

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

Investigative Journalist, British Medical Journal and BBC, London.

The IDEAL Collaboration and necessary evidence.

Peter McCulloch

Professor of Surgical Science and Practice; Chair of the IDEAL Collaboration, Oxford University, Oxford.

Discussion Groups

Topic	Presenter	Moderators	Reporters
A: Using a registry: How long term follow-up provides relevant evidence.	Andy Judge , Professor of Translational Statistics, University of Bristol.	Leeza Osipenko , Senior Lecturer in Practice, Department of Health Policy, London School of Economics and Political Science, London.	Mandy Payne , Freelance medical journalist; HealthWatch Newsletter Editor.
B: Evidence and evidence synthesis for non-randomised studies of medical devices and implants.	Barnaby Reeves , Professorial Research Fellow in Health Services Research, University of Bristol; Co-Chair, Cochrane Non-Randomised Studies Methods Group	Peter Wilmshurst , Consultant Cardiologist, Royal Stoke University Hospital, Stoke on Trent.	Alan Hennes , Director of the Nightingale Collaboration; HealthWatch Trustee
C: Risk vs numbers – where do we concentrate?	Andrew Cook , Consultant in Public Health Medicine; Fellow in Health Technology Assessment at the University of Southampton.	Roger Fiskin , Consultant Physician; HealthWatch Trustee	Jolene Galbreath , Royal United Hospitals Bath NHS Foundation Trust; HealthWatch Junior Doctor Representative
D: How can the healthcare community better support regulation for patient benefit?	Neil McGuire , Senior Clinician Devices, Medicines & Healthcare products Regulatory Agency, London.	Anne Raikes , Chartered Accountant; HealthWatch Trustee	Sofia Hart , HealthWatch Student Representative, London