BMJ Surgery, Interventions, & Health Technologies

Lighting a candle

Art Sedrakyan,[1] Peter McCulloch[2]

To cite: Sedrakyan A, McCulloch P. Lighting a candle. *BMJ Surg Interv Health Technologies* 2019;**1**:e000008. doi:10.1136/bmjsit-2019-000008

Accepted 21 March 2019

[1]Weill Cornell Medicine, New York City, New York, USA
[2]University of Oxford, Oxford, UK

Correspondence to
Art Sedrakyan;
ars2013@med.cornell.edu

Peter McCulloch;
peter.mcculloch@nds.ox.ac.uk

There has been enough cursing of the darkness engendered by inadequate evaluation of new health technology and surgical and interventional treatments. We can do better.

Surgical and interventional procedures using advanced technology currently represent one of the most exciting and innovative areas in medicine. Traditional surgical approaches to developing evidence for new techniques have been consistently criticised for many years[1] but some of the difficulties of generating evidence have been poorly understood. This field of work has changed dramatically in the past 10 years, with major advances in implantable devices, enabling platforms (eg, robotics) and ablation technologies that can save and improve lives. Such an important and fast-moving area of research and development needs robust evidence generation and a framework for safe innovation and evaluation that is rigorous and flexible.

Historically, standards of evidence for surgery and interventional procedures have lagged behind those in other clinical disciplines due to the complex nature of the interventions involved, their dependence on operator skill and the need to customise them to the individual patient. All of these have presented serious challenges to the traditional evidence based medicine (EBM) approach. Anxious to avoid stifling innovation, surgeons, interventional professionals and regulators have not developed clear and consistent guidance on generating adequate evidence. In the absence of such standards for adoption of new technology, the risks associated with innovation are increased. Consequently, public anxiety has been raised by widespread media coverage of high profile failures of some products such as metal-on-metal hips, surgical mesh and breast implants.[2]

Robust evidence generation is also needed to evaluate the economic sustainability of new technology. Technological transformation of care is one of the main contributors to raising healthcare costs,[3] and important questions about cost-benefit ratios frequently go unanswered. Insurers and hospitals are often key decision makers in adopting technologies and need high quality evidence for coverage and purchasing decisions.

BMJ Surgery, Interventions, & Health Technologies aims to provide a forum for serious scientific study of innovative surgical and interventional procedures and devices. Our ambition is to publish high quality evidence at all stages of the life cycle of new operations, therapeutic devices and procedures. We intend to promote high scientific standards by encouraging reporting using the IDEAL Recommendations, which form an integrated evaluation pathway for complex interventions,[4–6] but will welcome all types of rigorous and scientifically valid studies in relevant areas. We will, of course, welcome randomised trials, but are particularly interested in promoting publication of both early stage studies that explain the development and optimisation of new techniques and reports from registries and "real world evidence" sources evaluating the performance of devices and techniques already in common practice. Rigorous studies focused on improving the function of the clinical team delivering the intervention through quality improvement or other approaches are also welcome. A strong focus on health technologies will include a 'Policy and Regulation section' for news and statements from official bodies and expert observers, for example, alerts about technology, or legislative debates on relevant health policy.

With advent of real world evidence (RWE) — especially the adoption of unique device identification and the growth of electronic health records (EHRs) — there are increasing opportunities to use big data for scientific evaluation of healthcare. The limitations of RWE data and the questions that can be reliably answered using them are matters of active debate that will evolve over time. Some of these data sources enable longitudinal evaluation of patient outcomes and can be linked to enhance the data ecosystem. We encourage submissions that illustrate valid and appropriate use of RWE sources to answer important questions about interventional

treatments. An example of these data sources is the collection curated by the Medical Device Epidemiology Network (MDEpiNet). This includes coordinated registry networks (CRNs), which link registries and big data sources (http://mdepinet.org/). The US Food and Drug Administration (FDA),[7] and the EU through their new regulatory framework[8] are helping to build the new infrastructure for recording the real-world performance of medical devices. Collecting and purposefully analysing unique data and outcome information from such sources conforms to IDEAL Stage four and has the potential to detect underperforming and failing implanted devices earlier than other methods and to ensure their safe application.[9] Comprehensive recording and analysis of data from entire patient populations using such systems should provide vastly superior understanding of real-world performance than the voluntary, incomplete and sometimes non-transparent post-marketing surveillance systems that dominate the current regulatory evidence ecosystem.

The BMJ has long championed the campaign against research waste in healthcare.[10] Poorly conducted or reported research is an offence against medical ethics because it prevents information that could help future patients from reaching those who could use it. Inadequate evaluation of surgery, interventional procedures and technology represents a massive contribution to research waste and to the harm it causes. The reasons why this has occurred in the past are understandable, but the opportunities to prevent it from continuing in the future are obvious enough to represent a moral obligation. We will endeavour to work with the clinical communities and stakeholders to provide flexibility, speed and rigour in assessing and publishing important research on innovations, from first-in-human reports to long-term studies, in formats that maximise transparency and enhance the learning potential for the reader. Please help contribute to this effort by sending your most interesting work and join us in exploring this new concept in medical publishing.

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 Not commissioned; internally peer reviewed.

REFERENCES

1 Horton R. Surgical research or comic opera: questions, but few answers. *The Lancet* 1996;347:984–5.
2 International Consortium of Investigative Journalists. Explore more than 90,000 recalls, safety alerts and field safety notices of medical devices and their connections with their manufacturers, 2019. Available: https://medicaldevices.icij.org [Accessed 21 Mar 2019].
3 Frakt A. Blame technology, not longer life spans, for health spending increases, 2017. Available: https://www.nytimes.com/2017/01/23/upshot/blame-technology-not-longer-life-spans-for-health-spending-increases.html [Accessed 21 Mar 2019].
4 McCulloch P, Altman DG, Campbell WB, *et al*. No surgical innovation without evaluation: the ideal recommendations. *The Lancet* 2009;374:1105–12.
5 Hirst A, Philippou Y, Blazeby J, *et al*. No surgical innovation without evaluation: evolution and further development of the ideal framework and recommendations. *Ann Surg* 2019;269:211–20.
6 Sedrakyan A, Campbell B, Merino JG, *et al*. IDEAL-D: a rational framework for evaluating and regulating the use of medical devices. *BMJ* 2016;353.
7 Food drug administration center for devices and radiological health. guidance for industry and food and drug administration staff: use of real-world evidence to support regulatory decision-making for medical devices. *FDA Maryland* 2017.
8 European Commission. Regulatory framework, 2017. Available: https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework [Accessed 21 Mar 2019].
9 Sedrakyan A, Campbell B, Graves S, *et al*. Surgical registries for advancing quality and device surveillance. *The Lancet* 2016;388:1358–60.
10 Ioannidis JPA. Clinical trials: what a waste. *BMJ* 2014;349:g7089.