IDEAL-D

Sedrakyan A, Campbell B, Merino JG, Kuntz R, Hirst A, McCulloch P. IDEAL-D: a rational framework for evaluating and regulating the use of medical devices. BMJ. 2016 Jun 9;353:i2372. doi: 10.1136/bmj.i2372. PMID: 27283585.

In previous work, the IDEAL collaboration has proposed frameworks for new surgical techniques and complex therapeutic technologies, the central tenet being that development and evaluation can and should proceed together in an ordered and logical manner that balances innovation and safety.

The following agreement at the IDEAL Collaboration Council, a multidisciplinary working group was formed comprising 12 representatives from healthcare, academia, industry, and patient advocacy. The group conducted a series of discussions following the principles used in the development of the original IDEAL Framework. Importantly, IDEAL aims for maximal transparency, optimal validity in the evaluation of primary effects and minimisation of potential risk to patients or others. The proposals were subjected to further review and editing by members of the IDEAL Council before a final consensus version was adopted.

In considering which studies are required before a first-in-human study, they have: (1) classified devices according to what they do and the risks they carry, (2) classified studies according to what they show about the device, and (3) made recommendations based on the principle that the more invasive and high risk a device is, the greater proof required of their safety and effectiveness prior to progression to clinical studies (Stage 1).

The proposed recommendations for preclinical evaluation of medical devices represent a proportionate and pragmatic approach that balances the de-risking of first-in-human translational studies against the benefits of rapid translation of new devices into clinical practice [1].

This framework is a model developed recently by an international panel of experts dedicated to better understanding the data steps necessary to bring a device from idea to routine practice and further to marketing, approval, and monitoring. In this review, we use the example of fenestrated endovascular aortic devices to illustrate the IDEAL-D framework, how it can help cardiovascular physicians improve their understanding of new technology, and the evidence which surrounds it from inception to long-term use [2].

New surgical procedures, devices, and other complex interventions need robust evaluation for safety, efficacy, and effectiveness. Unlike new medicines, there is no internationally agreed evaluation pathway for generating and analyzing data throughout the life cycle of surgical innovations. The IDEAL Framework and Recommendations were designed to provide this pathway and they have been used increasingly since their introduction in 2009. Based on a Delphi survey, expert workshop and major discussions during IDEAL conferences held in Oxford (2016) and New York (2017), this article updates and extends the IDEAL Recommendations, identifies areas for future research, and discusses the ethical problems faced by investigators at each IDEAL stage.

Methods: The IDEAL Framework describes 5 stages of evolution for new surgical therapeutic interventions-Idea, Development, Exploration, Assessment, and Long-term Study. This comprehensive

update proposes several modifications. First, a “Pre-IDEAL” stage describing preclinical studies has been added. Second we discuss potential adaptations to expand the scope of IDEAL (originally designed for surgical procedures) to accommodate therapeutic devices, through an IDEAL-D variant. Third, we explicitly recognise the value of comprehensive data collection through registries at all stages in the Framework and fourth, we examine the ethical issues that arise at each stage of IDEAL and underpin the recommendations. The Recommendations for each stage are reviewed, clarified and additional detail added.

Conclusions: The intention of this article is to widen the practical use of IDEAL by clarifying the rationale for and practical details of the Recommendations. Additional research based on the experience of implementing these Recommendations is needed to further improve them [3].

1)
Marcus HJ, Bennett A, Chari A, Day T, Hirst A, Hughes-Hallett A, Kolias A, Kwasnicki RM, Martin J, Rovers M, Squire SE, McCulloch P. IDEAL-D Framework for Device Innovation: A Consensus Statement on the Preclinical Stage. Ann Surg. 2021 Apr 7. doi: 10.1097/SLA.0000000000004907. Epub ahead of print. PMID: 33856386.
2)
Zacharias N, Wang GJ, Sedrakyan A, Columbo JA, Boyle JR, Goodney PP. Using the Idea, Development, Exploration, Assessment, Long-Term Study Framework for Devices (IDEAL-D) to Better Understand the Evolution of Evidence Surrounding Fenestrated Abdominal Aortic Endovascular Grafts. Ann Vasc Surg. 2019 Aug;59:293-299. doi: 10.1016/j.avsg.2019.02.010. Epub 2019 Apr 19. PMID: 31009709.
3)
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