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Editorial

Editorial Note on Importance of Medical Device Safety

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EDITORIAL

After a joint investigation into the global medical devices industry, several media outlets published their findings of the Implant Files in 2018. The findings highlight an unacceptable lack of regulation of medical devices, leading to numerous patient complications worldwide, including some related to breast implants. In the UK alone, 1200 serious incidents have been linked to breast implants since 2015. Elsewhere, non-clinical grade materials continue to be used in breast implants, despite the 2010 PIP scandal in which implants were found to be manufactured with unapproved silicone gel and were prone to rupture. Clinical trials of breast implant safety also seem to have substantial amounts of missing data, calling into question the safety of these products. Reports have now emerged of an alarming association between textured breast implants and the development of breast implant-associated anaplastic large-cell lymphoma-a rare form of T-cell lymphoma that can occur in the fibrous scar capsule that forms around breast implants.

Although the underlying causal mechanisms have yet to be defined, early detection of localised disease and complete removal of the implant and capsule can lead to recovery. But, if undetected or untreated, progression can occur, and 16 related deaths have been recorded to date. Meanwhile, cases of breast implant-associated anaplastic large-cell lymphoma are increasing: 615 cases have been reported worldwide since the first report in 1997, including 45 cases in the UK, 72 in Australia, and 252 in the USA. The concern is so great that the French National Agency for Medicines and Health Products has recommended that surgeons switch to smooth implants as the link between textured implants and anaplastic large-cell lymphoma is investigated. For any woman undergoing mastectomy to treat breast cancer, the possibility of developing another cancer because of a medical device must be devastating. For women who had the procedure for cosmetic purposes, feelings of guilt might arise because complications have resulted from a procedure they chose to have. But, as for any medical procedure, blame cannot, and should not, be apportioned to the patient, especially when risks are not adequately recorded and reported, let alone communicated to the patient. Data for anaplastic large cell lymphoma are scarce, highlighting a wider concern about the worldwide regulation of medical devices. Many countries have systems in places for reporting adverse events associated with medical devices.

The US Food and Drug Administration (FDA) host the MAUDE database for medical device reports, and similar registries have been established in Australia and the UK. However, such systems do not appear to be compulsory—for example, the UK registry is not mandatory for clinicians and although it does include anaplastic large-cell lymphoma as a data item, reporting cases is optional. The MAUDE website lists its own limitations, stating that submitted data might be "incomplete, inaccurate, untimely, unverified, or biased". How can clinicians be expected to communicate risks to patients or make clinical decisions without accurate and reliable data? The existing system of passive monitoring of medical device safety clearly needs to be addressed. Drug safety monitoring could be a good model for the medical device industry and provide more reassurance to doctors and patients alike. Reporting of clinical trial data on new drugs has improved, and data from robust trials, including full reporting of adverse events, are essential for any drug approval. The same stringent data are not needed for medical devices; for example, in the European Economic Area, market approval is granted through CE certification, for which clinical trial data are not mandatory.

Furthermore, because of the commercial nature of medical devices, data transparency might be impeded by confidentiality rules. To strengthen regulation, the FDA outlined new policies to improve post-marketing device safety in their Medical Device Safety Action Plan in 2018. Similarly, a new EU regulation on medical devices, due to come into force in 2020, includes key issues of transparency around medical devices and reinforcement of rules of clinical evidence. The steps taken by the FDA and the EU are a good start in a long overdue assessment of medical devices, which undoubtedly hold much promise for many patients. However, the Implant Files investigation suggests that the industry is currently playing catch up in terms of regulating safety. The time for passive surveillance is over. The medical device industry and clinicians alike must be accountable and active in collecting clinical data, reporting safety, and communicating possible risks. Only then might medical device innovation and patient safety be improved in parallel.

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