

13th and 14th September 2018

MShed, Princes Wharf, Wapping Rd, Bristol, BS1 4RN

The IDEAL Conference 2018: No innovation without evaluation

Day 1: Thursday 13 September 2018

1: Innovation and evaluation in surgery

- 10:30** **Registration**
Refreshments
- 11:00** **Welcome, introduction and chair of morning session**
Professor Jane M. Blazeby, Professor of Surgery, University of Bristol, UK
- 11:10** **The importance of scientific evaluation of innovation**
Professor Chris Whitty, Government Chief Scientific Adviser, UK
- 11:25** **Real life innovation: two case studies (discussant: Professor Peter McCulloch)**
- A surgeon's experience**
Mr Gianluca Casali, Consultant Thoracic Surgeon, University Hospitals Bristol NHS Foundation Trust, Bristol, UK
- Innovation, glamour and risk (tbc)**
Deborah Cohen, Associate Editor, BMJ, UK
- 12:15** **Twenty years of vaginal mesh device equivalence and the problems it has caused**
Professor Carl Heneghan, Professor of Evidence-Based Medicine and Director of the Centre for Evidence-Based Medicine, University of Oxford, UK
- 12:45** **Using IDEAL in health technology assessment**
Dr Tammy Clifford, Chief Scientist and Vice-President, Evidence Standards, Canadian Agency for Drugs and Technologies in Health, Canada
- 13:15** **Lunch and poster viewing**

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

- 14:00** **Introduction and chair of afternoon session**

Professor Richard Huxtable, Professor of Medical Ethics and Law, University of Bristol

14:10 Identifying surgical innovation in real time: a pilot study

Professor Wendy Rogers, Professor of Clinical Ethics, Department of Philosophy and Department of Clinical Medicine, Macquarie University, Australia. (Second author: Dr Brett Blakeley, Research Fellow, Australian Institute for Health Innovation, Macquarie University, Australia).

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

Professor José Miola, Professor of Medical Law, University of Leicester, UK

3. Parallel sessions: Practical aspects of studying surgical innovation

Refreshments will be available throughout the workshops

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| <p>15:10 A. Recruitment: communicating clinical equipoise to optimise informed consent and participation in RCTs</p> <ul style="list-style-type: none">• Dr Leila Rooshenas, Lecturer in Qualitative Health Science, University of Bristol, UK• Dr Marcus Jepson, Lecturer in Qualitative Health Science, University of Bristol, UK• Professor Andrew Carr, Nuffield Professor of Orthopaedic Surgery, University of Oxford, UK• Professor David Beard, Professor of Musculoskeletal Sciences, University of Oxford, UK | <p>B. IDEAL in action: a practical guide to using IDEAL in interpreting, designing and reporting research</p> <ul style="list-style-type: none">• Professor Peter McCulloch, Professor of Surgical Science and Practice, University of Oxford, UK• Allison Hirst, IDEAL Collaboration Project Manager and Researcher, Nuffield Department of Surgical Sciences, University of Oxford, UK• Mr Barry Main, NIHR Clinical Lecturer, Oral and Maxillofacial Surgery, University of Bristol, UK• Dr Nicole Bilbro, Visiting IDEAL Clinical Research Fellow in EBM, Maimonides Medical Center, Brooklyn, New York | <p>C. Deviations from treatment protocols in surgical trials: how can they be measured and what can we learn about treatment effects when they are present?</p> <ul style="list-style-type: none">• Chair: Professor Marion Campbell, Professor of Health Services Research, University of Aberdeen, UK<ul style="list-style-type: none">i. Miss Natalie Blencowe, NIHR Clinical Lecturer, Surgery, University of Bristol, UKii. What counts as compliance to the allocation in surgical trials? Professor Jonathan Cook, Associate Professor, Clinical Trials Research Unit, University of Oxford, UKiii. Beyond ITT: how can we estimate per-protocol effects in surgical trials? Professor Jonathan Sterne, Professor of Medical Statistics and Epidemiology, University of Bristol, UK |
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4. Key note: An exemplar IDEAL stage 3 study

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

Professor David Jayne, BCUK & RCS Engl. Chair of Surgery, University of Leeds, UK

17:15 Summary and close of Day 1 (Jane Blazeby)

19:00 Conference Dinner: SS Great Britain, Great Western Dockyard, Gas Ferry Rd, Bristol BS1 6TY

Day 2: Friday 14 September 2018

5. Randomised controlled trials in surgery

- 09:00** **Welcome, introduction and chair of morning session**
Professor Peter McCulloch, Professor of Surgical Science and Practice, University of Oxford, UK
- 09:10** **The future of surgery and innovation**
Richard Kerr, Consultant Neurosurgeon, Oxford Radcliffe Hospitals NHS Trust
- 09:30** **Debate and live voting: *This house believes that RCTs are not needed before the widespread introduction of new procedures***
- Chair:** Professor Andrew Carr, Nuffield Professor of Orthopaedic Surgery, University of Oxford, UK
- For:**
- Professor Richard Lilford, Professor of Public Health, University of Warwick
 - Professor Art Sedrakyan, Professor of Healthcare Policy and Research and Surgery, Weill Cornell Medical College and Vice-Chair, IDEAL Collaboration
 - Patient representative
- Against:**
- Professor Marion Campbell, Professor of Health Services Research, University of Aberdeen
 - Professor David Jayne, Professor of Surgery and Honorary Consultant, University of Leeds, UK
 - Patient representative
- 10:45** **Refreshments**

6. Early phase evaluation of surgical interventions and devices

- 11:00** **Towards early evaluation of surgical innovations using an integrated approach: The SURGE Study**
Professor Maroeska Rovers, Professor of Evidence Based Surgery, Radboud University, The Netherlands
- 11:30** **Methods for transparent, safe and efficient surgical innovation: The Surgical Innovation Theme of the Bristol Biomedical Research Centre**
Professor Ashley Blom, Professor of Orthopaedic Surgery and Head of Translational Health Sciences, University of Bristol, UK and Professor Jane Blazeby, Professor of Surgery, University of Bristol, UK
- 12:10** **MHRA and regulation of devices and surgical procedures**
Professor Sir Michael Rawlins, Chair, Medicines and Healthcare Products Regulatory Agency, UK
- 12:30** **Lunch and poster viewing**

7. Parallel sessions: new findings and new ideas

13:15 **Oral presentations: The Evaluation of Innovation**
Chair: Professor Peter McCulloch, University of Oxford, UK

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, NIHR Academic Clinical Fellow in General Surgery, University of Birmingham**
2. Let's not talk about it: a conceptual study of surgical innovation. **Dr Giles Birchley, Senior Research Associate, University of Bristol**
3. PIRRIST: A patient and public involvement (PPI) intervention to enhance recruitment and retention in surgical trials. **Joanna Crocker, University of Oxford**
4. Development and delivery of a standardised investigator training package for an IDEAL Phase 3 multicentre interventional trial across low and middle income settings. **James Glasbey, NIHR Academic Clinical Fellow in General Surgery, University of Birmingham**
5. Scottish Health Technologies Group Experience of Using IDEAL. **Dr Jennifer Hislop, Senior Health Economist, Scottish Health Technologies Group**
6. Learning curve bias can significantly influence results of high quality surgical RCT's: the case of the Dutch D1-D2 trial. **Dr Frans van Workum, Radboud University Medical Centre**
7. A systematic review of the ethical, legal and regulatory issues pertaining to surgical innovation. **Miss Alice Toms, University of Bristol**
8. Introducing innovative invasive procedures and devices into clinical practice: an in-depth analysis of NHS Trusts' New Invasive Procedure governance. **Dr Sian Cousins, Senior Research Fellow, University of Bristol**

Discussion and debate: A surgical sandpit to develop IDEAL studies de novo

Chair: Professor Jane Blazeby, University of Bristol, UK

Research ideas:

1. An in-depth analysis and cohort study of the techniques used to repair complex incisional hernias after abdominal surgery. **Samir Pathak, University of Bristol**
2. Portuguese Inguinal Hernia Cohort Study. **António Sampaio Soares, Colorectal Surgeon, Portugal**
3. The Pre-Bra Study. **Kate Harvey, University of Bristol**
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. **Mr Simon Toh, Upper GI Surgeon, Portsmouth Hospital NHS Trust**

14:55 **Refreshments**

8. Reporting innovation

15:15 **The need for transparent and mandated outcome reporting for surgical innovation**
Professor Martin Elliott, Professor of Paediatric Cardiothoracic Surgery, University College London, UK

15:45 **Summary and close of Day 2**
Professor Jane M. Blazeby, Professor of Surgery, University of Bristol, UK

16:00 **Close of conference**

16:30 IDEAL Annual General Meeting (AGM)

Professor Peter McCulloch, Professor of Surgical Science and Practice, University of Oxford, UK.

All are welcome to attend. For further information, please contact: Allison Hirst, IDEAL Collaboration Project Manager and Researcher, Nuffield Department of Surgical Sciences, University of Oxford, UK (allison.hirst@nds.ox.ac.uk).

17:30 Close of IDEAI AGM