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LETTER TO THE EDITOR

Assessment of medical devices: the Emperor's new clothes: *Author reply*

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(The Editors do not hold themselves responsible for opinions expressed by correspondents)

To the Editor,

We thank Dr Braillon for his letter and the *British Journal of Radiology* for hosting this timely discussion.

Generating evidence for regulatory approvals is an important step in a long and complex process that aims to bring innovative devices and procedures to patients. A narrow focus on local regulatory approval may fail this aim due to the many objectives of stakeholders. Physicians and—more importantly—patients want to see proof of clinical efficacy, healthcare systems want to see proof of cost-effectiveness, and companies want to see timely return on investment.

We agree that more regulatory guidance could be useful to further define and harmonise evidentiary requirements across therapeutic interventions (*e.g.* drugs, devices, and procedures). "Raising the bar" should, however, not neglect the need for flexible approval pathways that take into account the opportunity cost of complex evidence generation in view of the rapid pace of innovation. Indeed, we do recognise that harmonisation is challenging due to the many national and intercontinental differences (*e.g.* health technology assessment, legal frameworks).

In the meantime, we cannot overemphasise the role of academics and clinicians in guiding the debate on appropriate standards for approval. The science that is here to serve our patients should inform regulation, not the other way around. Health technologies and services developed to adequate scientific standards will not only meet patients' expectations, but will also help other stakeholders meet their objectives. In other words, the scientific community needs to agree on convincing yet realistic standards that will help avoiding the "valleys of death" for potentially beneficial, yet incompletely evidenced, devices and procedures.

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