Recalls of Medical Devices Receiving 510(k) Clearance – Reply

Author Affiliations

Alexander O Everhart, PhD[1]

Yi Zhu, MS[2]

Ariel D Stern, PhD[1,3]

1. Harvard-MIT Center for Regulatory Science, Harvard Medical School, Harvard University, Boston, Massachusetts

2. Department of Information and Decision Sciences, Carlson School of Management, University of Minnesota, Minneapolis

3. Technology and Operations Management Unit, Harvard Business School, Harvard University, Boston, Massachusetts

Correspondence to:

Alexander O. Everhart, PhD

Harvard-MIT Center for Regulatory Science

200 Longwood Ave

Armenise Building, Room 109

Boston, MA 02115

Word Count: 499

References: 5

Dr Rathi's comments describe a fundamental challenge when studying 510(k) medical devices. Researchers can observe individual clearances, but when are devices actually "different" or "new"? Non-design changes that seem trivial *ex ante* could affect patient safety *ex post*. Labeling changes could nudge physicians to use devices more or less appropriately, while changes in manufacturing processes may improve or compromise device quality.

We take the position that there is no clear data-driven way to identify when changes are meaningful. We instead are "novelty agnostic" and assume that any change (as evidenced by a new clearance) could potentially affect patient safety.

Even devices cleared through the Special 510(k) pathway may have potential safety concerns. Among the 26,003 devices with Traditional 510(k) clearances in our analysis sample,[1] 10.63% experienced a recall (95% CI, 10.26% to 11.01%). Among the 8,043 Special 510(k) devices, 13.78% (95% CI, 13.03% to 14.53%) experienced a recall. As such, it would not be appropriate to exclude Special 510(k) devices from our analysis.

Recalls aside, Dr Rathi's larger point still stands that using device clearances as the unit of observation in empirical work will always be imperfect; being unable to identify truly duplicative 510(k) clearances does not mean such clearances do not exist. Ideally, rather than using clearances, researchers could track devices via unique device identifiers (UDIs), as called for by Dr Rathi and others.[2,3] Using UDIs to identify devices would allow researchers to explicitly describe different device models in circulation, the number of devices in circulation, and which devices were included in recalls. Unfortunately, UDIs are not readily available in most health care data sets.

In short, we believe that being "novelty agnostic" and using medical device clearances as the unit of observation is the best and most neutral analytic strategy, given available data. At the

same time, we underscore the potential of UDIs to support future regulatory science research and, more broadly, public health.

Regarding Dr Robles' comments, we agree regarding the limitations associated with identifying 510(k) predicates via algorithms. It is especially difficult to identify predicates for older 510(k) medical devices, but predicate information for newer devices is also inconsistently available. Both Dr Robles' work[4] and our study[1] illustrate the need for greater data availability and transparency from regulators and manufacturers.

However, to the extent that tracking the lineage of a process is possible, we disagree with the characterization that Dr Robles "introduced" the process of identifying 510(k) predicates with algorithms. Our team published a 2020 peer-reviewed conference proceeding that provided a step-by-step description of our text extraction algorithm and its limitations,[5] preceding Dr Robles 2021 article while offering more detail about how to implement the algorithm.[4]

Regardless of publication chronology, our study's Introduction was intended to summarize studies examining the relationship between cited predicates and medical device safety (our research question), rather than describe approaches to documenting predicate histories.[1] Given that Dr Robles' work did not examine the relationship between predicate features and device safety,[4] we consider it appropriate to have not included the reference.

Conflict of Interest Disclosures: Dr Everhart reported prior employment with Medtronic; receiving personal fees from the Digital Medicine Society and the University of Southern California; and receiving grant funding from the Agency for Healthcare Research and Quality, the National Institute on Aging, and the National Bureau of Economic Research. Dr Stern reported serving on the scientific advisory board of the German Society for Digital Medicine and on the strategic advisory board of HumanFirst and receiving personal fees from the US Department of Health and Human Services. No other disclosures were reported.

References

1. Everhart AO, Sen S, Stern AD, Zhu Y, Karaca-Mandic P. Association Between Regulatory Submission Characteristics and Recalls of Medical Devices Receiving 510(k) Clearance. *JAMA*. 2023;329(2):144-156. doi:10.1001/JAMA.2022.22974
2. Kadakia KT, Ross JS, Rathi VK. The Philips Respironics Recall of Ventilators and Positive Airway Pressure Machines—Breakdowns in Medical Device Surveillance. *JAMA Intern Med*. 2023;183(1):5-8. doi:10.1001/JAMAINTERNMED.2022.5141
3. Kadakia KT, Dhruva SS, Ross JS, Krumholz HM. Adding device identifiers to claims forms—a key step to advance medical device safety. *BMJ*. 2023;380:p82. doi:10.1136/BMJ.P82
4. Robles O. Mapping The Predicate Chain For Medical Device Approval. Law360. Published April 20, 2021. Accessed February 21, 2023. https://www.law360.com/articles/1377073/mapping-the-predicate-chain-for-medical-device-approval
5. Zhu Y, Everhart A, Karaca-Mandic P, Sen S. Using NLP to Extract Predicate History from Medical Device Approvals. *ICIS 2020 Proc*. Published online December 2, 2020. Accessed February 22, 2023. https://aisel.aisnet.org/icis2020/is_health/is_health/3