2019 Pulvertaft Essay: Innovation in Hand Surgery

Innovate to Collaborate- The Revolution in Hand Surgery Research.

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Associate Professor of Plastic and Hand Surgery University of Oxford and Imperial College NHS Trust London Innovation is defined as the act of introducing something new, be that a new idea or method (Riskin et al 2006). These new ideas come in many forms including technology or techniques, usually in combination. Defining true innovation from simple variation in practice is important and to facilitate this there has been an explosion in the concept of "innovation" with dedicated journals, academic degree courses and the establishment of innovation groups. Innovation can be truly groundbreaking, such as the discovery and subsequent use of penicillin, or result in incremental technological changes that lead to improvements of an existing device.

Plastic and orthopaedic surgeons have brought their talents to hand surgery, from the introduction of the operating microscope to the first prosthetic joint replacement. Their ingenuity and drive has resulted in advances ranging from hand transplants to novel drugs for the immunomodulation of Dupuytren's disease (Nanchahal et al 2018). Hand surgery has always been innovative however, with innovation comes a degree of risk. Some surgeons are early adopters, whereas others are risk-averse awaiting long-term outcomes on safety before committing. Medicine is littered with tragic cases of patient harm in the name of innovation. Recent scandals resulting in patient deaths (https://www.sciencemag.org/news/2018/03/two-controversial-stem-cell-trials-could-harm-patients-critics-say) and blindness (Kuriyan et al 2017) have drawn a spotlight on surgeons and how we test our new technologies. The rules on the introduction of new devices and techniques are being scrutinized (Lewis et al 2018) with the Royal College of Surgeons (RCS) helping guide safe introduction while at the same time preventing stifling of advancement in

practice (Surgical Innovation, New Techniques and Technologies. A Guide to Good Practice 2019)

Innovation is not the same as invention. The stages of surgical innovation are described in the IDEAL framework (Innovation, Development, Exploration, Assessment, Long-term Follow up) that includes the integration of an innovation into practice (McCulloch et al 2009). Surgeons are usually enthusiastic to try new techniques but, ultimately, only some are adopted and others discarded. A recent example in hand surgery has been the practice change following publication of the Distal Radius Acute Fracture Fixation Trial (DRAFFT) which saw a reduction in use of wrist plates in favour of K-wires (Costa et al 2016). The Distal Radius Acute Fracture Fixation Trial 2 (DRAFFT 2) is already underway and will answer the question of whether simple casting is superior to K-wire fixation for displaced distal radius fractures (Achten J et al 2019).

Clearly innovation and research are interlinked. Change in practice for the benefit of patients is important in both cases but innovation, unlike research, includes novel ways of delivering care. Since Horton's infamous article in the Lancet in 1996 in which he, the then editor of the journal, described surgical research as a "comic opera" surgeons have attempted to prove him wrong (Horton 1996). Historically it has proved challenging to organize large-scale clinical research in hand surgery. As a result clinical evidence is weak and based mainly on single centre case series. The reason for such poor clinical evidence is multifactorial but common across all of surgery (Ergina PL et al

2009). Randomized controlled trials (RCTs) are considered to provide the best clinical evidence to guide practice but studies have shown only 3% of hand surgery articles are RCTs and of these, only two to three multicentre RCTs are published each year (Voineskos et al 2016a; Voineskos et al 2016b). A recent systematic review of hand surgery RCTs has shown an increase in number but not quality (Long et al 2018). In the United Kingdom (UK) the National Institute for Health Research (NIHR) is the largest funder of health research and since its inception in 2006 over 5 million patients have benefitted from its clinical trials across the whole of medicine. Despite this only 2% of medical research funding goes to surgery (The Royal College of Surgeons of England. Surgical Research Report 2011).

In 2012 the RCS launched the clinical trials initiative to increase both the quantity and quality of surgical clinical research across all disciplines. Both the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) and the British Society for Surgery of the Hand (BSSH) recognized its importance and in 2013 supported the RCS initiative by appointing a joint Surgical Specialty Lead and the development of the Reconstructive Surgery Trials Network (RSTN) (http://reconstructivesurgerytrials.net). The RSTN has become the UK clinical trials and collaborative research network for plastic and hand surgery and enables access to methodological support from six dedicated surgical trials centers embedded in UK universities.

When the RSTN was established in 2013 it had a remit to develop a national collaborative research culture in both plastic and hand surgery. There was no

large scale funding and no existing infrastructure dedicated to this process. The task seemed impossible but challenge has always been a strong driver for surgeons. It was clear that the RSTN had to be innovative if it were to succeed.

In 2008 the general surgical trainees had pioneered the concept of trainee research collaboratives (Bartlett et al 2012). Trainees in the West Midlands had organized themselves into groups with the purpose of delivering high quality clinical research. Their first trainee led multicenter RCT, ROSSINI, recruited 769 patients to either use of a wound edge protection device or standard care during laparotomy. Twenty-one hospitals were involved and they finished recruitment ahead of schedule. While the results, published in the British Medical Journal, showed no benefit of wound protection (Pinkney et al 2013), the study was to have a much more profound and lasting impact on the national research culture. What these trainees demonstrated was that collaborative working could deliver high quality clinical research that changed patient care and at a cost much lower than traditionally possible.

Initial attempts at engaging senior academic surgeons in the RSTN failed. While the majority were supportive some were resistant to change and it became clear that if the RSTN was to deliver on its remit of collaborative research it would need to think differently. A conscious decision was made to engage trainees to achieve large, meaningful studies that would change practice. Up until this point the trainee collaboratives in general surgery had been small and regional, working together on specific projects. The trainee pool for both hand and plastic surgery was much smaller and a national collaborative approach would be needed. This seemed a much more daunting task as national engagement was a different proposition to organizing a local group of surgeons. Nevertheless, "tech savvy" RSTN trainees used technological and social media advances to establish the communications infrastructure needed to engage geographically distant groups. Through a series of technology based applications and innovative ways of applying them the RSTN established a national working group extremely quickly.

We are fortunate in hand surgery to have some of the most enthusiastic, intelligent and talented young trainees in the world and it became clear that many had been waiting for the opportunity to demonstrate their ability. Support from the BSSH, BAPRAS and RCS was crucial and facilitated national meetings to promote the concept of collaborative research. The RSTN established annual clinical research meetings; initially in London but more recently held in Edinburgh (2018) and Cardiff (2019). These meetings have an innovative approach with presentations on trial concepts emphasising engagement and idea generation rather than data presentation. These meetings use interactive web based audience participation software and are streamed live around the globe using teleconferencing applications. This has resulted in an increasing social media presence that has helped disseminate outcomes. In just 6 years the RSTN had grown from a few surgeons into a national organisation with over 650 members.

The RSTN has always been inclusive and ensured that there was no top down hierarchical role in the organization and is run by a committee of regional representatives composed of both plastic and orthopaedic surgeons. It has medical student members, with their own subgroup (RSTN Undergrad), and nurses and hand therapists as active members. Everyone brings a special and unique benefit to the team. The use of enabling technologies allowed the RSTN to engage in all aspects of collaborative working. The RSTN published an innovative Supportive Technology in Collaborative Research framework (STiCR) that documented all the technologies used to set up, run and disseminate projects (Kwasnicki et al 2019). This approach utilized existing free software but in a novel way allowing cost effective ways of undertaking traditionally expensive clinical research. The RSTN team is working on a "Technology Toolkit" to allow dissemination of this experience to the wider NHS and application to third world healthcare systems.

When faced with the task of kick starting a national clinical research culture it was important that the RSTN learnt to walk before it ran. Early scoping work made it clear that many aspects of hand surgery that are taken for granted are based on weak evidence. It is estimated that about 20%–25% of care provided in medicine is not needed or is potentially harmful (Grol and Grimshaw 2003). In order to ensure maximum engagement simple topics relevant to all level of hand surgeon were chosen. These included antibiotic use in hand trauma, mallet injury, paediatric nail bed injury, trigger finger, digital nerve repair and whether to bury K-wires. The first step in the process was to evaluate the current evidence in the form of systematic reviews. In

some topics this had already been done but in others we set up "virtual" teams of surgeons around the country to work together to deliver the evidence. Using online resources, social media and teleconferencing we published 12 systematic reviews, including Cochrane reviews, in hand and plastic surgery topics (Dinnes et al 2016; Dunlop et al 2019; Dunne et al 2019; Glass and Jain 2014; Glass et al 2016; Murphy et al 2016a; Murphy et al 2016b; Rodrigues et al 2019; Wormald et al 2017a; Wormald et al 2017b; Wormald et al 2019a; Wormald et al 2019b). In some cases team members only met in a virtual world but still worked together effectively.

Once the gaps in evidence had been established it was necessary to document NHS practice in order to highlight good practice and determine if a change was necessary. Scoping surveys were designed and delivered to surgeons electronically (Mylvaganam et al 2017; Sierakowski et al 2016; Tolkien et al 2017; Wormald et al 2019c). While these electronic surveys provided valuable information it was clear that survey responses are traditionally low. To improve survey responses, and hence national engagement, we trialled a novel collaborator approach to data collection. In our subsequent K-wire and breast reconstruction surveys trainees in all hand and plastic surgery units conducted face to face surveys with surgeons and patients (optiFLAPP Collaborative 2018; The Wire Collaborative 2018). In both of these surveys we demonstrated a significant increase in response rates and was yet another example of innovative ways of conducting clinical research. Furthermore, the RSTN ran the national BSSH trauma audits on

flexor tendon injuries and hand fractures collecting data on over 1200 patients across the UK in just 3 months using a trainee model (papers in preparation).

It was clear that the collaborative model of delivering large-scale clinical research was working and the RSTN launched its first NIHR funded multicentre RCT in 2018; The Nail bed INJury Analysis trail (NINJA). The RSTN had run a successful BSSH funded pilot study in 4 hand units demonstrating the feasibility of a large scale RCT (Grieg et al 2017; Jain et al 2015; Sierakowski et al 2016). The main NINJA trial started recruiting children in July 2018 and was due to recruit 416 children in 20 months; however, NINJA reached this target in just 12 months. The reasons for this success are multifactorial but rely on a number of innovative processes. Traditionally multicentre RCT's in hand surgery have recruited from small groups of select units. NINJA had an open door policy; any unit could be a recruiting centre if they wished. This led to previously research naive hand units taking part and a large geographical reach for the trial. Units across the whole of England, Scotland, Wales and Northern Ireland took part in the study. Surgeons who had not traditionally undertaken research were engaging and recruiting. The high recruitment targets have been reached with the help of readily available smart phone applications. The trainees set up novel local WhatsApp groups to identify and recruit patients to the trial. This allowed rapid identification and randomization of suitable children that was crucial in a trauma trial, as the time from presentation to surgery is short (Mikhail et al 2019). NINJA has led the way for the next large NIHR funded trial, NEON. NEON is a large scale, innovatively designed, randomized control trial that will recruit 480 patients

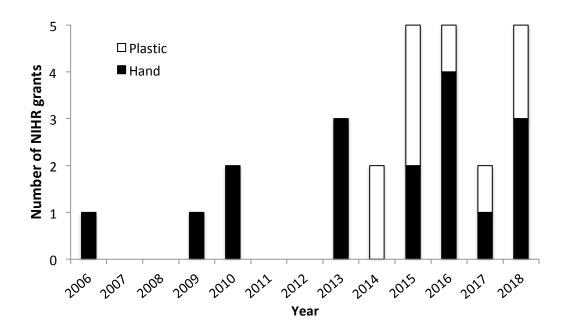
over 5 years to either having the digital nerve repaired or left unrepaired to determine efficacy of this common procedure (Dunlop et al 2019, Jain et al 2019, Wormald et al 2019c).

The RSTN's rapid growth and success has been recognised by the RCS and has received international attention. The Dutch have set up a similar model with the help of the RSTN and have engaged in collaborative studies and are leading TRIGGER, a multi-centre international trial on the management of trigger finger with RSTN support. Australia and the USA have also been in contact and have sought advice on setting up similar networks. The RSTN has also worked with other specialties resulting in large scale studies (Potter et al 2019, Durack et al 2019).

Innovation is about new ways of doing things with lasting engagement and improved patient care. In the last 6 years UK hand surgeons have made a significant and lasting impact on clinical research driven by many RSTN and BSSH initiatives. The impact of these initiatives is measurable with a three-fold increase in successful NIHR applications in hand surgery alone (Figure 1) (Nolan and Jain 2019). Hand surgeons have demonstrated that innovative ways of collaborating utilising technology and by inverting the traditional top down hierarchical approach to delivering research has resulted in a tangible change to patient care and our specialty. The lasting benefit of this strategy has been the return of the "team" approach to collaboration and a culture change amongst young surgeons, many of whom are now consultants and

leading projects themselves. Each cohort of trainees inspires the next building momentum and ensuring this change will last for generations to come.

FIGURE 1. Graph showing the increase in number of successful NIHR plastic and hand surgery grants since the NIHR was established in 2006 (Nolan and Jain 2019).



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