with this shortfall, the central tenet being that innovation and evaluation can and should proceed together in an ordered and logical manner.[2 14-18] Moreover, the FDA has recognised the need for reform and has announced a new vision for post-market surveillance of new devices.[19]

Industry was found to have a role in the development and regulatory approval of the majority of devices identified. For devices developed in academia, collaboration with industry was associated with greater regulatory approval. Interestingly, the proportion of 510(k), premarket approval, and other approvals that were awarded to industry and academia were comparable, suggesting that the greater regulatory approvals of devices developed by industry did not simply reflect a propensity for less disruptive and lower risk innovations. This finding supports efforts such as the Medical Device Innovation Consortium that facilitate collaboration among academia and industry to foster technology transfer.[20] Collaboration between academia and industry may also contribute to improved surveillance of devices after regulatory approval has been received.

Comparison with other studies

In keeping with the present study, several other groups have also found limited publically available evidence to support the regulatory clearance and approval of new devices. Zuckerman et al evaluated the types of scientific evidence used to support devices cleared using the 510(k) pathway.[5] Of the 50 devices included, eight had data to support the claim that they were substantially equivalent to a predicate device, and only three had data on safety or effectiveness. Chang et al found that even devices approved using the premarket approval pathway, which require considerably more scientific evidence, often had no published clinical trials.[21] When trials are published, comparators are often absent, and details may differ substantially from the data submitted to the FDA.[21 22]

In a previous study we investigated the translation of new devices from the laboratory to first-in-human studies.[9] In contrast with the present study we found that clinical rather than industry collaboration was the most important predictor of success; devices developed with clinical collaboration were over six times more likely to lead to a first-in-human study than those without. It is likely that this incongruity is the result of the varying role of clinical and industry collaboration through the device development pathway; early clinical studies may be more reliant on clinicians, and later regulatory approval more reliant on industry.

Limitations of this study

We recognise several limitations to this study. We restricted our analysis to clinical studies of new medical devices reported in the biomedical literature. It is likely that the publication practices of academia and industry vary. We speculate that academia may be more motivated to publish early clinical studies.

Our analysis may also have favoured more novel devices, which clinicians might have thought warranted publication in the biomedical literature. The proportion of devices cleared through the 510(k) pathway was therefore likely to be an underestimate.

We determined whether a device had regulatory approval using only the FDA medical device databases. The proportion of medical devices receiving regulatory approval was therefore also undoubtedly an underestimate; in particular it is likely that licenses were granted from the European Union, which does not require any evidence of clinical value.[11] The reason for selecting the FDA, rather than other licensing authorities, was because the FDA provides public databases and search engines that allowed for a systematic search strategy, the FDA acts as the central body for all medical devices receiving regulatory approval in the USA, and the USA represents the largest medical device market in the world. We hypothesise that most of the manufacturers of devices that received regulatory approval from another jurisdiction would have ultimately sought and obtained FDA approval within the timeframe of this study if they were successful.

We evaluated the contributions of academia and industry in the development of a device if a relation was described in the author affiliations, main text, or acknowledgments of the first published clinical study. We acknowledge that our cross sectional study design does not capture potential interactions between academia and industry during the early phase of a device's development, such as the creation of spin-out companies or the licensing of intellectual property to industry. This study does not identify why industry was superior in obtaining regulatory approval compared with academia alone. One possible explanation is that the profit-seeking motive of industry hones its choice as to which devices are pursued.

Conclusions

The optimal framework for the regulatory approval of medical innovations remains unclear. This study suggests that many new devices do receive regulatory approval but often lack clinical trial data supporting their safety and effectiveness.

The IDEAL model makes several proposals for the staged introduction of innovations in surgery (and other disciplines that offer complex interventions), including randomised controlled trials to assess safety and effectiveness. At present, few relevant randomised controlled trials are published, and fewer still meet current quality standards for optimal reporting. Changes in the regulatory approval of devices that would require trials for proof of safety and effectiveness might promote adherence to the IDEAL model.

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