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Have we made progress in identifying (surgical) innovation?

Earl (2019) correctly signals the ambiguous nature of innovation as a specific category of healthcare activity. His own definition – innovative practice is that which deviates from an idealised expert-consensus standard of care, which is based on evidence, experience and judgment – works adequately for the purposes of his argument. Yet identifying what is, and is not, innovation remains a very messy problem.

Our research focuses on surgical practice, which is often held to be the site of continual, significant ‘innovation’. Some of these innovations (like endovascular techniques in neurosurgery) prove successful. Others (like power morcellation of uterine fibroids) have been abandoned for causing serious harm. Surgical innovation appears lightly regulated, and surgeons apparently have discretion over when, where and why to innovate. This freedom brings serious challenges – for example, conflicts of interest may challenge surgeons’ abilities to offer patients, both vulnerable and trusting, unbiased advice. Preventing the premature adoption of innovations is difficult and, once adoption is widespread, risks harming patients and wasting resources should unanticipated risk-benefit profiles emerge. A balanced picture of effectiveness may only be discovered in large trials, which may happen too late, or not at all. These problems arise due to historical deficiencies in the rigor of surgical research, magnified by the effects of the learning curve. Regulation and oversight is particularly challenging because of difficulties in identifying what does, and does not, count as ‘surgical innovation’.

Identifying surgical innovation is complex. Some apparent innovations might not, on balance, be innovative. The profusion of ‘me-too’ devices that essentially duplicate existing innovations means that not all ‘new’ devices are innovative, and some may not require laborious appraisal. ‘Standard’ surgical procedures are frequently modified to take account of variations in patient anatomy. For the most part, these modifications constitute ‘normal variations’, which would appear wrongly classified

as 'innovative'. However, a small minority of variations may involve changes significant enough to constitute innovation.

Outside of formal research activity the systematic reporting of outcomes of innovations (especially deleterious ones) does not occur. Different techniques for performing standard procedures may develop locally, leading to potentially dramatic variations which may go unrecognised. Usually it is only when a new technique is established as in some sense 'safe' that case series of successful outcomes are reported – but without detailed description of false starts, failures and early lessons learned whilst the procedure was still evolving. Reporting only successes without detailing early development – including ideas that were tried and failed - puts patients at risk by (1) failing to prevent the repetition of mistakes, (2) failing to systemically capture evidence, and (3) giving the false impression to patients that 'innovation' will always be beneficial.

To protect patient safety (and protect surgeons), the impact of innovations should be better identified, evaluated and reported. One way to achieve this entails rigorously reporting and monitoring unexpected adverse outcomes of innovation, ideally using generic standardised reporting measures. Yet this requires us first to be able to reliably identify surgical innovation. Some progress has been made toward this goal: for example a team at Macquarie University have published a tool and definition to help surgeons identify innovation in their own practice (Hutchison et al. 2015). Meanwhile, by focusing on the *process* of innovation, rather than definition, the IDEAL framework has sought to identify stages of innovation that can be married with regulatory and ethical responses (Hirst et al. 2019).

A recent conceptual study has concluded that the defining feature of innovation is 'newness' (Hutchison et al. 2015). Based on empirical work showing differences between what surgeons themselves consider to be innovation (Rogers et al. 2014), these researchers have concluded that a significant problem is that surgeons need help to identify innovation in their own practice, and have produced (and are testing) a tool to facilitate this. The tool identifies several ways in which a

procedure or device could be innovative by being entirely new, new to an anatomical location or new to a patient group.

This is a major advance on previous, *ad hoc*, definitions of innovation, and we agree that ‘newness’ is an important element of innovation. Yet, we are concerned that, despite including examples of absolute, anatomical and patient group ‘newness’ aimed at guiding surgeon’s assessments, ‘newness’ is too subjective to reliably identify innovation. Because surgery will be composed of basic techniques (e.g. dissection), which are not themselves new, the newness of any innovation will be debatable. Additional qualifiers may be needed. For example, the economist Joseph Schumpeter defined innovation not as “new” but as “new combinations” in his seminal economic theory (Schumpeter 1949). Without such a qualifier, new procedures could always – rightly or wrongly – be classified as modifications to established procedures rather than as ‘new’. Furthermore, a definition of surgical innovation that is based on types of newness invites false positives and requires specificity, which passes the burden of identifying innovation using ‘newness’ to the surgeon. Yet it is questionable whether surgeons are always the most appropriate people to judge whether innovation is occurring, as they may have conflicts of interest in this regard (Rogers and Johnson 2013). Effective oversight of surgical practice can only be achieved if we have ways to identify innovation that are independent of surgeons’ own judgements.

Because surgical innovation is unlikely to involve a single discrete development, a model of the *process* by which surgical innovation develops is important. Such a model has been developed in the IDEAL framework (Hirst et al. 2019), based on the ‘classical’ model adopted in agricultural sociology and popularised by Everett Rogers (2003). This model suggests that the spread of surgical innovation has a clearly defined beginning and end, and follows the ‘S’ shaped curve of cumulative normal distribution. Yet, the development of complex innovations is often chaotic, with imprecise start- and end- points. In an agricultural context, Fliegel (1993) noted that, while this model works well on innovations like new seed corn varieties, where the innovation is a distinct and indivisible product, it

struggles with technologies made up of multiple related components. Using patents and publications as proxies for innovation, it has been claimed that fields of surgical innovation do broadly map onto an 'S' shape (Hughes-Hallett et al. 2014). Yet, the study that makes this claim also shows that patents and publications continue, albeit in diminished quantities, in mature technologies, where innovative fields had apparently stabilised. This suggests refinements and (further) innovations continue at a low level even when innovative fields are mature. We infer that surgical innovations may have indistinct borders between invention, adoption and diffusion, and improvements to current models of the process of surgical innovation may also be needed.

Despite advances in our understanding of innovation, much work remains. Without an empirically grounded understanding of what innovation is, and how and why innovation occurs in practice, ethical studies of the type Earl (2019) offers remain speculative. In our own research (Birchley et al. Accepted subject to revision), we mapped the way innovation was discussed and described in 72 academic sources and discovered a vast array of properties and facets, which we could broadly categorise into five conceptual areas. These were the drivers, context and consequences of innovation, the ways to differentiate innovation from 'normal' practice or research, and the identity of the innovator. Taken as a whole they signalled that innovation is a messy concept. We felt innovation did not represent a natural kind that was amenable to simple classification or discrete study. This leads us to propose an eliminativist approach. The word 'innovation' has a rhetorical flourish, but that rhetorical flourish makes it problematic. It is a truly 'rich' concept – both descriptive and evaluative – which, though agreeably flexible, is imprecise and susceptible to manipulation and equivocation. We therefore suggest that, for the purposes of serious study and for regulation, it should be avoided. Instead, we should closely consider *what* it is we are talking about and *why*, and spell that out precisely. In our case, our explicit focus is on ensuring the safe translation of surgical innovation into clinical practice; on procedures and devices which lack reported knowledge that can inform an assessment of their efficacy, effectiveness or safety. This, then, rather than trying to identify 'innovation', has formed the basis for our ongoing work.

In summary, recent studies have further elucidated surgeons' understandings of innovation, devised models of the process of innovation and developed a definition of innovation that has informed the first usable tool for surgeons to self-identify innovation. Yet, when attempting to clarify precisely what (surgical) innovation is, the profusion of possible understandings mean that the term itself is unhelpful. Thinking carefully about what we mean when we use the word 'innovation', and choosing to talk in those terms rather than about 'innovation', should avoid researchers talking at cross purposes and prevent the conceptual clutter around innovation from masking poor practice. Indeed, re-focusing in this way should allow us to continue to make progress on what really matters – such as, as Earl suggests, the ethical appropriateness of the procedure, however it is labelled or conceptualised.

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