**The value of trainee networks in paediatric surgical research**

**Clare Skerrit,**1 **Nigel J Hall**2

1. **Paediatric Surgical Trainees Research Network, UK**
2. **Faculty of Medicine, University of Southampton, Southampton, UK**

**Abstract**

In 2007, the first trainee led surgical research network was founded in the United Kingdom (UK). The West Midlands Research Collaborative was started by a group of enthusiastic adult surgical trainees who saw the benefits of altruistic collaboration to generate high quality, multicentre research. Seeing the success of their research projects, including randomized, controlled trials, trainees in other regions and specialties were spurred on to founding their own research collaboratives.

The Paediatric Surgical Trainee Research Network (PSTRN) was started in 2011 by a group of UK trainees with the aim to promote, facilitate and encourage trainee led research in paediatric surgery.

This article summarises the history and evolution of the surgical research collaboratives. It examines the challenges which multicentre research entails and the steps the collaboratives have taken to overcome them. We describe some of the projects which have been successfully completed and the benefits that the trainee networks have for patients and surgeons alike.

**Introduction**

Richard Horton, the editor of the Lancet, boldly stated in a recent editorial that ‘perhaps half …of the scientific literature may be simply untrue’ and is ‘afflicted by studies with small sample sizes and tiny effects’. [1] Perhaps nowhere is this a greater challenge than a small surgical specialty such as paediatric surgery. [2-6] The ‘common’ congenital abnormalities that a paediatric surgeon may expect to treat, such as an Hirschsprung disease (HD), only occur in 1-3 in 10,000 births. [7-9] The BAPS-CASS 2010 survey on HD revealed that half of paediatric surgeons treating this condition in the UK will perform the definitive pull-through operation only once a year. [7] This obviously creates logistical difficulties for conducting meaningful research in a single centre.

The Paediatric Surgical Trainee Research Network (PSTRN) was set up in 2011 by a group of UK trainees with the aim to promote, facilitate and encourage trainee-led, multicentre studies in paediatric surgery. We hope that by engaging trainees early in their careers we will create future generations of paediatric surgeons who are experienced and interested in collaborative research.

This article describes the evolution and development of surgical trainee collaboratives in the UK and outlines the potential benefits they can bring to conducting multicentre research.

1. **History**

The first surgical trainee collaborative, the West Midlands Research Collaborative (WMRC), was set up by a group of adult general surgical trainees in 2007. [10] They realised that by combining efforts of surgical trainees rotating between hospitals in their region it was possible to generate high quality, multi-centre research. Their ambition was to deliver clinical research that would change clinical practice and directly impact on patient care.

Witnessing the success of WMRC, trainees in other regions followed their lead and set up surgical research collaboratives. [11] Links were fostered between the regional collaboratives and these have enabled trainees to plan and run national studies. The idea gained momentum and the smaller, more specialised surgical disciplines also established networks but on a national basis. Enthusiasm has cascaded down to medical students; STARSurg is a national network of students with an interest in surgery. The collaborative ran their first study in 2013 and the group has already delivered 2 important studies published in high impact journals. [12,13] There are also now trainee networks established in other medical specialties such as anaesthesia and intensive care raising the possibility of cross-specialty collaboration. [14]

1. **Evolution of research and progression up the pyramid of evidence**

Surgical training in the UK includes the annual performance of a clinical research project by every trainee. Traditionally, these have been single centre, performed retrospectively, with small numbers of patients. Although of some educational value, they are time consuming, often have many missing data points and fail to generate results that are either statistically or clinically significant.

Members of the West Midland Research Collaborative recognised the power of collaboration and the strength of combining data from multiple sites. Initial studies were retrospective, case note reviews performed across multiple sites. [15] However the collaborative quickly progressed to performing prospective multi-centre observational studies and then to multi-centre, randomised controlled trials. This progress has been supported by the Royal College of Surgeons of England through the surgical specialty leads and clinical trials units initiatives. [16,17] Other trainee collaboratives have followed this lead and are also now designing and running randomised controlled trials. [18,19]

In 2012, having fostered links with other regional collaboratives across the UK, WMRC led the first national surgical research project conducted by trainees. The National Appendicectomy Study prospectively collected the post-operative outcomes of 3326 patients from 95 centres in just 2 months. To date it has resulted in at least 6 publications [20-25]. This was considered a turning point in the evolution of the trainee collaboratives - it demonstrated that high quality, multicentre research could be delivered by committed trainees in a robust fashion in short time frames.

1. **Challenges to conducting multicentre clinical research**

Initially there were reservations about whether trainees had the ability to conduct rigorous clinical research. Trainee networks have worked hard to demonstrate that their studies are conducted in accordance with the best practice guidelines for medical research and have sought the guidance and expertise from established researchers and clinical trials units.

* 1. **How research integrity is ensured**

Research misconduct is a difficult problem in medical research. [26] Trainee led collaboratives recognise the importance of ensuring data validity. Every trainee-led study to date has published their research protocol ahead of data collection usually via the collaborative website. Protocols have been designed and adjusted by discussion amongst trainees and with the help of established clinical researchers and consultants. The STARSurg collaborative recently ran a research day for medical students in their collaborative to come together and discuss the protocol for their forthcoming OAKS study. This is to enable trainees contributing data to agree on outcome definitions and ensure consistency in data collection.

Every participating centre has a designated study centre lead and these trainees must obtain the agreement of consultants in their hospital and institutional review board approval before commencement of the study. The trainee study lead liaises with a consultant in each centre who supervises the data collection and attests to its validity. Some collaboratives are now having submitted data independently checked by an external validator. [27]

Collaboratives who are conducting trials have sought and obtained input and support from clinical trials centres. All trainees who are consenting patients attend study days and training in research conduct.

* 1. **How well the research is delivered**

History is awash with stories of well-funded trials on important clinical questions that failed to deliver results. Many trials were abandoned because despite researchers’ best intentions recruitment targets were not met. Not only is this a distressing waste of time and effort it also delays the elucidation of potentially useful or harmful treatments for patients. [28,29]

The WMRC ROSSINI (Reduction of Surgical Site Infection using a Novel Intervention) trial recruited 760 patients from 21 centres randomised to either a wound edge protection device or standard practice. Patient recruitment ran ahead of schedule and there was minimal loss to follow-up. The success of this and the subsequent ROCSS trial delivered by the same collaborative have demonstrated the capability of trainees to deliver large randomised trials for complex interventions. The credibility of trainee networks now mean that trainee-led trials are attracting funding from the National Institute of Health Research (NIHR) such as the dex-CSDH trial from the British Neurosurgical Trainee Collaborative. [19]

The Royal College of Surgeons of England have established the RCS Surgical Trials Initiative to establish a network of surgical trials units across the UK. Their vision for trial delivery has trainee networks embedded within the system (Figure 1).

1. **Generation of ideas for research and the impact of social media**

Ideas for future projects are invited from any collaborative member and can be submitted easily via email or the collaborative website ([www.pstrn.org.uk](http://www.pstrn.org.uk)). PSTRN holds an annual research meeting with a ‘Dragon’s Den’ session for trainees to pitch their ideas to ‘Dragons’. Dragons at the 2015 meeting included the President of British Association of Paediatric Surgery (BAPS) and the President of Association of Paediatric Anaesthetists of Great Britain and Ireland and a lead researcher from the the National Perinatal Epidemiological Unit. These sessions are designed to allow the discussion of ideas and assessment of the research plan by well-established researchers. Trainees may also submit ideas for research projects throughout the year; these are evaluated by the PSTRN committee with invited reviewers.

The National Surgical Research Collaborative also holds ‘Dragon’s Den’ sessions at their annual meeting to generate ideas for the national studies and these are voted on by the trainees attending the meeting to decide forthcoming projects.

Regional collaboratives are able to hold regular face-to-face meetings of members however this becomes logistically challenging for national collaboratives. Strategies to circumvent this difficulty include group emailing, Facebook and Twitter communities and Youtube videos. Indeed several collaboratives now use Twitter to run regular journal clubs. [30]

1. **Collaborative approach to authorship and recognition**

Authorship is often where collaboration can become antagonistic when collaborators feel they have not received due recognition for their work. This potential difficulty has so far been avoided by having pre-defined criteria for authorship and recognition. The model which is most often followed is as follows:

1. The writing team comprises the overall study lead and trainees who were the top recruiters for the study and these are listed as authors.
2. Each participant who has contributed data is listed as a collaborator which is citable on Medline.
3. The senior author for each study is the research collaborative.

The aim is that every trainee receives due recognition for the work which they have contributed and collaboration leads to published papers which enhance a trainee’s CV.

1. **Benefits of trainee led research**
   1. **Benefits for trainees**

There is individual satisfaction for trainees to realise that they have contributed to large scale, multicentre research. Participation also leads to a greater understanding of the mechanics of conducting research. Trainees learn how to engage with their local research departments and initiate local collaboration. They gain understanding of research ethics through attending research days organised by the collaboratives and realise the obligations placed on researchers in clinical trials, such as Good Clinical Practice certification. Study leads learn where to find support and funding opportunities and gain valuable experience in leading projects and people. [31] As more ambitious research projects are delivered trainees develop experience in other components of the research process including recruiting patients and collecting data.

The collaboratives encourage the dissemination of research findings amongst their trainee groups and hopefully provoke interest in keeping up to date with other research in the same field.

* 1. **Benefits for consultants**

Each UK consultant is now expected to take part in clinical audit as part of the process of revalidation. If a national study is an audit, then there is a clear benefit to consultant participation. When their centre participates in trainee led studies consultants receive certification of participation for their professional portfolio. Results from the centre are also fed back to the local hospital to allow a comparison to the overall results (benchmarking).

They also reap the rewards of having trainees interested in clinical research within their specialty who have access to a network who can facilitate multicentre studies and can work together to bring about new collaborations.

* 1. **Benefits for patients**

One of the long term aims of the trainee collaboratives is to make sure that participation in clinical trials is not restricted to patients in ‘elite’ academic hospitals and that every patient may have the option to take part in research during their hospital stay. [32] By making sure that our practice is informed by good quality research we can ensure the best possible outcomes for our patients.

1. **PSTRN projects**

PSTRN collaborated in the National Appendicectomy study which took place in May and June 2012. This was a multicentre, observational study looking at 30 day outcomes from appendicetomy. Data was contributed from 19 UK paediatric surgical centres. 242 children were included from paediatric surgical centres and a further 461 from general surgery units. After publication of the main results, studies focussing on outcomes in patients under 16 years old were generated. Two oral presentations were given at the 2013 BAPS conference. These showed that children treated in paediatric surgery centres were younger, more likely to have a preoperative ultrasound, a laparoscopic procedure, a consultant present at the procedure and histologically advanced appendicitis than those treated in general surgery units. The normal appendicectomy rate in general surgery units was over twice that in paediatric surgery centres. These results set ‘a standard of care’, as espoused by Denis Browne, the first President of the BAPS. They were circulated in general surgical journals [23]. We hope they will influence practice and highlight areas where we could improve the care for children.

The PSTRN has subsequently coordinated the ORCHESTRA (ORCHidopexy: does Earlier Surgery affect TesticulaR Atrophy?) study. This is an ambitious study investigating early post-operative outcomes after orchidopexy and adherence to the British Association of Paediatric Urologists (BAPU) guidelines on ideal age for surgery. It has attracted external funding from the Mark Gorry Foundation charity. The primary outcome of the study is post-operative testicular atrophy based on clinical assessment. The protocol was developed with expert review from the British Association of Paediatric Urologists (BAPU) research committee and BAPU helped to advertise the study amongst the UK consultant body.

Data on over 400 patients has been collected from 29 hospitals including 4 international paediatric surgical centres. Interim results were presented at the 2015 BAPS Congress and a manuscript reporting consultant preferences for the age at orchidopexy has been submitted for publication. Results so far presented have shown that, despite guidance that orchidopexy should ideally performed before 12 months of age, only 12% of boys in the study had surgery at the recommended age. Follow-up data continues to be collected. We are now working towards using the observational data to plan a multicentre randomised trial on the age of orchidopexy.

Projects which are soon to be launched include a study on the safety of laparoscopic cholecystectomy, the time to surgery in testicular torsion and a survey on the use of prostaglandin in the management of congenital diaphragmatic hernia. Each of these ideas have been proposed and developed by trainees working in different centres around the UK. Coordinating and conducting the research through the PSTRN will allow all trainees and patients to benefit.

1. **Conclusion**

Medicine is a vocation and surgeons must aim to provide the best standard of care for their patients. In an increasingly complex field it is important that our clinical decisions are informed by high quality, clinical research.

In Richard Horton’s words ‘Can bad scientific practices be fixed?’ Well yes, but only if we ‘emphasise collaboration not competition’ and ‘improve research training and mentorship’. We believe that the trainee networks are a step on the journey towards achieving this.

**Get involved!**

Beyond a national collaborative we have the ambition of creating a truly global collaborative of trainee paediatric surgeons and welcome interest from any trainees around the globe. Please get in touch at [info@pstrn.org.uk](mailto:info@pstrn.org.uk)

**References**

1. Horton R. Offline: what is medicine’s 5 sigma? The Lancet. Vol 385: 1380. April 11, 2015.
2. Allin BS, Tse WH, Marven S, Johnson PR, Knight M. Challenges of improving the evidence base in smaller surgical specialties, as highlighted by a systematic review of gastroschisis management. PloS One. 2015; 10(1):e116908. doi: 10.1371/journal.ponr.0116908.
3. McGee RG, Craig JC, Rogerson TE, Webster AC. Systematic reviews of surgical procedures in children: quantity, coverage and quality. J Paediatr Child Health 2013; 49(4): 319-24. Doi: 10.1111/jpc.12156.
4. Hall NJ, Eaton S, Pierro A. The evidence base for neonatal surgery. Early Hum Dev 2009; 85(11):713-8. Doi: 10.1016/j.earlhumdev.2009.08.058.
5. Hardin WD Jr, Stylianos S, Lally KP. Evidence-based practice in pediatric surgery. J Pediatr Surg 1999; 34(5):908-12.
6. Baraldini V, Spitz L, Pierro A. Evidence-based operations in paediatric surgery. Pediatr Surg Int 1998; 13(5-6):331-5.
7. TJ Bradnock, M Knight, S Kenny, P Johnson, ES Draper, JJ Kurinczuk, GM Walker on behalf of BAPS-CASS Incidence, sub-specialisation and the provision of definitive surgery for Hirschsprung’s disease in the UK and Ireland: results of a prospective, national cohort study. Abstract presented at BAPS 2011.
8. Best KE, Addorr MC, Arriola L, Balku E, Barisic I et al. Hirschsprung’s disease prevalence in Europe: a register based study. Brith Defects Res A Clin Mol Teratol. 2014; 100(9): 695-702. Doi: 10.1002/bdra.23269
9. Schoellhorn J, Collins S. False positive reporting of Hirschsprung’s disease in Alaska: an evaluation of Hirschsprung’s disease surveillance, birth years 1996-2007. Birth Defects Res A Clin Mol Teratol. 2009; 85(110:914-9. doi:10.1002/bdra.20628.
10. [www.wmresearch.org.uk](http://www.wmresearch.org.uk)
11. [www.nationalresearch.org.uk](http://www.nationalresearch.org.uk)
12. STARSurg Collaborative. Impact of postoperative non-steroidal anti-inflammatory drugs on adverse events after gastrointestinal surgery. Br J Surg 2014;101(11):1413-23. doi: 10.1002/bjs.9614
13. Nepogodiev D, Chapman SJ, Glasbey J, Kelly M, Khatri C, Drake TM, Kong CY, Mitchell H, Harrison EM, Fitzgerald JE, Bhangu A, STARSurg Collaborative. Determining surgical complications in the overweight (DISCOVER): a multicentre observational cohort study to evaluate the role of obesity as a risk factor for postoperative complications in general surgery. BMJ Open 2015; 5(7):e008811 doi: 10.1136/bmjopen-2015-008811.
14. [www.raftrainees.com](http://www.raftrainees.com)
15. Johnstone M, Marriott P, Royle TJ, Richardson CE, Torrance A, Hepburn E, Bhangu A, Patel A, Bartlett DC, Pinkney TD, WMRC. The impact of timing of cholecystectomy following gallstone pancreatitis. The Surg 2014; 12(30:134-40 doi: 10.1016/j.surge/2013.07.006
16. Pinkney TD, Calvert M, Bartlett DC, Gheorghe A, Redman V, Dowswell G, Hawkins W, Mak T, Youssef H, Richardson C, Hornby S, Magill L, Haslop R, Wilson S, Morton D, WMRC. Impact of wound edge protection devices on surgical site infection after laparotomy: multicentre randomised controlled trial (ROSSINI trial) BMJ 2013;347 :f4305 doi: 10.1136/bmj.f4305
17. Hamilton E, Ravikumar R, Bartlett D, Hepburn E, Hwang MJ, Mirza N, Bahia SS, Wilkey A, Bodenham Chilton H, Handley K, Magill L, Morton D, WMRC. Dexamethasone reduces emesis after major gastrointestinal surgery (DREAMS) Trials 2013; 14:249 doi:10.1186/1745-6215-14-249
18. [www.rescueasdh.org](http://www.rescueasdh.org)
19. [www.nets.nihr.ac.uk/projects/hta/131502](http://www.nets.nihr.ac.uk/projects/hta/131502)

HTA- 13/15/02: A randomised, double blind, placebo-controlled trial of a two week course of dexamethasone for adult patients with a symptomatic Chronic Subdural Haematoma (Dex-CSDH trial)

1. National Surgical Research Collaborative. Multicentre observational study of performance variation in provision and outcome of emergency appendicectomy. Br J Surg 2013; 100(9): 1240-52.
2. Ferguson HJ, Hall NJ, Bhangu A, National Surgical Research Collaborative. A multicentre cohort study assessing day of week effect and outcome from emergency appendicectomy. BMJ Qual Saf. 2014
3. The United Kingdom National Surgical Research Collaborative. Safety of short, in-hospital delays before surgery for acute appendicitis: multicentre cohort study, systematic review and meta-analysis. Ann Surg 2014
4. Tiboni S, Bhangu A, Hall NJ, Paediatric Surgery Trainees Research Network and the National Surgical Research Collaborative. Outcome of appendicectomy in children performed in paediatric surgery units compared with general surgery units. Br J Surg. 2014; 101(6): 707-714
5. Singh P, Turner EJH, Cornish J, Bhangu A, National Surgical Research Collaborative. Safety assessment of resident grade and supervision level during emergency appendectomy: Analysis of a multicenter, prospective study. Surgery 2014; 156(1):28-38.
6. Strong S, Blencowe N, Bhangu A; National Surgical Research Collaborative. [How good are surgeons at identifying appendicitis? Results from a multi-centre cohort study.](http://www.ncbi.nlm.nih.gov/pubmed/25644545) Int J Surg 2015; 15:107-12. doi: 10.1016/j.ijsu.2015.01.032
7. George SL. Research misconduct and data fraud in clinical trials: prevalence and causal factors. Int J Clin Oncol 2015 Aug 20 Epub ahead of print.
8. [www.starsurg.org](http://www.starsurg.org)
9. Sumi E, Teramukai S, Yamamoto K, Satoh M, Yamanaka K et al. The correlation between the number of eligible patients in routine clinical practice and the low recruitment level in clinical trials: a retrospective study using electronic medical records.Trials2013; **14**:426  doi:10.1186/1745-6215-14-426
10. Doshi P, Dickersin K, Healy D, Swaroop Vedula S, Jefferson T. Restoring invisible and abandoned trials; a call for people to publish the findings. BMJ 2013; 346:f2865. doi: 10.1136/bmj.f2865
11. Khatri C, Chapman SJ, Glasbey J, Kelly M, Nepogodiev D, Bhangu A, Fitzgerald JE, STARSurg Committee. Social media and internet driven study recruitment: evaluating a new model for promoting collaborator engagement and participation. PloS One 2015; 10(3): e0118899 doi:10.1371/journal.pone.0118899.
12. Chapman SJ, Glasbey JC, Khatri C, Kelly M, Nepogodiev D, Bhangu A, Fitzgerald JE. Promoting research and audit at medical school: evaluating the eduational impact of participation in a student-led national collaborative study. BMC Med Edu 2015; 15:47. Doi: 10.1186/s12909-015-0326-1.
13. Bhangu A, Marriott P, Nepogodiev D, Kolias AG, Jamjoom A et al. Surgical training and clinical trial involvement- the trainees’ view. BMJ 2015; 350:h2045