FDA'S MAUDE DATA AND ITS CONTRIBUTION TO MEDICAL TECHNOLOGY ASSESSMENT AND PATIENT SAFETY.

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Introduction: The most prevalent medical device markets have adopted vigilance systems for medical devices (MD) as a requirement of their regulatory frameworks[1]. According to the vigilance systems the MD manufacturers are enforced to report to the authorities any adverse event (AE) involving any of their MDs. USA Food and Drug Administration (FDA) has a database for these reports, which receives more than 400.000 reports annually[2]. Some of these vigilance reports lead to corrective actions, with obvious benefits for the patients. However, this huge amount of data is used at a second stage for retrospective analysis and data extraction techniques offering spin-off benefits in terms of patient safety and MD technology assessment.

Materials and Methods: Five international bibliographic databases have been queried with terms relevant to Manufacturer and User Facility Device Experience Database (MAUDE). The aim was to measure the contribution of MAUDE[3] to patient safety and MD technology assessment. In order to retain only the papers containing studies carried out based on the MAUDE data, firstly a set of eligibility criteria was applied and then the paper abstracts were studied by two individual researchers in order to identify the ones lying within the scope of the present research.

Results: The queries of the databases resulted to an initial number of 1.016 publications (duplicates not included). This set of results was filtered according to a number of eligibility criteria referring to the publication type, language and time (only literature papers published in English from 2005 up to 2014). A number of 381 literature papers remained. After having read independently those papers, the two researchers agreed that 117 of them were relevant to the scope of the research.

Discussion: Out of the 117 papers examined, 29 addressed Cardiology Devices, 22 addressed Implantable Devices and 14 Endoscopy Devices. The majority of the papers contribute directly to patient safety (review the AE related with MD (31 papers), evaluate AE (22), explain why these AE occur (15)). Additionally, the contribution to technology assessment is also significant (evaluation of the MD design characteristics (14), overview of a medical technology (10)).

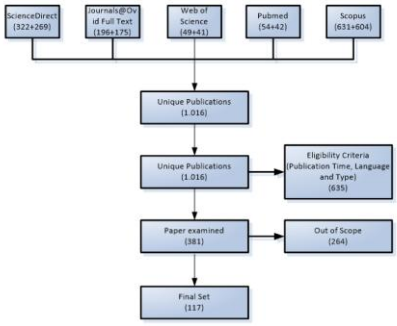

Figure 1. PRISMA flow chart for FDA system search

Conclusions: 1. Although MAUDE has certain limitations[3], it appears that it is a source of data with an increasing contribution to MD technology assessment and patient safety. 2. Cardiology Devices, implants, and sophisticated devices are the MD that the researchers mostly focused on. 3. The number of MD groups examined by the papers is considered relatively small, revealing that there is space for more research to be done on this database in the future.

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[2] F. Magrabi, M. Ong, W. Runciman, and E. Coiera, "Patient safety problems associated with heathcare information technology: an analysis of adverse events reported to the US Food and Drug Administration.," *AMIA Annu. Symp. Proc.*, vol. 2011, no. 1, pp. 853–7, 2011.
[3] S. E. Gurtcheff, "Introduction to the MAUDE database.," *Clin. Obstet. Gynecol.*, vol. 51, no. 1, pp. 120–123, Mar. 2008.