EMPIRICAL EVALUATION OF A CONCEPTUAL MODEL FOR THE PERCEIVED VALUE OF HEALTH SERVICES

EMPIRIČNO PREVERJANJE KONCEPTUALNEGA MODELA ZAZNANE VREDNOSTI ZDRAVSTVENE STORITVE

Teodor PEVEC[1*], Aleksandra PISNIK[2]

[1]General Hospital Ptuj, Surgery Department, Potrčeva 23, 2250 Ptuj, Slovenia
[2]University of Maribor, Faculty of Economics and Business, Razlagova 14, 2000 Maribor, Slovenia

ABSTRACT

Keywords:
health services,
perceived value,
satisfaction, loyalty,
reputation, quality,
price, factor analysis,
linear structural
equation modelling

Introduction: Perceived value and its antecedents and consequences have been claimed to be important in industries with higher customer involvement. The aim of this paper is therefore to empirically assess the conceptual model, with perceived service value as its central component. It also investigates how it affects loyalty and satisfaction, how it is influenced by its antecedents, and to compare with other studies investigating partial relationship between variables.

Methods: A total of 800 patients were enrolled in the main study, and the data was analysed using exploratory and confirmatory factor analyses. By modelling linear structural equations, we assessed reliability and established the convergent and discriminant validity of the questionnaire in the same way as in the pilot study.

Results: In the conceptual model for testing our hypotheses, we also included the relationship between patient satisfaction and loyalty. In this manner, the fitting of data to the model was significantly improved. After including the additional relationship, global fit indices had the following values: Chi-square=349.6 (sig.=0.00), df=143, RMSEA=0.05, NFI=0.96, CFI=0.97. All relationships between the constructs were statistically significant, thus confirming all our hypotheses.

Conclusions: The major conclusion of this paper is that an especially higher reputation and higher perceived service quality can contribute to perceived service value and therefore to more satisfied patients. The research approach has a few limitations. In the future, the model of perceived service value can be extended with variables such as emotions, patient trust, and commitment as well.

IZVLEČEK

Ključne besede:
zdravstvene storitve,
zaznana vrednost,
zadovoljstvo, zvestoba,
ugled, kakovost,
cena, faktorska
analiza, modeliranje z
linearnimi enačbami

Uvod: Koncept zaznane vrednosti storitev spada s svojimi predhodniki in posledicami med temeljne koncepte predvsem v storitveni dejavnosti. Namen članka je empirična preverba konceptualnega modela zdravstvenih storitev z njihovo zaznano vrednostjo kot središčno komponento ter povezav s predhodniki (zaznana kakovost storitve, cena, ugled) in posledicami (zadovoljstvo, zvestoba).

Metode: Za razvoj merilnega instrumenta smo naredili pilotno raziskavo, s čimer smo preverili zanesljivost in veljavnost vprašalnika. Uporabili smo eksploratorno (EFA) in konfirmatorno (CFA) faktorsko analizo ter Cronbachov koeficient alfa. V glavno raziskavo smo vključili 800 bolnikov. S pomočjo linearnih strukturnih enačb smo testirali hipoteze.

Rezultati: V naš model smo dodatno vključili še povezavo med zadovoljstvom in zvestobo. Na ta način smo dobili tako vsebinsko kot statistično ustrezen model. Med samimi gradniki so bile različno močne povezave, ki pa so bile vse statistično potrjene, tako da smo potrdili vse naše hipoteze. Indeksi globalne ustreznosti kažejo, da smo izbrali primeren model (Hi-kvadrat 349,6, df = 143, RMSEA = 0,05, NFI = 0,96, CFI = 0,97).

Zaključki: Večji ugled in zaznana višja kakovost storitve vodita v zaznano večjo vrednost storitve in k zadovoljnejšim bolnikom. V prihodnosti bomo razširili model zaznane vrednosti storitev s spremenljivkami, kot so čustva, zaupanje, predanost.

*Corresponding author: Tel. + 386 41 650 335; E-mail: teodor.pevec@sb-ptuj.si

1 INTRODUCTION

In recent decades, the entire world economy has seen a rise in the importance of services due to their ever-increasing share in national GDPs, especially in the so-called emerging economies, such as Slovenia. This trend is reflected in the vast number of research projects that are service-focused (1). Perceived service value and its antecedents and consequences are considered important in industries with higher customer involvement (2), where the relationship and cooperation between the provider and the customer are of high significance, such as in the health sector. Suppliers require a closer understanding of the concept of perceived service value, which represents one of the key and basic concepts, not only in marketing (3, 4), but also in the business of any organisation in the market. Using insights from other services, such as Hospitality (5), Internet Banking (4, 6), Banking (7), and Tourism (8), in which the concept of perceived service value has been explored thoroughly and tested empirically, we have transferred this concept to the field of Healthcare Services and defined its elements and the relationships between them. Furthermore, results of prior research (9) have shown that both perceived service value and perceived service quality dimensions should be incorporated into customer satisfaction models to provide a more complete picture of the drivers of satisfaction.

In previous studies the authors focused on the connections between individual elements, for instance, the effect of reputation on quality, satisfaction, and loyalty (10), the relationship between satisfaction and loyalty (11), the relationship between quality, satisfaction, and value (12), the relationship between non-monetary price, perceived value, and satisfaction (13), or they tried to determine the dimensions of perceived service value (14-16). From additional studies of other service industries, we know that the concept of perceived service value is the concept around which revolve both the benefits, such as the most frequently described perceived service quality and reputation and the costs in the form of prices, both monetary and non-monetary. On the other hand, customer satisfaction with performed services and customer loyalty are the most researched consequences of perceived service value.

While the relationship between perceived service quality and customer satisfaction has been well explored in the past, perceived service value has remained a comparatively neglected aspect of customers' experiences (17-19), especially in the healthcare industry, where international experiences have shown the rising importance of this concept in healthcare.

The aim of this paper is to assess the conceptual model empirically, with perceived service value being its central component. Examining the perceived service value of health services in an emerging economy makes sense from the scientific, as well as from the professional point of view. Customer behaviour in general, as well as perceived service value, has been studied mainly from a rational perspective. Nowadays, especially in the services` context, increasing attention is being paid to emotional components. From that point of view, it is necessary to incorporate not only a cognitive variable, but also affective variables into the research of perceived service value (8). Furthermore, in health services, previous research usually used different criteria, which were primarily economic in nature, with objective measures, neglecting more subjective aspects, in particular, perceived service quality (20) or perceived service value. With changes in emerging economies, where private competitors in the sector of health care evoke, it is important to understand what activities contribute to more satisfied customers and, consequently, to sustainable competitive advantage. Therefore, our aim is to contribute to the field with incorporating more subjective aspects into the research of perceived service value in healthcare.

To analyse direct and indirect relationships between researched concepts, we used structural equation modelling, a multivariate method, which, in contrast to ordinary regression analysis, considers all the variables in the model simultaneously instead of separately (21).

1.1 Theoretical Description of Model Elements and Hypotheses` Development

Zeithaml's definition (22) states that the perceived service value is a ratio between what you gain and what you have to sacrifice for it. When possible, patients chose those healthcare providers they perceive as valuable (16). Numerous researchers (23-25) have claimed that the perceived service value set by a patient represents an overall assessment of a health service, which is based on patients' perceptions of what was gained and what was invested. As the consequences of perceived service value for patients, various authors have listed (26-28) patients' satisfaction and loyalty.

In general, perceived service quality is one of the most important benefits for the customer. In healthcare, perceived service quality is defined as the gap between patients' expectations and their perceptions of health services (29). Also, two dimensions of perceived service quality are distinguished in the field of healthcare, namely, technical and functional quality (30). Technical quality in the healthcare industry refers to the accuracy of diagnostic and therapeutic processes; whereas functional dimension refers to the manner and behaviour of the healthcare providers during the service delivery process.

The next benefit for the customers, in general, is reputation. Due to the lack of information that would

be helpful to patients in selecting their healthcare providers, their choice often depends on the reputation of health services providers (31). Satir (32) suggested that the reputation of medical institutions should be assessed through patients' perceptions. The public sector is thought to be a knowledge-based industry, whose reputation depends on the perception that customers have of its services (33). Hibbard et al. (34) believe that a diminished hospital reputation can easily lead to a considerable drop in patient visits. A relevant article in Healthcare Collector (35) informs us that as much as 75% of patients use reputation as their primary criterion of choice. In specialised institutions, patients try to seek out those doctors who have gained more respect in the eyes of the people whose opinions they solicited (information by word of mouth).

On the 'give' side of perceived service value equation price (36) is among the most important, because it is something that the customer has to consider sacrifice in order to obtain some products. The definition of price as a sacrifice is in line with other researchers' conceptualizations of this notion (37). For Hafer (37), this sacrifice includes, in the strictest sense, the monetary and non-monetary elements of the price, as well as the risks attached to the services rendered. The non-monetary element of the price is exclusively a function of time, and Hafer distinguishes between the time needed to get to the service provider, the time spent waiting for the service, and the time needed to finish the rehabilitation after the service is performed. Certainly, time spent waiting for some services to be performed is very important and may even be the most important aspect of health services. Other scholars include additional elements in the concept of non-monetary price. For instance, Sloan (38), included ease of access and the waiting time for the service, i.e., the waiting queue (39). Furthermore, certain psychological factors are also added to the aforementioned elements of the price, such as the patient's fear or apprehension, and the treatment upon admission to the facility for treatment (40, 41).

Considering the consequences of perceived service value, customer satisfaction is one of those mentioned most commonly. Oliver (42) defined satisfaction as a psychological phenomenon that results from one's expectations about the emotions and experiences prompted by a purchase. If a patient's expectations have been met, it results in their satisfaction. As stated, perceived service quality is defined as the difference between the expected and the perceived. The response to this is shown as satisfaction. Therefore, perceived service quality is an antecedent of customer satisfaction. Likewise, in healthcare, patient satisfaction represents a key indicator. Healthcare providers must understand their patients' expectations and strive to fulfil them (43).

Satisfied patients are important for healthcare providers too, because they tend to obey all instructions given by medical personnel, they spread positive reviews, and are more loyal to institutions with which they are satisfied (44).

The next consequence of perceived service value, customer loyalty, is defined by Oliver (42) as a commitment to repeat purchases, or the regular use of a product in the future, that actually leads to repeat purchases or the use of the same brand. Patient loyalty may be viewed more appropriately as a behavioural intention. Regardless of whether the discussion focuses on patient loyalty in the healthcare context, there is no question that the same benefits of customer loyalty apply – whether it is a hospital, bank, or retail business. Patients are loyal because they were satisfied in the past, so it is more important to find out why they were either satisfied or dissatisfied.

1.1.1 Hypotheses

Perceived service value is a customer's perception of the perceived service quality in comparison with other service providers (12).

Likewise, authors such as Cronin, Brady, and Hult (41) found that, besides the direct impact of perceived service quality on perceived service value, perceived service quality influences customer satisfaction.

H1: The higher the perceived service quality of a health service, the higher its perceived service value.

H2: The higher the perceived service quality of a health service, the higher the patient satisfaction.
Reputation plays an important role in distinguishing between different healthcare service providers (45). Researchers such as Chen (46) and Wood (47) show a positive connection between reputation and the perceived service value and quality of services.

H3: The higher the reputation of a health service provider, the higher its perceived service quality.

H4: The higher the reputation of a health service provider, the higher its perceived service value.

Higher perceived service value leads to higher satisfaction (48). In the long term, service providers' success is linked to customer loyalty (48). Atilgan, Askoy, and Akinci (49) believe that customer loyalty is strongly linked to perceived value.

H5: The higher the perceived service value of a health service, the higher the patient satisfaction.

H6: The higher the perceived service value of a health service, the higher the patient loyalty.

There are more uncertainties when describing the relationship between perceived service quality and perceived price. The meta-analysis of Hussey, Wertheimer, and Mehrota (50), which includes all relevant studies analysing the influence of prices on the quality of health services, concluded that the connection is inconsistent, or the connection is either negative or positive. On the other hand, numerous researchers (51, 52) have proposed that higher perceived prices lead to higher perceived service quality. Jensen's study (53) showed that health service users are willing to pay more for higher quality services because they believe that higher prices mean higher quality. Tellis and Geath (54) also claimed that customers use prices as quality indicators.

H7: The higher the perceived price of a health service, the higher its perceived service quality.

The price has a double impact on the perceived service value. As a factor of sacrifices, it lowers the perceived service value. Anything built into health care services to reduce price, time, effort can cause an increase in hospital perceived service value, but, on the other hand, it has a positive impact on the perceived service quality and, through this impact, it has an indirect, positive effect on perceived service value.

This is why we expect that the perceived price will have a small negative impact on the perceived service value.

H8: The lower the perceived price of a health service, the higher its perceived service value.
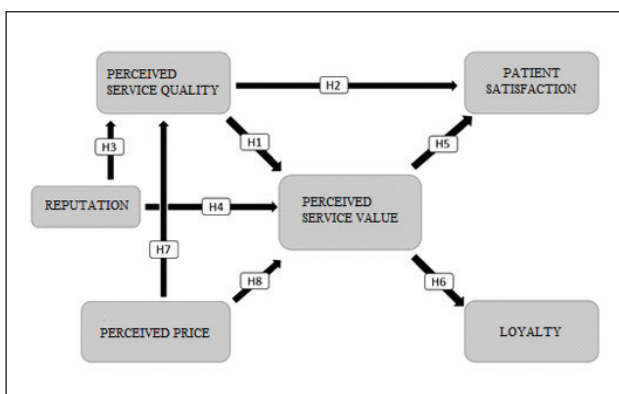

Figure 1. Conceptual model, relationships between elements of them, and hypotheses.

2 METHODS

2.1 Measurement Instrument Development

The measurement instrument for the empirical study was developed in two steps. First, after the literature review, some of the relevant items were identified for the questionnaire.

In the second step, a pilot survey was conducted on a sample of 200 patients. A 5-point Likert-type scale was used to measure the latent constructs in this study (1="strongly disagree" and 5="strongly agree"). The first questionnaire consisted of 53 questions. For reliability, we used an Exploratory Factor Analysis (EFA) and Cronbach's alpha. In all the factor analyses, the assumptions pertinent to this method were assessed, and, in all cases, the final factor analyses met the criteria (55).

The Cronbach's coefficient for the construct of price was too low (0.40), which revealed its low reliability. Therefore, we included additional questions in the second questionnaire. We did not have such problems with the other constructs.

Unlike CFA, EFA does not test unidimensionality explicitly (56), which means it has to be followed by CFA. Furthermore, CFA makes it possible to estimate the reliability of the constructs of a measuring instrument, based on the value of R2 (57). In addition, CFA is also used for estimating the discriminant validity of constructs, which can be estimated in the following two ways: Using the Fornell-Larcker criterion (21) and the Chi-square difference test (56, 58). Based on the results of statistical analysis, we designed the second questionnaire (59) with 29 questions that covered all six categories. The items in the second questionnaire were measured on a 7-point Likert scale (from 1="strongly disagree" to 7="strongly agree"). After all statistical procedures, three items were used to measure perceived service quality, three were used for perceived price (1 for non-monetary price, and 2 for monetary price), four for reputation, three for perceived service value, three for patient satisfaction, and three for patient loyalty.

For complete data processing, the SPSS statistical package and corresponding AMOS software were used, together with a LISREL software package.

2.2 Sampling and Data Collection

We enrolled 800 patients, 18 years of age or older, and who were intellectually capable of filling out the questionnaire after finishing their treatment. The questionnaire was given to all the patients in the ward. The response rate was 100%. The time period in which data collection took place was four months. We used a convenience sample and included those patients who were easy to obtain; in our case, we focused on patients in one private and one public hospital who were, at the time, patients in the Surgical Department.

The patients received instructions on how to complete the questionnaire, which was anonymous, and it was answered with a pen on a paper form.

3 RESULTS

Cronbach's α for the construct of perceived service quality was 0.87, reputation 0.96, perceived service value 0.83, price 0.88, satisfaction 0.89, and loyalty 0.90. In the conceptual model for testing our hypotheses, we included additionally the relationship between patient satisfaction and loyalty. In this manner, the fitting of data to the model was improved significantly. Before including the additional relationship, global fit indices had the following values: Chi-square=421 (sig.=0.00), df=144, RMSEA=0.08, NFI=0.93, CFI=0.94.

After including the additional relationship, global fit indices had the following values: Chi-square=349.6 (sig.=0.00), df=143, RMSEA=0.05, NFI=0.96, CFI=0.97.

RMSEA shows how well a model with optimally chosen parameters would fit the population covariance matrix. Its desirable value is less than 0.06. With NFI, we looked at the Chi-square derivation. Its desirable value should be 0.95 or more. CFI is an indicator that compares the current and the null model that should be 0.95 or more.

All relationships between the constructs (Figure 2) were statistically significant, thus confirming all our hypotheses.
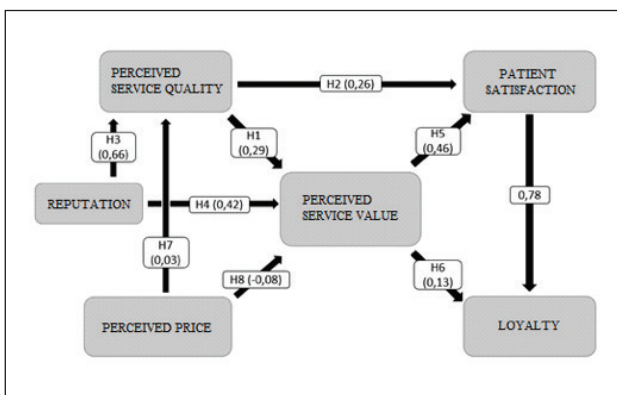

Figure 2. The conceptual model with coefficient of path (beta coefficient).

4 DISCUSSION

This paper examines the concept of the perceived service value of health services. This concept has been very well known and researched in other branches of the service industry (such as Banking and Tourism), while knowledge of it in the health industry has been rather fragmented. Based on the findings from other service industries, we created a conceptual model, in which we put a perceived service value at the centre of the research; we identified satisfaction and loyalty as the consequences of perceived service value and reputation, price, and perceived service quality as its antecedents.

The final study was conducted on a large sample (800 patients), and the data was analysed using exploratory and confirmatory factor analyses, and by modelling linear structural equations. Based on the statistical results of the model, and to achieve considerably better global fit indices, we added into the model an additional relationship between the two constructs, namely, between patient satisfaction and patient loyalty.

The relationship between patient satisfaction and patient loyalty was the strongest in our model. The relationship between the constructs of patient satisfaction and patient loyalty also had wide theoretical support (11, 27, 60), because patient satisfaction can affect desirable patient behaviours, such as loyalty, including recommendation to friends and relatives and improved treatment compliance (61).

We also found a strong direct relationship between reputation and perceived service quality, as well as perceived service value. Further, strong indirect connections with reputation and patient satisfaction were detected, as well as loyalty. A positive hospital reputation increases perceived service quality by a patient, and also increases perceived service value. These results are consistent with the study by Wu (10) from Taiwan, who confirmed a strong relationship between reputation and patient loyalty. Our findings are substantively the same as those of Bloemer, de Ruyter, and Peeters (62) from Belgium and the Netherlands, which showed the indirect effect that reputation has on loyalty through perceived service quality and satisfaction.

Our results show a statistically significant direct impact of perceived service quality on satisfaction and perceived service value. This view is in line with Weiss' conclusion (63), which states that ensuring customer satisfaction is the goal of process management and the overall platform of process improvement, which leads to higher service quality. In our model, perceived service value had a greater impact on patient satisfaction than perceived service quality, which is contradictory to the findings of Choi, Cho, Lee, Lee, and Kim from South Korea (12), who constructed their conceptual model around patient satisfaction. They found that service quality emerged as the most important determinant of patient satisfaction. Nevertheless, they concluded that their findings should not be viewed as denigrating the significance of perceived value. For them, healthcare providers should seek ways in which they can reduce monetary and non-monetary service costs and increase perceived benefits.

Our results imply the weakest relationship among perceived price, perceived service quality and perceived service value. Health services are financed in such a way that the consumer never really stops to consider the actual cost of a particular service. With most health services, providers do not compete by setting different monetary prices. Moliner from Spain (64) reported a similar result, and argued that this is logical, as the patient of a private hospital makes a direct payment to the hospital, while, in a public hospital, this payment is indirect, through taxation. Those survey questions specifically aimed at identifying the non-monetary price aspect were already eliminated in the process of refining the model, which is why the final model included only one such question (for non-monetary price). Our construct of price refers primarily to monetary costs. Örgev and Bekar from Turkey (13) concluded in their model of perceived service value that non-monetary costs should be taken into consideration as a key component of hospital perceived value, and not be regarded as less important than any other factor.

5 CONCLUSION

Nowadays, it is crucial for every service provider who wants satisfied clients to offer as many benefits as possible, and to minimise their monetary and non-monetary costs. Based on Choi et al. (12), who called for a rather more complex model to explain the patients' behaviour intentions, this paper has attempted to extend existing knowledge with perceived service value as a central point and has researched the relationships between its antecedents and consequences with the goal of achieving satisfied and loyal patients. The results proved that an especially higher reputation and higher perceived service quality can contribute to perceived service value and to more satisfied patients. The recommendation is, therefore, that health service providers should introduce into their strategies the concept of perceived service value and overcome a vision that is focused excessively on perceived service quality.

Our results imply that Hospital Managers should pay attention to constructing a positive hospital reputation with putting more energy into building a trustworthy organisation, empower employees towards respected individuals, and build on a positive image in public. It is also important to assure patients that they will obtain their desired and expected service level at the time they are admitted to the hospital. Besides medical staff demonstrating excellent technical skills and professionalism, the softer components, e.g., empathy, kindness, and reputation, are also important in developing a holistic perception of perceived service value among patients.

However, in assessing the implications of this study, the research approach has a few limitations. Because the results are directly relevant only to patients in two—one private and one public—hospitals, generalizations of the findings beyond the immediate population observed should be made with caution. Another limitation of the study is that perceived service value and loyalty are continuous variables, measured at one point of time in this study, while it would be much better to test the hypotheses in time series. Regarding the construct of perceived price, which refers primarily to monetary costs, it might be more useful to treat monetary and non-monetary costs as two distinct constructs in future research. Furthermore, we also think that, in the future, it would be appropriate to analyse the role of emotions and incorporate emotional and social value, as well as the relationship between perceived service value and patients' trust and commitment as consequences.

CONFLICTS OF INTEREST

FUNDING

ETHICAL APROVAL

The research carried no risk of violating ethical principles.

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OUTPATIENT ANTIBIOTIC CONSUMPTION FOR URINARY INFECTIONS IN CROATIA 2005 - 2014: WHAT CAN BE LEARNED FROM UTILIZATION TRENDS

PORABA AMBULANTNO PREDPISANIH ANTIBIOTIKOV PRI OKUŽBAH SEČIL NA HRVAŠKEM MED LETI 2005 IN 2014: KAJ SE LAHKO NAUČIMO IZ TRENDOV PORABE

Željko VOJVODIĆ[1]*, **Danijela DAUS ŠEBEĐAK[2]**

[1]Ordinacija obiteljske medicine, "Željko Vojvdić, dr med", Bijelo Brdo, Croatia
[2]Ordinacija obiteljske medicine "Daus Šebeđak Danijela, dr med" Podvinje, Slavonski Brod, Croatia

ABSTRACT

Keywords:
antibiotics, utilisation trends, urinary tract infections, bacterial resistance

Aim: The aim of this study was to determine quantities of antibiotics used mainly or exclusively for urinary tract infections in Croatia between 2005 and 2014, to describe utilisation trends, and general consequences of antibiotic consumption on antimicrobial resistance.

Methods: Antibiotic utilisation data were obtained from annual reports of both the Croatian Drug Agency and Croatian Academy of Medical Sciences. Antibiotic consumption was expressed in DDD/1000 inhabitants/day (DDD TID). Antimicrobial resistance was analysed for E. coli, E. faecalis, E. faecium, P. aeruginosa, Klebsiella spp., P. mirabilis. Descriptive statistics were used to process data and calculate trends.

Results: Overall, utilisation of antibacterials decreased by 4.8% (from 3,35 to 3,19 DDD TID), while trends of individual agents varied substantially – from 87% decline for ceftibuten to 160% rise for levofloxacin. The consumption of quinolones increased by 32.3%. This was mostly due to increased ciprofloxacin consumption (144% raise). Sulfamethoxazole-trimethoprim declined by 57%, while nitrofurantoin increased by 86%. The use of fosfomycin was marginal. Antimicrobial resistance of E. coli increased against quinolones by 54.5%, and against nitrofurantoin by 2–3%. Quinolone resistance of other pathogens (Klebiella spp, Proteus mirabilis), increased variably – between 17.2% (Klebsiella) and 90% (Proteus), while for P. aeruginosa remained the same at 22%.

Conclusion: High rates of antimicrobial utilisation require prescribing restrictions and educational interventions. The increased use of fluoroquinolones is a potentially serious public health threat due to the rapid development of resistance among uropathogens. This threat can be avoided by greater use of nitrofurantoin and fosfomycin.

IZVLEČEK

Ključne besede:
antibiotiki, trendi porabe, okužba sečil, odpornost bakterij

Cilj: Cilj te študije je ugotoviti količino antibiotikov, ki so bili porabljeni za okužbe sečil na Hrvaškem med leti 2005 in 2014 in prikazati trende porabe in njene posledice glede odpornosti mikrobov na zdravila.

Metode: Podatki o porabi antibiotikov izhajajo iz letnih poročil hrvaške agencije za zdravila in hrvaške akademije medicinskih znanosti. Poraba antibiotikov je izražena v obliki DDD/1000 prebivalcev/dan (DDD TID). Odpornost mikrobov na zdravila je analizirana za E. coli, E. faecalis, E. faecium, P. aeruginosa, Klebsiella spp., P. mirabilis. Za obdelavo podatkov in izračun trendov je uporabljena opisna statistika.

Rezultati: Splošna poraba antibiotikov se je zmanjšala za 4,8 % (iz 3,35 na 3,19 DDD TID), medtem ko so se trendi porabe posameznih zdravil občutno spreminjali – od upada v višini 87 % za ceftibuten do dviga za 160 % za levofloksacin. Poraba kinolonov se je zvišala za 32,3 % predvsem zaradi povišane porabe ciprofloksacina (dvig za 144 %). Poraba trimetoprim sulfametoksazola (kotrimoksazola) se je zmanjšala za 57 %, medtem ko se je poraba nitrofurantoina povišala za 86 %. Odpornost mikroba E. coli na kinolone se je zvišala za 54,5 %, na nitrofurantoin pa za 2-3 %. Odpornost na kinolone pri drugih patogenih (Klebiella spp, Proteus mirabilis) se zvišuje spremenljivo, in sicer med 17,2 % (Klebsiella) in 90 % (Proteus), vrednost pa je ostala enaka pri patogenu P. aeruginosa, in sicer 22 %.

Zaključek: Visoka poraba antibiotikov zahteva omejitve predpisovanja zdravil in izobraževanje populacije. Zaradi hitrega razvoja odpornosti pri uropatogenih predstavlja povišana poraba fluorokinolonov grožnjo javnemu zdravju. Tej grožnji se lahko izognemo z večjo porabo nitrofurantoina in fosfomicina.

***Corresponding author:** + 385 31 597 866; E-mail: vojvodic58@gmail.com

1 INTRODUCTION

Urinary tract infections (UTIs) are a frequent occurrence in routine work of both family doctors and hospital specialists. They are the second most frequent indication for antibiotics, after respiratory infections. The predominant pathogens are *Escherichia coli* (75-90% of cases), *Staphylococcus saprofiticus* (5-15%), followed by *Proteus mirabilis*, Klebsiella spp i enterococci (1). The key principles in their management are knowledge of common pathogens, antimicrobial susceptibility and empirical choice of agents. Microbiological verification and susceptibility testing are performed mostly in situations of failure of initial therapy, or in complicated infections (2). International guidelines conclude that there is no a singular optimal regimen in management of uncomplicated urinary infections (2), and also that there is a need for the development of "double strategy" for virtually any antimicrobial indication: assessment of efficacy (pathogen eradication) together with minimizing the risk of collateral damage (induction of antibiotic resistance) (3). According to one study from primary care the prevalence of urinary infections in Croatia was 49.7/1000 in 2004, of which 38.2/1000 were uncomplicated cystitis (4). According to Croatian health statistics, there were 228 313 recorded cases of cystitis in family medicine offices in 2014 (out of 10 187 976 consultations/ visits/ prescriptions, or 2.24% of all encounters) (5).

In Croatia, treatment guidelines for urinary infection are developed by ISKRA (Interdisciplinary Section for Control of Antibiotic Resistance) in 2007, with an update in 2012 (6, 7). Prescription of all antibiotics in primary care is allowed without restrictions, except for ciprofloxacin. Its use is only allowed after recommendation of a hospital specialist, which is supported in ISKRA and the Croatian Institute for Health Insurance – CIHI recommendations (8). The effects of that restriction are questionable since norfloxacin is unrestrained and all fluoroquinolones induce cross-resistance (9, 10).

Antibiotic resistance surveillance in Croatia is performed by the Committee for Monitoring of Antibiotic Resistance of the Croatian Academy of Medical Sciences (CAMS), Public Health Department. Systematic surveillance of 16 most significant pathogens, from 30 microbiological laboratories across the country, began in 1996 (11–13). The sampling method included both inpatient and outpatient specimens. Resistance of *E.coli* in 2014 exceeded 20% for co-trimoxazole, 17% for ciprofloxacin, and 2% for nitrofurantoin. The proportion of *E. coli* strains producing extended-spectrum beta-lactamases (ESBL), was relatively low at only 2%. A sharp increase of ESBL strains has been recorded for *K. pneumoniae* – from 22% in 2006 to 32% in 2007, remaining at this level until now (12, 13).

Antibiotic prescribing practices vary across the EU countries (14). Since the pattern of prescribing has a major impact on the development and dissemination of resistance (15, 16), analysis of antibiotic utilisation trends in general, as well as of their specific subgroups, could provide valuable information in developing guidelines as well as in changing prescribing practice. The overall outpatient utilisation of antibiotics in Croatia was close to the European average in 2014 (21.4 defined daily doses per 1000 inhabitants, DDD TID), without greater fluctuations in the last five years (17). Due to the growth of resistance of *E. coli* against amoxicillin, oral cephalosporins, co-trimoxazole and fluoroquinolones, guidelines encourage the use of older antibiotics with a lower potential for the development of resistance: fosfomycin, nitrofurantoin and pivmecillinam (not registered in Croatia), in the course of 3 – 5 days. Each of them preserved over 90% efficiency against *E. coli*, nitrofurantoin even over 95%, despite decades in use (2, 18, 19). The ratio of older antimicrobials – nitrofurantoin and fosfomycin against all other subgroups (co-trimoxazole, beta-lactams, and fluoroquinolones) is of great importance as a potential predictor of national resistance trends. The aim of this study was (i) to analyse utilisation of antibiotics used mainly (among other indications) or exclusively for urinary tract infections in a ten-year period (2005–2014), (ii) to compare consumption trends between "low-resistance" antimicrobials (nitrofurantoin, fosfomycin) and others, especially fluoroquinolones, and to (iii) discuss the broad consequences of increasing antibiotic utilisation on advancement of antimicrobial resistance.

2 MATERIALS AND METHODS

This is observational study based on routinely collected data on the utilisation of antimicrobials for urinary infections, with emphasis to fluoroquinolones, and trends in antibiotic resistance, in a period from 2005-2014 for antibiotics, and 2007 – 2014 for resistance. Antibiotic consumption from the ATC group J01M (quinolones) and J01XE (nitrofuran derivatives, nitrofurantoin) was extracted from the annual reports of the Croatian Agency for Medicines (HALMED) (20). These HALMED reports display reimbursement data from the network of community and hospital pharmacies, expressed in DDD TID, while the Resistance Committee of the CAMS collected data from wholesale suppliers up to 2009, and reimbursement data from 2010 onward (12, 13). Although both sources provide information on antibiotic consumption, we have chosen HALMED as more reliable because of their method of data collection and the clear separation between outpatient and inpatient consumption. Only the utilisation of co-trimoxazole (in DDD TID) was extracted from the CAMS records, because it was expressed only in financial terms

in HALMED (12, 13). Antibiotics from beta-lactam group were omitted from more detailed analysis and calculation of trends due to their wide range of indications. However, since ISKRA guidelines recommend amoxicillin-clavulanic acid, cephalexin, cefuroxime, cefixime and ceftibuten as alternative drugs and in some cases as first-line agents (amoxicillin-clavulanic acid in uncomplicated pyelonephritis) (7), we have included their use in the discussion.

Resistance was expressed in percentages. The Resistance Committee of the CAMS surveilled samples from 30 microbiological laboratories countrywide, as well as from several bigger hospitals and university clinics, using EARSS-Net project methodology. Data obtained through this methodology are expressed as national resistance rates (population level of resistance) and used in guidelines as a predictor of clinical efficacy of complementary antibiotic groups (12, 13). Health statistics data of urinary infections, under ICD10 codes N30, were taken from the Croatian Health Statistics Yearbook, edition 2014 (5). The average annual increase for quinolones, co-trimoxazole and nitrofurantoin were calculated, and expressed in percentages. The annual prevalence of resistant pathogens (*E. coli*, *K. pneumoniae*, *P. mirabilis*, *P. aeruginosa*, *E. faecalis* and *E. faecium*), against beta-lactams, fluoroquinolones (ciprofloxacin, norfloxacin), co-trimoxazole and nitrofurantoin between 2007 – 2014 were expressed in percentages. Descriptive statistics and Microsoft Excel software were used to process data, calculate trends and create tables and graphs.

3 RESULTS

The outpatient consumption of fluoroquinolones was between 85 and 90% of the total and of co-trimoxazole between 93 and 95%. The overall quinolone consumption increased by 32.3%, or from 1.27 DDD TID in 2005, to 1.68 DDD TID in 2014. Norfloxacin utilisation in 2005 was 0.95 DDD TID or almost four times that of ciprofloxacin (0.25 DDD TID), but decreased to 0.86 DDD TID in 2014, while ciprofloxacin increased by the rate of 144% (14% annually) to 0.61 DDD TID. The use of levofloxacin, registered in 2012, increased from 0 to 0.13 DDD TID in just two years, while the moxifloxacin remained at 0.08 DDD TID (Table 1). There was a disproportionately high increase of norfloxacin in 2006 (from 0.95 DDD TID to 1.25 DDD TID, or by 31.6%), followed by a decrease in 2007, to 0.8 DDD TID, with a later moderate drop of utilisation rate. Ciprofloxacin showed, contrary to this, a balanced increasing trend (Table 1).

Table 1. Utilisation of quinolones, co-trimoxazole and nitrofurantoin in Croatia, 2005 – 2014, according to HALMED (DDD TID).

|	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	% of change
QUINOLONES											
ciprofloxacin	0.25	0.41	0.45	0.47	0.58	0.59	0.59	0.55	0.59	0.61	144
pefloxacin	0.01	0.01	0	0	0	0	0	0	0	0	
norfloxacin	0.95	1.25	0.8	0.81	0.77	0.8	0.7	0.77	0.83	0.86	-9.37
levofloxacin	0	0	0	0	0	0	0	0.05	0.13	0.13	
moxifloxacin	0.07	1.1	0.08	0.12	0.12	0.12	0.11	0.1	0.09	0.08	
tot quinol	1.27	1.76	1.34	1.41	1.47	1.52	1.39	1.47	1.63	1.68	32.28
CO- TRIMOXAZOLE											
Outpatient DDD	1.57	1.35	1.4	1.17	0.98	0.87	0.73	0.72	0.67	0.66	
Hospital DDD	0.08	0.07	0.07	0.06	0.06	0.05	0.05	0.06	0.04	0.05	
Total DDD	1.65	1.42	1.47	1.23	1.04	0.92	0.78	0.78	0.71	0.71	-57
HRK	4.32	5.3	3.9	9.89	3.53	3.23	2.68	2.46	2.55	2.45	
NITROFURANTOIN											
nitrofurantoin	0.43	0.65	0.37	0.6	0.69	0.66	0.68	0.7	0.75	0.8	86.05
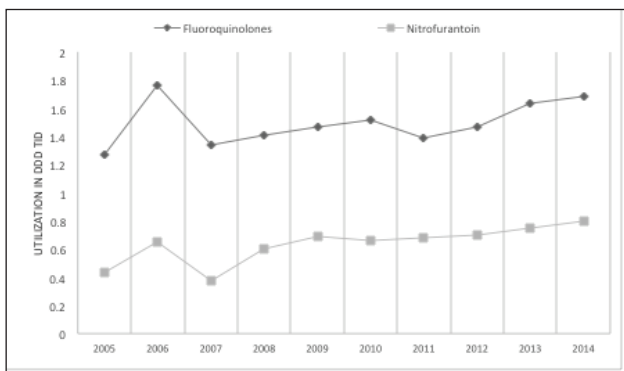
Figure 1. Utilisation of quinolones and nitrofurantoin in Croatia, 2004 – 2015 (DDD TID).

The consumption of nitrofurantoin almost doubled – from 0.43 DDD TID in 2005 to 0.80 DDD TID in 2014, or by 8.6% annually. Its use approached that of co-trimoxazole, and even slightly exceeded (0.71 DDD TID in 2014) (Table 1, Figure 1). Consumption trends of all four antibiotics converged in 2014 toward roughly equal volumes (norfloxacin 0.86, ciprofloxacin 0.61, co-trimoxazole, and nitrofurantoin 0.80 DDD TID) (Figure 2). In 2007 nitrofurantoin suddenly dropped from 0.65 DDD to 0.37 DDD TID (43%), and then recovered to 0.6 DDD TID in 2008 onwards (Figure 2).

The use of co-trimoxazole steadily decreased from 1.65 DDD TID in 2005 to 0.71 DDD TID in 2014 (Table 1, Figure 2). In HALMED reports, the utilisation of beta lactams (in DDD TID) were as follows: amoxicillin-clavulanic acid 8.65, cephalexin 0.85, cefuroxime 1.68, cefixime 0.18 and ceftibuten 0.03 (2014).
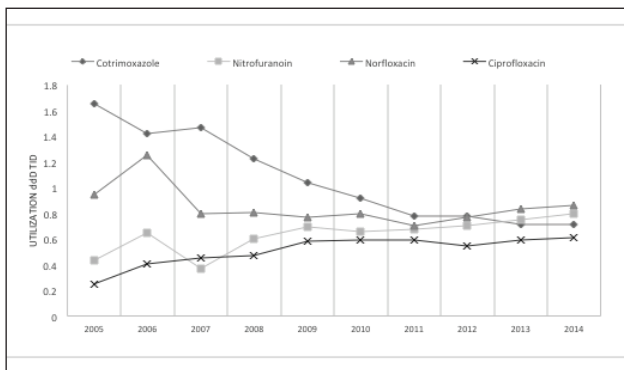
Antibiotic resistance increased against all standard therapeutic agents, but disproportionately and with great variations between individual drugs, during the eight-year period (Table 2). The resistance of *E. coli* increased sharply to amoxicillin-clavulanic acid – from 4% in 2008 to 16% in 2014 (Table 2, Figure 3), for cefixime from 3%–7%, and for cefuroxime from 4%–8%. In 2014 the resistance of *E. coli* to cephalexin and cefuroxime was between 8–10%, to cefixime and ceftibuten between 4% and 6%. There was a high level of insusceptibility to co-trimoxazole (24%), which increased to 26% in 2014, while resistance to both fluoroquinolones (ciprofloxacin and norfloxacin) advanced from 12% in 2007 to 17% in 2014, or by 54.5% (Table 2, Figures 3 and 4).

Resistance of *K. pneumoniae* increased mostly to amoxicillin-clavulanic acid (94.4%), from 18% of isolates in 2008 to 35% in 2014. Insusceptibility to cephalosporins was between 35% and 39% (cefuroxime 39%, cephalexin 39%, cefixime 35%), and for co-trimoxazole and nitrofurantoin at 36–37%. Resistance to norfloxacin and ciprofloxacin increased, as in the case of *E. coli*, from 29% in 2008 to 34% in 2014, or by 17.2%. *P. mirabilis* strains resistant to cephalosporins increased between 35.7% (cefuroxime) and 54.4% (cefixime), for amoxicillin-clavulanic acid by 38.4%, while for norfloxacin and ciprofloxacin upsurged by 90% – from 11% to 21% (Table 2). The resistance of *P. aeruginosa* to norfloxacin and ciprofloxacin was between 23–25%, without greater changes. *E. faecalis* preserved good susceptibility to amoxicillin and nitrofurantoin, while in 2014 it became highly resistant to quinolones (21%). Resistance patterns of *E. faecium* were similar to *P. aeruginosa* (Table 2).

Figure 2. Utilisation of co-trimoxazole, nitrofurantoin, norfloxacin and ciprofloxacin in Croatia, 2005 – 2014 (DDD / TID).

Table 2. Resistance of main uropathogens in Croatia, 2007 – 2014 (in %).

	2007 hospital	community	2008	2009	2010	2011	2012	2013	2014
E coli									
co-amoxiclav	15	19	4	5	5	6	7	7	16
cefuroxime			4	5	6	7	8	8	8
cotrimoxazole			24	24	24	24	24	24	26
norfloxacin	12	14	11	12	13	13	14	14	17
ciprofloxacin	12	14	11	11	13	13	14	14	17
nitrofurantoin			2	3	4	3	3	3	3
Klebsiella p									
co-amoxiclav			18	21	21	28	26	25	35
cefuroxime				35	37	40	39	37	39
cotrimoxazole			36	40	37	40	41	36	37
norfloxacin			29	32	31	34	35	32	34
ciprofloxacin			29	32	30	33	34	31	34
nitrofurantoin			35	37	36				
Proteus m									
co-amoxiclav			13	13	16	16	19	18	18
cefuroxime				14	17	17	20	20	19
cotrimoxazole			35	35	38	36	38	38	36
norfloxacin			12	14	16	17	21	21	21
ciprofloxacin			11	13	16	17	20	20	21
nitrofurantoin			97	98	97	100	100	100	100
Pseudomonas									
gentamicin			29	28	28	27	28	26	23
norfloxacin			24	25	23				
ciprofloxacin			24	24	22	24	24	23	22
E faecalis									
nitrofurantoin			1	1	1	1	1	1	0
norfloxacin									21
E faecium									
nitrofurantoin			34	40	23				
norfloxacin									80
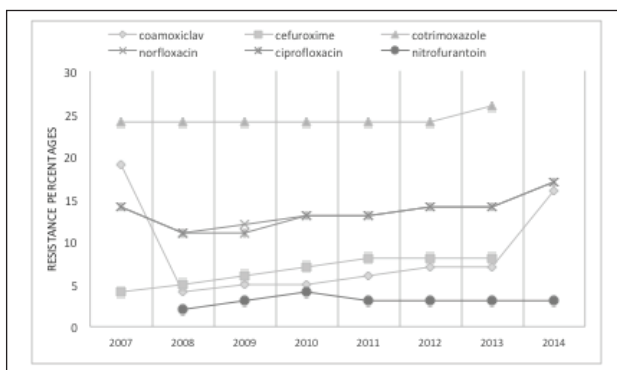
Figure 3. *E. coli* isolates resistant to amoxicillin-clavulanic acid, co-trimoxazole, ciprofloxacin, norfloxacin and nitrofurantoin, in Croatia, 2008 – 2014.

The antimicrobial resistance against ciprofloxacin was relatively stable during a seven-year period. There were 25–30% resistant strains of *K. pneumoniae* and *P. aeruginosa*, and 10–15% of *E. coli* and *P. mirabilis*. Resistance of *E. coli* and *P. mirabilis* increased to 17% and 21% in 2014. Both norfloxacin and ciprofloxacin had an equal percentage of resistant uropathogens (*E. coli*, *K. pneumoniae* and *P. mirabilis*) (Table 2, Figure 4).
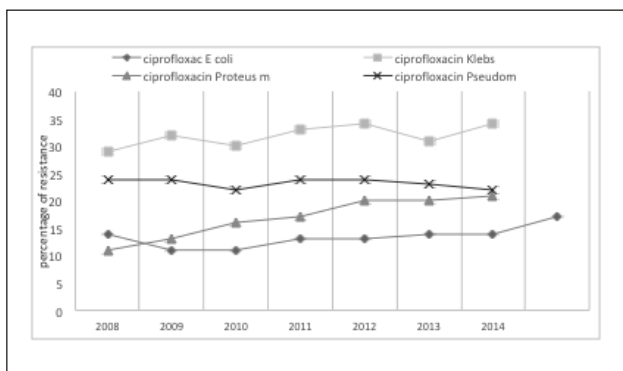
Figure 4. Resistant isolates of main uropathogens to ciprofloxacin, in Croatia, 2008 – 2014.

4 DISCUSSION

There is very little research in Croatia about the actual prevalence of urinary infections in primary care. The figure from health statistics of 2.24% of UTI diagnoses out of all registered health encounters (5), although relatively imprecise, still provides some impression on their public health burden. In the USA, from 1997-2003, more than 8 million primary care visits associated with UTI were recorded (21). The estimated annual costs for their treatment exceeded 3.5 billion USD (21). In a hospital setting they represent between 12.9 and 19% of the total hospital infections (22).

Management of urinary infections has become a therapeutic challenge because of rapid dissemination of antimicrobial resistance. Due to variable prevalence of resistant strains, as well as differences in antibiotic prescribing practice among EU countries, different recommendations for empirical antibacterials are present in guidelines (23). ISKRA guidelines, developed by a multidisciplinary team in 2007 and updated in 2012, are still a reliable model for empirical treatment of urinary infections in primary care (6). However, they differ from some international guidelines in classification of urinary infections (5 groups of urinary infections versus 3 groups), and choice of first line antibiotics (omitting of co-trimoxazole) (2, 24).

For uncomplicated UTIs in women drug of choice is either nitrofurantoin, 100 mg every 12 hours per dose, for 7 days, or fosfomycin 1x3 grams, one dose (7). Nitrofurantoin, in use for almost 65 years, is a first choice for both women's and men's UTIs due to its low potential for the development of resistance (25, 26), and triple mechanism of action (27, 28). The macrocristallinic 50 mg form (the only available in Croatia) requires dosing every 6 hours, while the dosing of macrocristallinic-monohydrate 100 mg form is every 12 hours. However, guidelines (7, 29), recommend 12 hour-dosing, which is apparently suboptimal. This drug is of great importance,

apart from uncomplicated cystitis, in catheter-associated infections. In catheterized hospitalized patients with bacteriuria the most common pathogens are *E. coli* or Enterococci, and nitrofurantoin retained its efficacy for years (25, 26), even against vancomycin-resistant strains (VRE). A 68% growth of its consumption and 0.8 DDD TID in 2014 is encouraging (Table 1), because it reflects a positive change in prescribing practice of family doctors. According to the ESAC-Net database, nitrofurantoin use (2014) in some neighbouring countries was as follows: 0.26 DDD TID in Austria, 0.25 DDD in Slovenia and 0.19 DDD in Hungary (30). Prescribing of fosfomycin (registered in Croatia in 2012) was marginal: in 2013 – 7 packages, in 2014 – 50 packages (20). Its use is difficult to compare between countries because of classification in ATC group with 10 other drugs (31).

The two most represented quinolones: norfloxacin and ciprofloxacin dominated in prescribing practice for UTIs in 2014, with 1.47 DDD TID (Table 1). Together, they were prescribed almost twice as much as co-trimoxazole (0.71 DDD TID) or nitrofurantoin (0.80 DDD TID). The ratio of utilisation volumes between quinolones and nitrofurantoin decreased from 2.8:1 in 2004 to 1.8:1 in 2014, which is definitely a positive phenomenon. But, despite that, ciprofloxacin annual utilisation has been increasing 14% between 2005 and 2014. If we consider that this medicine may only be prescribed by the judgment of hospital specialists, it is difficult to explain such an upswing. Norfloxacin was prescribed at 0.86 DDD TID, nitrofurantoin in 0.80 DDD TID, that is the alternative drug and is more frequent than the first-line drug (Table 1). Given that ISKRA guidelines recommend norfloxacin only as an alternative in uncomplicated cystitis in women, it is clear that the use of both quinolones has come out of scope of guidelines. In addition to that, norfloxacin is less potent in vitro than ciprofloxacin against gram negative bacteria in general (32). Ciprofloxacin, a "reserve" drug for UTIs in men and pyelonephritis, is rapidly approaching the consumption of norfloxacin and nitrofurantoin (Table 1). Restrictions in use, proposed by CIHI and ISKRA guidelines, to reduce overutilisation and preserve efficacy, generally failed to achieve this aim: it's use increased almost 4.5 time faster than all other quinolones – from 0.25 DDD TID in 2005 to 0.61, or by 144% (Table 1, Figure 1). A similar trend was documented in Austria: from 1998 – 2007 ciprofloxacin use increased by 118.9% (33). However, data from HALMED (increase in quinolone use from 1.27 to 1.68 DDD TID) are different from the ESAC Net (decrease in quinolone use from 1.60 to 1.50 DDD TID) (30) probably because of differences in assembling, as described in the methods. Among the ESAC participating countries the overall quinolone consumption in 2014 was 1.30 DDD TID in Austria, 1.11 DDD in Slovenia and 2.41 DDD in Hungary (30). From countries that did not participate in the ESAC project total consumption

(in 2011) was 4.4 DDD TID in Montenegro, 2.5 DDD in Serbia, and only 0.75 DDD in Azerbaijan (34). However, we do not know the proportion used for urinary infections only. In Switzerland quinolones were prescribed to 37.2% of women with urinary infections, far more than the recommended maximum of 5% (35).

Overutilisation of quinolones probably contributed to increase of fluoroquinolone resistance on a country level (54% rise for *E. coli* and 90% for *P. mirabilis*) (Table 2). It is important to note that the potential for resistance of both norfloxacin and ciprofloxacin is virtually equal (9, 10). The frequency of quinolone-resistant *E. coli* was 17% in 2014, and further advancement will probably soon reach the threshold of 20%, when both of them become clinically inefficient, according to IDSA guidelines (2). Fluoroquinolone resistance is of particular clinical importance because of the close connection with ESBL production in gram-negative pathogens (36). The range of quinolone-resistant isolates in uncomplicated community acquired infections (CA-UTIs) varied from 10% in ESBL negative strains to 70% in ESBL positive strains, extending up to 90% in complicated CA-UTIs (37). Previous fluoroquinolone use was an important risk factor for the acquisition of ESBL-producing *E. coli* in non-hospitalized patients with uncomplicated UTIs (38, 39).

It is difficult to estimate beta lactam utilisation in urinary infections due to their overlap with other indications (respiratory and other). However, in 2014 their use was substantial: amoxicillin-clavulanic acid (8.65 DDD TID) surpassed fluoroquinolones (1.47 DDD TID), by almost 6:1, and cefuroxime (1.68 DDD TID) by 1:0.9. In European urological guidelines cephalosporins are not mentioned; not even as a second choice in uncomplicated cystitis (24), while in ISKRA guidelines they are simply second choices in both cystitis and pyelonephritis, thus giving false impression of their equal efficacy in all clinical scenarios (7). Resistance, however, threatens to eliminate all three generations of oral cephalosporins. Insusceptibility of *E. coli*, although relatively low at present (ceftibuten 5%, cefixime 7%, cefuroxime 8%, in 2014), progress at rates of between 66 and 133% (Table 2). Co-trimoxazole declined by 57% in ten years – to 0.66 DDD TID (Table 1), and this change is probably justified due to a high prevalence of resistant strains in 2014: *E. coli* 26%, *K. pneumoniae* 37%, *P. mirabilis* 36%, *P. aeruginosa* 100% (Table 2). Its use varied considerably between individual countries: from 0.07 DDD TID in Austria (2014), and 0.19 DDD in Slovenia, to 0.50 DDD in Hungary (30).

Urinary infections in children are also frequent in primary care, with 9180 recorded cases of cystitis (up to 6 years), in 2014 (5). In the UK their prevalence is 3.6% for boys, and 11% for girls (40). The spectrum of oral antibiotics is limited to beta-lactams, co-trimoxazole and nitrofurantoin, because fluoroquinolones are not registered for children

under 14 years, and fosfomycin for children under 6 years (41). Nitrofurantoin is a first choice for children too (42). Due to unavailability of suspension in Croatian market, it can be applied as an ex-temporanous formulation. Urinary infections in men are classified as complicated in most guidelines. While some guidelines advise ciprofloxacin (2, 24), other recommend trimethoprim and nitrofurantoin as a first choice, and performing urinary culture in case of failure (43).

5 STRENGHTS AND LIMITATIONS

The main strength of this study is the use of data on the consumption of antibiotics from the HALMED database, which collects information from public pharmacies (for the outpatient sector), and clearly separate inpatient from outpatient sources from the beginning of systematic surveillance. Also, the observational period is long enough to draw conclusions on trends on antibiotic consumption and to compare the obtained data with those in international publications. There are several limitations: national resistance rates shown in the CAMS reports do not separate hospital from outpatient samples. Secondly, antimicrobial resistance is induced by many antibiotics – the overuse of "respiratory" antimicrobials is also reflected in the resistance of urinary pathogens. Finally, many antibiotics, especially beta-lactams, are indicated for infections other than urinary. Also, the information from HALMED database does not allow visibility of the actual application of specific antibiotic groups.

6 CONCLUSIONS

Utilisation of antimicrobials for UTIs in Croatia is characterized with a high proportion of fluoroquinolones (norfloxacin and ciprofloxacin) compared to older agents – nitrofurantoin and fosfomycin, which retained excellent efficacy for most gram-negative urinary pathogens, despite more than five decades of being in use. Prescribing restrictions imposed on ciprofloxacin were basically inefficient. The utilisation rapidly increased instead of being under control. Overutilisation of both ciprofloxacin and norfloxacin represents an important public health hazard, due to their powerful impact on induction and advancement of resistance, while underutilisation of nitrofurantoin and fosfomycin by family doctors requires clarification in further research.

Medicine today fights a grim battle with resistant bacteria, and its outcome decides on the very essence of our profession and even on human society as a whole. Family doctors, being on the first line of healthcare, need freedom in their clinical decisions, as well as clear and unambiguous rules, and not administrative measures.

The essential advice in management of UTIs in primary care should be "keep it simple" (44) – or make treatment decisions based on simplest diagnostic tests: symptom score, nitrites and leukocyturia, avoid treatment of asymptomatic bacteriuria (except in pregnancy), and always prescribe nitrofurantoin or fosfomycin first, only when and if necessary.

AUTHOR CONTRIBUTION

Both authors contributed equally to the work described in the manuscript.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

Estimated as unnecessary from the Ethical Committee because of the absence of human subjects.

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WORK-RELATED STRESS FACTORS IN NURSES AT SLOVENIAN HOSPITALS – A CROSS-SECTIONAL STUDY

STRESNI DEJAVNIKI MED MEDICINSKIMI SESTRAMI V SLOVENSKIH BOLNIŠNICAH – PRESEČNA RAZISKAVA

Mojca DOBNIK[1,4]*, Matjaž MALETIČ[2], Brigita SKELA-SAVIČ[3]

[1]University Medical Centre Maribor, Ljubljanska ul. 5, 2000 Maribor, Slovenia
[2]University of Maribor, Faculty of Organizational Sciences, Kidričeva cesta 55a, 4000 Kranj, Slovenia
[3]Angela Boškin Faculty of Health Care Jesenice, Spodnji Plavž 3, 4270 Jesenice, Slovenia
[4]University of Maribor, Faculty of Health Sciences, Žitna ulica 15, 2000 Maribor, Slovenia

ABSTRACT

Keywords:
stressors, validity, workload, cross-sectional study

Background: Surveys conducted among healthcare workers revealed that nursing staff often face various stressors associated with occupational activities, which reduce their work efficiency. The aim of the study was to establish the level of stress in nurses working at hospitals in Slovenia and to identify stress-related factors.

Methods: A cross-sectional epidemiological design and a standardized instrument called the "Nursing stress scale" were used. The sample included 983 nurses from 21 Slovenian hospitals. The research was conducted in 2016.

Results: Prevalence of high level of stress was 56.5% of respondents (M (median)=75). Prevalence of high level of stress and stress factors may be statistically significant attributable to dissatisfaction at work (p<0.001), disturbing factors at work (p<0.001), inability to take time off in lieu after working on weekend (p=0.003), shorter serving (p=0.009), fixed-term work (p=0.007), and an increased number of workdays on Sunday (p=0.030).

Conclusion: The stress rate and stress factors are substantially influenced by variables reflecting work organization, competences and skills of healthcare management to work with people. Results reflect the need for nursing management and policy makers to design strategies to ensure adequate staffing, efficient organization and an encouraging work environment.

IZVLEČEK

Ključne besede:
stresorji, veljavnost, delovna obremenitev, presečne študije

Uvod: *Raziskave, opravljene med zdravstvenimi delavci, so pokazale, da se zaposleni v zdravstvu pogosto srečujejo z različnimi stresorji, povezanimi s poklicnimi dejavnostmi, kar zmanjšuje učinkovitost dela. Cilj raziskave je bil ugotoviti stopnjo stresa medicinskih sester v bolnišnicah v Sloveniji in opredeliti dejavnike, povezane s stresom.*

Metode: *Metoda raziskovanja je bila presečna epidemiološka raziskava in modificiran standardiziran instrument »lestvica stresa med medicinskimi sestrami«. V vzorec je bilo vključenih 983 medicinskih sester iz 21 slovenskih bolnišnic. Raziskava je bila izvedena leta 2016.*

Rezultati: *Prisotnost stresa je opredelilo 56,5 % anketirancev (M (mediana) = 75). Prisotnost stresa in dejavniki stresa so lahko statistično pomembne posledice nezadovoljstva pri delu (p < 0,001), motečih dejavnikov na delovnem mestu (p < 0,001), nezmožnosti koriščenja prostih dni po delovnem vikendu (p = 0,003), krajšega delovnega časa (p = 0,009), dela za določen čas (p = 0,007) in števila delovnih nedelj v enem mesecu (p = 0,030).*

Zaključek: *Na stopnjo stresa in dejavnike stresa znatno vplivajo spremenljivke, ki odražajo organizacijo dela, kompetence in veščine vodenja v zdravstvu za delo z ljudmi. Rezultati odražajo potrebo, da menedžment zdravstvene nege in oblikovalci politike oblikujejo strategije za zagotavljanje kompetentnih zaposlenih, učinkovitosti organizacije in ustreznega delovnega okolja.*

*Corresponding author: Tel. + 386 40 480 568; E-mail: mojcadobnik@hotmail.com

1 INTRODUCTION

Occupational stress mostly results from unexpected situations or issues requiring personal engagement and undertaking tasks that do not comply with one's knowledge, expertise, or expectations, resulting in person's inability to manage the situation (1).

Surveys conducted among healthcare workers revealed that nursing staff often face various stressors associated with occupational activities, which reduce work efficiency (2). According to the ANA (American Nurses Association) (3) stress in healthcare arises from work assignments, job roles, material and social environment such as lifting patients, needle stick injuries or other sharps injuries, physical and psychological assault committed by patients or their relatives, exposure to infectious diseases and toxic chemicals.

Exploring stress in nurses is of key importance in order to eliminate the sources of stress. By defining risks to health and safety in healthcare, the European Commission (4) also focuses on stress in healthcare workers. Studies investigating stress in nurses are well accessible to professionals on a global level; however, this kind of survey has not yet been conducted in Slovenia.

Stress is an important aspect for nurses, associated with the constant challenge to ensure proper care for patients and their families. However, stress levels in healthcare exceed the capacities of many nurses. An infrastructure that is not supportive of ensuring healthcare quality is often referred to as a stress factor in healthcare (5). As a result, there is a lack of encouragement in the work organization. The following factors are considered as stress factors: lack of break time (6) poor salaries (7), poor social and peer support (5), role conflicts in healthcare teams (7) poor access to physicians (2), lack of information and work equipment, delayed problem solving, lack of resources to perform tasks, unrealistic goals, high expectations related to work carried out on time, and in line with standards (6). Important factors for stress occurrence in nursing care are night work, shift work and overtime (8, 9).

Management often increases the workload in nursing care (9) and does not ensure sufficient staff resulting in a high operating speed (6) as well as varied workload in units (10). Overload reduces the capabilities of staff in solving emotional distress in patients, coping with death (7) and communication with family members. Poorly developed teamwork often leads to poor work relationships. Unfulfilled needs in the process of acquiring new knowledge are also of great importance as well as experiencing feelings of injustice, uncertainty around expectations at work, and inadequate rewards (11). Employees often consider difficulties in balancing between work and private life as the most common

stressors, conflicts among peers and vague values in an organization (2), poorly addressed daily work issues as well as the establishment of conditions for a safety culture by managers (12, 13).

2 METHODS

The aim of the study was to identify the level of occupational stress among nurses working at hospitals in Slovenia and to identify stress-related factors. A cross-sectional epidemiological design was used.

All Slovenian public hospitals were invited to participate in the research (N=26), 21 hospitals confirmed their participation. The study covered a large systematic sample, nurses who have completed at least upper secondary education (N=8787) in 21 Slovenian hospitals. A total of 1802 (20.5%) questionnaires were distributed, the response rate was 55% (983). A cross-sectional way of distribution was used. We decided to use at least 10% of the population consisting of 10.000 units (14). Questionnaire 19 demographic and 24 items job characteristics.

Nursing Stress Scale (NSS) (18) was compiled to capture stress-related data at workplace. For the purposes of this study, the questionnaire was translated from English into Slovene language and adjusted to only 24 statements out of 34 so that it adapts to a daily nursing practice in Slovenian hospitals. The original NSS was already used in several previous researches (15-18). After the pilot test (n=30), it was not modified. Respondents were asked to rate given situations on a 5-points scale (1=not stressful to 5=extremely stressful). 24-48 points mean low stress levels, 49-72 medium stress levels, and 73-120 points high stress levels. Before the distribution of the Slovene version of the questionnaires, the draft was initially submitted to experts as well as to a group of respondent (n=30) to ensure face and content validity. After the pilot test, it was not modified. Respondents were asked to rate given situations on a 5-points scale (1=not stressful to 5=extremely stressful). 24-48 points mean low stress levels, 49-72 medium stress levels, and 73-120 points high stress levels. Cronbach's Alpha reliability coefficient (α) for NNS 24 items was 0.935. A factor analysis delivering 4 factors was conducted (Table 3), which explaining the variances of 62% and the loading factors of all items within each scale exceeded 0.5. The research was conducted from March to July 2016.

2.1 Statistical Analysis

Descriptive and inferential statistics were obtained using the SPSS 20.0 for Windows. We used descriptive, correlational and exploratory linear regression methods. Principal Axis Factoring with Direct Oblimin rotation was performed to identify an optimal factor structure

of the 24-item Adapted NSS. Items with factor loadings <0.400 and cross-loadings >0.200 between primary and secondary loading were excluded to obtain convergent and discriminant validity (19). Examination of scree plot and initial eigen values were used to determine the optimal number of factors. Kaiser-Meyer-Olkin (KMO) and the Bartlett's test indicated appropriateness of the data structure for applying factor analysis (KMO=0.906; Bartlett: x2(105)=8531.781; p<0.005) (20).

3 RESULTS

The sample represents 11.18% of nurses in 21 Slovenian hospitals (Table 1).

Table 1. Sample (frequencies).

Type of work	Category	N	N%
Highest level of nursing education	PNs	461	46.9%
	RN or BSc Nur	492	51.1%
	Master's degree	28	2.8%
	PhD	2	0.2%
Job position	PN	461	46.9%
	RN or BSc Nur	416	42.3%
	Professional Dpt. Head of Nursing / Dpt./Unit Head Nurse	77	7.8%
	Professional Div. Head of Nursing /Div. Head Nurse	3	0.3%
	Other	26	2.6%
Employment status	Temporary job	96	9.8%
	Permanent job	886	90.1%
	No reply	1	0.1%
Overtime	Yes	771	78.4%
	No	207	21.1%
	No reply	5	0.5%

Legend: PN – practical nurse, RN – Registered nurse, BS – bachelor's degree, PhD – doctorate

3.1 Respondents' Job Characteristics

In the study, monthly, respondents work 0 to 5 Saturdays and 0 to 4 Sundays. Following a weekend-shift, 164 respondents can take a day off, 542 respondents occasionally take a day off, and 129 respondents never take a day off after working a weekend-shift. Overtime was done by 771 respondents. 327 respondents consider them as occasionally present disturbing factors, 390 respondents consider them as frequently present, and 199 respondents consider them as continuously present disturbing factors. Nevertheless, 815 respondents are satisfied with their job, 165 respondents are dissatisfied with their job, and 3 respondents did not submit their answer.

Table 2. Characteristics of a sample.

Variable	N	M	SD
Age	983	39.94	10.18
Years of Service	983	18.53	11.31
Years of Service (Institution)	983	16.81	11.43
Number of working Sunday peer month	873	1.72	0.73
Number of working Saturday peer month	881	1.94	0.88

Legend: N – Number of valid cases, M – Mean, SD – Standard deviation

A factor analysis delivering 4 factors were conducted (Table 3).

Table 3. Descriptive characteristic of Adapted Nursing Stress Scale and Cronbach's α for observed factors.

Factor / item Cronbach α = 0,910, explains the variance of 62%	N	M	SD	Me	Sk	Ku
Factor 1 – Organizational Stress Factors Cronbach α = 0.842, explains the variance of 42.1%	979	3.22	0.79	3.17	-0.105	-0.150
Factor 2 – Conflictual Communication among Peers Cronbach α = 0.929, explains the variance of 9.6%	982	2.90	1.07	3.00	0.185	-0.779
Factor 3 – Poor Relationships with patients and family Cronbach α = 0.826, explains the variance of 6.2%	982	3.31	0.92	3.33	-0.129	-0.507
Factor 4 – Management Requirements Cronbach α = 0.742, explains the variance of 4.2%	977	2.87	0.94	3.00	-0.013	-0.359

Legend: N – Number of valid cases, M – Mean on 5-point scale, SD – Standard deviation, Me – Median, Sk – Skewness, Ku – Kurtosis

3.2 Adapted Nursing Stress Scale (A-NSS)

A high level of stress was determined by 56.5% of respondents (M=75, SD=16.7). The total average value for each four factors delivered a mean value. Differences between genders were significant for Management Requirements (F4), where women had a significantly higher mean value than men (p=0.040). Differences between temporary and permanent jobs were significant for Organizational Stress Factors (F1) (p=0.025) and Conflictual Communication among Peers (F2) (p=0.027), where temporary jobs had a significantly higher mean value. Differences between Satisfied with Job or Dissatisfied with Job were significant for all factors with a significantly higher mean value for Satisfied with Job (Table 4).

Table 4. Comparison of NSS-A factor's mean values between groups.

	S		Factor 1		Factor 2		Factor 3		Factor 4	
Categorical Variables (dichotomous)	*t*	*p*	*t*	*p*	*t*	*p*	*t*	*p*	*t*	*p*
Gender (male)	0.840	0.401	0.341	0.733	1.394	0.164	-0.793	0.428	2.052	0.040
Employment status (Temporary)	2.198	**0.028**	-2.239	**0.025**	2.216	**0.027**	1.145	0.253	1,.693	0.093
Job satisfaction? (Yes)	7.863	**<0.001**	-9.822	**<0001**	4.005	<0.001	5.248	**0.000**	3.200	**0.001**
Categorical Variables (more than 2 categories)			*F*	*p*	*F*	*p*	*F*	*p*	*F*	*p*
Job Role	0.573	0.564	0.212	0.809	4.998	**0.007**	1.317	0.268	0.247	0.781
Institution	5.541	**0.004**	8.129	**<0.001**	1.791	0.167	0.861	0.487	0.895	0.409
Department	1.716	0.144	0.981	0.417	1.991	0.094	5.091	**0.007**	3.136	**0.016**
Continuous Variables	*r*	*p*	*r*	*p*	*r*	*p*	*r*	*p*	*r*	*p*
Years of Service (Institution)	-0.001	0.983	-0.010	0744	-0.041	0198	0.052	0.104	0.072	**0.024**
Years of Service (Department)	-0.002	0.948	-0.006	0.860	-0.068	0.033	0.041	0.200	0.063	**0.048**
The average number of workdays on Sundays in a month	0.069	**0.046**	0.065	0.055	-0.063	0.064	0.161	**<0.001**	0.006	0.868
The average number of workdays on Saturdays in a month	0.062	0.072	0.043	0.203	-0.064	0.056	0.132	**<0.001**	-0.005	0.883
Ordinal variables	r_s	*p*	r_s	*p*	r_s	*p*	r_s	*p*	r_s	*p*
Highest level of nursing education	0.034	0.298	0.021	0.503	0.118	**<0.001**	-0.053	0.099	-0.010	0.761
After working a weekend shift can you have time off in lieu?	0.129	**<0.001**	0.128	**<0.001**	0.084	**0.013**	0.099	**0.003**	0.065	0.056
On a scale from 1 – 5, how would you rate the presence of disturbing factors in your job?	0.367	**<0.001**	0.349	**<0.001**	0.221	**<0.001**	0.287	**<0.001**	0.238	**<0.001**

Legend: Factor1 – Organizational Stress Factors, Factor 2 – Conflictual Communication among Peers, Factor 3 – Poor Relationships with Patients and Family, Factor 4 – Management Requirements, t - , p – p-value, r – Pearson's correlation coefficient, r_s – Spearman's correlation coefficient

ANOVA was used to test the differences in factor's mean values between three or more independent groups. We found significant differences in Conflictual Communication among Peers (F2), and the mean values between respondents working in different work positions (p=0.007). Differences were also significant in Organizational Stress Factors (F1) mean values (p=<0.001), where the group University Medical Centre had significantly higher mean values compared to others. Differences were also significant in Management Requirements (F4) mean values (p=0.016), where the group Care Unit had a significantly higher mean value compared to the group Intensive Care Unit, Clinic, and Emergency.

The Spearman correlation coefficient was used to compute how factors correlate with ordinal variables (Table 4). Variables for Highest Level of Nursing Education and Free Days after Working at Weekend significantly correlated with some factors, but all correlations were relatively small (p<0.001). The variable Assessment of Doing Your Job Without Disturbing Factors had weak, but statistically significant positive correlation with Organizational Stress Factors (F1) (p<0.005), Conflictual Communication with co-workers (F2), (p<0.005), Insufficient Relationships with Patients and Family (F3) (p<0.005) and Management Requirements (F4) (p<0.005).

The condition for inclusion into the regression model was a significant correlation between the independent and dependent variables using the Enter method (Table 5).

Table 5. Results of the multiple linear regression analyses for stress levels and factors obtained.

Characteristics	(R^2=0.169) Level of Stress achieved				(R^2=0.181) Factor 1				(R^2=0.089) Factor 2				(R^2=0.100) Factor 3				(R^2=0.061) Factor 4			
	b	SE_b	ß	p	b	SE_b	ß	p	b	SE_b	ß	p	b	SE_b	ß	p	b	SE_b	ß	p
Gender (male)																	-0.137	0.099	-0.047	0.166
Employment status (Temporary)	-3.331	1.799	-0.060	0.064	-0.147	0.082	-0.055	0.073	-0.340	0.126	-0.093	0.007								
Job satisfaction? (Yes)	-7.870	1.410	-0.185	<0.001	-0.481	0.065	-0.235	<0.001	-0.243	0.095	-0.087	0.010	-0.246	0.079	-0.110	0.002	-0.187	0.083	-0.076	0.025
Job position RN and BSc Nur									0.177	0.254	0.082	0.486								
Practical Nurse									0.017	0.255	0.008	0.948								
Professional Head of Nursing Care / Head Nurse of Dpt. / Division									0.340	0.282	0.088	0.228								
Years of Service (Institution)									-0.009	0.003	-0.092	0.009					0.005	0.005	0.066	0.270
Years of Service (Department)													0.128	0.059	0.099	0.030	0.000	0.005	-0.002	0.976
Number of workdays on Sundays in a month.	0.646	0.754	0.028	0.392									0.022	0.046	0.022	0.626				
													0.133	0.090	0.052	0.138				
Number of workdays on Saturdays in a month.													0.412	0.065	0.226	<0.001				
Time off in lieu after work at weekend (never).	4.499	1.502	0.098	0.003	0.200	0.068	0.092	0.003	0.320	0.100	0.105	0.001								
Job without disturbing factors (1-5 Scale).	9.204	1.120	0.273	<0.001	0.403	0.050	0.253	<0.001	0.400	0.074	0.182	<0.001					0.329	0.066	0.170	<0.001

R^2=Adjusted R-Squared, b=Regression coefficient, SE_b=Standard regression coefficient error, ß=Standard regression coefficient, p=p value, Factor1 – Organizational Stress Factors, Factor 2 – Conflictual Communication among Peers, Factor 3 – Poor Relationships with patients and their Families, Factor 4 – Management Requirements

Three variables can be used to explain the stress level in 16.9%, the same number of variables can be used to explain Organizational Factors (F1) in 18.1%, Conflictual Communication among Peers (F2) in 8.9% using 5 variables, Insufficient Relationships with Patients and Family (F3) 10.1% using 3 variables, and Management Requirements (F4) in 6.1% using 2 variables. The following are the independent and statistically significant variables to clarify the stress levels and the background of stress: Dissatisfaction with the Job affects the stress level; to Perform Work without any Disturbing Factors has a positive impact on all response variables; Inability to have a day off after working at weekend has a positive impact on the stress level and Organizational Stress Factors (F1) as well as on Conflictual Communication among Peers, while the Fixed-Term Employment has a negative impact on Conflictual Communication among Peers (F2). Years of Service has a negative impact on Conflictual Communication among Peers (F2), the number of workdays on Sundays in a month has a positive impact on the Insufficient Relationships with Patients and Family (F3).

4 DISCUSSION

This study investigated the level of stress in nurses working at hospitals in Slovenia and to identify stress-related factors. Key findings of the study are that the overall occurrence of stress levels among respondents working as nursing staff at Slovenian hospitals are high and comparable with research undertaken in other hospitals (21, 22). Stress levels in our study can be explained by the levels of job satisfaction, performing work without disturbing factors and a possibility to have a day off in lieu after working overtime, which has a significant impact on stress perception in Slovenian hospitals. In addition, comparable stress factors were highlighted by other authors as well (23), who used different measuring scales.

By means of the adapted NSS scale, stress was also specified using four reliable factors. Organizational stress factors could best explain the source of stress using the NSS scale (16-18, 24, 25). Organizational stress factors in our study were explained by working conditions not including disturbing factors, job satisfaction, and

possibilities to take time off in lieu after working overtime, which was not emphasized by other authors as well (8, 9). Stress is explained to a smaller extent by the remaining three factors, which identified the importance of good relationships among nurses' work environment, appropriate relationship with patients and their families, and direct management operations. The study (25) concluded that poor work organization and conflictual communication among peers have a negative impact on the wellbeing of employees. The findings of our study were confirmed by previous studies (27) highlighting work load as the most stressful factor.

Our study finds important observation for demographic variables. Female respondents rated the significantly important higher stress levels in relation to "Management Requirements", which is in line with the results of other studies investigating stress and confirming the gender role in the perception of stress levels (21, 22).

Temporary jobs have a statistically significant positive correlation to stress levels. "Conflictual Communication with Peers" has a statistically significant negative correlation to "Organizational Stress Factors" confirming the results of previous studies (23, 24). Respondents who are not satisfied with their jobs in hospitals evaluated/ rated the stress levels as statistically significant with all factors, hence the results are in line with the findings of other studies (25, 26). Respondents working as PNs rate their jobs as less stressful compared to RNs or BSc Nur, who consider "Conflictual Communication with Peers" and "Insufficient Relationships with patients and family". This can be explained by the Slovene educational structure in nursing care, as there are 8.6 nurses per 1000 people of which only 2.5 are RN or BSc Nur, with completed higher education in accordance with EU directives (2013/55/EU, 2005/36/E). The rest are PNs with completed secondary education, which places Slovenia at the bottom of the list of European countries. The research shows that RN or BSc Nur – as nursing care pillars – has an increased workload and are therefore more exposed to stress (27). This confirms the results of previous studies (28) that education levels have an impact on job satisfaction. The institution or department itself can also affect stress levels. Staff employed at university hospitals evaluated the presence of stress as statistically significant compared to staff employed at general hospitals or specialized hospitals in view of "Organizational Stress Factors" (29). Staff working at a hospital department rated the presence of stress as statistically significant in view of "Management Requirements", whereby previous studies highlighting Intensive Care Units (ICUs) and Emergency Departments (30–36) could not have been confirmed.

Because the instruments were translated into Slovenian prior to validation, there is a possibility of slight differences in the local terminology compared to the original instruments. In research, the original questionnaire was not used in its entirety. The sample is not balanced in terms of participants' educational achievement, but this reflects the actual educational structure of employees in Slovenian hospitals, where the share of RNs or BSc Nur does not correspond to comparable studies. The entire population of nurses working at 21 Slovenian hospitals was included in the study; all employees had the chance to participate. It is possible that the respondents were overly positive or negative towards stress factors; therefore, caution should be applied if generalizing the findings. This is especially relevant for international comparisons because the share of nurses with a higher education in Slovenia is significantly lower compared to other EU countries. Finally, the accuracy of self-report survey techniques may be limited as nine items were excluded due to low factor loadings, high cross-loadings or both. FA as part of the comparative research featuring 34 statements delivered seven subscales, whereas the adapted NSS delivered four subscales.

5 CONCLUSION

Stress in hospital nurses is related to work organization. The research shows that the nursing in Slovenian hospital has a high level of stress. Stress is one of the factors that contributes to inefficiency, increasing staff turnover and sick leave, and reduces the quality and quantity of care, affecting health costs and diminishing work satisfaction. It would be helpful to pursue research in specific areas where caregivers define the presence of stress to the greatest extent, and how in these areas patients define quality and safe treatment.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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ETHICAL APPROVAL

Research includes human data, which have been performed in accordance with the Declaration of Helsinki and have been approved by the Republic of Slovenia National Medical Ethics Committee (No. 0120-10/2017-4). Before interviews, the nature and the purpose of the study were explained, and full confidentiality was assured to all participants. All participants were informed about their right not to participate in the study and gave their oral consent before the study. Design of the study and interviewing with oral consent was approved by the Republic of Slovenia National Medical Ethics Committee.

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VALIDATION OF THE SLOVENIAN VERSION OF MOTOR IMAGERY QUESTIONNAIRE 3 (MIQ-3): PROMISING TOOL IN MODERN COMPREHENSIVE REHABILITATION PRACTICE

VALIDACIJA SLOVENSKE VERZIJE VPRAŠALNIKA O GIBALNI PREDSTAVI – 3 (MIQ-3): OBETAVNO SREDSTVO V SODOBNI REHABILITACIJSKI PRAKSI

Armin PARAVLIĆ[1*], Saša PIŠOT[1], Petar MITIĆ[2]

[1]Science and Research Centre Koper, Institute of Kinesiology Research, Garibaldijeva 1, 6000 Koper, Slovenia
[2]University of Niš, Faculty of Sport and Physical Education, Univerzitetski trg 2, 18106 Niš, Serbia

ABSTRACT

Keywords:
mental simulation, movement, reliability, validity, rehabilitation

Purpose: The high rate of injury incidence and its severity is estimated to cause approximately 9% of global mortality, while a large proportion of people surviving their injuries experience temporary or permanent disabilities. To reduce the occurrence of disability and improve general health of survivors, a more comprehensive rehabilitation approach is needed. Motor imagery is recognized as the promising cognitive strategy to counteract impaired functional capacity of the neuromuscular system. Thus, we aimed to provide to the Slovenian-speaking community a valid and reliable version of Motor Imagery Questionnaire – 3 [MIQ-3], that consists of kinaesthetic imagery [KI] and visual [i.e., Internal Imagery [IMI] and external imagery [EVI]] items.

Methods: We investigated both absolute and relative test-retest repeatability; construct validity and internal consistency of the KI, IMI and EMI items of the Slovenian version of MIQ-3 in 86 healthy adult subjects.

Results: Results showed high to very high average intra-class correlation coefficient [ICC] for the visual items [ICC=0.89] and KI items [ICC=0.92], whilst the measure of absolute variability presented as coefficient of variation [CV%] ranged from 4.9% [EVI] to 6.7% [KI]. The internal consistency was satisfactory [Cronbach α=0.91 [KI] and 0.89]) for both visual items. Confirmatory analysis confirmed a two-factorial structure of MIQ-3.

Conclusion: Understanding the content of the questionnaire is of utmost importance to ensure its effectiveness in rehabilitation practice. The Slovenian translation of the MIQ-3 is culturally and linguistically equivalent to the original English version.

IZVLEČEK

Ključne besede:
mentalna simulacija, gibanje, zanesljivost, veljavnost

Namen: Raziskave ocenjujejo, da visoka stopnja pojavnosti poškodb in njihova raven povzročata tudi do 9 % vzrokov za umrljivost, medtem ko se velik delež ljudi, ki preživijo poškodbe, sooča z začasno ali trajno invalidnostjo. Za zmanjšanje možnosti nastanka invalidnosti in izboljšanje splošnega zdravja poškodovancev je potreben bolj celovit pristop k procesu rehabilitacije. Gibalna predstava je prepoznana kot obetavna kognitivna strategija za preprečevanje poškodovanih oz. okrnjenih funkcionalnih zmogljivosti nevromuskularnega sistema. S tem namenom smo želeli zagotoviti veljavno in zanesljivo različico vprašalnika za merjenje gibalne predstave (angl. Motor Imagery Questionnaire – 3) v slovenskem jeziku, ki zajema kinestetično (KI) in vizualno predstavo (npr. notranje [IMI] in zunanje perspektive [EVI]).

Metode: Uporabili smo tako absolutni kot relativni test – retest ponovljivosti, opredelili veljavnost in notranjo konsistentnost postavk KI, IMI in EMI slovenske različice MIQ-3 pri 86 odraslih zdravih osebah.

Rezultati: Rezultati so pokazali visok do zelo visok povprečni korelacijski koeficient znotraj razreda (ICC) za spremenljivke vizualne predstave (ICC = 0,89) in kinestetične predstave (KI) (ICC = 0,92), medtem ko je absolutna variabilnost, predstavljena kot koeficient variacije (CV %), variirala od 4,9 % (EVI) do 6,7 % (KI). Notranja konsistentnost je bila zadovoljiva (Cronbach a = 0,91 [KI] in 0,89 za obe vizualni spremenljivki [IMI] in [EVI]). Analiza je potrdila dvofaktorsko strukturo MIQ-3.

Zaključek: Razumevanje vsebine vprašalnika je izredno pomembno za njegovo uporabo in učinkovitost v rehabilitacijski praksi. Slovenski prevod MIQ-3 je kulturno in jezikovno enakovreden izvirni angleški različici. Rezultati te študije podpirajo uporabo MIQ-3 kot zanesljivega in veljavnega instrumenta za oceno gibalne predstave tudi slovensko govoreče populacije.

*Corresponding author: Tel. + 386 68 612 638; E-mail: armin.paravlic@zrs-kp.si

1 INTRODUCTION

Various acute events of everyday living that has an effect on our locomotor system are common. Injuries are the fourth most common cause of death, immediately after cardiovascular disease, cancer and respiratory diseases (1, 2). On a global level, injuries are responsible for approximately 9% of mortality (2). It is estimated that for every death, there are dozens of hospitalizations, hundreds of emergency department visits, leaving a large proportion of people surviving their injuries as temporary or permanently disabled (2, 3). Since both the incidence and prevalence of injuries and other musculoskeletal conditions increase with age (4-6) the longer life expectancy that is being faced globally will result in greater proportion of people suffering from locomotor impairment. Thus, more comprehensive rehabilitation and training practice is necessary.

Currently, motor imagery [MI] that refers to mental representation of an action without any concomitant body movement (7), is a widely used cognitive strategy to enhance functional performance for both sports-based (8, 9) and therapeutic interventions (10, 11). Hence, it shows a promising indication of implementation in the rehabilitation practice of orthopaedic (12, 13) and Parkinson's disease patients (11), following immobilization (14) or stroke rehabilitation (10, 15). The efficiency of MI practice might be examined by the functional equivalence principle (7, 16), which is based on the theory that imagery enhances performance because of the similar neurophysiological processes that underlie both imagery and actual movement (17, 18), and has found its support elsewhere (19-21). More precisely, during both motor execution and MI tasks, acute differences were shown in the supplementary motor area, the premotor cortex and the primary motor cortex during imagined or executed movement when compared to resting conditions. This suggested that imagining the motor task and its actual execution do share similar neural patterns (20). Although similar patterns of cerebral activation were seen between actual movement execution, kinaesthetic imagery [KI] and visual imagery [VI], direct comparison of KI and VI revealed some differences. VI activates predominantly the occipital regions and the superior parietal lobules, whereas KI yields more activity in motor-associated structures and the inferior parietal lobule (22). Further, Stinear et al. (2005) demonstrate that KI, but not VI, modulates corticomotor excitability, primarily at the supraspinal level [assessed by transcranial magnetic stimulation]. These results suggest that VI and KI are mediated through separate neural systems, which contribute differently during processes of motor learning and neurological rehabilitation. That said, recruitment of the brain regions associated with motor imagery is correlated with the subject's ability to imagine the movement (18) and depends on the way it is imagined

[VI or KI] (28). When using KI, the movement is imagined from a first-person perspective, e.g. as though viewing through one's own eyes, seeing the body part move while feeling kinaesthetic sensations. In contrary, when using the VI, it is a third-person view of oneself performing the motor action [e.g., movement of any body part], as one would see itself on a video. However, both first and third-person perspectives entail KI or VI (23). Next to imagery perspective, the imagery ability may have had a significant impact upon its effectiveness, as it is likely that someone who cannot clearly imagine performing a motor task will not benefit much from MI practice (24-26). Therefore, to improve rehabilitation practice, by a more individualized approach, imagery ability of each patient should be assessed.

To date, different methodologies were used to measure MI ability that relies on neurophysiological, behavioural, psychometric and psychophysiological foundations (22, 27). However, due to low costs and time-saving benefits, self-report questionnaires represent the most suitable tool to assess MI ability of the individual. One of the most popular and commonly used questionnaires is the revised version of the Movement Imagery Questionnaire [MIQ-R], that is an appropriate instrument for the assessment of VI and KI motor imagery (28). In order to be used in rehabilitation practice, the previous version of MIQ-R was revised (29, 30), and its validity was confirmed (29-32). Since both the incidence and prevalence of diseases such as cardiovascular, neuro-musculo-skeletal increase with age (5, 33) the longer life expectancy that is being faced globally will result in an increase rate of disabled individuals. Epidemiological data collected among Slovenian citizens showed that a stroke represents the second and third most common cause of mortality among females and males, respectively, while a great number of patients experienced prolonged disability (34). Further, the same report indicated that Slovenia came fifth in Europe in incidence of pain, where 40% of citizens have serious health problems associated with musculo-skeletal diseases, of which up to 30% reported chronic pain for longer than three months at a time (34). Recognized as a beneficial rehabilitation tool, it is very important for clinical as well as for research purposes to investigate whether the Slovenian translation of the MIQ-3 is a valid assessment tool of MI ability among the Slovenian population.

2 METHODS

2.1 Translation Procedure

Translation of the questionnaire was executed by a Slovenian researcher with an English Language Certificate of Proficiency, after the translated version in Slovene was retranslated in English, again by a native Slovene

studying and working in the United States for 30 years. It was rechecked by a native American. The final stage of the adaptation process was to test the pre-final version. Pretesting of the prefinal Slovenian version for comprehensibility on 10 randomly selected subjects revealed no further difficulties with the questionnaire, after which the questionnaire was approved by the authors to be used in the experimental setting.

2.2 Study Sample

The sample was recruited via printed advertising and consisted of various population that lives, works and/ or studies in the Slovenian Primorska region. All the participants were older than 18 years of age. Participants' age [younger vs. older than 50 yrs. of age], gender [male vs. females] and current athletic status and/or level [athlete vs. non-athlete] were assessed. For the athletes, we considered only those subjects who were actively engaged in any kind of sport on competitive level. In total 86 subjects completed the questionnaire in Time 1. The study protocol was approved by the local research and ethics committee of Orthopaedic Hospital Valdoltra [number: 16/2016]. Informed consent was obtained from each subject prior to participation.

2.3 Procedure

At first [Time 1], the questionnaire was completed by 86 subjects [mean±SD; aged 35.26±16.1 years] of which 47.7% were females. To evaluate the reproducibility (test-retest reliability) of the questionnaire, approximately one week later [±2 days, Time 2], 80 persons filled out the same questionnaire under identical conditions. The subjects were asked to continue with their common daily activities in the period between testing, to control a possible disruption on MI ability that could have occurred. Questionnaires were assessed in a calm room, in optimal climatic conditions. In order to avoid [overcome] a possible variability of understanding the instructions, researchers explained the protocol and demonstrated the movements according to the instructions.

The MIQ-3 is a questionnaire consisting of total of 12 items to assess individual's ability to image four movements [leg raise, jump, arm abduction and adduction, standing hip flexion [bending forward]] using visual imagery [from internal [IVI] or external [EVI] perspective] and KI. Each scale comprises seven possible responses [7-point Likert scale], where the per-item score consequently ranged from 1="very hard" to 7="very easy" [questionnaire in the Appendix]. For each scale [VI and KI] and for each participant, a mean score ranging from 1 to 7 was obtained, with a higher score representing a better mental imagery ability regarding the tested modality. It takes approximately 15 minutes to administer the test.

2.4 Determining the Internal Consistency of the MIQ-3 [Slovenian Version]

The internal consistency of the questionnaire was assessed by computing the standardized Cronbach alpha coefficient. Internal consistency is generally deemed acceptable with a coefficient greater than 0.7, good at 0.8 minimum, and excellent when superior to 0.9.

2.5 Determining the Test-Retest Reliability of the MIQ-3 [Slovenian Version]

The repeatability [test-retest] of the scores on each of the scales [visual and kinaesthetic] was assessed through comparison of the scores registered for Time 1 and Time 2. The relative reliability of all dependent variables was estimated using the intra-class correlation coefficient [ICC], two-way random model [consistency type]. ICC values were considered as very high if >0.90, high if between 0.70 and 0.89, and moderate if between 0.50 and 0.69. Standard error of estimate [SEM] followed by the coefficient of variation [CV] were calculated as measures of absolute reliability, which indicates within subject variation, as previously suggested in the literature (35). To further address the reliability issues of the data a minimal detectable change [MDC] was calculated, a measure of minimal amount of change unrelated to variations of the assessment, as reported elsewhere (36).

2.6 Construct Validity of the MIQ-3 [Slovenian Version]

First, validity was tested by exploratory factor analysis, and on the basis of the obtained data and data from previous research (38), a confirmatory factor analysis [CFA] was used in order to test construct validity. For verifying the adequacy of the data with regard to expected models we used the following adjustment indexes: Comparative Fit Index [CFI], Tucker-Lewis index [TLI] [for both index values greater than .90 are usually considered satisfactory] (37), Root Mean Square Error of Approximation [RMSEA], Root Mean square Residual [RMR] and the Standardized RMR [SRMR] [for all of them values of about .05 indicate close fit of a model to data a values of about .08 indicate reasonable fit of a model (37)].

2.7 Statistical Analyses

All data are presented with a mean ± SD and 95% of confidence intervals. All statistical analysis was done with SPSS statistical software [version 20.0, IBM Inc, Chicago, USA]. Normality was confirmed by visual inspection and using the Shapiro-Wilk test, while the homogeneity of variances was tested using the Levene's test for all dependent variables [IMI, EVI, KI]. Statistical significance was accepted at $p < 0.05$.

3 RESULTS

3.1 Population

Eighty-six volunteers [41 female], mean age of 35.3 years [range from 18 to 70 yrs., SD 16.1 yrs.] completed the questionnaire in Time 1, while eighty subjects [40 female], mean age of 34.8 years [range from 18 to 70 yrs., SD 15.7] completed second questionnaire one week later [Time 2].

3.2 Motor Imagery Scores: Visual and Kinaesthetic Scales According to Gender, Age, and Sport Participation

Table 1 presents the mean scores and SD for IMI, EVI and KI recorded in our population regarding the first and second tests. The overall score [n=86 subjects] at Time 1 was higher for combined visual imagery [VI-comb; 5.76±0.84] than for kinaesthetic imagery [5.30±1.26]. Slightly lower scores were observed for IMI [5.63±0.98] compared to EVI [5.89±0.85]. Considering either scale independently, there is no statistical difference between Time 1 and Time 2 [Z ranged between -1.647 and -0.222; P ranged between 0.099 and 0.824, respectively] for the 80 subjects having participated in both testing sessions. However, for both KI and IMI scales, there is a trend of a slight increase, except for EVI, which stay unchanged from Time 1 to Time 2, indicating that minor learning effects occurred.

There were no statistically significant differences observed for the mean IMI, EVI and KI scores considering all dependent variables for analysed sub-groups [i.e., younger vs. older adults; females vs. males and athletes vs. non-athletic population][Table 2].

Table 1. Descriptive statistics for the motor imagery scores: kinaesthetic and visual [internal and external] scales at Time 1 and Time 2.

Dimensions	n	Mean	Standard deviation
Time 1 (test)			
KI	86	5.30	1.26
IVI	86	5.63	0.98
EVI	86	5.89	0.85
VI-comb	86	5.76	0.84
KI	80	5.31	1.29
IVI	80	5.67	1.00
EVI	80	5.92	0.85
VI-comb	80	5.79	0.85
Time 2 (re-test)			
KI	80	5.38	1.29
IVI	80	5.79	0.89
EVI	80	5.88	0.88
VI-comb	80	5.84	0.83

KI – kinaesthetic imagery; n – number of investigated subjects; IMI – internal visual imagery; EVI external visual imagery; VI-comb – combined results of both the IVI and EVI

Table 2. Differences in imagery ability scores for kinaesthetic and visual [internal and external] scales considering participants' characteristics such as age, gender and sport participation. Data were presented as Means ± Standard deviations [SD] for all participants assessed in Time 1 [n=86].

Dimensions	Category	Number of subjects	Mean±SD	Z value	P value between groups
KI	**Age**				
	younger adults	63	5.36±1.27		
	older adults	23	5.13±1.22	-1.137	0.256
	Gender				
	females	41	5.33±1.20		
	males	45	5.27±1.33	-0.252	0.801
	Athlete or not				
	athlete	22	5.14±1.30		
	non-athlete	64	5.36±1.25	-0.984	0.325
IVI	**Age**				
	younger adults	63	5.71±0.97		
	older adults	23	5.43 ± 0.99	-1.130	0.259
	Gender				
	females	41	5.75±0.87		
	males	45	5.53±1.06	-0.862	0.389
	Athlete or not				
	athlete	22	5.69±0.84		
	non-athlete	64	5.61±1.03	-0.70	0.944
EVI	**Age**				
	younger adults	63	5.95±1.22		
	older adults	23	5.71±0.79	-1.488	0.137
	Gender				
	females	41	5.94±0.68		
	males	45	5.84±0.98	-0.061	0.951
	Athlete or not				
	athlete	22	5.90±0.80		
	non-athlete	64	5.89±0.87	-0.229	0.819

KI – kinaesthetic imagery; n – number of investigated subjects; IMI – internal visual imagery; EVI external visual imagery

Table 3 presents the mean scores, the SD and the minimum and maximum scores reached by the 86 subjects, taken together during Time 1.

Table 3. Analysis of the means, standard deviations, minimum and maximum scores for each item at T1 [n=86 subjects].

Items	Scale	Mean score	Standard deviation	Minimum score	Maximum score
1	KI	5.27	1.47	1.00	7.00
2	IVI	5.42	1.33	2.00	7.00
3	EVI	6.01	0.93	3.00	7.00
4	KI	5.20	1.39	1.00	7.00
5	IVI	5.81	1.14	3.00	7.00
6	EVI	5.81	1.18	2.00	7.00
7	KI	5.42	1.52	1.00	7.00
8	IVI	5.44	1.28	1.00	7.00
9	EVI	5.88	0.98	3.00	7.00
10	KI	5.47	1.50	1.00	7.00
11	IVI	5.86	1.17	3.00	7.00
12	EVI	5.85	1.16	2.00	7.00

KI – kinaesthetic imagery; n – number of investigated subjects; IMI – internal visual imagery; EVI external visual imagery

3.3 Determining the Internal Consistency of the MIQ-3 [Slovenian Version]

The Cronbach alpha coefficient for the KI was 0.91. In addition, the same coefficients of 0.89 were found for both the IMI and EVI, suggesting that the internal consistency of the Slovenian version of the MIQ-3 may be considered excellent.

3.4 Determining the Test-Retest Reliability of the MIQ-3 [Slovenian Version]

The reliability analysis showed a high to very high average ICC [relative reliability assessment] of 0.92 for the different kinaesthetic items and 0.89 for the different visual items, whilst the measure of absolute variability CV% ranged from 4.9% [EVI] to 6.7% [KI] [Table 4].

Table 4. Between Time 1 and Time 2 reliability analysis of the kinaesthetic and visual [internal and external] motor imagery scales.

Variable	Time 1	Time 2	P_{ANOVA}	CV (%)	MDC	SEM	ICC (95% CI)
KI	5.31±1.29	5.38±1.29	0.420	6.7	1.04 points	0.38	0.92 (0.87-0.95)
IVI	5.67±1.00	5.79±0.89	0.059	5.9	0.88 points	0.31	0.89 (0.82-0.93)
EVI	5.92±0.85	5.88±0.88	0.508	4.9	0.79 points	0.29	0.89 (0.83-0.93)

P_{ANOVA} – P-value of repeated measures analysis of variance; CV – within subject coefficient of variation; MDC – minimal detectable change; SEM – standard error of estimate; ICC [95% CI] – intra-class correlation coefficient with 95% confidence intervals.

3.5. Construct Validity of the MIQ-3 [Slovenian Version]

The results of the exploratory factor analysis indicate that it is possible to distinguish two factors that explain 59.8% of variance [Table 5]. By their structure, these factors can be defined as Visual Imagery and Kinaesthetic Imagery. Previous studies have shown that the two-factor model does not have very good adjustment indexes, so three-factor models have been tested with a confirmatory factor analysis. The MODEL 1 is the correlated trait–correlated uniqueness model with IVI, EVI and KI as separate factors. The MODEL 2 is the correlated trait–correlated uniqueness model with external and internal visual imagery perspectives on one factor and KI on the other. The MODEL 3 is the correlated trait–correlated uniqueness model with IVI and KI on one factor and external visual imagery on the other. Results are presented in Table 6. We can see that the present study showed very comparable results to the previous one conducted among the English-speaking population (38). Best model fits were achieved with Model 1 [three-factor model with IVI, EVI and KI all as separate factors]. Fit indices were lower in some cases [for example RMSEA] but results still show a reasonable approximate fit. The graphic representation of the first two models can be seen in Figure 1.

Table 5. Result of exploratory factor analysis for the Slovenian version of the MIQ-3.

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	4.656	38.796	38.796	4.656	38.796	38.796
2	2.521	21.006	59.802	2.521	21.006	59.802
3	.945	7.878	67.680			
4	.770	6.418	74.098			
5	.634	5.281	79.379			
6	.511	4.257	83.637			
7	.473	3.943	87.579			
8	.427	3.562	91.141			
9	.303	2.526	93.667			
10	.297	2.478	96.145			
11	.258	2.151	98.295			
12	.205	1.705	100.000			

Table 6. MIQ-3 Confirmatory Factor Analysis Goodness-of-Fit Indices for the Models with a Proper Solution.

Model	Chi^2	df	p	CFI	TLI	RMR/SRMR	RMSEA
Present Study (Slovenian population)							
MODEL 1 (EVI vs. IVI vs. KI)	75.403	51	0.015	0.94	0.93	0.108	0.07
MODEL 2 (EVI and IVI vs. KI)	91.36	53	0.001	0.91	0.89	0.120	0.09
MODEL 3 (IVI and KI vs. EVI)	191.10	53	<0.001	0.67	0.59	0.332	0.18
Previous Study (38)							
MODEL 1 (EVI vs. IVI vs. KI)	75.12	39	<0.001	0.98	0.97	0.04	0.05
MODEL 2 (EVI and IVI vs. KI)	369.13	41	<0.001	0.82	0.71	0.11	0.15
MODEL 3 (IVI and KI vs. EVI)	243.66	41	<0.001	0.88	0.82	0.07	0.12

KI – kinaesthetic imagery; IMI – internal visual imagery; EVI external visual imagery; Chi^2 – chi-squared test; df – degrees of freedom; p – statistical significance of test; CFI – Comparative Fit Index; TLI – Tucker-Lewis index; RMR/SRMR – Root Mean square Residual and Standardized RMR; RMSEA – Root Mean Square Error of Approximation
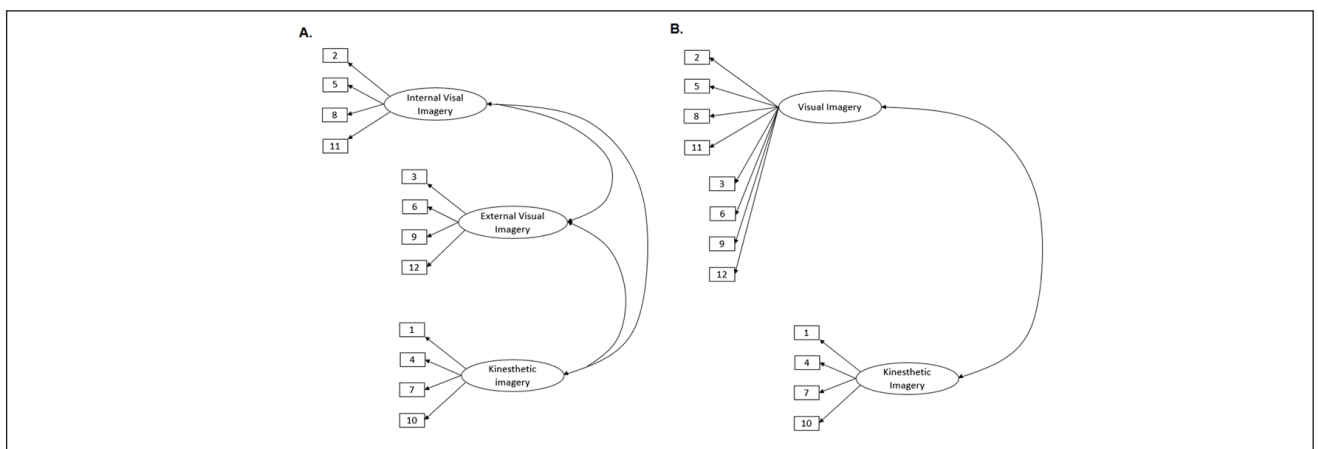

Figure 1. The graphic representation of two models tested by the confirmatory factor analysis: A) MODEL 1 is the correlated trait–correlated uniqueness model with IVI, EVI, and KI all as separate factors and B) MODEL 2 is the correlated trait–correlated uniqueness model with EVI and IVI perspectives as one factor and KI as another. The numbers in the rectangles represent the number of items in the questionnaire, and in the ellipses are the names of the factors. Best model fits were achieved with Model 1 [three-factor model with IVI, EVI and KI all as separate factors].

4 DISCUSSION

The most important finding of the present study is that MIQ-3 translated to Slovenian language is effectively validated, suggesting that it can be proposed to the Slovene-speaking public. More in detail, both the absolute and relative reliability of MIQ-3 proven its high to very high repeatability, confirming that no learning effect occurred within one-week period. Further, assessing construct validity of the questionnaire, we confirmed its two-dimensional [i.e., visual and kinaesthetic] structure, similarly to previous findings of the original study assessed among the English-speaking population (38). Additionally, we are not able to detect any significant difference in imagery ability considering participants' gender, age and status of sports engagement [i.e., athlete vs. non-athlete].

Although some studies have detected gender differences in imagery ability [e.g., based on spatio-visual characteristics assessed by mental rotation test only] (39), our findings are in accordance with studies demonstrating no significant differences between males and females in the ease of ability to imagine the movement (31, 32). Additionally, no difference was confirmed between younger and older adults, comparable to previous studies aimed to investigate the self-assessment of imaging capacity (39). While the performance-based test of imaging capacity showed a tendency towards a greater ability of younger individuals (39), which might be prescribed to well-known slower speed of cognitive processing in older subjects (40). Nonetheless, younger individuals showed a slightly greater ability to imagine a movement for all investigated scales; however, due to an overestimation of younger subjects in our sample, a robust conclusion could not be drawn. Therefore, for any additional interpretation of observed tendency, specifically designed studies aimed to address this issue are encouraged. Similarly, to gender and age comparisons, our results showed comparable abilities of both the kinaesthetic and visual scales considering the athletic status [i.e., athletes vs. non-athletes]. However, previous studies aimed to address this question, showed that the regular practice of sport evoked greater kinaesthetic ability (41), which in our sample was not the case. To successfully employ motor images, it should be critical to have well-developed motor representations (42). This means that, in order to "feel and/or see the movement like it is actually executed", it is of great importance to actually have the necessary motor skills to be able to perform the action physically. This is well documented in elite vs. amateur athletes in high jump performance practice (43). Since MIQ-3 consists of very simple, every day movement patterns, tasks like moving the arm in front of the body, or raising the knee at hip level, and given that our study sample had no serious locomotion difficulties, we were not able to detect any differences among individuals.

In general, MI ability questionnaires are widely used among both the symptomatic and asymptomatic population. However, the difficulty to perform included motor tasks among different MI questionnaires might constrain their general usability. Therefore, consisting of three very simple and one more complex task [i.e., jump] MIQ-3 might be a useful tool to assess MI ability among various population [with and without mobility problems]. Previous studies showed that type [kinaesthetic vs. visual] and perspective [i.e., internal vs. external] of imagined tasks (44), elicit greater brain activity of motor related areas during a MI session (43). Consequently, those alterations on the cortical level lead to greater descending command of the involved muscles, improving its motor unit recruitment and activation, finally improving the muscle mechanical output following MI practice. That is, overall imagery ability may have had a significant impact upon its effectiveness. It is likely that someone who cannot clearly imagine performing a motor task will not benefit much from MI practice (24, 25). Since present findings confirmed two-dimensional characteristics of MIQ-3 imagery, from a neuro-functional stand point it has a great clinical value in planning individualized motor imagery practice. The absence of significant differences between men and women regarding imagery ability proves that planning of the MI practice should be same for both genders. The similar guidelines should be accounted regardless of age of participants, given that any significant difference for three MI scales was not observed.

4.1 Limitations of Present Study and Suggestions for Further Research

Some limitations of the present study must be outlined. One limitation might be the overestimation of the study sample regarding younger individuals vs. older ones and those who were classified as non-athlete vs. athlete, therefore the interpretation of those results should be taken with caution. Another one is that our study sample consisted of a healthy population in general and individuals up to 70 years of age only, which limit us to give general guidelines regarding MI practice. Therefore, providing the evidence of MI ability among people older than 70 years of age and those individuals with various disease-related symptoms and/or pathologies [e.g., musculo-skeletal disease, orthopaedic patients, stroke patients etc.] should be encouraged.

5 CONCLUSION

Understanding the content of the questionnaire is of utmost importance for the validity of its use and effectiveness in the rehabilitation practice. The Slovenian translation of the MIQ-3 is linguistically and culturally equivalent to the original English version. The results of this study support the use of the MIQ-3 as a reliable and valid motor imagery ability assessment instrument in Slovenian-speaking population. From a neuro-functional standpoint it was confirmed that two-dimensional characteristics of MIQ-3 imagery have a great clinical value in planning individualized motor imagery practice. In addition, given that non-significant differences in MI quality were observed, the same MI practice could be implemented for both genders, regardless of the age of participants.

CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

FUNDING

The study had no financial support.

ETHICAL APPROVAL

Research has been performed in accordance with the Declaration of Helsinki. The study protocol was approved by the local research and ethics committee of Orthopaedic Hospital Valdoltra (number: 16/2016).

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SURGICAL SITE INFECTIONS IN SLOVENIAN ACUTE CARE HOSPITALS: SURVEILLANCE RESULTS, 2013-2016

OKUŽBE KIRURŠKE RANE V SLOVENSKIH BOLNIŠNICAH ZA AKUTNO OSKRBO: REZULTATI EPIDEMIOLOŠKEGA SPREMLJANJA, 2013-2016

Irena KLAVS[1][*], Tanja KUSTEC[1], Mojca SERDT[1], Jana KOLMAN[1], SSI-Sur network[2]

[1]National Institute of Public Health, Communicable Diseases Centre, Zaloška 29, 1000 Ljubljana, Slovenia
[2]SSI-Sur network: Irena Klavs (National Institute of Public Health), Jana Kolman (National Institute of Public Health), Tanja Kustec (National Institute of Public Health), Mojca Serdt (National Institute of Public Health), Mojca Savnik Iskra (General hospital Brežice), Aleksandra Krznar (General hospital Celje), Sandra Tušar (General hospital Jesenice), Irena Piltaver Vajdec (General hospital Slovenj Gradec), Katja Kalan Uštar (General hospital Trbovlje), Tatjana Mrvič (University Medical Centre Ljubljana), Božena Kotnik Kevorkijan (University Medical Centre Maribor)

ABSTRACT

Keywords:
healthcare-associated infections, surgical site infections, surveillance, Slovenia

Introduction: The objective was to present the results of the Slovenian National surgical site infections (SSIs) surveillance system from 2013 to 2016 and to compare them to the reference data for the European Union (EU) and European Economic Area (EEA) countries.

Methods: Surveillance was conducted according to the Slovenian protocol consistent with the European Centre for Disease Prevention and Control protocol. Descriptive analyses were performed.

Results: Data were collected for 1080 patients of whom 57.4% were patients with cholecystectomy (from three hospitals), 29.0% with caesarean sections (from four hospitals) and 4.7%, 4.5% and 4.4% patients with hip prosthesis, knee prosthesis and colon surgery (each surgical category from one hospital). The pooled in-hospital SSI incidence density for caesarean section was 3.7 (95% CI: 1.4-8.1; inter-hospital range: 0.0-11.5) and for cholecystectomy 6.8 (95% CI: 3.5-11.9; inter-hospital range: 4.1-11.9) per 1000 post-operative patient-days. The in-hospital SSI incidence density for colon surgery was 24.8 (95% CI: 12.5-44.0) and for hip prosthesis 2.6 (95% CI: 0.1-14.2) per 1000 post-operative patient-days. No SSIs were reported among the 49 patients with knee prostheses.

Conclusions: The estimated SSIs incidence rates varied between different surgical categories and the different participating hospitals. In some of the participating hospitals and for some of the surgical procedures under surveillance they were rather high in comparison to the reference data for hospitals from EU/EEA countries. It is urgent to expand standardised SSIs surveillance to all Slovenian acute care hospitals with surgical wards to contribute to evidence-based SSIs prevention and control in Slovenia.

IZVLEČEK

Ključne besede:
okužbe, povezane z zdravstvom, okužbe kirurške rane, epidemiološko spremljanje, Slovenija

Izhodišča: Cilj je bil predstaviti rezultate slovenskega nacionalnega sistema epidemiološkega spremljanja okužb kirurške rane (OKR) za obdobje od leta 2013 do leta 2016 in jih primerjati z referenčnimi podatki za države Evropske unije (EU) in Evropskega gospodarskega območja (angl.: European Economic Area - EEA).

Metode: Epidemiološko spremljanje OKR je potekalo v skladu s slovenskim protokolom, ki je bil skladen s protokolom Evropskega centra za preprečevanje in obvladovanje bolezni (angl.: European Centre for Disease Prevention and Control - ECDC). Izvedene so bile opisne analize zbranih podatkov.

Rezultati: Podatki so bili zbrani za 1080 pacientov, od katerih je bilo 57,4 % pacientov s holecistektomijo (iz treh bolnišnic), 29,0 % pacientk s carskim rezom (iz štirih bolnišnic), 4,7 % pacientov po artroplastiki kolka (iz ene bolnišnice), 4,5 % pacientov po artroplastiki kolena (iz ene bolnišnice) in 4,4 % pacientov po operaciji debelega črevesa (iz ene bolnišnice). Skupna ocena incidenčne gostote OKR pred odpustom za carski rez je bila 3,7 na 1000 bolniško oskrbnih dni po operaciji (95-% interval zaupanja (IZ): 1,4-8,1; razpon vrednosti za posamezne bolnišnice: 0,0-11,5). Skupna ocena incidenčne gostote OKR pred odpustom za holecistektomijo je bila 6,8 na 1000 bolniško oskrbnih dni po operaciji (95-% IZ: 3,5-11,9; razpon vrednosti za posamezne bolnišnice: 4,1-11,9). Incidenčna gostota OKR pred odpustom po operaciji črevesa je bila 24,8 (95-% IZ: 12,5-44,0) in za artroplastiko kolka 2,6 (95-% IZ: 0,2-14,2) na 1000 bolniško oskrbnih dni po operaciji. Med 49 pacienti z artroplastiko kolena ni bilo nobene OKR.

Zaključki: Ocenjene incidenčne stopnje so se razlikovale med različnimi operacijami in med različnimi sodelujočimi bolnišnicami. V nekaterih bolnišnicah so bile nekatere ocene incidenčnih stopenj za nekatere od operacij, vključenih v epidemiološko spremljanje, zelo visoke v primerjavi z referenčnimi podatki za države EU in EEA. To nakazuje, kako nujno je v Sloveniji razširiti v Evropi standardizirano epidemiološko spremljanje OKR na vse slovenske bolnišnice za akutno oskrbo s kirurškimi oddelki in s tem prispevati k na dokazih temelječemu preprečevanju in obvladovanju OKR v Sloveniji.

*Corresponding author: Tel. + 386 41 344 196; E-mail: irena.klavs@nijz.si

1 INTRODUCTION

Surgical site infections (SSIs) were the third most common type of healthcare-associated infections (HAI) in the second national HAI one-day prevalence survey (1). It was conducted in all Slovenian acute care hospitals within the European point prevalence survey of HAI and antimicrobial use (2). SSIs are associated with longer post-operative hospital stays, additional surgical procedures, treatment in intensive care units and higher mortality (3). Surveillance of SSIs contributes towards lowering their incidence rates and to monitoring the quality of healthcare (4, 5).

Surveillance of HAI is mandatory according to the Slovenian Communicable Diseases Act (Official Gazette of the Republic of Slovenia number 33/06) and has been recommended by the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of HAI (2009/C 151/01). The Slovenian National HAI surveillance (HAI-Sur) system is being developed by the National Institute of Public Health (in Slovene: Nacionalni inštitut za javno zdravje – NIJZ) in collaboration with acute care hospitals that cooperate in the HAI-Sur network (6). SSIs surveillance (SSI-Sur) one of the HAI surveillance modalities has been implemented by the SSI-Sur network, sub-network of the HAI-Sur network.

The objective of this paper is to present the results of SSIs surveillance in Slovenian acute care hospitals for the period from 2013 to 2016 and compare them to the reference data for European Union (EU) and European Economic Area (EEA) countries published by the European Centre for Disease Prevention and Control (ECDC) (7). The aim is to contribute to evidence-based SSIs prevention and control in Slovenian acute care hospitals.

2 METHODS

2.1 Data Collection

Between 2013 and 2016 surveillance of SSIs in voluntarily participating Slovenian acute care hospitals was conducted according to the Slovenian SSI-Sur protocol (version 1.0), which was consistent with the ECDC protocol for SSIs surveillance (version 1.02) (8, 9). In brief, the surgical procedures under surveillance were caesarean section, cholecystectomy, colon surgery, hip prosthesis and knee prosthesis. The shortest surveillance period during which all patients with the selected surgical procedure under surveillance in a participating hospital were enrolled, was three months (a quarter of a year). Data collected for all patients included their age, date of admission, date of surgery, whether the operation was urgent, whether the patient received antibiotic prophylaxis within two hours before the incision (or during surgery for caesarean section) and date of discharge. Furthermore, data for the

estimation of the US National Healthcare Safety Network (NHSN) risk index (basic SSI risk index according to the ECDC SSI surveillance protocol), which is based on the presence of three major risk factors (duration of the operation, wound contamination class and the American Society of Anaesthesiologists (ASA) physical status classification), was collected (9–11). SSIs cases were ascertained and classified according to the 2012 EU case definitions (12). Only information about SSIs detected within 30 days after surgery were recorded, except for SSIs following orthopaedic operations with an implant in place (hip and knee prostheses), where SSIs up to one-year after surgery were recorded (7, 8). The SSIs data collected included the date of onset, type of SSI according to the EU case definitions (superficial, deep or organ/space) and, if available, information on microorganisms identified in SSI.

2.2 Data Management and Analysis

Data was entered by hospital staff using a data entry programme Epi Info (Epi Info, version 7, CDC, Atlanta, GA, USA) prepared by the NIJZ with built-in code range and filter checks. After each data collection period, the participating hospitals sent their quarterly SSI-Sur data sets to the NIJZ.

We performed descriptive analyses using the national SSI-Sur data set from 2013 to 2016, using the statistical software SPSS (Statistical Package for the Social Sciences, version 21.0, Chicago, IL, USA). We described characteristics of patients, surgical procedures, SSIs, microorganisms identified, and patients' length of hospital stay. For continuous variables such as age or duration of the operation we calculated the mean, median and inter-quartile range (IQR), the range between 25th percentile (P25) and 75th percentile (P75). We calculated three main indicators for each surgical procedure: (a) cumulative SSIs incidence (the percentage of SSIs diagnosed during hospital stay and after discharge (detected at hospital readmission or by post-discharge surveillance) per 100 operations); (b) cumulative in-hospital SSIs incidence (the percentage of SSIs diagnosed during hospital stay per 100 operations); and (c) in-hospital SSIs incidence density (number of in-hospital SSIs per 1 000 post-operative patient-days). The latter indicator only includes SSI diagnosed during hospital stay in patients with a known discharge date from hospital. We used the Clopper-Pearson exact method for calculating the 95% confidence intervals. As most Slovenian SSIs surveillance data were collected from 2013 to 2014, we compared our results with the reference data for EU/EEA countries for the same period (from 2013 to 2014) published by ECDC, although the data cannot be considered fully representative for all surgical wards in EU/EEA acute care hospitals (7).

2.3 Legal Basis and Ethics

Surveillance of SSIs was conducted according to the Slovenian Communicable Diseases Act (Official Gazette of the Republic of Slovenia number 33/06) within the Slovenian SSI-Sur network of voluntarily participating acute care hospitals. Only personnel in participating hospitals knew the identity of all patients enrolled into SSIs surveillance and treated this data confidentially. The data submitted to NIJZ did not contain information on the identity of patients.

Before the start of data collection, NIJZ obtained ethical consent to the data collection within the Slovenian National HAI-Sur system, which includes the SSI-Sur system from the Medical Ethical Committee of the Republic of Slovenia at the Ministry of Health (Consent number: 68/04/08).

3 RESULTS

3.1 Participating Hospitals

SSIs surveillance data for selected surgical procedures for different quarters from 2013 to 2016 were reported to NIJZ by seven hospitals: General hospital (GH) Brežice, GH Celje, GH Jesenice, GH Slovenj Gradec, GH Trbovlje, University Medical Centre (UMC) Ljubljana and UMC Maribor.

3.2 Surgical Procedures under Surveillance

We collected data from 1080 patients. The highest proportion of patients enrolled in the SSIs surveillance were patients with cholecystectomy (57.4%), followed by patients with caesarean section (29.0%), hip prosthesis (4.7%), knee prosthesis (4.5%) and colon surgery (4.4%). Item response rates for all individual variables in the SSI-Sur data set for 2013-2016 were above 95%.

3.2.1 Caesarean Section

Information about 313 caesarean section operations from April 2013 to December 2013 was submitted to NIJZ by four hospitals. The mean age of patients was 31 years (median: 31 years; IQR: 27-34 years). One percent of patients had ASA score ≥3, corresponding to a severe systemic disease or worse. A total of 55.9% of operations were urgent (inter-hospital range: 50.0%-66.0%). There were no contaminated or dirty wounds. 91.4% of patients received antibiotic prophylaxis during surgery (inter-hospital range: 82.4%-97.9%). The mean duration of an operation was 38 minutes (median: 35 minutes; IQR: 30-45 minutes). The median length of post-operative stay was five days (inter-hospital range: four to six days).

A total of 14 SSIs were reported within 30 days of the operation. Six SSIs were detected before discharge. Two hospitals conducted post-discharge surveillance. Among 14 SSIs, eight were superficial incisional SSI, three were deep incisional SSIs, two were organ/space SSIs and one was of unknown type.

The estimated pooled cumulative SSIs incidence was 4.5% (95% CI: 2.5%-7.4%; inter-hospital range: 0.0%–13.8%). The estimated pooled cumulative in-hospital SSIs incidence was 1.9% (95% CI: 0.7%-4.1%; inter-hospital range: 0.0%–6.4%). Pooled in-hospital SSIs incidence density was 3.7 (95% CI: 1.4-8.1) per 1000 post-operative patient-days (inter-hospital range: 0.0-11.5 SSI per 1000 post-operative patient-days).

Microbiological data was available for one SSI. A coagulase-negative staphylococcus was isolated.

3.2.2 Cholecystectomy

Information about 620 cholecystectomies from April 2013 to December 2016 was submitted by three hospitals. The mean age of patients was 54 years (median: 55 years; IQR: 40-65 years). 13.2% of patients had an ASA score ≥3. 18.7% of operations were urgent (inter-hospital range: 2.6%-26.6%). There were 3.4% of contaminated or dirty wounds (inter-hospital range: 0.0%-8.8%). 27.3% of patients received antibiotic prophylaxis before surgery (inter-hospital range: 3.9%-37.6%). The mean duration of operation was 59 minutes (median: 52 minutes; IQR: 40-71 minutes). The median length of post-operative stay was two days (inter-hospital range: one to four days).

A total of 36 SSIs were detected within 30 days of the operation. All three hospitals conducted post-discharge surveillance. Twelve SSIs were detected before discharge. Among 36 SSIs, 20 were superficial incisional SSIs, nine were deep incisional SSIs, six were organ/space SSIs and one was of unknown type.

The estimated pooled cumulative SSIs incidence was 5.8% (95% CI: 4.1%-7.9%; inter-hospital range: 3.3%-22.1%). The estimated pooled cumulative in-hospital SSIs incidence was 1.9% (95% CI: 1.0%-3.4%; inter-hospital range: 1.0%–4.1%). Pooled in-hospital SSIs incidence density was 6.8 (95% CI: 3.5-11.9) per 1000 post-operative patient-days (inter-hospital range: 4.1-11.9 SSI per 1000 post-operative patient-days). The annually estimated in-hospital SSIs incidence density in the only hospital that conducted SSIs surveillance for three consecutive years, the point estimates dropped from 9.8 SSIs per 1000 post-operative patient-days in 2014 to 2.8 SSIs per 1000 post-operative patient-days in 2016.

Microbiological data was available for six SSIs. For four SSIs one microorganism was identified (*Escherichia coli* (two SSIs), *Staphylococcus aureus* and *Preudomonas aeruginosa*).

3.2.3 Colon Surgery

Information about 47 colon surgeries from July 2013 to June 2014 was submitted by one hospital. The mean age of patients was 72 years (median: 75 years; IQR: 63–80 years). 36.2% of patients had ASA score ≥3. 21.3% of operations were urgent. 14.9% of wounds were contaminated or dirty. 97.9% of patients received antibiotic prophylaxis before surgery. The mean duration of operation was 136 minutes (median: 125 minutes; IQR: 104–166 minutes). The median length of post-operative stay was seven days. A total of 11 SSIs were detected before discharge and two after discharge. Among the 13 SSIs, three were superficial incisional SSIs, seven were deep incisional SSIs and three were organ/space SSIs.

Estimated cumulative SSIs incidence was 27.7% (95% CI: 15.6%–42.6%). The estimated cumulative SSIs in-hospital incidence was 24.4% (95% CI: 12.9%–39.5%). In-hospital SSIs incidence density was 24.8 (95% CI: 12.5–44.0) per 1000 post-operative patient-days.

Microbiological data was available for eight SSIs. For two SSIs one microorganism was identified (*Escherichia coli* and *Streptococcus haemoliticus*).

3.2.4 Hip Prosthesis

Information about 51 hip prostheses from October 2013 to February 2014 was submitted by one hospital. The mean age of patients was 67 years (median: 71 years; IQR: 58–78 years). 43.1% of patients had ASA score ≥3. There were no urgent operations and no contaminated or dirty wounds. 94.1% of patients received antibiotic prophylaxis before surgery. The mean duration of operation was 81 minutes (median: 70 minutes; IQR: 55–90 minutes). The median length of post-operative stay was six days.

Two SSIs were reported within a year of the operation, one was detected before and one after discharge. Among two SSIs, one was organ/space SSI and for the other there was no information about SSI type.

The estimated cumulative SSIs incidence was 3.9% (95% CI: 0.5%–13.5%). The estimated cumulative in-hospital SSIs incidence was 2.0% (95% CI: 0.0%–10.4%). In hospital SSIs incidence density was 2.6 (95% CI: 0.1–14.2) per 1000 post-operative patient-days.

Microbiological data was available for both SSIs and from both more than one microorganism was isolated.

3.2.5 Knee Prosthesis

Information about 49 knee prostheses from October 2013 to February 2014 was submitted by one hospital. The mean age of patients was 69 years (median: 72 years; IQR: 63–76 years). 57.1% of patients had ASA score ≥3. There were no urgent operations and no contaminated or dirty wounds. 89.8% of patients received antibiotic prophylaxis before surgery. The mean duration of operation was 76 minutes (median: 75 minutes; IQR: 68–84 minutes). The median length of post-operative stay was six days. The hospital conducted post-discharge surveillance.

No SSIs were reported.

3.3 Comparison of Slovenian SSI Surveillance Results to the EU/EEA Reference Data

Table 1 shows pooled patient and operation related characteristics, pooled SSIs cumulative incidence and SSIs incidence density by surgical category for all participating Slovenian acute care hospitals and all surveillance periods from 2013 to 2016 and respective reference data for the EU/EEA countries for the period from 2013 to 2014 published by ECDC (7).

4 DISCUSSION

These are the first results of the Slovenian National SSIs surveillance system. As expected, the estimated SSIs incidence rates varied between different surgical categories and between different participating hospitals. Since we used standardised European SSIs surveillance methodology, our results can be compared to the reference SSIs surveillance data for EU/EEA countries published by ECDC (7). These comparisons suggest that the estimated SSIs incidence rates for some surgical procedures under surveillance in some participating hospitals were rather high.

Among the three different SSIs incidence indicators estimates for different surgical categories in different Slovenian acute care hospitals in different surveillance periods, the incidence density of in hospital SSIs is most suitable for comparisons between hospitals and between countries. This indicator includes only SSIs diagnosed during hospital stay and does not depend on whether hospitals conduct post-discharge surveillance. It is adjusted for differences in post-operative hospital stay between hospitals.

Table 1. Patient and operation related characteristics, surgical site infections (SSIs) cumulative incidence and SSIs incidence density by surgical category: Slovenian SSIs surveillance results (2013-2016) and EU/EEA SSIs surveillance results (2013-2014).

	Caesarean section		Cholecystectomy		Colon surgery		Hip prosthesis		Knee prosthesis	
	Slovenia	EU/EEA[a]	Slovenia	EU/EEA[a]	Slovenia	EU/EEA[a]	Slovenia	EU/EEA[a]	Slovenia	EU/EEA[a]
SSI surveillance period	2013	2013-2014	2013-2016	2013-2014	2013-2014	2013-2014	2013-2014	2013-2014	2013-2014	2013-2014
Number of hospitals	4	-	3	-	1	-	1	-	1	-
Number of operations	313	199 546	620	102 622	47	61 031	51	329 749	49	201 197
Median age (years)	31	31d	55	56 [d]	75	69 [d]	71	72 [d]	72	70 [d]
ASA[b] ≥ 3 (%)	1.0	-	13.2	-	36.2	-	43.1	-	57.1	-
Urgent operations (%)	55.9	53.6 [d]	18.7	17.4 [d]	21.3	18.2 [d]	0	10.5 [d]	0	2.1 [d]
Contaminated or dirty wounds (%)	0	6.3 [d]	3.4	15.4 [d]	14.9	30.4 [d]	0	1.3 [d]	0	0.7 [d]
Antibiotic prophylaxis[c] (%)	91.4	84.6 [d]	27.3	48.3 [d]	97.9	90.2 [d]	94.1	97.2 [d]	89.8	98.2 [d]
Median duration of operation (minutes)	35	37 [d]	52	60 [d]	125	140 [d]	70	75 [d]	75	79 [d]
Total number of SSIs	14	4443	36	1855	13	5784	2	3553	0	1103
Median length of post-operative stay (days)	5	4 [d]	2	3 [d]	7	8 [d]	6	7 [d]	6	5 [d]
Number of post-operative patient-days	1 611	852 321	1 758	454 281	443	688 931	391	2 674 019	322	1 322 030
Total number of SSIs before discharge	6	594	12	684	11	3 902	1	1 231	0	256
SSIs cumulative incidence (%)	4.5	2.2	5.8	1.8	27.7	9.5	3.9	1.1	0	0.6
(95 % CI)	(2.5-7.4)	(2.2-2.3)	(4.1-7.9)	(1.7-1.9)	(15.6-42.6)	(9.2-9.7)	(0.5-13.5)	(1.0-1.1)	(0.0-7.3)	(0.5-0.6)
Individual Slovenian hospitals estimates	0 / 0 / 0,8 /13.8		3.3/4.0/ 22.1		NA		NA		NA	
Variation in European hospitals Mean Median (10th percentile – 90th percentile)		1.8 0.8 (0.0-4.7)		1.6 0.9 (0.0-4.3)		9.2 8.3 (1.4-18.1)		1.2 0.7 (0.0-3.1)		0.6 0.0 (0.0-1.8)
In-hospital SSIs incidence density / 1000 post-operative patient-days	3.7	0.7	6.8	1.5	24.8	5.7	2.6	0.5	0	0.2
(95 % CI)	(1.4-8.1)	(0.6-0.8)	(3.5-11.9)	(1.4-1.6)	(12.5 – 44.0)	(5.5-5.8)	(0.1-14.2)	(0.4-0.5)	(0.0-11.4)	(0.2-0.2)
Individual Slovenian hospitals estimates	0 / 0 / 0 / 11.5		4.1 / 9.2 / 11.9		NA		NA		NA	
Variation in European hospitals Mean Median (10th percentile – 90th percentile)		0.7 0.0 (0.0-1.8)		1.4 0.0 (0.0-4.2)		5.6 4.8 (0.0-11.5)		0.5 0.0 (0.0-1.4)		0.2 0.0 (0.0-0.6)

SSIs: surgical site infections; EU: European Union; EEA: European Economic Area; ASA: American Society for Anaesthesiology; CI: confidence interval; NA: not applicable (only one hospital); data was not available.

[a] results of SSIs surveillance conducted in EU/EEA countries published by the European Centre for Disease Prevention and Control (see reference 7);

[b] ASA score was ascertained according to the protocol for the surveillance of SSIs in Europe published by the European Centre for Disease Prevention and Control (see reference 9);

[c] antibiotic prophylaxis within two hours before incision or during surgery for caesarean section;

[d] results based only on patient-based data collected according to the protocol for the surveillance of in Europe published by the European Centre for Disease Prevention and Control (see reference 9).

A strikingly high in-hospital SSIs incidence density estimate was 11.5 in-hospital SSI (95% CI: 4.2-24.9) after caesarean section per 1000 post-operative patient-days in one hospital in comparison to the respective 90th percentile of 1.8 in-hospital SSIs per 1000 post-operative patient-days in EU/EEA hospitals (7). Another high estimate was 24.8 in-hospital SSIs (95% CI: 12.5-44.0) after colon surgery per 1000 post-operative patient-days in one hospital in comparison to the respective 90th percentile of 11.5 in-hospital SSIs per 1000 post-operative patient-days in EU/EEA hospitals (7). Also, the pooled estimate of 6.8 in-hospital SSIs (95% CI: 3.5-11.9) after cholecystectomy per 1000 post-operative patient-days for three Slovenian hospitals was rather high in comparison to the respective 90th percentile of 4.2 in-hospital SSIs per 1000 post-operative patient-days in EU/EEA hospitals (7).

In contrast, it was reassuring that the point estimates for in-hospital SSIs incidence density after cholecystectomy in one of the hospitals that conducted the SSIs surveillance continuously for three consecutive years, dropped from 9.8 in-hospital SSIs per 1000 post-operative patient-days in 2014 to 2.8 in-hospital SSIs per 1000 post-operative patient-days in 2016, although the differences were not statistically significant. The first point estimate was above and the later well below the 90th percentile of 4.2 in-hospital SSIs per 1000 post-operative patient-days in EU/EEA hospitals (7). It is well known that the surveillance of SSIs contributes to lowering their incidence (4, 5).

When interpreting our results, we should be cautious. The methods for the ascertainment of SSIs for surveillance purposes usually have lower than 100% sensitivity, which results in underestimations (13). In addition, the sensitivity and specificity of methods used for ascertaining SSIs may have varied between different hospitals and countries, which may have distorted comparisons. Regretfully, the numbers of patients enrolled in the Slovenian National SSIs surveillance system for the majority of different operation categories were rather low, which resulted in rather wide 95% CI for all estimations of SSIs incidence indicators making inferences about differences between Slovenian hospitals and comparisons to the reference data published for EU/EEA countries by ECDC difficult. Finally, as the number of hospitals participating, and the number of patients surveyed were rather low, this resulted in poor representativeness of the SSI surveillance data for Slovenia for the period 2013 to 2016.

5 CONCLUSIONS

These first results of the Slovenian National SSIs surveillance gave us some insight into the occurrence of SSIs in Slovenian acute care hospitals. The estimated

SSIs incidence rates varied between different surgical categories and different participating hospitals. There were rather high for some surgical procedures under surveillance in some participating hospitals in comparison to reference data for hospitals from EU/EEA countries published by ECDC. We can conclude that it is urgent to expand the standardised SSIs surveillance to all acute care hospitals with surgical wards in Slovenia to contribute to evidence-based SSIs prevention and control in Slovenian acute care hospitals. This could be supported by raising awareness of the importance of SSIs surveillance through regular annual meetings of the SSI-Sur network, the sub-network of HAI-Sur network, and regular annual feedback of the results to the participating hospitals.

CONFLICTS OF INTEREST

No conflicts of interest exist.

ETHICAL APROVAL

The Medical Ethics Committee of the Republic Slovenia consented to the development and implementation of the National HAI surveillance, with one of its components, SSIs surveillance (consent number: 68/04/08).

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CORRELATION BETWEEN THE DAI AND ICON INDICES USED FOR ASSESSMENT OF ORTHODONTIC TREATMENT NEED IN CROATIAN SCHOOLCHILDREN

KORELACIJA MED INDEKSOMA DAI IN ICON PRI VREDNOTENJU POTREBE PO ORTODONTSKEMU ZDRAVLJENJU PRI ŠOLOBVEZNIH OTROCIH NA HRVAŠKEM

Renata VIDAKOVIĆ[1], Stjepan ŠPALJ[2], Mladen ŠLAJ[1], Martina ŠLAJ[1], Višnja KATIĆ[2*]

[1]University of Zagreb, School of Dental Medicine, Department of Orthodontics, Gundulićeva 5, 10000 Zagreb, Croatia
[2]University of Rijeka, School of Medicine, Department of Orthodontics, Krešimirova 40, 51000 Rijeka, Croatia

ABSTRACT

Keywords:
DAI index, ICON index, orthodontic treatment need, mixed dentition, permanent dentition, malocclusion prevalence

Introduction: The aims were: evaluation of the correlation between the Dental Aesthetic Index (DAI) and Index of Complexity, Outcome and Need (ICON); the assessment of orthodontic treatment need for schoolchildren in a population with two indices, separately for schoolchildren with mixed and permanent dentition; the estimation of the population share that could not receive orthodontic treatment because of the presence of caries and/ or gingivitis.

Methods: A total of 2652 Zagreb school children (7 - 19 years old, 52.4% of them were females) completed a questionnaire regarding previous orthodontic treatment and the type of appliance used. Their oral cavity was also inspected. The DAI and ICON indices were used for the assessment of malocclusion prevalence.

Results: The subjects with mixed dentition had a greater need for orthodontic treatment, when compared to subjects with permanent dentition, when using the DAI index (p<0.001). When using the ICON index, 11.7% of subjects with mixed dentition had very severe malocclusion, as opposed to 5.8% of subjects with permanent dentition. The DAI and ICON scores correlated positively linearly (r=0.521; p<0.001). A higher prevalence of both gingivitis and caries was recorded more often in boys; caries more often in the group with the mixed dentition, and gingivitis in the group with permanent dentition (p<0.05).

Conclusion: The DAI and ICON indices have moderate agreement in assessment of malocclusion severity scores. One third of all schoolchildren with various degrees of both ICON and DAI indices have gingivitis, and half of them have caries.

IZVLEČEK

Ključne besede:
indeks DAI, indeks ICON, potreba po ortodontskem zdravljenju, menjalno zobovje, stalno zobovje, razširjenost malokluzije

Uvod: Cilji študije so: vrednotenje korelacije med indeksom estetskega videza zob (Dental Aesthetic Index, DAI) in indeksom zahtevnosti, izida in potrebe (Index of Complexity, Outcome and Need, ICON); vrednotenje potrebe po ortodontskem zdravljenju v populaciji šoloobveznih otrok z obema indeksoma, posamezna obravnava pri šoloobveznih otrocih z menjalnim in stalnim zobovjem; določanje deleža prebivalstva, ki ni prejela ortodontskega zdravljenja zaradi prisotnosti kariesa in/ali gingivitisa.

Metode: 2.552 učencev iz Zagreba (od 7. do 19. leta; od tega 52,4 % učenk) je izpolnilo vprašalnik o njihovem prejšnjem ortodontskem zdravljenju in vrsti zdravljenja, temu je sledil pregled ustne votline. Za vrednotenje razširjenosti malokluzije sta se uporabila indeksa DAI in ICON.

Rezultati: Učenci z menjalnim zobovjem imajo večjo potrebo po ortodontskem zdravljenju v primerjavi z učenci s stalnim zobovjem pri uporabi indeksa DAI (p<0,001). Pri uporabi indeksa ICON je imelo 11,7 % učencev z menjalnim zobovjem zelo resno in resno malokluzijo, učenci s stalnim zobovjem pa je 5,8 %. Rezultati indeksov DAI in ICON so medsebojno povezani pozitivno in linearno (r = 0,521; p < 0,001). Večja razširjenost gingivitisa in kariesa je zabeležena pogosteje pri fantih, karies pa bolj pogosto v skupini z menjalnim zobovjem, gingivitis pa v skupini s stalnim zobovjem (p < 0,05).

Zaključek: Indeksa DAI in ICON se zmerno ujemata pri rezultatih vrednotenja resnosti malokluzije. Glede na različne stopnje indeksov DAI in ICON ima ena tretjina šoloobveznih otrok gingivitis, polovica pa karies.

***Corresponding author:** Tel. + 385 51 345 638; E-mail: visnja.katic@medri.uniri.hr

1 INTRODUCTION

Today, there are several indices being used in orthodontics, like the Dental Aesthetic Index (DAI) (1), the Peer Assessment Rating (PAR) (2), the Index of Complexity, the Outcome and Need (ICON) (3), the Index of Orthodontic Treatment Need (IOTN) (4). Indices in general were developed and employed for determination of the orthodontic treatment need in population, subsequent planning of an integrated public health solution, and evaluation of outcome of orthodontic treatment.

The DAI is often used in epidemiological studies, its

use being accepted by the World Health Organisation (WHO) (5-7). This index gives an insight into the orthodontic treatment need from the point of view of socially acceptable aesthetic appearance of ten occlusal characteristics; and is also valid as a cross-cultural index (5-7). Many of the characteristics that give better insight into malocclusion severity (like the presence of cross bite, tooth impaction, mid-line shift or deep bite) are not accounted for with their specific weight in treatment need, and therefore generate discrepancies when compared to some other indices, as noted for the modified IOTN (8). The threshold for orthodontic treatment need can be modified according to the available financing and resources, as part of the public health program, and this is helpful in epidemiological studies (9-13). In Slovenia, for example, the Eismann-Farcnik index was developed and is currently been used for a comprehensive evaluation of an orthodontic treatment need, considering occlusal traits in deciduous, mixed and permanent dentition as well as the existence of a functional impairment (14).

On the other hand, the ICON measures orthodontic

treatment complexity, outcome and need, giving more information about the specific case, but also considering the important aspect of dental aesthetics (3). A better understanding of malocclusion complexity helps better planning of the resources and funds needed for treatment, as well as the duration of treatment and the expected outcome. The ICON has also been accepted as a valid tool for use in epidemiological studies and is simple to use (8, 12-13, 15).

Previously, the comparison of the DAI and ICON indices has been investigated in studies that involved the evaluation of study casts by experienced examiners when using one or another index (12, 13). Those studies showed good reliability in assessing orthodontic treatment need with either of the indices employed; also, these indices were found to be valid for use in epidemiological studies (9-13, 15-17). Malocclusion assessment, recorded and measured intraorally, was found to be as reliable as the assessment on study casts (17). However, a significantly larger sample is required if comparisons between indices have

to be made, as opposed to the sample sizes presented in previous studies (10-13, 15). Furthermore, none of the previous comparisons evaluated differences observed in indices' scores or categories, nor tried to converse malocclusion severity score from one index to another. The aims of this study were:

1. Evaluation of the correlation between the DAI and ICON indices employed,
2. Assessment of an orthodontic treatment need in schoolchildren population with the DAI and ICON indices, separately for schoolchildren with mixed and with permanent dentition,
3. Estimation of the population share that could not receive orthodontic treatment due to the presence of caries and/or gingivitis.

2 SAMPLE AND METHODS

This epidemiological cross-sectional survey involved a total of 2652 children and young adolescents in Zagreb, Croatia (5% of Zagreb school children) (18). Subjects were between 7 and 19 years of age (median 15, inter-quartile range 12-16), and 52.4% of them were females. The initial sample size was considered adequate concerning the following parameters: around 100.000 schoolchildren in Zagreb, an expected prevalence of treatment need of 30%, alpha type 1 error of 5% and confidence level of 95%. Data was collected during an epidemiological survey lasting from September 2006 to February 2007. Examinees were selected in a cluster sampling procedure with special attention to administrative area for primary schools (107 schools in total) and the school type for secondary schools (55 schools in total). From each of four Zagreb's administrative areas three primary schools were randomly selected, and from each of three secondary school types (gymnasiums, technical, vocational) four schools were randomly selected. Intraoral measurements and questionnaires were administered upon written parental informed consent; participants aged 18 years and older provided their own written consent. The research has been conducted in full accordance with the World Medical Association Declaration of Helsinki. Individuals attending private and special needs schools, as well as those not attending any school, were excluded from this study.

The ICON and the DAI were used for assessment of orthodontic treatment need. Modified DAI scoring was used for assessment in subjects with mixed dentition (10). Both DAI and ICON indices use continuous scale based upon the regression equation to describe severity of one's malocclusion traits. DAI index takes into calculation of final score the following traits: tooth agenesis, spacing/ crowding, overjet, anterior open bite and occlusal sagittal relationship. The scores are grouped into four malocclusion categories (≤25=Normal, 26–30=Definite,

31–35=Severe, ≥36=Handicapping), which also describe treatment needs (in range from little or no need, elective need, highly desirable treatment to mandatory treatment) (1). ICON takes the Aesthetic Component (AC), crowding/spacing, cross bites, anterior open bite/overbite, and sagittal posterior occlusion into calculation of final score. The AC has 10 colour photographs showing dentition in frontal view graded from 1 (most attractive) to 10 (least attractive). The final ICON score is divided into malocclusion complexity grades (<29=Easy, 29–50=Mild; 51–63=Moderate, 64–77=Difficult, >77=Very difficult). A cut-off point of 43 was set to mark definite need for orthodontic treatment (3). A questionnaire was administrated for acquiring information on previous orthodontic treatment (choice of answers "yes/no") and the type of orthodontic appliance used (choice of answers "removable/fixed/both"). Examination of oral cavity included the assessment of periodontal health by Community Periodontal Index (CPI), and the caries experience by the sum of decayed, missing, and filled teeth (DMFT index) (19). The X-rays and study casts were not used during examination. Twenty examiners (orthodontic residents) were trained and calibrated for the inspection of oral cavity, for which they used the WHO's manual probe (19), a mouth mirror, and a forehead-mounted light lamp. Inter- and intra-examiners reproducibility was evaluated by the repeated measurements on ten examinees in one-week interval, agreement proportion resulting in above 80% (intra-class correlation coefficient $r>0.87$, Cohen Kappa>0.64, $p<0.001$).

Statistical analysis used x^2 test, Fisher's exact test, Kendall's tau-b coefficient, and regression analysis. All data was analysed in the SPSS 10.0 statistical software (SPSS Inc., Chicago, Illinois, USA), at $p<0.05$ significance level.

3 RESULTS

3.1 Assessment of the Orthodontic Treatment Need with the DAI and ICON Indices

Based on the x^2 test, the subjects with mixed dentition had a greater need for orthodontic treatment, when compared to subjects with permanent dentition, when using the DAI index ($p<0.001$), but with minor effect size (Kendall's τ-b=-0.131), accounting for just 1.7% of the variability of orthodontic treatment need.

When using the ICON index, the subjects with mixed dentition had a more complex degree of malocclusion, when compared to the subjects with the permanent dentition ($p<0.001$), with minor effect size (Kendall's τ-b=-0.163) of the dentition type on the prediction of an orthodontic treatment need. 11.7% of subjects with mixed dentition had very severe to severe malocclusion, opposed to 5.8% of subjects with permanent dentition.

When the ICON limit for orthodontic treatment need (cut-off point at 43) was set, the subjects with mixed dentition needed orthodontic treatment more often, when compared to the subjects with permanent dentition (34% vs. 18%; $p<0.001$). Still, the effect size was minor (Kendall's τ-b=-0.163). Mixed dentition was associated with almost two times greater chance for orthodontic treatment need (OR=1.96; 95% CI=1.68-2.29).

3.2 Correlation between the DAI and ICON Indices

The DAI and the ICON score (expressed as variables on the continuous scale) demonstrated moderate positive linear correlation ($r=0.521$; $p<0.001$), with stronger correlation for the subjects with permanent dentition ($r=0.516$; $p<0.001$), when compared to the subjects with mixed dentition ($r=0.493$; $p<0.001$). The prediction equations (Figure 1) enabled calculation of the ICON score via acquired DAI score, separately for mixed and permanent dentition, and vice versa.
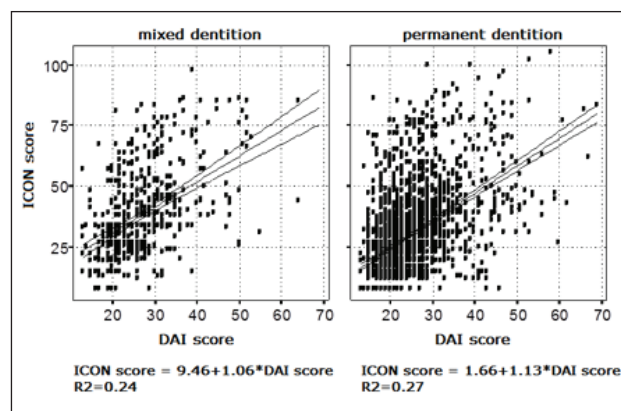

Figure 1. The prediction equations for calculation of the ICON score via acquired DAI score, separately for mixed and permanent dentition.

The DAI and ICON categories correlated positively moderately, the correlation being weaker for the subjects with mixed dentition, when compared to the subjects with permanent dentition (τ-b=0.367 vs. 0.426; $p<0.001$), accounting for 13.5% and 18.2% of the variability. The differences in the distribution of ICON categories within every DAI category were significant for the "0" and "3" DAI categories ($p<0.05$), in subjects with both mixed and permanent dentition.

The DAI categories and the ICON divisions for orthodontic treatment need (cut-off point at 43) correlated positively moderately, with the stronger effect for the subjects with permanent dentition, when compared to those with mixed dentition (τ-b=0.347 vs. 0.313; $p<0.001$). Significant differences in the distribution of the ICON divisions within

Table 1. Distribution of the ICON degrees with cut-off point of 43 between dentition types within the DAI categories (0=Normal, 1=Definite, 2=Severe, 3=Handicapping).

DAI categories	Dentition type		ICON cut-off point of 43		Total	p*	OR (95% CI)	τ-b
			No treatment need	Treatment needed				
0	Mixed	N	179	48	227			
		%	78.9	21.1	100.0			
	Permanent	N	1265	115	1380			
		%	91.7	8.3	100.0	<0.001	2.54(1.87-3.45)	-0.148
	Total	N	1444	163	1607			
		%	89.9	10.1	100.0			
1	Mixed	N	79	36	115			
		%	68.7	31.3	100.0			
	Permanent	N	277	94	371	0.228	1.24(0.90-1.71)	-0.057
		%	74.7	25.3	100.0			
	Total	N	356	130	486			
		%	73.3	26.7	100.0			
2	Mixed	N	29	38	67			
		%	43.3	56.7	100.0			
	Permanent	N	110	68	178			
		%	61.8	38.2	100.0	0.014	1.49(1.12-1.97)	-0.167
	Total	N	139	106	245			
		%	56.7	43.3	100.0			
3	Mixed	N	24	44	68			
		%	35.3	64.7	100.0			
	Permanent	N	92	99	191			
		%	48.2	51.8	100.0	0.088	1.25(0.99-1.56)	-0.114
	Total	N	116	143	259			
		%	44.8	55.2	100.0			

*Fischer exact test

the "0" and "2" DAI categories were found for both mixed and permanent dentition (p<0.05, Table 1).

3.3 Assessment of Orthodontic Treatment Need in Schoolchildren, Regarding Previous Orthodontic Treatment

In total 67.7% of Zagreb schoolchildren never received orthodontic treatment, 84.5% of them with mixed dentition and 63.9% with permanent dentition.

During examination, 12.2% of the subjects were undergoing orthodontic treatment with removable appliances (8.7% with mixed dentition, 13% with permanent dentition). At the same time, 3.3% of the subjects were treated with fixed appliances (1% with mixed dentition, 3.8% with permanent dentition).

The subjects with orthodontic treatment history showed no differences in the current need for orthodontic treatment, when compared to the subjects without previous orthodontic treatment, regardless of the dentition type (ICON cut-off point at 43, Table 2).

Table 2. Distribution of orthodontic treatment need in schoolchildren who were not undergoing orthodontic treatment at the time of the study, with respect to dentition type and previous orthodontic treatment, with the ICON cut-off point of 43.

Dentition type	Previous treatment		ICON cut-off point of 43		Total	p
			No treatment need	Treatment needed		
Mixed	No	N	264	136	400	
		%	66.0	34.0	100.0	
	Yes	N	17	11	28	0.545
		%	60.7	39.3	100.0	
	Total	N	281	147	428	
		%	65.7	34.3	100.0	
Permanent	No	N	1115	236	1351	
		%	82.5	17.5	100.0	
	Yes	N	326	79	405	0.376
		%	80.5	19.5	100.0	
	Total	N	1441	315	1756	
		%	82.1	17.9	100.0	

*Fischer exact test

The tendency towards a greater need for orthodontic treatment was observed among previously treated subjects in both dentition type groups (Table 3).

Table 3. Distribution of the ICON categories (0=Easy, 1=Mild, 2=Moderate, 3=Difficult, 4=Very Difficult) in schoolchildren who were not undergoing orthodontic treatment at the time of the study, with respect to dentition type and previous orthodontic treatment.

Dentition type	Previous treatment		ICON complexity					Total	p*
			0	1	2	3	4		
Mixed	No	N	143	166	47	23	21	400	
		%	35.8	41.5	11.8	5.8	5.3	100.0	
	Yes	N	10	10	5	2	1	28	
		%	35.7	35.7	17.9	7.1	3.6	100.0	0.870
	Total	N	153	176	52	25	22	428	
		%	35.7	41.1	12.1	5.8	5.1	100.0	
Permanent	No	N	737	469	72	45	28	1351	
		%	54.6	34.7	5.3	3.3	2.1	100.0	
	Yes	N	221	129	27	17	11	405	0.561
		%	54.6	31.9	6.7	4.2	2.7	100.0	
	Total	N	958	598	99	62	39	1756	
		%	54.6	34.1	5.6	3.5	2.2	100.0	

*x^2 test

Previously treated subjects with permanent dentition more often had a higher degree of malocclusion, when compared to the untreated subjects, when using the DAI categories (p=0.032, Table 4).

Table 4. Distribution of the DAI categories (0=Normal, 1=Definite, 2=Severe, 3=Handicapping) in schoolchildren who were not undergoing orthodontic treatment at the time of the study, with respect to previous orthodontic treatment.

Dentition type	Previous treatment		ICON complexity				Total	p*
			0	1	2	3		
Mixed	No	N	191	104	54	60	409	
		%	46.7	25.4	13.2	14.7	100.0	
	Yes	N	18	5	2	3	28	
		%	64.3	17.9	7.1	10.7	100.0	0.343
	Total	N	209	109	56	63	437	
		%	47.8	24.9	12.8	14.4	100.0	
Permanent	No	N	925	243	109	97	1374	
		%	67.3	17.7	7.9	7.1	100.0	
	Yes	N	265	70	31	48	414	
		%	64.0	16.9	7.5	11.6	100.0	0.032
	Total	N	1190	313	140	145	1788	
		%	66.6	17.5	7.8	8.1	100.0	

*x^2 test

3.4 Estimation of the Population Share that could not Receive Orthodontic Treatment due of the Presence of Caries and/or Gingivitis

Subjects had carious teeth more often in the mixed dentition group, when compared to the subjects with permanent dentition, but the association was weak (p<0.001, τ-b=-0.082) with minor effect size. There was a 1.08 times greater chance for caries in the mixed dentition group, opposed to the permanent dentition group (95% CI 1.04-1.12).

Gingivitis occurred more often in the permanent dentition group, although the association is weak (p<0.001; τ-b=0.095). There was a 1.64 times greater chance for gingivitis in the permanent dentition group, when compared to the mixed dentition group (95% CI 1.33-2.01). Figure 2 shows the distribution of gingivitis and caries according to the dentition types. Both gingivitis and caries were found more often in boys, caries more often in the mixed dentition group, and gingivitis in the permanent dentition group (p<0.05). Girls more often fulfilled the criteria for enrolment in orthodontic treatment in both mixed (39% vs. 32%) and permanent dentition (42.2% vs. 36.9%), all at p<0.05.
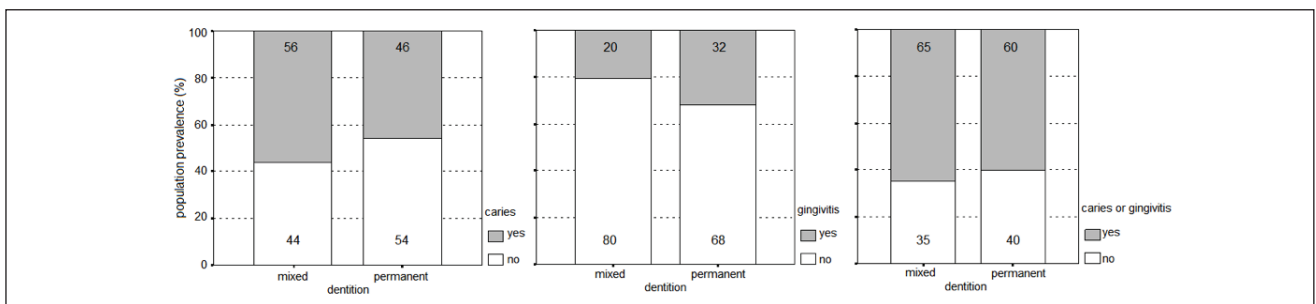
Figure 2. Distribution of gingivitis and caries in the population, separately for schoolchildren in mixed and permanent dentition.

Between 50% and 66.2% of schoolchildren did not meet the criteria for enrolment in orthodontic treatment due to caries, for the DAI malocclusion degrees ≥1 or ICON 43 cases.

Between 51% and 66% of previously untreated subjects with the ICON categories ≥2 did not meet the criteria for enrolment in orthodontic treatment due to caries.

At ICON cut-off value of 43, 62.1% of the previously untreated schoolchildren did not meet the criteria for enrolment in orthodontic treatment due to caries (64.7% subjects with mixed dentition vs. 60.6% subjects with permanent dentition), and 33% of them had gingivitis (40.9% with permanent dentition vs. 19.9% with mixed dentition).

One third of all subjects with various degrees of both the ICON and DAI indices had gingivitis as the excluding criteria for enrolment in orthodontic treatment.

4 DISCUSSION

The results showed that the DAI and ICON indices showed moderate correlation in the intraoral assessment of orthodontic treatment need with slightly higher correlation among schoolchildren with permanent dentition, when compared to the schoolchildren with mixed dentition. Conversion of the malocclusion severity score from one index to another could be made by here presented regression equation. This linear regression accounts for up to the 27% of the variability.

Previous research suggested that the ICON could replace the PAR and IOTN (15), since the ICON was developed from the PAR and IOTN, and correlated highly with both of these indices. Another study found good agreement between the ICON and the dental health component (DHC) of the IOTN, and moderate agreement with the aesthetic component of the IOTN, suggesting that the ICON could substitute the DHC IOTN (19). Still, the ICON is primarily focused on space problems in maxillary arch, and this contributes to disparity in its comparison to other indices.

Results also showed that one in six schoolchildren with permanent dentition is in need for orthodontic treatment; the need is greater in schoolchildren with mixed dentition and in previously treated schoolchildren with permanent dentition. Also, previously untreated schoolchildren with mixed dentition have greater need for orthodontic treatment, when compared to the previously treated schoolchildren. Generally, schoolchildren with severe malocclusions were enrolled in orthodontic treatment, but the real concern comes from the cognition that the schoolchildren with the most severe malocclusions had already previously received orthodontic treatment.

At the time of the study, the national health insurance fund made orthodontic care available free of costs to all schoolchildren, regardless of their malocclusion severity. These limitless treatments had the unpredictably high overall costs, and still did not contribute to reduction of the population share with severe malocclusions. The data on residual treatment need obtained from this study urge for better planning of future costs, considering prevalence of treatment need in population and establishing criteria for enrolment in orthodontic therapy. Suitable threshold value for the DAI index could be established in accordance with the projection of treatment costs and funding available for orthodontic treatment within the state insurance fund, taking into account the DAI results from this study. The ICON supplied data about malocclusions complexity, expected treatment duration and outcome; all of which are important factors in the financial planning and evaluation of treatment results, and here presented results give useful information for the health care reform planning. Present study does not give reasons for the high share of severe malocclusions in already treated patients, those lie probably both in patients' drop-outs as well as in inappropriate treatment plan. Our study showed that schoolchildren enrolled in orthodontic treatment were four times more often treated with some type of removable appliance, compared to treatment with fixed appliances. Treatment with removable appliances are dependant more on the patients' cooperation, and are often combined with subsequent fixed appliance in order to achieve better aesthetics and lessen the severity of the malocclusion. High share of severe malocclusions in already treated schoolchildren calls for evaluation of treatment results, and possibly for treatment options that rely less on patients compliance. It was found that both children and their parents are prone to under-assess their malocclusion severity and treatment need, which could contribute to the increase in drop-out rate (21-24).

The percentage of schoolchildren that have either decay or gingivitis was high, indicating the need for better oral health care, oral hygiene education and prevention programs. Also, general dentists in Croatia frequently avoid curing caries on deciduous teeth and refer patients to an orthodontic consultation with active carious lesions (25). Caries can contribute to the development of malocclusions, especially in midline shift problems; extractions caused by severely decayed teeth and loss of space in dental arches result in crowding (26, 27). As 56% of schoolchildren with mixed dentition and 46% of schoolchildren with permanent dentition have caries, one can assume that the overall orthodontic treatment need in population might be lowered if caries prevention and timely treatment were employed (27). Recent research showed strong correlation between the oral health and

number of preserved teeth and self-reported general health (28). This indicates that putting the emphasis on the caries prevention and teeth preservation should be a continuous public health agenda of greatest importance. Furthermore, the gingival inflammation is associated with the plaque build-up and presents strong indicator of the unsatisfactory oral hygiene maintenance (29, 30), and resolving problems of the excessive plaque accumulation is important for the upcoming orthodontic treatment. Adverse effects of orthodontic therapy, like white spot lesions and gingivitis, can be avoided by reduction of plaque accumulation (31).

The limitation of the study is in its sample, because the study described prevalence for the capital's schoolchildren population, and the findings from rural areas and other regions could differ from here presented data. Therefore, the conclusions can be made only for Zagreb's schoolchildren population, and not for the whole country. However, the strength lies in the fact that the agreement between DAI and ICON indices does not depend on type of the area inspected.

Taking all above-mentioned reasons into account, the intent of this comprehensive study was to initiate changes within the Croatian public health system. As a result of this investigation, the threshold occlusal traits for enrolment into orthodontic treatment were set. The evaluation of the changes made should be conducted in the future. Also, stronger emphasis should be put on caries and gingivitis prevention, as a public health goal which is important for a persons' own general health perception.

Evaluation of the changes made within the healthcare system would be necessary in a future similar study. The determination of the orthodontic treatment need is complex and future studies should include several evaluation methods, because different indices have their own special grading and are not in perfect agreement with each other.

5 CONCLUSIONS

The DAI and ICON indices have moderate agreement in assessment of malocclusion severity scores. One third of all schoolchildren have gingivitis, and half of them have caries which would postpone enrolment in orthodontic treatment. The degree of malocclusion severity is not the sole factor in public health orthodontic treatment need analysis; dental and periodontal health, co-operability and willingness to undergo orthodontic treatment should also be taken into account.

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ANALYSIS OF 22 YEARS OF SURVEILLANCE FOR PRION DISEASES IN SLOVENIA, 1996 TO 2017

ANALIZA 22-LETNEGA EPIDEMIOLOŠKEGA SPREMLJANJA PRIONSKIH BOLEZNI V SLOVENIJI, 1996-2017

Nuška ČAKŠ JAGER[1], Mara POPOVIĆ[2], Mateja BLAŠKO MARKIČ[1], Alenka KRAIGHER[1*]

[1]National Institute of Public Health, Trubarjeva 2, 1000 Ljubljana, Slovenia
[2]University of Ljubljana, Medical Faculty, Institute of Pathology, Korytkova 2, 1000 Ljubljana, Slovenia

ABSTRACT

Keywords:
Creutzfeldt-Jakob disease, prion diseases, surveillance, epidemiology

Introduction: The objective was to present the results of surveillance of prion diseases in Slovenia that was established in 1996 and then to assess the interdisciplinary approach according to the algorithm of case management and reporting data to the National Register at the National Institute of Public Health.

Methods: A descriptive study of Creutzfeldt-Jakob disease (CJD) recorded in the period from 1996 to 2017 was carried out.

Results: A total of 123 cases of prion disease were notified between 1996 and 2017. Out of these, 68 were recorded and confirmed by autopsy as sporadic CJD with an average incidence rate of 1,5 cases per million population per year. In one case a gene analysis showed mutation E200K in prion protein gene, PRNP. Two cases of the Gerstman-Sträussler Scheinker syndrome and one clinical case of fatal insomnia with new PRNP mutation, N181S, were notified. Diagnostic value of protein 14-3-3 analysis in the liquor reached 82% sensitivity and 71% specificity. 25 cases of notified clinically possible/probable CJD were disproved after autopsy. In eleven notified possible CJD cases the autopsy had not been performed. Variant CJD has not yet been proven in Slovenia.

Conclusion: Incidence rates were comparable with other European countries. Completeness of reporting and proper management of CJD cases according to the algorithm of reporting, management and case confirmation would need some improvement. A well-functioning surveillance system, including timely notifications, would enable an appropriate epidemiological investigation and an effective response to public health risks, thus the awareness of prion diseases should not decline.

IZVLEČEK

Ključne besede:
Creutzfeldt-Jakobova bolezen, prionske bolezni, spremljanje, epidemiologija

Uvod: Glavni cilj vzpostavitve sistema spremljanja prionskih bolezni, ki so redke nevrodegenerativne bolezni z različnimi fenotipi, epidemiologijo in patogenezo, ki jih povzroča akumulacija prionov in posledično hitro propadanje nevronov v osrednjem živčnem sistemu, je odkrivanje variantne oblike Creutzfeldt-Jakobove bolezni (vCJB). V Sloveniji smo z aktivnim epidemiološkim spremljanjem prionskih bolezni začeli v letu 1996. Pri presoji sistema spremljanja z vidika učinkovitosti interdisciplinarnega pristopa in delovanja stroke po algoritmu v primeru možne/ verjetne CJB v Sloveniji, je bilo treba oceniti odstotek možnih ali verjetnih primerov CJB, ugotovljenih na kliničnih oddelkih, ki niso bili obducirani, in popolnost podatkov, sporočenih v nacionalno bazo podatkov o nalezljivih boleznih na Nacionalnemu inštitutu za javno zdravje (NIJZ).

Metode: Izvedena je bila deskriptivna analiza podatkov o prionskih boleznih, zabeleženih v obdobju od leta 1996 do leta 2017 v bazi podatkov, ki jo upravlja Nacionalni inštitut za varovanje zdravja (NIJZ). Podatki so bili povezani s podatki o primerih, obduciranih na Inštitutu za patologijo na Medicinski fakulteti Univerze v Ljubljani. Prikazali smo letne prijavne stopnje glede na tip prionske bolezni in demografske podatke bolnikov ter deleže obduciranih primerov in ocenili specifičnost in občutljivost diagnostičnega testa za analizo beljakovin 14-3-3 v cerebrospinalni tekočini.

Rezultati: 123 primerov CJB je bilo prijavljenih v nacionalno bazo podatkov o nalezljivih boleznih na NIJZ med 1. januarjem 1996 in 31. decembrom 2017. Od tega je bilo potrjenih 68 primerov sporadične oblike CJB (sCJB), to je 1,5 primera na milijon prebivalcev letno. Pri enem bolniku je šlo za genetsko CJB (gCJB) zaradi mutacije E200K na genu za prionski protein, PRNP. Potrjena sta bila tudi primera Gerstmann-Sträussler-Scheinkerjevega sindroma (GSS). Odkrit je bil primer fatalne familiarne insomnije (FFI) z novo PRNP-mutacijo, N181S, ki ni bil potrjen z obdukcijo. Diagnostična vrednost testov za analizo beljakovine 14-3-3 v cerebrospinalni tekočini je dosegla 82-% specifičnost in 71-% občutljivost. Po obdukciji je bilo ovrženih 25 primerov, prijavljenih kot klinično možnih/verjetnih oblik CJB. Pri enajstih prijavljenih možnih/verjetnih primerih CJB obdukcija ni bila opravljena. V Sloveniji nismo potrdili vCJB.

Zaključek: Sistem spremljanja prionskih bolezni v Sloveniji temelji na interdisciplinarnem sodelovanju strokovnjakov. Popolnost prijavljanja in pravilno ravnanje lečečih zdravnikov v skladu z algoritmom poročanja ob možnih/verjetnih primerih ter ustrezno potrjevanje kliničnih sumov bi izboljšali učinkovitost sistema spremljanja za odkrivanje prionskih bolezni, vključno z vCJB. Dobro delujoč sistem spremljanja, vključno s pravočasno prijavo, bi omogočal ustrezno epidemiološko preiskavo in učinkovit odziv na tveganje za javno zdravje, saj se pozornost tem boleznim ne sme zmanjšati.

*Corresponding author: Tel. + 386 41 782121; E-mail: alenka.kraigher@nijz.si

1 INTRODUCTION

The epidemic of Bovine Spongiform Encephalopathy (BSE) and onset of variant Creutzfeldt-Jakob disease (vCJD) in United Kingdom between 1986 and 1996, created a global crisis with very serious health and economic implications (1, 2). It conditioned the need, especially in Europe, to strengthen the system for surveillance of prion diseases for the purpose to detect particularly variant vCJD that could pose a wider public health threat.

Prion diseases are rare neurodegenerative diseases caused by the accumulation of misfolded prion protein molecules, named PrPSc or prions, which has been defined in 1982 by Stanly B. Prusiner as 'an infectious proteinaceous particle without nucleic acid', in the cerebrospinal fluid (CSF) (3). Prion diseases in humans are distinguished on the basis of a variety of clinical symptoms and distribution, as well as forms of the pathological changes in the cerebrospinal fluid, the presumed causes of occurrence and possible genetic differences (4, 5, 6, 7, 8).

All forms of the disease are incurable. In humans, CJD is the most frequent prion disease. There are four types of CJD: sporadic (sCJD), iatrogenic (iCJD), genetic or familial (g/fCJD), and variant (vCJD) described so far (4, 9).

Up to 80% of all CJD cases represent a spontaneous appearing neurodegenerative sporadic form (sCJD), which occurs in the world with an incidence of 0.5 to 1.7 cases per million population per year. Other, rarer forms of human prion diseases are Gerstman-Sträussler-Scheinker syndrome (GSS) and Fatal Familial Insomnia (FFI), which are genetic, and already eradicated kuru disease of the Fore tribe at Papua New Guiney (10, 11).

So far, a reliable diagnosis of CJD in a patient's life cannot be set with 100 % assurance. During clinical investigation of a patient an important diagnostic tool for the validation of possible CJD is the immunoassay test, which proves the presence of 14-3-3 protein in the CSF (12). The World Health Organization has recognized it as a diagnostic test for sCJD in 1998 (6). Cellular protein 14-3-3 can normally be found in many tissues, while its presence in the cerebrospinal fluid reflects more extensive damage to the neurons in patients with clinically suspected CJD. However, the presence of the protein in CSF can be detected in patients with stroke, meningoencephalitis or certain other neurological diseases too (13, 14).

Another diagnostic test of even longer use than protein 14-3-3 is electroencephalogram (EEG) with periodic sharp-waves complexes (PSWCs) in otherwise slow thelta of which the wave background is characteristic but not specific for sCJD. Magnetic resonance imaging (MRI) is another clinical tool used in the diagnostic criteria of sCJD with high signal in striatum and some cortical regions.

Since prion diseases are rare and still quite insufficiently known communicable diseases, a thorough study of the clinical and epidemiological characteristics of this disease was necessary, as is a setup of a standardized approach and implementation of best practices. According to Slovenia's law and by-laws on infectious diseases, notification of CJD is obligatory. General and specific measures for the prevention and control should be carried out. It is also mandatory to carry out an autopsy, wherein a suspicion of any form of prion diseases has been placed (15).

Surveillance, control and prevention of prion diseases require a broad multidisciplinary approach of many fields in human and veterinary medicine. A prion disease interdisciplinary expert group (PDIEG) for the epidemiological surveillance of CJD in Slovenia operates at the NIJZ. It consists of a team of medical doctors from various fields: psychiatry, neurology, neuropathology, infectiology, transfusion and epidemiology. The PDIEG's tasks are to encourage a proper management of patients with clinical suspicion of CJD. There are appointed central coordinators in the field of neurology and psychiatry, who provide an in-depth treatment and monitoring of patients with possible/probable CJD in hospitals. The aim of such an integrated approach is to provide a qualitative assessment of the situation, monitoring of patients with possible/probable CJD, ensuring an autopsy to confirm or disprove clinical diagnosis of CJD with implementation of the appropriate preventive measures to protect public health.

NIJZ is responsible for the surveillance of CJD, as well as collection and analysis of the data and international reporting of probable and confirmed vCJD.

Slovenia is included in the network of prion diseases monitoring at the European Centre for Disease Prevention and Control (ECDC), to which a project EUROCJD was attached. The network connects EU member states and European Free Trade Association (EFTA) and eight countries from other parts of the world for the mutual exchange of scientific knowledge on the epidemiological pattern, diagnosis and treatment of prion diseases in humans (8, 16).

The aim of the study was to present the results of surveillance of prion diseases in Slovenia to assess the interdisciplinary approach according to the algorithm of case management and reporting data to the National Register at the National Institute of Public Health.

2 METHODOLOGY

2.1 Database

Data on possible, probable, confirmed or disproved CJD cases and other prion diseases are collected through a national surveillance system of communicable diseases. In Slovenia, an active data collecting of possible, probable, confirmed or disproved CJD cases and other prion diseases has begun in 1996. The database has been supplemented with retrospective data from several different sources, such as the National Register of communicable diseases at NIPH, databases of CJD cases at Institute of Pathology, Faculty of Medicine, University of Ljubljana, data from the Death Registry and the information actively obtained through targeted inquires among medical doctors. Only probable and definite diagnoses of CJD were included in the calculation of incidence, since that is the measure that was reported in the EUROCJD surveillance and allowed the comparison of our data with other countries.

2.2 CJD Reporting System in Slovenia

Based on the clinical picture of rapidly progressive dementia with non-characteristic findings in electroencephalography (EEG), and magnetic resonance imaging (MRI), a possible CJD should be notified to NIJZ (17). At the same time a laboratory test of the samples of CSF is carried out, with the intention of determining the 14-3-3 protein and the protein tau. In a case of a characteristic MRI or EEG for CJD or a positive result of 14-3-3 protein and very high tau level in CSF, the doctor amends the previously notified possible CJD to a probable CJD and notifies NIJZ. Central coordinators in the field of neurology and psychiatry collaborate with neurologists and psychiatrists in defining the clinical characteristics, carrying out of diagnostic procedures, treatment and associated diseases, and epidemiological and demographic characteristics of the patient with possible/probable CJD. The coordinators also periodically monitor the course of the disease in cooperation with the treating physician and in accordance with the guidelines of the expert group of CJD.

Depending on the progress of the clinical picture and the results of the investigations, the treating physician may decide that the case does not correspond to the definition of a possible CJD and notify the decision to the NIJZ. Upon the results of autopsy the pathologist completes the notification as a confirmed or disproved case of clinically possible/probable CJD. Regular exchange of information between the epidemiologists and members of the PDIEG during the year ensured an assessment of notified patient. However, the classification was subject to change until an agreement was reached by the PDIEG during the annual meeting. Patients who were still alive at the time of the annual meeting were monitored until death and

discussed during the meeting of the following year for final classification. The surveillance data were based on the year the patient died.

The Communicable Diseases Centre regularly informed physicians about the incidence of notified diseases and new developments through the monthly epidemiological e-bulletin, eNBOZ.

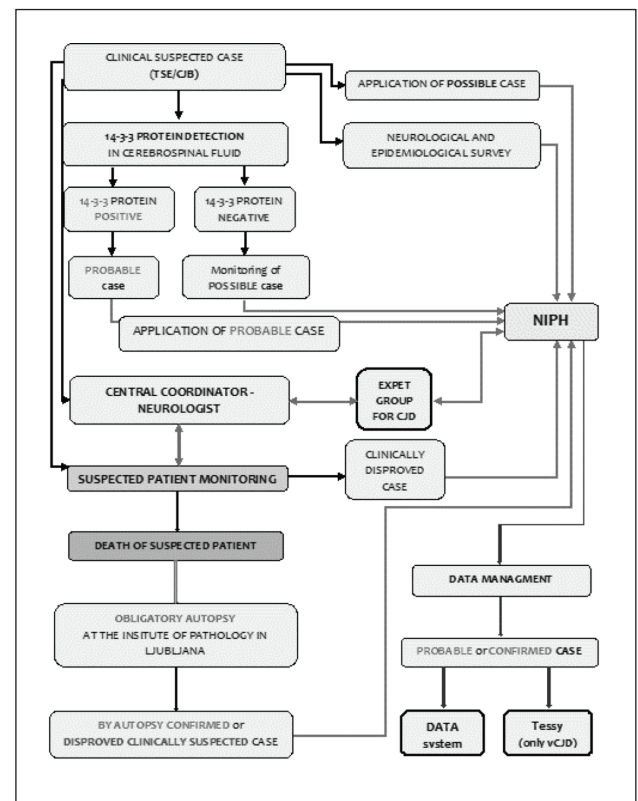The CJD algorithm of reporting, management, and case confirmation is shown in Figure 1.

Figure 1. CJD algorithm of reporting, management and case confirmation, Slovenia.

3 RESULTS

Of the 123 cases in total notified to the National Institute of Public health from 1996 to 2017, 68 were confirmed as sCJD. The sCJD incidence rate for this period was 1.5/1.000,000 population per year (Figure 2). The autopsy disproved 25 cases of clinically possible/probable CJD. In two cases the treating physicians rejected clinically suspected cases of CJD already during the patients' lifetimes. In total, 11 cases of clinically possible CJD mandatory autopsy was not performed.

The first ever case of GSS in Slovenia was confirmed in 2007. In 2015 the first case of the genetic form of CJD was confirmed. The suspicion to genetic form of the fatal familial insomnia (FFI) was set in 2016 (Figure 3 and Figure 4).
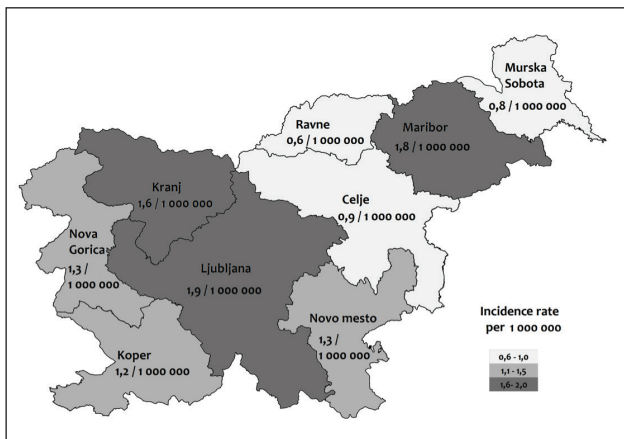

Figure 2. Incidence rate of confirmed sCJD (per 1 million population), according to place of residence in regions of Slovenia, 1996-2017 (n=68).

The highest incidence rate was recorded in the Ljubljana and Maribor region, the two most populated regions.

3.1 Notified Types of Prion Diseases in Slovenia
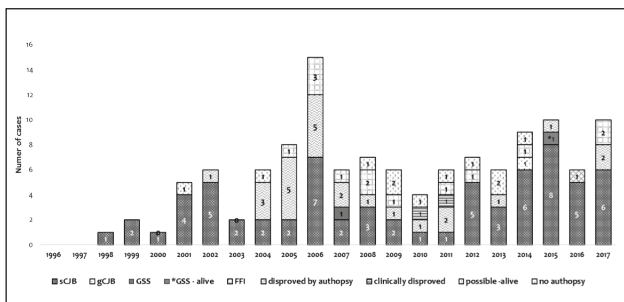
Figure 3. Notified cases of different types of prion diseases, Slovenia, 1996-2017 (n=123).
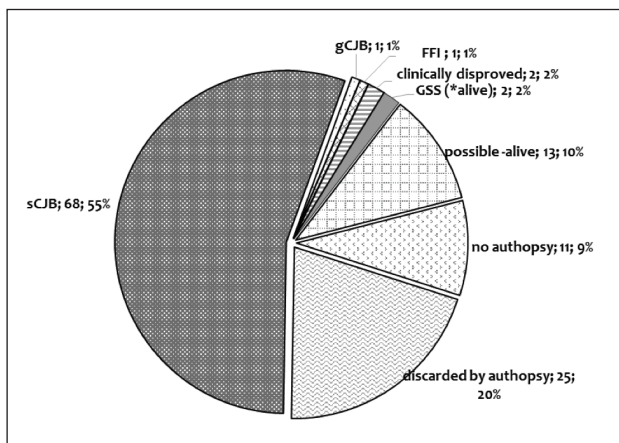
Figure 4. Cumulative number of notified cases of different types of prion diseases, Slovenia, 1996-2017 (n=123).

3.2 Age and Sex Distribution of Prion Diseases in Slovenia

Females were affected a bit more (56%) than males (44%), but the difference is not statistically significant.

Persons with confirmed sCJD were between 44 and 85 years of age, a mean of 68 years old. The vast majority of patients were between 50 and 80 years of age (Figure 5).
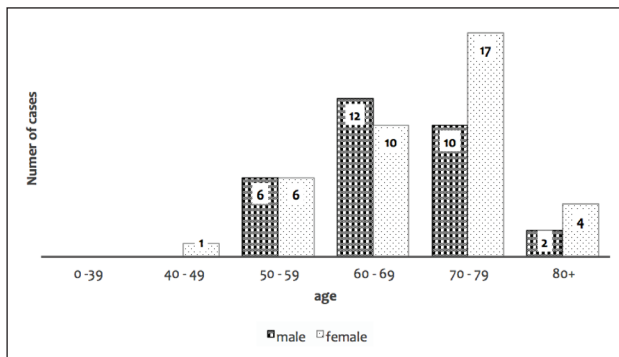

Figure 5. Age and gender distribution of confirmed sCJD, Slovenia, 1996-2017 (n=68).

3.3 Sensitivity and Specificity of 14-3-3 Test, MRI and EEG

To define the sensitivity and specificity of a 14-3-3 test we included only notified possible/probable CJD in which the CSF test for 14-3-3 protein was performed. There were 47 positive findings of the protein 14-3-3 out of 57 confirmed sCJD cases. This represents an 82% sensitivity of the test. Among the 25 by autopsy disproved cases of possible/

probable CJD cases the data show only 14 cases being tested on protein 14-3-3, out of which 4 cases came out to be positive. The specificity in this small sample is 71%. Sensitivity of EEG was 59.3% (38 characteristics out of 64 performed) and specificity was 66.7% (8 characteristics out of 12 performed). Sensitivity of MRI was 39.1% (18 characteristics out of 46 performed) and specificity was 100% (performed only in four cases).

4 DISCUSSION

After 1996 most European countries, including Slovenia, strengthened or developed their systems for surveillance of prion diseases in humans and enhanced control and prevention of BSE in animals. The first animal was diagnosed with BSE in the United Kingdom in November 1986. BSE epidemic reached its peak between 1991 and 1995, when there were 37.000 cases of BSE diagnosed in only one year, 1992 (11).

Implementation of very strict preventive measures allowed for a drastic fall of BSE cases in the EU and globally in the last four years. Since 2001 the EU has been carrying out a comprehensive program of active and passive monitoring of animals in accordance with Regulation of European Commission 999/2001. By the end of 2015 nearly 465.000 brains of cattle were examined by rapid tests in Slovenia. BSE was found in eight cattle, all of them born before the introduction of total ban on feeding the animals with bone meal in 2001 (18, 19).

The data from surveillance of CJD between 1996 and 2017 in Slovenia confirmed that sCJD is the most frequent form of prion diseases, as is the case in other developed countries (6).

During the period 1993–2013 EUROCJD indicates the highest incidence rate of sCJD for France (1.51/1.000,000 population per year) and the lowest for Finland (0.22/1.000,000 population per year). During the same period the incidence rate for Slovenia in the EUROCJD database is 1.23/1.000,000 population per year and ranks in the middle of European countries (8).

Differences in incidence rates among the regions of Slovenia dictate consideration regarding factors that influence these. Amongst those factors there are also disparities in access of these patients to a more specific treatment. This can vary depending on the size of the region and distance from major medical centres, awareness, and socio-economic background and ultimately the effectiveness of the monitoring system of patients in each region, from the layout of possible prion disease to ensuring an autopsy.

Slovenia has confirmed the first, and so far the single case of familial/genetic form of CJD in 2015. The percentage

of f/gCJD in the world has never exceeded 10–15% of all CJD cases, except in Slovakia and Israel. In point of fact, Slovakia and Israel recorded an unusually high number of patients with f/gCJD. Regarding these form of prion disease, there is a major ethical problem present of informing the families and relatives of the nature of the disease and advisement on the possibility of inheritance of this incurable disease (20, 21, 22).

In 2015 there was also a confirmed first case of genetic form of CJD in Slovenia. A first-time suspicion to a genetic form of the fatal familial insomnia (FFI) was set in 2016. PRNP gene analysis revealed a novel mutation, N181S, very close to well-known PRNP mutation of FFI at codon 178. Unfortunately, no autopsy was performed. Despite the fact that the case was included in the register as probable FFI according to clinical presentation, since the new mutation was not yet proved to be connected to the disease. The first case of GSS in Slovenia was confirmed in 2007. The living but affected descendant of this first case is also reported as a confirmed case of the GSS diagnosed by PRNP gene analysis bearing the same mutation, P102L, as his mother (23). EUROCJD database does not separately show GSS and FFT examples but rather leads them along with other forms of prion diseases. Therefore, it is not possible to obtain data on the number of such cases in Europe (8).

In Denmark prospective surveillance of CJD was initiated in 1997 to detect and monitor vCJD in order to be able to take appropriate public health measures. The Danish national surveillance system for CJD, that integrates the expertise of different professionals and has a multidisciplinary approach, registered an incidence rate of 1.26 probable and definite sCJD cases per million between 1997 and 2008. No patients with vCJD were found in Denmark (24).

The first ten definite cases of vCJD were reported in the United Kingdom in 1996 (9, 25).

Most cases of vCJD records United Kingdom was exposed to BSE prions primarily between 1980 and 1990. Between 1995 and May 2015 the United Kingdom confirmed 177 cases of vCJD, France 27 cases, Spain five, both Ireland and the United States of America four, the Netherlands three, Italy, Canada and Portugal two cases, while Taiwan, Japan and Saudi Arabia all had one confirmed case of vCJD during the same period (8). Slovenia has not confirmed the case of vCJD yet.

The first case of iatrogenic forms of CJD in the world was detected in 1974, after a corneal transplant from a deceased with vCJD. The data collected in the world until 2012 show that there were 469 cases of iatrogenic forms of CJD, mainly in Japan (n=142) and France (n=133). Causes were mostly transplantation of dura mater or treatment with growth hormone (11).

Iatrogenic forms of CJD have also yet to be notified in Slovenia.

Among the important clinical diagnostic procedures is 14-3-3 protein test, of which sensitivity and specificity in the world occur in a fairly wide range of values. Despite the current belief that the test presents a high degree of specificity and sensitivity in diagnosing CJD, the experts point out that the predictive value of this method in the clinical diagnosis of CJD and possible different values of the test at different forms of the CJD is still to be further studied in-depth. Studies actually indicate various values of the test for CJD, namely between 43%-100% sensitivity and 47%-97% specificity (26, 27).

Slovenia has less data to properly assess the specificity and sensitivity of the tests in determining CJD, as in many of the reported cases a test for protein 14-3-3 and MRI were not conducted.

Based on the collected data and incidence rates of sCJD it can be concluded that Slovenia does not deviate from the situation in other countries around the world in monitoring cases of CJD. Confirmation of a small number of cases of familial/genetic forms of prion diseases in Slovenia also indicates the ability of the system to identify rare forms of prion diseases.

The number of possible cases of CJD that did not undergo the autopsy to confirm or disprove the disease according to the algorithm, definitely points to the need for improvement in the system similar like with other communicable diseases, which request confirmation of cases with relevant diagnostics (28, 29).

The establishment of PDIEG in Slovenia ensures coordination at the national level and a reference point for collaboration with ECDC. The system of monitoring of prion diseases in Slovenia allows for a good mutual informing of the members of the expert group on the national level. However, it does not necessarily represent the effective functioning of individual areas of expertise and services, which are horizontally mounted in the monitoring system (7).

This is also suggested by the finding that 28% of definite CJD cases were not timely notified to NIPH according to the algorithm but only later after the confirmation with an autopsy.
The reasons why autopsies were not performed in 11 persons are not known; therefore, it is not possible to comment on this deviation in the system.

Differences in incidence rates among the regions of Slovenia dictate consideration regarding factors that influence these. Amongst those factors there are also disparities in access of these patients to a more specific treatment, which can vary depending on the size of the region and distance from major medical centres,

awareness, and socio-economic background and ultimately the effectiveness of the monitoring system of patients in each region, from the layout of possible prion disease to ensuring an autopsy.

5 CONCLUSION

The surveillance system for CJD in Slovenia provides essential data for response at the emergence of a potential risk to public health. The results of the first Slovenian national CJD surveillance system analysis showed that there are still many challenges in improving the present system, especially in compliance with legislation with regards to the timeliness and completeness of the CJD cases reporting, assuring of post-mortem confirmation of the disease, interdisciplinary collaboration and communication that the nature of the disease dictates. There is a need for standardized comprehensive management of patients with CJD regardless of the size of the region, which will ensure access to the health care service, appropriate diagnosis, patient treatment and care. The introduction of a regular epidemiological survey of each confirmed case of prion diseases can contribute to appropriate public health preventive measures and response, if needed. Due to the challenging confirmation of the disease during the patient's lifetime and of the non-mandatory tracking and reporting of the disease in some countries, the number of reported cases of prion diseases around the world is probably still underestimated.

Functioning surveillance systems for human and animal prion diseases and preparedness to respond to public health risk is important because of the sources of the infection in animals, the potential risk for transmission of prions with blood, blood products and medical procedures, and, last but not least, because of known prevalence of vCJD prions in the UK (30).

Undoubtedly, it would be wise to improve and maintain existing structures for surveillance of human prion diseases in Slovenia. The evaluation of prion disease control in a wider context and debates at European level and beyond would be an important step in this public health issue.

AUTHORS' CONTRIBUTION

All authors contributed to the planning and writing of this article.

CONFLICT OF INTEREST

Authors declare that there was no conflict of interest in the research for this study.

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ETHICAL APPROVAL

The study is based on the retrospective analysis of registry data and is, as such, an exempt from ethical approval.

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4. Anon. Early drinking said to increase alcoholism risk. Globe. 1998;2:8-10.

example for the article in a journal with organization as author:

5. Women's Concerns Study Group. Raising concerns about family history of breast cancer in primary care consultations: prospective, population based study. Br Med J. 2001;322:27-8.

example for the article from journal volume with supplement and with number:

6. de Villiers TJ. The role of menopausal hormone therapy in the management of osteoporosis. Climacteric. 2015; 18(Suppl 2):19-21. doi: 10.3109/13697137.2015.1099806.

example for the article from collection of scientific papers:

7. Hickner J, Barry HC, Ebell MH, Ettenhofer T, Eliot R, Sugden K, et al. Suicides and non-suicidal deaths in Slovenia: molecular genetic investigation. In: 9th European Symposium on Suicide and Suicidal Behaviour. Warwick: University of Oxford, 2002:76.

example for master theses, doctor theses:

8. Shaw EH. An exploration of the process of recovery from heroin dependence: doctoral thesis. Hull: University of Hull, 2011.

example for electronic sources:

9. EQ-5D, an instrument to describe and value health. Accessed January 24th, 2017 at: https://euroqol.org/eq-5d-instruments/.

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Type on the place in the text where they belong. Tables should be composed by lines and columns which intersect in fields. Number tables consecutively. Each table should be cited in the text and supplied with a brief title. Explain all the abbreviations and non-standard units in the table.

ILLUSTRATIONS

Illustrations should be professionally drawn. When preparing the illustrations consider the black-and-white print. Illustration material should be prepared in black-and-white (not in color!). Surfaces should have no tone-fills, hatchings should be chosen instead (in case of bar-charts, so called pie-charts or maps). In linear graphs the individual lines should also be separated by various kinds of hatching or by different markers (triangles, asterisks ...), but not by color. Graphs should have white background (i. e. without background).

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Should be in accordance with International System of Units (SI).

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Avoid abbreviations, with the exception of internationally valid signs for units of measurement. Avoid abbreviations in the title and abstract. The full term for which an abbreviation stands should precede its first use in the text, abbreviation used in further text should be cited in parentheses.

EDITORIAL WORK

The received manuscript is submitted by the editor to three international professional reviewers. After the reviewing process, the contribution is sent to the author for approval and consideration of corrections. The final copy is than again submitted to the Editorial Office. The Editorial Office allows for a maximum of three revisions to be dealt with. If the third revision of the manuscript does not take into account all the comments of the reviewers, the manuscript will be withdrawn from the editorial process. During the editorial process, the secrecy of the contribution content is guaranteed. All the articles are language edited. Author receives in consideration also the first print, but at this stage corrigenda (printing errors) only are to be considered. Proofreading should be returned in three days, otherwise it is considered that the author has no remarks.

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When the manuscript is accepted for publication, the author must assigns copyright ownership of the material to the National Institute of Public Health as a publisher. Any violation of the copyright will be legally persecuted.

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NAVODILA AVTORJEM

Revija: **Zdravstveno varstvo (ZV)** ISSN 0351-0026 (tiskana izdaja) / **Slovenian Journal of Public Health (SJPH)** ISSN 1854-2476 (elektronska izdaja)

Navodila so v skladu z Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Popolna navodila so objavljena v N Engl J Med 1997; 336: 309-15 in v Ann Intern Med 1997; 126: 36-47 in na spletni strani http://www.icmje.org.

ETIČNI STANDARDI

Uredništvo sprejema v obdelavo le članke s širšo mednarodno javnozdravstveno tematiko, ki še niso bili in ne bodo objavljeni drugje. Dele članka, ki so povzeti po drugi literaturi (predvsem slike in tabele), mora spremljati dovoljenje avtorja in založnika prispevka, da dovoli naši reviji reprodukcijo.

Oddan rokopis morajo prebrati vsi avtorji in se z njegovo vsebino strinjati.

Raziskave na ljudeh (vključno s človeškimi materiali in osebnimi podatki) morajo biti izpeljane v skladu s Helsinško deklaracijo in potrjene s strani nacionalne etične komisije. V izjavi na koncu rokopisa morajo avtorji podati izjavo o etiki raziskav na ljudeh, ki mora vsebovati ime etične komisije in referenčno številko obravnave. Poročanje o raziskavah na ljudeh brez potrdila etične komisije zahteva dodatno razlago v poglavju o metodah dela. Na zahtevo Uredništva je avtor dolžan predložiti vso dokumentacijo o obravnavi raziskovalne etike njegovega rokopisa. Uredništvo si pridržuje pravico, da kontaktira etično komisijo.

Prav tako morajo avtorji, ki poročajo o ljudeh ali posredujejo javnosti njihovo slikovno gradivo, pridobiti dovoljenja vseh sodelujočih, da se z vključitvijo v raziskavo strinjajo (v primeru otrok so to starši ali skrbniki). Izjavo o pridobitvi teh dovoljenj morajo avtorji podati v poglavju o metodah dela. Uredništvo si pridržuje pravico vpogleda v to dokumentacijo.

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V izjavi na koncu rokopisa morajo biti zapisani morebitni finančni ali drugi interesi farmacevtske industrije ali proizvajalcev opreme ter inštitucij, povezani z objavo v ZV/SJPH.

Avtorji morajo na koncu rokopisa zapisati sledeče izjave:

CONFLICTS OF INTEREST (The authors declare that no conflicts of interest exist.)

FUNDING (The study was financed by …)

ETHICAL APPROVAL (Received from the… ali opis etičnega vidika raziskave)

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Kadar uredništvo ugotovi, da je rokopis plagiat, se rokopis takoj izloči iz uredniškega postopka. Plagiatorstvo ugotavljamo s programom za odkrivanje plagiatov CrossCheck plagiarism detection system.

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Priporočamo uporabo videoposnetka z navodili za avtorje. Prispevke oddajte v elektronski obliki s pomočjo spletne aplikacije Editorial Manager, ki se nahaja na spletnem naslovu http://www.editorialmanager.com/sjph/. V uredništvo sprejemamo po pošti le še Izjave o avtorstvu in avtorskih pravicah, ki zahtevajo lastnoročni podpis. Prosimo, da jih pošljete hkrati z elektronsko oddajo prispevka na naslov: Nacionalni inštitut za javno zdravje, za revijo Zdravstveno varstvo, Trubarjeva 2, 1000 Ljubljana.

V spletno uredniško aplikacijo se prijavite kot 'avtor'. Prva prijava zahteva vnos podatkov o avtorju, vse naslednje prijave pa le še vnos podatkov za prijavo, ki jih na svoj elektronski naslov prejmete po prvi prijavi v sistem.

Po uspešni prijavi izpolnite vsa zahtevana strukturirana polja. Potrdite izjavo, da vaš prispevek še ni bil objavljen ali poslan v objavo kakšni drugi reviji, da so prispevek prebrali in se z njim strinjajo vsi avtorji, da so raziskave na ljudeh oz. živalih opravljene v skladu z načeli Helsinško-Tokijske deklaracije oz. v skladu z etičnimi načeli.

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Polje 'Comments' je namenjeno vašim dodatnim razlagam, navedete lahko tudi predlog recenzentov z imeni, nazivi, e-naslovi in zaposlitvijo.

Podatke o avtorju in soavtorjih vnesite kar se da natančno in popolno. Naveden naj bo korespondenčni avtor (s polnim naslovom, telefonsko številko in elektronskim naslovom), ki bo skrbel za komunikacijo z uredništvom in ostalimi avtorji.

Jezik prispevka je angleščina. Objavljamo izvirne znanstvene članke, sistematične pregledne znanstvene članke, metodologije raziskav in vabljene uvodnike. Pri izvirnih, metodoloških in sistematičnih preglednih znanstvenih prispevkih morajo biti naslov, izvleček in ključne besede prevedeni tudi v slovenščino.

Naslov, ključne besede in izvleček se oddajajo dvojezično v angleščini in slovenščini v strukturirana polja. Posebno polje za zapis v drugem jeziku obstaja le za izvleček, preostale podatke vnesite v obeh jezikih v ustrezno isto polje. Prvi izvleček je vselej v angleškem jeziku (do 250 besed - sistem vam besede sproti šteje), drugi pa v slovenskem jeziku (razširjen izvleček - do 400 besed).

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Pri oddaji sledite napotkom, ki vam jih ponuja sistem, pomagate pa si lahko tudi z 'Editorial Manager's Tutorial for Autors'.

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Če pri oddajanju rokopisa naletite na nepremostljive težave, se za pomoč obrnite na naslov uredništva: zdrav.var@nijz.si.

V nadaljevanju podajamo še nekaj natančnejših napotkov.

ROKOPIS

Besedila naj bodo napisana z urejevalnikom Word for Windows 97-2003. Robovi naj bodo široki najmanj 25 mm. Znanstveni članki naj imajo naslednja poglavja: uvod, metode, rezultati, razpravljanje in zaključek. Uvodniki in sistematični pregledni članki so lahko zasnovani drugače, vendar naj bo razdelitev na poglavja in podpoglavja jasno razvidna iz velikosti črk naslovov. Poglavja in podpoglavja naj bodo številčena dekadno po standardu SIST ISO 2145 in SIST ISO 690 (npr. 1, 1.1, 1.1.1 itd.).

DOLŽINA PRISPEVKOV

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NASLOV IN AVTORSTVO

Naslov v angleškem in slovenskem jeziku naj bo kratek in natančen, opisen in ne trdilen (povedi v naslovih niso dopustne). Navedena naj bodo imena piscev z natančnimi akademskimi in strokovnimi naslovi ter popoln naslov ustanove, inštituta ali klinike, kjer je delo nastalo. Avtorji morajo izpolnjevati pogoje za avtorstvo. Prispevati morajo k zasnovi in oblikovanju oz. analizi in interpretaciji podatkov, rokopis morajo intelektualno zasnovati oz. ga kritično pregledati, strinjati se morajo s končno različico rokopisa. Samo zbiranje podatkov ne zadostuje za avtorstvo.

IZVLEČEK IN KLJUČNE BESEDE

Izvleček v angleškem in slovenskem jeziku naj bo pri znanstvenem in metodološkem članku strukturiran in naj ne bo daljši od 250 besed v angleščini in 400 besed v slovenščini, izvlečki ostalih člankov so lahko nestrukturirani. Izvleček naj vsebinsko povzema in ne le našteva bistvene vsebine dela. Izogibajte se kraticam in okrajšavam. Napisan naj bo v 3. osebi.

Izvleček znanstvenega članka naj povzema namen dela, osnovne metode, glavne izsledke in njihovo statistično pomembnost ter poglavitne sklepe (struktura IMRC - Introduction, Methods, Results, Conclusions).

Navedenih naj bo 3-10 ključnih besed, ki nam bodo v pomoč pri indeksiranju. Uporabljajte izraze iz MeSH - Medical Subject Headings, ki jih navaja Index Medicus.

KATEGORIJA PRISPEVKA

Kategorijo prispevka predlaga z vnosom v ustrezno polje avtor sam, končno odločitev pa sprejme urednik na osnovi predlogov recenzentov. Objavljamo izvirne znanstvene članke, metodološke članke, sistematične pregledne znanstvene članke in vabljene uvodnike.

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Avtorjem priporočamo, da pregledajo objavljene članke na temo svojega rokopisa v predhodnih številkah naše revije (za obdobje zadnjih pet let).

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Navedite imena vseh avtorjev, v primeru, da je avtorjev šest ali več, navedite prvih šest avtorjev in dodajte et al.

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PRIMERI ZA CITIRANJE LITERATURE

primer za knjigo:

1. Anderson P, Baumberg P. Alcohol in Europe. London: Institute of Alcohol Studies, 2006.
2. Mahy BWJ. A dictionary of virology. 2nd ed. San Diego: Academic Press, 1997.

primer za poglavje iz knjige:

3. Urlep F. Razvoj osnovnega zdravstva v Sloveniji zadnjih 130 let. In: Švab I, Rotar-Pavlič D, editors. Družinska medicina. Ljubljana: Združenje zdravnikov družinske medicine, 2002:18-27.
4. Goldberg BW. Population-based health care. In: Taylor RB, editor. Family medicine. 5th ed. New York: Springer, 1999:32-6.

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5. Florez H, Pan Q, Ackermann RT, Marrero DG, Barrett-Connor E, Delahanty L, et al. Impact of lifestyle intervention and metformin on health-related quality of life: the diabetes prevention program randomized trial. J Gen Intern Med. 2012;27:1594-601. doi: 10.1007/s11606-012-2122-5.

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12. EQ-5D, an instrument to describe and value health. Accessed January 24th, 2017 at: https://euroqol.org/eq-5d-instruments/.

TABELE

Tabele v angleškem jeziku naj bodo v besedilu prispevka na mestu, kamor sodijo. Tabele naj sestavljajo vrstice in stolpci, ki se sekajo v poljih. Tabele oštevilčite po vrstnem redu, vsaka tabela mora biti citirana v besedilu. Tabela naj bo opremljena s kratkim angleškim naslovom. V legendi naj bodo pojasnjene vse kratice, okrajšave in nestandardne enote, ki se pojavljajo v tabeli.

SLIKE

Slike morajo biti profesionalno izdelane. Pri pripravi slik upoštevajte, da gre za črno-beli tisk. Slikovno gradivo naj bo pripravljeno:

- črno-belo (ne v barvah!);
- brez polnih površin, namesto tega je treba izbrati šrafure (če gre za stolpce, t. i. tortice ali zemljevide);
- v linijskih grafih naj se posamezne linije prav tako ločijo med samo z različnim črtkanjem ali različnim označevanjem (s trikotniki, z zvezdicami...), ne pa z barvo;
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Vsaka slika mora biti navedena v besedilu. Besedilo k sliki naj vsebuje naslov slike in potrebno razlago vsebine. Slika naj bo razumljiva tudi brez branja ostalega besedila. Pojasniti morate vse okrajšave v sliki. Uporaba okrajšav v besedilu k sliki je nedopustna. Besedila k slikam naj bodo napisana na mestu pojavljanja v besedilu.

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MERSKE ENOTE

Naj bodo v skladu z mednarodnim sistemom enot (SI).

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Kraticam in okrajšavam se izogibajte, izjema so mednarodno veljavne oznake merskih enot. V naslovih in izvlečku naj ne bo kratic. Na mestu, kjer se kratica prvič pojavi v besedilu, naj bo izraz, ki ga nadomešča, polno izpisan, v nadaljnjem besedilu uporabljano kratico navajajte v oklepaju.

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