

HealthWatch

for science and integrity in healthcare



Registered Charity No 1003392

Please reply to:
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The Baroness Cumberlege,
Chair,
The Independent Medicines & Medical Devices Safety Review,
King's College London,
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SE1 1UL

6th November 2019

Dear Julia,

I write on behalf of HealthWatch UK, a registered charity founded in 1988 which campaigns for science and integrity in healthcare, in the hope of contributing to your work.

Healthwatch held a symposium in June 2019 on the subject of medical devices and their regulation informed by a commissioned background paper. This was attended by many UK experts in the field of evidence-based medicine (including Carl Heneghan, Director of the Centre for Evidence-Based Medicine in Oxford), professionals working in the area of healthcare products regulation (including two members of staff from the MHRA), as well as the Chair of the IDEAL Collaboration, (Peter McCulloch Professor of Surgical Science and Practice, Oxford University), representatives from public health organisations and a variety of other stakeholders including, most importantly, patients, including from "Sling the Mesh". The symposium and its working groups discussed a variety of topics connected to medical devices, the current state of their regulation and possible ways of improving device regulation and approval (particularly, but not exclusively focusing on implantable devices).

In brief, our conclusions were as follows:

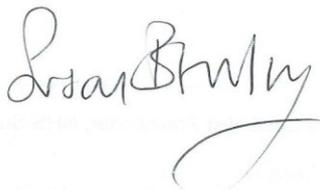
- The 'equivalence' system of device approval using Notified Bodies has failed and device approval has been a technical rather than a medical process. We feel that implant approval should be graduated, and supported by step-by-step evidence.
- Using and recording all device serial numbers would be a simple first step.
- Those who implant a device must know (and be able to explain to the patient):
 - what it is and what its constituents are;
 - how it is identified and tracked;
 - how the evidence shows that it works;
 - what risks are involved;
 - what to do if things go wrong.

- The IDEAL-D framework described in 2016 (BMJ 2016;353:i2372) provides for evidence-based implant development.
- Databases are not enough; adequately funded registries are also needed, with compliance monitoring.
- Political action will be required to influence the developing rules, to draw agencies together and consider funding, e.g. via pooled levies.
- There are academic responsibilities: early reporting; development of evidential standards; guidelines for data reporting and appropriate data amalgamation procedures.
- Putting the issues into simple statements will be a powerful aid to progress.

We hope our work is of interest to you, especially the symposium outcomes. We would very much like to see our recommendations incorporated into your final report. A fuller account of the symposium and its discussions can be found here: [https://www.healthwatch-uk.org/images/Projects/Medical_devices/HealthWatch_Symposium_Report_2019 - Evidence Healthcare and Medical Devices Implants.pdf](https://www.healthwatch-uk.org/images/Projects/Medical_devices/HealthWatch_Symposium_Report_2019_-_Evidence_Healthcare_and_Medical_Devices_Implants.pdf)

If we can do anything further to assist the work of your committee we would be very happy to contribute.

Yours sincerely,



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