

SUMMARY MINUTES OF THE INTERIM DEVICES WORKING GROUP MEETING HELD ON TUESDAY 4TH JULY 2023

Information is being withheld, under Section 43 of the Freedom of Information Act 2000, on the grounds that information regarding the issue under consideration and advice from the IDWG remains confidential at the date of this summary and will remain so until a final decision has been taken. Any request for future information should be made direct to the MHRA (via info@mhra.gov.uk) and will be considered in accordance with the FOI Act.

Papers for advice

Effect of darker skin pigmentation on the accuracy of pulse oximeters

The Group was presented with a summary of the MHRA's proposed risk mitigation strategy to address the risk of inaccuracy with pulse oximeters on different skin pigmentation.

The Group agreed with MHRA's proposed strategy which included proposals for communication and education to raise awareness about the limitations and appropriate use of pulse oximeters and particularly including the risk of inaccuracy with darker skin tone. Additionally, longer-term regulatory approaches were proposed to ensure the impact of skin tone on the accuracy of pulse oximeter is addressed during the conformity assessment process and during post market surveillance of these devices.

The MHRA will develop a communication package and dissemination plan and will bring this back to the Group for consideration and discussion.

Any other business

The Group were advised by the Chair that there will be a standing item going forward, dedicated to internal Agency device related updates.

The Group were presented with an update regarding a bed rail entrapment 'signal'.

The Group heard an update regarding revision of the current Managing Medical Devices guidance.

The Group were advised that the V60 ventilator national patient safety alert has now been published.

Procedural Items

In addition, the Group completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interests, apologies, announcements, approval of minutes, and updates on items previously considered. Professor Daniel Martin declared an interest in one or more agenda items and the appropriate action was taken.

A list of members who participated in the meeting is at **Annex A**.

Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.

The meeting held on Tuesday 4th July 2023 started at 10:03 and finished at 11:19.

The next meeting is scheduled to take place on Tuesday 5th September 2023 at 10:00.

Useful website links

MHRA Website:

[Medicines and Healthcare products Regulatory Agency - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

MHRA Alerts, recalls and safety information:

[Alerts, recalls and safety information: drugs and medical devices - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

Yellow Card Website:

[Yellow Card Scheme - MHRA](http://www.mhra.gov.uk)

Drug Safety Update:

<http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm>

MEMBERSHIP OF THE INTERIM DEVICES WORKING GROUP**Chair****Professor Tom Clutton-Brock** MBE MB ChB FRCP FRCA FFICM

Director, Medical Devices Testing and Evaluation Centre, Clinical Director, NIHR Trauma Management MedTech Cooperative, Chair, NICE Interventional Procedures Advisory Committee, Associate Medical Director, University Hospitals Birmingham NHS Foundation Trust, Professor of Anaesthesia & Intensive Care Medicine, University of Birmingham

Members**Mr Jonathan Boyle** MB ChB MD MA (Cantab) FRCSEd FRCSEng FRCS (Gen.Surg)

Consultant Vascular Surgeon and affiliate Assistant Professor, Cambridge University Hospitals NHS Trust

Professor Alastair Denniston MA MRCP FRCOphth PhD (*apologies*)

Consultant Ophthalmologist (Uveitis and Medical Retina), University Hospitals Birmingham NHSFT, Honorary Professor and Deputy Director Centre for Regulatory Science and Innovation, University of Birmingham

Dr Rebecca Harmston

Lay member

Professor Daniel Martin OBE

Professor of Perioperative and Intensive Care Medicine, Peninsula Medical School, University of Plymouth

Dr Rubeta Matin PhD BSc (Hons) MBBS FRCP[Derm]

Consultant Dermatologist, Oxford University Hospitals NHS Foundation Trust; Honorary Senior Clinical Lecturer, University of Oxford

Dr Tom Pelly MBBS BSc (Hons) DCH PGCE FRCP FRCGP

GP Partner, Horfield Health Centre, Bristol; Clinical Director, Phoenix Primary Care Network, Bristol; RCGP Representative

Dr Neil Smart BSc (Hons) MBChB FCAI MBA

Chair of the Scottish Health Technologies Group, Consultant Anaesthetist NHS Greater Glasgow and Clyde and Honorary Clinical Senior Lecturer, University of Glasgow

Ms Josephine Tapper

Lay member

Invited Expert**Professor S. Ramani Moonesinghe**

National Clinical Director for Critical and Perioperative Care, NHS England

Director, NIHR Central London Patient Safety Research Collaboration

Professor and Head of Centre for Perioperative Medicine, Charles Bell House, University College London

Head of Research Department for Targeted Intervention, Division of Surgery and Interventional Science, University College London

Honorary Consultant in Anaesthesia and Perioperative Medicine, University College London Hospitals

Observers

Peter Barry

Consultant Clinical Advisor, Centre for Guidelines
National Institute for Health and Care Excellence

Sarah Jennings

Patient Safety Clinical Lead - Medical Devices
NHS England

Iain Robertson

Medical Advisor Medical Devices and Legislation Unit
Scottish Government