



Update on BOA Orthopaedic Surgery Research Centre (BOSRC)

July 2015 to June 2016

1. Grant applications submitted

Over the second year of the project we have submitted nine grant applications to NIHR HTA programme: six expressions of interest and three full applications (Table 1). The applications include feasibility, pilot and full multi-centre randomised controlled trials. The applications have drawn on the multi-disciplinary expertise of York Trials Unit (YTU) including trial methodologists, statisticians, economists, mixed methods researchers (including qualitative, survey, systematic review and Delphi methods) and the wider infrastructure including trial co-ordination, data management and research project management. The applications include researcher-led as well as commissioned calls, the former being more resource intense as the topic needs to be justified as a research priority for NHS.

Four of the six expressions of interest were successful and we are awaiting the outcome of the other two (expected by end of July). Of the four successful EOIs, we have submitted full applications for three. For the fourth we were asked by the HTA Panel to submit a new EOI for a full RCT with internal pilot rather than an external pilot as originally applied for. Of the three full applications submitted, one was successful (subject to contract therefore must not be publicised yet), one was rejected and we are awaiting the outcome of the third. In addition, a further collaboration has obtained industry funding. The unsuccessful application was a high quality application; it was rejected due to a change in NICE guidance which the HTA Panel felt made it unethical to randomise patients to current standard care. This was very disappointing for the whole team given the limitations of the evidence on which the guidance was based and the considerable amount of work that went into this application from the CI, the ambulance services and the trials unit team.

Five of the seven orthopaedic surgeons we have worked with over the past year are first-time chief investigators (CIs) so we are very proud of the success rate of our applications. The range of previous research experience has been varied and we have worked very intensively with the majority of applicants to ensure a high quality submission. The CIs we have worked with also come from a wide geographical spread: Bristol, Leicester, Hull, South Tees and London. When orthopaedic surgeon co-applicants are also considered this widens the spread even further to include Royal Orthopaedic Hospital NHS Foundation Trust in Birmingham, Robert Jones & Agnes Hunt Orthopaedic Hospital NHS Foundation Trust in Oswestry, University Hospital Southampton NHS Foundation Trust, University Hospitals Birmingham NHS Foundation Trust, Derby Hospitals NHS Foundation Trust, Norfolk & Norwich University Hospitals NHS Foundation Trust, Royal Liverpool University Hospital.

2. Projects starting

Our activity is starting to gain momentum. Four projects have started or will commence by the Autumn:

- (i) Mixed methods study developing an occupational advice intervention prior to hip and knee replacement for evaluation in a future RCT.
- (ii) RCT investigating compression bandage for knee swelling following total knee arthroplasty which has been designed to be delivered at very low cost through using routinely collected data. In addition plans are currently underway for part of this work to form an MD project for an orthopaedic surgeon (**subject to contract**).

(iii) RCT comparing surgical fasciectomy and collagenase injection for Dupuytren's contracture (**must not be publicised yet as still subject to contract**);

(iv) Fellowship project on surgical treatment of rib fractures which will form the basis of an MD. Funding for this was awarded from ORUK in our first year.

3. Education and engagement activities

Senior staff from YTU have supported a range of events across the country focusing on building knowledge amongst orthopaedic surgeons about RCT methods, the practicalities of delivering RCTs, making grant applications to national peer-reviewed funding competitions and promoting the support that BOSRC and other trials units can provide (Table 2).

During the year we also were invited to join the RCS Surgical Trial Initiative as a Surgical Trials Centre.

4. Extent to which milestones have been met

Our original milestones were:

- a) Engagement and networking activities
- b) Support six high quality grant submissions (outline or full)
- c) 20% of collaborating centres with new PIs
- d) At least one new CI leading a grant application

a) We have continued with a similar range of engagement activities as our first year. This has included having a stand at BOA Congress in Liverpool, though we have found that there has been very limited interest. We have a presentation slot for Belfast which we hope will be a more effective approach. We would welcome more requests to support education and engagement activities related to trials and making grant applications. In our experience there is quite a range amongst surgeons in extent and depth of knowledge and interest in research methods, RCTs, sources of funding available, role of trials units, and chief investigator and co-investigator roles and responsibilities.

b) We have supported nine EOIs/outlines or full applications in the past year (seven projects)

c) We do not have enough projects with recruited sites to provide a reliable estimate of this yet. In the Opal project which is a three-site project, as far as we are aware are first-time co-investigators on a NIHR funded project.

d) Five of the seven orthopaedic surgeons we supported in the past year are first-time CIs.

5. Problems and challenges

Because of how the deadlines are scheduled for the NIHR programmes there tends to be three very intense periods across the year. We have managed this by drawing on the resources of the wider YTU team, where necessary, and it has been one of the advantages of spreading the BOA funding across a few individuals rather than a single researcher which would make the work flow impossible to manage.

Surgeon interest in being involved in leading trials appears to be variable across specialities with some specialities “harder to reach” for us. We found it challenging to get surgeons interested in the HTA commissioned call on thoracolumbar fractures. NIHR had to advertise this call twice as, at the first round, no-one applied. We tried to get a group interested for the first call but failed to do so. At the second call we have managed to get a collaboration together.

5. Plans for 2016-2017

- We expect to be making two full applications and two EOI/outline applications to NIHR HTA and EME programmes in Autumn/Winter 2016. This includes the following:
 - Assuming our two outstanding EOIs are successful we will be developing two full proposals for submission to NIHR in September (pilon fractures, researcher-led call; thoracolumbar fractures, commissioned call).
 - There is currently an orthopaedic surgery topic on NIHR HTA’s list of proposed topics for the next HTA commissioned call. If this makes it to the final commissioned list, which is due to be advertised in July, we intend to submit an EOI (deadline likely to be mid-September).
 - The NIHR EME programme currently has a call out on evaluation of new surgical procedures through the use of novel study designs. We are in the process of developing an application (deadline 1 November).
- If the two EOI/outlines we intend to submit in Autumn/Winter are successful, we will have two full applications Spring/Summer 2017 to develop. It is difficult to be precise about the remaining programme of work for the second half of the year as the number of applications and specific programmes we apply to depends partly on what is commissioned and the interests and level of experience of the clinicians who approach us. We expect to have the capacity to make 1-2 EOIs, in addition to the two full applications, in the second half of the year.
- We will continue our education and engagement activities. Although these can be resource intensive, such as the two-day workshop we run, we find these activities are a useful way of engaging with research-interested surgeons.

Table 1: Grant applications made July 2015 to June 2016

Funding stream	EOI/full Date of submission	Chief Investigator	Title	Outcome	Project value
HTA Researcher-led	EOI Sept 2015	Michael Whitehouse <i>University of Bristol</i>	Antibiotic delivery for open lower limb fracture	Successful through to next round	N/A
HTA Commissioned	EOI Sept 2015	Harvinder pal Singh <i>University Hospitals of Leicester NHS Trust</i>	A feasibility study on the role of augmentative patches in surgical management of rotator cuff tears	Successful through to next round	N/A
HTA Commissioned	EOI Sept 2015	Joseph Dias <i>University Hospitals of Leicester NHS Trust</i>	Dupuytren's Intervention Surgery versus Collagenase (DISC): a RCT	Successful through to next round	N/A
HTA Commissioned	Full Sept 2015	Paul Baker <i>South Tees NHS Trust</i>	Occupational advice initiated prior to planned surgery for lower limb joint replacement: a feasibility study	Awarded Project started	£542,855
HTA Researcher-led	EOI Dec 2015	Hemant Sharma <i>Hull & East Yorkshire NHS Trust</i>	External frame versus internal locking plate for articular pilon fracture fixation: a multi-centre pilot RCT	Resubmission requested for full trial	N/A
HTA Researcher-led	Full January 2016	Michael Whitehouse <i>University of Bristol</i>	Antibiotic delivery for open lower limb fracture	Rejected	£523,958
HTA Commissioned	Full January 2016	Joseph Dias <i>University Hospitals of Leicester NHS Trust</i>	Dupuytren's Intervention Surgery versus Collagenase (DISC): a RCT	Awarded subject to contract (not to be publicised yet)	£1.9million
HTA Commissioned	Full April 2016	Harvinder pal Singh <i>University Hospitals of Leicester NHS Trust</i>	A feasibility study on the role of augmentative patches in surgical management of rotator cuff tears	Awaiting outcome	£237,684
HTA Commissioned	EOI May 2016	Arun Ranganathan <i>Barts Health NHS Trust</i>	Surgical fixation versus non-operative management for patients with stable thoracolumbar fractures: a feasibility study	Awaiting outcome	N/A
HTA Researcher-led	EOI June 2016	Hemant Sharma <i>Hull & East Yorkshire NHS Trust</i>	External frame versus internal locking plate for articular pilon fracture fixation: a multi-centre pilot RCT	Awaiting outcome	N/A
Industry	N/A	Mike Reed <i>Northumbria Healthcare NHS Foundation Trust</i>	Compression bandage for knee swelling following total knee arthroplasty: a RCT	Successful. At contract stage	TBC

Table 2: List of BOSRC Engagement activities July 2015 to June 2016

Event	Date and location	Activity and Attendees from BOSRC
Undertaking Clinical Trials in Trauma and Orthopaedics	University of York, 27-28 June 2016	Workshop on design and conduct of surgical trials for orthopaedic surgeons. Prof Torgerson, Prof Hewitt, Dr McDaid, Prof Rangan, Dr Brealey, Ms Hughes-Morley, Ms Keding
Reconstructive Surgery Trials Network	Royal College of Surgeons of England, 18 June 2016	Presentation by Prof Torgerson
Orthopaedic Surgical Trials Day	Royal College of Surgeons of England, 14 March 2016	Presentation on Efficient Design and Conduct in Surgical Trials by Dr Catriona McDaid
NIHR Trials in Musculoskeletal Trauma Annual Meeting	Warwick, 27 January 2016	Dr Stephen Brealey promoted BOSRC support available (leaflets and stand),
Orthopaedic Trauma Society Annual Meeting	Warwick, 28 January 2016	Professor Torgerson contributed as a panel member for a 'Dragon's Den' activity
National Research Collaborative meeting	Sheffield University, 4 December 2015	Prof David Torgerson attended this one-day educational event, hosted by South Yorkshire Surgical Research Group, to promote surgical research amongst surgical trainees and others (leaflets and stand).
Optimising Outcomes from Shoulder Arthroplasty	University of York, 25 September 2015	We hosted this ORUK supported training event "Optimising Outcomes from Shoulder Arthroplasty" and provided the venue meaning that delegate costs could be minimised. Two members of YTU staff also delivered presentations (Caroline Fairhurst & Belen Corbacho).
BOA Annual Congress	13-16 September 2015	Presentation by Dr Catriona McDaid on role of a clinical trials unit BOSRC stand for two days of BOA Congress to promote the support available.