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HEY, I JUST DID A BETTER OPERATION! TOWARDS AN IDEAL INNOVATION MODEL --Manuscript Draft--

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HEY, I JUST DID A BETTER OPERATION! TOWARDS AN IDEAL INNOVATION MODEL

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LETTER TO THE EDITOR

Sagar and colleagues¹ present a simple and accountable approach of institutional governance for surgeons wanting to introduce innovative procedures and/or new medical devices. While the authors are congratulated for articulating an explicit strategy for the introduction of innovative therapy in their own center, they failed to acknowledge the substantial progress made in the science and thinking of surgical innovation over the last few years.

In 2009, the Balliol Collaboration proposed a model for safe surgical innovation called the IDEAL model: **I**dea (stage 1), **D**evelopment (stage 2a), **E**xploration (stage 2b), **A**ssessment (stage 3) and **L**ong-term monitoring (stage 4).² An additional stage described, although not part of the original IDEAL acronym, is a pre-clinical stage or stage 0 which may include simulator and/or animal/cadaveric studies. The IDEAL model provides a structured, rigorous yet non-stifling framework for evolution and evaluation of surgical innovations (<http://www.ideal-collaboration.net/>).³ It applies to both 'development' of a new procedure (stages 0 to 2a) as well as 'dissemination' of an innovation that has been validated elsewhere (stages 2b and beyond); the latter scenario being the subject of the commentary by Sagar et al.¹

While the pathway offered by Sagar and co-workers might make the ethics clearance process less formidable and outcomes reporting more transparent at the local level,

some potential drawbacks of their model are worth discussing. First, although the administrative processes described by the authors are undeniably non-stifling and innovator-friendly, one consequence of their process might be loss of the unique experience gained in both the success and failure of implementing a new procedure or device from the public knowledge repository. For example, adverse events noted by surgeons (at a given institution) during adoption of a surgical innovation/new device may translate into improved practice patterns at the local level but in absence of peer-reviewed reporting, this knowledge will not help clinicians in other centers seeking to adopt the procedure (as in the framework proposed by the authors—there is no provision for outcomes reporting beyond the institutional level). This is in contrast with the recommendations of the IDEAL collaboration which supports public reporting of outcomes.

Second, although patient safety is central to the governance of surgical innovation in their model, they fail to explicitly mention an objective methodology that monitors it during implementation of a new procedure or device. We have previously shown, in accordance with the IDEAL recommendations, that patient safety during a novel technique of robotic kidney transplantation may be monitored in an objective real-time manner using statistical process control (SPC) methods.⁴ SPC techniques, which are well established for evaluating the learning curve after surgical training,⁵ can also be used to track surgeon progress when learning an innovative procedure. Hence, the authors might consider employing such methods for outcome monitoring in a comparative effectiveness framework—the comparison might be with publicly available

outcomes from other institutions/groups for the new procedure implemented, or with outcomes of the approach that is considered the standard-of-care. Incorporating such methods may lead to a more objective oversight of the outcomes.

Lastly, surgeons wanting to adopt a new technique but restricted by financial constraints or the might of the administrative burden, may not want to pursue a formal study. In that setting, the pathway offered by the authors is an important step forward. However, in order to decide when a new technique can be considered non-experimental, and therefore can be adopted outside of a research framework, we posit that this critical assumption should only be made when comparative outcomes with intermediate to long-term follow-up are available, showing non-inferiority/superiority of the new operation. The goal is not to say “Hey, I just did a *new* operation,” but rather, “Hey, I just did a *better* operation.”

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Detroit, February 5th, 2015

Keith D. Lillemoe, MD
Editor-in Chief, Annals of Surgery
Massachusetts General Hospital, Harvard Medical School
The W. Gerald Austen Professor of Surgery

Dear Dr. Lillemoe and the Distinguished Editorial Board

On behalf of all authors I wish to submit our manuscript (Letter to the Editor) entitled “HEY, I JUST DID A BETTER OPERATION! TOWARDS AN IDEAL INNOVATION MODEL”. We thank you and the editorial board for the opportunity to have our work reviewed at Annals of Surgery.

The manuscript is in full compliance with the requirements of the journal. All authors have made a substantial contribution to the information or material submitted for publication and all have read and approved the final manuscript. The manuscript or portions thereof are not under consideration by another journal or electronic publication, have not been previously published and represent an original contribution.

Kind regards,

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