Evidence, Healthcare and Medical Devices & Implants
The Garden Room, St Luke’s Community Centre, 90 Central Street, London EC1V 8AJ.

Aim: To clarify the current issues facing evidence based healthcare in the field of implants and medical devices and to identify areas where organisations (including HealthWatch) might most productively concentrate their efforts.

Objectives: By the end of the symposium participants will:
- Have a clearer picture of the rules and regulations relating to medical devices
- Be able to identify areas where evidence requirements coincide with the interests of healthcare organisations
- Have developed a priority list of potential actions and activities

Structure: Briefing paper on current and proposed approval and regulatory processes in advance, coffee on arrival, brief plenary presentations, working groups with invited introductory presentations and discussants, coffee, report back, summing up.

Programme:
13:00 Welcome
Introduction and presentation of briefing paper
13:10 Plenary presentations
14:00 Breakout workshops / discussion groups
  Part 1: 4 groups charged with dealing first with one of four major topics.
  Invited presenter: very brief information handout plus 10 min introduction
  Structured discussion with conclusions to feedback including proposed actions.
14:45 Coffee and return to groups for Part 2: General discussion of the other 3 topics prior to plenary session
15:30 General session:
  5min Feedback from each group in turn plus 5min comments from the floor (which will have been enabled by the part 2 workshop discussions) plus final 5 mins to gain some sense of collective opinion of main points
16:15 Round up session: Presenters and discussants to give 2 mins on their thoughts from the meeting
16:25 Closing comments
16:30 Close
16:30 – 17:00 Optional networking session with tea.

Post meeting: Meeting report collated and developed from:
- Main briefing paper
- Slides from plenary presenters
- Brief papers from group presenters
- Reporters from discussion groups / workshops
- Report of final plenary session
Introduction

Introduction and Symposium Chair
John Kirwan, Emeritus Professor of Rheumatic Diseases, University of Bristol; HealthWatch Trustee

Regulatory Frameworks background paper:
An overview of medical device governance in the UK
Till Bruckner, TranspariMED & Transparify, Bristol and London, UK

Plenary presentations

Lessons from surgical mesh. Carl Heneghan
Professor of Evidence-Based Medicine; Director of the Centre for Evidence-Based Medicine, Oxford University, Oxford.

Current regulations fail to protect. Deborah Cohen

The IDEAL Collaboration and necessary evidence. Peter McCulloch
Professor of Surgical Science and Practice; Chair of the IDEAL Collaboration, Oxford University, Oxford.

Discussion Groups

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<tr>
<th>Topic</th>
<th>Presenter</th>
<th>Moderators</th>
<th>Reporters</th>
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<td>B: Evidence and evidence synthesis for non-randomised studies of medical devices and implants.</td>
<td>Barnaby Reeves, Professorial Research Fellow in Health Services Research, University of Bristol; Co-Chair, Cochrane Non-Randomised Studies Methods Group</td>
<td>Peter Wilmshurst, Consultant Cardiologist, Royal Stoke University Hospital, Stoke on Trent.</td>
<td>Alan Henness, Director of the Nightingale Collaboration; HealthWatch Trustee</td>
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<td>C: Risk vs numbers – where do we concentrate?</td>
<td>Andrew Cook, Consultant in Public Health Medicine; Fellow in Health Technology Assessment at the University of Southampton.</td>
<td>Roger Fisken, Consultant Physician; HealthWatch Trustee</td>
<td>Jolene Galbreath, Royal United Hospitals Bath NHS Foundation Trust; HealthWatch Junior Doctor Representative</td>
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