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, their use 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 persons.

Medical device vigilance refers to collection, assessment and understanding of information regarding the risks arising from the use or application of medical devices. Aside from manufacturers, healthcare professionals and lay users also participate in the vigilance system by incident reporting. 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.

Materials and methods

Research included all incident reports received from pharmacists from year 2012 to 2021. Total number of reports included in this study is 30. Incident form fields are assigned 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.

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.

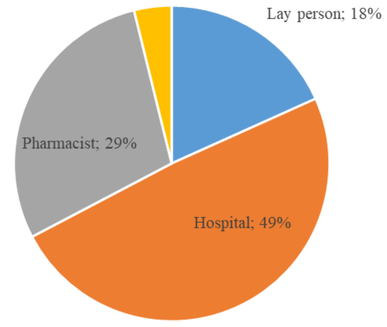

Figure 1. Percentage of reports by source

Results

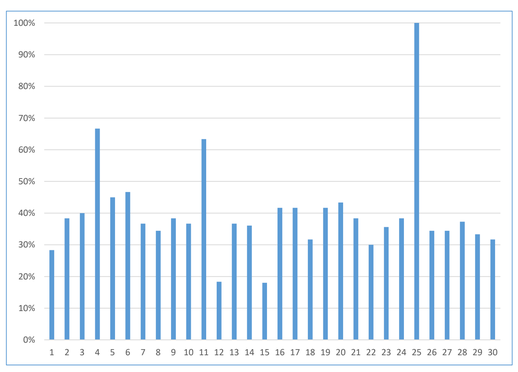

Figure 2. Quality of the reports

Reporter information	Name	73.33%
	E-mail	70%
Manufacturer information	Name	50%
	E-mail	3.33%
	Country	3.33%
Distributer information	Name	13.33%
	E-mail	3.33%
Medical device information	Commercial name/ brand name / make	96.67%
	Serial or lot/batch number(s) (if applicable)	13.33%
Incident Information	Date the incident occurred	90%
	Incident description narrative	98.33%
	Medical device current location/disposition (if known)	10%
Patient information	Patient outcome	93,33%

Table 1. Rate of population of critical fields in incident reports

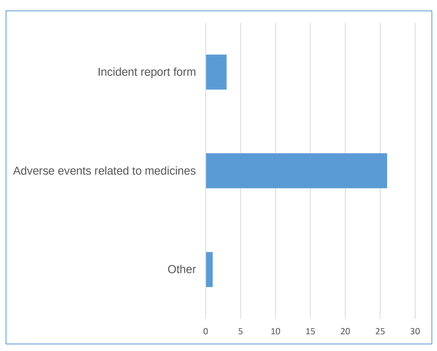

Figure 3. Number of the reports per form

- The quality of the reports (Fig 2.) reached 100% in only one report, two reports are at a barely satisfying level of 65% in average, all other reports are unsatisfactory with an average score of 35.81%.
- Thirteen fields of the designated form were recognized as critical (Table 1.) 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%. The other nine fields falls into the unqualified level of data quality by an average of 13.81%.
- Most received reports were on the form for adverse events related to medicines (86.67%) whose fields do not correspond to the required data for incidents related to medical devices (Fig 3.).

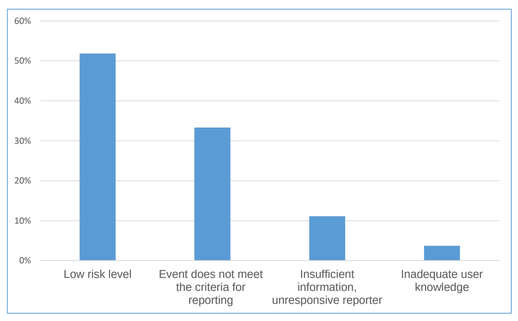

Figure 4. Reasons incident reports did not trigger investigation

The outcome of the report in 90% of cases did not result in the initiation of an incident investigation (Fig 4.). 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 (1);
- 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 (2).

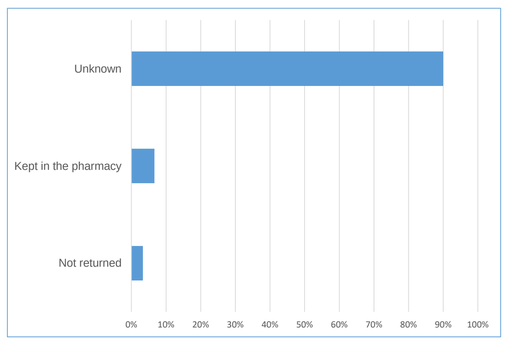

Figure 5. Reported medical device location/disposition at the time of the report

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.

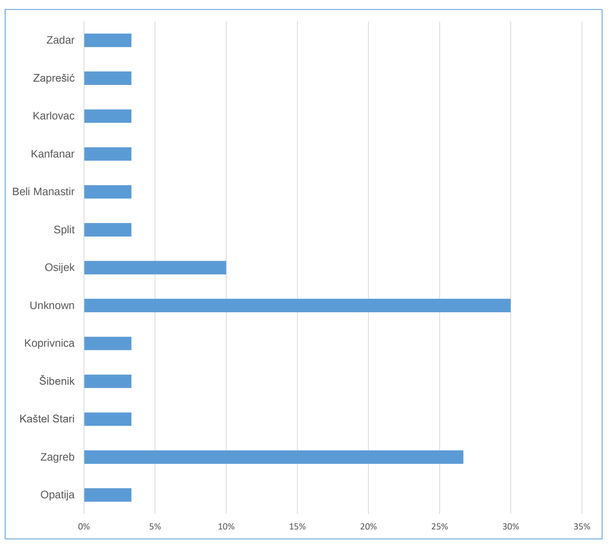

Figure 7. Percentage of reports by city

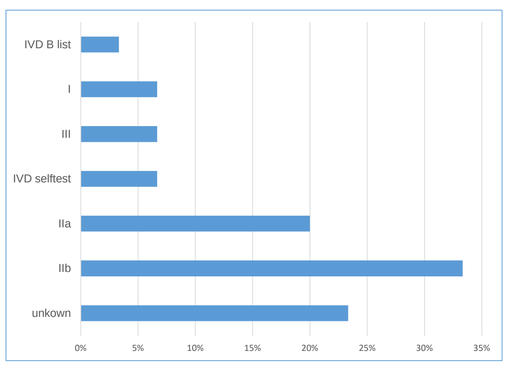

Figure 6. Percentage of each medical device risk class in received reports

The two most reported medical device risk classes are IIa and IIb, which cover a wide range of invasive and non-invasive devices used in hospitals and sold in pharmacies.

References
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