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Authors' response

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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.[1]

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,[2] 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.[3]

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.[4] 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.[5] 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.[6] 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.[7]

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.

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