An insight into developing a trainee led multi-site research project

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Abstract

Research should be an integral part of paediatric training, it guides our practice every day, but also drives improvements in the clinical care of our patients. Currently the paediatric academic workforce remains small. If we want UK child health research to flourish we need to empower trainees to become the skilled academic clinicians of the future. To reach this goal trainees have been organising themselves into regional research collaboratives. One such collaborative is REACH (Research, Evaluation and Audit for Child Health), a pan-London, trainee-led network that exists to support the conception and coordination of multicentre research, audit and service evaluation projects. As the team leading one of the first REACH projects, we want to share the valuable insights we have gained. We have set up FIRE (Febrile Infants Regional Evaluation), a multicentre retrospective research study. We have learnt an incredible amount and have had the opportunity to gain experiences not usually on offer for trainees not on an integrated academic training pathway. We have learned about the process of setting up a multicentre research project, including writing a study protocol and completing the IRAS (Integrated Research Application System). We have also gained many non-technical skills that will help us in our future careers. We would encourage other general paediatric trainees to get involved and join trainee led research collaboratives to get this opportunity too.

1. BACKGROUND

Why paediatric trainees must engage in research

Research must be an integral part of paediatric training. Critical thinking, the ability to analyse information, trends and patterns, and to ask and answer relevant questions are essential to practising medicine. The RCPCH progress curriculum acknowledges this with a dedicated research and scholarship curriculum domain,[1] which from September 2023 expands the focus on research skills and engagement with, for example, all trainees having to maintain up to date GCP training (Box 1).[2] More important than ticking curriculum boxes though, is the fact that research guides our practice every day through guidelines, new treatments and evidence-based decision making. We must breed curious and questioning trainee paediatricians to continuously drive improvements in the clinical care our patients receive. Neither must we forget how uniquely suited trainees are to identifying *relevant* research questions: they rotate through different trusts and departments, can pinpoint variation in practice and work at the forefront of clinical care, intimately in touch with patients and families and thus able to identify what matters to them.

Our academic paediatric workforce

Growing a cadre of future paediatric consultants that are research literate, have undertaken a significant amount of research activity and aspire to become future research leaders is much needed. Five years beyond the first impactful Turning the Tide report,[3] the paediatric academic workforce remains small with only an estimated 4.2% of the total consultant-level workforce being clinical academics.[4,5] Total numbers are decreasing and most markedly so at the level of junior clinical academics, with the number of lecturers having nearly halved between 2001 and 2015.[4,6] Irrespective of holding an official academic position, it is imperative that all consultants are research literate and active to the degree desired and necessitated by their role. However, the average number of research dedicated Programmed Activities (PAs) in consultant job plans is less than 0.5, with 80% holding no research PAs at all and evidence suggesting that consultants conduct at least 50% of their research activities outside of official PA time.[4,5] If we want UK child health research to flourish we need to empower trainees to become the skilled academic clinicians of the future.

Research for all trainees

The NIHR (National Institute for Health and Care Research) integrated academic training pathways cater to a small subset of trainees, and out-of-programme (OOP) time allows the undertaking of higher degrees or involvement in academic projects. That said, there is currently an unmet demand for wider and more varied opportunities open to all trainees to gain research experience and skills.[7,8] Time constraints exacerbated by workforce shortages and a lack of opportunities have been identified as key barriers to trainee engagement in research.[7] Whilst the RCPCH trainee charter states trainees should have 8-16 hours per month of protected time within their work schedule to complete Supporting Professional Activity (such a quality improvement (QI) or research),[9] there is limited uptake of this recommendation. Other barriers to opportunities for trainees are a lack of guidance on how to get involved in research and the high frequency of rotations, making involvement in long-term research activities almost impossible within the confines of the standard training pathway.

Current research-supportive initiatives

There are several promising initiatives aiming to support trainees in their academic experience. The Academic Paediatrics Association (APA)'s aims include supporting clinical trainees who wish to acquire research experience as well as supporting and developing academic training and training

opportunities.[10] The Academic Toolkit provides a growing repository of advice and tips for trainees interested in research.[11] Trainee groups such as the London School of Paediatrics Trainees Committee are acting as point of contact and offer support, peer advice, educational and networking opportunities to all trainees interested in research.[12]

Importantly, over the last 5 years, trainees have been organising themselves into regional research collaboratives with national level support from the RCPCH.[13] Trainee-led research networks cater to an increasing focus on collaborative, team-based QI and research projects, acknowledging the value of increased study power through multicentre data collection. They help to overcome the limitations imposed by trainee rotations and offer opportunities for all trainees to develop not only QI and research but also vital leadership, team working and management skills.[8]

2. THE REACH EXPERIENCE SO FAR

REACH (Research, Evaluation and Audit for Child Health) was created as a pan-London, trainee-led network that exists to support the conception and coordination of multicentre research, audit and service evaluation projects to answer relevant clinical general paediatric questions.[14] It offers trainee ownership and leadership of collaborative, multicentre QI and research projects as well as opportunities for peer networking and steering of research priorities.

As the team leading one of the first REACH projects, we want to share the valuable insights we have gained, with the hope that they will encourage other trainees to get involved in trainee-led research networks and other initiatives. Through REACH we have had the chance to set up FIRE (Febrile Infants Regional Evaluation), a multicentre retrospective research study, with up to 25 sites across London participating in data collection. We have learnt an incredible amount and have had the opportunity to gain experiences not usually available for trainees outside of integrated academic training pathways or OOP time.

First Impressions

When we started work on FIRE, we felt overwhelmed by a host of unfamiliar research terminology: IRAS, CRF, OID, SoECAT, HRA, PPI. What do all these abbreviations mean? With time we have not only gained insight into what these terms mean (Table 1) but now have first-hand experience in all of them.

***Table 1**. Glossary of research abbreviations and terms.*

CRF – Case Report Form
The formalised data collection tool for clinical studies. It needs to be developed in line with the study protocol and represents the way in which all data for your study will be captured. Getting this right is key; it informs what data you will collect and therefore what results you can get.
GCP – Good Clinical Practice
GCP is the international ethical, scientific and practical standard to which all clinical research is conducted. Everyone undertaking research should have appropriate training or experience to carry it out and so the NIHR offers a range of GCP training courses.

HRA – Health Research Authority
The organisation which provides assurances that NHS based health research is safe, legal and ethical. They set standards for responsible research and create processes for assessing research proposals.
HRA Approval
Used for all NHS based studies across all four nations, it brings together the assessment of legal compliance and ethical approval such as review by a REC. Previously this assessment was done by each individual site's R&D department. Now each site can rely on centralised HRA Approval, removing a significant burden of work.
IRAS – Integrated Research Application System
A single online system for applying for the permissions and approvals for health and social care/community care research in the UK, including from the HRA.
Local Information Pack
The collection of documents which is provided to each of the research sites taking part in a study – vital for multi-centre research projects. Each local R&D department will require this to participate. It supports local study set-up and comprises many documents including the OID, SoECAT, research protocol, IRAS form & HRA approval (see below).
OID – Organisation Information Document
An outline of the study information, organisation information, roles & responsibilities, timescales and any other set up & delivery arrangements that are needed for the study to run locally. Usually this is provided by the study sponsor.
PPI – Patient & Public Involvement
PPI refers to the active partnership with patients and the public to plan, manage, design and carry out and disseminate research. There are a huge range of ways in which this can be achieved and identifying the most suitable, effective and beneficial methods is vital to good research.
R&D – Research and Development
R&D departments support and facilitate research locally. Each site in a multi-site study needs local R&D approval, who will then support and advise on the running of the project locally.

REC – Research Ethics Committee
Review research protocols to determine whether the study is ethical, contain a mix of experts and lay persons. Your IRAS submission may link to a REC or your sponsor might organise REC review.
Research Protocol
A comprehensive description of your research study that acts as a manual for all members of the research team. It ensures everyone adheres to the methods outlined and can be used as a reference for all aspects of the study, from set-up to analysis and dissemination. It is good practice to publish and/or register your protocol for transparency, information-sharing and accountability.
Sponsor
The organisation which takes formal responsibility for a research study. They are responsible for ensuring the study is conducted appropriately, keeps to protocol and is of good quality. They ensure the study protocol undergoes peer review or advise review by a Research & Ethics Committee (REC - see below) as needed.
SoECAT – Schedule of Events Cost Attribution Template
A cost attribution template designed to support correct cost attribution at application for research cost funding, to ensure that full site level costs are recovered. Usually provided by the study sponsor.

We have also learned a lot about the process of developing a multicentre study. Figure 1 gives an overview of steps that we took to set up this project.

The Protocol

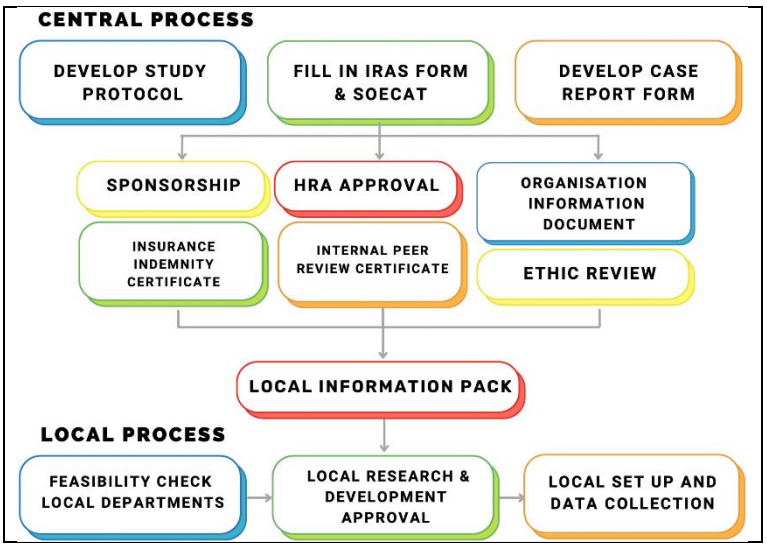

***Figure 1** - The process of setting up a multi-site research project.*

We started by writing a research protocol. With no prior experience, this was an incredibly daunting task. Writing a protocol is a time consuming exercise as it entails writing a detailed and specific description of everything that will happen during the study and requires scientific writing skills not dissimilar to writing a paper. It's probably very useful to know that sponsors (Figure 1) often have a template protocol available which can guide you. The sections that we included were: 1) introduction with the relevant background to the study, 2) rationale for the current study, 3) specific primary and secondary study objectives, and how these will be measured, 4) study design with inclusion and exclusion criteria, 5) data management, 6) public and patient involvement, 7) possible adverse events, 8) statistical and data analysis and 9) regulatory approval including ethics approval, consent and confidentiality and funding. To write our protocol we also had to learn about other core research principles including statistical methodology like calculating power to determine necessary sample size. We also reviewed the literature, learned about the details needed when defining inclusion and exclusion criteria and how objectives will be measured. Furthermore, we spent a lot of time considering how best to involve patients and the public in this study as we have come to understand how important this is when developing a new research project.

Integrated Research Application System (IRAS)

Whilst finalising our protocol, the next big hurdle to face was IRAS. This is an online system, used to apply for the permission and approval for health research in the UK. Through the IRAS we were able to submit our research application to the Health Research Authority (HRA) (Box1). The IRAS form covers everything from summarising your research methods and design of your study, to explaining the risks to your participants, justifying your choices about sample size and recruitment and explaining the practicalities of how your data will be stored.

Understanding the intricacies of this process was challenging and there were many stumbling blocks along the way. We discovered that simply ticking the wrong box on your IRAS form can generate pages upon pages of questions, which can take hours of work to answer, only to find out later they weren't relevant to your study at all. This form is a lesson in attention to detail. Although it has its challenges, completing an IRAS form helps to refine your methods and ensure that you have designed your study in such a way that you will be able to effectively answer the question you set out to answer. Ultimately, it is there to make sure that your study is safe and operating within the legal and ethical frameworks for research in the UK.

Case Report Form (CRF)

Once these documents were ready, which involved numerous revisions and committee meetings, we started working on the CRF - our data collection tool (Box1). To create this, we had to think of all

possible variables we wanted to collect and then define precisely what each one meant, so that there would be no confusion during the data collection phase. We also had to strike a balance between being comprehensive and inclusive in our data collection, ensuring we collect all the data that might be needed for analysis versus being feasible and realistic about the data that we could collect given the time and effort required for data entry.

Writing the CRF was the point where the study really felt it was coming to life as we thought carefully about what information we needed to know about each participant in order to achieve our study objectives and how to frame the questions to make sure our data was accurate. The next step is to turn our CRF into a user-friendly form using REDCap (an online survey and database building tool) which our local leads will use to input the information that will become our final dataset.

Ethics and Other Approvals

After months of working on our protocol, CRF, IRAS forms and a number of other documents they are finally completed and have been submitted to our sponsor for review. Now we wait to hear what steps they decide we need to take next in order for our study to go ahead. Some studies may need no further action, others may need peer review or full Research Ethics Committee (REC) (Box 1) approval. Once we have the green light and all our approvals are in place, we will collate all of these documents into a Local Information Pack (Box 1) for our local leads , who can then register the study with their own R&D (Box 1) departments, bringing us one step closer to the most exciting part - actually collecting our data!

Non-Technical Skills

As much as we learnt about the technical aspects involved in setting up a multi-site study, we gained just as much insight into the non-technical skills involved in research: decision-making, negotiation, leadership and communication to name a few. Setting up such a large network has involved working within different organisational structures - the FIRE project team, the REACH central committee, local leads and advisory consultants. Going through this process we've gained valuable insight into the skills needed to balance differing views and priorities and to reach consensus on everything from our primary research question to the particular wording of a question on our CRF. Our ability to lead and motivate was pushed by the need to create local buy-in and maintain enthusiasm for the project with trainees and consultants across a large region over more than a year. We also improved our IT skills when setting up remote meetings and webinars, using online workspaces to work on collaborative documents and keep up with committee meetings, and creating online surveys. It was amazing to see how well such a big group of trainees could work together to help achieve the first steps of this multi-site retrospective study. Setting up such a project also involves patience as the road to success can sometimes feel long. The key is to persevere to achieve the goal!

3. CONCLUSIONS AND FINAL INSIGHTS

The RCPCH rightly recognises that research is vital to the future of our speciality and must be embedded in both paediatric training and clinical practice. The current limitations on training and minimal protected time for research-based activities mean that these vital skills can only be gained through seeking opportunities outside of the usual training programme.

Through REACH, we have had the privilege to gain invaluable knowledge and experience into the processes and challenges of developing multi-site research studies. This, alongside a wealth of non-technical skills, will be of enormous value throughout our careers and has motivated us to continue our involvement in research for years to come. We would encourage all paediatric trainees to seek

experiences and participation in similar trainee-led collaboratives, not only for their own educational needs but also to help create a generation of paediatricians that can enable general paediatric research in the future to flourish.

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