnership with the health research departments of England, Scotland and Wales, the Economic and Social Research Council and the Engineering and Physical Sciences Research Council, Wellcome Trust, and British Heart Foundation. A number of other charity, government and industry partners have also pledged their support and it is anticipated that additional organisations will participate in this ambitious endeavour. The RCPCH would like to see the development and capture of child health datasets and inclusion of these in HDR-UK.

2.7 Improvement Research Institute

The University of Cambridge is developing a new Improvement Research Institute, supported by £40 Million funding from the Health Foundation over a period of 10 years. Health improvement research builds and utilises knowledge to improve the quality of health services for the benefit of patients and populations. The new Institute aims to strengthen the evidence base for how to improve patient care, produce practical high-quality learning, and build research skills in the NHS and academia, as well as working with partners within the wider research and improvement communities, NHS staff, patients and carers to identify, design and test improvements. The Institute will also fund fellowship programmes to build skills in improvement research in the UK. The RCPCH welcomes the development of the Institute, and hopes to see representation of the needs of infants, children and young people in their work.

2.8 Twelve actions to support research in NHS England

In April 2017, NHS England set out initial goals to support research. Following this NHS England, NIHR, the Office for Life Sciences, the HRA and other partners outlined 12 actions to support and apply research. These centre on simplifying NHS research processes, articulating NHS research priorities, enhancing data infrastructure, supporting advanced research in cutting-edge technologies, and improving and simplifying adoption ecosystems. NHS England, with NIHR, Office for Life Sciences, HRA and other partners, will implement these actions [13]. Clinicians are central to the successful delivery of patient-centred research, particularly studies involving infants, children and young people, where expert knowledge and skills are required. The RCPCH also considers it essential to incorporate the views and priorities of patients throughout the research pipeline. The RCPCH therefore wishes to draw attention to the necessity for close collaboration between NHS England, NHS Employers, Health Education England, NIHR and patient groups, to ensure consultant job-plans reflect their contribution to the delivery of research studies, capture of high quality clinical data, and the acquisition of generic research skills during the training of doctors, nurses and allied health professionals.

2.9 Improving the quality of paediatric research

A number of initiatives are underway to improve the quality of paediatric research. Standards for Research (StaR) in Child Health [14] was founded in 2009 and involves methodologists, clinicians, patient advocacy groups and policy makers in developing practical, evidence-based standards for enhancing the reliability and relevance of paediatric clinical research.

Core Outcomes in Neonatology (COiN) is a project initiated in 2015 to develop a neonatal Core Outcomes Set based upon data routinely recorded during clinical care and held in the National Neonatal Research Database. This will ensure that outcomes of importance to all stakeholders, including patients and parents, are reported in a standard way that is relevant to everyday neonatal care. Embedding a core outcomes set into clinical datasets will enhance the usefulness of routine information in informing practice, enhancing patient care and improving outcomes.

2.10 The EU (Withdrawal) Bill

The departure of the UK from the EU has potential to have a profound influence on many aspects of biomedical research, including the pharmaceutical and medical device industries, regulation of medical products, and the underpinning UK preclinical and clinical research base. The RCPCH has been observing developments closely and has

been pleased that at the end of 2017, confirmation was issued that UK institutions can continue to bid for EU Horizon 2020 funding post-Brexit, in 2019 and 2020 [15]. However, clearly many uncertainties remain.

A new Clinical Trial Regulation, which will streamline approval processes for international trials and create a new registration portal for all studies conducted in the EU was passed in 2014 but has not yet been implemented (Regulation (EU) No 536/2014) [16]. The European Medicines Agency Management Board has confirmed the intention that the Clinical Trials Regulation will be outside the scope of the EU (withdrawal) Bill (Letter from the Department for Exiting European Union, 12 October 2017) [17] but it is unclear how this will be interpreted by the UK, particularly in a potential implementation period.

2.11 Children's medicines development

Historically, variation in legislation and standards presented a significant obstacle to developing medicines for children. Additionally, infants, children and young people have long been recognised to be served poorly by market forces in relation to the development and supply of medicines. Paediatric considerations have been an integral part of pharmaceutical research and medicines development across the EU in recent years [18]. The specific needs of infants, children and young people were recognised in the European Regulation No 1901/2006 on medical products for paediatric use. The "Paediatric Regulation", implemented in 2007, received extensive UK input. It provided pan-European incentives to the pharmaceutical industry to develop paediatric products. This had a positive impact, as discussed in the 2016 European Medicines Agency "*10-year Report to the European Commission*" [18], resulting in more than 10,000 paediatric investigation plans, and a decrease in off-label use of adult medicines in infants, children and young people. However, the report identified little progress in treatments for diseases that only affect infants, children and young people, or where conditions, particularly rare diseases, show biological differences between adults and children. Overall, however, the benefits of the Paediatric Regulation to-date, in respect of children's medicines development, have outweighed any related financial or administrative burdens. With the UK exiting the EU there is growing concern that this framework and the standing of the UK in relation to children's medicines development will be lost, and that the pace of reduction in the continuing high usage of off-label and unlicensed medicines in children will be halted. Further, if research in the UK is not completely aligned with the European Paediatric Regulations, the volume of commercial research in the UK will be reduced with strong negative impacts on child health, the NIHR portfolio, and the UK life sciences industries.

European regulatory frameworks for licencing medicines have been instrumental in speeding access to products by creating a larger market in which to launch new drugs, and facilitating post-licensing surveillance using evidence from across the EU.

Harmonised regulation facilitates international collaboration including clinical trials involving children, and rare diseases, where eligible patient numbers can be small. There have been considerable benefits to the UK from being a member of the European Medicines Agency. The costs and burdens of developing and supplying paediatric medicines have been minimised as the UK has been embedded in a strong international collaboration that includes the free-flow of medicines and shared international standards. The UK does not have the capability to work as a standalone regulatory jurisdiction in paediatrics and does not have sufficient market size to justify commercial investment in UK-only development programmes for infants, children and young people. If the UK Medicines and Healthcare products Regulation Agency (MHRA) is to become a 'sovereign regulator', operating outside of the European framework, it will need to increase capability and capacity rapidly to manage the increased workload and develop strategies to overcome the diseconomies of scale arising from the relatively small UK population of children, especially those with rare conditions.

The RCPCH has strongly advocated that any post-Brexit arrangements with respect to the development of medicines take into account the specific needs of children. Whatever the future arrangements, a priority must be for UK infants, children and young people to have timely access to medicines that have been evaluated rigorously and in a standard way. They will best be served by the strongest possible involvement of the UK with the European medicines regulatory network, the European Medicines Agency and opportunity for involvement in pan-European studies. For these reasons, the RCPCH has called for the UK to maintain a close working relationship with the European Medicines Agency and that paediatric capability at the MHRA is expanded as necessary to meet the challenges of a post-Brexit era.

2.12 100,000 Genomes Project

The 100,000 Genomes Project aims to bring the benefits of personalised medicine to the NHS. It involves a UK Government commitment to sequence 100,000 human genomes by the end of 2017. NHS England has established 13 NHS Genomics Medicine Centres to deliver an end-to-end genomic medicine pathway across the country. They obtain informed consent from patients and family members, collect samples for DNA extraction and sequencing, capture clinical information and establish infrastructure to make genomic medicine a routine part of NHS care. Training is an integral part of the long-term plan to incorporate genomic information into mainstream clinical medicine. Health Education England runs a Genomics Education Programme comprising short and

postgraduate courses, and other resources for doctors and healthcare workers. There is also a programme to educate the public about genomics and its implications. The RCPCH is pleased that neonates will be among the first wave of patients to benefit from the commissioning of genomic sequencing.

2.13 Medical technology initiatives

There is increasing opportunity to improve patient care through the use of technology. A number of medical-technological initiatives have been introduced to identify and tackle unmet needs and improve clinical practice.

Technology Innovation Transforming Child Health (TITCH) is national network dedicated to the development of technology solutions to improve children's healthcare. TITCH brings together a number of children's hospitals and specialist centres, medical technology co-operatives (centres of expertise that work with industry to develop new medical device concepts to improve treatment and quality of life for patients), small-medium enterprises, academic partners and charities. TITCH provides a platform to facilitate the development and commercialization of innovations for the benefit of children and families. To date TITCH has worked with the NIHR Med-Tech Co-operative Devices for Dignity and leveraged approximately £5.5 Million to support the development of health technologies for children and young people. This included a funding call supported by TITCH as part of the NHS England Small Business Research Initiative in 2016-17 focusing on self-care and independence in children with long-term conditions.

In April 2017, TITCH and the Northern Health Science Alliance hosted a workshop 'Bridging the Gap', bringing together clinical experts, industry experts, designers, engineers and academics to discuss barriers to the adoption and implementation of technology for child health. Following on from this the TITCH Network and the Children's Clinical Research Network brought together multiple high-level stakeholder representatives to determine approaches to accelerating child health technology development and adoption in the NHS. In early 2018, TITCH will support the Small Business Research Initiative in the funding call for Child and Adolescent Mental Health.

Sheffield Children's Hospital hosts the NIHR Children and Young People MedTech Co-operative established to support the development of technology specifically for child health, supported by a £1.1 Million grant from the NIHR in 2017. Sheffield Children's Hospital will work as a centre of expertise in collaboration with other children's healthcare Trusts across the country bringing together patients, clinicians, researchers, commissioners and industry to focus on themes that include epilepsy, muscle disorders, respiratory conditions, ventilation in children, sleep disorders, childhood cancer, rare diseases, transition and paediatric surgery.

The Children's Research Industry Group facilitates collaboration with industry, linking the NIHR children's research network and other organisations with representatives in industry working on children's medicines, devices and other areas. The aim is to improve collaboration and the support offered to industry particularly during early programme development, facilitate the NIHR children's research network and other affiliated organisations to obtain advice on industry matters, and attract additional studies to the UK.

GOSgene was established in 2010 funded by the NIHR Biomedical Research Centre at Great Ormond Street Hospital and University College London to improve gene identification in uncharacterised diseases, diagnostic testing, genetic counselling, and functional analyses aimed at understanding pathogenesis, improving patient management and developing new therapies. Collaborations have been built with industry through links with the North-East Thames Regional Genetics Service.

The Leeds in vitro diagnostics co-operative is a partnership between Leeds Teaching Hospitals NHS Trust and the University of Leeds. The co-operative acts as a catalyst for the generation of high quality evidence on clinical validity, utility, cost effectiveness and benefits of commercially-supplied tests, fosters collaboration between industry, healthcare professionals, patients, commissioners and researchers, creates new, world class methodologies for the assessment of in-vitro diagnostics and engages with patients to shape strategies and identify new opportunities.

2.14 Pregnancy Research Review Group

This specialist group was established following the annual report "The Health of the 51%: Women" from the UK Chief Medical Officer in 2014 [19]. The Group has multi-organisational representation that includes the RCPCH. It was established through the UK Clinical Research Collaboration to develop strategic approaches in priority areas of pregnancy research and work with research funders to review needs and spend. Particular research areas highlighted include pre-conception interventions to improve maternal and child mental and physical health, screening tests, prevention and treatment of pre-eclampsia, fetal growth restriction and preterm birth, and optimum models for antenatal and postnatal care. The remit of the group also includes the development of strategies to promote the UK as an excellent environment for pregnancy research given the unique ability of the NHS to undertake long-term follow-up at scale, and develop and foster academic-NHS-industry links.

2.15 Conclusions

There have been many developments over the last five years in the UK life sciences, and in clinical research organisation and regulation. These highlight the drive and commitment to develop and strengthen biomedical research in the UK. The inclusion of a focus on infants, children and young people offers opportunity for wide-ranging, long-term benefit, particularly in areas such as life-course research which requires multi-disciplinary collaboration and is facilitated by integrated health systems such as exist in the UK. This, together with the uncertainties posed by Brexit, provides strong justification for continued drive to strengthen UK infrastructure for children's research, increase the involvement of paediatric expertise in discovery science, and advocate for regulatory frameworks harmonised with international partners and appropriate for child populations.

3 Child health research activity, outputs and funding

3.1 Children's medical research facilities in the UK

Biomedical Research Centres (BRC) and Biomedical Research Units (BRU) were established in 2008 to carry out research for the benefit of patients. They are funded by the NIHR and based within the NHS and universities. In 2012, 11 BRC and 20 BRU were funded to lead the translation of biomedical research into clinical research. Only one BRC was child focused, and no BRU. The NIHR 2017 funding round combined funding for centres and units under the title of BRC (Table 1). Twenty BRC were funded in England, only one of which is exclusively focused upon children (Great Ormond Street Hospital for Children and University College, London), although others have a child focus within adult-centred core themes.

Clinical Research Facilities (CRF) are dedicated facilities, where specialist clinical research and support staff from universities and NHS Trusts work together on patient-orientated commercial and non-commercial experimental medicine studies. There are 19 NIHR funded CRF, eight of which receive additional funding from other sources or with NIHR funding routed through Trusts (e.g. Great Ormond Street Hospital for Children and Sheffield Children's NHS Foundation Trust).

Table 1 NIHR Biomedical Research Centres 2017-2022

	Organisation	Academic partner	Research themes
1	Barts Health NHS Trust	Queen Mary University of London	Cardiovascular devices and innovative trials, inherited cardiovascular disorders
2	Cambridge University Hospitals NHS Foundation Trust	University of Cambridge	Antimicrobial resistance, cancer, cardiovascular and respiratory disease, dementia and neurodegenerative disease, gastrointestinal disease, integrative genomics, mental health, metabolism, endocrinology and bone, neuroscience, nutrition, diet and lifestyle, population and quantitative science, transplantation and regenerative science, women's health and paediatrics
3	Central Manchester University Hospitals NHS Foundation Trust	University of Manchester	Advanced radiotherapy, cancer prevention and early detection, cancer precision medicine, dermatology, hearing health, respiratory medicine, targeted therapy in musculoskeletal diseases
4	Great Ormond Street Hospital for Children NHS Foundation Trust	University College London	Advanced treatments for structural malformation and tissue damage, gene, stem and cellular therapies, genomics and systems medicine, novel therapeutics and their translation into childhood disease
5	Guy's and St Thomas' NHS Foundation Trust	King's College London	Cardiovascular disease, cutaneous medicine, genomic medicine, imaging sciences, infection and immunity, oral health, regenerative medicine and cellular therapy, transplantation, women and children's health
6	Imperial College Healthcare Trust	Imperial College London	Brain sciences, cancer, cardiovascular, gut health, immunology, infection and AMR, metabolic medicine and endocrine, surgery and technology
7	Leeds Teaching Hospitals NHS Trust	University of Leeds	Preventing disease and disability in immune mediated inflammatory disease, improving treatment of osteoarthritis
8	Moorfields Eye Hospital NHS Foundation Trust	University College London	Gene therapy, genomic medicine and informatics, inflammation and immunotherapy, regenerative medicine and pharmaceuticals, visual assessment and imaging

9	Newcastle upon Tyne Hospitals NHS Foundation Trust	Newcastle University	Dementia, liver disease, musculoskeletal disease, neuromuscular disease, skin and oral disease
10	Nottingham University Hospitals NHS Trust	University of Nottingham	Deafness and hearing problems, gastrointestinal and liver disorders, mental health and technology, musculoskeletal disease, respiratory disease
11	Oxford Health NHS Foundation Trust	University of Oxford	Adult mental health, older adults and dementia, precision psychological treatments
12	Oxford University Hospitals NHS Foundation Trust	University of Oxford	Antimicrobial resistance and microbiology, cardiovascular, diabetes and metabolism, gastroenterology and mucosal immunity, genomic medicine, haematology and stem cells, multi-modal cancer therapies, multi-morbidity and long-term conditions, musculoskeletal, neurological conditions, obesity, diet and lifestyle, respiratory, stroke and vascular dementia, surgical innovation and evaluation, technology and digital health, vaccines for emerging and endemic diseases
13	Royal Marsden NHS Foundation Trust	Institute of Cancer Research	Breast cancer, gastrointestinal cancers, novel cancer therapeutics, prostate cancer, targeted physical therapies, uncommon cancers
14	Sheffield Teaching Hospitals NHS Foundation Trust	University of Sheffield	Translational neuroscience for chronic neurological disorders
15	South London and Maudsley NHS Foundation Trust	King's College London	Affective disorders and interface with medicine, bioinformatics and statistics, biomarkers and genomics, child and neurodevelopmental disorders, clinical and population informatics, dementia and related disorders, mobile health, neuroimaging, obesity, pain, patient and carer involvement and engagement, psychosis and neuropsychiatry, substance use, translational therapeutics
16	University College London Hospitals NHS Foundation Trust	University College London	Cancer, cardiovascular disease, deafness and hearing, dementia and mental health, immunity, inflammation and immunotherapeutics, neurological diseases, obesity, oral health and disease
17	University Hospitals Birmingham NHS	University of	Inflammatory arthritis, inflammatory bowel disease, inflammatory sarcopenia

	Foundation Trust	Birmingham	
18	University Hospitals Bristol NHS Foundation Trust	University of Bristol	Cardiovascular disease, mental health, nutrition, diet and lifestyle (including obesity), reproductive and perinatal health, surgical innovation
19	University Hospitals of Leicester NHS Trust	University of Leicester	Cardiovascular, lifestyle, respiratory
20	University Hospital Southampton NHS Foundation Trust	University of Southampton	Life-course nutrition, lifestyle and health, respiratory and critical care

3.2 Child health research activity

Review of the NIHR Portfolio shows how activity has changed over time. Over the period 2010/11 to 2016/17 there has been a mean annual increase of 6.2% (202) in studies adopted onto the Children's Speciality Portfolio, including an increase in commercial studies (Figure 1)¹. In 2012, the Children's Speciality Portfolio represented 2.9% of the total number of open studies across the NIHR CRN portfolio, but by 2015 this had risen to 7.6%. The [NIHR open data platform](#) shows that approximately 460,000 participants have been recruited to studies in the Children's Specialty Portfolio since 2010/2011 (Table 2). There are many other examples of strong involvement of children in clinical trials. For example, the Oxford Vaccine Group has enrolled over 10,000 children and young people into phase II, III and IV clinical trials since 2001 [20].

Some of the participants recruited to studies in the Children's Specialty Portfolio may be parents or carers and some studies that involve children, for example in cancer and child mental health, are not led by the Children's Specialty, so that the exact number of children recruited and their age distribution are unknown. Going forward, the RCPCH suggests that recording age or year of birth of all study participants would address this information gap.

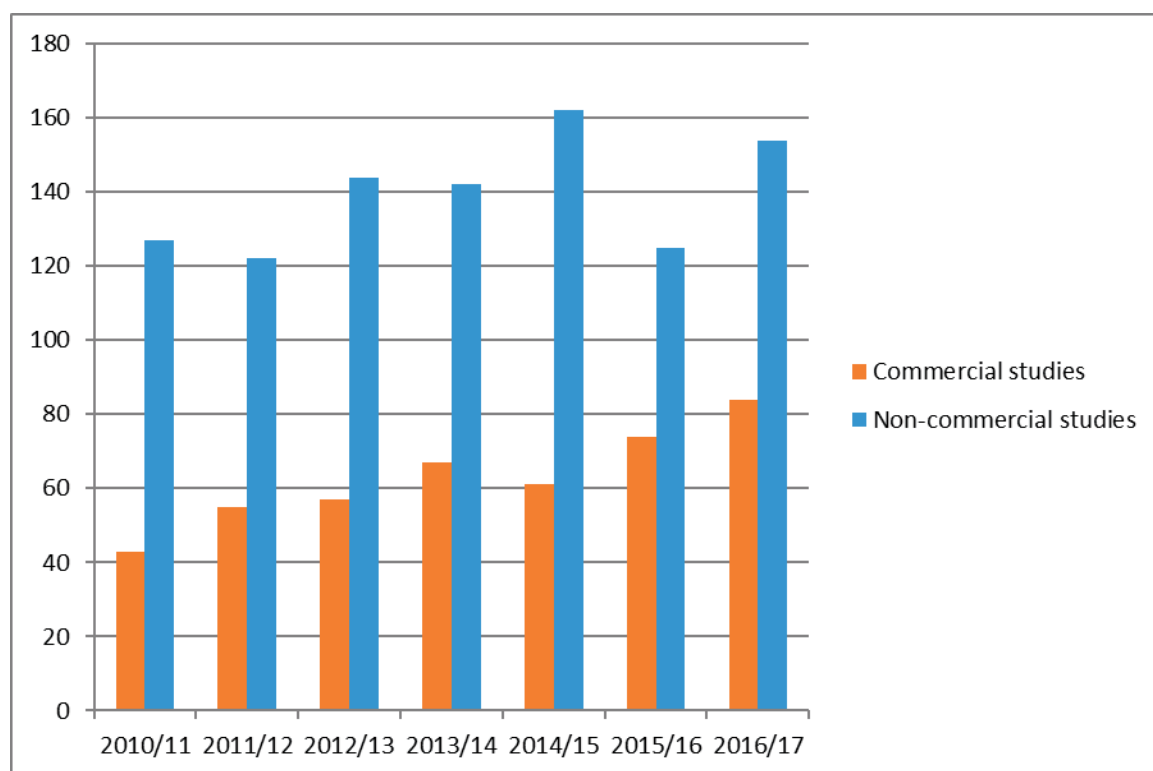
Table 2 Annual UK recruitment to studies on the NIHR CRN Children's portfolio*

Year	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	Total
Total recruitment	39,643	57,266	71,296	80,043	83,727	62,571	65,041	459,587

*Studies led and supported by the Children's Portfolio

¹ The NIHR financial year runs from April to March.

Figure 1 **Number of commercial and non-commercial studies adopted onto the NIHR Children's Speciality Portfolio by year**



[Data provided by the NIHR Children's Speciality Portfolio, obtained from NIHR Open Data Platform]

3.3 Registered children's clinical trials

A systematic search carried out by Pandolfini and Bonati [21] in 2009 identified clinical trials involving children across nine registries. A similar search was undertaken for the 2012 *Turning the Tide* report [1] and repeated in 2017. The 2012 and 2017 searches found an additional 11 registries that were not included in the 2009 Pandolfini and Bonati publication. A total of 14.0% of registered trials were identified as being conducted in the paediatric population in 2017, compared to 14.6% in 2012² (data from the ReBec registry was not included as it does not provide an accurate figure for the number of paediatric trials). Although this percentage has remained essentially unchanged, there has been an increase in the absolute number over the last five years, from 75,854 paediatric clinical trials registered in 2012 to 116,363 in 2017. This equates to a 61% increase in paediatric clinical trials undertaken worldwide (Table 3). Trends in the percentage of trials that are

² Some caution is required in interpreting the raw data presented in table 3 for individual registries, as many studies are entered into multiple databases.

paediatric are however inconsistent across registries. In some regional registries, such as the Australian and New Zealand Clinical Trials Registry, the percentage has increased, but in the largest trial database, Clinicaltrials.gov, the percentage has consistently decreased since 2009. The extent to which the increase in the absolute number of registered paediatric clinical trials represents a genuine increase as opposed to improved registration or variability in categorisation is also unclear.

Table 3 Clinical trials registered in trial databases across the world, and the percentage recruiting participants aged <18 years (searches conducted August 2012 and August 2017)

Register	Remit of Register	Number of paediatric trials (2017)	Number of trials in register (2017)	% of paediatric trials (2017)	Number of paediatric trials (2012)	Number of trials in register (2012)	% of paediatric trials (2012)	% of paediatric trials (reported in 2009)	Search strategy
AMGEN (www.amgen.com)	Separate register now subsumed by clinicaltrials.gov. Link on the AMGEN website allows search of clinicaltrials.gov for registered pharmaceutical trials being conducted by AMGEN.	100	952	10.5	38	409	9.3	4.8	Clinicaltrials.gov searched using Amgen as sponsor and age limit <18 years
ANZCTR (www.anzctr.org.au/)	Hospital, university and pharmaceutical research. Observational and interventional studies. All studies are recruiting, but not necessarily hosted in the Australasia.	3639	20620	17.6	853	6916	12.3	8.5	Age limit <18 years
Chinese Clinical trial Registry (www.chictr.org/en/)	Hospital, university and pharmaceutical research. Observational and interventional studies. All studies are recruiting, but not necessarily hosted in the China.	594	12398	4.8	109	2398	4.6	8.5	Searched the following terms individually, then excluded duplicates: child, infant, paediatric, pediatric, adolescent, toddler, baby, babies,

										neonate, newborn.
Clinicaltrials.gov	Hospital, university and pharmaceutical research. Observational and interventional studies. Open to all research globally.	52297	252580	20.7		29443	130838	22.5	26.1	Age limit <18 years
India-Clinical Trials Registry (ctri.nic.in)	Hospital, university and pharmaceutical research. Observational and interventional studies. All studies are recruiting, but not necessarily hosted in the India.	1066	9453	11.3		274	2889	9.5	31.4	Searched the following terms individually, then excluded duplicates: paediatric, pediatric, child, children, kids, adolescent, infant, newborn, toddler, baby, babies, neonate.
ISRCTN (www.controlled-trials.com/)	NHS, university and pharmaceutical research. Observational and interventional studies. All studies are recruiting, but not necessarily hosted in the UK.	3696	16123	22.9		2712	10853	25.0	23.2	Searched using the following strategy: "pediatr% OR paediatr% OR adolesc% OR neonat% OR newborn% OR infant OR child% OR toddler OR babies OR baby OR kids"
MRC CTU (www.ctu.mrc.ac.uk/study_search.aspx)	Mainly RCT currently being undertaken by the MRC clinical trials unit.	-	-	-		21	216	9.7	5.9	Searched the following terms individually, then excluded duplicates: paediatric, pediatric, child, children, kids,

												adolescent, infant, newborn, toddler, baby, babies, neonate.
Netherlands Trial Register (www.trialregister.nl)	Hospital, university and pharmaceutical research. Observational and interventional studies. All studies are recruiting, but not necessarily hosted in the Netherlands.	439	6421	6.8	425	3391	12.5	11.9	Searched the following terms individually, then excluded duplicates: child, infant, paediatric, adolescent, toddler, baby, babies, neonate, newborn.			
Registers included in Pandolfini and Bonati (2009) (21), but with incomplete data:												
Sri Lanka Clinical Trials Registry (www.slctr.lk/)	Hospital, university and pharmaceutical research. Observational and interventional studies. All studies are recruiting, but not necessarily hosted in Sri Lanka.	25	240	10.4	7	76	9.2	-	Now possible to search this registry using the following terms individually, then excluded duplicates: paediatric, pediatric, child, children, kids, adolescent, infant, newborn, toddler, baby, babies, neonate.			
National Organisation for Rare Disorders (NORD) register (www.rare	Trials currently recruiting patients with rare diseases.	-	-	-	-	-	-	33.3	Database no longer appears to be functional			

diseases.org/)																	
Roche (www.roche-trials.com/)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Not possible to search this registry, or quantify the number of included studies.
UK pharm. industry (ABPI) (www.abpi.org.uk)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Database no longer in existence.
Registers not included in Pandolfini and Bonati (2009) (21):																	
CRIS (Republic of Korea) (cris.nih.gov.kr)	367	2411	15.2	104	499	20.8	-	-	-	-	-	-	-	-	-	-	"Under the age of 18" filter
DRKS (Germany) (drks-neu.uniklinik-freiburg.de/drks_web/)	1348	6089	22.1	290	1233	23.5	-	-	-	-	-	-	-	-	-	-	pediatr* OR paediatr* ORadolesc* OR neonat* OR newborn* OR infant OR child* OR toddler OR babies OR baby OR kids
EudraCT (EU) (eudract.eudra.europa.eu)	4809	30978	15.5	2450	18660	13.1	-	-	-	-	-	-	-	-	-	-	Using age range limit "under 18"

eu)	studies have at least one investigator based in the EU.											
IFPMA Clinical trials portal (clinicaltrials.gov/)	Trials conducted by the pharmaceutical industry. Observational and interventional studies.	-	-	19785	136137	14.5						pediatr* OR paediatr* ORadolesc* OR neonat* OR newborn* OR infant OR child* OR toddler OR babies OR baby OR kids
IRCT (Iran) (www.irct.ir/)	Hospital, university and pharmaceutical research. Observational and interventional studies. All studies are recruiting, but not necessarily hosted in Iran.	3062	14488	21.1	396	13.2						pediatr* OR paediatr* ORadolesc* OR neonat* OR newborn* OR infant OR child* OR toddler OR babies OR baby OR kids
Pan African CTR (www.pactr.org/)	Hospital, university and pharmaceutical research. Interventional studies only (RCT or CCT). All studies are recruiting, but not necessarily hosted in Africa.	51	495	10.3	103	83.0						pediatr* OR paediatr* ORadolesc* OR neonat* OR newborn* OR infant OR child* OR toddler OR babies OR baby OR kids
ReBec (Brazil) (www.ensaiosclinicos.gov.br)**	Hospital, university and pharmaceutical research. Observational and interventional studies. All studies are recruiting, but not necessarily hosted in Brazil.	?	4970	-	?	-						The search software on the website was not functional and emails to the registry received no response.

RPCEC (Cuba) (registro clínico) (nco.sld.cu)	Hospital, university and pharmaceutical research. Observational and interventional studies. All studies are recruiting, but not necessarily hosted in Cuba.	29	250	11.6	10	418	2.4	-	Age limit < 18 years
UK Clinical Research Network: Portfolio Database (UK) (public.ukcrn.org.uk)	Hospital, university and pharmaceutical research. Observational and interventional studies. Includes studies in set up, recruiting and closed studies. To register, all studies have to meet set criteria for portfolio adoption.	6409	22781	28.1	454	10496	4.3	-	pediatr* OR paediatr* OR adolesc* OR neonat* OR newborn* OR infant OR child* OR toddler OR babies OR baby OR kids
UK Clinical Trials Gateway (UK) (www.ukctg.nihr.ac.uk)	NHS, university and pharmaceutical research. Observational and interventional studies. Hosted, but not limited to UK studies. Currently recruiting trials.	1230	22781	5.4	292	2881	9.9		pediatr* OR paediatr* OR adolesc* OR neonat* OR newborn* OR infant OR child* OR toddler OR babies OR baby OR kids
UMIN-CTR (Japan) (www.umin.ac.jp/ctr/)	Hospital, university and pharmaceutical research. Observational and interventional studies. All studies are recruiting, but not necessarily hosted in Japan.	1434	28542	5.0	1514	8567	17.7	-	2012: Age limit <18 years. 2017: Searched the following terms individually, then excluded duplicates: paediatric, pediatric, child, children, kids, adolescent, infant, newborn, toddler, baby, babies,

											neonate.
WHO - ICTRP		35768	383553	9.3	16574	179422	9.2	-			pediatr* OR paediatr* ORadolesc* OR neonat* OR newborn* OR infant OR child* OR toddler OR babies OR baby OR kids
Total		116363	831155	14.0	75854	519607	14.6	-			

(CCT: Controlled clinical trial; RCT: Randomised controlled trial)

**Data not included in final results

Some caution is required in interpreting the data presented in Table 3 for individual registries, as many studies have been entered into multiple databases.

[Searches completed and data compiled by Dr Matthew Hyde, Imperial College London]

3.7 Queen's Anniversary Prizes

The Prizes, one of the most prestigious awards in higher education, are part of the honours system and are awarded every two years by the Queen on the Prime Minister's advice. UK universities and colleges were invited in October 2016 to submit entries on any aspect of their work for assessment against the scheme's criteria of excellence, innovation and practical benefit, to the institution, UK education, UK economy, society and public benefit in general. In total, 21 UK universities and colleges of further education were recognised in 2017, seven of which are funded by the research councils. The awards include recognition of child health research, e.g. the Infant Sleep Information Source at Durham University funded by Economic and Social Research Council, the [University of Edinburgh MRC Centre for Reproductive Health](#) that has helped reduce stillbirths, and work at Cardiff University on the diagnosis and treatment of visual deficits in children with Down Syndrome. The RCPCH is pleased to see high quality representation of children's research in these prestigious awards.

3.8 Children's research funding

Turning the Tide [1,2] reported that total UK public and charitable medical research expenditure in the 2010/2011 financial year was £2.2 Billion, of which approximately 5% was directed at children's research. To ascertain whether there has been any change over the last five years, information on research expenditure was sought from UK funding bodies and charities (Table 4). Only data for organisations that provided figures for financial years 2012 to 2017 have been included in order that current research expenditure can be compared to that published in *Turning the Tide*. On this basis, overall research expenditure has increased to £2.8 Billion in 2015/16 of which £154 Million was directed at children's studies. The proportion of total expenditure on child health research rose to 8.5% in 2011-12, but then fell year on year to 5.4% in 2015-16.

3.9 European Commission child health research funding

A search was carried out of the [European Commission's Community Research and Development Information Service website](#) to ascertain the amount of funding received by the UK. The search was limited to all Horizon 2020 projects which were either Coordinating Actions or Research Innovation Actions, using the search terms "paediatr*" and "child*", from 01.01.2012 to 23.01.2018. The search identified 40 child health related projects with funding contributions from the EU, of which 32 had UK involvement. The total EU contribution to the 32 projects was just over €200 Million with €64 Million (32%) directed to the UK. The UK is the coordinator for 14 of the 32 projects.

Table 4 UK annual total public and charitable research expenditure, and proportion for child health research, 2011-12 to 2015-16

Charity	2011-2012			2012-2013			2013-2014			2014-2015			2015-2016		
	Total research spend (£Million)	Total children's research spend (£Million)	% of total for child health research	Total research spend (£Million)	Total children's research spend (£Million)	% of total for child health research	Total research spend (£Million)	Total children's research spend (£Million)	% of total for child health research	Total research spend (£Million)	Total children's research spend (£Million)	% of total for child health research	Total research spend (£Million)	Total children's research spend (£Million)	% of total for child health research
NIHR CCF	58.558	18.406	31.4%	64.758	11.039	17.0%	61.393	11.610	18.9%	81.900	7.561	9.2%	83.368	6.921	8.3%
NIHR NETS	74.702	14.292	19.1%	95.870	19.125	19.9%	121.062	22.223	18.4%	145.373	21.742	15.0%	155.672	21.985	14.1%
Medical Research Council	736.800	56.900	7.7%	769.800	49.200	6.4%	877.300	48.800	5.6%	801.400	45.400	5.7%	927.800	43.400	4.7%
Biotechnology and Biological Sciences Research Council	-	-	-	-	-	-	-	-	-	509.720	0.272	0.1%	444.537	0.213	0.1%
Arthritis Research UK	28.400	1.600	5.6%	12.200	1.000	8.2%	17.900	1.400	7.8%	28.200	3.700	13.1%	16.700	0.700	4.2%
British Heart Foundation	78.620	3.212	4.1%	83.708	0.418	0.5%	95.377	1.637	1.7%	68.718	1.922	2.8%	100.976	5.959	5.9%
British Lung Foundation	1.415	0.000	-	1.106	0.000	0.0%	0.305	-	-	0.694	0.051	7.3%	1.498	0.284	19.0%
Cancer Research UK	331.743	8.610	2.6%	350.997	8.276	2.4%	350.981	7.197	2.1%	341.403	4.665	1.4%	375.956	5.441	1.4%
Diabetes UK	5.981	0.349	5.8%	-	-	-	7.067	0.380	5.4%	6.105	0.090	1.4%	5.588	0.000	0.0%
Epilepsy Research	1.189	0.150	12.6%	0.687	0.149	21.7%	0.685	0.108	15.8%	0.840	0.022	2.6%	0.687	0.240	36.4%
Meningitis Research Foundation	0.421	0.324	77.1%	0.041	0.027	64.1%	0.160	0.123	76.9%	0.367	0.236	64.0%	0.245	0.150	61.0%
Wellcome Trust	511.100	52.507	10.3%	537.800	70.691	13.1%	308.000	25.584	8.3%	673.100	79.107	11.8%	752.900	68.889	9.2%
Total	1828.929	156.350	8.5%	1916.967	159.925	8.3%	1840.231	119.062	6.5%	2657.818	164.769	6.2%	2,865,926	154,181	5.4%

³ Data presented are not directly comparable with the 2012 Turning the tide report as some organisations have made minor adjustments to previously reported figures

3.9 Research publications

3.9.1 Contributions by NHS paediatricians

In *Turning the Tide* a third of consultant level paediatricians reported authoring one or more peer reviewed papers in the two-year period from 2009 to 2011. The 2015 RCPCH survey of research participation found that 35% of consultant paediatricians had authored one or more peer reviewed papers during the two-year period up to May 2015 [22]. On average, men authored almost twice as many publications as women (4.0 versus 2.2) and sub-speciality paediatricians an average of 5.4 publications compared with 1.2 by general paediatricians.

3.9.2 Publications in the top biomedical, medical and paediatric journals

Using a list of UK paediatric consultants from the RCPCH 2015 Medical Workforce Census [23], a systematic search was carried out of the PubMed database to identify the number of paediatric consultant publications between 2010 and 2015. The analysis was undertaken using the Pubmed Application Programming Interface (<http://www.ncbi.nlm.nih.gov/books/NBK25501/>) and R (version 3.4.0) with the XML package (version 3.98-1.9). An author with the same name as a UK consultant paediatrician was identified for 659,266 PubMed records. Of these, 70,050 were identified as originating from an institution with a UK address for the corresponding author. Of the UK publications, 551 (mean 92 per year) were published in one of the top 10 biomedical journals, 874 (mean of 146 per year) in the top 10 medical journals, and 207 (mean of 35 per year) in one of the top 10 paediatric journals (based on 2011 impact factors published by Thomson Reuters; table 5) (Table 6). There has been an increase in the annual number of publications in the top 10 paediatric journals from 30 in 2010 to 48 in 2015, but no substantial change in the number of publications in the top 10 biomedical and medical journals.

Table 5 Thomson Reuters 2011 top 10 biomedical, medical and paediatric journals

Top 10 biomedical journals	Top 10 medical journals	Top 10 paediatric journals
CA Cancer J Clin	N Eng J Med	J Am Acad Child Adolesc Psychiatry
N Engl J Med	Lancet	Pediatrics
Ann Rev Immunol	JAMA	Arch Pediatr Adolesc Med
Nat Rev Mol Cell Biol	Ann Intern Med	J Pediatr
Lancet	PLoS Med	Dev Disabil Res Rev
Nat Rev Genet	BMJ	Semin Fetal Neonatal Med.
Nat Rev Cancer	Arch Intern Med	Pediatr Infect Dis J
Nature	CMAJ	J Adolesc Health
Nature Genet	BMC Med	Pediatr Crit Care Med
Ann Rev Biochem	Cochrane Database Syst Rev	Arch Dis Child Fetal Neonatal Ed

Table 6 Total research publications from UK institutions that include a consultant paediatrician in the authorship, by year, from 2010 to 2015

	2010	2011	2012	2013	2014	2015	All Years
Total UK publications	82269	95378	105375	116178	127395	132671	659266
Total UK publications excluding reviews	75435	87730	96776	106604	116135	120742	603422
Publications from UK institutions including reviews	11114	11907	12934	13044	11071	9980	70050
Publications from UK institutions†	9778	10340	11278	11323	9621	8678	61018
Publications from UK institutions† in top 10 biomedical journals	92	91	85	102	82	99	551
Publications from UK institutions† in top 10 medical journals	140	154	162	173	120	125	874
UK publications in top 10 paediatric journals†	30	21	35	32	41	48	207
Total reviews	6834	7648	8599	9574	11260	11929	55844
Reviews from UK institutions in top 10 biomedical journals	10	11	18	10	4	14	67
Reviews from UK institutions in top 10 medical journals	18	19	42	29	14	17	139
Reviews from UK institutions in top 10 paediatric journals	2	2	7	14	3	13	41

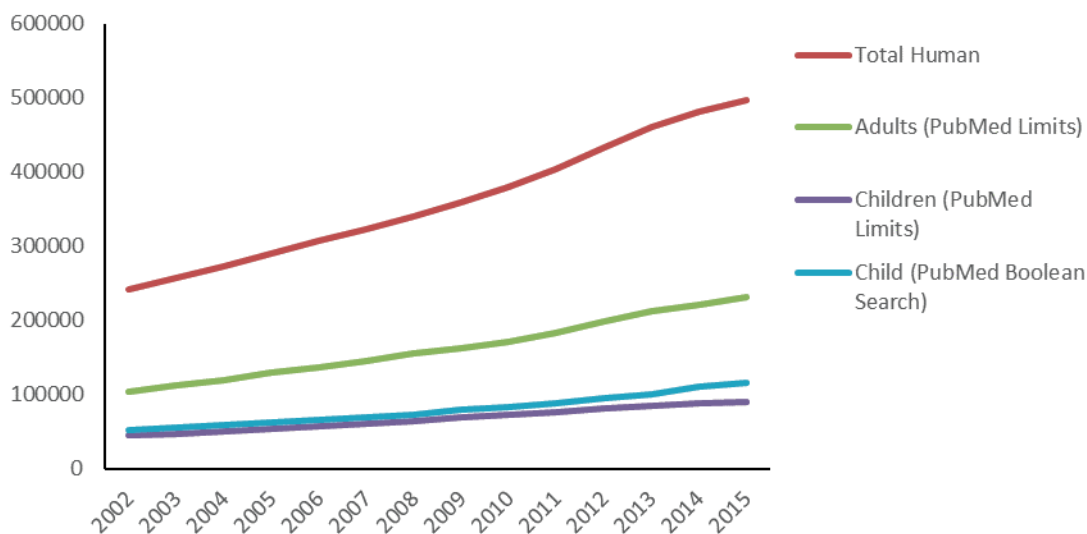
†excluding reviews

[Searches and data compiled by Dr Andrew Prayle, University of Nottingham]

3.9.3 Publications involving children's studies

A series of systematic searches of PubMed were carried out covering the years 2002-2015 to determine the total number of papers in each year, the total number of studies involving adults and the total number involving children. The searches were independently tested (using a Boolean Search) to ensure they maximised the number of hits returned. The results are shown in Figure 2, as “Children (PubMed Boolean Search)” and show strong concordance, albeit a slightly higher number of publications, than the results obtained by using the PubMed children’s study search. This shows that over the last 15 years the proportion of child to adult studies has remained unchanged at around third.

Figure 2 Number of publications in children and adults in PubMed from 2002 to 2015³



[Searches completed and data compiled by Dr Matthew Hyde, Imperial College London]

³ Figures are not directly comparable to *Turning the Tide*, as additional studies have been retrospectively indexed.

3.9.4 Publications in Archives of Disease in Childhood

“Archives of Diseases in Childhood” is the principle journal of the RCPCH. This international peer review journal has an independent editor and editorial board. Established in 1926, the journal aims to keep paediatricians and others up to date with advances in the prevention, diagnosis and treatment of childhood diseases, and informed on advocacy issues. The overall acceptance rate from 2010 to 2015 for papers submitted to Archives of Disease in Childhood by UK paediatricians has remained relatively constant at around 50% (Table 7).

Table 7 Submissions to Archives of Disease in Childhood and acceptance rates in 2005, 2010 and 2015

	2005	2010	2015
Total submissions	1656	2214	2061
UK submissions	764	787	722
Rest of EU submissions‡	302	484	482
Non-EU Europe	70	98	73
UK acceptance rate (%)	45.6	49.5	53.0
Rest of EU acceptance rate‡ (%)	21.5	18.7	18.3
Non-EU Europe acceptance rate (%)	14.2	10.2	20.5

‡EU excluding UK

3.9.5 National guidelines

The National Institute of Health and Care Excellence (formerly Health and Clinical Excellence) (NICE) was established in 1999 with the aim of producing evidence-based guidelines and ending variation by geographical location in the delivery of treatments across the UK. Over the years, the remit of NICE has broadened in parallel with a change to becoming a non-departmental public body in 2013.

Turning the Tide highlighted the limited evidence base for children’s health care and the resulting predominance of consensus-based guidelines. Paediatric specific clinical and public health guidelines have fluctuated year on year but the number of paediatric Quality Standards has increased (Table 8).

Table 8 National Institute of Health and Care Excellence, outputs 2007-2016

Clinical guidelines	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Total	8	12	13	19	21	18	20	18	21	22
Paediatric-specific	2	1	2	5	2	2	4	0	5	1
Paediatrics included	1	5	2	1	6	8	5	6	9	12
Wholly non-paediatric	5	6	9	13	13	8	11	12	7	9
Public Health Guidelines	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Total	5	8	5	9	5	6	5	8	6	6
Paediatric-specific	3	2	3	5	0	1	1	1	0	1
Paediatrics included	1	2	0	2	2	4	0	3	3	3
Wholly non-paediatric	1	4	2	2	3	1	4	4	3	2
Social Care Guidelines	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Total	0	0	0	0	0	0	0	1	3	2
Paediatric-specific	0	0	0	0	0	0	0	0	0	1
Paediatrics included	0	0	0	0	0	0	0	0	0	1
Wholly non-paediatric	0	0	0	0	0	0	0	1	3	0
Quality Standards	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Total	0	0	0	4	10	10	26	26	30	36
Paediatric-specific	0	0	0	1	0	1	5	7	2	8
Paediatrics included	0	0	0	0	1	0	8	7	11	15
Wholly non-paediatric	0	0	0	3	9	9	13	12	17	13

(The figures in this table represent new guidelines developed; updates of existing guidance are not included)

3.10 Conclusions

BRC and CRF have strengthened opportunity for the translation of biomedical research. Harnessing the potential of developmental biology, children's sciences and life-course research would also bring substantial benefit to the UK population, no less children. The RCPCH would welcome increased representation of child health research in NIHR BRC and CRF.

Recruitment of children to studies in the last five years has increased, as have publications by UK paediatricians in the world's top ten paediatric journals. The number of publications by UK paediatricians in the top 10 biomedical and medical journals has remained steady. A worrying finding is that men appear to author almost twice as many publications as women, though the reasons are unknown. Globally, the number of research publications relating to children's studies has increased in absolute terms but has remained constant as a proportion of all clinical studies. The proportion of funding awarded to child health by the research councils and major charities has also remained steady over the past five years.

Taken as a whole, these findings are testament to the strong contribution of UK paediatricians to research, despite the current pressures facing the NHS. The findings also emphasise the necessity of addressing barriers to research involvement, and strengthening the competitiveness of child health researchers in order to assist them in securing a larger proportion of research council and charity awards.

4 The paediatric clinical academic workforce

4.1 The senior clinical academic workforce

The RCPCH Medical Workforce Census [23] identified 168 clinical academic consultant-level paediatricians (professors, readers and senior lecturers) in the UK in 2015 (Table 9). This represents 4.2% of the total consultant-level workforce compared with 3.8% in 2013, 4.6% in 2011 and 9.6% in 2001. The Medical Schools Council reported similar numbers, identifying 153 Full Time Equivalent academic consultant paediatricians in 2016 [24].

Table 9⁴ Whole time equivalent professors, readers and senior lecturers from 2001 to 2015 [RCPCH 2015 Medical Workforce Census]

	2001	2003	2005	2007	2009	2011	2013	2015
Professors	82	75	84	79	87	74	70	103
Readers	9	10	9	6	11	14	12	9
Senior lecturers	100	97	86	79	78	68	61	56
Total academic consultants	191	182	179	164	176	156	143	168

4.2 NHS consultant involvement in research

In 2011, the RCPCH conducted a survey [25], of all paediatric consultant and Staff, Associate Specialist and Specialty (SASS) doctors recorded in the 2009 workforce census achieving a response rate of 67%. Of respondents, 66% of consultant-level paediatricians had no allocated Programmed Activities (PA; representing 4 hours per week) for research, 26% had one PA or less, and 7% had 1.5 to 5 PA. Only 1%, all of whom hold academic appointments, reported receiving more than 5 research PA. The average number of research PA in consultant job plans was 0.5.

The survey was repeated in 2015 [22]. All consultant and SASS doctors recorded in the RCPCH 2013 workforce census [26] and any new holders of a Certificate of Completion of Training (CCT) in paediatrics up to May 2015 were invited to participate. The response rate was 44% and was representative of the paediatric workforce with regard to sex,

⁴ Data are presented from the 2015 RCPCH medical workforce census and are may not be directly comparable to data reported in the 2011 Turning the Tide report due to retrospective confirmation of figures.

grade and location of work. The average number of research PA in consultant job plans was 0.4 (Figure 4), however the average number of research PA actually worked was 0.7. Though no research PA were reported by 80%, research involvement was reported by 49%.

The Royal College of Physicians (London) reported similar findings. Over 2016-17, a mean of 0.6 contracted PA was identified for academic work [27]. In 2015, the Royal College of Physicians also conducted a survey specifically focusing on research. This showed that doctors across all adult specialities and all career stages spent an average of 4.7 hours per week on research activities [28].

A substantial number of the RCPCH 2015 survey respondents (89%) reported having received no grants for research [22]. Awarders of the largest number of grants were local research charities (82), followed by national research charities (73) and the NIHR (54). Over a third of grant holders (127) were in receipt of grants totalling £200,000 or more from a single awarding body. Approximately 42% were in receipt of small grants i.e. less than £100,000.

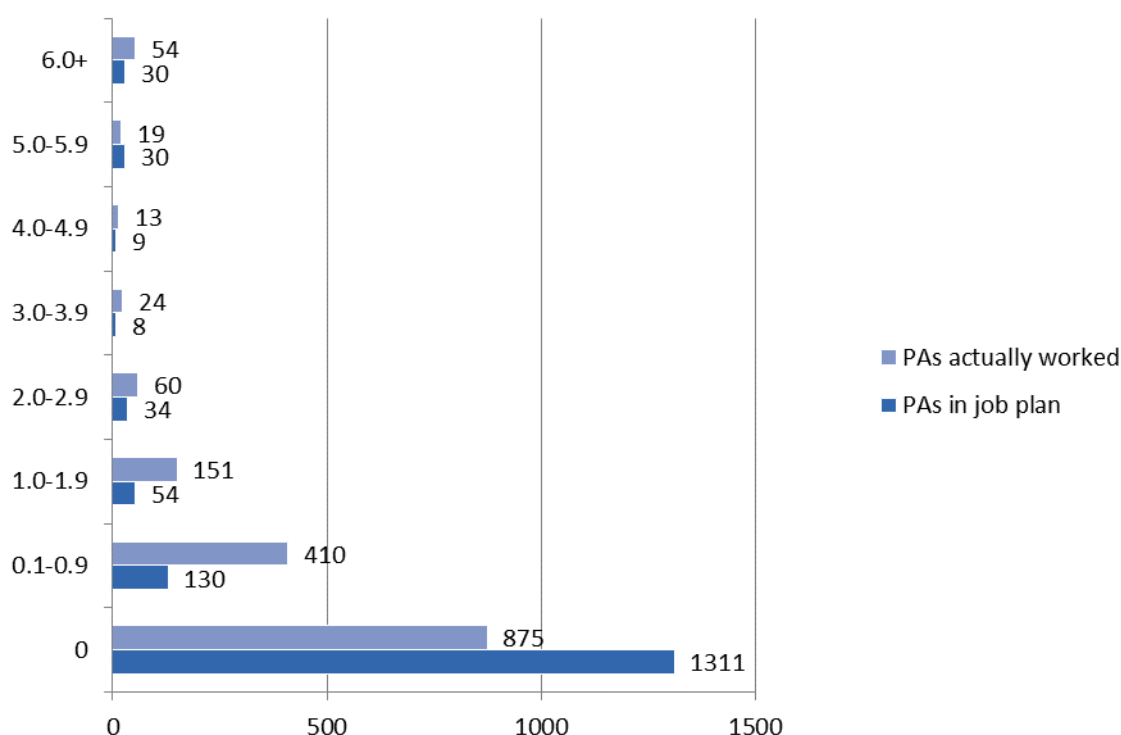
Only a minority of paediatric consultants were involved in PhD supervision (7.6%); 88% reported having never undertaken any PhD supervision.

In 2017, the RCPCH surveyed trainees who obtained a paediatric CCT in 2015 or who obtained a place on specialist register through the Certificate of Eligibility for Specialist Registration route. Three hundred and twenty-four trainees were identified, of whom 179 responded (55%). The purpose of the survey was to identify career intentions and working patterns. Of 128 respondents, 47% (60/128) stated they would like to be undertaking more academic/research work but only 23% (29/128) expected to do so (Table 10).

Table 10 Career development expectations

Career development statement	Expect career to develop		Would like career to develop	
	Number	%	Number	%
I will be carrying out more specialist work	79	62	76	59
I will be undertaking more medical education work	60	47	82	64
I will be more involved in trust/ service management	49	38	52	41
I will be undertaking more academic/research work	29	23	60	47
I will be undertaking roles for the RCPCH	19	15	54	42
I will be undertaking less resident shift working	31	24	29	23
I will be undertaking less Direct Clinical Care	20	16	28	22
I will be working in a different area of paediatrics	17	13	24	19
I will not be working in the UK	17	13	13	10
I will be working in a different medical specialty	2	2	14	11
I will not be working in medicine	4	3	9	7

Figure 4 **Programmed activities for research in job plan and actually worked**
(consultants only) [RCPCH 2015 research participation survey]



4.3 Research fellowships

Clinical academics bridge practice and research and fellowships are critical to support career progression. The MRC carried out a survey on behalf of 13 research funders, the Medical, Dental and Veterinary Schools Councils and the Association of Medical Research Charities, on personal fellowship awards⁵ active in March 2017 [29]. Data include individuals awarded clinical and health research fellowships who were medically qualified, dentists, nurses and midwives, veterinarians, allied and other health professionals, and non-health professionals. This provided a snapshot of fellowship funding “live” in March 2017 across England, Wales, Scotland and Northern Ireland. Overall, 2840 active fellowships were identified across all medical specialities and career stages from pre-doctoral to senior academic appointments, with a 71% increase from 2009, equating to 1180 additional fellowships.

There was a marked increase in the award of early career fellowships, possibly due to the Academic Clinical Fellowships established by the NIHR. The Integrated Academic Training pathway was established in 2006 and includes Academic Clinical Fellowships

⁵ Fellowship awards supporting the salary of the recipient (the fellow), usually for between 1 and 5 years; most fellowships pay for 100% of the fellow’s contracted working time to enable a consolidated period to be focussed on research.

(ACF) and Academic Clinical Lectureships (ACL), coordinated by the NIHR Trainees Coordinating Centre. In 2017, the Centre undertook a strategic review of training [30]. This recommended the integration of all current academic training and higher career personal awards into a new academic structure with the creation of a new entity, the NIHR Academy. The NIHR Academy will replace the NIHR Trainees Coordinating Centre to host all academic training and career development activity. NIHR trainees will become NIHR academy members and criteria will be established for individuals who are not fully funded by NIHR to be eligible for Academy membership as associates, allowing them to become part of the research training ecosystem.

The Integrated Academic Training pathway is a tool for expanding capacity in priority areas. Allocation by formula, where decisions about speciality are made at the local partnership level, is meant to support academic strengths locally but risks lowering competitiveness. Hence, the review recommended that the balance between the allocation of posts by formula and competition should be modified to ensure a closer link with NIHR strategic priorities, as well as addressing underrepresented areas and future health challenges identified through consultation. For competitive posts, themes have been developed where research is linked to complex challenges [31].

Data over the period 2010/11-2016/17 from the NIHR Trainees Coordinating Centre (Table 8) highlights an average of 254 ACF appointed each year. The number of annual paediatric ACF awards has fallen from 31 to 16, though the proportion following an abrupt drop from 13% to 7% over 2010/11 to 2011/12 has remained steady. The number of ACL appointed each year has averaged 89 since 2010/11 with the number of paediatric awards ranging from two to nine.

Data for 2016 provided by the Medical Schools Council shows the number of paediatric lecturers to have fallen to 23.2 WTE (personal communication).

Table 11 National Institute for Health Research Academic Clinical Fellowship (ACF) awards and Academic Clinical Lectureship (ACL) awards, 2010/11 to 2016/17

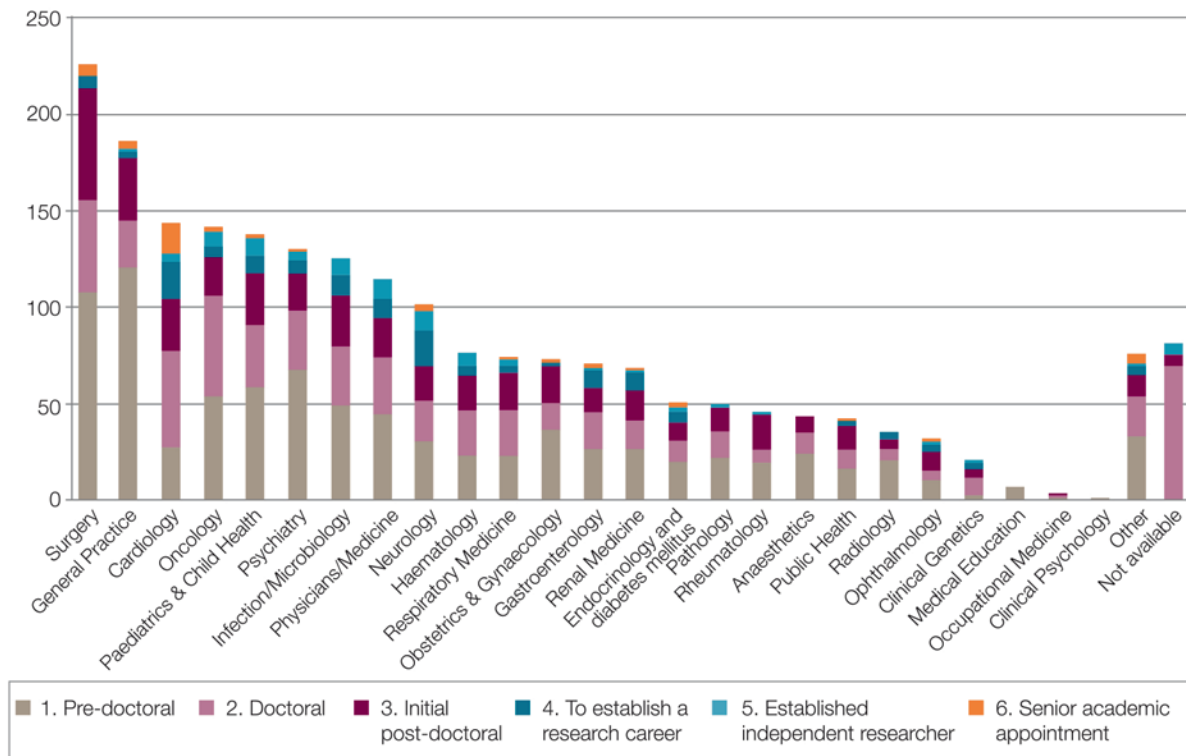
	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	Mean
Paediatric ACF posts	31	18	20	23	18	19	16	21
Total ACF posts	244	254	252	266	259	255	248	254
Percentage of ACF posts awarded to paediatrics	13	7	8	9	7	8	7	8
Paediatric ACL posts	5	2	9	2	8	5	6	5
Total ACL posts	89	67	80	101	100	95	88	89
Percentage of ACL posts awarded to paediatrics	6	3	11	2	8	5	7	6

*Including paediatric cardiology and surgery

4.4 Medically qualified researcher progression

The 2017 MRC survey [29] reported that the number of pre-doctorial (awards supporting initial research experience; i.e. a Masters course or NIHR ACF award) and doctoral awards (awards supporting a PhD or other higher degree) supported by the UK funders partnering in this survey has increased since 2009. The total number of awards supporting the initial post-doctoral career stage has almost doubled since 2009 demonstrating an improvement in the breadth of routes available to individuals to access academic training post-PhD. However, the survey identified the need for more support for post-doctoral fellows, as there has been a 13% decline in awards supporting fellows to establish an independent research career. In 2009, 198 live awards were identified, compared with 172 in 2017, suggesting this represents an increasing bottleneck in the pathway to a senior clinical academic position. In total, 2149 medically qualified fellows across all career stages were identified, compared to 1343 in 2009. Paediatrics and child health was shown to have the fifth highest number of medically qualified fellows across all medical specialities and all career stages [29], and has featured within the top ten since 2009 (Figure 5).

Figure 5 Distribution of medically qualified fellows by medical speciality and career stage (NIHR ACF, In-Practice Fellowships (IPF) and ACL) in 2017

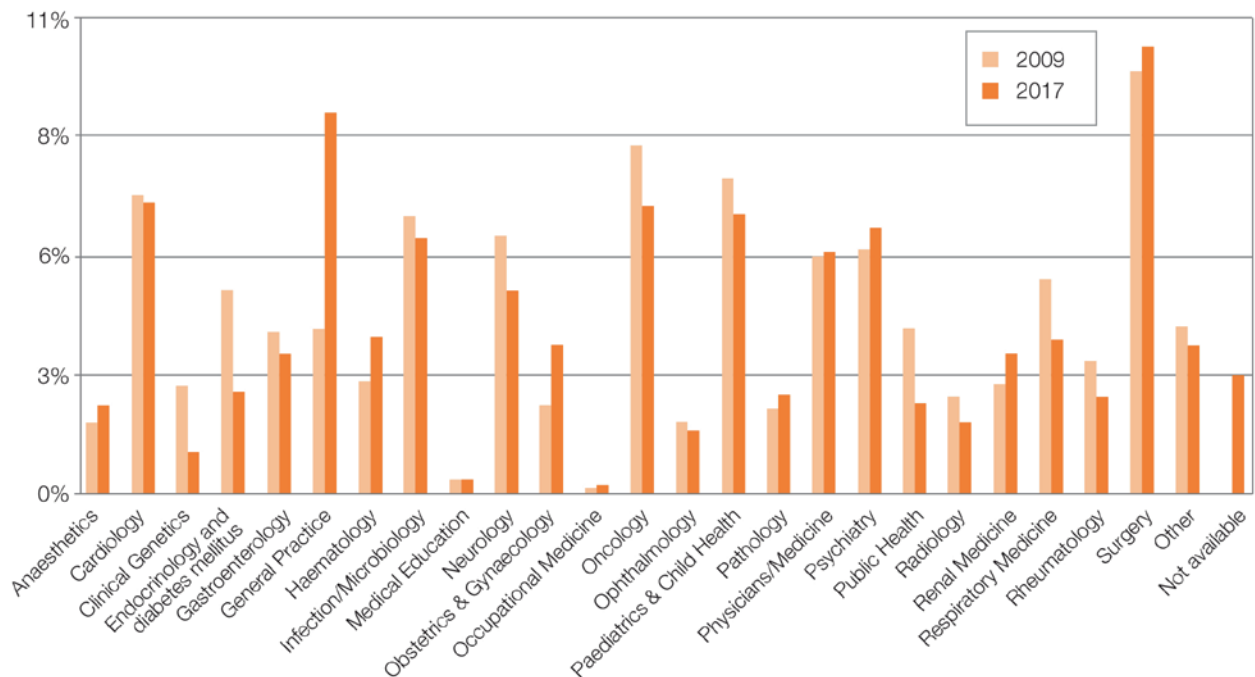


[Graph supplied by Medical Research Council 2017

<https://www.mrc.ac.uk/publications/browse/clinical-and-health-research-fellowships-survey-2017/>]

Figure 6 shows the change in the proportion of fellowships across specialities, including pre- doctoral (ACF, IPF, Masters) and ACL awards. There has been a small decline in the proportion of fellowships in paediatrics and child health between 2009 and 2017.

Figure 6 Change in the proportion of fellowships by medical speciality in 2009 and 2017, including pre-doctoral and ACL awards



[Graph supplied by Medical Research Council 2017

<https://www.mrc.ac.uk/publications/browse/clinical-and-health-research-fellowships-survey-2017/>]

4.5 Trainees taking time out of clinical training for research

Out of Programme is a term that refers to trainees who undertake activities outside their planned training programme. One of the circumstances where an individual may want to go Out of Programme is to gain training and experience in research. The number of trainees Out of Programme for Research (OOPR) in paediatrics on or after March 2017 was estimated to be 146 using RCPCH databases. Data provided by Health Education England across the same period noted a total of 102 OOPR trainees in England.

An RCPCH survey was sent to paediatric specialist trainees in 2009 when they were expected to have completed their first year of Specialty Training or Fixed Term Specialty Training Appointments and to the same cohort in 2011 at the time of completion of their third year. The response rates were 79% and 81% respectively. The attrition rate from the paediatric training scheme between the first year and third year was 15%. Of those still training in paediatrics after the third year, 3.5% aspired to be academic paediatricians [32]. A 2015 survey carried out by the Royal College of Physicians (London) of all doctors across all specialities and career grades found 64% of respondents (out of a total of 1966) stated that they were interested in increasing their research involvement [28].

4.5 Academic pay differentials

In 2016, Health Education England under the direction of the Department of Health, introduced new terms and conditions of service for doctors and dentists in approved postgraduate training programmes. This included the introduction of “pay premiums” for certain specialities including academic trainees. The academic pay premium is configured to reflect the additional time taken during clinical training by individuals who undertake a formal period of research, typically, but not exclusively, a PhD project or as a component of their academic career pathway. Once awarded, the academic pay premium will remain payable while the individual remains in postgraduate medical training. This only applies to doctors and dentists employed by NHS England and decisions regarding the payment of the premium to individuals employed by universities are uncertain [33]. The likely impact of the introduction of academic pay premiums is unknown.

4.6 Conclusions

There are encouraging signs that following a low point in 2013, the total consultant level paediatric academic workforce may be increasing, but absolute numbers are small. A concern is that the number of senior lecturers and lecturers is continuing to decline and that representation of consultant level academics in relation to the total consultant

workforce remains low. Paediatric consultant involvement in research is frequently undertaken outside of programmed activities, but overall, activity is also low.

Paediatric consultants are best positioned to influence and inspire trainees hence these data are additionally troubling in suggesting that young doctors are likely to have limited exposure to clinical research, potentially fuelling a downward trend in the number of research-active clinicians. Paediatrician research publications have however held steady and NICE Quality Standards relevant to child health are increasing. Paediatrics appears to have maintained representation in academic training pathways despite a number of challenges, principally those arising from a shortage of clinical trainees and increased pressure upon NHS clinical services. The numbers of Clinical Lecturer posts and trainees undertaking higher degree research outside the Integrated Academic Training pathway is uncertain. Going forward the RCPCH aims to capture improved data on career progression and the number of Clinical Lecturers and trainees in non-NIHR research positions.

The MRC cross-funder review of early-career progression highlighted enablers and barriers to academic training [34]. Enablers included the ability to secure funding, mentorship and early-career research experience and training. Recommendations included better support to lessen the personal financial impact of embarking on an academic career, and improved career structures to provide greater job security and balance of clinical and academic commitments during training.

The Academic Paediatric Association of Great Britain and Ireland is developing an academic toolkit to be launched in March 2018. This aims to aid early stage researchers in navigating their way through the complex issues around funding, regulatory and other processes, and identifying a research group and supervisor. The toolkit will provide signposts to help in the development of early stage ideas, and practical support in identifying potential supervisors and mentors. The RCPCH has also responded to these findings by putting in place initiatives, described in Section 6 and 7 below, to increase the number of paediatricians in academic training.

5 Paediatrician representation on research boards and committees

5.1 Changes in paediatric representation

In 2012, *Turning the Tide* highlighted that paediatric and child health representation on major research boards across the UK was weak. Only six of around 500 MRC and Wellcome Trust board and committee members was a paediatrician. Further to this, the 2015 RCPCH survey of consultants and SASS doctor involvement in research found 93% of respondents had no involvement in research boards or ethics committees [22].

To ascertain if there has been any change in paediatric representation on boards and committees a search was carried out of MRC, Wellcome Trust and NIHR websites. The MRC currently has 12 research boards and panels in specialist areas. Of these out of over 230 members, seven are paediatricians. The NIHR has nine boards that guide funding decisions and priorities, four (Efficacy and Mechanism Evaluation, Health Technology Assessment, Public Health Research, Invention for Innovation) of which include five child health professionals. The Health Services and Delivery Research, Policy Research Programme, Programme Grants for Applied Research, Research for Patient Benefit, and Systematic Reviews boards have no child health professional involvement. The Wellcome Trust has 17 science panels with over 200 members, which include six child health professionals across four panels.

The National Research and Ethics Advisors Panel, an independent, multidisciplinary expert panel which provides advice to the HRA, currently includes one child health professional, an improvement from 2012, when there was none. The UK Clinical Research Collaboration board consists of representatives from all partner organisations. There is currently one child health professional on this board. The upcoming Research Excellence Framework panel members will be announced in March 2018, and it is hoped these will include paediatricians.

5.2 Conclusions

The number of paediatricians on national research boards and committees has risen over the last five years but overall, representation remains low. A paediatric perspective at national level is an important means of highlighting aspects of national policy that are relevant to children, hence the RCPCH is committed to advocating for representation to be strengthened.

6 Involvement of children, young people and families in research

6.1 Child rights

The views of children, young people and their families are important considerations for all researchers. Their rights in this respect are clearly set out in the UN Convention on the Rights of the Child 1989. Article 12 states “parties shall assure to the child who is capable of forming his or her own views, the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child” [35].

6.2 INVOLVE, &Us and related initiatives

INVOLVE was established in 1996 to support public and patient involvement (PPI) in NHS, public health and social care research. INVOLVE is now funded by the NIHR, as is the Generation R network, a national young people's advisory forum with local groups established across the UK to support the design and delivery of paediatric research. In 2015, the RCPCH established the &Us network. This is a platform for children, young people, parents, carers and families to shape the work of the RCPCH. The International Children's Advisory Network was established to help investigators obtain children and young people's perspectives on many aspects of clinical research [36]. These initiatives are helping change perceptions about involving children and young people in research design and delivery.

6.3 RCPCH survey

The 2015 RCPCH survey of consultant and SASS doctor involvement in research (see section 2.4) included questions on the importance of PPI [22]. Responses were received from 44% of SASS doctors and consultants. Only 29% of respondents reported that they thought that PPI was central to research within their organisation with 46% reporting they were not aware of any available PPI support. Only 22% had access to a PPI team, 15% to a children and young people's volunteer group, 14% to a parent and carer's volunteer group and 10% to a PPI lead.

6.4 Infant, Children's and Young People's Research Charter

In 2016, the RCPCH developed the Infant, Children's and Young People's Research Charter [37] through a series of consultation workshops and surveys involving children and young people. The purpose was to identify how children, young people and families

wish to be involved in and be told about research. Children and young people were clear that they wanted to be given the opportunity to be involved not only as research participants but also in research design and dissemination. They wanted professionals to speak about research positively, avoiding using words such as “trial” or “investigate” that have potentially negative interpretations (both made children and young people think about errors and mistakes) and help them understand difficult concepts and make informed decisions.

6.5 Improving children’s understanding of research concepts

In May 2017, the RCPCH co-hosted a meeting with the Education Endowment Foundation to launch a school intervention trialled in Uganda to improve the ability of children to assess health claims. The intervention featured a combination comic book and textbook, and a linked study targeting parents. The Research Council of Norway funded the study, which was published in the Lancet [38].

6.6 Conclusions

Patient engagement has grown substantially in recent years but paediatricians would benefit from opportunities to learn how best to involve children and young people in designing, developing and delivering research, and disseminating findings. Nationally, initiatives that commence in childhood, to improve public understanding of uncertainties in clinical care, how to make informed choices, and research methods, would be welcome. The RCPCH Infant, Children’s and Young People’s Research Charter and related materials provides a useful set of resources.

7 RCPCH actions

7.1 UK Child Health Research Collaboration

In 2012, the RCPCH Vice-President for Science and Research began discussions with children's research charities and other organisations to establish a UK child health research collaboration. In January 2015, the UK Child Health Research Collaboration (UKCHRC) was launched, supported by the RCPCH, Wellcome Trust and Medical Research Council. The purpose was to support the strategic alignment of charities and large funding bodies to fund research posts, early-stage projects and infrastructure [39]. Since launch, the UKCHRC has catalysed the development of fellowship opportunities. For example, Children with Cancer UK approached the RCPCH for help in contacting paediatricians and as a result, three new co-badged clinical PhD studentships that attracted high-quality applicants were awarded in 2016.

7.2 Children's research ethics guidance

In 2014, RCPCH published "Guidance for the Ethical Conduct of Research Involving Infants, Children and Young People: an update for researchers and research ethics committees" [40]. This was an update of guidance first published in 1980 and revised in 2000. Structural and governance changes in the NIHR and the introduction of European Union regulations have facilitated children's research and provided a greater focus on involving children and parents in design, review and conduct of studies. This guidance addresses children's rights and interests, perceived burdens and risks, and consent and assent in relation to research involving the pregnant woman, infant, child, and young person, and in particular, highlights new and emerging areas of ethical consideration.

7.3 Improving research skills and competences

In 2015, the RCPCH published a national indicative undergraduate curriculum for child health, outlining knowledge and skills to be covered during medical training. It was noted that greater emphasis on research in these early years would be beneficial. A new postgraduate paediatric training curriculum, *RCPCH Progress*, will be implemented from 1st August 2018, with acquisition of research and critical appraisal skills an integral requirement for all trainees. These goals are spread throughout the ST1-8 training programme. Research and scholarship is also one of eleven curriculum domains in which trainees must demonstrate they have met specific learning outcomes by the end of each of the three training levels. The full curriculum and supporting syllabus are available at www.rcpch.ac.uk/progress.

To help enhance research skills the British Association of Perinatal Medicine, Neonatal Society and RCPCH have developed a research training package aimed at trainee neonatologists and nurses to develop their awareness of the importance of clinical research and parent engagement [41]. This has been running since 2015, with regional events held in Scotland and Wales. The excellent uptake and positive feedback have led to discussions with other paediatric sub-speciality groups around adapting the content for their specific needs.

7.4 RCPCH &Us Network

Infants, children, young people and families are at the centre of all the work of the RCPCH. The RCPCH is proud to have launched the RCPCH *&Us* network in 2015. This is a platform for children, young people, parents, carers and families to shape the work of the RCPCH through roadshows, challenges, projects and events. The RCPCH “Engagement Collaborative” provides information, advice, guidance and resources to healthcare professionals to help them develop meaningful, relevant, high-quality engagement with families, children and young people, including involvement in research-related areas.

7.5 Infant, Children’s and Young People’s Research Charter

In 2016, the RCPCH launched the Infant, Children’s and Young People’s Research Charter [37]. This stemmed from *Turning the Tide* which highlighted the importance of involving children and young people in research. The Charter was developed to present the views of children and young people. The Charter provides a framework that supports children, young people, families and health care professionals in discussions around research, with a resource and external links guide directing professionals to tools and eLearning. Since launch, the Charter has been promoted widely with presentations at national (RCPCH Conference 2016 & 2017) and international conferences (International Children’s Advisory Network summit 2016, Excellence in Paediatrics 2016), as well as local events (NIHR clinical research network meetings). Three hospitals (Milton Keynes, Stoke Mandeville and Great Ormond Street Hospital) have placed the Charter in their wards to promote key points to staff and patients. The RCPCH continues to collect case studies from organisations and individuals on how they are using the Charter. These case studies can be viewed on the RCPCH website (<https://www.rcpch.ac.uk/cyp-research-charter>).

7.6 Research funding database

To aid paediatricians, child health professionals and researchers in pursuing grant funding, the RCPCH established a research funding database in 2016. This provides details of over 160 local, national and international research funding opportunities. There has been interest in the uptake and development of this database from the Royal College

of Physicians' Research and Academic Medicine Committee and other Medical Royal Colleges.

7.7 Strengthening research training

The RCPCH encourages medical students to choose paediatrics and has brought together all UK medical school paediatric societies in the "*Aspiring Paediatricians Society*". In 2013, the RCPCH published "*Training in Research for the Benefit of Children*". This provides information to assist trainees who wish to advance their involvement in research [42]. The RCPCH has also established a network of Academic Regional Representatives throughout the UK to provide guidance and support to academic trainees and those wishing to undertake research alongside clinical training. In October 2017, the RCPCH with the Wellcome Trust and MRC hosted a networking and mentoring event for paediatric trainees undertaking research. It is hoped this will be run on a regular basis.

7.8 Protected time for participation in research ethics committees

In 2016 the RCPCH and Nuffield Council on Bioethics published a statement [43] calling for NHS workforce planning bodies to ensure that paediatricians have protected time to participate in Research Ethics Committees and for this to be recognised as a valuable contribution to UK research.

7.9 BMJ Paediatrics Open

In 2017, the RCPCH and BMJ Publications launched a new open access, online-only, general paediatrics journal, BMJ Paediatrics Open, covering all aspects of child health from fetal life to adolescence [44]. The journal publishes high quality research, reviews and protocols that address any aspect of child health. Publication decisions are made on the scientific validity, ethical rigour and transparency of the research. The journal welcomes papers from all health professionals across the world.

7.10 Child Health Surveillance Unit

The RCPCH Executive Committee has supported a proposal by the President to move towards establishing a "Child Health Surveillance Unit". The aim would be to focus on common childhood conditions, complementing the existing British Paediatric Surveillance Unit that is primarily concerned with rare conditions. A UK-wide Child Health Surveillance Unit could play an important part in quantifying the burden of common childhood conditions and facilitating data acquisition to improve the evidence base for paediatrics and child health. The Unit would provide a unique facility for researchers from

academia, the public sector, and industry, facilitating research and establishment of disease registers, development of new products for infants, children and young people, and informing national policy.

7.11 Engagement with industry

In 2017, the RCPCH issued a detailed revision of due diligence processes underpinning interactions with industry, to facilitate greater dialogue and transparent productive collaborations. The RCPCH is grateful to the Faculty of Pharmaceutical Medicine for facilitating engagement with pharmaceutical companies. The RCPCH are also in active discussions with Innovate UK, the British Pharmacological Society, and industry to establish paediatric fellowships and short-term observerships.

7.12 RCPCH Children's Research Fellowship Fund

The necessity of securing the next generation of child health researchers and the limited availability of post-doctoral research positions was the stimulus for the President to establish the RCPCH Children's Research Fellowship Fund in 2017. The RCPCH Children's Research Fellowship Fund is aimed at supporting a global increase in clinical and non-clinical training posts, and identifying and nurturing future children's research leaders. The fund will provide salary support for high calibre researchers and aid a new generation of research leaders to build collaborative partnerships across institutions in the UK and abroad. The MRC and Wellcome Trust have committed to providing matched funding and processing applications through their established peer-review routes.

Timeline of RCPCH actions

2012	Turning the Tide published
2013	Guide to Training in Research for the Benefit of Children published
2014	Updated Guidance for Researchers and Research Ethics Committees published
2015	UK Child Health Research Collaboration launched &Us Network established RCPCH, Neonatal Society and British Association of Perinatal Medicine research skills training day piloted
2016	Research funding database created Infant, Children's and Young People's Research Charter launched Statement issued on protected time for paediatricians to serve on Research Ethics Committees
2017	BMJ Paediatrics Online launched Due diligence processes for engagement with industry updated Children's Research Fellowship Fund established
2018	Children's Research Fellowship Fund formally launched

8 Conclusions

8.1 Changes in the last five years

There have been many positive developments in UK basic science and clinical research and the life sciences industries over the last five years. These are welcome, in redefining and reinforcing the strong commitment at national level to further strengthening the sector. Paediatrician research involvement and outputs relevant to child health have been maintained. The total number of consultant-level paediatric academics shows signs of increasing, and ACF and ACL numbers have remained steady.

However, there are areas of concern. Differences from adults in disease processes, physiology, and metabolism, provide the rationale for biomedical research, including the development of medicines, devices, and health technologies, focussed specifically upon infants, children and young people. The senior paediatric academic workforce remains small in absolute terms, and of particular concern, the number of senior lecturers continues to decline. Limited time for research in clinician job plans is coupled with a health service under severe pressure. There is inadequate representation of children's interests in the UK life science industries strategy and very few paediatricians on national research boards and committees. Reliable paediatric and related data sources are growing in number and improving in quality but more could be done to advance the pace of change. Looming throughout are the many uncertainties inherent upon the departure of the UK from the EU.

8.2 Paediatric academic workforce

The UK needs a strong workforce to deliver the life sciences strategy, academics to lead basic science and patient-centred research, and research active clinicians to deliver studies and translate research into changes in clinical practice. The RCPCH wishes to see expansion in the paediatric academic workforce. We have therefore established a Children's Research Fellowship Fund to increase the number of post-doctoral research opportunities and support academic track trainees in bridging the gap to independence. We also aim to promote collaboration between charities, industry and academia in creating new research positions at all levels.

Following the NIHR strategic review of training, more posts are being allocated by open competition. Here, the research area is decided centrally and aligned to NIHR strategic priorities and specialities where capacity is felt to be weak. However, the majority of posts will still be made by formula. There is danger that over-reliance on awarding research training fellowships through institution-based formulas will detract from growth

in currently under-represented areas such as public health, nutrition research and primary care. Deciding on areas upon which to concentrate, whether this is at institutional or funder level, risks disadvantages talented young researchers whose focus is in less well-established domains. We would like to see a flexible approach adopted that maximises opportunity for young researchers with potential, regardless of their area of interest, to identify an appropriate supervisor and institution, and secure funding and independent mentorship. A focus on young talent could be an important means of widening the breadth of UK research, and stimulating a growth in expertise in areas that are not currently strong, and is an area upon which both funders and universities might reflect. We also suggest that NIHR and UKRI consider further how best to identify high calibre academic-track researchers at an early career stage, regardless of the area of their research interest, and place them in appropriate environments with suitable supervisors.

8.3 Strengthening the involvement of NHS clinicians

The RCPCH has made a clear commitment to strengthening the generic research skills of all paediatric trainees through curriculum development, appraisal, examination and expectation. We aim to see evidence of involvement in research assessed at annual reviews of clinical progression, and evidence of research experience by applicants for paediatric consultant positions. We will review and strengthen the national indicative undergraduate curriculum for child health to ensure research skills are included. We will promote basic science and clinical research through the UK Aspiring Paediatricians Society and related networks.

We will continue to ensure trainees acquire research skills throughout paediatric training, and have embedded relevant goals in our new postgraduate curriculum, *RCPCH Progress*. Better data on trainees undertaking research would be helpful and we aim to give careful consideration as to how we might capture these, so we can support them fully throughout their careers. We also aim to ensure that the RCPCH representatives on consultant appointment committees emphasise the importance of research experience.

Health Education England, NHS England, NHS Providers, relevant agencies in the devolved nations, and central government, have an important part to play if the UK is to maintain its position of pre-eminence in clinical research. These include resolving the current clinical workforce shortage and sustaining adequate numbers in the future. The involvement of clinicians in delivering studies requires their support, though Trusts have a clear part to play, as there are funding mechanisms available to them through the comprehensive local research networks. Above all, there is a need to engender a strong research ethos within UK health services. The RCPCH is committed to playing its part here. We also suggest Health Education England, Health Education Wales and the

Scottish Government might amend the term ‘Out of Programme’, to reflect the importance and relevance of research to clinical training.

8.4 Fostering collaboration

We offer the support of the UK Child Health Research Collaboration and the RCPCH Paediatric Sub-Specialities Committee to foster engagement between public bodies, charities and industry. We will also build on our revised due diligence processes and collaborations with, for example, the Faculty of Pharmaceutical Medicine, British Pharmacological Society and Association of British Pharmaceutical Industries, to facilitate paediatric medicines development, and improve paediatrician understanding of research and development pathways.

The importance of international collaboration in research cannot be underestimated. The UK has benefited through substantial research funding from the European Union and has been prominent in providing leadership in pan-European studies. The RCPCH therefore hopes to see strong research links maintained with the European Union and for the UK to remain part of the European Trials Networks. The RCPCH also looks to grow industry focus on child health through enhanced opportunity for paediatric involvement and contribution of expertise from the earliest stages of the development of medicines, devices, and technologies.

8.5 Representing children’s interests

The RCPCH will continue to advocate for paediatric expertise and the perspectives of the paediatric population to be represented on national research boards and committees. We aim to continue our work to ensure ever-greater involvement of families and young people in setting research agendas, and involving them in multiple aspects of clinical studies. The RCPCH &Us Network, the Infant, Children’s and Young People’s Research Charter, and other materials are invaluable resources and we welcome requests from researchers to access these.

We suggest the inclusion of infants, children and young people as the default in research studies unless there is specific justification for their exclusion. In order to track the involvement of the paediatric population in clinical research, the NIHR might consider how best to capture information on the age of participants recruited to studies.

8.6 RCPCH commitment

Since the launch of *Turning the Tide* in 2012, the RCPCH has strengthened its commitment to improving child health research across the UK. We will continue to monitor progress over time to ensure not only infants, children and young people, but so

too, UK population wellbeing and prosperity benefit from a sustained focus on research to improve child health.

9 References

- 1) Royal College of Paediatrics and Child Health Turning the Tide Harnessing the Power of Child Health Research. 2012.
<https://www.rcpch.ac.uk/system/files/protected/page/Turning%20the%20Tide%20Full%20Report.pdf>. [Last accessed 22.10.2017]
- 2) Modi N, Clark H, Wolfe I *et al*. A healthy nation: strengthening child health research in the UK. *Lancet* 2013; 381:73-87
- 3) Lythgoe H, Price V, Poustie V *et al*. NIHR Clinical Research Networks: what they do and how they help paediatric research. *Arch Dis Child* 2017; 102:755-9
- 4) Technopolis. The impact of collaboration: The value of UK medical research to EU science and health. 2017. <http://www.technopolis-group.com/report/impact-collaboration-value-uk-medical-research-eu-science-health/> [Last accessed 29.01.2018]
- 5) Jackson E, Feldschreiber P, Breckenridge A. Regulatory consequences of “Brexit” for the development of medicinal products *Clin Pharmacol Therapeutics* 2017; 102:183-4
- 6) Life sciences industrial strategy: a report to government from the life sciences sector. 2017. <https://www.gov.uk/government/publications/life-sciences-industrial-strategy> [Last accessed 22.10.2017]
- 7) Royal College of Paediatrics and Child Health. 2017. State of Child Health. <https://www.rcpch.ac.uk/system/files/protected/page/SoCH%202017%20UK%20web%20Updated.pdf> [Last accessed 14.11.17]
- 8) Modi N, Ellis J, Marsh M. The UK Royal College of Paediatrics and Child Health Policy on Funding from Commercial Organizations. *JAMA Pediatr* 2017; 171:1016-17
- 9) Health Research Authority. 2017. UK Framework for Health and Social Care. <http://beta.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/> [Last accessed 22.10.2017]
- 10) UK Research and Innovation. 2017. <https://www.ukri.org/> [Last accessed 22.10.2017].
- 11) Innovate UK 2007. <https://www.gov.uk/government/organisations/innovate-uk> [Last accessed 21.12.2017]
- 12) Health Research Data UK Medical Research Council. 2017.
<https://www.mrc.ac.uk/about/institutes-units-centres/uk-institute-for-health-and-biomedical-informatics-research/> [Last accessed 22.10.2017].
- 13) NHS England. Board paper: 12 actions to support and apply research in the NHS
<https://www.england.nhs.uk/wp-content/uploads/2017/11/08-pb-30-11-2017-supporting-and-applying-research.pdf> [Last accessed 26.01.2018]
- 14) Van't Hoff W, Offringa M. StaR Child Health: developing evidence-based guidance for the design, conduct and reporting of paediatric trials. *Arch Dis Child* 2015; 100:189-92

- 15) UK Research Office.
https://www.ukro.ac.uk/authoring/public/Documents/factsheet_brexit_public.pdf
[Last accessed 30.01.2018]
- 16) European Commission Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration. 2001. <http://eurlex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0018&from=en> [Last accessed 22.10.2017]
- 17) Letter from the Department for Exiting European Union, 12 October 2017.
<http://www.parliament.uk/documents/commons-committees/science-technology/Correspondence/171012-Robin-Walker-to-Norman-Lamb-Work-of-the-Science-Minister.pdf> [Last accessed 29.01.2018]
- 18) European Medicines Agency. 10-year Report to the European Commission. 2016.
https://ec.europa.eu/health/sites/health/files/files/paediatrics/2016_pc_report_2017/ema_10_year_report_for_consultation.pdf [Last accessed 22.10.2017]
- 19) Annual Report of the Chief Medical Officer. The health of 51%: Women. 2014.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/595439/CMO_annual_report_2014.pdf (Last accessed 29.01.18)
- 20) The Jenner Institute. <http://www.jenner.ac.uk/about-us> [Last accessed 30.01.2018]
- 21) Pandolfini C, Bonati M. Children's presence in research: a review of online registers. *Eur J Clin Pharmacol* 2009; 65:873-80
- 22) Royal College of Paediatrics and Child Health. Participation in child health research: A survey of the paediatric workforce 2015. 2016. <https://www.rcpch.ac.uk/improving-child-health/research-and-surveillance/participation-child-health-research/participation-c> [Last accessed 22.10.2017]
- 23) Royal College of Paediatrics and Child Health. Medical Workforce Census 2015. 2017.
<https://www.rcpch.ac.uk/sites/default/files/user31401/2015%20RCPCH%20Workforce%20Census%20FULL.pdf> [Last accessed 22.10.2017]
- 24) Medical Schools Council. Survey of medical clinical academic staffing levels 2017. 2017.
<https://www.medschools.ac.uk/media/2026/medical-clinical-academic-staffing-levels-2017.pdf> [Last accessed 12.02.2018]
- 25) Royal College of Paediatrics and Child Health. Medical Workforce Individual Census. 2011.
https://www.rcpch.ac.uk/system/files/protected/page/individual%20census%20FINAL_0.pdf. [Last accessed 21.12.2017]
- 26) Royal College of Paediatrics and Child Health. Medical workforce census 2013. 2014.
<https://www.rcpch.ac.uk/sites/default/files/user31401/RCPCH%20Workforce%20Census%203%20Feb%202015%20Final.pdf> [Last accessed 26.01.18]

- 27) Royal College of Physicians. Focus on physicians: census of consultant physicians and higher speciality trainees 2016-17. 2017.
<https://www.rcplondon.ac.uk/projects/outputs/2016-17-census-uk-consultants-and-higher-specialty-trainees> [Last accessed 12.02.2018]
- 28) Royal College of Physicians. Research for all. 2016.
<https://www.rcplondon.ac.uk/projects/outputs/research-all> [Last accessed 12.02.2018].
- 29) Medical Research Council. UK-wide survey of clinical and health research fellowships. 2017. <https://www.mrc.ac.uk/publications/browse/clinical-and-health-research-fellowships-survey-2017/> [Last accessed 13.12.2017]
- 30) National Institute of Health Research Trainees Coordinating Centre. Ten years on: adapting and evolving to new challenges in developing tomorrow's health research leaders. 2017. <https://www.nihr.ac.uk/our-faculty/documents/TCC-NIHR-Strategic-Review-of-Training-2017.pdf>. [Last accessed 22.10.2017]
- 31) National Institute for Health Research. Guidance notes: NIHR Integrated Academic Training Allocation of ACF and CL Posts for 2019 Recruitment. 2017.
<https://www.nihr.ac.uk/funding-and-support/documents/IAT/TCC-IAT-Guidance-Notes-Competition-2019.pdf> [Last accessed 30.01.2018]
- 32) Shortland D, Roland D, Lumsden DE., *et al.* Career intentions and choices of paediatricians entering training in the UK. *Arch Dis Child* 2015; 100:537-41
- 33) National Institute of Health Research. Junior doctors contract and academic pathways: Guidance for the implementation of the contract in England.
<https://www.nihr.ac.uk/funding-and-support/documents/IAT/Implementation%20Guidance.pdf> [Last accessed 30.01.2018]
- 34) Medical Research Council. A cross-funder review of early-career clinical academics: enables and barriers to progression. 2015.
<https://www.mrc.ac.uk/documents/pdf/review-of-early-career-clinical-academics/> [Last accessed 30.01.2018]
- 35) United Nations Convention on the Rights of the Child 1989.
<https://www.unicef.org.uk/what-we-do/un-convention-child-rights/> [Last accessed 30.01.2018]
- 36) Gwara M, Smith S, Woods C *et al.* International Children's Advisory Network: A multifaceted approach to patient engagement in pediatric clinical research. *Clin Ther* 2017; 39:1933-38
- 37) Hunter L, Sparrow E, Modi N *et al.* Advancing child health research in the UK: The Royal College of Paediatrics and Child Health Infants' Children's and Young People's Research Charter. *Arch Dis Child* 2017;102: 299-300

- 38) Nsangi A, Semakula D, Oxman A *et al*. Effects of the Informed Health Choices primary school intervention on the ability of children in Uganda to assess the reliability of claims about treatment effects: a cluster-randomised controlled trial. *Lancet* 2017; 390:374-88
- 39) Hunter L, Mensah A, Jordan M *et al*. The United Kingdom Child Health Research Collaboration. *Arch Dis Child* 2017; 102:793-4
- 40) Modi N, Vohra J, Preston J *et al* for a Working Party of the Royal College of Paediatrics and Child Health, Guidance on clinical research involving infants, children and young people: an update for researchers and research ethics committees. *Arch Dis Child* 2014; 99:887-91
- 41) Menon G, Turner MA, Ogilvy-Stuart AL *et al*. Training in research competencies: a strategy for neonatology. *Arch Dis Child Education and Practice* 2017; 102:51-4
- 42) Royal College of Paediatrics and Child Health. Training in research for the benefit of children. 2013. <https://www.rcpch.ac.uk/system/files/protected/page/RCPCH-Training-in-research-for-benefit-of-children.pdf> [Last accessed 22.10.2017]
- 43) Royal College of Paediatrics and Child Health and Nuffield Council on Bioethics. Protection. Statement on the protection of time for paediatricians to take part in Research Ethics Committees. 2016. <https://www.rcpch.ac.uk/news/statement-protection-time-paediatricians-take-part-research-ethics-committees> [Last accessed 21.12.2017]
- 44) BMJ Paediatrics Open. 2017. <http://bmjpaedsopen.bmj.com/> [Last accessed 22.10.2017]

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