ENSURING SAFE SURGICAL INNOVATION IN YOUR HOSPITAL: DO TRY THIS AT HOME.

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Surgeons have always had an ambivalent relationship with innovation. On the one hand, the boldness required to traumatise the bodies of our fellow humans in order to heal them has ensured that surgeons have, throughout history, been ambitious, confident people willing to take risks. On the other, the traditional surgical apprenticeship model of learning encourages conservatism: as we learn, we find out why our mentors advise against some apparently attractive ideas, and develop respect for their prohibitions. We also live and die professionally by our reputation, and few things can tarnish this as fast as failed innovations which harm patients. In previous generations, when weak clinical research methodology meant than expert opinion was valued more than data, surgical innovators were acutely aware of the risks they ran if they alienated their peers. Successful innovators were usually marked by the great care they took to reassure opinion leaders by adopting an attitude of humility and caution, at least in public.

Both the risks and the appeal of surgical innovation have grown rapidly and in parallel in recent decades. Technological advances have resulted in a seemingly endless rise in the number of new devices and techniques for surgical or quasi-surgical treatment. Techniques which might, in the pre-internet age, have spread slowly over decades, become globally known within months, and the relentless rise in medical publishing ensures widespread dissemination of claims for new treatment. Compared to pharma, operations and devices remain very lightly regulated, and this has had an adverse effect on the quality of the evidence which supports them[1]. It has also become increasingly clear that the complexity and variability of delivery of surgery requires different approaches to research from those which have served drug treatments well[2]. Modern surgical practice requires valid evidence and complete transparency to ensure that efficacy and safety are demonstrated clearly. We are still in the early stages of developing the new paradigm which will ensure this, and since ideas about what constitutes “good enough” evidence are still in flux, it is not surprising that ideas about how innovation should be regulated are changing too. Both in North America and in Europe, regulators are demanding better initial clinical evidence and more careful surveillance for new therapeutic devices[3]. At the institutional level, hospitals are also recognising that changes are needed in how they ensure that innovation occurs as safely as possible, without putting up barriers which will prevent it from happening. Institutional Review Boards (IRBs) should play a major role here, but anecdotal evidence suggests that they are seen as excessively risk averse by many surgical innovators, and are relatively easily bypassed for the initial phase of introduction of a new procedure, and harm can result to patients from this kind of unreviewed semi-clandestine innovation. The irony involved here should not escape us, given the good intentions underpinning the IRB system, and the unintended consequence.

The paper by Marcus, Lillemoe et al in this issue of Annals[4] reports a promising new system for dealing with the challenges of surgical innovation at the institutional level in a modern setting, and restoring a sensible degree of oversight which does not result in gridlock. The evidence that their institutions’ system has allowed safe innovation is still preliminary, but the process adopted is clearly a major advance on reliance on the IRB, or the various ad hoc systems relied on elsewhere. The key features are the comprehensive nature of the process, catching all new procedures and devices, and

the expertise of the panel running it, which contained both surgical experience and professional safety and quality know-how. The undeniable major improvement in the speed of decision making apparently also derived from this – the previous system at this institution was slowed by the justifiable reluctance of panels with mainly business focused expertise to make judgement calls on safety matters.

Pioneers are always judged (by non-pioneers) for the shortcomings of their ranging shots, and this was by no means a perfect scientific study. The simple before-after design was likely inevitable, given the controversy which would have attended any attempt to randomise innovations to the new system or the old. No control could be imposed on the nature or number of the innovations coming through, and data collection methods were unavoidably different in the historical and prospective arms of the study. Some products were deemed to need an intraoperative trial and others not, for reasons which were not explained. In terms of safety, these differences, together with the relatively small sample and the short follow-up, invalidated any convincing attempt to support a claim of improved safety using statistical inference. Nevertheless the claim is reasonable, even if not yet proven. Safety is a slippery word when it comes to healthcare, and is often used disingenuously to indicate lack of proof of harm, which is not the same thing. Safety, in terms of accurate global risk prediction, cannot be truly assessed for any treatment until long-term data exist for large numbers of cases, by which time it is rather too late. What we can and ethically must do during innovation is to take all reasonable precautions indicated by our current understanding of the risks, and to be completely honest with patients. This includes explaining the known risks, the current experience of the team and the possible existence of Mr Rumsfeld's famous "unknown unknowns". The new system described in the paper forced surgeons to think carefully about these issues, and this seems to have been part of the secret of its apparent success. The various recommendations made by the CQUIT panel for cadaveric or simulated practice, team rehearsal and other preparations in specific cases seem eminently sensible as strategies to reduce the risk of harm in situations where it can be predicted but not easily estimated. Both historically and currently there has been an acceptance that a surgical learning curve, measurable in terms of patient harm, is inevitable during the introduction of innovations. This initiative represents an encouraging attempt to reduce or eliminate this.

An important principle, championed by the IDEAL Collaboration whose work the authors of this paper quote, is that surgical innovation should always be accompanied by adequate evaluation[]. The CQUIT system falls short of the IDEAL Recommendations in this regard, in that it allows introduction with or without IRB, and in the latter category it appears that systematic data collection is not guaranteed. Just as the FDA have introduced requirements for formal clinical studies as part of the 510K process for higher risk devices[5,6], it would seem reasonable for systems like CQUIT to require a limited phase of IDEAL Stage 2a or 2b evaluation for all new devices or processes, whether an IRB is required or not. This would be inexpensive and would further enhance the validity of the evaluation process[REF]. An important question touched upon but not fully answered by the current paper is how long such formal data collection for innovations should continue in institutional systems. The current results are very short term, and it would make sense to maintain some sort of surveillance at least until the data suggest that the results for the new intervention have reached a steady state.

Whilst very new and arguably in need of improvement, the system described clearly represents a major step in the right direction when it comes to the safe introduction of complex interventional therapies. Non-pioneers will hopefully feel emboldened to adopt and improve upon it.

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