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Medical Device Incident Reports by Professional Users in Finland 2014-2021

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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. Among the total 5,897 records, annual numbers of incident reports varied between 463 and 1,190. Approximately 80% of the medical device incident reports were near misses, 18.7% were person injuries and 1.3% deaths. The number of annual medical device incident reports between hospital districts varied more than expected when related to the population of catchment area. There was a tendency towards lesser reports per population from smaller hospital districts. In conclusion, medical device incident reporting activity of the professional user varied both annually and geographically. A high number of incidents caused person injuries or even death, which arouses safety concerns. A further analysis is required to explore the causes behind our findings.

Keywords. Medical devices, safety incident, Professional user, Finland

1. Introduction

Incident reporting systems obtain information about patient safety, and help individual and organizational learning [1,2]. In Finland, according to a decree on a plan for quality management and for ensuring patient safety authorized by the Health Care Act from 2011, all healthcare organizations shall describe how patient safety incidents are reported [3]. Based on European Union regulations, submitting a medical device incident report in Finland is a legal obligation for professional users defined in Medical Devices Act. The regulatory authority responsible for incident repository is the Finnish Medicines Agency.

Technology related patient safety incidents in Finland have been studied earlier either in hospital district's or regulatory authority's registers [4,5] but rarely comprising

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all medical device incidents [6,7]. Incident reporting of medical devices has similarities but also differences to medication adverse reaction reporting system [8].

In this study, we aimed to assess trends, effects and consequences of medical device incidents reported by professional users into the nationwide medical device incident database at Finnish Medicines Agency (Fimea) from 2014 to 2021.

2. Methods

Professional users report medical device incidents by filling in an electronic form and sending it to Fimea's email address, filling in a pdf-format form and sending it to Fimea's fax or by post or, in cases of emergency, by telephone.

As part of the Prime Minister's Office development project [9], Fimea granted us access to professional users' medical device incident reporting data from January 1, 2014 to August 10, 2021. We processed these incident registry data according to the European general data protection regulations (GDPR).

We report the results as numbers and proportions.

3. Results

Our study material consists of 5,897 (100%) medical device incident reports recorded into the national incident repository from January 2014 to August 2021. The highest annual number of reports was 1,190 in 2018, and lowest in 463 in 2014 (Figure 1).

Totally 460 (7.8%) incident reports were empty, but had data recorded on incident's effects and consequences. In addition, 218 (3.7%) incident reports were classified 'spam' according to their incident-unrelated trash contents. Thus, our study data consist of 5,219 (88.5%) genuine medical device incident reports.

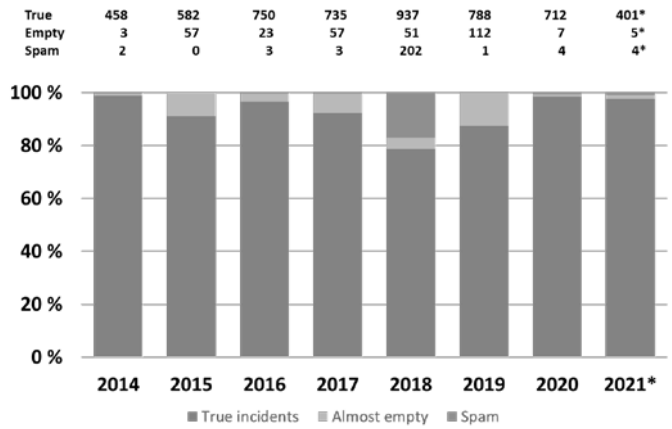

Figure 1. Annual number of medical device incident reports by professional users recorded into the national incident repository in the Finnish Medicines Agency Fimea from January 1, 2014 to August 10, 2021 (n=5,897), classified as genuine (n=5,219; dark grey), almost empty (n=460; light grey) and 'spam' (n=218; medium grey) incident reports.

All the 20 mainland Finland hospital districts reported medical device incidents (n=5,363; 90.9% of incident reports). Cumulative numbers of incident reports by hospital districts varied between 15 and 904 (21.3–229.2 per 100 000 population) in the study period (Table 1). The number of incidents reported by public organizations (n=4,488) was manifold compared to private organizations (n=883). Smaller hospital districts tended to make fewer medical device incident reports per population compared to larger hospital districts (correlation co-efficient 0.51; one outlier removed from calculation).

Table 1. Annual number of professional user recorded medical device incident reports into the national incident repository in the Finnish Medicines Agency Fimea by hospital districts from January 1, 2014 to August 10, 2021 (n=5,363). (* = Calendar year from January 1 to August 14, 2021 extrapolated by (365/222)*[count]. Hospital districts in bold include university hospitals. Pop = population (millions). C. = Central, E. = East, N. = North, S. = South, SW. = Southwest).

Hospital district	Pop	2014	2015	2016	2017	2018	2019	2020	2021	Total
S. Karelia	0.13	6	38	64	33	45	35	28	21*	262
S. Ostrobothnia	0.19	6	11	8	24	18	7	10	20*	96
S. Savonia	0.10	5	8	11	11	15	18	5	12*	80
HUS	**1.70**	**43**	**31**	**49**	**60**	**131**	**94**	**66**	**49***	**504**
E. Savonia	0.04	5	3	3	0	3	0	0	3*	16
Kainuu	0.07	6	8	10	10	14	12	14	15*	83
Kanta-Häme	0.17	13	15	27	9	20	25	29	30*	156
C. Ostrobothnia	0.08	0	4	4	4	2	0	1	3*	17
C. Finland	0.25	3	18	17	15	23	36	47	10*	165
Kymenlaakso	0.16	8	8	17	12	13	25	30	15*	123
Lapland	0.12	4	5	10	4	13	9	19	10*	70
Länsi-Pohja	0.06	6	1	0	1	2	4	1	0*	15
Pirkanmaa	**0.54**	**162**	**141**	**112**	**105**	**122**	**93**	**61**	**58***	**831**
N. Karelia	0.16	13	10	13	4	23	44	46	38*	176
N. Ostrobothnia	**0.41**	**62**	**35**	**83**	**104**	**85**	**66**	**76**	**76***	**557**
N. Savonia	**0.24**	**49**	**53**	**90**	**70**	**100**	**86**	**59**	**43***	**550**
Päijät-Häme	0.21	16	37	33	68	86	62	85	59*	423
Satakunta	0.22	13	15	16	20	20	16	11	31*	130
Ostrobothnia	0.17	6	43	33	32	50	14	12	15*	199
SW. Finland	**0.48**	**32**	**98**	**150**	**149**	**152**	**141**	**112**	**125***	**910**
Total	5.54	458	582	750	735	937	788	712	659*	5363

According to preliminary analyses, there were 4,721 (80.1% of reported incidents) near misses, and 1,102 person injuries (18.7%) and 74 deaths (1.3%) among the 5,897 medical device incident reports during the study period.

4. Discussion and Conclusion

Incident reports made by health care professionals are an important source of information about injuries and near missed harm caused by medical devices. In our study, numbers of reports between hospital districts varied more than expected in relation to the population of the catchment area. This might indicate differences in safety culture or lack of adherence to national guidelines for medical device incident reporting. Furthermore, there was a tendency towards fewer reports per population in smaller hospital districts. A considerable proportion (20%) of incidents caused person injury or even death, which arouses safety concerns. A recent article suggested there might be underreporting of severe incidents [10]. Further studies are required to draw conclusions about differences between hospital districts. Interestingly, the reporting activity of two latest years during COVID-19 pandemic did not seem to alter from the overall trend of incident reports.

Since May 2010, Finland has introduced national, centralized, shared, integrated and interoperable electronic data system services (Kanta Services) for citizens, healthcare, social welfare, and pharmacy service providers [11]. Kanta Services standardize data structures to make transmitting data between care providers interoperable by utilizing the national Code Service. The data structures include code sets, classifications, form structures, texts, register data, as well as vocabularies and terminologies related to them. The standardized data structures required by the electronic client data systems in social welfare and health care, as well as the central code sets of the statistical and register data collection, are available on the CodeServer free of charge. IMDRF code set for medical devices is not widely used yet.

According to a guideline of the health statistics authority, recording the adverse effects of medical treatment has been mandatory since 1997. Adverse effects of medication are recorded according to ICD-10 and ATC-classification to the hospital discharge and primary health care registries. Medical device incident reporting might benefit from a similar classification-based reporting system.

This material was collected as a part of project funded by the Prime Minister's Office aiming at national metrics for patient safety. Standardization of medical device coding for social and health care registries, and national guidelines on reporting medical device incidents are elementary for surveillance of medical device safety. The registry data should be published regularly.

A further analysis is required to find out, whether the observed variation is related to reporting activity or differences in the true occurrence of incidents, as well as to identify the root causes of reported medical device incidents.

References

[1] Berwick DA. A promise to learn – A commitment of act: improving the safety of patients in England. London (U.K.): National Advisory Group of Safety of Patients in England; 2013 Aug, p. 1–47.

[2] Stavropoulou C, Doherty C, Tosey P. How effective are incident-reporting systems for improving patient safety? A systematic literature review. Milbank Q. 2015 Dec;93(4):826–866.

[3] Finnish Health Care Act 2010/1326. Ministry of Social Affairs and Health, Finland; Dec 2010. https://www.finlex.fi/fi/laki/kaannokset/2010/en20101326.pdf

[4] Palojoki S, Mäkelä M, Lehtonen L, Saranto K. An analysis of electronic health record–related patient safety incidents. Health Inform J. 2017 Jun;23(2):134–145.

[5] Palojoki S, Saranto K, Lehtonen L. Reporting medical device safety incidents to regulatory authorities: an analysis and classification of technology-induced errors. Health Inform J. 2019 Sep;25(3):731–740.

[6] Sievänen H. User reporting of medical device related incidents. Med Device Technol. 2003 May;14:26–29.

[7] Sievänen H, Pommelin P. Quality analysis of medical device vigilance reports. Technol Health Care. 2003 Oct;11(4):275–281.

[8] Vainiola T. Incident reporting ensures the safety of medical devices. Finnish Medicine Agency publication SIC! 2021 Dec;(4). https://urn.fi/URN:NBN:fi-fe2021122162853

[9] Virkki M, Leskelä R-L, Ikonen T, Haatainen K, Welling M, Rauhala A, et al. Current situation of patient and client/customer safety and follow-up procedures in Finland: A suggestion for a measurement framework. Publications of the Government´s analysis, assessment and research activities 2021:68. Helsinki (Finland): Prime Minister's Office; 2021 Nov, p. 1–183. http://urn.fi/URN:ISBN:978-952-383-334-0

[10] Lalani C, Kunwar EM, Kinard M, Dhruva SS, Redberg RF. Reporting of Death in US Food and Drug Administration Medical Device Adverse Event Reports in Categories Other Than Death. JAMA Intern Med. 2021 Sep;181(9):1217–1223.

[11] Jormanainen V. Large-scale implementation and adoption of the Finnish national Kanta services in 2010–2017: a prospective, longitudinal, indicator-based study. Finnish J eHealth eWelfare. 2018 Apr;10(4):381–395.