

# The IDEAL Conference 2018

## No innovation without evaluation

The M Shed, Bristol, 13 & 14 September 2018

#IDEAL2018

Idea, Development, Exploration, Assessment, Long-term Follow-up (IDEAL):  
Improving the Quality of Research in Surgery





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# Welcome

Welcome to the 2018 IDEAL conference and to the M Shed.

Below is some information that you may find useful during the conference.

## Accessing the Wi-Fi

To access the wi-fi please use the **BOpen** network. This does not have a username or password. Delegates will need to accept the terms of use before logging on.

## Getting from the Mercure hotel or the M Shed to SS Great Britain

Mercure Bristol Holland House Hotel & Spa, Redcliffe Hill, BS1 6SQ

M Shed, Princes Wharf, Wapping road, Bristol BS1 4RN (for the conference)

SS Great Britain, Great Western Dockyard, Gas Ferry Road, Bristol BS1 6TY (for the dinner)

It takes approx. 17 minutes to walk from The Mercure hotel to SS Great Britain and approx. 10 minutes from The M Shed. For directions, please see the map on the next page.

## M Shed: galleries

As a delegate you have access to the Bristol Galleries at the M Shed. Information on the exhibits currently on show can be found here: <https://www.bristolmuseums.org.uk/m-shed/whats-at/?nav=menu>

## SS Great Britain: dinner

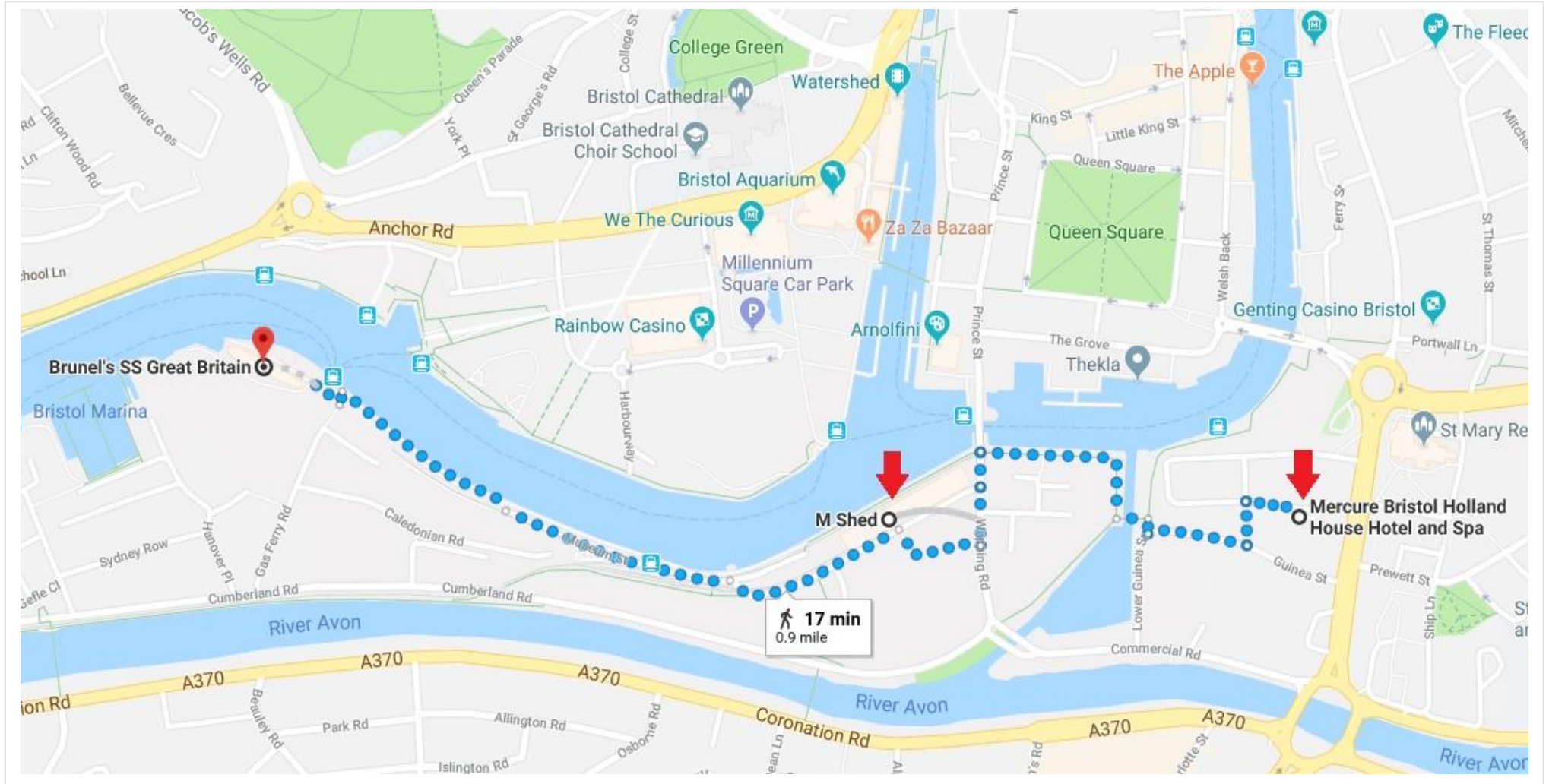
The conference dinner, which takes place at 7pm on Thursday 13 September, will be at The SS Great Britain.

The SS Great Britain is one of the most important historic ships in the world. After dinner you have the option of joining a guided tour of the ship. If you would like to sign-up for the tour, please see one of the helpers wearing an orange lanyard.

## Any problems?

If you have any problems, please find one of the helpers wearing orange lanyards.

# Map



# Programme

DAY 1: THURSDAY 13 SEPTEMBER 2018

## Innovation and evaluation in surgery

**10:30 Registration (and refreshments)**

**11:00 Welcome, introduction and chair of morning session:** Jane Blazeby

**11:05 The importance of scientific evaluation of innovation:** Chris Whitty

**11:20 Real life innovation: two case studies (chair: Peter McCulloch)**

*A surgeon's experience:* Gianluca Casali

*Patient and public perspective:* comments from Sarah Squire and Liz Philpots

**11:55 Innovation, glamour and risk:** Deborah Cohen

**12:15 Twenty years of vaginal mesh device equivalence and the problems it has caused:** Carl Heneghan

**12:45 Using IDEAL in health technology assessment:** Tammy Clifford

**13:15 Lunch and poster viewing**

## Ethical and legal frameworks of innovation: what they are and what they should be

**14:00 Introduction and chair:** Richard Huxtable

**14:05 Identifying surgical innovation in real time: a pilot study:** Wendy Rogers

**14:40 Legal aspects of informed consent for innovative procedures and surgery:** José Miola

## Parallel sessions: Practical aspects of studying surgical innovation

(Refreshments will be available throughout the workshops)

**15:10 Introduction and chair:** Jane Blazeby

Group A	Group B	Group C
<b>Recruitment: communicating clinical equipoise to optimise informed consent and participation in RCTs</b>	<b>IDEAL in action: a practical guide to using IDEAL in interpreting, designing and reporting research</b>	<b>Deviations from treatment protocols in surgical trials: how can they be measured and what can we learn about treatment effects when they are present?</b>
Leila Rooshenas, Marcus Jepson, Andrew Carr and David Beard	Peter McCulloch, Allison Hirst, Barry Main and Nicole Bilbro	Marion Campbell, Natalie Blencowe and Jonathan Sterne

## Keynote: An exemplar IDEAL stage 3 study

**16:30 Development and randomised evaluation of robotic surgery for rectal cancer:** David Jayne

**17:15 Summary and close of Day 1:** Jane Blazeby

## Randomised controlled trials in surgery

**09:00 Welcome back and chair of morning session:** Peter McCulloch

**09:05 The future of surgery and innovation:** Richard Kerr

**09:30 Debate and live voting:** Surgical RCTs – not always needed

**09:30 Introduction by chair:** Andrew Carr

### 09:35 Pre-debate vote

Go to [www.menti.com](http://www.menti.com) and enter the code given on the main screen

**09:40 For the motion:** Richard Lilford

**09:50 Against the motion:** Marion Campbell

**10:00 Patient and public perspective:** comments from Sarah Squire and Liz Philpots

**10:05 Questions from the floor**

**10:20 Respondent against the motion:** David Jayne

**10:25 Respondent for the motion:** Art Sedrakyan

**10:30 Patient and public perspective:** comments from Sarah Squire and Liz Philpots

### 10:35 Post-debate vote

Go to [www.menti.com](http://www.menti.com) and enter the code given on the main screen

**10:45 Refreshments**

## Early phase evaluation of surgical interventions and devices

**11:00 Towards early evaluation of surgical innovations using an integrated approach: The SURGE Study:** Maroeska Rovers

**11:30 Methods for transparent, safe and efficient surgical innovation: The Surgical Innovation Theme of the Bristol Biomedical Research Centre:** Ashley Blom and Jane Blazeby

**12:10 MHRA and regulation of devices and surgical procedures:** Michael Rawlins

**12:30 Lunch and poster judging**

## Parallel sessions: new findings and new ideas

(See abstracts in conference brochure)

**13:15**

ORAL PRESENTATIONS: THE EVALUATION OF INNOVATION

**Chair:** Peter McCulloch

RESEARCH TALKS

1. Reinforcement of Closure of Stoma Site (ROCSS) randomized controlled trial: A multicentre, international evaluation of biological mesh reinforcement of stoma. **James Glasbey**
2. Let's not talk about it: a conceptual study of surgical innovation. **Giles Birchley**
3. PIRRIST: A patient and public involvement (PPI) intervention to enhance recruitment and retention in surgical trials. **Joanna Crocker**
4. Development and delivery of a standardised investigator training package for an IDEAL Phase 3

DISCUSSION AND DEBATE: A SURGICAL SANDPIT TO DEVELOP IDEAL STUDIES DE NOVO

**Chair:** Jane Blazeby

RESEARCH IDEAS

1. An in-depth analysis and cohort study of the techniques used to repair complex incisional hernias after abdominal surgery. **Samir Pathak**
2. Portuguese Inguinal Hernia Cohort Study. **António Sampaio Soares**
3. The Pre-Bra Study. **Kate Harvey**
4. Proposed Randomised Controlled Feasibility Trial of a Novel Polyvinylidene fluoride (PVDF) Mesh (Dynamesh@-HIATUS) Cruroplasty versus Suture only Repair of Large Hiatus Hernia – The DYNAMIC Study. **Simon Toh**

multicentre interventional trial across low and middle income settings. **James Glasbey**

5. Scottish Health Technologies Group Experience of Using IDEAL. **Jennifer Hislop**

6. Learning curve bias can significantly influence results of high quality surgical RCT's: the case of the Dutch D1-D2 trial. **Frans van Workum**

7. A systematic review of the ethical, legal and regulatory issues pertaining to surgical innovation. **Alice Toms**

8. Introducing innovative invasive procedures and devices into clinical practice: an in-depth analysis of NHS Trusts' New Invasive Procedure governance. **Sian Cousins**

**14:55 Refreshments**

## Reporting innovation

**15:10 Introduction and chair:** Jane Blazeby

**15:15 The need for transparent and mandated outcome reporting for surgical innovation:** Martin Elliott

**15:45 Summary and close of Day 2:** Jane Blazeby

**16:00 Close of conference**

**16:30 IDEAL Annual General Meeting (AGM):** Peter McCulloch

All are welcome to attend. For further information, please contact: Allison Hirst ([allison.hirst@nds.ox.ac.uk](mailto:allison.hirst@nds.ox.ac.uk)).

**17:30 Close of IDEAL AGM**



# Faculty and speaker profiles



DAVID BEARD

David Beard is Professor of Musculoskeletal Sciences at the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) in the University of Oxford. He is also co-Director of the Royal College of Surgeons (RCS) Surgical Intervention Trials Unit (SITU-Oxford) and Professorial Fellow of Kellogg College.

His academic qualifications include an MSc in Biomedical Science (Kings College London), an MA by Resolution (Kellogg College, Oxford), and a Doctorate in Medicine (Oxford). Previous clinical work includes posts in Bath, Jersey, and Canada and as senior academic at Oxford, Bristol and Australia.

Initially qualified as a physiotherapist he maintains an active clinical role as an NHS Specialist Practitioner (Complex Knee) in West Wales. He was recently awarded an honorary Fellowship by the Royal College of Surgeons (Eng). David has completed several clinical trials in surgery and rehabilitation and is currently Chief Investigator or Co-applicant in 16 substantial clinical trials in the fields of orthopaedics, plastics and ENT.

Research interests include surgical clinical trials methodology, including placebo control designs, outcome measurement in health and a variety of musculoskeletal intervention studies. He has over 200 papers (many trial related). As a trialist he sits on, or chairs, several NIHR/Charitable Steering or Funding committees, both nationally and internationally.

NICOLE BILBRO

Nicole Bilbro is a general surgery resident at Maimonides in Brooklyn, NY, completing an evidence-based medicine research fellowship with the IDEAL Collaboration and the Patient Safety Academy at Oxford University.

Nicole has been integral in the development of patient safety initiatives at Maimonides as part of her work in the Resident Quality Council, as a CLER senior leadership representative, and as an elected delegate to the Committee of Interns and Residents.

During medical school, she was inducted into the Gold Humanism Honor Society for her work in education and outreach with local women's groups as president of the Women in Medicine organization. She remains interested in women's health and is pursuing a fellowship in breast oncological surgery. Nicole is originally from Denver, CO and enjoys snowboarding and hiking in the mountains.



JANE BLAZEBY



Jane Blazeby is Professor of Surgery at the University of Bristol and an Honorary Consultant Surgeon at University Hospitals Bristol NHS Foundation Trust. She founded and leads the Bristol Centre for Surgical Research based within Population Health Sciences at the University of Bristol. The centre aims to promote and establish evidence-based surgical practice in the NHS and worldwide. She directs the MRC ConDuCT-II (Collaboration and Innovation in Difficult randomised Controlled Trials in Invasive procedures) Hub for Trials Methodology Research, co-leads the Royal College of England Surgical Trials Centre and directs the Surgical Innovation theme of the NIHR Bristol Biomedical Research Centre.

Jane is busy succession planning and working hard to develop a new generation of surgeons who understand, participate and can lead high quality research. The Bristol Centre now hosts three Clinician Scientists posts funded by the NIHR or MRC.

Jane studied Medicine at the University of Bristol, undertook higher surgical training in the South West of England. She was an MRC Clinician Scientist between 2000 and 2006. She chaired the Quality of Life Group of the European Organisation for Research and Treatment of Cancer (EORTC) between 2001 and 2005 and maintains her long-standing interest in outcomes research as a member of the Core Outcome Measures in Effectiveness Trials (COMET) management group.

Jane is the chief investigator for the By-Band-Sleeve Study (funded by NIHR HTA), which is a large trial in bariatric surgery. She is actively supporting NHS and academic surgeons to design and deliver multiple surgical trials. In 2015 she was appointed as an NIHR Senior Investigator.

#### NATALIE BLENCOWE

Natalie Blencowe is an NIHR academic clinical lecturer and a specialty registrar in upper GI surgery. She is currently the research representative for ASiT and an NIHR RfPB panel member. She co-leads the Severn and Peninsula Audit and Research Collaborative for Surgeons (SPARCS) and is a member of the NIHR Bristol BRC.

Natalie is particularly interested in developing methods for optimising the quality assurance of surgical interventions and understanding how innovative procedures evolve and are adopted into clinical practice.



#### ASHLEY BLOM

Ashley Blom is an NIHR Senior Investigator, Fellow of the Academy of Medical Sciences and President of the European Orthopaedic Research Society. He leads a number of major research programmes including two NIHR Programme Grants on improving outcomes in arthroplasty and treating infected hip and knee replacements.

His team at the Musculoskeletal research Unit are responsible for the analysis of the National Joint Registry, the largest arthroplasty database in the world. Publications from this include seminal work in the Lancet on safety of metal-on-metal hip replacements, hip resurfacing, mortality after hip and knee replacement and the longevity of arthroplasty.

#### MARION CAMPBELL

Marion Campbell is Professor of Health Services Research in the Health Services Research Unit (HSRU), University of Aberdeen and is also Vice-Principal for Research for the University.

Marion is a medical statistician and clinical trialist. Her main research interests are in the methodology of evaluative research, especially the design, conduct and analysis of clinical trials of surgical and other complex interventions. She has published widely on clinical trials methodology including cluster randomised trials.

She has served on many national and international funding agencies and committees and is an elected Fellow of the Royal Society of Edinburgh, the Faculty of Public Health and the International Society for Clinical Trials.





#### ANDREW CARR

Andy Carr is the Nuffield Professor of Orthopaedic Surgery at the University of Oxford. He is an inter-disciplinary researcher distinguished for evaluating and developing surgical implants and technologies and for his leadership in surgical and musculoskeletal research. He trained as a surgeon in Sheffield, Oxford, Seattle and Melbourne and undertook research fellowships at the Weatherall Institute of Molecular Medicine in Oxford and the Royal Children's Hospital in Melbourne, Australia.

While training with John Goodfellow in Oxford his research into surgical implants included defining the use of the Oxford Knee as a partial knee replacement. He established the shoulder surgery unit in Oxford and is a past President of the British Shoulder and Elbow Society.

He has published over 400 peer reviewed articles in journals including the Lancet, Nature Biotechnology, Science Translational Medicine, Science Robotics, Cell Stem Cell and the BMJ. He is head of the Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences (NDORMS) which has grown under his leadership from 20 staff in 2001 to over 450 staff and 120 postgraduate research students in 2018. He founded the Botnar Research Centre, Oxford University's Institute of Musculoskeletal Sciences in 2002 and led the relocation of the Kennedy Institute for Rheumatology to Oxford and NDORMS in 2011 (a total investment of over £80M). From 2008 to 2017 he was director of the NIHR Oxford Musculoskeletal Biomedical Research Unit.

#### GIANLUCA CASALI

Mr Casali is a thoracic surgeon and executive coach. He trained in Italy and completed his specialist training in Edinburgh with a VATS lobectomy fellowship. He is passionate about non-technical skills and technology that supports healthcare professionals to train in a virtual environment moving the learning curve away from patients.

He practices Thoracic Surgery at Bristol Royal Infirmary in Bristol UK. He has been Lead Clinician for Thoracic Surgery in Southampton and Bristol, Deputy Director of Surgery Head and Neck Division within the University Hospital Bristol NHS Foundation Trust.

He is a Director for the Non-Technical Skill Course of the SCTS (Society for Cardio-Thoracic Surgery in Great Britain and Ireland) and ESTS (European Society of Thoracic Surgeons). He is the founder of Casali Consultancy Limited a company that focuses on transforming health care using available resources within a more efficient proprietary framework (Switch Inside Out TM).

He has offered consulting services, run training, and he is a member of advisory boards for large medical devices and healthcare companies like Covidien, Medtronic, Johnson and Johnson, Ethicon, McKesson. He has published over 30 papers on international peer review journals. His primary interests: human performance in complex environments, automation, behavioural economics, data mining, patient safety, simulation, robotic surgery.





#### TAMMY CLIFFORD

Dr. Tammy Clifford is the Canadian Agency for Drugs and Technology in Health's (CADTH) Chief Scientist and Vice President, Evidence Standards. Over the past dozen years, she has held a number of senior leadership roles at CADTH. She is actively engaged in many national and international HTA activities, including serving as a deputy editor with the International Journal of Technology Assessment in Health Care, and was the co-chair of the International Scientific Programme Committee for HTAi 2018, that was held in Vancouver in June 2018. Tammy holds a PhD in Epidemiology & Biostatistics and is on faculty with the University of Ottawa's School of Epidemiology and Public Health.

#### DEBORAH COHEN

Deborah is an award winning medically qualified TV, print and radio reporter and academic journal editor. She has been an editor of The BMJ for fourteen years and has worked on both academic and journalistic sections.

As well as writing for print – such as The Telegraph - she has reported and co-produced documentaries for Panorama, Newsnight, File on 4, Channel 4 News, The One Show and Dispatches focusing on health and social issues.



#### MARTIN ELLIOT



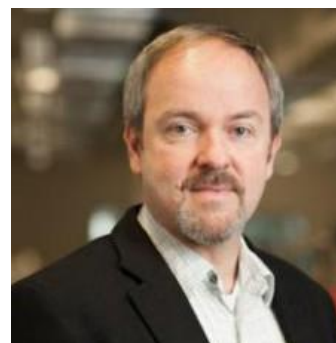
Martin Elliott MD FRCS is Professor of Paediatric Cardiothoracic Surgery at UCL, Emeritus Professor of Physic and Fellow at Gresham College, and until 2015 was Medical Director at The Great Ormond Street Hospital for Children NHS Trust (GOSH) where he has worked as a cardiothoracic surgeon since 1984. He has recently been appointed as Chief Medical Officer for Allocate Software Ltd and as a Non-Executive Director at the Royal Marsden Hospital, London, UK.

Committed to quality and innovation, he helped set up many teams, notably thoracic transplantation and ECMO at GOSH, and formed the Tracheal Service at GOSH, which has pioneered several techniques, including most recently (and controversially), the world's first stem cell supported tracheal transplantation in a child. He has led research into the pathophysiology of cardiopulmonary bypass, outcomes research and clinical databases and tracheal transplantation.

He has held several international visiting professorships, is widely published (<http://bit.ly/2vRDsIW>), and has delivered >400 invited lectures (many named), worldwide. He was the 2015 Hunterian Orator at the Royal College of Surgeons. He has operated and taught throughout the world. A key theme has been the use of data to drive change, and he established the European Congenital Heart Defects Database (now the EACTS database) in the early 1990s. He has worked with several other industries, including software, F1, airlines and hotels, and advised international health systems. His public lectures for Gresham College can be seen, read and downloaded here <http://bit.ly/2nDBFCt>

#### CARL HENEGHAN

Carl Heneghan is Professor of Evidence-Based Medicine at the Department of Primary Care Health Sciences at the University of Oxford, Director of the Centre for Evidence-Based Medicine, Editor in Chief of BMJ EBM and an NHS urgent care GP. Carl is a clinical epidemiologist and a world-leading expert in EBM and research methods. His work focuses on changing healthcare both nationally and internationally for the better. He has extensive experience in systematic reviews and quantitative methodologies. He has also led ground-breaking work, which notably includes the Tamiflu systematic reviews, and he is Director of a World Health Organization Collaboration Centre.



Carl's work also includes investigating the evidence base for drug and device regulation, advising governments on the regulatory and evidence requirements for devices and drugs and evidence-based projects in the public interest. He has worked with Panorama to examine the evidence for sports drinks and for IVF 'Add-on' treatments, and with channel 4 and the BMJ he exposed problems with metal-hips and is an advisor to the UK Gov't APPG on surgical mesh.

His international expertise in assessing evidence has been recognised by multiple global agencies including the WHO, US FDA and the UK government amongst others. He is one of the founders of the AllTrials campaign and is Director of the Centre for Evidence-Based Medicine (CEBM), which is dedicated to the practice, teaching and dissemination of high quality EBM. CEBM devotes a large proportion of its time to capacity building through outreach teaching and training activities.

Carl is editor in chief of the BMJ EBM journal and developed with the BMJ the EvidenceLive conference, now in its 6th year and he runs an active twitter account (@carlheneghan)



#### ALLISON HIRST

Alison has been Project Manager/Researcher for IDEAL since March 2013. Her role is to develop and coordinate the work of the Collaboration primarily identifying and organising collaborative projects internationally to progress and evaluate IDEAL research methodologies in innovative surgery and new devices. Alison's work includes research, organising conferences and meetings, educational workshops and management of the IDEAL website <http://www.ideal-collaboration.net> and Twitter account @IDEALCollab.

#### RICHARD HUXTABLE

Richard Huxtable is Professor of Medical Ethics & Law, and Deputy Director of the Centre for Ethics in Medicine at the University of Bristol. He has held visiting positions at the Ethox Centre in the University of Oxford, the Centre for Biomedical Ethics in the National University of Singapore and the Hastings Center, New York. A long-standing participant in clinical ethics consultation, Richard is a member of the UHBT Clinical Ethics Advisory Group and a Trustee of the National Council for Palliative Care.





DAVID JAYNE

David is Bowel Cancer UK and RCS England Professor of Surgery at the University of Leeds. His clinical interests include robotic and minimally invasive surgery for colorectal cancer and pelvic floor dysfunction. His research interests include the development of new surgical technologies and devices for minimally invasive surgery.

He is Chief Investigator for several NIHR portfolio clinical trials, including MRC/EME/NIHR ROLARR (robotic versus laparoscopic surgery for rectal cancer), HTA/NIHR FIAT (fistula plug versus surgeon's preference for fistula-in-ano), HTA/NIHR SaFaRI (sacral nerve stimulation versus Fenix magnetic anal sphincter for adult faecal incontinence), and MRC/EME/NIHR IntAct (intraoperative fluorescence angiography to prevent anastomotic leak).

He was formerly an NIHR Research Professor and currently an NIHR Senior Investigator. He has served on several NIHR committees, including EME/NIHR Prioritisation Panel and Strategy Group, NIHR DRF, and NIHR CSA panels. He is Clinical Director of the Leeds NIHR MedTech Co-operative in Surgical Technologies (MIC), a national network of clinicians, academics, patient and public representatives, and commercial partners interested in novel solutions to unmet surgical need. He is Clinical Director for the Leeds NIHR Global Health Research Group in Surgical Technologies, developing and evaluating frugal innovation to improve surgical outcomes in Sierra Leone and rural India.

MARCUS JEPSON

Dr Marcus Jepson is a Lecturer in Qualitative Health Sciences at the School of Social and Community Medicine, University of Bristol. His research interests include using qualitative and mixed methods to optimise the design and conduct of randomised controlled trials (RCTs), with a particular focus on recruitment.



RICHARD KERR



Mr Richard Kerr BSc MS FRCS is a Consultant Neurosurgeon with special interest in Skull Base and Vascular Neurosurgery.

Having qualified from the University of London at The London Hospital, Richard trained in general surgery before moving to Oxford to specialise in Neurosurgery. After writing his MS thesis following research at The Walter and Eliza Hall Institute in Melbourne, he was appointed Reader in Neurosurgery at the University of Oxford in 1990 before taking a full time NHS appointment in 1992. Richard was the co-principle investigator of the International Subarachnoid Aneurysm Trial (ISAT) that has changed the management of intracranial aneurysms worldwide. He became President

of the Society of British Neurological Surgeons before then being elected to the Council of the Royal College of Surgeons in 2013. He is now the Chair of the Independent Commission on the Future of Surgery and Surgical care.

#### RICHARD LILFORD

Richard Lilford, Professor of Public Health at the University of Warwick, directed the previous NIHR CLAHRC for Birmingham and Black Country and currently directs the NIHR CLAHRC-WM, Warwick Centre for Applied Health Research and Delivery (WCAHRD), and an NIHR Global Health Research Unit (£5.6million). Over the four years since WCAHRD was established, 33 externally-funded research projects worth over £30 million have been secured and 134 papers published. Lilford's global health work mirrors his UK work in terms of content (service improvement) and use and development of novel methodology.



Lilford has published over 325 peer-reviewed articles and has a Google Scholar h-index of 83. Over his career he has won 134 externally-funded research projects and has been/is principal investigator on 68 of these projects, worth over £56million. He has particular research methodological expertise in the evaluation of complex interventions and prospective health economic evaluations of service delivery interventions. He has published extensively in top journals on Bayesian methods, while the CLAHRC-WM Methodology Theme is widely recognised as the world's premier group for statistical methods for step-wedge cluster trials, with high-impact publications in STATA journal, Statistics in Medicine, and the BMJ.



#### BARRY MAIN

Barry Main is a National Institute for Health Research Clinical Lecturer in Oral and Maxillofacial Surgery. He is based at the Centre for Surgical Research in Bristol.

His PhD developed a core information set for informed consent in head and neck cancer surgery, and he continues to work in this area. Other areas of interest include the evaluation and reporting of innovative surgical techniques, and the ethics of research.

#### PETER MCCULLOCH

Peter was appointed Reader (Assistant Professor) in surgery at University of Oxford in 2004, and full Professor in 2013. He graduated from Aberdeen University and underwent surgical and academic training in Glasgow, before becoming Senior Lecturer at Liverpool University in 1992. Peter has a long-held interest in the problems of clinical research in surgery and other areas where treatments are complex and depend on practitioner skill.

He has published extensively on the difficulties of doing RCTs in these areas and was the driving force for the development of the IDEAL Framework and Recommendations. These attempt to provide an integrated evaluation pathway for complex interventions throughout their life cycle, analogous to that which exists for pharmaceuticals. Peter currently chairs the IDEAL Collaboration, an initiative to improve the quality of clinical research in surgery and other complex treatments. He also has a major interest in patient safety issues and runs a research group (QRSTU) and a training group (Patient Safety Academy) focused on this area.





#### JOSE MIOLA

Jose Miola is Professor of Medical Law at the University of Leicester. He has published widely in the area of medical law and ethics and has been quoted in the courts in the UK, Australia and Singapore. He is Associate Editor of the Medical Law Review, and on the Wellcome Trust's Social Science and Bioethics interview panel. His latest work concentrates on laws relating to experimental and innovative medical treatments, and 'right to try' laws.

#### LIZ PHILPOTS

Liz is head of research and impact at AMRC, where she works to support the grant-giving activities of the medical research charities, from advising on developing research strategies to evaluating the impact of funding. She oversees AMRC's data and knowledge management and strategy, providing sector-wide analyses of figures and trends in medical research grant-giving. Liz also leads AMRC's 'passion capital' work, supporting charities that are developing ways of using venture philanthropy to fund research that will benefit patients.

Liz has worked in research management within the NHS and public bodies and has a scientific background in Neuroscience with a PHD from UCL.



#### MICHAEL RAWLINS

Professor Sir Michael Rawlins is chairman of the Medicines and Healthcare products Regulatory Agency (since December 2014). He is a clinical pharmacologist and specialist in internal medicine. He was professor of clinical pharmacology in Newcastle (1973-2006), and physician at the Newcastle Hospitals, from 1999-2006.

He was chairman of the Committee on Safety of Medicines (1992-1998), chairman of the Advisory Council on the Misuse of Drugs (1998-2008) and founding chairman of the National Institute for Clinical Excellence (1999-2013). He is recent past president of the Royal Society of Medicine (2012-2014).

Currently Sir Michael is chairman of UK Biobank, honorary professor at the London School of Hygiene and Tropical Medicine, and emeritus professor at the University of Newcastle upon Tyne.

In 2017, Sir Michael was appointed the Knight Grand Cross of the Most Excellent Order of the British Empire (GBE) for services to the safety of medicines, healthcare and innovation.

#### WENDY ROGERS

Wendy Rogers is Professor of Clinical Ethics at Macquarie University, where she holds a joint appointment across the Department of Philosophy and the Department of Clinical Medicine. She has a long-standing interest in the ethics of surgical research and innovation. With her team, she has developed a practical way to identify planned surgical innovations using a checklist.

In addition, she has contributed to guidance on addressing the ethical considerations that arise at each of the IDEAL stages of surgical innovation and evaluation. Wendy also has a program of research in overdiagnosis that investigates





the relationship between overdiagnosis and disease definition, and the ethical issues associated with overdiagnosis. Through her membership on the Australian Health Ethics Committee, she has made contributions to national policy and guidance in research ethics and in organ donation over many years.



#### LEILA ROOSHENAS

Leila Rooshenas is a Lecturer in Qualitative Health Sciences at the School of Social and Community Medicine, University of Bristol.

Her research interests include using qualitative and mixed methods to optimise the design and conduct of randomised controlled trials (RCTs), with a focus on recruitment.

#### MAROESKA ROVERS

Prof. Maroeska Rovers is trained as a clinical epidemiologist, and professor of evidence-based surgery at the Radboudumc, The Netherlands. Her ambition is to revolutionize surgical clinical science, so that surgical procedures will become more patient tailored, safer and efficient. Her group (established as from 2011) consists of 17 researchers, including 14 PhD researchers. The group publishes about 20 papers per year and is recognized as one of the leading international groups on evidence-based surgery.

Her research has been characterized as visionary, innovative, international, and highly productive. Her international (multi-centre) projects have shown that she can bring together the joint efforts of internationally leading experts to further develop worldwide innovations. She also has ample experience with the scientific co-ordination of clinical studies, and these studies have demonstrated real impact through the uptake of published findings in international clinical guidelines and by practitioners and methodologists. Furthermore, once or twice a year she does “science4kids” as she likes to share her passion for science.



#### ART SEDRAKYAN



Art Sedrakyan is a Professor at Weill Cornell Medical College and is also leading US Food and Drug Administration’s (FDA) Medical Device Epidemiology (MDEpiNet) Coordinating, Science and Infrastructure Centre <http://www.mdepinet.org/> At Cornell he also directs patient centred comparative outcomes research centre projects. He is a trained CT surgeon and a graduate of Johns Hopkins University with Ph.D in Health Policy and Management. He was a senior adviser at FDA and had appointments as senior service officer/senior adviser at the Agency for Healthcare Research and Quality (AHRQ) from 2005 to 2009. He was a lead adviser on interventions (including surgery), implantable devices and cardiovascular and orthopaedic content

areas. He was one of initiators of the Effective Healthcare Cardiovascular Consortium and supervised centres for Education and Research in Therapeutics (CERTS); Cardiovascular CERT and orthopaedic Device CERT. Prior to appointments at DHHS he worked in the United Kingdom and has registry research, evidence synthesis and teaching experience from Royal College of Surgeons (RCS) of England and London School of Hygiene (LSHTM), where he served as a faculty and was Senior Adviser for National Collaborating Centre for Acute Care (part of UK National Institute of Clinical Excellence (NICE)). He is currently serving as a ranking member and was previously the Vice-Chair of Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). He is serving on MEDCAC from June 1, 2010. <http://www.cms.gov/Regulations-and->

[Guidance/Guidance/FACA/MEDCAC.html](#). Dr. Sedrakyan is the Vice-Chair of the IDEAL initiative with special interest/leadership area in devices ([www.ideal-collaboration.net](http://www.ideal-collaboration.net)). The IDEAL is the main international organization dealing with technology innovation and its evaluation. Since January 2017 he is serving as specialist advisor for Australian Therapeutic Goods Administration (TGA) and Honorary Professor at the University of New South Wales Big Data Centre where he established MDEpiNet Sydney, AUS branch. Dr. Sedrakyan is the initiator (with FDA) and principal investigator of the FDA's International Consortium of Orthopedic Registries (ICOR, [www.icor-initiative.org](http://www.icor-initiative.org)), International Consortium of Cardiac Registries (ICCR) and International Consortium of Vascular Registries (ICVR, [www.icvr-initiative.org](http://www.icvr-initiative.org)) and national coordinated registry network (CRN) community of practice: 15 coordinated registry network leveraging registries and big data.

#### SARAH SQUIRE

Sarah Squire is a member of the Patient Liaison Group of ACPGBI, PPI member on the Specialist Colorectal Clinical Reference Group, trustee of Colostomy UK and currently sits on two clinical trial steering committees. Sarah had colostomy surgery in 2007 and is passionate about patients having a voice to influence in a positive way future research, and ensure the needs of colorectal patients, current and future are both met and improved on. She is involved in many areas of Colostomy UK including administering a large and active Facebook support group, attending and presenting at conferences on behalf of the charity and is Co-Editor of the quarterly magazine, Tidings. Sarah also works full time at the University of Oxford as a Research Assistant working on therapies to treat Duchenne Muscular dystrophy.



#### JONATHAN STERNE

Jonathan Sterne is Professor of Medical Statistics and Epidemiology in the University of Bristol's Department of Population Health Sciences, and Deputy Director of the NIHR Bristol Biomedical Research Centre. He has a longstanding interest in methodology for systematic reviews and meta-analysis, led development of the ROBINS-I tool for assessing risk of bias in non-randomized studies of interventions, and co-leads development of version 2 of the Cochrane risk of bias tool for randomized trials. He leads a large-scale collaboration of HIV cohort studies that led to advances in our understanding of prognosis of HIV positive people in the era of effective antiretroviral therapy. He has published highly cited papers on causal inference and statistical methodology.

#### CHRIS WHITTY

Professor Chris Whitty is Chief Scientific Adviser for the Department of Health and Social Care (DHSC). He has overall responsibility for the department's research and development, including being head of the National Institute for Health Research (NIHR) and first deputy Chief Medical Officer. He is currently the Professor of Public and International Health at the London School of Hygiene & Tropical Medicine, Consultant Physician in acute medicine and infectious diseases at University College London Hospitals and Gresham Professor of Physic (the term for medicine when the post was created in 1597).

He was interim Government Chief Scientific Adviser 2017-2018 and previously Chief Scientific Adviser at the Department for International Development (DFID). Chris has worked in the UK, Africa and Asia as a doctor and researcher.



# The IDEAL Collaboration

Help us to improve research quality in surgery, radiotherapy, physiotherapy and other areas of complex intervention

## Who we are

The IDEAL Collaboration is an initiative to improve the quality of research in surgery and other complex therapeutic interventions. IDEAL comprises:

- A model (IDEAL Framework) that describes the stages of innovation in complex therapies:  
**Idea, Development, Exploration, Assessment, Long-term study**
- A set of IDEAL Recommendations for study formats and reporting standards at each stage of the model
- The IDEAL Collaboration, an international group of surgeons, researchers, journal editors, methodologists, statisticians, and other people who are committed to producing, disseminating, and evaluating quality research about evaluating complex therapies.

The Collaboration is coordinated from the University of Oxford, Nuffield Department of Surgical Sciences.

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## Research and Debate

The Recommendations and Framework are themselves the product of expert consensus, not evidence.

They should therefore be empirically tested using real examples to determine whether the system of classifying innovation stages, and the proposed study design and reporting methods appear to be useful in practice, or whether they throw up problems which suggest a need for further refinement.

The Collaboration organises study and writing groups to consider these issues and publish consensus papers, analyses and reports on current challenges and problems in methodology in this area.

More detailed recommendations, suggestions for specific problems and proposals for extending the framework need lively debate and discussion, and we aim to build a vibrant online community to do this. Join this community to take part in our projects.

## Advocacy

We have identified in the Proposals a number of actions which specific groups such as Editors, Funders etc. could take to improve the environment for evaluating interventional therapies.

We are interested in developing advocacy campaigns to persuade these groups to take the necessary actions.

## Education

We aim to disseminate knowledge of the IDEAL framework and recommendations as widely as possible amongst clinicians, researchers and the public, so as to improve general understanding of the issues affecting research on this type of treatment.

We have developed teaching resources for this and encourage members to use them to disseminate knowledge of IDEAL throughout the healthcare community and to the public.

# Abstracts

## ORAL PRESENTATIONS

### **“Reinforcement of Closure of Stoma Site (ROCSS) randomized controlled trial:**

### **A multicentre, international evaluation of biological mesh reinforcement of stoma”**

**Glasbey J & Reinforcement of Closure of Stoma Site (ROCSS) Collaborative and the West Midlands Research Collaborative**  
University of Birmingham

#### **Background**

Closure of complex and contaminated abdominal wounds is challenging, with high complication rates, including wound dehiscence and incisional hernias. Stoma closure is a controlled example of such a wound. The Reinforcement of Closure of Stoma Site (ROCSS) trial aimed to assess whether a biologic mesh (collagen tissue matrix) safely reduces the incidence of stoma closure incisional hernias.

#### **Aim**

The ROCSS study evaluated a previously untested implantable device requiring adoption of a novel, unstable technique. This report aims to describe development of ROCSS in-line with the IDEAL Framework.

#### **Results**

The initial technique for mesh implantation was developed in seven consecutive patients (IDEAL phase 1). The procedure was then refined and stabilised by experienced surgeons within the trial management group (IDEAL phase 2a). The procedure for mesh reinforcement was made publicly available via YouTube ([bit.ly/ROCSStechnique](http://bit.ly/ROCSStechnique)). An internal pilot study of 90 patients from eight centres proved that the technique was widely deliverable with acceptable stability and safety (IDEAL phase 2b). The main phase study randomised a total of 790 patients from 36 centres (IDEAL phase 3). Two-year follow-up is now complete and the study is ready to report (ClinicalTrials.gov registration number NCT02238964).

#### **Conclusion**

ROCSS is an exemplar of surgical innovation through the IDEAL pathway. It demonstrates that trainee research networks can develop and deliver early to late phase evaluation of complex procedural surgical innovations.

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### **“Let’s not talk about it: a conceptual study of surgical innovation”**

**Birchley G<sup>1</sup>, Huxtable R<sup>1</sup>, Ives J<sup>1</sup> & Blazeby J<sup>2</sup>**

1 Centre for Ethics in Medicine, University of Bristol; 2 Centre for Surgical Research, University of Bristol

#### **Background**

Effective evaluation and governance of surgical innovation is impeded by difficulties in defining surgical innovation.

#### **Aim**

Robustly conceptualise surgical innovation and clarify the scope of workable definition(s) that can aid effective evaluation and governance.

#### **Results**

Five conceptual areas of surgical innovation were identified, which we labelled Purpose, Place, Process, Product and Person. Purpose identifies the reasons for innovation, including patient benefit and efficiency; Place relates to the context of innovation within practice or research and the part played by changes to setting; Process relates to how innovation is differentiated from standard care; Product pertains to consequences of innovation, including putative risks/benefits; and Person relates to the motivation, intention and personal characteristics of the innovator.

#### **Conclusion**

The results of the conceptual study showed that innovation was an elastic concept, potentially defined in numerous ways. Our study may provide a conceptual template from which to derive robust definitions of innovation, which follow established use. It may also provide reporting categories for future registries of surgical innovations. However, the breadth of the concept of innovation meant that any definition was unlikely to specify innovation sufficiently for evaluation and governance purposes. Instead, we suggest an eliminativist approach is taken, where the language of innovation is avoided in favour of more descriptive, identifiable markers.

## **“PIRRIST: A patient and public involvement (PPI) intervention to enhance recruitment and retention in surgical trials”**

**Crocker J<sup>1</sup>, Rees S<sup>2</sup>, Locock L<sup>1,3</sup>, Petit-Zeman S<sup>4</sup>, Chant A<sup>5</sup>, Treweek S<sup>3</sup>, Cook J<sup>6</sup>, Farrar N<sup>7</sup>, Woolfall K<sup>8</sup>, Bostock J<sup>5</sup>, Harmston R<sup>5</sup>, Ferrey A<sup>9</sup> & Bulbulia R<sup>10,11</sup>**

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### **Background**

Poor recruitment and retention are common challenges to the successful delivery of surgical trials. Patient and public involvement (PPI) has the potential to improve recruitment and retention in surgical trials but there have been few attempts to investigate this.

### **Aim**

To develop an evidence-based PPI Intervention to enhance Recruitment and Retention In Surgical Trials (‘PIRRIST’).

### **Methods**

Four stages: (1) Online survey to identify current PPI practice in UK surgical trials; (2) Focus groups and interviews with stakeholders in surgical trials to explore PPI needs and challenges, barriers to participant recruitment and retention, and how PPI might improve these outcomes; (3) Two online surveys to estimate the frequency and importance of barriers to recruitment, retention and PPI in surgical trials; (4) Stakeholder workshop to determine key features of the final PPI intervention.

### **Results**

393 individuals took part across four stages of data collection. Based on the findings, we have several recommendations for PPI in surgical trials, including: PPI in trial design and decisions about randomisation; PPI in developing patient-facing materials including follow-up questionnaires; involving PPI contributors with personal experience of the target health condition; budgeting for staff time on PPI in the funding proposal.

### **Conclusion**

We will use our findings to develop practical intervention resources, and we are seeking potential collaborators for a feasibility study of the intervention in surgical trials. This study was supported by the MRC Network of Hubs for Trials Methodology Research and NIHR Oxford Biomedical Research Centre.

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## **“Development and delivery of a standardised investigator training package for an IDEAL Phase 3 multicentre interventional trial across low and middle income settings”**

**Glasbey J, NIHR Unit on Global Surgery**  
University of Birmingham

### **Background**

This study describes the development and delivery of a standardised investigator training package for an IDEAL Phase 3 interventional surgical randomised trial across low and middle-income countries (LMICs).

### **Methods**

Key stakeholders were identified from across a trainee-led research collaborative network to design an investigator training package for an international evaluation of two stable surgical site infection reduction technologies (Chloraprep™ skin preparation, and triclosan-coated sutures for fascial closure). The network was engaged in a needs assessment and design process using a nominal group consensus methodology. Essential components of training delivery were pre-defined and refined iteratively through a pilot phase at an international investigator meeting.

### **Results**

Essential components of package delivery were defined as: (1) ability to be delivered through an online learning environment, (2) acceptable and accessible to a variety of study investigators, (3) in-built ‘training the trainers’ for delivery to local networks, and (4) low resource burden. Four core modules were developed including ‘Good Clinical Practice’ certification, ‘Pre-operative processes’ (recruitment), ‘Intraoperative processes’ (randomisation and application of up to two stable interventions), and ‘Postoperative processes’ (follow-up and blinding). Fifty national principal investigators from 28 LMICs were trained using two online modules and two face-to-face modules at an international meeting. The final training package was delivered through an online Moodle® platform, with completion monitored across sites.

## Conclusion

A four-module training package for an IDEAL Phase 3 randomised trial is both accessible and deliverable to frontline collaborators in global surgery settings, allowing quality assurance of evaluation of these innovations.

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### **“Scottish Health Technologies Group Experience of Using IDEAL”**

*Hislop J, Gaijanu L, Harbour J, Kelly J, MacPherson K, Thompson L & Clifton E*

Healthcare Improvement Scotland, Delta House, 50 West Nile Street, Glasgow, G1 2NP, Scotland

#### **Background**

The Scottish Health Technologies Group (SHTG) provides evidence-based advice to the Scottish NHS on the clinical and cost-effectiveness of health technologies; defined to include devices, diagnostics, medical and surgical procedures and organizational systems used in health and social care.

#### **Aim**

To describe the SHTG experience of using the IDEAL and IDEAL-D frameworks to improve quality in reporting the state of the evidence in rapid reviews and provide further research recommendations to support national policy decision-making on surgical techniques and devices.

#### **Methods**

The IDEAL or IDEAL-D stage is reported in SHTG evidence reviews at the draft stage, including hyperlinks and reference to further details about each framework. Upon reviewing the draft, our committee members are free to ask questions or amend the proposed IDEAL stage before advice is finalised.

#### **Results**

SHTG have published 9 advice statements incorporating the relevant framework. This has helped clarify the appropriate strength of advice, given the stage of the evidence. Further work is needed to improve committee members' awareness of the meaning of each stage. Some confusion surrounds whether stage numbering in each framework implies similar stages, although discussions to clarify this often help validate the initial assessment of the evidence stage.

A framework for diagnostic interventions is desirable given the proportion of diagnostic technology referrals SHTG receive. We are also interested in how IDEAL might link with guideline recommendation frameworks.

#### **Conclusion**

Incorporating the IDEAL and IDEAL-D frameworks into SHTG reviews has been a positive experience. We look forward to on-going links with the collaboration.

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### **“Learning curve bias can significantly influence results of high quality surgical RCT's: the case of the Dutch D1-D2 trial.”**

*Dr Van Workum F<sup>1</sup>, Hannink G<sup>2</sup>, Bonenkamp JJ<sup>1</sup>, Van de Velde C<sup>3</sup>, Nagtegaal I<sup>4</sup>, Rovers M<sup>5</sup> & Rosman C<sup>1</sup>*

1 Department of surgery, Radboudumc, Nijmegen, the Netherlands; 2 Department of orthopaedic research, Radboudumc, Nijmegen, the Netherlands; 3 Department of surgical oncology, Leiden University Medical Centre, Leiden, the Netherlands; 4 Department of Pathology, Radboudumc, Nijmegen, the Netherlands; 5 Departments of health evidence and operating rooms, Radboudumc, Nijmegen, the Netherlands.

#### **Background**

Learning curves are often observed after introduction of innovative surgical techniques, but it is currently unknown whether learning curves can influence outcome of high quality surgical RCT's.

#### **Methods**

Individual patient data was acquired from the Dutch D1-D2 trial, in which 996 patients were randomised between D1 gastrectomy (old intervention) or D2 gastrectomy (innovative intervention). This RCT concluded that postoperative complications (25% versus 43%) and mortality (4% versus 10%) were higher in the D2 group. Data from centres that included at least 10 consecutive cases (the minimum to perform meaningful trend analysis) were pooled for individual consecutive case numbers. Weighted moving average analysis was performed for the main outcome parameters and incidence graphs showing trends in outcome were plotted.

#### **Results**

The incidence of postoperative death was 6% in the D1 group and no trend was observed during the trial, but in the D2 group, the incidence of postoperative death decreased from 10% to 3%. The incidence of postoperative complications increased from 19% to 20% in the D1 group (no significant trend). However, the incidence of postoperative complications decreased from 42% to 25% in the D2 group.

#### **Conclusion**

This study showed significantly improving trends in the D2 group (innovative intervention) but not in the D1 group (old intervention), probably reflecting learning curve bias. Learning curve bias can significantly influence high quality RCT results. Incorporation of trend analysis in RCT's can assist clinicians with the interpretation of trial outcome data. Methodology to incorporate this into the design of RCT's is proposed.

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## **“A systematic review of the ethical, legal and regulatory issues pertaining to surgical innovation.”**

**Toms A**

University of Bristol, Centre for Surgical research and Centre for Ethics in Medicine

### **Background**

There are a number of ethical concerns when discussing surgical innovation including accountability, harms to patients and conflicts of interest. Whilst some preliminary research has been undertaken to conceptualise surgical innovation, and its identifiable ethical issues, and some discussion has arisen as a result of new surgical procedures going wrong, it is unclear if innovation has been discussed in sufficient detail.

### **Aim**

To explore how the regulation of innovation within surgery has been discussed within the literature.

### **Methods**

A Critical Interpretative Synthesis was conducted. Four databases – PubMed, Westlaw, JSTOR and HeinOnline - were searched to identify literature on the topic. The literature was screened in four stages, and the principles of theoretical sampling used to select literature for review from the screened results. Key extracts were highlighted and coded, and then aggregated into themes.

### **Results**

The search yielded 54 documents for review. Four main themes were identified: criticisms of current regulation, the driving factors behind innovation, what reform must do (should the current regulatory system change), and further examination of proposed alternative regulatory models (which include responsive regulation, meta-regulation, triple-loop learning and detailed reporting). The review also identified a gap in the literature, with the views of patients not being voiced. These opinions should be explored in more detail.

### **Conclusion**

The regulation, governance and associated ethical issues pertaining to surgical innovation have not been discussed in sufficient detail, and more discussion regarding regulatory reform is necessary.

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## **“Introducing innovative invasive procedures and devices into clinical practice: an in-depth analysis of NHS Trusts’ New Invasive Procedure governance”**

**Cousins S<sup>1</sup>, Richards H<sup>1</sup>, Zahra J<sup>1</sup>, Elliott D<sup>1</sup>, Avery, K<sup>1</sup>, Robertson H<sup>1</sup>, Paramasivan S<sup>1</sup>, Wilson N<sup>1</sup>, Mathews J<sup>1</sup>, Tolkien Z<sup>1</sup>, Main B<sup>1,2</sup>, Blencowe N<sup>1,2</sup>, Hinchliffe R<sup>1,3</sup> & Blazeby J<sup>1,2</sup>.**

1 National Institute for Health Research Bristol Biomedical Research Centre Surgical Innovation Theme, Population Health Sciences, Bristol Medical School, University of Bristol, 39 Whatley Road, Clifton, Bristol, UK. BS8 2PS; 2 University Hospitals Bristol NHS Foundation Trust, Bristol, UK. BS2 8HW; 3 North Bristol NHS Trust, Bristol, UK. BS10 5NB.

### **Background**

The introduction of pharmaceutical products into clinical practice is strictly governed, however regulation surrounding new invasive procedures and devices is less clear. Invasive procedures and devices may be introduced with research approvals, and NHS Trusts may also allow introduction using local Trust policies. The latter have not been previously studied.

### **Aim**

To summarise NHS Trust policies for introduction of invasive procedures and devices into clinical practice.

### **Methods**

All acute NHS Trusts in England were asked to provide policies for the introduction of invasive procedures and devices. Response rates and type of governance (written policy; no written policy; no written policy, but process outlined) were captured. Data regarding policy rationale, scope and implementation, roles and responsibilities, application/policy processes, outcome monitoring and audit, and patient information and consent were extracted using a standardised form, with double data extraction undertaken for 20%.

### **Results**

The response rate was 91% (137/150). 119 (79%), 18 (12%) and 10 (7%) Trusts had a written policy, no written policy, and were able to outline a process only, respectively. Early data shows inconsistencies in guidance related to when policies are implemented (e.g. what is understood by a ‘new/innovative procedure’), the monitoring/reporting of outcomes of innovative procedures, and patient information provision, with some requiring specific information sheets and others leaving this to the discretion of the surgeon.

## Conclusion

There is variation in policies related to the introduction of new invasive procedures and devices in NHS Trusts. This requires attention and consideration of using a systematic approach.

## SANDPIT PRESENTATIONS

### “An in-depth analysis and cohort study of the techniques used to repair complex incisional hernias after abdominal surgery”

**Pathak S<sup>1,2</sup>, Smart N<sup>3</sup>, Rees J<sup>1,2</sup>, Blazeby J<sup>1,2</sup> & Messenger D<sup>1</sup>**

1Bristol Royal Infirmary; 2Bristol University; 3Royal Devon and Exeter Hospital

#### Rationale

Incisional hernia develop in approximately 15% of patients following midline incisions for abdominal surgery. Midline fascial reconstruction with mesh reinforcement is the recommended technique, but often requires separation of the abdominal wall layers (component separation). Anterior component separation has been used, but recently posterior component separation (PCS) has been introduced to improve outcomes. However, the PCS technique is still developing and has not been widely implemented.

#### Aim

- Study the evolution of PCS as a technique
- Identify core outcome sets
- Describe a UK based case-series

#### Methods

In-depth literature analysis followed by a prospective cohort study (IDEAL 2A)

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### “Portuguese Inguinal Hernia Cohort Study”

**Soares AS<sup>1</sup>, João AA<sup>1</sup>, Simões J<sup>1</sup>, Peyroteo M<sup>1</sup> & Azevedo JM<sup>1</sup>**

1 Portuguese Surgical Research Collaborative

#### Rationale

Inguinal hernia repair with mesh has been documented to be associated with chronic pain in a minority of patients. However, the individual prediction of the development of chronic pain is still not possible and different countries expressed differences in the incidence of this complication. The factors leading to these differences have still not been identified.

#### Aim

To identify factors associated with chronic pain after elective inguinal hernia repair with mesh.

#### Methods

IDEAL phase 2b study with a multicentric national prospective design, with three 2-week inclusion periods delivered through a collaborative research group of trainees

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### “The Pre-Bra Study”

**Harvey KL<sup>1</sup>, Potter S<sup>1</sup>, Mills N<sup>1</sup> & Holcombe C<sup>2</sup>**

1Centre for Surgical Research, Bristol Medical School; 2Royal Liverpool University Hospital

#### Rationale

Implant-based breast reconstruction (IBBR) is the most commonly performed reconstructive technique worldwide. Pre-pectoral reconstruction in which the implant, wrapped in mesh, is placed on top of the muscle is the latest innovation but subcutaneous IBBR was previously abandoned due to high complication rates.

#### Aim

Safe introduction and efficient evaluation of pre-pectoral breast reconstruction.

#### Expected IDEAL study design

We propose the Pre-BRA study; a prospective multicentre cohort study which will explore the feasibility of using a novel mixed-methods approach in the context of an early phase IDEAL 2a/2b surgical study.



**“Proposed Randomised Controlled Feasibility Trial of a Novel Polyvinylidene fluoride (PVDF) Mesh (Dynamesh®-HIATUS) Cruroplasty versus Suture only Repair of Large Hiatus Hernia – The DYNAMIC Study”**

*Toh S, Knight B, Fogg C, Baddesley E, Dr. Higginson A, Dr. Beable R, Babu S, Hawes E, Moon M, Shoebridge J, Meredith P, Amos-Lyons M & May-Miller P*

Portsmouth Technologies and Trials Unit, Portsmouth Hospital NHS Trust & University of Portsmouth

**Background**

Gastro-oesophageal reflux disease (GORD) is a significant health problem affecting up to 25% of adults. Keyhole surgical treatment of chronic GORD has become an alternative to medical treatment over the past 20 years. However, patients with large hiatus hernias more than 5cm in size appear to have poorer results with recurrence in up to half the patients. The use of mesh reinforcement has been considered to improve this, as this has been efficacious in other hernia repairs but with hiatal hernia repair, there have been concerns about risks of mesh erosion and infection and results to date have been equivocal.

**Aims**

A feasibility RCT comparing suture versus mesh+suture repair (with blinded patient and assessor) for large hiatus hernias more than 5cm.

**Methods**

This feasibility study utilises a novel permanent synthetic circumferential mesh tailored specifically for hiatal hernia repair. The material PVDF is unique with less risk of shrinkage or erosion. It is MRI visible uniquely allowing study of its position in vivo. 40 patients will be randomised in theatre with outcome data to 3yrs including GERD-QOL, EQ50, evidence of recurrent reflux or hiatus hernia on barium swallow and utilising a new classification of mesh position on MRI correlating this to outcome.

**Conclusion**

This study will commence in November 2018 with recruitment phase over one year and follow-up to three years. A multidisciplinary team including academics, patients and clinicians have produced a new protocol that sets the standard for future RCTs in hiatal hernia surgery.

**“A systematic review to assess the reporting of surgical innovation: a case study of the Subdural Evacuating Port System (SEPS)”**

**Storror AT<sup>1</sup>, Main BG<sup>1,2</sup>, Blazeby JM<sup>1,2,3</sup>, Kolia A<sup>4</sup> & Blencowe N<sup>1,2,3</sup>**

1Bristol Centre for Surgical Research, Population Health Sciences, Bristol Medical School, Bristol, UK; 2National Institute for Health Research, Bristol Biomedical Research Centre, Bristol, UK; 3University Hospitals Bristol NHS Foundation Trust, Bristol, UK; 4Department of Clinical Neurosciences, Addenbrooke's Hospital and University of Cambridge, Cambridge, UK

**Background**

The evaluation and reporting of innovations in surgery are often to a poor standard. In response to this, the IDEAL framework (Idea, Development, Exploration, Assessment, Long-term follow-up) was developed, aiming to improve the developmental process and outcome reporting of surgical innovations. The Subdural Evacuating Port System (SEPS) is a new approach for the evacuation of chronic and subacute haematomas. A novel variant of the twist-drill craniotomy, the SEPS poses several advantages to current management options, including a reduced pneumocephalus risk and the need for only local anaesthesia.

**Aim**

Using the SEPS as a case study of surgical innovation, this study aims to explore the reporting of outcomes and evolution in technique and application in accordance with IDEAL guidelines.

**Methods**

A systematic literature search was conducted using Medline, EMBASE and the Cochrane Central Register of Controlled Trials and Database of Systematic Reviews. Data was collected on the number and type of reported outcomes, surgeon and unit expertise, chronological changes in technique and descriptors and modifications of the intervention.

**Results**

1545 patients were included from a total of 13 papers. 8 papers could be classified into an IDEAL stage, with one study stating its stage in-text. 61 different clinical outcomes were reported on, with the reported outcomes per paper ranging from 1 to 18. Only one paper provided data on the surgeon number and any pre-specified criteria for surgeon eligibility.

**Conclusions**

Application of the IDEAL framework in the reporting of the SEPS would be beneficial.

**“Integrating inter-surgeon variability and learning effects into the interpretation of a surgical RCT”**

**Vach W & Saxer F**

Department of Orthopaedics and Traumatology, University Hospital Basel, Switzerland

**Background**

Inter-surgeon variability and learning effects are a thread to the generalizability of the results of surgical RCTs.

**Aim**

Understanding the magnitude of such effects can assist in interpreting the results of a surgical RCT. We try to get insights into inter-surgeon outcome variability, inter-surgeon treatment effect variability, learning effects at the system level and learning effects at the level of a single surgeon.

**Method**

We consider a variety of statistical methods with parameters reflecting the quantities of interest. To circumvent the lack of power when considering the primary outcome, we consider intermediate outcomes more sensitive to inter surgeon variability or learning effects and summary measures cumulating information from several outcomes. We apply these methods to data from an RCT comparing the lateral transgluteal Harding approach with the anterior minimally-intensive Hueter approach in elder patients suffering from a femoral neck fracture.

**Results**

Although all quantities of interest can only be estimated with rather large confidence intervals, we can obtain some new insights. In particular there is little evidence for a positive learning effect under the experimental treatment, but in contrast some evidence for a negative learning effect under the standard treatment.

**Conclusions**

A systematic investigation of inter-surgeon variability and learning effects can assist in interpreting treatment effects estimated in an RCT. We discuss advantages and disadvantages when compared to various approaches to modify the treatment effect estimation directly.

**“Applying the IDEAL framework to a methodological complex intervention (PIRRIST)”**  
*Crocker J<sup>1</sup>, Farrar N<sup>2</sup>, Treweek S<sup>3</sup>, Petit-Zeman S<sup>4</sup>, Chant A<sup>5</sup>, Bostock J<sup>5</sup>, Woolfall K<sup>6</sup>, Locoock L<sup>1,3</sup>,  
Rees S<sup>7</sup> & Bulbulia R<sup>8,9</sup>*

1Health Experiences Research Group, Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK; 2Population Health Sciences, University of Bristol, Bristol, UK; 3Health Services Research Unit, University of Aberdeen, Aberdeen, UK; 4Formerly NIHR Oxford Biomedical Research Centre and Unit, Oxford, UK; 5Patient/Lay Partner, UK; 6Institute of Psychology, Health and Society, University of Liverpool, Liverpool, UK; 7Oxford Academic Health Science Network, Oxford, UK; 8Clinical Trial Service Unit, Nuffield Department of Population Health, University of Oxford, Oxford, UK; 9Cheltenham General Hospital, Gloucestershire Hospitals NHS Foundation Trust, Cheltenham, UK

**Rationale**

Patient and public involvement (PPI) in surgical trials is widely conducted but under-evaluated. PIRRIST is an evidence-based PPI intervention which aims to improve recruitment and retention in surgical trials.

**Aim**

Refine the PIRRIST intervention and develop a feasibility study proposal. Explore how the IDEAL framework can be applied to a methodological complex intervention.

**Expected IDEAL study design**

IDEAL Stage 2a (Development) to refine the intervention. IDEAL Stage 2b (Exploration) to demonstrate whether it can be widely adopted in practice and determine whether an RCT of one or more components is desirable and feasible.

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**“The introduction and evolution of an innovative endovascular device for venous arterialisation: A systematic analysis of current practice”**

*Morley RL<sup>1,2</sup>, Edmondson M<sup>1,3</sup>, Dovell G<sup>1,2</sup>, Blencowe N<sup>1,3</sup>, Main B<sup>1,3</sup>, Blazeby JM<sup>1,3</sup> & Hinchliffe R<sup>1,4</sup>*

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3University Hospital Bristol, NHS Foundation Trust, United Kingdom; 4North Bristol NHS Trust, Bristol, United Kingdom

**Background**

The regulation and evaluation of innovative surgery and novel devices is very different to that required for new drugs. Understanding the current situation will inform future developments in standardisation of innovation reporting. Venous arterialisation is a novel procedure used to treat patients with chronic limb threatening ischaemia (CLTI). This study is an in-depth analysis of methods used to introduce and modify venous arterialisation and a CE marked endovascular device, LimFlow (Paris, France).

**Methods**

Systematic searches in Medline, EMBASE and Pubmed databases identified all clinical studies in English reporting venous arterialisation. Data about study design, rationale for use of novel procedure, components of the procedure and co-intervention, outcomes, and governance arrangements were recorded.

**Results**

Searches identified 262 abstracts; 21 full-text papers were included (4 case reports, 11 case series, 5 cohort studies, 1 non-randomised study). 4 studies gave no inclusion criteria. The other 17 included patients in whom standard revascularisation approaches were not feasible for CLTI, but diagnostic methods identifying these patients varied. Only 24% (5/21) studies described more than half of the standardised components of the procedure. Co-interventions (e.g. anaesthesia or heparin administration) were inconsistently reported. The most commonly reported outcomes were amputation (100%, 21/21) and wound/ulcer healing (52%, 11/21), although definitions varied. Ethical approval was reported in 14% (3/21).

**Conclusion**

It is not possible to reliably assess the safety and efficacy of this technique for treatment of patients with CLTI at present. Reporting of surgical innovations must be standardised to allow quality evaluation of new procedures/devices.

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**“Introducing and reporting surgical innovation: a case study in magnetic sphincter augmentation (MSA) of the lower oesophagus”**

*Kirkham EN<sup>1</sup>, Main BG<sup>2,3,4</sup>, Blazeby JM<sup>2,3,4</sup> & Blencowe NS<sup>2,3,4</sup>*

1Gloucestershire Hospitals NHS Foundation Trust; 2Bristol Centre for Surgical Research, Population Health Sciences, Bristol Medical School, Bristol, UK; 3National Institute for Health Research Bristol Biomedical Research Centre, Bristol, UK;

4University Hospitals Bristol NHS Foundation Trust, Bristol, UK

**Background**

MSA is reported to be an innovative alternative to anti-reflux surgery. The evidence behind this is, however, uncertain and little is known about its safety and long-term outcomes.

## **Aim**

We aimed to undertake an in-depth analysis of literature reporting MSA, to summarise current evidence.

## **Methods**

Systematic searches identified all studies reporting MSA. Data collection included characteristics of studies, governance arrangements, patient selection, and outcome reporting including criteria for device removal.

## **Results**

Searches identified 549 abstracts; 35 full-text papers were included (2 cohort, 4 case-control, 21 case-series, 8 case-reports). Two studies (144 patients) were undertaken prior to regulatory approval. 71%(n=25) included authors working with device manufacturers. 49%(n=17) documented ethical approval, six specifically informed patients about the innovative nature of MSA. 51%(n=18) followed FDA approved inclusion/exclusion criteria and a further five included complex patients outside these guidelines. Nineteen reported device removal (85 in total); reasons included persistence of symptoms or device erosion, but no pre-specified criteria were provided. Follow-up ranged from four weeks to five years.

## **Conclusion**

This robust and scientific analysis is the first to summarise all published literature on MSA. Current evidence is limited to non-randomised studies, often with no comparator. Limited governance arrangements were identified. Changes in the type of study design over time were not evident, suggesting studies were not building on existing knowledge. Guidelines are required to improve the rigour with which innovative surgical procedures are evaluated; to optimise transparency, maximise patient benefit and reduce harms.

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## **“Treatment of Hidradenitis Suppurativa Evaluation Study (THESEUS)”**

*Ingram J<sup>1</sup>, Thomas K<sup>2</sup>, Burton T<sup>3</sup>, Rodrigues J<sup>4</sup>, Howes R<sup>5</sup>, Hood K<sup>1</sup>, Thomas-Jones E<sup>1</sup>, Cannings-John B<sup>1</sup>, Collier F<sup>6</sup>, Tappenden P<sup>7</sup> & Leighton P<sup>2</sup>*

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## **Background**

Hidradenitis suppurativa (HS) is a common, painful skin disease characterised by recurrent boils, which affects young people's quality of life, relationships and economic productivity, and poses significant health service costs. Treatments range from topical agents, through to major surgery to remove the apocrine sweat glands of axillae and groins, with poorly-defined roles for different treatments, and probably undesirable variation in practice. Additionally, a simpler procedure to deroof disease areas, developed in continental Europe, may have advantages over these but appears to not be used in the UK.

## **Aim**

To establish current UK HS care pathways and stakeholders' preferences, to inform the development of an NIHR Health Technology Assessment bid, including an IDEAL Stage 2B assessment of the deroofing procedure.

## **Methods**

As part of a series of UK-wide online stakeholder surveys, a REDCap-based bespoke survey of surgeons was conducted. Local collaborators established a denominator list to establish response rates. This complemented surveys of people with HS, dermatologists, and GPs.

## **Results**

Of 612 total stakeholder responses, 225 surgeons completed the survey. Across all disease sites, deroofing was the preferred surgical technique in only 14/842 (1.7%) of responses. Further data were obtained regarding rationale for preferences. From the surveys, a bespoke training package for surgeons has been developed, as part of the NIHR-bid to five different second-line treatments of HS, including deroofing, in keeping with IDEAL Stage 2B.

## **Conclusion**

Besides generating standalone landscape data, the use of national surveys can support the justification and informed the design of IDEAL 2B studies.

## **“Patient experiences of pain relief following major lower limb amputation in the PLACEMENT randomised study”**

*Milosevic S<sup>1</sup>, Strange H<sup>1</sup>, Brookes-Howell L<sup>1</sup>, Ambler GK<sup>2,3</sup>, Waldron C-A<sup>1</sup>, Thomas-Jones E<sup>1</sup>, Bosanquet DC<sup>2</sup> & Twine CP<sup>2,3</sup>*

1Centre for Trials Research, Cardiff University; 2Aneurin Bevan University Health Board, Royal Gwent Hospital; 3Division of Population Medicine, Cardiff University

### **Background**

The PLACEMENT study explored perineural catheter usage for postoperative pain relief in amputees. A perineural catheter is a thin plastic tube placed adjacent to a major nerve at the time of amputation, through which a local anaesthetic infusion can be given. Qualitative interviews with study participants enabled detailed exploration of patient experiences of pain relief.

### **Aim**

To explore patient experiences of pain relief following major lower limb amputation.

### **Methods**

Fourteen study participants (aged 48-88) who had undergone major lower limb amputation with or without a perineural catheter were recruited for interview. Twenty semi-structured interviews were conducted; ten within the postoperative period (up to one month following amputation) and ten 6-16 months following amputation. Six participants completed an interview at both time points. Interviews were audio-recorded and transcribed verbatim. Thematic analysis was conducted in order to identify key patterns in the data.

### **Results**

Participants who received the perineural catheter valued the localised and continuous nature of this method of analgesia in comparison to opioids, highlighting for instance the benefit of having pain relief ‘on tap’. Concerns about opioid dependence and side effects of pain relief medication were raised both by patients with and without a perineural catheter, with some reporting trying to limit their intake of analgesics.

### **Conclusion**

Unanticipated benefits of perineural catheter usage for postoperative pain were identified, including reduced patient anxieties and excess self-restriction of pain relief medication. Insights such as these may be overlooked in traditional quantitative studies, emphasising the value of qualitative approaches to surgical research.

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## **“Design and rationale of the Pilonidal sinus Treatment - Studying the Options (PITSTOP) study: a Multicentre cohort, nested mixed-methods case study and discrete choice experiment.”**

*Beal E<sup>1</sup>, Hind D<sup>1</sup>, Bradburn M<sup>1</sup>, Lee E<sup>1</sup>, Howard A<sup>1</sup>, Shackley P<sup>1</sup>, Lee M<sup>1</sup> & Brown S<sup>2</sup>*

1 University of Sheffield; 2 Sheffield Teaching Hospitals NHS Foundation Trust

### **Background**

Pilonidal Sinus (PS) involves rupture of hair follicles in the natal cleft, leading to abscess and sinus formation. There is uncertainty regarding classification, front-running interventions, clinical equipoise, as well as which outcome measures are both relevant to patients and sensitive to change.

### **Methods**

An observational cohort (n=800) will recruit adults with PS, classified by pit/track anatomy/pathology at 15 UK hospitals. The method of excision/closure will be recorded. Outcomes will include: wound healing, infection, recurrence and satisfaction. We anticipate ~100 participants per front-running management strategy and will estimate proportions to a standard error of <=5%. Risk models that predict healing and recurrence will be built for each treatment pathway. Propensity score matching of patients (based on patient characteristics & pit anatomy/pathology at screening) will be used to estimate risk-adjusted outcomes for each treatment pathway. Nested mixed method case substudy. Brief semi-structured interviews at baseline & 6 months to elicit decision making regarding surgery & outcome preferences (n=20-25). Sampling based on variation by pit anatomy and surgical technique. A discrete choice experiment will be designed & used to elicit patient preferred outcomes in the wider cohort (n=300). The findings from this work will be used to identify gaps in knowledge and to inform possible routes for further research. Nominal group technique (n=40 surgeons; 15 patients) will be used to achieve consensus on front running procedures by disease characteristics with stratified sampling to assure national representation.

### **Conclusion**

The PITSTOP study will gather evidence necessary to inform future policy and practice.

## **“Handling of informed consent and inclusion in research on geriatric trauma patients – A matter of protection or disrespect?”**

*Sabrina Jensen J<sup>1</sup>, Vach W<sup>1</sup>, Reiter-Theil S<sup>2</sup>, Celio D<sup>3</sup>, Jakob M<sup>1</sup> & Saxer F<sup>1</sup>*

1Department of Orthopedics and Traumatology, University Hospital Basel, Switzerland; 2Clinical Ethics Unit, University Hospital Basel / Psychiatric Hospitals of the University Basel, Switzerland; 3Department for Visceral, Thoracic and Vascular Surgery, Triemli Hospital, Zürich, Switzerland

### **Background**

Despite the aging of numerous societies, clinical research in the elderly is underrepresented. Restrictive handling of informed consent (IC) and inclusion criteria can exclude relevant subpopulations from research.

### **Aim**

We want to depict the current practice in geronto-traumatology with respect to handling IC and inclusion criteria.

### **Methods**

A literature search identified geronto-traumatologic studies published between 2005 and 2015. Studies were evaluated for handling of IC and in-/exclusion criteria, patient characteristics and reference to ethical guidelines.

### **Results**

187 studies met the inclusion criteria, 118 being RTCs. 74 studies excluded patients with age-related comorbidities. 76 studies excluded patients because of frailty. 72 studies excluded patients due to cognitive impairment. 88 studies excluded patient incapable of informed consent. The reported age distributions indicate that half of the studies lack patients above the age of 90 completely. Only 23 studies reported an attempt to use guardians, relatives or proxies to obtain informed consent. Conformity with the Declaration of Helsinki was stated in 34 studies, and with GCP in 7 studies.

### **Conclusion**

The current choice of exclusion criteria and the handling of informed consent implies a risk of generating biased result by excluding relevant subpopulations. This may impede scientific progress in elderly patients. Exclusion criteria in geronto-traumatological studies should not exclude those patients who may benefit most or least from new interventions.

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## **“Postoperative coffee consumption for accelerated resolution of ileus following abdominal surgery: a systematic review and meta-analysis of randomised controlled trials”**

*Cornwall HL<sup>1</sup>, Edwards B<sup>1</sup>, Curran JF<sup>2</sup> & Boyce S<sup>3</sup>*

1Oxford Clinical School, Division of Medical Sciences, University of Oxford, Oxford, UK; 2Oxford University Hospitals, Oxford, UK; 3Department of Colorectal Surgery, Churchill Hospital, Oxford University Hospitals, Oxford, UK.

### **Background**

Ileus following abdominal surgery is a common post-operative complication. It is a source of considerable morbidity to patients and prolongs hospital stay. Despite its ready availability, there is limited evidence to support the use of coffee to promote resolution of post-operative ileus. Aim We review relevant randomised controlled trials (RCT).

### **Methods**

We performed a systematic review, a risk of bias assessment (ROB), and meta-analysis of RCT identified using search criteria ‘coffee’, ‘ileus’, ‘bowel’, ‘colon’, ‘gastrointestinal motility’, derivatives and MeSH terms in PubMed, EMBASE, CINAHL, ISI Web of Science, clinicaltrials.gov, Cochrane Library, CENTRAL, WHO ICTRP, and Google Scholar, from inception to 24th February 2018.

### **Results**

Data from seven RCT were extracted (606 patients). 31% were men. 69% were women. 342 underwent colorectal surgery (CRS), 114 gynaecological surgery (GS) and 150 elective caesarean section (CS). Coffee consumption reduced (95% confidence interval) time to flatus by 0.5 hours (11.3-(-)10.3 hours) in CRS, 11.9 hours (8.8-15.0 hours) in GS, and 3.0 hours (7.2-(-)1.1 hours) in CS. Time to defecation was reduced by 14.8 hours (11.9-17.7 hours) in CRS, 17.8 hours (13.6-22.0 hours) in GS, and 0.6 hours (0.4-(-)1.6 hours) in CS. Complications and length of hospital stay were similar for coffee and control groups. Coffee was well-tolerated with no adverse effects. Cost was low.

### **Conclusion**

ROB was unclear or high across studies. Assessed with GRADE criteria, there is low to moderate quality evidence that coffee accelerates postoperative recovery of gastrointestinal function, particularly after CRS and GS. (Prospero registration number CRD42018087962).

## **“Hybrid revascularisation: early outcomes following Common Femoral Endarterectomy and concurrent endovascular intervention.”**

*Dovell G<sup>1,2</sup>, Hardy T<sup>2</sup>, Brooks M<sup>2</sup> & Hinchliffe R<sup>1,2</sup>*

1 Bristol Centre for Surgical Research, University of Bristol; 2 Bristol, Bath and Weston Vascular Network

### **Background**

Hybrid revascularisation (HR) allows simultaneous open and endovascular intervention (EI) for multilevel peripheral artery disease (PAD). Despite being a relatively novel technique HR has been adopted as standard practice in vascular centres globally. The aim of this study was to examine the peri-operative outcomes following Common Femoral Endarterectomy (CFE) with concurrent endovascular intervention.

### **Methods**

A retrospective analysis of HR was conducted between September 2014 and October 2017 at a single vascular institution. Consecutive patients undergoing CFE with concurrent EI for PAD were included. Statistical analysis was performed using binary logistic regression on IBM SPSS ver 24. The primary outcome was surgical site infection (SSI), secondary outcomes included major limb amputation, length of stay (LOS), 30-day mortality and return to theatre (RTT) with wound complication.

### **Results**

Some 146 patients underwent CFE with concurrent EI. SSI occurred in 18.5% of patients, 4.8% RTT for SSI related intervention, 3.4% underwent major ipsilateral limb amputation, median LOS was 3 days (1-55) and 30-day mortality was 1.4%. Diabetes was found to be the only significant factor for SSI (OR 3.06 (CI 1.15-8.13),  $p=0.025$ ). There was a trend towards longer operative time affecting surgical site infection, but it did not reach statistical significance  $p=0.051$ .

### **Conclusion**

The results of this contemporary review of a novel, but widely adopted, vascular technique suggests that diabetes is a significant risk factor for the development of SSI following HR. With a larger prospective series operative time may also have an effect of increasing SSI.

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## **“The role of multiparametric Magnetic Resonance Imaging (mpMRI) for different follow-up schemes in active surveillance of men with low-risk prostate cancer in the US: a cost-effectiveness modeling study.”**

*Patel S<sup>1</sup>, Maroeska M. Rovers<sup>1,2</sup>, Fütterer JJ<sup>3</sup>, Boltynkov A<sup>4</sup> & Rongen JJ<sup>1</sup>*

1Department of Operating Rooms, Radboud university medical centre, Radboud Institute for Health Sciences, Nijmegen, The Netherlands; 2Department of Health Evidence, Radboud university medical centre, Radboud Institute for Health Sciences, Nijmegen, The Netherlands; 3Department of Radiology and Nuclear Medicine, Radboud university medical centre, Nijmegen, The Netherlands; 4Siemens Healthcare GmbH, Strategy and Innovation, Erlangen, Germany.

### **Background**

Active surveillance (AS) is accompanied by limitations concerning missing high-risk tumors and unnecessary biopsies. The use of multiparametric magnetic resonance imaging (mpMRI) in AS may overcome these limitations, but its cost-effectiveness remains uncertain.

### **Aim**

To determine the cost-effectiveness of three AS strategies: AS with transrectal ultrasound guided biopsy (TRUSGB), AS with mpMRI and MRI ultrasound guided biopsy (MR-TRUSGB), AS with mpMRI without biopsies.

### **Methods**

A Markov cohort model for men with low-risk prostate cancer was developed to assess the three strategies. Input data were derived from meta-analysis, other published literature and national cost reports. A healthcare perspective was used for an European setting. Healthcare costs and quality adjusted life years (QALYs) were modeled over a lifetime horizon. Deterministic and probabilistic sensitivity analyses were performed to address uncertainty in model parameters.

### **Results**

In the base case analysis, expected mean costs per men screened were €5150 for the TRUSGB, €5994 for mpMRI without biopsy and €4848 for mpMRI with biopsy. Corresponding QALYs were higher for mpMRI with biopsy compared to TRUSGB (18.67 vs 18.66) and lower for mpMRI without biopsy compared to TRUSGB (18.27 vs 18.66). Due to lower costs and higher effects, the mpMRI with biopsy strategy was cost-effective compared to the TRUSGB strategy.

### **Conclusion**

mpMRI with MR-TRUSGB appears to be the most cost-effective active surveillance strategy for men with low-risk prostate cancer.

## **“Health Technology Wales – Assessing Value, Optimising Use”**

*Poolle RL, Jarrom D & Myles S*

Health Technology Wales, Velindre University NHS Trust

### **Background**

Health Technology Wales (HTW) was formally launched in 2017 in order to deliver a strategic, national approach to the identification, appraisal and adoption of non-medicines technologies across NHS Wales. Its remit includes surgical and interventional procedures, medical devices, diagnostics, clinical and organisational interventions.

### **Methods**

HTW appraisals typically follow rapid review methodology, systematically reviewing literature at the highest level of quality available to quickly make recommendations for decision-makers. Various factors are considered, including clinical and cost effectiveness, organisational issues, patient issues, and the Welsh context. Expert stakeholders are involved throughout the appraisal process. Topics are not eligible for appraisal if up-to-date NICE guidance applies. Occasionally we may adapt advice from other Health Technology Appraisal agencies.

### **Results**

Two “Decision-Makers’ Summaries” have been published on our website to date (June 2018). Health Boards are expected to “Adopt or Justify” this advice, and adoption will be monitored by HTW. A recent open topic call led to submission of 40-50 topics. We are currently piloting adaptation of reports from Scotland, Ireland and Europe.

### **Conclusion**

HTW is already delivering advice to benefit patients and the NHS. Future plans include development of a scientific advice function, supporting industry to produce relevant evidence. HTW aims to align its work with the IDEAL framework, encouraging improved design, conduct and reporting of interventional procedures. Meeting attendees will be invited to consider a) submitting a topic for appraisal b) their potential role as an expert reviewer and c) how implementation of advice might impact on their work.

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## **“First Sutureless Veriset™ Patch Laparoscopic Repair of Perforated Duodenal Ulcer”**

*Toh S KC<sup>1</sup> & Parasmeswaran R<sup>1</sup>*

<sup>1</sup> Portsmouth Hospital NHS Trust & Victory Institute for Minimal Access & Robotic Surgery

### **Aim**

A new haemostatic patch (Veriset™ Medtronic) to stop bleeding was recently introduced. Its triple layer construction of oxidized regenerated cellulose, trilytine and reactive polyethylene glycol forms a hydrogel barrier and adherent sealant that can withstand high systolic pressures. These unique properties of an impenetrable barrier with strong adhesion within 30 seconds, and full absorption after 28 days, led us to postulate that it could be used for other indications, like bowel perforations.

### **Methods**

The patch was trailed in lab and human cases before relevant permission was sought to seal a perforated ulcer.

### **Results**

A fit 67yr old lady (57.2kg, BMI21) presented with an acute abdomen in April 2017. She had been taking NSAIDs recently for arthritis. Chest X-ray showed free gas and CT a perforated duodenal ulcer. A small acute D1 perforation (<5mm) was found with only local contamination. A suture was initially placed with omental patch poised but this was in fact not required as a circular 8cm<sup>2</sup> Veriset™ patch was placed which adhered firmly. A thorough washout was performed and drain left close to the site. She had an uncomplicated post-operative course with no leak from her drain and was discharged Day 3 on omeprazole. She was well at 3-month review.

### **Conclusion**

This encouraging first case shows Veriset™'s potential for sealing visceral perforations. It negates the need for suturing and could be useful in cases where there is no omentum available to patch. Further investigation of its role in conditions like colonic perforations, fistulae closure and anastomotic leaks merits exploring.



## **“Exploring training, standardisation and monitoring of medical devices in assisted vaginal birth studies: protocol for a systematic review”**

**Hotton E<sup>1,2</sup>, Renwick S<sup>2</sup>, Barnard K<sup>2</sup>, Lenguerrand E<sup>1,2</sup>, Wade J<sup>3</sup>, Crofts J<sup>2</sup> & Blencowe N<sup>3,4</sup>**

<sup>1</sup>Translational Health Sciences, University of Bristol, Bristol, UK; <sup>2</sup>Southmead Hospital, North Bristol NHS Foundation Trust, Bristol, UK; <sup>3</sup>Centre for Surgical Research, Population Health Sciences, University of Bristol, Bristol, UK; <sup>4</sup>University Hospitals Bristol NHS Foundation Trust, Bristol, UK

### **Background**

Introduction of novel medical devices into clinical practice has limited guidelines on evaluating the device's journey. This poor methodological rigor can be a risk to patient safety. Assisted vaginal birth is a vital tool within obstetrics. In skilled hands, it can markedly improve maternal and neonatal outcomes arising from complications in the second stage of labour. Historically, both forceps and ventouse devices have been used to assist birth. As new devices for assisted vaginal birth are being developed, consideration for how the efficacy and effectiveness of new technologies is evaluated, is required.

### **Aim**

To evaluate the reporting of device standardisation, monitoring and training within assisted vaginal birth studies.

### **Methods**

Relevant search terms and keywords will be used to conduct a comprehensive search of the relevant databases for randomised controlled trials and pilot/feasibility studies evaluating assisted vaginal birth. Information extracted will be synthesised into; accoucher expertise, accoucher training, accoucher related outcomes, devices monitoring and device standardisation. Risk of bias will be assessed.

### **Results**

2500 abstracts were screened after removal of duplicates and 81 full text papers identified. Final papers included are yet to be determined but results will be available for presentation at time of the meeting. Narrative syntheses will summarise the findings of the review.

### **Conclusion**

This work will enable us to establish what is already known about these methodological issues of novel medical device implementation, in the context of assisted vaginal birth. This can inform future obstetric studies as well as providing suggestions for any novel device implementation.

# NIHR Bristol Biomedical Research Centre

The National Institute for Health Research Bristol Biomedical Research Centre (NIHR Bristol BRC) is a partnership between University Hospitals Bristol NHS Foundation Trust and the University of Bristol, which launched in April 2017. We are one of 20 BRCs across England, carrying out innovative translational medical science research to drive through improvements in health and healthcare, and encourage closer working with industry. What sets the Bristol BRC apart is the strand of exciting and ground-breaking population health research that runs through all Themes, with a focus on translating scientific discoveries that have arisen from population science into better care for NHS patients.

There are five research themes:

- Cardiovascular Disease
- Mental Health
- Nutrition, Diet and Lifestyle
- Perinatal and Reproductive Health
- Surgical innovation

And three cross-cutting themes:

- Translational Population Science
- Biostatistics, Evidence Synthesis and Informatics
- Training, Patient and Public Involvement and Engagement (PPI and PPE)

The Bristol BRC is also supported by a Qualitative Research Network.

## THE SURGICAL INNOVATION RESEARCH THEME

### Developing better ways to evaluate new surgical techniques and devices

Our aim is to transform the introduction and evaluation of novel and evolving invasive procedures including surgery and the use of devices. We aim to accelerate the implementation of safe and effective surgical techniques and devices as well as the rejection of those that are ineffective.

This will be achieved by developing and applying new methods for efficient, safe and timely design and conduct of early phase studies in this area. We will also develop and secure funding for new studies evaluating innovative procedures and devices with integrated methodological research.

<p><b>Academic Lead</b> Professor Jane Blazeby 01179287332 <a href="mailto:j.m.blazeby@bristol.ac.uk">j.m.blazeby@bristol.ac.uk</a></p>	<p><b>Theme Manager</b> Harriet Downing 01173314098 <a href="mailto:harriet.downing@bristol.ac.uk">harriet.downing@bristol.ac.uk</a></p>
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## Our research is divided into 6 workstreams

### Workstream 1

Early phase study design and timing for randomised evaluation (lead Professor Jane Blazeby, Dr Sian Cousins, Dr Natalie Blencowe)

The IDEAL framework was developed for evaluation of surgical innovation from first-in-human to Phase IV studies. However, IDEAL has not been widely adopted and surgical innovation continues without transparent and structured evaluation or oversight. Based on our new work in this field, and our surgical and methodological expertise and leadership we will:

- Establish practical and transparent definitions for stages of innovative surgical interventions.
- Develop methods that can be used to classify the stage of innovation of novel surgical interventions and establish whether and when an intervention is ready for safe transition between these stages.
- Test and refine the methods for classifying stages of surgical innovation in case studies, in partnership with NHS and academic surgeon innovators;
- Work with key stakeholders, including through conferences and stakeholder workshops, to disseminate and ensure adoption of the finalised methods by studies evaluating surgical innovation.

### Workstream 2

Information provision and informed consent for new and evolving surgeries (lead Professor Jane Blazeby, Dr Daisy Elliott)

Current evidence suggests it is unclear how to best provide information and informed consent to patients undergoing new and evolving invasive procedures. We will be using survey, consensus and qualitative research methods to explore these issues with key stakeholders.

This will include:

- Conducting interviews with a range of people (including clinicians, patients, governance representatives and bioethicists)
- Audio-recording healthcare interactions where novel procedures are discussed with patients
- Exploring what guidance and policies exist in relation to informing patients about new procedures in the UK. We will develop guidance and interventions to ensure that patients receive clear and consistent information about innovative surgical procedures. To do so, we will use our methods for establishing 'Core Information Sets' and our expertise in developing interventions for informed consent and recruitment to clinical trials.

### Workstream 3

Benefit and harm outcomes of early phase studies (co-led by Dr Kerry Avery and Miss Shelley Potter)

New innovative surgical devices and procedures are currently not subject to the same testing and regulation as medicines. This is because early phase studies are haphazard, may be poorly designed and inconsistently reported, and there is no current consensus on how to select, measure and report outcomes at each stage of innovation. This limits evidence syntheses, risking outcome reporting bias, and may lead to over-optimistic assessment of new interventions and under reporting of adverse effects (harms).

Our aim in this workstream is to investigate whether it is possible to develop a Core Outcome Set to use in early phase studies of trials of invasive procedures and/or devices. A Core Outcome Set is a scientifically agreed minimum list of which outcomes should be measured and reported in all studies of a specific condition. We will further our collaboration with COMET (Core Outcome Measures for Effectiveness Trials) initiative and collaborate with surgeon innovators in many different specialities to do this work. We will apply this expertise to develop a system for standardised real-time reporting of outcomes for the monitoring of innovative invasive procedures.

### Workstream 4

Network Meta-Analyses to identify active novel interventions (lead Professor Nicky Welton)

Surgical procedures are complex interventions that interact with other interventions within a surgical trial, to influence outcomes. Other interventions could include wound dressings, anaesthesia, other medications, physiotherapy and pre-existing medical conditions. A better understanding of the effects of different interventions (or intervention combinations) on outcomes has the potential to inform surgical treatment. To gain a better understanding, we will conduct a Network Meta-Analysis (NMA), which enables the simultaneous comparison of multiple interventions in a single analysis, respecting the randomised structure of the evidence. This includes:

- Synthesising the literature in two case studies where evidence for multiple novel (but potentially interacting) interventions is available.
- Apply Network Meta-Analysis to these case studies to identify active interventions or pairs of interventions for further evaluation.
- Case Study 1: in collaboration with Dr Jo Dumville of the Wounds Research Group in the Manchester BRC, to identify promising packages of care to help reduce the risk of surgical site infection
- Case Study 2: to identify effective features of endovascular interventions for chronic lower limb peripheral artery disease

### **Workstream 5**

Improving outcomes after surgery using novel outlier prediction methods within the National Joint Registry (lead Professor Ashley Blom)

Investigation of factors that determine outcomes of joint replacement is primarily based on the National Joint Registry. This is the largest arthroplasty registry in the world, with data from more than two million individuals, and a unique platform for identifying associations and generating hypotheses for improving care. We will:

- Develop methods to identify surgeon and unit innovators and outliers (good and bad)
- Develop methods that enable registries to assess safety of new technologies and surgical techniques in a more generalizable, cost-effective and timely manner.

### **Workstream 6**

Design novel complex interventions to optimise outcomes after elective surgery (lead Professor Rachael Goberman-Hill, researcher Dr Katie Whale)

Joint replacement operations are common in the UK today. People have this type of operation to relieve pain and improve their mobility. We now know that up to one in five people who have this kind of operation will have long-term pain afterwards. Our research aims to improve how well people do after this kind of operation.

Our research is developing ways to support people through their joint replacement operations, so that they can have the best chance of a good outcome afterwards. We are focusing on practical help that can be given, particularly how to improve people's sleep. This is because we know that better sleep reduces people's pain, and that reduced pain improves sleep.

The research is finding out how to improve people's sleep around the time of knee replacement. We are looking at what research has already been done and are speaking with people about their sleep at the time of knee replacement. Using this information, we will work with health professionals and patients to work out how best to support people's sleep. We will then design research to find out whether we help people to have better sleep, and whether this then means that they have better outcomes after a joint replacement.

# Bristol Centre for Surgical Research

**Surgical care is core to the NHS and most people benefit from surgery at some point in their lives. Safe surgery is delivered by skilled, well equipped teams that make and deliver good decisions. Good decision-making is informed by high quality evidence. The creation of evidence requires research.**

The purpose of the Bristol Centre for Surgical Research is to design and deliver high quality research that is relevant to patients and the NHS

The Bristol Centre for Surgical Research includes the Royal College of Surgeons of England Bristol Surgical Trials Centre and the MRC Hub for Trials Methodology Research, the ConDuCT-II Hub (Collaboration and iNnovation in Difficult randomised Controlled Trials in Invasive Interventions) and the Surgical Innovation Theme of the NIHR Bristol Biomedical Research Centre. The Centre works closely with the two UKCRN registered clinical trials units in Bristol and the Musculoskeletal Research Unit.

Over the next decade the Bristol Centre for Surgical Research, working with other centres, surgeons and scientists, will establish evidence for surgical practice

In addition to undertaking research, the Centre aims to develop a new generation of surgeons who understand and participate in evidence-based surgery. Courses for surgical trainees and undergraduate medical students run annually. There are funded opportunities for surgeons to spend time in the Centre to undertake research and develop applications for career development awards.

We aim to train a new generation of surgeons who understand and participate in randomised controlled trials and in due course to deliver evidence-based practice informed by the results of the trials

# Delegate list

NAME	INSTITUTION
Adiamah, Alfie	NIHR Nottingham BRC
Ambler, Graeme	Gwent Hospital & Cardiff University
Beard, David	University of Oxford
Berlin, Jesse	Johnson & Johnson (USA)
Bhangu, Aneel	University of Birmingham
Bilbro, Nicole	Maimonides, Brooklyn
Birchall, Martin	University College London
Birchley, Giles	University of Bristol
Birkbeck, Beth	University of Bristol
Blazeby, Jane	University of Bristol
Blencowe, Natalie	University of Bristol
Blom, Ashley	University of Bristol
Bokor, Nibert	The Royal Bournemouth Hospital
Bolton, William	University of Leeds
Brewster, Oliver	ASiT
Broekman, Marike	LUMC/HMC
Brown, Nick	Maimonides, Brooklyn
Bryne, Ben	Royal Surrey County Hospital NHS
Campbell, Marion	University of Aberdeen
Carr, Andrew	University of Oxford
Casali, Gianluca	Bristol Royal Infirmary
Chapman, Stephen	University of Leeds
Clifford, Tammy	Canadian Agency for Drugs and Technology in Health
Cohen, Deborah	The BMJ, UK
Colvin, Carolyn	Poole Hospital
Corrigan, Neil	University of Leeds
Cousins, Sian	University of Bristol
Croft, Julie	University of Leeds
Currie, Andrew	Royal Surrey County Hospital NHS
Curtis, Nathan	Imperial College London
Daliya, Prita	NIHR Nottingham BRC
Daniel, Prieto-Alhambra	University of Oxford
Davies, Carol	University of Bristol
Davies, Gareth	University of Bristol
Dexter, Molly	University of Bristol

Dietrich, Thomas	University of Birmingham
Dovell, George	University of Bristol
Downey, Candice	University of Leeds
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Lilford, Richard	University of Warwick
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McCulloch, Peter	University of Oxford
McNair, Angus	University of Bristol
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Miola, Jose	University of Leicester
Mohammad, Sophie	Intuitive Surgical

Mousoulis, Christos	Nottingham
Ogunbayo, Dapo	NIHR Innovation Observatory
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Rawlins, Michael	Medicines and Healthcare Products Regulatory Agency
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Robertson, Harry	University of Bristol
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Rooshenas, Leila	University of Bristol
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Rovers, Maroeska	Radboudumc, The Netherlands
Royal, Richard	M D Anderson Cancer Center (US)
Sase, Kazuhiro	Juntendo University (Japan)
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Sedrakyan, Art	Weill Cornell Medical College
Sequeira-Byron, Patrick	University of Berne
Sewart, Emma	University of Bristol
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Sterne, Jonathan	University of Bristol
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Stille, Tip	Radboud University Medical Centre
Stocken, Deborah	University of Leeds
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Tan, Jing	West China Hospital - Sichuan University



Thomas, Kim	University of Nottingham
Thomas, Helen	NHS Blood and Transplant
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Toff, William	University of Leicester
Toh, Simon	Portsmouth Hospital NHS Trust
Toms, Alice	University of Bristol
Tummers, Marcia	Radboud University Medical Centre
van Workum, Frans	Radboud University Medical Centre
Waldron, Cherry-Ann	South East Wales Trials Unit
Welford, Paul	North Bristol NHS Trust
Whitty, Chris	Department of Health and Social Care (DHSC)
Wijin, Stan	Radboud University Medical Centre
Wilkinson, Victoria	NIHR CRN North West Coast
Wilson, Lizzie	University of Bristol
Woudstra, Kas	Radboud University Medical Centre
Zahra, Jez	University of Bristol

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## **DEVELOPMENT OF A CORE OUTCOME SET FOR EARLY-PHASE EVALUATION OF INNOVATIVE SURGICAL PROCEDURES AND DEVICES**



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The NIHR Bristol Biomedical Research Centre is a partnership between University Hospitals Bristol NHS Foundation Trust and the University of Bristol.

# Acknowledgements

A big thank you to the following people for their hard work in making this conference possible.

## Scientific organising committee

Allison Hirst  
Barry Main  
Harriet Downing  
Jane Blazeby  
Natalie Blencowe  
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