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LETTER TO THE EDITOR

MEDICAL DEVICES FAIL, SURE, BUT HOW OFTEN? SYNTHESIS OF REPORTS FROM THE UNITED STATES IN 2022

LOS DISPOSITIVOS MÉDICOS FALLAN, CLARO, PERO ¿CON QUÉ FRECUENCIA? SÍNTESIS DE REPORTES DE ESTADOS UNIDOS EL AÑO 2022

DISPOSITIVOS MÉDICOS FALHAM, CLARO, MAS COM QUE FREQUÊNCIA? SÍNTESE DOS RELATÓRIOS DOS ESTADOS UNIDOS EM 2022

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Dear Editor:

There is no doubt that, nowadays, clinical practice depends largely on technology. At the same time, it is known that technology is not free of difficulties and could fail for various reasons. One of these reasons is the presence of design flaws, which leads to withdrawing the unsafe equipment from the market (recall), or aging equipment that could present mechanical malfunctions and battery issues, among other problems – the list is long.

The question that remains for medical devices users is to what extent they can trust the equipments, considering the frequency of malfunctions and their origin. However, obtaining concrete data that allows us to adequately assess the magnitude of the problem is not an easy task, and there is an abundance of literature on the complexity of this monitoring and the different approaches to techno-vigilance,[1-3] beyond the reports presented by *Instituto de Salud Pública*,[4] or the incipient observatory of medical devices in Chile.[5] Certain international systems offer an interesting proposal since their

reports are available for free consultation, which makes it possible to obtain precise, abundant, and dense information to analyze. The most notorious of them is the Manufacturer and User Facility Device Experience system (MAUDE), which follows the adverse events reported to the Food and Drug Administration (FDA) in the United States.[6]

We want to use this space to share a synthesis of the reports of events associated with medical devices in the US during 2022, to be able to quantify the problems associated with these devices. The reports published in MAUDE were automatically obtained. These include a list of devices, such as ventilators, that we selected according to their level of criticality, as defined by the Chilean Ministry of Health, or to their frequency of use in the country, which is the case of hospital beds. Table 1 shows the number of incidents reported in one year, including malfunctions, injuries, and patient deaths.

Table 1: Number of reports associated with the medical devices in the first column during the year 2022, MAUDE system, USA.

Type of Equipment	Malfunctions	Patient Injuries	Patient Deaths
Category: Ventilator[a]	21993	920	163
Category: Defibrillator[b]	14601	165	190
Category: Monitor[c]	1342	206	125
Category: Bed[d]	973	149	7

[a] Included in this category: Continuous use ventilator in hospital facilities; high-frequency ventilator; powered emergency ventilator; non-life-support continuous use ventilator; ventilator for continuous use at home; continuous use ventilator with minimal ventilatory support in hospital facilities; continuous use ventilator with minimal ventilatory support at home.
[b] Included in this category: Low-energy DC defibrillator (up to 360 J), automatic external defibrillator (non-wearable).
[c] Included in this category: Physiological monitor, with and without arrhythmia detection and/or alarms; bedside monitor.
[d] Included in this category: Adjustable hospital bed with AC power, adjustable therapeutic bed with AC power for home use.

Source: Own elaboration based on reports.

Regarding equipment malfunctions, the reports show 190 deaths associated with defibrillators, 163 with mechanical ventilation devices, 125 with monitoring problems, and 7 due to problems with the hospital bed – 3 of which happened outside the hospital. Reports associated with ventilators amounted to around 22,000 throughout 2022, with around 1,000 patients suffering damage due to equipment malfunction. We are probably observing effects that are specific to the year 2022, with the recalls of devices associated with ventilation, but this allows us to highlight the magnitude of events that possibly most health professionals in Chile do not fully dimension, such as the number of incidents associated with defibrillators, monitors, or even hospital beds.

According to the MAUDE system's classification, the causes that result in greater lethality are problems in the alarm system, which confirms what has been found in previous instances by organizations such as the Emergency Care Research Institute (ECRI).[7] It is also important to emphasize that deaths linked to issues with the power supply of devices amount to 34 in one year. Beyond the deaths, the MAUDE reports show that, in the 293 cases of injury, the origin could be traced to the state of the device. It is essential to insist on continuous monitoring of medical devices, including their maintenance.

Now, the aforementioned data correspond to what was reported last year in a country with approximately 333 million inhabitants, whereas Chile has slightly under 20 million inhabitants. We do not intend to evaluate the rate of incidents related to medical devices, nor to directly extrapolate these data to what should be observed in Chile. No matter how elaborate they are, techno-vigilance and reporting systems still have limits, as MAUDE emphasizes. Furthermore, the health systems of

the countries in question are structured in ways that are too different to allow for extrapolation. However, through this synthesis, we wish to offer a quantitative estimate of what was observed in a country where access to techno-vigilance reports is open. We have also presented a subset of specific devices. Having a longer list could be possible; however, the objective of this communication is not to provide an exhaustive report on medical devices but rather to offer an estimate of the magnitude of adverse events associated with them, which we believe is greater than the common perception of service users. Maintenance programs and a thorough evaluation of the state of medical devices are essential to guarantee quality health care that is timely, and above all does not cause additional harm to the patient.

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