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Medical device transformation without delay

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Abstract

The medical device industry is a significant and major contributor to global health, yet innovation and research remains suboptimal. Current data focuses on devices, recalls and economics without genuine reflection on health impact and outcomes. Additionally, current understanding of medical device innovation and regulation has provided recommendations that have yet to be implemented. The medical device industry has ample opportunity to transform. Recommendations in strengthening pre and post market data, clinical trial parameters and impact, measurement of health outcomes and global surveillance can advance this transformation. Acknowledgement of ongoing successes in reform, such as device exemption approval turnaround times, can be a catalyst for the larger industry. Health service and outcome research, improved policies and application of recommendations can transform medical devices for best practice and optimal global health.

Keywords: Medical device, Device regulation, Device recall

Commentary

There are many choices as well as solutions to be considered in healthcare. Decisions about change and best practice are formed over consensus and debate of these options. For the medical device industry, the debate has been unnecessarily long and ongoing. The medical device industry and regulation must change without further delay.

Medical devices are critical for the advancement of healthcare and they create immense economic impact. In 2009, the United States medical device industry revenue totaled $146 billion. Throughout the decade from 2000–2010, there were 30,000 medical devices cleared by the Food and Drug Administration (FDA) [1]. It is an industry that continues to grow, with both large and small company interest.

The regulation of medical devices varies by country. The United States has tasked the FDA with the responsibility of assurance of safety and effectiveness of medical devices, allowing the FDA full authority of device approval. The Pharmaceuticals and Medical Devices Agency (PMDA) has similar authority in Japan, and China has recently created the China Food and Drug Administration (CFDA). In Europe, devices can be marketed after a Notified Body (NB) evaluates the device. NBs are for-profit, private organizations and are overseen by individual country Competent Authority (CA) regulators. There is no EU equivalent to medical device administration oversight such as the FDA or CFDA, and no EU equivalent or medical device oversight similar to medicine oversight at the European Medicines Agency (EMA) [2]. In Latin America, medical devices are regulated by various ministries of health and public health administrators [3]. Overall, public interest by foundation and structure in medical device approval is present in many countries, but the enforcement, analytics, approval and post-marketing surveillance varies [4]. Countries that have universal national health plans are afforded government oversight, and thus government accountability, in device regulation. This translates into optimal choice for medical device in reimbursement, an alternative mechanism of regulation [5].

Level of regulation based on risk of device is the method classification in multiple countries. This classification system varies by individual nations, however. Additionally, approval processes based on these risk classifications are of debate. Premarket approval requirements in the United States are based on classes, and even a review of the highest risk classification showed only 79% of the riskiest devices underwent premarket

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approval. Other countries also have varying levels of missed opportunities in premarket approval requirements [1].

Post market surveillance is assisted by adverse event reporting. For the FDA, the Medical Device Reporting (MDR) is the designated system. In Europe, it is the Eudamed [1]. Focus of the FDA has been moving toward post market evaluation as opposed to pre market analytics [5], in part due to clinical trial appropriateness and reliability. Likewise, when clinical trials are of less importance, there is less drive from industry to perform them [1]. Understanding these dynamics can move consensus forward.

There are well documented recommendations to transform the medical device industry while optimizing safety and public health priority. Ongoing expert consensus and reports should drive this transformation, with industry and regulation cooperation and without delay.

Scope and understanding of clinical trial research within the medical device industry must be reviewed by understanding the differences in regulation between devices and pharmaceuticals. Pharmaceuticals are brought through four different stages of clinical trials, receive approval for marketing in the United States [6] and also receive classification in conjunction with the Drug Enforcement Administration (DEA). The entire drug development process may take 8–10 years. Devices are given classification by the FDA, with limited premarket clinical trial data. Post-market surveillance, however, is lengthier for devices. Both drug and devices must get approval from the FDA before marketing to the public, both must comply with regulations and ethical conduct, and both have means for humanitarian use. Unlike drug manufacturers, however, device manufacturers are not often inspected by the FDA. Additionally, all drugs must prove safety and efficacy for the public, while only class III devices are required to do so [6].

Clinical trials provide understanding into a device's impact over time on human individual health. There is great debate in the medical device industry over clinical trials, as population testing before approval may not be appropriate and matched sample populations may not be feasible. It is difficult to randomize clinical trials for devices that are for specialty care, and in populations that cannot be blinded or unbiased. Additionally, long-term clinical trial data is often not collected. The FDA requires one pivotal and one non pivotal study for device approval, at minimum. A recent review of clinical trials found that the majority of devices have been approved with these minimal requirements, though some companies have ongoing studies throughout the device lifespan [7]. Regulatory bodies are left with the burden of navigating grey areas in approval and current accepted "best practices" in clinical trials. Literature can be found on recommendations, with some suggesting device companies work toward the optimal clinical trial design and others suggesting cultural and understanding of clinical trial design be reformed. Recommendations also include the consideration that long term data is crucial to understand the device, safety and effectiveness, and can provide insight into new considerations and uses for the device [7].

Definite and concrete change to clinical trial data requirements require an appreciation for flexibility. With an increased attention to cost effectiveness and comparative effectiveness in health policy and reimbursement, the industry has sought to strengthen post-market technique in surveillance. It is crucial to remain vigilant in pre-market clinical studies, however. While often difficult to implement in comparison to drug trials, device clinical trials require flexibility. Too, while appropriate design for one device clinical trial may not be appropriate for another, fundamentals and best practice approaches should be promoted. Industry and academia expertise can be complimented by national and international regulatory guidance in consideration of best practices in clinical trial design. While clinical trials in medical devices may not be able to provide double-blinded advantage, endpoint assessments in patient quality of life and subjective responses are valuable for the industry [7]. In ongoing evaluations, masking the investigator will allow distinct advantage in these newly considered endpoints. Additionally, randomization of specific devices may not be feasible but randomization of product or software additions may be. There is ample room for flexibility in clinical trial design and best practices, but clinical trials must be encouraged rather than viewed as irrelevant in the medical device industry. Clearly, the importance of clinical trial data cannot be overestimated.

Recall data should drive process change in regulation. Recalls of medical devices increased from 2003–2012 in the United States, with the most common reason being device design failures. Within the design of devices, failures and issues with software are problematic. Other common causes of recalls include non-conforming materials and component issues [8]. In instance, 71% of high-risk recalls in the United States were originally approved by the 501 k process [1]. 18% of medical devices through 501 K have been part of high and moderate risk recalls in recent years [5]. Approval processes accompanied by stronger post-market surveillance can assist in better outcomes with recalls, but new strategies for medical device regulation must also be introduced. Benchmarks should be set by independent authorities so that the collective medical device industry, along with regulators and governments, meet identified standards set with recalls. Using data can assist in the argument

for sustained change to regulation processes and may even assist in reduction of device recalls altogether In fact, the FDA has stated that working alongside industry, medical device recalls may be decreased by as many as 400 annually [8].

The differences in regulatory requirements between drugs and devices should be sound in evidence. Additionally, differences should be compared with international peers and system improvements should be implemented globally. Use of patient outcomes and comparative effectiveness research may aid in these decisions. Should strong evidence for or against current differences in drugs and device regulations present, revision in regulator and industry practices should follow suit.

Consumption of medical devices also differs greatly by country, but this consumption is not accurately or consistently documented in much literature. Correlation between medical device consumption, physical health outcomes and quality of life must be addressed. While an extensive undertaking, partnerships between public health, government and industry are already present. As the medical device industry expands within high-use populations as well as in new markets and new boundaries, post-market reporting will grow. As such, true correlation and significance of medical device and outcomes can be researched, measured and can assist in policy and regulatory formation. In fact, it has been reported that some reform measures in Europe are already seeking to shape policy around public interest and device impact. Outcome understanding is the ideal approach, and it is within grasp.

Speculative commentary on industry and government regulatory job movement is widespread in literature and media. Commentary on lobbying and lawmaker decisions that favor the device industry is also common. Yet, full analyses is not allotted. Criticism and innuendo cause friction in trust and alarm in medicine. Researchers should analyze all factors that weigh decisions from government administration, and transparency in all facts is helpful. Recent policy changes in the United States that reflect physician disclosure with company partnerships is a wonderful step, other countries should follow suit and future decision making should strive for similar transparency.

Ongoing improvements should be celebrated and set as example for future change. Too, these improvements are contingent on full commitment, which means that policy and regulation changes must be accompanied by thorough enforcement and research. Unique identifier requirements on devices are an example of positive change for surveillance, contingent on enforcement and vigilance in process. Another example of positive change is the FDA approval of Investigational Device Exemption (IDE), which took an average of 400 days in 2001 but was reduced to 30 days in 2015 [9]. Health service research should investigate and support health outcomes alongside shortened approval times, assuring staff and administration that what may feel like carelessness is not. Similar efforts nationally and internationally, as well as strategic plan objectives met, should be applauded.

Conclusions

The medical device industry is a major player in healthcare. Medical device impact, from individual health to collective economy, is immense. Driving change starts with acknowledgement of current recommendations for improvement as well as swift implementation of these ideals, including regulation, surveillance and global data collaboration. Health service and outcome research, improved policies and application of recommendations can transform medical devices for best practice and optimal global health.

Abbreviations

CA: Competent Authority; CFDA: China Food and Drug Administration; DEA: Drug Enforcement Administration; EMA: European Medicines Agency; FDA: Food and Drug Administration; PMDA: Pharmaceuticals and Medical Devices Agency; NB: Notified Body

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