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**26. POSVET MEDICINA, PRAVO IN DRUŽBA:  
Varnost pacienta in zdravstvenih delavcev  
(23. - 24. marec 2017, Maribor, Slovenija)**

(konferenčni zbornik)

**Urednice:**

Suzana Kraljič  
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Vesna Rijavec

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## Varnost pacienta kot parameter kakovostne zdravstvene oskrbe

MARTA SJENIČIĆ

**Povzetek** Kakovostno zdravstveno varstvo pomeni organizacijo zdravstvenih virov na najbolj učinkoviti način z namenom, da se zadovolji potrebam pacientov za varno zdravljenje. Na področju zdravja obstaja več ravni kakovosti in varne zdravstvene oskrbe na najbolj osnovni ravni. To vključuje, med drugim, identifikacijo, analizo in korekcijo neželenih dogodkov, z namenom, da bo zdravstvena oskrba bolj varna in da bi se zdravstvena tveganja za paciente zmanjšala na minimum. Sčasoma je postalo znano, da neželeni učinki mnogokrat niso posledica posameznih opustitev, ampak kumulativni rezultat številnih razlogov. Zato je treba za zagotovitev varnosti pacientov in preprečitve neželenih dogodkov sprejeti ustrezne organizacijske in vodstvene ukrepe.

**Ključne besede:** • organizacija • management • opustitev • neželeni učinki • prevencija

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## Patients' Safety as Parameter of Health Care Quality

MARTA SJENIČIĆ

**Abstract** Qualitative health care implies the organisation of health resources in a most efficient way, in order to satisfy patients' needs for the safe treatment. There are several levels of quality in health, and the safe health care in the most basic level. It comprises, amongst other things, identification, analysis and correction of the adverse events, with the purpose to make health care safer and to bring health risks for the patients down to the minimum. Over time, it has become recognizable that adverse events are not often the consequence of individual omissions, but the cumulative result of many reasons. Therefore, some organizational and managerial steps should be undertaken in order to secure patients safety and prevent adverse events.

**Keywords:** • organisation • management • omission • adverse events • prevention

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## 1 Introduction

Health care quality is the extent to which health services provided to individuals and patient populations improve desired health outcomes and which is in line with the professional knowledges (Institute of Medicine (<http://www.pearpt.com/performancequality-improvement/the-definition-of-healthcare-quality-and-the-institute-of-medicine/>); Lohr & Shroeder, 1990: 707-12). It can also be defined as the result of measures undertaken in line with contemporary knowledges in health procedures, and which ensure the highest possible desired outcome of treatment and reducing the risks of adverse events and consequences for humans' health (Article 2 Zakon o kvaliteti zdravstvene zaščite i socialne skrbi (NN 124/2011)). More precise definition of quality health care, that add organizational, policy and financial interests is the one given by Ovretveit (Ovretveit, 1995: 2): Quality health care is full satisfaction of needs of those who need health services, at the lowest expenses for organization, and within the limitations and guidelines set up by health authorities and financiers. All definitions are focused to the health services/measures undertaken in line with contemporary knowledges and desired outcomes. The last one add more realistic view related to the expenses and organizational limitations. Common denominator of the previous definitions is sensitivity to the actual needs of health care users. However, quality is not just the reflection of patients' needs, since patients sometimes do not know what they can require or need. In most of the cases, patients' request (based on his autonomy) has to be followed by the medical indication for treatment/diagnostics (except, for example, in aesthetic surgery). These two conditions are the main pillars of the liable health acting. When only the patients' request would be followed, this could lead to inadequate or harmful treatment. Of course, even when satisfied patients' needs, health service can be inefficient or too expensive, and thus treated as low quality (having in mind the abovementioned most comprehensive definition). So, qualitative health service is not the one provided at any price, but the one that satisfies patients' and professional needs and purposes, and in parallel provided in the most efficient way. And, of course, all in line with the legal and ethical requirements. These considerations, obviously, lead to the conclusion that quality health care is the resultant of sometimes contradictory requirements of the different interest groups (Agencija za kvalitet i akreditacijo u zdravstvu FBIH).<sup>1</sup>

There are many dimensions of the health care quality or qualitative health activity. Fulfillment of these dimensions are parameters of delivery qualitative health care. These are: efficiency, accessibility, efficacy, continuity, equity, acceptability, timeliness, appropriateness, availability, safety, effectiveness. One of the basic parameter is patients' safety. When assessing conditions for health service delivery in one health institution, relevant assessment body (inspection – health, but also sanitary, construction, etc.), in the first step, checks whether health care provider has fulfilled basic, general conditions for provision of health services. These are usually prescribed in mandatory health regulation

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<sup>1</sup> Agencija za kvalitet i akreditacijo u zdravstvu FBIH, [http://www.akaz.ba/Index/Sta\\_je\\_kvalitet.htm](http://www.akaz.ba/Index/Sta_je_kvalitet.htm) (12.1.2017).



of one state, as necessary for opening and functioning of health care facilities.<sup>2</sup> However, basic conditions are usually not enough to guarantee patients' safety. Basic standards must not be the optimal standards. We are still not considering here the quality of health care, nor the patients' safety, as its basic feature.

## 2 Patients' Safety as the basic feature of the qualitative health care

Patients' safety is the basic feature and condition of qualitative health care. It is *conditio sine qua non*, but, at the same time, the main objective of an adequate health service delivery. It is also the fundamental principle of patient care and critical component of quality management. Its achievement demands a complex systemwide effort, involving a broad range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice and safe environment of care. Patients' safety embraces nearly all health-care disciplines and actions, and thus requires comprehensive, multifaceted approach to identifying and managing actual and potential risks to patient safety in individual services and finding broad long-term solutions for the system as a whole. Problems in practice, products, procedures or systems may result with adverse events (World Alliance for Patient Safety, 2004: 3). Therefore, emphasize should be put on every component of patients safety, as opposed to solutions driven by narrower and more specific aspects of the problem, which tend to underestimate the importance of other perspectives (World Alliance for Patient Safety, 2004: 4). Current conceptual thinking on the safety of patients places the prime responsibility for adverse events on deficiencies in system design, organization and operation rather than on individual providers or individual products (World Alliance for Patient Safety, 2004: 3).

## 3 Adverse events as the parameter of patients' (un)safety

In 2004, World Health Organization established the World Alliance for Patients' Safety which published, so called, Forward Program. Program exposes the data on adverse events rate from several countries which varies from 3,2 to 16,6% and also the data estimating the costs of nosocomial infection in several countries (World Alliance for Patient Safety, 2004: 2-8). Several studies, including a total of 74.485 patient records

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<sup>2</sup>For example: Pravilnik o pogojih, ki jih morajo izpolnjevati primarni centri za dojke (Uradni list RS, št. 110/04); Pravilnik o pogojih, ki jih mora izpolnjevati zavod za izvajanje praktičnega pouka dijakov zdravstvenih šol in študentov visokošolskih zavodov za podelitev naziva učni zavod (Uradni list RS, št. 103/05); Pravilnik o pogojih za opravljanje lekarniške dejavnosti (Uradni list RS, št. 39/06 in 85/16 – ZLD-1); Pravilnik o pogojih za opravljanje zasebne zdravstvene dejavnosti (Uradni list RS, št. 24/92 in 98/99 – ZZdrS), and other; Pravilnik o bližim uslovima za obavljanje zdravstvene delatnosti u zdravstvenim ustanovama i drugim oblicima zdravstvene službe ("Sl. glasnik RS", br. 43/2006, 112/2009, 50/2010, 79/2011, 10/2012 - dr. pravilnik, 119/2012 - dr. pravilnik i 22/2013); Pravilnik o minimalnim uvjetima u pogledu prostora, radnika i medicinsko-tehničke opreme za obavljanje zdravstvene djelatnosti (Narodne novine, Službeni list Republike Hrvatske: NN 61/2011, br. 1374); Pravilnik o bližim uvjetima prostora, opreme i kadra za osnivanje i obavljanje zdravstvene djelatnosti u zdravstvenim ustanovama („Službene novine Federacije BiH“, br. 26/12, 23/13, 90/13, 15/14, 82/14 i 83/2015).

show that median overall incidence of in-hospital adverse events was 9.2%, with a median percentage of preventability of 43.5%. More than half (56.3%) of patients experienced no or minor disability, whereas 7.4% of events were lethal. Operation- (39.6%) and medication-related (15.1%) events constituted the majority (Vries et al., 2008: 216-223).

Alliances' common attitude is that appearance of adverse events is the consequence of the omissions in organization and activities of the system, and not the consequence of the individual or the products. Actually, current conceptual thinking on the safety of patients places the prime responsibility for adverse events on deficiencies in the system design, organization and operation rather than on individual providers and producers. Every point in the process of care giving contains a certain inherent lack of safety: side-effects of drugs or drug combinations, hazards posed by medical device, substandard or faulty products entering the health service, human shortcomings, or system (latent) failures. For example, adverse drug events in the Utah Colorado Study in the USA, provide an example, 75% of them being attributable to system failures (World Alliance for Patient Safety, 2004: 2-8). Adverse events occur not because people intentionally hurt patients. They are, rather, due to the complexity of today's health-care systems, especially in developed countries, where the successful treatment and outcome for each patient depend on a range of factors and not just the competence of one individual health-care provider. When so many different types of health-care providers (doctors, nurses, pharmacists and allied healthcare workers) are involved, it is very difficult to ensure safe care unless the system of care is designed to facilitate timely and complete information and understanding by all the health professionals (WHO Patient safety curriculum guide: multi-professional edition, 2011: 29). Countermeasures based on changes in the system are therefore more productive than those that target individual practices or products.

Enhancing the safety of patients includes three complementary actions: preventing adverse events; making them visible; and mitigating their effects when they occur. Despite growing interest in the safety of patients, there is still widespread lack of awareness of the problem of adverse events. Capacity for reporting, analyzing and learning from experience is still seriously hampered by lack of methodological uniformity in identification and measurement, inadequate adverse event reporting schemes, undue concerns over breaches in confidentiality of data, the fear of professional liability and weak information systems (World Alliance for Patient Safety, 2004: 4).

Alliance for Patient Safety decided to deal with the so called Global Patient Safety Challenges. First Global Patient Safety Challenge was health-health care associated infection. Due to in-hospital infection complications, some patients become more seriously ill than they would have been otherwise, some have prolonged stays in hospital, some experience long-term disability and some die. This generates additional financial burden for the system. Some countries assessed the expenses of nosocomial infections even in 80ties, and found out that they were very high, but still different depending on the type of infections prevalent in the hospitals, the infection rate and the cost of health care (World Alliance for Patient Safety, 2004: 7-9). The conclusion was that health-care

associated infection presents the major characteristics of a major patient safety problem, and it affects large numbers of patients world-wide; it has multiple causes, with many factors relating to the systems and processes of care provision, to human behavior; it cannot be eliminated but some healthcare institutions have controlled the problem and the risks to patients much better than others (World Alliance for Patient Safety, 2004: 9). It was planned that Global Patient Safety Challenge for 2005 to 2006 would have the motto: Clean Care is Safer Care. By this WHO challenge, countries are invited to adopt the following principles: formally assessing the scale and nature of health-care-associated infection within the health-care system; adopting an internationally recognized approach to surveillance of the problems so that current baseline incidence of infection can be established and change can be monitored; conducting an analysis of the root causes of the problem with particular emphasis on “systems thinking”; developing solutions to improve safety and reduce risk by focusing on five action areas in particular: clean hands, clean practices, clean products, clean environment, clean equipment; relying on evidence-based best practice in all aspects of addressing the challenge; fully engaging patients and service users as well as health care professionals in improvement and action plans; ensuring the sustainability of all action beyond the initial two-year Challenge period (World Alliance for Patient Safety, 2004: 9-10).

Although motto and the action “Clean Care is Safer Care” sounds simple, a number of countries did not make the assessment of nosocomial infections and adverse events in the hospitals. It is questionable if it can at all be done in this moment, having in mind the weak reporting systems on adverse events and the weak response, in many countries. Example of a failure to report adverse event, and thus to react further for saving the patients' health, or failure in organization, is the example of Mr. M.S. from Belgrade which had hiatus hernia and GERB, and was operated in one Belgrade clinic. He underwent treatment of laparoscopic Nissen procedure. A month later in the postoperative process the infection was found in the area of left lateral incision for trocar, since it seemed that the incision was too high positioned, with a doubt to chondritis (inflammation of cartilage). Mr. M.S. was prescribed antibiotic (Ciprofloxacin), but in parallel the smear was done. Smear results showed existence of bacteria – *Pseudomonas aeruginosa*, sensitive only to Collystin, which was not on the Serbian positive list of drugs. A month later the chondritis of the lower ribs was diagnosed and it was concluded that operative treatment is indicated. However, the patient was released from the hospital day after the conclusion, without operative treatment with the documented explanation that it will be “scheduled later”. Two weeks later, the patient insisted on the operation in another clinic, and was operated: fistulectomy and resection of the ribs cartilage were done, and Collystin was applied. A month later additional excision of the soft tissue was done with additional resection of the parts of ribs cartilage. A week later, pus appeared in the wound again and the Collystin was applied again with the additional curettage. Patient was then transferred to the infection department with fever, pains and with pus in the wound. On his own request, patient was released from the hospital, and departed abroad, where he was operated a month later in a private clinique. Wide debridement of necrotic wound in the chest left side, cutting of necrotic and inflamed tissue, debridement of the inflamed cartilage of the seventh and eighth rib, biopsy, taking of culture, were

performed. After that, left chest was reconstructed by transferring of right vertical abdominal rectus muscle. Reconstruction was necessary in order to close the wound and for the efficient treatment of infection, in order to enable the blood flow and concentration of antibiotic in the infected area. Collystin had been applied for 6 weeks. A month later one more debridement was done. Patients life was saved, but with huge consequences on his health, body, spiritual stability, working capability, finances, carrer, etc. He is missing most of tissue that protects the heart. If the trocar was not placed too high with the infected instruments, if the first hospital reacted earlier with the operational treatment and with the right antibiotic (no matter the positive list) the damage would be prevented or reduced. However, it seems that fear, trying to reject responsibility for bad organization, sticking to the positive list of drugs (instead of informing patient on the need to buy the medicine), or avoiding to acknowledge the lack of knowledge and to refer to the health institution competent for this issue, brought to enormous damage, and litigation. This case leads us towards two main conclusions: 1. Physician must not know everything, but he must be aware of the fact that he doesn't know something (Radišić, 2007: 81); in such cases he should refer the patient to another health instance, another health institution; 2. If such adverse events would be reported, this would lead to prevention of further adverse events. The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures in the health-care system. There is an evidence that most problems are not just a series of random, unconnected, one-off events. Health-care errors are known to be provoked by weak systems and often have common root causes that can be generalized and corrected. Although each event is unique, there are likely to be similarities and patterns in the sources of risk that may otherwise go unnoticed if incidents are not reported and analyzed (World Alliance for Patient Safety, 2006-2007: 40).

#### **4 Reducing the risks of health care and improving its safety**

As it is already emphasized, enhancing the safety of patients includes three complementary actions: preventing adverse events; making them visible; and mitigating their effects when they occur. Namely, consequences of adverse events are huge and affect all sides in the process of treatment. On one side, financial costs of adverse events in terms of additional treatment and extra days in hospital is vastly greater than the costs of litigation. Besides that, costs of lost working time, disability benefits and the wider economic consequences are making this financial loss even bigger. Human cost is also enormous – many patients suffer increased pain, disability and psychological trauma and may experience failures in their treatment as a betrayal of trust. Damage on the side of medical staff can be seen as shame, guilt and depression after making a mistake, with litigation and complaints imposing an additional burden. Doctors or nurses whose confidence has been impaired will work less effectively and efficiently and, at worst, they may abandon medicine as a career (World Alliance for Patient Safety, 2004: 17-18).

Prevention of adverse effects, require measurement of health care quality by setting the quality indicators. It is very important to determine what is being measured, by which indicators, and sources of data for their calculation, to set the process of analysis and

understanding this process, till distribution of the results. Indicators should be specific and sensitive, valid and reliable, should differ quality from lack of quality, should relate to identified event, should be comparable, and should be evidence-based. Quality indicators could be related to structure, process or result. For example, structural indicator is the availability of specific units (for stroke), or that clinical guidelines are reviewed every two years. Processual indicators are, for example, proportion of patients with diabetes that receives counsels for the leg care, or proportion of patients that were examined within 24 hours. Result indicators are, for example, value of blood pressure at patients with hypertension, or mortality, morbidity, etc. These pointing to the nosocomial infections are bacteremia with *Staphylococcus aureus* related to health care delivery or infection with *Clostridium difficile*.

The next step in the process of prevention of adverse events and enhancing the patients' safety is setting the reporting system. It is the response to reports that leads to change. Within a health-care institution, the reporting of a serious event or serious near-miss should trigger an in-depth investigation to identify underlying systems failures and lead to efforts to redesign the systems to prevent recurrence. In a state or national system, expert analyses of reports and dissemination of lessons learned are required if reports are to influence safety. Merely collecting data contributes little to the advancement of patient safety. Even monitoring for trends requires considerable expert analysis and oversight of the reported data. The important point is that a reporting system must produce a visible, useful response by the recipient to justify the resources expended in reporting, or, for that matter, to stimulate individuals or institutions to report. Reporting and response system can lead in several ways to learning and improved safety. Firstly, it can generate alerts regarding significant new hazards (e.g. complications of a new drug). Secondly, lessons learned by hospitals from investigating a serious event can be disseminated. Thirdly, analysis of many reports by the receiving agency can reveal unrecognized trends and hazards requiring attention. Finally, analysis of multiple reports can lead to insights into underlying systems failures and generate recommendations for "best practices" for all to follow. The best-practice guidelines that can be used to facilitate the development of new reporting systems to improve patient safety and to improve existing reporting systems, should be developed. The core principles underlying the guidelines should be: the fundamental role of reporting systems is to enhance safety by learning from failures, i.e. errors and injuries caused by medical treatment; reporting must be safe, individuals who report incidents must not be punished or suffer other consequences; reporting is only of value if it leads to a constructive response. At a minimum, this entails feedback of findings from data analysis. Ideally, it also includes recommendations for changes in processes and systems of health care; meaningful analysis of, learning from, and dissemination of lessons learnt from reports require expertise and other human and financial resources. The agency that receives reports must be able to influence solutions, disseminate information and make recommendations for changes (World Alliance for Patient Safety, 2004: 23-24).

Beside the guidelines of WHO, some states set their own system of patients' safety and prevention of adverse events. National Health Service of UK (hereinafter: NHS) outlined

through reference guide seven steps to patients ‘safety, as a general pathway, but also specifically, in mental health, in primary care and in general practice. “Seven steps to patients’ safety” contains detailed guide of the UK National Reporting and Learning Service (NRLS)’s (National Patient Safety Agency<sup>3</sup>) to good practice, which covers building a safer culture and managing, reporting and learning from patient safety incidents. It sets out the seven steps that NHS organizations should take to improve patient safety. It builds on recommendations from two reports and findings from studies in the UK, USA, Australia, New Zealand and Denmark. These highlighted the number of patient safety incidents, whether they contributed to patient deaths, and whether they could have been prevented. The steps provide a simple checklist to help NHS organizations plan their activity and measure performance in patient safety. Following them will help ensure that the care they provide is as safe as possible, and that when things go wrong the right action is taken. They will also help NHS organizations meet their current clinical governance, risk management and controls assurance targets. The steps are: 1. Build a safety culture. 2. Lead and support your staff. 3. Integrate your risk management activity. 4. Promote reporting. 5. Involve and communicate with patients and the public. 6. Learn and share safety lessons. 7. Implement solutions to prevent harm (Seven steps to patient safety: full reference guide, 2004: 11).

Slovenia adopted The National Strategy for Quality and Safety in Health Care in 2010 (Simčič, 2010) and the Accreditation Council was nominated in 2011. Such bodies/agencies for quality in health and accreditation are, very often, the bodies assessing and tending to give support to the health care providers in improvement of delivery of safe and qualitative health care. The initiative for these steps in Slovenia were improvement of the general health quality, for provider, as for the user of health services. It was seen as a great challenge, having in mind the lack of outer motivation (like market stimulus) in public sector. The success in health sector was seen as dependent of intellectual and moral potentials, efforts focused on doing right things in the right time and in the right manner, during the health diagnostics and treatment. In practice, this means: evidence based medicine; following the needs and expectations of patients; adequately educated medical staff; and availability of necessary resources. Ministry of Health of Slovenia supported the introduction of the system of self-evaluation and external accreditation by issuing the several documents – programs for internal and external quality assessment (Simčič, 2010: 7).

Complete system of quality management was introduced in several hospitals in Slovenia. Ministry of health set the system for monitoring of adverse events in 2002. However, the National Program emphasizes, that professional quality is being changed very slow and that the continuous, long term and systematic improvement of this process is necessary. Challenges in this area, set by the Strategy, are lack of trust and fear from sanction in the case of adverse events reporting. The communication between employees, IT support and different approaches to the patients’ treatment are considered as a challenges in drafting and issuing the clinical pathways, which would considerably fortify health care quality,

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<sup>3</sup> Available : <https://report.nrls.nhs.uk/nrlsreporting/Default.aspx> (10.2.2017).

and patients' safety (Simčić, 2010: 9-10). However, Slovenian Ministry of Health has issued in 2009. Guide for Drafting the Clinical Pathways (Priročnik za oblikovanje kliničnih poti, 2009).<sup>4</sup>

Slovenian National Strategy contains the Action Plan with the objectives, relevant bodies and deadlines, set for the purpose of improvement of health care quality and patients' safety. It emphasizes the necessity of introducing the patients' safety issue into the formal education of health professionals, especially at the high education level curricula (Simčić, 2010: 10-11).

Republic of Serbia adopted the Strategy for continuous improvement of health care quality and patients' safety (Strategija za stalno unapređenje kvaliteta zdravstvene zaštite i bezbednosti pacijenata (Službeni glasnik RS, br. 15/2009). Agency for accreditation of health care institutions of Serbia enacted the Guide for implementation of measures for patients' safety (Priručnik za sprovođenje mera za bezbednosti pacijenata prema zahtevima Agencije za akreditaciju zdravstvenih ustanova Srbije, 2010).<sup>5</sup> According to the Guide, depending on the level of standards health care provider would like to accept and implement in its practice, initial steps for ensuring the patients safety based on the international goals are: 1. Fortifying the procedures in surgery related to safety; 2. Reducing the possibilities of infection in health institutions to minimum; 3. Safe handling of medicaments; 4. Care and treatment of the "right" patient; and 5. Safe treatment by eliminating of adverse events. Guide is quite precise in pointing out what should, stepwise, be done in order to ensure patients' safety, within these steps. In surgery, for example, the WHO Surgical control list has to be applied, as follows: Preoperative period • Communication between the operative team and the patient confirming the procedure and the consent for treatment; • confirmation of patient allergies; • comprehensive examination of the anesthetic machinery and medications; • communication between the surgeon and anesthesia provider. Perioperative period • Confirmation of imaging and laboratory results; • confirmation of sterility of the instruments and equipment; • appropriate and timely administration of antibiotics; • communication of critical events that will occur during the procedure. Immediate postoperative period • Reconciliation of instrument and sponge counts; • communication between the surgeon, nurse and anesthesia provider regarding the intraoperative events and the postoperative care plan (Priručnik za sprovođenje mera za bezbednost pacijenata prema zahtevima Agencije za akreditaciju zdravstvenih ustanova Srbije, 2010: 9; World Alliance for Patient Safety, 2006-2007: 24).

Related to the objective of reducing of in-hospital infections, health institution has to apply strategy for hands hygiene and to monitor its implementation continuously. Regarding safe drugs management, health institutions have, according to the Guide, to keep

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<sup>4</sup> Available:

[http://www.mz.gov.si/fileadmin/mz.gov.si/pageuploads/kakovost/Klinicne\\_poti/prirocnik\\_OBLI\\_KOVANJE\\_KP\\_slo\\_170310.pdf](http://www.mz.gov.si/fileadmin/mz.gov.si/pageuploads/kakovost/Klinicne_poti/prirocnik_OBLI_KOVANJE_KP_slo_170310.pdf) (10.2.2017).

<sup>5</sup> Available : <http://www.azus.gov.rs/wp-content/uploads/2010/01/prirucnik-sa-koricama.pdf> (11.2.2017).

concentrated electrolytes out of in-hospital departments, to apply program for safe use of narcotics and to provide program of education for using of infusion pump. Regarding care and treatment of the “right” patient, Guide points out the necessity of application of the system for identification of patient, as the necessary set of activities. Separate objective set out in the Guide is safety of the patient through elimination/reducing to minimum of adverse events. Requested activity is application of the system for early and easy detection of adverse events.

Accreditation in Serbia is not a mandatory process. It is conducted on a voluntary basis, per request of health care providers. Therefore, some health institutions went through this process and improved the quality of health service provision, which includes the increasing the level of patients’ safety. Of course, some of them did not go through this process. Besides, there is no established system of adverse events reporting. This is pretty much still considered as an individual fault, instead of putting the emphasize on the improvement of organisation and quality management, in line with the enacted Strategy and Guide, and with WHO documents.

## **5 Conclusion**

Qualitative health care implies the organisation of health resources in a most efficient way, in order to satisfy patients’ needs for the safe treatment. Safe health care in the most basic level of quality. It comprises, amongst other things, identification and reporting on adverse events, their analysis and an adequate response, with the purpose to prevent further adverse events and to make health care safer and bring health risks for the patients down to the minimum. Over time, it has become recognizable that adverse events are not often the consequence of individual omissions, but the cumulative result of many reasons. Therefore, organizational and managerial steps should be undertaken in order to make the right working environment for medical professionals, in which they would perform their activities in line with the procedures and standards that secure safe diagnostics and treatment of patients, and prevent adverse events. Also the adverse events reporting and response system should be set up in the manner which would disable punishment of individuals for the omissions, which are on the side of bad quality management.



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