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Electronic Health Records on the Top of Medical Device Incident Reports

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Abstract. Medical Device incident reporting is a legal obligation for professional users in Finland. We analyzed all medical device incident reports recorded into the national incident repository from January 2014 to August 2021. Almost 30% of the total of 5,897 recorded incidents were caused by top ten devices, of which electronic health records were the most common (332 incidents). High number of incidents caused by electronic health records arouses safety concerns. A further analysis is required to explore the causes of findings.

Keywords. Medical device, safety incident, electronic health records

1. Introduction

Submitting a medical device incident report in Finland is a legal obligation for professional users. Reporting an incident applies to all medical devices and requires health of a person being in danger and a problem in relation to a medical device, and situations that could possibly have endangered a person's health. By definition, Parts of the Electronic Health Records (EHR) belong to medical devices. In Finland, technology related patient safety incidents have been studied in hospital district's or regulatory authority's registers [1] but rarely comprising all medical device incidents [2].

In this study, we assess frequencies of top ten medical device incidents reported by professional users into the nationwide medical device incident database at Finnish Medicines Agency, the regulatory authority responsible for incident repository.

2. Methods

The incidence reports from professional users contain data on user and affiliation, the medical device concerned in detail, type and severity of harm and additional device

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details (e.g., device maintenance, etc.). As part of the Prime Minister's Office development project [3], we analyzed professional users' medical device incident reporting data January 1, 2014 - August 10, 2021 in accordance to GDPR regulations.

3. Results

Altogether 5,897 medical device incident reports were recorded. Ten most often reported categories made up to 29.3% (1,725/5,897) of all incidents in the study period. Of the top ten incident categories, EHRs had the highest number of reports (n=332; 5.6%), followed by hip artificial joint (n=294; 5.0%) and patient bed (n=202; 3.4%) (Figure 1).

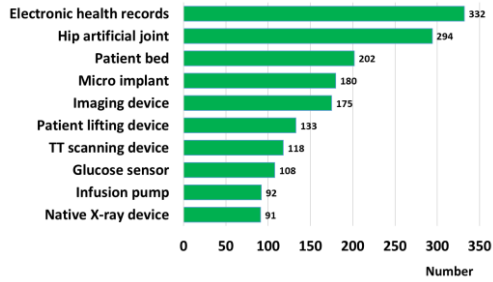

Figure 1. Ten most frequent medical device incident report categories recorded by professional users into the national incident repository from January 1, 2014 to August 10, 2021 (n=5,897).

4. Discussion and Conclusion

In Finland, the ten most reported devices were related to 30% of all incident reports, of which EHRs were the most frequent. Healthcare service providers use various EHR systems. Standardization of data structures, classifications and codes are inadequate. User interfaces are suboptimal for daily use, and systematic user education is a challenge [4]. Finland has introduced national, centralized, shared, integrated and interoperable electronic data system services for standardization and interoperability [5]. Further analyses are required to identify the root causes of reported medical device incidents.

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