

# Authors' response

Jack L Cronenwett <sup>1</sup>, Adam Beck,<sup>2</sup> Daniel Bertges,<sup>3</sup> Jens Eldrup-Jorgensen<sup>4</sup>

**To cite:** Cronenwett JL, Beck A, Bertges D, *et al*. Authors' response. *BMJ Surg Interv Health Technologies* 2020;**2**:e000067. doi:10.1136/bmjst-2020-000067

Received 11 September 2020  
Accepted 14 September 2020



- ▶ <http://dx.doi.org/10.1136/bmjst-2020-000065>
- ▶ <https://doi.org/10.1136/bmjst-2020-000039>



© Author(s) (or their employer(s)) 2020. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

<sup>1</sup>Department of Surgery, Dartmouth College Geisel School of Medicine, Hanover, New Hampshire, USA

<sup>2</sup>Department of Surgery, University of Alabama School of Medicine, Birmingham, Alabama, USA

<sup>3</sup>Department of Surgery, University of Vermont College of Medicine, Burlington, Vermont, USA

<sup>4</sup>Department of Vascular Surgery, Maine Medical Center, Portland, Maine, USA

**Correspondence to**  
Dr Jack L Cronenwett;  
J.CRONENWETT@DARTMOUTH.EDU

We appreciate Professor Fraser's conclusion that it is more cost-effective to collect post-market data for medical device evaluation using a professional society-based registry than an industry-led study, and that manufacturers should support such studies to ensure the sustainability of these registries. We would add that device evaluation using broadly based professional society registries is much more likely to represent real-world device performance than more focused industry trials; hence, the many recommendations to use real-world evidence for regulatory decision-making.<sup>1</sup>

We take strong exception, however to Professor Fraser's suggestion that our study represents "scientific misconduct" because it lacked sufficient methodological detail or transparency to be properly interpreted. The specific vascular devices evaluated by the Food and Drug Administration (FDA) using the Vascular Quality Initiative (VQI) data are not material to the conclusions reached. Each device was compared individually to its counterfactual estimate using an established model for such cost calculation,<sup>2</sup> performed by unbiased FDA analysts, and confirmed by coauthors from all companies whose devices were evaluated. Given that the categories of costs incurred by registry-based versus industry-sponsored studies are completely different, it is impossible to compare more than total costs, which still allowed the conclusion that registry-based studies are more cost-effective. Furthermore, analyses involving other devices using the identical cost model have been published in this journal, establishing the precedent for such an approach.<sup>3</sup>

Professor Fraser recommends international collaboration to pool registry data for device evaluation. VQI completely supports this concept through its co-sponsorship of the International Consortium of Vascular Registries, which is heavily focused on device evaluation.<sup>4</sup> The fragmented nature of the US healthcare system with multiple payers and a disjointed electronic medical record systems is

a disadvantage when compared with Sweden. The VQI has overcome these limitations by establishing a geographically representative network of >700 participating centers across the USA.<sup>5</sup> Further, VQI recognizes the value of synergy with other data sources, so works in partnership with the Vascular Implant Surveillance and Interventional Outcomes Network to link other data, such as Medicare claims, to its registry.<sup>6</sup> Finally, VQI is a key partner in the Registry Assessment of Peripheral Interventional Devices initiative, a public-private partnership of academia, professional societies, federal regulatory agencies, and industry dedicated to the advancement of peripheral arterial device evaluation throughout the total product lifecycle.<sup>7</sup>

Professor Fraser also suggests that the device studies reported in our study included too few patients, yet these patient numbers were the requirements established by the US FDA. He further suggests that registries disclose device identifiers when performance deficiencies are detected, which VQI fully supports. Our current study, however, was not about device performance, but rather the cost efficiency of device evaluation. Thus, while we agree with many of Professor Fraser's overall comments, most did not apply to our study.

**Contributors** Each author participated in writing and editing the rebuttal.

**Funding** The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

**Competing interests** None declared.

**Patient consent for publication** Not required.

**Provenance and peer review** Commissioned; internally peer reviewed.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

**ORCID iD**  
Jack L Cronenwett <http://orcid.org/0000-0002-6920-1631>



## REFERENCES

- 1 U.S. Food & Drug Administration, Center for Devices and Radiological Health. Strengthening our national system for medical device Postmarket surveillance: update and next steps, 2018. Available: <https://www.fda.gov/media/84409/download> [Accessed 5 May 2020].
- 2 Wimmer NJ, Robbins S, Ssemaganda H, *et al.* Assessing the cost burden of United States FDA-mandated post-approval studies for medical devices. *J Health Care Finance* 2016;2016. (Spec Features).
- 3 Pappas G, Berlin J, Avila-Tang E, *et al.* Determining value of coordinated registry networks (CRNs): a case of transcatheter valve therapies. *BMJ Surg Interv Health Technologies* 2019;1:e000003.
- 4 Behrendt CA, Venermo M, Cronenwett JL, *et al.* VASCUNET, VQI, and the International Consortium of Vascular Registries - Unique Collaborations for Quality Improvement in Vascular Surgery. *Eur J Vasc Endovasc Surg* 2019.
- 5 Participating centers VQI. Available: <https://www.vqi.org/about/vqi-participating-centers/> [Accessed 10 Sep 2020].
- 6 Tsougranis G, Eldrup-Jorgensen J, Bertges D, *et al.* The vascular implant surveillance and interventional outcomes (vision) coordinated registry network: an effort to advance evidence evaluation for vascular devices. *J Vasc Surg* 2020.
- 7 Jones WS, Krucoff MW, Morales P, *et al.* Registry assessment of peripheral interventional devices (rapid): registry assessment of peripheral interventional devices core data elements. *J Vasc Surg* 2018;67:637–44.