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Availability and Access to Clinical Evidence for Medical Devices in Europe

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Introduction

Patients, organizations, healthcare providers and even nations at large are challenged on a day-to-day basis with decisions related to the right use of medical devices. It could either be a general practitioner from a rural region, using a particular kind of suture over other kinds or a cardiologist opting to utilize a bare metal stent or a drug-eluting stent on a patient who has been recently diagnosed with a coronary ailment, on the basis of its cost and availability. It could also be a health system that decides the kind of technologies that can be used for screening of colon cancer; there are several medical devices, it is expensive and its utility cannot be overlooked within the realm of medical practice [1].

There are hardly a handful of people including patients and physician who truly comprehend what outlines a medical device and the procedure through which medical devices are reviewed and obtain approval to be used in the medical domain. Though it is true that medical devices have to mandatorily undergo reviews before it can be made available to the public, still it lacks transparency. Clinical evidence pertaining to the effectiveness of the device or the benefits a particular device offers as compared to other similar devices is not made available to the public or even physicians for that matter. This highlights a lack of transparency in terms of clinical evidence for medical devices. Further, there are not many research articles that have covered this facet of transparency of medical devices. One particular paper by Fraser et al., [2] is reviewed and this commentary is based on the said paper.

Commentary

While as per the new European Union (EU) law of 5th April 2017 pertaining to medical devices has at Recital 43 declared that appropriate access to information is very much necessary to facilitate professionals in the healthcare domain to arrive at informed decisions. In addition, the law also states that it is mandatory for the manufacturer to sum up the key performance and safety related aspects of the medical device and the results of the clinical evaluation. However, this requirement is only applicable to class IIb, class III (high risk) and implantable medical devices. But this seems to be a skewed decision as it leaves the field open for many other medical devices that exist and are being currently utilized. There is clearly an imbalance considering that only class II and implantable medical devices are included whereas class IIa medical devices are exempted. For instance; devices that fall under class IIa include active systems such as magnetic resonance imaging or ultrasound. Even such medical devices require Summary of Safety and Clinical Performance (SSCP). Furthermore, some devices are introduced in the market without adequate clinical evaluation which can lead to severe complications.

Certain cardiovascular devices that were not subjected to adequate clinical evaluation prior to its approval led to severe complications during actual use [3]. Prior to the

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current EU law being implemented, there had been a very prominent case wherein there was failure on the part of a heart-valve manufacturer to reveal all information regarding fractures that occurred at the time of testing the device in the laboratory [4]. Another instance was observed in 2005 when there was a delay on the part of the manufacturer in revealing the risk of depletion of battery in a specific model of implantable cardioverter defibrillator. This resulted in several deaths which could have been averted if there had been no delay in revealing the pertinent information [5]. Similarly, in 2008, a delay in reporting fractures in lead resulted in unfortunate instances of electric shocks [6].

Implications

Negative outcomes arising from the lack of public information with regards to medical devices have been emphasized in several settings. It has been concluded by the European Clinical Research Infrastructure Network (ECRIN) that an absence of transparency during protocols and results from scant studies conducted in the past and restricted availability of trial data for secondary analyses are key bottlenecks in conducting suitable randomized trials of medical devices. Potential challenges with regards to the efficacy or safety of devices that are approved and used in surgery are hidden due to the absence of transparency.

This implies that surgeons are not in a position to arrive at informed decisions about using a particular device or choosing a device amongst other devices. This has resulted in innovation that is erroneous, unstructured and heterogeneous [7]. This in turn has led to an increment in the risk of unsuitable monitoring of medical devices. According to the European Patients Forum, it is necessary for patients as well as medical professionals to have access to superior quality information related to medical devices, allowing them to make informed decisions and beware of risks, if any, of using a particular medical device, irrespective of its class.

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