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Short communication

Extensive underreporting and insufficient quality of incident reports received from pharmacists in Croatia from 2012 to 2021

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Introduction

Medical devices continue to gain in importance, offering fast-growing technological advances in management of a high variety of conditions. However, every medical intervention is associated with expected risks as well as unforeseen risks, which may lead to serious deterioration in state of health or even death of a patient, user or other person (Kramer et al., 2014; Zippel and Bohnet-Joschko, 2017). Medical device vigilance refers to activities related to collection, assessment, understanding of information as well as responding to new knowledge about the risks arising from the use or application of medical devices, especially adverse incidents, interactions with other substances or products, contraindications, counterfeiting, performance failures and poor construction or design of medical devices. Incident related to medical devices is defined as any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect (MEDDEV, 2013; Medical Devices Act, 2013). Manufacturers, healthcare professionals and lay users participate in the vigilance system. There is no regulatory requirement for healthcare professionals to actively participate in the vigilance system, but their role is key to ensuring the health and safety of patients, users and others. The purpose of the research is to determine the quality of reports of incident reports received at the Croatian Agency for Medicines and Medical Devices by pharmacists from 2012 to 2021.

The quality of the report itself directly affects the course of the manufacturer's investigation of the incident and its outcome, which further has an impact on the safety of patients and users of the medical devices.

Materials and methods

Materials

Study included all incident reports received from pharmacists from year 2012 to 2021. Total number of reports included in this study is 30. All reports that were submitted in any form other than designated incident form were translated into the corresponding form fields before the assessment.

Method

HALMED assessors with relevant experience in vigilance report processing reviewed all incident form fields and assigned them with 1 or 2 points, according to importance of information. Fields were then assessed and scored based on the content of provided information which should be sufficient to allow for further processing of the incident. Final scores were translated to percentages then ranked. Report quality was categorized according to the evaluation system's five levels of classification (total score = 100%): Excellent: total incident report quality evaluation score ≥90: Good: score 80–89; Medium: score 70–79; Qualified: score 60–69; Unqualified: score <60 points.

Results and discussion

Of the 30 reports received, the designated form for incident reporting was used in only 10% of reports, most

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reports received were on the form for adverse events related to medicines (86.67%) whose fields do not fully correspond to the required data for reporting incidents related to medical devices. The quality of the report reached 100% in only one received report, two reports are at a barely satisfying level of 65% in average, and all other reports were assessed as unsatisfactory with an average score of 35.81%. Thirteen fields of the designated form were recognized as critical in reporting the incident due to the importance of the information, but only four of those fields were satisfactorily populated by an average of 94.58% (commercial name of the medical device, date of occurrence of the incident, description of the incident and patient outcome). The other nine fields falls into the unqualified level of data quality by an average of 13.81%. The outcome of the report in 90% of cases did not result in the initiation of an incident investigation for the following reasons: the report was assessed as the lowest level of risk in the risk assessment process and was recorded in the database after notification of the manufacturer (51.85%); the event does not meet the criteria for reporting according to the medical device legislation (33.33%); insufficient information in the report to initiate further investigation of the incident alongside the unresponsiveness of the reporter for further information collection (11.11%) and inadequate user knowledge (3.7%). The three reports that resulted in the initiation of the incident investigation had the following conclusions: the incident was not related to the medical device, but to the concomitant drug; the incident was due to using the medical device in a manner not in accordance with the manufacturer's specifications and unexpected, but isolated event that the manufacturer will continue to monitor. Most reports were received for medical device class risk IIb (33.33%). For the incident investigation, it is of great importance to keep the medical device involved in the event, but only in 6.67% of reports the medical device was kept in the pharmacy, while in 90% of reports the location of the medical device is unknown. Most reports were received from Zagreb 26.67%, followed by Osijek 10%, and in 30% of cases the city is unknown.

Conclusion

The poor quality of received incident reports can be attributed to the use of the incorrect reporting forms and a lack of education on vigilance and medical devices. Healthcare professionals should be further educated on the vigilance of medical devices and their role in the system, and encouraged to report suspected serious incident at national level in a harmonized manner.

References

European Commission, 2013. MEDDEV 2 12-1 rev. 8 Vigilance, European Commission, (July 2013), pp. 1–64. Available at: https://ec.europa.eu/docsroom/documents/32305/attachments/1/translations.

Kramer, D.B., Tan, Y.T., Sato, C., Kesselheim, A.H., 2014. Ensuring medical device effectiveness and safety: a cross--national comparison of approaches to regulation. Food and drug law journal 69(1), 1–26.

Medical Devices Act (Narodne novine, number 76/13).

Zippel, C. and Bohnet-Joschko, S., 2017. Post market surveillance in the german medical device sector – current state and future perspectives. Health Policy. Elsevier Ireland Ltd, 121(8), 880-886. http://dx.doi.org/10.1016/j.healthpol.2017.06.005