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Patient Safety in Primary Health Care – the Challenges of the Present and the Future

Mirna Macur*
Angela Boškin Faculty of Health Care, Spodnji Plavž 3, 4270 Jesenice,
mmacur@fzab.si

Suzana Šuklar
Community Health Centre Murska Sobota, Grajska ulica 24, 9000 Murska Sobota,
suzanas@zd-ms.si

Abstract:

Background and Originality: Patient safety is a very important component of quality which is often emphasised by health care managers and policymakers; however, its integration in national health policies and organisational measures is not self-evident. This paper explores how frequently Slovenian Community Health Centres (CHCs) report on patient safety and whether their reporting is consistent with the OECD definition of patient safety. The originality of this research is finding the actual value of patient safety for Slovenian CHC independently of official statements at national and organisational levels.

Method: A qualitative descriptive analysis of the publicly available annual reports of twenty-six Slovenian CHCs with an integrated management system was conducted. Thematic analysis was applied to the term "safety" and related terms ("harm", "adverse" for adverse events, etc.). The frequency of these terms was reported, and the context of the words was explained.

Results: In the annual reports, 11 different keywords related to safety, harm and adverse events were found, but only 6 keywords met the OECD definition of patient safety: patient safety education or preventive activities (n = 20); patient safety measures (n = 14); general healthcare safety (n = 3); drug safety, hygiene standards (n = 7); safety culture (n = 10); and risk management (harm prevention) (n = 8). These keywords were found in only 16 of 26 CHCs annual reports.

Society: Patient safety is the responsibility of healthcare providers, both individuals and organisations. The social responsibility of CHCs is to report on patient safety in their annual reports, create a culture of safety, and take corrective action when necessary because their mission is to contribute to a higher quality of life for patients and society as a whole. This research shows that this is not always the case, even for CHCs with an integrated management system - not all have publicly available annual reports. The research is an incentive for all CHCs, not just CHCs with an integrated management system, to create a culture of safety, report on patient safety and learn from mistakes by developing safety protocols.

Limitations / further research: The research was limited to CHCs with an integrated management system (n = 34) and publicly available annual reports (n = 26). It is crucial to conduct such research for all Slovenian CHCs and encourage them to report on patient safety. A true insight into the culture of patient safety must also include an analysis of the actions taken by the CHC management in recent years.

Keywords: patient safety, health care quality, OECD dimensions of quality, adverse events, preventable harm for patients.

* Korespondenčni avtor / Correspondence author

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1 Introduction

Patient Safety is a high priority of EU health policies; however, its integration into national health policies and organisational measures is not self-evident. Various health care policies and actions are taken in the name of patient safety, but they do not always serve patient safety. Day-to-day healthcare practice and interventions result from current medical and nursing evidence, so we need to continuously monitor and assess patient safety in health care facilities. It is critical to obtain feedback on the patient safety of healthcare services, assess the impact of interventions on patient safety, and be able to take corrective action to ensure greater patient safety.

Patient safety is an important component of medical and nursing education; however, safety culture varies by country, region, and organisation. Some organisations report patient safety regularly and take corrective action monthly when needed, while others tend to cover up adverse events and not take corrective action. A culture of safety builds slowly, it cannot be implemented overnight, but the first step in this endeavour is reporting patient safety.

Many definitions of health care quality emphasise the importance of patient safety, including the definition of the Organisation for Economic Cooperation and Development (OECD), which the EU has adopted. Patient safety is also very important for Slovenian healthcare institutions: Community Health Care Centres (CHCs) and hospitals. Our study focused on the primary health care level, i.e. Slovenian CHCs. Our aim was to determine the importance of patient safety for Slovenian CHCs by analysing their annual reports. The annual reports of Slovenian CHCs with integrated quality management system were analysed to answer the following research questions:

RQ1: Do CHCs with an integrated quality management system report on patient safety?

RQ2: If yes, in what ways do they report on patient safety?

RQ3: Is their reporting consistent with the OECD definition of patient safety?

2 Theoretical framework

Most of the recommendations on quality and safety in health care date back to 2002 and the start of the OECD project on quality of health care. The main aim of the project was to assess and compare the quality of health care in different countries. The project was extended in 2014 when the European Commission recommended all member states to monitor the effectiveness of health care and facilitate access to health care for all (EUR Lex, 2014). In the same year, the EU agenda on quality of healthcare was published ("Expert panel on effective ways of investing in health (EXPH) - Future EU Agenda for Quality of Healthcare with a Special Focus on Patient Safety (2014)"). The document extended the OECD's thinking on quality to a wide range of healthcare services and specified that they must be as follows:

1. »Effective, and improve health outcomes;

2. Safe, and prevent avoidable harm related with care;

3. Appropriate, and comply with current professional knowledge as well as meeting agreed standards;

4. Patient-centred, and involve patients/people as key partners in the process of care;

5. Efficient and equitable, and lead to the best value for the money spent and to equal access to available care for equal need, utilisation and equal quality of care for all« (EC, 2014, p.8).

In this document, patient safety is seen not only as a critical dimension of quality, but also as an outcome of high quality health care delivery. The World Health Organization (WHO) emphasises that patient safety is essential to the delivery of quality essential health services. There is a clear consensus that quality health services worldwide should be effective, safe and people-centered (WHO, 2019, para. 3).

The definition of safe health care service includes the avoidance of preventable harm (EC, 2014; EC, 2017; Kelly & Hurst, 2006, p.13; WHO, 2019, para.2; Robida, 2009, p. 8). "It is estimated that 8-12% of patients admitted to a hospital in the EU suffer from adverse effects whilst receiving healthcare, such as healthcare-associated infections, errors in diagnosis, and medication-related and surgical error" (EC, 2017, p.1). WHO recognises that one of the top ten causes of death and disability in the world is due to adverse events caused by unsafe care. In low and middle income countries, 2.6 million people die each year as a result of unsafe care. In OECD countries, 15% of total hospital activity and expenditure is a direct result of unsafe care (WHO, 2019, para. 1). There are many reasons why patient safety should be a high priority for all healthcare institutions: it is estimated that medical errors cause more deaths than AIDS, motorcycle accidents or breast cancer (McFadden, Stock & Goven, 2015, pp. 24-34). Adverse events are estimated to be the fourth leading cause of death in Slovenia, just after cardiovascular disease, cancer and injuries, but are not statistically recorded (Robida, 2015, p.25).

There are various causes of adverse events; they may be due to the workplace (inappropriate design), equipment (instructions in a foreign language, unfamiliarity with equipment), the organisation of a healthcare facility, and the tasks assigned to an employee (too many tasks, incompetence) (Robida, 2013, p.10). Mitchell (2008, p.3) adds patient management (improper delegation, errors in follow-up, incorrect referral or misuse of resources) and clinical performance (before, during and after the procedure) and communication (errors between patient or patient representative and practitioner, practitioner and non-medical staff or between practitioners). According to Matthew et al. (2017, pp. 34-42), most adverse events for patients are due to inappropriate communication when conveying information about patients or even misuse of information about patients.

Not all errors in health care facilities are harmful to patients: some errors have no impact on patient health, and some errors are detected and corrected in a timely manner. "According to WHO, major patient safety concerns are medication errors, health care-associated infections,

unsafe surgical care procedures, unsafe injection practices, diagnostic errors, unsafe transfusion practices, radiation errors, sepsis, and venous thromboembolism (blood clots)" (WHO, 2019, para. 8). However, the nature of adverse events may vary depending on the care setting: in primary and ambulatory care, adverse events may include delayed diagnoses, diagnostic errors, adverse drug reactions, untimely follow-up, falls, and medication errors in patients with polypharmacy (OECD, 2020, para. 4).

This paper focuses on Slovenian primary health care. Some believe that primary health care is safer for patients than hospital care, where patients feel more vulnerable. "While much attention is given to patient safety in hospitals, about 50% of the global burden arising from patient harm originates in primary and ambulatory care" (OECD, 2019, p.4). "Globally, up to as many as 4 in 10 patients are harmed in primary and outpatient health care. Up to 80% of harm is preventable. The most detrimental errors are related to diagnosis, prescription and the use of medicines" (WHO, 2019, para.1). Primary health care has great potential to improve health outcomes by reaching patients at early stages of disease, thereby reducing illness and morbidity and prolonging life (Kontopantelis et al., 2015, p. 5).

Patient safety, then, is not just a component of health care quality but an important health care concern in its own right. "Patient safety requires continuous detection, analysis and risk management for patients with the aim to implement safe health care and reduce harm for patients to the minimum." (Kristensen, Mainz, and Bartels, 2007 in Robida, 2013, p. 25). It is extremely important to identify and report adverse events and threats to patient safety. This depends on the safety culture in the healthcare facility, which consists of three key elements (ECRI, 2019, para. 5): fair and just culture, reporting culture, and learning culture.

Our paper focuses on the reporting culture in Slovenian primary health care; it examines the importance of patient safety for Slovenian CHCs using one indicator: patient safety reporting.

3 Method

The annual reports of Slovenian CHCs with integrated management systems were collected from their websites. Those that did not publish their annual reports for 2018 were asked to provide them. Contrary to our assumption, not all CHCs have publicly available annual reports, so our sample included only 26 reports out of 34 for 2018.

Our aim was to determine the importance of patient safety for Slovenian CHCs by analysing their annual reports: how frequently they report on patient safety and whether their reporting is in line with the OECD definition of patient safety. Slovenian CHCs are not required to report on quality and safety; they are only required to report financial and management indicators (efficiency, cost-effectiveness, expenditure) to the health insurance company and the Ministry of Health. We focused on CHCs with an integrated management system (n = 34) and expected them to report on quality and patient safety. Although they report on quality, they are not required to report on the six OECD quality dimensions, which include patient safety.

Patient safety was broken down into several key concepts using the theory of patient safety adopted by the OECD and the EU. The focus was not on staff safety measures, but on patient safety measures and all other activities that improve patient safety.

The authors recognise that patient safety is an integral part of health professional (nursing, medical) education, but the complexity of health care systems brings new threats to patient safety that need to be addressed. Prevention of patient harm refers to a system of care that (1) prevents errors, (2) learns from errors that occur, and (3) builds on a culture of safety that involves health care professionals, organisations, and patients (Mitchell, 2008, p. 2). The first step in this direction is patient safety reporting. CHCs that report on patient safety can learn from errors and hopefully avoid them in the future.

A qualitative descriptive analysis of the publicly available 2018 annual reports was conducted: The occurrence of the words "safety", "harm" and "adverse" (for adverse events) was calculated and the context of these words was analysed. Vogrinc's (2008) thematic analysis was applied, a kind of qualitative analysis with a quantitative character (the results are presented in a frequency table). As these keywords are expected to occur in different contexts, the keywords in Slovenian were classified according to the meaning in which they appear in the annual reports. The frequency of these keywords was counted and presented in Table 1.

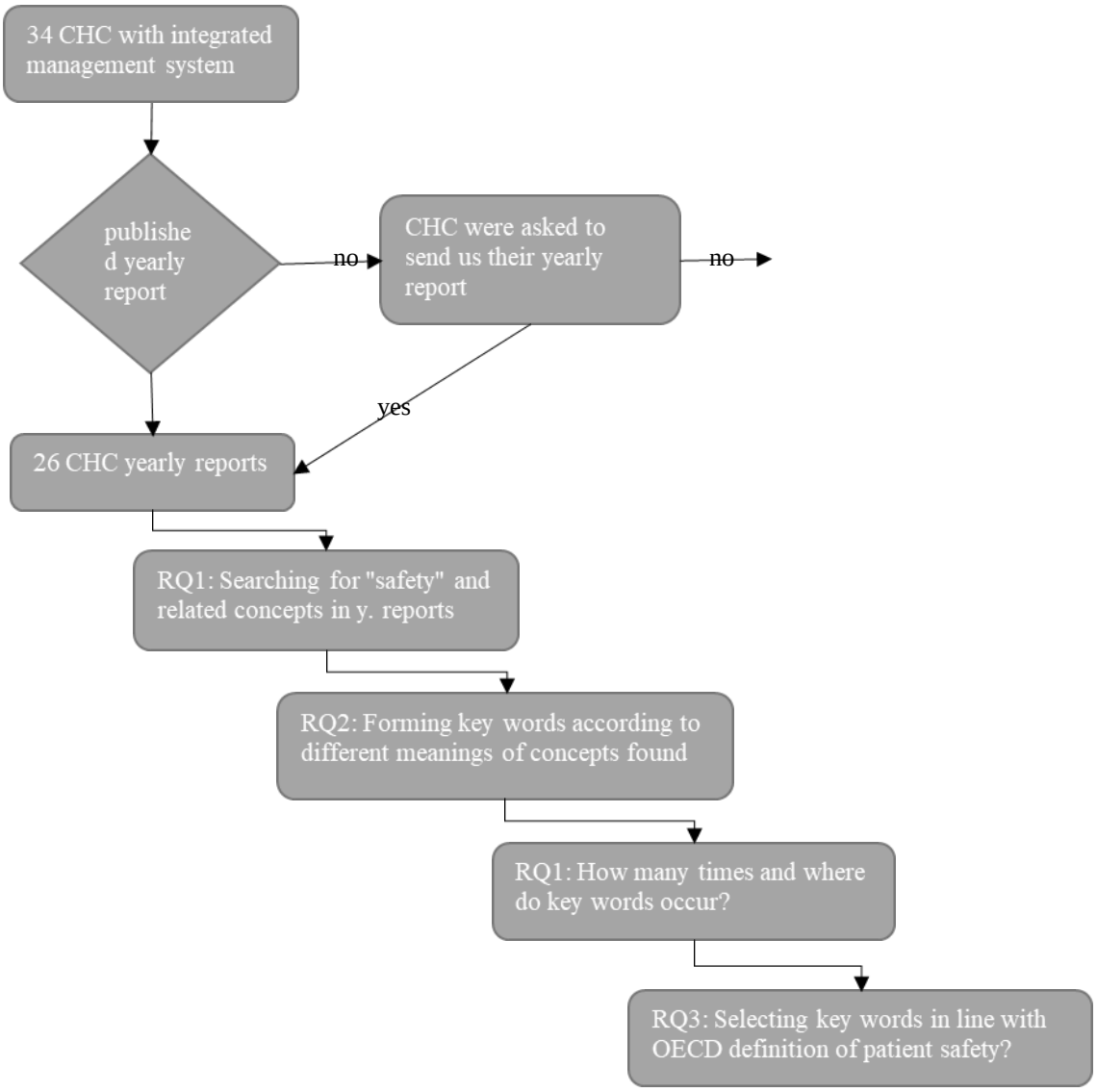

Figure 1. Research model

The validity of the study was ensured by two independent procedures performed by both authors, and a list of keywords was compared and agreed upon. The frequency of these keywords was counted in each annual report. This type of analysis is the least subjective among the different types of qualitative analysis and can be replicated by other researchers.

4 Results

In the annual reports, 11 different keywords related to safety, harm, and adverse events were found (Table 1). The most frequently found keyword was "social security", which refers to employees (n = 55). The reason for this result is the fact that there is only one term for safety and security in the Slovenian language, so many of our results refer to employees, including social security (n = 55), the safety of employees against fire and other accidents (n = 29), and safety and security of employees (n = 29).

Table 1. Keywords related to (patient) safety, harm and adverse events in CHCs annual reports

Key word/ CHC	Social security	Safety of employees against fire and other accidents	Physical safety & security of employees	Information security (also GDPR)	Patient safety – education or prevention activities	Patient safety - measures	Safety of health care - general	Drug safety, hygiene standards	Safety culture	Risk management (harm prevention)	Unwanted events	other	SUM
Ajdovščina	2	1			2								5
Celje	1	3	2				1						7
Cerknica	3									1			4
Črnomelj	3			9			1						13
Dravograd	1	1	2										4
Grosuplje	6	2								1			9
Ivančna Gorica		1							2				3
Kamnik	4	1										2	7
Koper		4	2	3				3					12
Laško	6												6
Lendava		3											3
Litija	1												1
Ljubljana	5	4	9		9	13			4	1		23	68
Medvode	3		6	2									11
Murska Sobota	4	1			7								12
Nazarje			1										1
Nova Gorica		1		1	1			4	2			2	11
Novo mesto		2								1			3
Piran		3	2						2	2			9
Ptuj	4												4
Sežana	3				1							1	5
Slovenska Bistrica	2	1		1		1							5
Slovenske Konjice	2		1										3
Trebnje	2	1	3				1			1			8
Velenje	3									1			4
Zagorje ob Savi			1										1
SUM	55	29	29	16	20	14	3	7	10	8	0	28	219

A very important issue in recent years has been the information security of patient and employee data. The General Data Protection Regulation (GDPR) was implemented in Slovenia in 2018, introducing stricter rules for collecting and using personal data; therefore, the topic of information security (n = 16) can be found in the 2018 annual reports.

The remaining keywords (grey colour in Table 1) no longer belong to 'security', but to 'safety', which relates to patients: Patient safety education or preventive measures (n = 20); Patient safety measures (n = 14); General healthcare safety (n = 3); drug safety, hygiene standards (n

= 7); Safety culture (n = 10); Risk management (harm prevention) (n = 8); There were no "unwanted events" in the annual reports. The last column refers to the term safety or security (in Slovenian this is one and the same term), which occurs in contexts other than those described in Table 1, but does not contribute to patient safety, i.e., other (n = 28).

5 Discussion

In our study, we investigated whether CHCs with an integrated management system (1) report on patient safety, (2) in what way, and (3) whether their reporting is consistent with the OECD definition of patient safety. Table 1 shows that the term safety and related terms appear 219 times in 26 annual reports.

Eleven keywords related to (patient) safety, harm and adverse events were found, but not all of them correspond to the OECD and EU definition of patient safety. Only six keywords correspond to the OECD definition of patient safety (i.e. they contribute to patient safety): patient safety education or preventive activities; patient safety measures; general healthcare safety; drug safety, hygiene standards; safety culture; risk management (harm prevention); adverse events. The "correct" keywords, i.e. keywords consistent with the OECD definition of patient safety, were found 62 times in 16 of 26 CHCs annual reports. It is difficult to comment on these results because there is no reference point: we only analysed the annual reports of Slovenian CHCs and have no information on how foreign CHCs report on patient safety. We expected that all CHCs with an integrated management system would report on quality and patient safety, as they have committed to report not only on financial indicators. They revise their processes annually in line with the standards set out in ISO and the revision is followed by a report and remedial action. The reports submitted by CHCs with integrated management systems are not structured according to the six OECD quality criteria, and CHCs are not instructed to report on patient safety.

Another interesting finding is that patient safety is not often mentioned in the annual reports of these 16 CHCs. In most cases, we find only one keyword that occurs only once (n = 8 CHCs). Only 8 CHCs mention patient safety more than once, with the largest CHC - Ljubljana CHC - taking the leading role, as patient safety is covered extensively there (n = 27). The annual report of Ljubljana CHC is not only extensive because it is very large (there are several departments of this CHC at different locations in Ljubljana), but it is also more detailed than other reports.

The results are somewhat disappointing, as we had expected all CHCs with integrated quality management systems to report on patient safety. Nevertheless, we cannot assume that CHCs that do not report on patient safety are negligent. We know that patient safety is part of the training of healthcare professionals: medicine, nursing, physiotherapy. They also have internal professional controls on patient safety and a strong mentoring system for young professionals that address patient safety.

We believe that patient safety is an important topic in CHCs' internal communications and procedures but is rarely mentioned in their reports. We believe that the safety culture in Slovenia

is not developed. Physicians in Slovenia are reluctant to report adverse events; most understand (medical) errors as moral disgrace or evidence of incompetence, even though 80% of these adverse events are a problem of the system and not caused by an individual physician (Robida, 2013, p.17). It is extremely important to build a culture of safety and encourage all healthcare workers to report on patient safety and analyse adverse events. Healthcare professionals and managers need to understand that most errors cannot and should not be attributed to any individual, but rather are due to the system's complexity. According to Mitchell (2008), the root causes of harm are identified as follows:

- "Latent failure—removed from the practitioner and involving decisions that affect the organisational policies, procedures, allocation of resources
- Active failure—direct contact with the patient
- Organisational system failure—indirect failures involving management, organisational culture, protocols/processes, transfer of knowledge, and external factors
- Technical failure—indirect failure of facilities or external resources" (Mitchell, 2008, p.3).

Health care professionals, especially physicians, feel threatened by this discussion; they are afraid of the "blame" effect and possible lawsuits. This contributes to covering up mistakes rather than bringing transparency to the system. Defensive medicine is more prevalent than safety culture (Robida, 2013), so much needs to be done in this area. Similar experiences with physicians have been seen in countries that have developed incident reporting systems (Denmark, Australia, United Kingdom), where mostly nurses report, but rarely physicians (Mitchell, Schuster, Smith, Pronovost & Wu, 2015, pp. 1-8).

This practice, however, must change. Many errors cannot be traced to a specific person; most so-called errors in the health care system are due to the complexity of the system and organisational problems. Sometimes the information system does not work as expected, sometimes there are communication errors, and sometimes a patient receives the wrong medication because of a mix- up due to similar packaging. In all of these cases, it is difficult or impossible to hold anyone responsible for the harm done. "To err is human, and expecting flawless performance from human beings working in complex, high-stress environments is unrealistic... Therefore, focusing on the system that allows harm to occur is the beginning of improvement, and this can only occur in an open and transparent environment where a safety culture prevails. This is a culture where a high level of importance is placed on safety beliefs, values and attitudes and shared by most people within the workplace" (WHO, 2019, para. 6). This study allowed us to assess awareness of the problem and willingness to talk about patient safety issues. The results show that improvements are needed in building safety culture . CHCs need to report regularly on patient safety to learn from mistakes and improve internal procedures to increase patient safety.

6 Conclusion

In our paper, the importance of patient safety for Slovenian community health centres was investigated by analysing their annual reports. Eleven different keywords related to safety, harm and adverse events were found in 26 CHCs with an integrated management system, but only six keywords met the OECD definition of patient safety: patient safety education or preventive activities (n = 20); patient safety measures (n = 14); general health care safety (n = 3); drug safety, hygiene standards (n = 7); safety culture (n = 10); risk management (harm prevention) (n = 8). These keywords were found in only 16 out of 26 CHCs annual reports.

This approach is a novelty because quality assurance procedures follow different protocols. External auditors evaluate selected processes and quality indicators. They recommend improvements, which are implemented by management. CHC's annual reports have a different purpose and structure. They reflect CHC's activities and contain certain statistical information. Nevertheless, we decided to analyse these reports to gain insight into the importance of patient safety for Slovenian CHCs. This research is an incentive for all CHCs, not only CHCs with an integrated management system, to build a safety culture, report on patient safety, learn from errors and mistakes, and develop safety protocols. Patient safety reporting is an important first step in achieving all of these goals.

Health care organisations like the CHC are accountable not only to their patients, but also to the taxpayers, so more comprehensive reports are welcome. Because CHCs have an important mission to improve the quality of life not only for patients but also for society as a whole, we encourage them to monitor patient safety in all their processes.

There are several limitations that affect the research: we did not analyse all CHCs, but only those that had an integrated management system. Contrary to our assumptions, not all CHCs had publicly available annual reports, so only 26 reports were analysed. We propose to conduct a similar research protocol that includes all Slovenian CHCs. Other important missing information relates to CHCs' reporting on patient safety: we need information on actions taken by management to improve patient safety. This data is important but was not available to us. Management practises are critical in this area - qualitative research in this area is welcomed to provide clarity on safety culture in primary health care.

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Mirna Macur, PhD, is an Associate Prof. at the Angela Boškin Faculty of Health Care, Slovenia. She is a sociologist and teaches methodological courses. Her research interests include various health topics such as quality of health care and behavioural addictions.

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Suzana Šuklar, PhD, is an expert in nursing, health care management and quality assessment. She completed her PhD in 2020 at the Faculty of Organisation Studies in Novo mesto. Since 2012, she has been a quality assurance manager at Community Health Center Murska Sobota. She is a member of the Quality Committee of the Association of Health Care Institutions in Slovenia and an external partner and SIO 9001 assessor at SQI.

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Povzetek:
Varnost pacientov v primarnem zdravstvenem varstvu – izziv sedanjosti in prihodnosti

Ozadje in izvirnost: Varnost pacientov je zelo pomembna dimenzija kakovosti, zato jo managerji v zdravstvenem varstvu in politiki pogosto naslavljajo, kar pa ne pomeni avtomatične integracije varnosti pacientov v nacionalne politike in ukrepe na ravni zdravstvenih organizacij. Ta prispevek raziskuje, kako pogosto slovenski zdravstveni domovi (ZD) poročajo o varnosti pacientov in ali je njihovo poročanje o varnosti pacientov skladno z OECD definicijo tega pojma. Originalnost te raziskave je v odkrivanju pravega pomena varnosti pacientov za ZD, ne glede na prevladujoče uradne izjave na nacionalni in organizacijski ravni.
Metoda: Raziskavo smo izvedli s pomočjo vsebinske analize po Vogrincu (2008, p.61) s katero smo iskali pojavnost besede varnost in sorodnih pojmov, ki poročevalcem pomenijo varnost. Analiziranih je bilo 26 poročil slovenskih ZD z integriranim sistemom kakovosti.
Rezultati: V letnih poročilih smo našli 11 ključnih besed, ki se navezujejo na pojem varnosti, a le 6 ključnih besed se je skladalo z OECD definicijo pojma varnosti: varnost pacientov – izobraževanje o tem ali izvajanje preventivne aktivnosti (n=20); ukrepi glede varnosti pacientov (n=14); varnost zdravstvene obravnave – splošno (n=3); varnost zdravil, varnostno higienski predpisi in standardi (n=7): kultura varnosti (n=10); obvladovanje tveganj (n=8).
Družba: Varnost pacientov je odgovornost tako zdravstvenih delavcev kot zdravstvenih ustanov. Družbena odgovornost ZD je poročati o varnosti pacientov v svojih letnih poročilih, graditi kulturo varnosti in sprejemati korektivne ukrepe takrat, ko je to za varnost pacientov potrebno, saj je poslanstvo ZD prispevati k višji kakovosti življenja tako pacientov kot družbe kot celote. Ta raziskava kaže na to, da celo ZD z integriranim sistemom kakovosti ne poročajo vsi o varnosti pacientov – nekateri celo nimajo javno dostopnih letnih poročil. Namen prispevka je spodbuditi vse ZD, ne le tistih z integriranim sistemom kakovosti, k rednemu poročanju o varnosti pacientov, učenju iz lastnih napak, izdelavi varnostnih protokolov ter graditvi kulture varnosti v svoji organizaciji.
Omejitve/nadaljnje raziskovanje: Raziskava je bila omejena na ZD z integriranim sistemom kakovosti (n=34), ki so imele javno dostopna letna poročila (n=26). Ključno je izvesti podobno raziskavo za vse ZD v Sloveniji in jih spodbuditi k poročanju o varnosti pacientov. Pomemben vpogled v kulturo varnosti bi predstavlja tudi analiza ukrepov vodstva ZD v zadnjih letih.

Ključne besede: varnost pacientov, kakovost v zdravstvu, OECD dimenzije kakovosti, neželeni dogodki, preprečevanje škode za paciente.

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