

Regulatory oversights for implantable neurodevices

Implantable medical devices have yielded life-changing benefits. For instance, deep brain stimulation has substantially improved the treatment of patients with movement disorders, and clot retrieval devices for mechanical thrombectomy have revolutionised stroke care. However, as the indications for these devices expand and new devices come into clinical practice, the delicate balance between safety and innovative care is in continuous tension. Regulatory oversight places patients, health-care finances, and societal trust in biomedicine at risk.

The deficiencies surrounding approvals, monitoring, and recall mechanisms are highlighted in a report from the International Consortium of Investigative Journalists.¹ The report led to promises by the US Food and Drug Administration (FDA) and Canada's Ministry of Health to overhaul their regulatory systems.^{2,3} It underscored the limitations of the regulatory environment for medical devices, including an inadequate approval process, the scarcity of device registries, and a recall process that relies primarily on device manufacturers to notify regulatory agencies of adverse events. In the International Medical Devices Database (IMDD), in which information regarding recalls, safety alerts, and filed safety notices from 11 countries are gathered, of approximately 70 000 separate reports over 2008–17, 780 were for neurological devices,⁴ and 229 were for implantable neurological devices.

None of the implantable neurological devices in the IMDD is classified as class I, low-risk objects, such as band-aids and tongue depressors. 131 (57%) of 229 implantable neurological devices listed in the IMDD are class II, intermediate risk devices, such as cerebrospinal fluid shunts, temporary

aneurysm clips, and cranial bone flap fixation plates and screws. 91 (40%) implantable neurological devices are class III, high-risk devices, such as deep brain stimulation components and spinal cord stimulators. Seven implantable neurological devices are used under the FDA Humanitarian Device Exception, and thus not subject to classification.

New class III neurological devices are subject to the FDA premarket approval process, which requires extensive testing to show the existence of "valid scientific evidence [...] providing reasonable assurance that the device is safe and effective for its intended use".⁵ Devices can also be approved using the alternative and substantially less burdensome 510(k) process. In this pathway, a new device is exempt from the premarket approval process if it is substantially similar to a previously approved device that is already on the market, known as a predicate device.

We are concerned about the absence of rigour in the FDA approval process for medical devices, the limited rigour of the premarket approval process, and an overreliance on the 510(k) mechanism. We suggest that a redefinition of predicate device is needed such that the 510(k) process becomes rarely, rather than routinely, used for implantable neurological devices. We also propose a mandatory registry for all implanted neurological devices. Examples from research can be drawn from existing registries such as the pediatric international deep brain stimulation (PEDIaBS) registry.⁶ Information regarding adverse events and recalls should be required and made readily available on a publicly accessible, searchable website to ensure adequate post-market surveillance.

We argue that physician reporting of adverse events should be mandatory. Detailed, mandatory disclosure will allow for easier identification and subsequent notification of patients in whom devices have been implanted.

Consistent disclosure of adverse events would expedite the identification of medical device defects that require a recall. Indeed, in our analysis of the IMDD, we found that the time elapsed between the date of initial approval and the date of class 1 recall initiation for implanted neurological devices was a staggering 15 years on average, with the longest period being 29 years.

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- 2 CBC News. Health minister vows to strengthen oversight of medical devices after investigation reveals problems. Nov 29, 2018. <https://www.cbc.ca/news/health/health-minister-responds-the-implant-files-1.4926186> (accessed Jan 4, 2019).
- 3 Perrone M. FDA says it will overhaul criticized medical device system. Bloomberg. Nov 26, 2018. <https://www.bloomberg.com/news/articles/2018-11-26/ap-newsalert-us-officials-plan-to-overhaul-decades-old-system-for-approving-most-medical-devices-after-global-investigation> (accessed Jan 4, 2019).
- 4 US Food and Drug Administration. Recalls, corrections and removals (devices). <https://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/recallsandremovals/default.htm>. (accessed May 21, 2019).
- 5 U.S. Food and Drug Administration. Premarket approval (PMA). 2018. <https://www.fda.gov/medicaldevices/deviceregulationandguidance/howto-market-your-device/premarket-submissions/premarket-approval-pma/> (accessed May 21, 2019).
- 6 Marks W, Bailey L, Sanger TD. PEDIaBS: the pediatric international deep brain stimulation registry project. *Eur J Paediatr Neurol* 2017; **21**: 218–22.

For more on the International Medical Devices Database see <https://medicaldevices.icij.org>