POVEZANOST ŠPORTNE DEJAVNOSTI S STRESOM IN Z ZADOVOLJSTVOM Z ŽIVLJENJEM PRI ODRASLIH SLOVENCIH

CORRELATION OF SPORTS ACTIVITY WITH STRESS AND SATISFACTION WITH LIFE AMONG ADULT SLOVENIANS

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Izvleček

Izhodišča: *Namen raziskave je bil ugotoviti povezanost med športno dejavnostjo (ŠD) in doživljanjem stresa ter vrednotenjem zadovoljstva z življenjem odraslih Slovencev.*
Metode: *Podatki so bili pridobljeni s pomočjo anketnega vprašalnika na reprezentativnem vzorcu 856 odraslih Slovencev in Slovenk (povprečne starosti 39 ± 13,7 leta). ŠD je bila opredeljena s številom dni ukvarjanja s katero koli športno dejavnostjo tedensko. Stres je bil opredeljen s pogostostjo doživljanja devetih znakov stresa na štiristopenjski lestvici. Pri oceni zadovoljstva z življenjem so udeleženci raziskave izrazili strinjanje oziroma nestrinjanje s petimi postavkami na petstopenjski lestvici. Vrednosti prve glavne komponente stresa in lestvice zadovoljstva z življenjem je bila določena z Anderson-Rubinovo metodo. Povezanost spremenljivk je bila ocenjena s Spearmanovim koeficientom korelacije in s splošnimi linearnimi modeli.*
Rezultati: *ŠD je bila statistično značilno povezana s stresom (p = ,03) in z zadovoljstvom z življenjem (p < ,01). V linearnih modelih imajo izbrani dejavniki (ŠD, starost, spol in izobrazba) skupaj statistično značilen vpliv (pri stresu: R^2 = ,040; p < ,001; pri zadovoljstvu: R^2 = ,068; p < ,001); ŠD ima statistično značilen vpliv le na oceno zadovoljstva z življenjem ($\eta^2_{part.}$ = ,020; p = ,002). Na stres statistično značilno vplivajo vsi preostali dejavniki, na zadovoljstvo z življenjem pa le izobrazba.*
Zaključki: *Na podlagi dobljenih rezultatov lahko sklepamo, da so športno dejavnejši odrasli Slovenci manj pod stresom in bolj zadovoljni s svojim življenjem, vendar je ta vpliv ob upoštevanju vpliva starosti, spola in izobrazbe razmeroma majhen.*

Ključne besede: športna dejavnost, zdravje, Slovenci

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Abstract

Objective: *The aim of the study was to investigate the correlation of sports activity (SA) with stress experience and evaluation of satisfaction with life among adult Slovenians.*
Methods: *Data was collected with a survey on a representative sample of 856 adult Slovenians (average age 39±13.73 years). We determined sports activity with incidence of any sports activity – times per week. To determine mental health, the respondents marked how often the 9 signs of stress appeared within a last month and how satisfied they were with their life. Scores on the first component of stress and satisfaction with life scale were computed using Anderson-Rubin method. The correlations between variables were evaluated using the Spearman correlation coefficient and general linear models.*
Results: *SA is statistically significantly correlated with stress (p= .03) and satisfaction with life (p= .00). In the models for prediction of stress and satisfaction with life, the set of predictors (SA, age, gender and education) has a significant effect (R^2= .040, p< .001; R^2= .068, p< .001), with SA having a statistically significant effect only on value of life satisfaction (η^2_{part} = .020, p= .002). A set of all mentioned predictors has significant effect on stress, while only education beside SA has a statistically significant effect on satisfaction with life.*

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Conclusions: *It could be concluded that individuals that are more active in sports experience the signs of stress less often and that they are more satisfied with their lives, but taking age, gender and education into consideration, SA is not the main predictor.*

Key words: sports activity, health, Slovenians

1 UVOD

V zadnjih letih se številni raziskovalci ukvarjajo s proučevanjem vpliva telesne/športne dejavnosti kot ene izmed sestavin zdravega življenjskega sloga na človekovo zdravje. Dokazani so pozitivni vplivi na telesno in tudi duševno zdravje (1–7). Telesna dejavnost (TD) je opredeljena precej širše kot športna dejavnost (ŠD) in se nanaša na katero koli mišično delo (tudi nenačrtno), ki se konča s porabo energije nad ravnjo mirovanja (3, 8–11). ŠD je načrtovana in strukturirana ter namenjena predvsem izboljšanju kazalnikov telesnega zdravja (8, 9). Široka opredelitev TD pomeni, da poleg športa (ki vsebuje določeno obliko tekmovanja) in namerne telesne vadbe vključuje tudi vse druge vrste TD, vključno s hojo ali kolesarjenjem v transportne namene, tradicionalnimi igrami in z razvedrili, vrtnarjenjem in s hišnimi opravili ter podobno. Raziskovalci navajajo, da je ŠD pomemben del TD (12), saj v današnjem večinoma sedečem slogu življenja ob izjemno nizki energetski porabi za TD postaja ŠD vse bolj obvezna, nujna in nenadomestljiva (13). Športni dejavnosti gre pripisati intenzivnejše učinke na zdravje (14); posebno vrednost imajo aerobne dejavnosti (15). ŠD ima ugodne učinke na zdravje samo takrat, kadar je primerno izbrana, za uporabnika prilagojena in se redno izvaja skozi vsa življenjska obdobja (15–17). Priporočena mera ukvarjanja s ŠD pa je od tri- do petkrat tedensko od pol ure do ene ure dnevno (18). Po podatkih Regionalnega urada Svetovne zdravstvene organizacije za Evropo je 60 % evropskega prebivalstva manj kot enkrat tedensko športno dejavnih (19).

V naši raziskavi smo se osredinili na povezanost ŠD in duševnega zdravja, ki smo ga opisali s pogostostjo pojavljanja znakov stresa in z vrednotenjem zadovoljstva z življenjem. Avtorji stres najpogosteje opredelijo kot telesno in psihološko obremenjenost organizma, ki nastane kot prilagoditveni odgovor na dražljaje v okolju (20) in se izraža v različnih simptomih, kot so: glavobol, telesna in psihična utrujenost, pomanjkanje energije, anksioznost, zaskrbljenost, živčnost, napetost, razdražljivost, težave s komunikacijo, zmanjšana produktivnost in kakovost dela (21). Prav tako je lahko kronično pomanjkanje časa, ki je značilno za današnji način življenja, vir stresnih znakov. Tem so bolj podvržene ženske (22, 23), ki tudi navajajo večje pomanjkanje časa (24). Stres predstavlja resno grožnjo zdravju (11); v nekaterih državah je poglaviten vzrok za odsotnost z dela, celo pogostejši od težav skeletno-mišičnega sistema (25). Najbolj naj bi prizadel ljudi med 35. in 45. letom starosti (22). Zadovoljstvo z življenjem smo vrednotili kot kognitivno oceno posameznika o svojem življenju, saj predstavlja temeljno komponento subjektivnega blagostanja. Koncept subjektivnega blagostanja se lahko označi kot neko splošno oceno dobrega počutja in sreče (26). Večinoma so ljudje s svojim življenjem prej zadovoljni kot nezadovoljni (27). Pri tem je subjektivno življenjsko zadovoljstvo kompromis med tistim, kar je za nas pomembno in kar je dejansko dosegljivo. Deiner, Suh in Oishi (28) ter Myers in Dyner (29) navajajo, da so posamezniki, ki so zadovoljnejši, tudi uspešnejši na različnih področjih življenja.

Raziskave kažejo pozitivne vplive TD na zmanjšano pojavljanje znakov stresa (6, 30) in boljšo odpornost na stres (3). V švedski študiji so bile na vzorcu zavarovalniških agentov ugotovljene pozitivne povezave med TD in zmanjšanjem stresa, prav tako so dejavnejši navajali manj težav z depresijo in anksioznostjo (31). Azar in sodelavci so ugotovili, da TD zmanjšuje znake prisotnosti depresije, ni pa bila ugotovljena količina TD, ki je potrebna za zagotavljanje prepoznanih učinkov (32). Rezultati finske študije, opravljene na populaciji odraslih od 25 do 64 let, so pokazali, da so se pri posameznikih, ki so bili dejavni vsaj dvakrat tedensko, pomembno izboljšali nekateri kazalniki zdravja (manj znakov prisotnosti depresije, zmanjšanje stresa in boljše splošno zadovoljstvo z življenjem) (1). Podobno študijo so opravili na Norveškem in prav tako dokazali, da se pri tistih, ki so dejavni od dva- do trikrat tedensko, znaki stresa redkeje pojavljajo kot pri tistih, ki so dejavni le enkrat tedensko ali manj (33). Pri ugotavljanju odziva živčnega sistema na stresno situacijo, pri čemer so v vzorec zajeli profesionalne športnike, neprofesionalce in nedejavne ljudi, so raziskovalci ugotovili, da je najmočnejši odziv pri skupini nedejavnih ljudi, najmanj stresno pa so situacijo zaznali redno športno dejavni (34). Nadalje so študije pokazale, da je pogostost TD povezana tudi z večjim zadovoljstvom z življenjem (35, 36, 17). Raziskovalci navajajo, da so srečnejši tisti, ki so

telesno dejavnejši (36–38). Poleg tega imajo dejavnejši višjo samozavest in boljšo samopodobo ter so bolj optimistični in boljšega razpoloženja (39, 40, 3); višje ocenjujejo kakovost svojega življenja (41).
Zaznati je pomanjkanje raziskav, ki bi obravnavale razlike in povezave v kazalnikih duševnega zdravja (s stresom in z zadovoljstvom z življenjem) pri različno dejavnih skupinah z nadzorom starosti, spola in izobrazbe. Pri pregledu literature je zaslediti tudi manj raziskav, ki bi opisovale povezanost ŠD (ločeno od preostalih telesnih dejavnosti) z duševnim zdravjem. Ta raziskava se osredinja na povezave med ŠD in kazalniki duševnega zdravja, ki smo ga opredelili s stresom in z zadovoljstvom z življenjem. Odgovoriti želimo na vprašanje, katere so razlike v doživljanju stresa in zadovoljstva z življenjem pri različno športno dejavnih skupinah. Predpostavljamo, da bodo pogosteje športno dejavni doživljali znake stresa manj pogosto in da bodo zadovoljnejši s svojim življenjem.

2 METODE

2.1 Vzorec udeležencev raziskave

Vzorec je obsegal 856 odraslih Slovencev (50 % moških, 50 % žensk) starih 39 ± 13,7 leta. Anketiranci so bili povprečno visoki 172,76 (± 9,15) cm in težki 75 (± 16) kg. Največji delež anketirancev (45 %) je imel srednješolsko izobrazbo. Vzorec je pridobljen iz Centralnega registra prebivalstva in je naključen ter stratificiran glede na slovenske regije. Elementi vzorčenja so bili: delež prebivalcev v regiji (12 regij), starost (5 starostnih skupin: 18–24, 25–34, 35–44, 45–54, 55–64) in spol (delež je različen tudi glede na starost). Upoštevan pa je bil tudi delež stopnje izobrazbe v vzorcu, ki naj bi bil proporcionalen deležu v populaciji. Vzorčenje je bilo opravljeno na Centru za psihodiagnostična sredstva v Ljubljani. Vsi udeleženci so v anketi sodelovali prostovoljno; anonimnost je bila zagotovljena.

2.2 Vzorec spremenljivk

Podatki so bili zbrani z osebnim terenskim anketiranjem. Tvorili smo pet izobrazbenih stopenj (I – končana ali nedokončana osnovna šola, II – končana 2- ali 3-letna poklicna šola, III – končana srednja šola, IV – končana višja strokovna šola in V – končana visoka šola ali več). ŠD je bila opredeljena s pogostostjo ukvarjanja s katero koli športno dejavnostjo tedensko. Različno dejavne skupine smo tvorili na podlagi merila iz raziskave Special Eurobarometer (19), pri čemer redna dejavnost pomeni vsaj 5-krat tedensko udejstvovanje, pogosta od 1- do 4-krat tedensko, redka od 1- do 3-krat mesečno ter nedejavnost manj kot 1-krat mesečno. Za potrebe raziskave smo merilo nekoliko priredili in kategorijo pogosto razdelili v dve skupini (od 1- do 2-krat tedensko in od 3- do 4-krat tedensko) ter tako oblikovali pet različno dejavnih skupin. Udeleženci raziskave so opredelili stopnjo doživljanja stresa kot enega izmed kazalnikov duševnega zdravja. Osredinili smo se le na simptome (opozorilne znake oziroma posledice) stresa, ki se pojavljajo na telesnem, čustvenem, kognitivnem, vedenjskem in na motivacijskem področju (42). V raziskavo smo vključili od enega do tri znake z vsakega področja. Lestvico stresa tako sestavlja 9 znakov (nespečnost, težave s telesno težo, pesimizem, strah, neuspešnost, jeza, nočne more, brezvoljnost in izčrpanost) (42), za katere so udeleženci navedli, kako pogosto so jih zaznali v zadnjem mesecu. Uporabljena je bila štiristopenjska lestvica: 1 – nikoli, 2 – redko (do 3-krat mesečno), 3 – pogosto (od 1- do 6-krat tedensko), 4 – redno (vsak dan) (42). Za ugotavljanje zadovoljstva z življenjem so bile uporabljene postavke Lestvice zadovoljstva z življenjem (SWLS) (43). Lestvico sestavlja pet postavk, na katere so udeleženci raziskave odgovarjali na lestvici od 1 (sploh ne drži) do 5 (popolnoma drži).

2.3 Metode obdelave podatkov

Podatki so bili obdelani s statističnim paketom SPSS 18.0 for Windows. Izračunani sta bili osnovna statistika in frekvenčna porazdelitev za spremenljivke. Vrednosti prve komponente stresa in lestvice zadovoljstva z življenjem so bile izračunane z analizo glavnih komponent z uporabo Anderson-Rubinove metode za izračun faktorskih vrednosti (skorov). Povezanost ŠD in stresa ter zadovoljstva z življenjem je bila izračunana s Spearmanovim koeficientom korelacije. Vplivi ŠD na doživljanje stresa in vrednotenje zadovoljstva z življenjem so bili pridobljeni s splošnimi linearnimi modeli. Vsi testi hipotez so bili opravljeni na stopnji tveganja $\alpha = 5$ %.

3 REZULTATI

Največji delež udeležencev raziskave se s športom ukvarja od 1- do 2-krat tedensko (45 %), najmanj pa je takih, ki niso nikoli dejavni (8 %) ali pa se s športom ukvarjajo manj kot 1-krat tedensko (6 %) (Tabela 1).

Tabela 1. *Pogostost ukvarjanja s športno dejavnostjo vzorca odraslih Slovencev.*
Table 1. *Frequency of sport activity of study sample of Slovenian adults.*

Spremenljivka/Parameter	Športna dejavnost /Sport activity
	F (%)
Športna dejavnost= nikoli /Sport activity= never	8
Športna dejavnost <1x/teden / Sport activity <1x/week	6
Športna dejavnost =1-2x/teden / Sport activity =1-2x/week	45
Športna dejavnost =3-4x/teden / Sport activity =3-4x/week	22
Športna dejavnost =5x ali več/teden / Sport activity =5x or more/week	19

f – frequency of responses.

Z vrednostmi prve glavne komponente za stres in zadovoljstvo z življenjem smo pojasnili 39,9 % variance stresa in 65,9 % variance zadovoljstva z življenjem. Za oba vprašalnika smo izračunali notranjo konsistentnost, in sicer so znašale vrednosti Cronbachovega alfe 0,80 za Vprašalnik o stresu in 0,86 za Lestvico zadovoljstva z življenjem.

Iz Tabele 2 je razvidno, da se pri udeležencih raziskave med znaki stresa najpogosteje pojavlja izčrpanost (mediana Me = 2,01; interkvartilni razmik IQR = ,86), sledita pa jeza (Me = 1,86; IQR = ,78) in brezvoljnost (Me = 1,61; IQR = ,70). V splošnem znakov stresa ne doživljajo pogosto (v povprečju manj kot enkrat tedensko pri vseh znakih). Večina udeležencev raziskave je za postavke o stresu izbrala odgovor 1 (nikoli) ali 2 (redko). Pri vrednotenju zadovoljstva z življenjem je največ udeležencev raziskave izbralo odgovor 4 (določena 'postavka zame drži'). Najbolj se strinjajo s postavko Zadovoljen sem s svojim življenjem (Me = 3,51; IQR = ,97).

Tabela 2. *Teža glavnih komponent in porazdelitvena statistika za stres in zadovoljstvo za vzorec odraslih Slovencev.*
Table 2. *Principal component weights and distribution statistics for stress and satisfaction scale of study sample of Slovenian adults.*

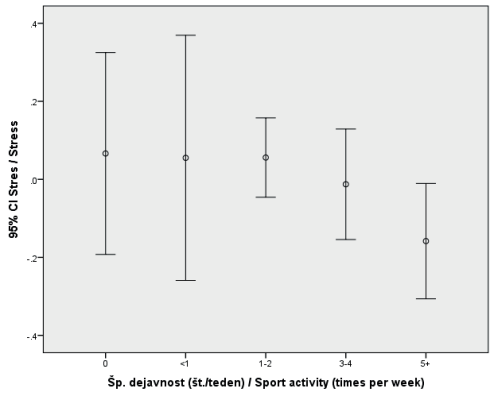
Lestvica/ Scale	Postavka/Item	n	a	Me	IQR
Stres/Stress	Nespečnost/ Sleeplessness	821	,53	1,49	,71
	Težave s telesno težo/ Body weight fluctuation	802	,44	1,37	,65
	Pesimizem/Pessimism	792	,71	1,40	,63
	Strah/Fear	794	,70	1,42	,62
	Neuspešnost/Failure	791	,71	1,42	,62
	Jeza/Anger	807	,63	1,86	,78
	Nočne more/Nightmares	794	,53	1,19	,46
	Brezvoljnost/Lethargy	810	,73	1,61	,70
	Izčrpanost/Exaustion	816	,64	2,01	,86
Zadovoljstvo /Satisfaction	V večini pogledov je moje življenje blizu mojemu idealu. / In most ways my life is close to my ideal.	852	,88	3,44	,85
	Moji življenjski pogoji so odlični. / The conditions of my life are excellent.	852	,80	3,51	,97
	Zadovoljen sem s svojim življenjem. / I am satisfied with my life.	853	,87	3,57	,91
	V življenju sem doslej dosegel tiste pomembne stvari, ki sem jih želel. / So far I have gotten the important things I want in life.	846	,79	3,48	,97
	Če bi lahko še enkrat živel, v svojem življenju ne bi ničesar spremenil. / If I could live my life over, I would change almost nothing.	849	,72	3,14	1,12

n–število odgovorov*; a*–utež na prvi glavni komponenti; *Me*–mediana; *IQR*–interkvartilni razmik; *f* – pogostost odgovorov.

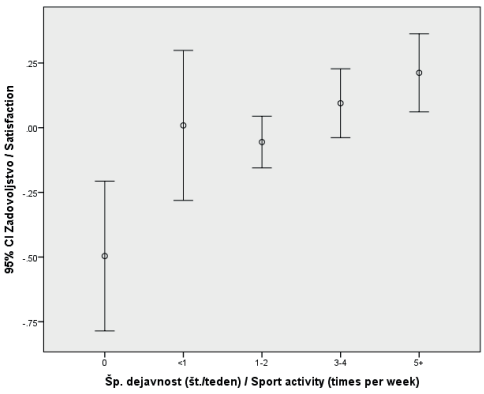
n–number of cases; *a*–weight on first principal component; *Me*–Grouped median; *IQR*–inter quartile range; *f*–frequency of responses.

Stres (izražen z rezultatom na prvi glavni komponenti) je šibko, toda statistično značilno povezan s ŠD (r = –0,07; p = ,03). Doživljanje stresa je manjše pri športno dejavnejših skupinah. Na podlagi enofaktorske analize variance smo ugotovili, da so razlike med različno dejavnimi skupinami v pojavljanju znakov stresa majhne in statistično neznačilne (p = ,22) (Slika 1). Zadovoljstvo z življenjem pa se s pogostostjo športne dejavnosti povečuje, in sicer je pri skupini redno športno dejavnih zadovoljstvo z življenjem najvišje (slika 1). Povezanost je statistično značilna (r = ,15; p = ,00), prav tako so statistično značilne (p < 0,01) razlike med različno pogosto športno dejavnimi skupinami, vendar je treba upoštevati dejstvo, da v tej analizi ni bil upoštevan nadzor izobrazbe, starosti in spola.

Stres/Stress
(r = -,07; p= ,03)



Zadovoljstvo/ Satisfaction
(r = ,15; p= ,00)



Slika 1. *Grafikon napake (povprečje +/- standardna napaka) za oceno stresa in zadovoljstva glede na ŠD.*

Figure 1. *Error bars (mean +/- SE) for stress and satisfaction scores by activity frequency.*

Da bi lahko ocenili vpliv ŠD na stopnjo stresa in zadovoljstvo z življenjem ob nadzoru (izločitvi vpliva) starosti, spola in izobrazbe, smo oblikovali splošne linearne modele. Končni modeli za stres in zadovoljstvo z življenjem vključujejo le glavne vplive (Tabela 3), saj so bile vse dve- in trismerne interakcije majhne in statistično neznačilne.

Tabela 3. *Splošna linearna modela za pojasnitev stresa in zadovoljstva s ŠD, starostjo, spolom in z izobrazbo.*
Table 3. *General linear models for the prediction of stress and satisfaction by sport activity, age, gender and education.*

Spremenljivka/Parameter	Stres/Stress (R^2= 0,040; p< ,001)			Zadovoljstvo/Satisfaction (R^2= 0,068; p< ,001)		
	F	p	$\eta^2_{part.}$	F	p	$\eta^2_{part.}$
Presečišče / Intercept	1,874	,163	.002	1,662	,182	,002
Športna dejavnost/Sport activity	4,77	,195	.007	1,74	,002	,020
Starost (leta)/Age	15,14	,029	.006	10,09	,115	,003
Spol/Gender	4,44	,000	.018	4,18	,188	,002
Izobrazba/Education	1,52	,001	.021	2,49	,000	,046

F – vrednost F-testa; *p* – statistična pomembnost; $\eta^2_{part.}$ – parcialna Eta kvadrat.
F – F-test value; *p* – statistical significance; $\eta^2_{part.}$ – partial Eta sqared.

V modelu, ki napoveduje stres (Tabeli 3 in 4, leva stran) imajo vsi izbrani dejavniki (ŠD, starost, spol in izobrazba) skupaj majhen, a statistično značilen vpliv (prilagojen R^2 = ,040, p < ,001). Vsak posamični dejavnik razen ŠD statistično značilno vpliva na pogostost doživljanja znakov stresa. Največji vpliv ima stopnja izobrazbe ($\eta^2_{part.}$ = ,021, p = ,001), in sicer imajo udeleženci raziskave s končano ali z nedokončano osnovno šolo (stopnja izobrazbe = I) za 0,513 (p= ,000) višjo pričakovano z-vrednost pri doživljanju stresa v primerjavi s tistimi v najvišji izobrazbeni kategoriji (končana visoka šola ali več) (Tabela 4). Analiza je pokazala, da ŠD ne vpliva statistično značilno na doživljanje stresa. Le skupina udeležencev raziskave, ki se s ŠD ukvarja od 1- do 2-krat tedensko, ima za 0,23 (p = ,016) višjo pričakovano z-vrednost doživljanja stresa v primerjavi z referenčno kategorijo (petkrat tedensko ali več). Rezultati kažejo, da se z vsakim letom starosti stres zmanjša za 0,006 z-vrednosti (p = ,029). Razlike med spoloma so statistično značilne, in sicer imajo moški za 0,265 z-vrednosti nižjo pričakovano vrednost doživljanja stresa od žensk.

Tabela 4. *Parametri splošnih linearnih modelov vpliva ŠD na stres in zadovoljstvo z življenjem z nadzorom starosti, spola in izobrazbe.*

Table 4. *Parameters of general linear models for the prediction of sport activity on stress and life satisfaction, controlled for age, gender and education level.*

Spremenljivka/Parameter	Stres/ Stress (R^2= 0,040; p< ,001)				Zadovoljstvo / Satisfaction (R^2= 0,068; p< ,001)			
	β	SE	p	$\eta^2_{part.}$	β	SE	p	$\eta^2_{part.}$
Presečišče/ Intercept	-,084	,158	,596	,000	,370	,155	,017	,007
Športna dejavnost= nikoli /Sport activity= never	,192	,152	,207	,002	-,572	,150	,000	,017
Športna dejavnost <1/teden / Sport activity <1/week	,190	,166	,254	,002	-,236	,094	,012	,008
Športna dejavnost =1-2/teden / Sport activity =1-2/week	,230	,095	,016	,007	-,117	,164	,474	,001
Športna dejavnost =3-4/teden / Sport activity =3-4/week	,116	,105	,271	,001	-,102	,104	,325	,001
Starost (leta)/ Age (years)	-,006	,003	,029	,006	,004	,003	,115	,003
Spol=moški/ Gender=male	-,265	,068	,000	,018	,088	,067	,188	,002
Stopnja izobrazbe=I /Education level=I	,513	,130	,000	,018	-,744	,128	,000	,039
Stopnja izobrazbe =II /Education level=II	,250	,137	,068	,004	-,483	,135	,000	,015
Stopnja izobrazbe =III /Education level=III	,281	,117	,017	,007	-,305	,116	,008	,008
Stopnja izobrazbe =IV /Education level=IV	,142	,165	,387	,001	-,296	,162	,068	,004

Referenčna kategorija za športno dejavnost je 5 (5x ali več/teden), za izobrazbo pa V (končana visoka šola ali več).
Reference category for sport activity is 5 (5x or more/week) and for education level is V (university degree or more).
β – beta koeficient; *SE*–standardna napaka; *p* – statistična pomembnost; $\eta^2_{part.}$ – parcialna Eta kvadrat.
β – beta coefficient; *SE*–standard error; *p* – statistical significance; $\eta^2_{part.}$ – partial Eta sqared.

V primerjavi z modelom stresa (Tabela 3, desna stran) imajo izbrani dejavniki (ŠD, starost, spol in izobrazba) v modelu zadovoljstva z življenjem nekoliko večji vpliv (prilagojeni R^2 = ,068, p < ,001). Na zadovoljstvo z življenjem najbolj vpliva izobrazba ($\eta^2_{part.}$ = ,046, p = <,001); udeleženci raziskave z nižjo izobrazbo kot končano srednjo šolo (stopnja izobrazbe = III) so statistično značilno manj zadovoljni s svojim življenjem kot najbolj izobražena skupina (stopnja izobrazbe = V). ŠD je statistično značilen dejavnik vpliva; manj kot 1-krat

tedensko dejavni udeleženci raziskave so statistično značilno manj zadovoljni z življenjem kot najdejavnejši (vsaj 5-krat tedensko). Ob nadzoru preostalih dejavnikov spol in starost nimata značilnega vpliva na vrednotenje zadovoljstva z življenjem.

4 RAZPRAVA

Namen te raziskave je bil osvetliti učinke ŠD na duševno zdravje pri stratificiranem vzorcu odraslih Slovencev ter ugotoviti, ali športno dejavnejši ljudje doživljajo manj stresa in so bolj zadovoljni s svojim življenjem. Številne prej omenjene raziskave so že pokazale, da TD lahko dvigne kakovost življenja odraslih in da je redna športna vadba lahko učinkovita tehnika spoprijemanja s stresom, saj ima ugoden vpliv na izboljšane razpoloženja, dviguje samozavest ter ublaži psihološke in telesne stresne odzive. Hassmen idr. (1) so dokazali, da ukvarjanje s ŠD vsaj dvakrat tedensko pomembno znižuje stres in zvišuje zadovoljstvo z življenjem.

Rezultati naše raziskave kažejo, da se 67 % udeležencev s športom ukvarja od 1- do 4-krat tedensko, od tega jih je 45 % aktivnih od 3- do 4-krat tedensko. Redno aktivnih (merilo v naši raziskavi je bilo 5-krat tedensko in več) je 19 %, kar je več, kot kažejo podatki raziskave Special Eurobarometer (19) pred dvema letoma. Po podatkih zadnje študije o športnorekreativnih navadah Slovencev iz leta 2008 se s športno dejavnostjo ukvarja 63 % prebivalstva (44), v raziskavi »Z zdravjem povezan življenjski slog«, ki je bila na nacionalni ravni izvedena v letih 2004 in 2008 in je del projekta Evropskega urada Svetovne zdravstvene organizacije (CINDI Health Monitor Survey), je bilo športno dejavnih 77 % odraslih Slovencev (45). Ob upoštevanju priporočil TD oziroma ŠD za zdravje lahko sklenemo, da je večina udeležencev ustrezno pogosto športno dejavna. Rezultati naše raziskave torej kažejo na večji odstotek dejavnejšega prebivalstva kot v predhodnih raziskavah, kar je lahko tudi posledica večje ozaveščenosti o pomembnosti ukvarjanja s športom za zdravje in vedno boljše ponudbe športnih dejavnosti.

Ugotovili smo, da večina udeležencev raziskave znake stresa doživlja redko (manj kot enkrat tedensko) ali nikoli. Zaletel Kragelj, Pahor in Bilban (46), ki so prav tako raziskovali prisotnost stresa med odraslimi prebivalci Slovenije, so ugotovili, da se 99,4 % odraslih pogosto počuti napete, pod stresom ali velikim pritiskom, kar ne sovpada z našimi rezultati. Prav tako je po podatkih raziskave Special Eurobarometer (19) v Sloveniji le 4 % ljudi, pri katerih se znaki stresa nikoli niso pojavili, v našem primeru pa od 31 % do 84 % ljudi ni nikoli občutilo določenega znaka stresa. Raziskovalci menijo, da naj bi stresne situacije in napetosti začele naraščati po 25. letu in dosegle vrh med 35. in 45. letom starosti (22). To je lahko posledica številnih obremenitev v službi in širšem družbenem življenju, saj si večina ljudi v tem obdobju ustvarja kariero in prevzema številne odgovornosti. Čeprav v to starostno skupino spada tudi večina naših udeležencev raziskave, jih večina stresa ne občuti pogosto. Največkrat imajo sicer težave z občutenjem izčrpanosti, saj jih je 29 % vsaj enkrat tedensko izčrpanih, kar je lahko odziv na hiter tempo sodobnega načina življenja. Večje odstopanje naših rezultatov od omenjenih raziskav bi lahko imelo vzrok v vprašalniku, ki smo ga uporabili za ugotavljanje stresa. Mogoče določenih znakov stresa v našem vprašalniku nismo zajeli in s tem udeležencem omejili možnost odločitve za posamezen odgovor. Rezultati zgoraj omenjenih raziskav se namreč nanašajo na splošno vprašanje o tem, kako pogosto se ljudje spopadajo s stresom (in ne na posamične znake stresa), kar je lahko pripeljalo do ugotovitev o pogostejšem doživljanju stresa.

Ljudje, ki so redno telesno dejavni in vzdržujejo razmeroma visoko raven telesne pripravljenosti, so manj občutljivi na negativne posledice stresa (30, 38). Rezultati naše raziskave so pokazali, da je pri pogosteje športno dejavnih povprečni stres manjši, kar sovpada z ugotovitvami drugih raziskav (1, 3, 6, 30). Najnižji povprečen stres je bil ugotovljen pri športno najdejavnejših, kar smo tudi predpostavljali. Ob nadzoru starosti, spola in izobrazbe pa ne moremo trditi, da je ŠD pomemben dejavnik vpliva na doživljanje znakov stresa. Pokazalo se je le, da skupina od 1- do 2-krat tedensko dejavnih občuti manj stresa kot tisti, ki se s športom ukvarjajo skoraj vsak dan (5-krat tedensko in več). Moljord idr. (33) so prišli do podobnih ugotovitev, in sicer so imeli tisti, ki so bili dejavni vsaj dvakrat tedensko, statistično značilen nižji stres. Naših ugotovitev v tem segmentu (ob kontroli starosti, spola in izobrazbe) ne moremo podpreti z večino preostalih raziskav, čemur gre verjetno iskati vzrok v tem, da v nekaterih raziskavah ni bil upoštevan nadzor preostalih dejavnikov ter da so bili uporabljeni drugačni merski instrumenti za ugotavljanje doživljanje stresa. Naš vprašalnik je udeležencem ponujal le možnost izbora devetih znakov stresa, za katere seveda ni nujno, da so se pojavljali pri vseh udeležencih v primerjavi z npr. drugimi (30), pri katerih je bila za doživljanje stresa analizirana le ena postavka.

Nasprotno pa se je pokazalo, da stres ob nadzoru preostalih dejavnikov upada s starostjo in stopnjo izobrazbe ter da je odvisen od spola. Najpomembnejši

dejavnik, ki določa stopnjo stresa, je v našem primeru izobrazba. Najpogosteje se z znaki stresa spopadajo najmanj izobraženi. Rezultati namreč kažejo, da je vsaj končana strokovna srednja šola ustrezen pogoj za manj pogosto doživljanje stresa. Nekateri raziskovalci (47) so ugotovili, da imajo ljudje z višjo izobrazbo boljša delovna mesta, boljše plače in so bolj optimistično naravnani. Posledično bi se lahko manj pogosto spopadali z znaki stresa, ki so lahko vezani tudi na slab socialni status. Nižji stres pri starejših bi verjetno lahko razlagali z manj obveznostmi, ki jih imajo ti v primerjavi z mlajšimi. Nadalje ugotavljamo, da ženske intenzivneje doživljajo stresne situacije od moških, kar potrjujejo tudi številne druge raziskave (22, 23, 48). Vzrok za to so lahko družbena pričakovanja, ki ženskam narekujejo, da so odgovorne za druge in da zanje skrbijo ter imajo posledično večje pomanjkanje prostega časa od moških. Kronično pomanjkanje časa je prav tako lahko vir stresnih znakov.

Različni raziskovalci (27–29) so ugotovili, da so na splošno ljudje prej zadovoljni kot nezadovoljni s svojim življenjem, kar sovpada z rezultati naše raziskave, ki so pokazali, da smo odrasli Slovenci s svojim življenjem zadovoljni. Pokazala se je povezanost med stopnjo ŠD in zadovoljstvom z življenjem, in sicer so s svojim življenjem najbolj zadovoljni tisti, ki so najbolj športno dejavni, kar sovpada z našimi pričakovanji. Ugotovitev potrjujejo tudi izsledki raziskav, ki so jih opravili Thogersen-Ntoumani, Fox in Ntoumanis (37). Rezultati nakazujejo, da se je za višje vrednotenje zadovoljstva z življenjem treba vsaj enkrat tedensko ukvarjati s športom. Podobno so ugotovili tudi Moljord idr. (33), ker so bili srečnejši in zadovoljnejši v življenju tisti, ki so bili vsaj enkrat tedensko dejavni. V našem primeru je bila z življenjem najzadovoljnejša skupina, ki se je ukvarjala s športom vsaj 5-krat tedensko. Ugotovitev, da je telesna dejavnost povezana z večjim zadovoljstvom v življenju, sama po sebi seveda še ne potrjuje neposredne vzročne povezanosti. Vključevanje telesne dejavnosti v svoje življenjske navade in splošno pozitivno vrednotenje življenja pa nedvomno govorita o dejavnem odnosu do sebe in dogajanj, v katera se posameznik vključuje, ter o motiviranosti za to, da aktivno prispeva k izboljšanju svojega počutja.

Kot dejavnik, ki najbolj vpliva na zadovoljstvo z življenjem ob nadzoru preostalih dejavnikov, se je pokazala izobrazba. Najbolj nezadovoljni s svojim življenjem so tisti z najnižjo izobrazbo. Na podlagi rezultatov je mogoče sklepati, da že srednješolska izobrazba predstavlja ustrezno raven, ki omogoča ljudem višje subjektivno vrednotenje lastnega zadovoljstva z življenjem. Višja izobrazba v večini omogoča tudi višji družbeni status, boljšo službo in višji dohodek, s čimer je omogočena višja kakovost življenja (47). Ljudje z nižjo izobrazbo in posledično verjetno nižjim socialnim statusom se tudi manj ukvarjajo s športom, kar si je mogoče razlagati z manjšo športno ozaveščenostjo pa tudi s tem, da so določene športne dejavnosti povezane z večjimi gmotnimi stroški, ki si jih ne morejo privoščiti (49). Rezultati podpirajo splošno znano dejstvo, da izobrazba in z njo povezan dohodek v največji meri določata vsesplošno zadovoljstvo v življenju. Niti starost niti spol pa ob nadzoru preostalih dejavnikov ne določata različnega vrednotenja zadovoljstva z življenjem.

5 ZAKLJUČEK

Rezultati raziskave so pokazali, da dejavniki, ki smo jih vključili v splošne linearne modele (ŠD, starost, spol in izobrazba), vplivajo na pogostost doživljanja stresa in zadovoljstva z življenjem, vendar je njihov vpliv majhen. Najmočnejši dejavnik vpliva v obeh primerih predstavlja izobrazba, in sicer je pri bolj izobraženih stopnja stresa manjša, prav tako so zadovoljnejši s svojim življenjem. ŠD ob nadzoru preostalih dejavnikov značilno vpliva le na vrednotenje zadovoljstva z življenjem. Zadovoljnejši s svojim življenjem so tisti, ki so vsaj enkrat tedensko športno dejavni.

Raziskovalci menijo, da so za proučevanje povezav med TD in kazalniki zdravja potrebne številne študije na različnih vzorcih, ki omogočajo dobro ponovljivost. Ta raziskava je izvedena na velikem, naključnem in stratificiranem vzorcu odraslih Slovencev, kar ji daje ustrezno vrednost. Vsekakor pa je treba upoštevati določene omejitve. Raziskava temelji na subjektivnih podatkih o športni dejavnosti, stresu in o zadovoljstvu z življenjem. Zavedamo se, da je splošna težava anketnih vprašalnikov slabša veljavnost, vendar so v primerjavi z dragimi neposrednimi metodami dostopnejši in uporabnejši za raziskave na velikih vzorcih. Posebno za športno dejavnost bi bila objektivna merjenja v prihodnjih raziskavah priporočljiva. Prav tako bi bilo treba vključiti tudi informacije o trajanju, intenzivnosti in o vrsti športne dejavnosti. Treba je omeniti tudi to, da omenjena vprašalnika o stresu in zadovoljstvu z življenjem predstavljata vpogled le v en del duševnega zdravja. Ne nazadnje bi bilo priporočljivo izvesti longitudinalne študije, ki bi dale informacije o pozitivnih vplivih telesne oziroma športne dejavnosti na izbrane kazalnike zdravja v daljšem časovnem obdobju.

Za konec naj zapišemo, da je obravnavana tema aktualna, ker se zaradi vse resnejših težav, ki jih

povzročata hitri ritem in sedeči slog sodobnega življenja, ljudje vedno bolj zavedamo pomena zdravja in njegovega ohranjanja. Pomembno in potrebno je poznavanje povezav med telesno dejavnostjo in zdravstvenim stanjem, ker sta osebno zadovoljstvo in optimalno zdravje, ki ga s pomočjo redne in zadostne telesne dejavnosti ohranjamo in izboljšujemo, pogoja za kakovost življenja.

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POVEZANOST STATUSA TELESNE TEŽE IN GIBALNE UČINKOVITOSTI OTROK V SLOVENIJI

RELATIONS OF WEIGHT STATUS AND PHYSICAL FITNESS OF CHILDREN IN SLOVENIA

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Izvleček

Izhodišče: *Namen raziskave je bil ugotoviti, ali obstajajo razlike v gibalni učinkovitosti med otroki z normalno telesno težo, s prekomerno telesno težo in z debelostjo.*
Metode: *Raziskava je bila opravljena na vzorcu 572 otrok iz severovzhodne Slovenije (povprečna starost 7,3 leta, SO = 1,29). Na osnovi indeksa telesne mase (ITM) so bili otroci razdeljeni v skupine z normalno telesno težo, s prekomerno telesno težo in z debelostjo. Za ugotavljanje gibalne učinkovitosti je bilo uporabljenih šest testov različnih gibalnih sposobnosti (moč, vzdržljivost, hitrost, ravnotežje in koordinacija gibanja). Razlike v gibalni učinkovitosti med otroki z normalno telesno težo, s prekomerno telesno težo in z debelostjo so bile izračunane z analizo variance, statistično značilnost razlik pa smo ugotavljali na ravni tveganja p < 0,05 in so bile natančneje opredeljene s pomočjo preizkusa Scheffe post-hoc.*
Rezultati: *Rezultati kažejo, da ima primerno telesno težo 73,8 % otrok, prekomerno telesno težo 16,6 % otrok in debelost 9,6 % otrok. Med otroki z normalno telesno težo, s prekomerno telesno težo in z debelostjo obstajajo statistično značilne razlike (p < 0,05) v vseh obravnavanih gibalnih sposobnostih. Najbolj gibalno zmogljivi so otroci z normalno telesno težo, nekoliko nižja je gibalna učinkovitost otrok s prekomerno telesno težo, medtem ko je gibalna učinkovitost najnižja pri skupini otrok z debelostjo.*
Zaključek: *Rezultati dokazujejo, da obstaja tesna povezanost med gibalno učinkovitostjo in statusom telesne teže otrok.*

Ključne besede: predpubertetni otroci, gibalni razvoj, gibalne sposobnosti, gibalna dejavnost, gibalne kompetence, antropometrija

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Abstract

Aim: *The main aim of the research was to find out whether there are any differences in physical fitness between non-overweight, overweight and obese children.*
Methods: *Research has been carried out on 572 children from the north-eastern part of Slovenia (aged 7.3 years, SD=1.29). Children were classified as non-overweight,*
overweight and obese according to age and sex specific body mass index (BMI) cut off points. In order to assess physical fitness, six different tests that cover explosive power, balance, coordination, speed and endurance were used. ANOVA was used to assess the differences in physical fitness between non-overweight, overweight and obese groups. Statistical significance was set at an α level of 0.05.
Results: *Results show that 73.8% of children were in the non-overweight group, 16.6% in overweight group and 9.6% in obese group. Differences in all physical fitness tests between non-overweight, overweight and obese children are statistically significant (p<0.05). We have established that the non-overweight children achieved a higher level of physical fitness than overweight and obese children. In addition, overweight children achieved a higher level of physical fitness than obese children.*

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Conclusions: *This data suggests that the level of physical fitness and weight status are closely related.*

Key words: prepubertal children, motor development, physical fitness tests, physical activity, motor competence, anthropometry

1 UVOD

Debelost je ena najbolj razširjenih zdravstvenih težav, s katero se v zadnjem desetletju spopada razviti svet. Posebej skrb vzbujajoče je, da se v zadnjih letih še vedno povečuje delež otrok s prekomerno telesno težo in z debelostjo (1), kar predstavlja enega glavnih izzivov javnega zdravstva (2). Debelost v obdobju otroštva in adolescence ima kratkoročne in dolgoročne posledice. Kratkoročne posledice so večinoma telesne in psihosocialne narave; odražajo se v nižji kakovosti življenja, nižji telesni samopodobi, nižjem samospoštovanju, vedenjskih težavah in v socialni izolaciji (3–5). Dolgoročno pa je debelost v otroštvu povezana z večjo verjetnostjo, da bo človek debel, tudi ko odraste, ter seveda s tem povezanim večjim tveganjem za pojav bolezni srca in ožilja, sladkorne bolezni tipa 2, nekaterih oblik raka in z umrljivostjo (3, 6, 7).

Redna gibalna dejavnost v otroštvu predstavlja pomembno razvojno spodbudo, ki je koristna za krepitev in varovanje zdravja, ohranjanje primerne ravni telesne učinkovitosti in za višjo kakovost življenja, hkrati pa pripomore k oblikovanju takšnih navad in vedenjskih vzorcev, ki zagotavljajo vseživljenjsko gibalno dejavnost (3, 8). Številni raziskovalci ugotavljajo, da redna gibalna dejavnost sodi med najpomembnejša sredstva za preprečevanje debelosti, zmanjšanje količine podkožnega maščevja, spodbujanje razvoja mišic in skeleta ter za preprečevanje nastanka poškodb pri otrocih (9–11). Redna in raznovrstna gibalna dejavnost vpliva na razvoj in raven gibalnih sposobnosti v otroštvu in obdobju adolescence (12, 13). Seveda pa gibalna dejavnost pozitivno vpliva tudi na duševno zdravje otrok, ker preprečuje pojav depresije in anksioznosti ter zmanjša posledice stresa, hkrati pa dviguje samospoštovanje in oblikuje samopodobo (11, 14).

Gibalno učinkovitost opredeljujejo različne gibalne sposobnost, kot so: vzdržljivost, mišična moč, koordinacija, hitrost, ravnotežje, gibljivost, ki človeku zagotavljajo uspešno opravljanje vsakodnevnih dejavnosti brez večjega napora (15). Za otroke, mladostnike in odrasle ljudi je pomembno, da dosežejo in ohranjajo primerno raven gibalne učinkovitosti, saj lahko le tako uspešno opravljajo številne dejavnosti v šoli, službi ali v prostem času.

V nekaterih študijah ugotavljajo, da so otroci z debelostjo manj gibalno učinkoviti kot njihovi vrstniki s primerno telesno težo, predvsem v moči, vzdržljivosti in v hitrosti teka (16–20), zmogljivejši pa so v moči stiska roke (21). Do zelo podobnih spoznanj so prišli tudi Casajús in sod. (22), ki ob tem navajajo še, da med skupinami otrok glede na status telesne teže ni bilo razlik v tapingu z roko in predklonu sede. Očitno je, da otroci s prekomerno telesno težo in z debelostjo dosegajo nižjo raven gibalne učinkovitosti od primerno težkih vrstnikov predvsem v tistih gibalnih nalogah, pri katerih je treba premikati lastno telo v prostoru ali premagovati breme lastne telesne teže.

Številne raziskave kažejo, da so gibalne sposobnosti v veliki meri odvisne od tega, koliko je posameznik gibalno dejaven (19). Po drugi strani je redna gibalna dejavnost povezana s telesno težo, in sicer so otroci s primerno telesno težo večinoma bolj gibalno dejavni kot otroci s prekomerno telesno težo in z debelostjo (23). Priporočljivo je, da so otroci zmerno gibalno dejavni vsaj eno do dve uri dnevno (24).

V dozdajšnjih raziskavah so navadno poročali o povezavah statusa telesne teže z vzdržljivostjo, močjo in s hitrostjo (19, 21, 22), drugi vidiki gibalne učinkovitosti, predvsem koordinacija gibanja in ravnotežje, pa so bili deležni manjše pozornosti. Poleg tega v Sloveniji raziskave na tem področju še niso bile opravljene. Zato smo na vzorcu slovenskih otrok izvedli presečno pregledno raziskavo, katere glavni namen je bil ugotoviti, kako je gibalna učinkovitost, izražena v različnih gibalnih sposobnostih, povezana s statusom telesne teže otrok. Na osnovi nekaterih dozdajšnjih ugotovitev predpostavljamo, da so otroci s primerno telesno težo gibalno učinkovitejši v vseh obravnavanih sposobnostih od vrstnikov s prekomerno telesno težo in z debelostjo.

2 METODOLOGIJA

2.1 Vzorec merjencev

V vzorec je bilo zajetih 572 otrok (povprečna starost 7,3 leta, SO = 1,29) iz različnih osnovnih šol severovzhodne Slovenije, in sicer 301 deček in 271 deklic. Podatki so bili pridobljeni v okviru raziskave ciljnega raziskovalnega projekta Otrok med vplivi sodobnega življenjskega

sloga – gibalne sposobnosti, telesne značilnosti in zdravstveni status slovenskih otrok. Med meritvami so bili vsi otroci zdravi. Starši sodelujočih otrok so bili seznanjeni z namenom raziskave in s potekom meritev ter so predhodno podpisali soglasje o vključitvi njihovega otroka v raziskavo. Anonimnost otrok, ki so bili vključeni v raziskavo, je bila zagotovljena.

2.2 Vzorec spremenljivk

Merjenje gibalne učinkovitosti. Za ugotavljanje gibalne učinkovitosti je bilo uporabljenih šest testov gibalnih sposobnosti: tek na 300 metrov (vzdržljivost), skok v daljino z mesta (eksplozivna moč), flamingo (ravnotežje), plosk spredaj – zadaj (hitrost gibanja rok), hoja skozi obroče nazaj (koordinacija gibanja vsega telesa) in sestavljanje kock (vizualno-motorična koordinacija). Testna baterija je uporabljena v različnih slovenskih študijah in se je izkazala kot primerna za otroke (12).

Merjenje antropometričnih značilnosti. Antropometrične značilnosti otrok so bile izmerjene z uporabo standardiziranega antropometričnega instrumentarija. Stojna višina je bila izmerjena z uporabo Martinovega antropometra z natančnostjo 0,1 cm, pri čemer je bil merjenec bos, v stoji sonožno in glavo v položaju frankfurtske horizontalne ravnine. Telesna teža je bila izmerjena z umerjeno tehtnico Seca Beam Balance 710, z natančnostjo 0,1 kg, pri čemer so bili merjenci bosi, oblečeni v športno opremo. Na osnovi izvedenih meritev je bil izračunan indeks telesne mase (ITM = kg/m^2).

Merila za opredelitev prekomerne telesne teže in debelosti. Vsak otrok je bil na osnovi izračunanega indeksa telesne mase, upoštevaje spol in starost na pol leta natančno, razporejen v skupine z normalno telesno težo (NTT), s prekomerno telesno težo (PTT) in z debelostjo (D) po merilu, ki so ga predlagali Cole in sod. (25).

Potek meritev. Meritve so bile izvedene spomladi, vedno v dopoldanskem času, v posebej opremljenem prostoru. Tek na 300 metrov je bil izveden na prostem. Celotno testiranje je trajalo manj kot eno uro za posameznega merjenca. Meritve so izvajali posebej izurjeni merilci.

2.3 Metode obdelave podatkov

Statistična analiza. Podatki so bili obdelani s programom SPSS 18 za Windows. Izračunani so bili: aritmetične sredine (AS), standardni odkloni (SO) in enosmerna analiza variance (ANOVA), s katero smo ugotavljali statistično pomembnost razlik v gibalni učinkovitosti med otroki z NTT, s PTT in z D. Za natančnejšo opredelitev statistično značilnih razlik med skupinami smo uporabili preizkus Sheffe post-hoc. Statistično pomembnost razlik smo ugotavljali na ravni tveganja $p < 0,05$.

3 REZULTATI

V Tabeli 1 so prikazani osnovni statistični parametri antropometričnih značilnosti otrok z NTT, skupine s PTT in skupine D. 73,8 % (n = 422) otrok sodi v skupino z normalno telesno težo, 16,6 % (n = 95) otrok sodi v skupino s prekomerno telesno težo in 9,6 % (n = 55) jih sodi v skupino z debelostjo. Skupine otrok NTT, PTT in D se po starosti ne razlikujejo statistično značilno ($p > 0,05$), medtem ko se v telesni višini, telesni teži in v ITM razlikujejo statistično značilno ($p < 0,05$).

Tabela 1. *Antropometrične značilnosti (AS – aritmetična sredina, SO – standardni odklon), otrok z normalno telesno težo (NTT), s prekomerno telesno težo (PTT) in z debelostjo (D).*

Table 1. *Anthropometric characteristics (Mean, Standard Deviation -SD) of non-overweight (NOW), overweight (OW) and obese (O) children.*

Spremenljivke/Variables	NTT/ NOW (n = 422)	PTT/OW (n = 95)	D/O (n = 55)
	AS ± SO Mean ± SD	AS ± SO Mean ± SD	AS ± SO Mean ± SD
Starost	7,24± 1,29	7,56± 1,35	7,27± 1,162
Višina/Standing height (cm)	132,24 ± 8,56	136,78 ± 8,92	137,28 ± 7,68
Teža/Weight (kg)	27,68 ± 5,34	37,45 ± 7,26	45,64 ± 9,04
ITM/BMI (kg/m^2)	15,68 ± 1,56	19,80 ± 1,55	23,99± 2,68

V Tabeli 2 so prikazani osnovni statistični parametri testov gibalnih sposobnosti in statistična značilnost razlik med rezultati testov med skupinami NTT, PTT in D. Rezultati testa Hoja skozi obroče nazaj kažejo, da se skupine otrok NTT, PTT in D v koordinaciji celotnega telesa razlikujejo statistično značilno ($p < 0,05$). Pri tem testu so najuspešnejši otroci iz skupine NTT, nekoliko manj uspešni so otroci iz skupine PTT in najmanj otroci iz skupine D, pri čemer je treba omeniti, da nižje vrednosti pomenijo boljši dosežek. Analiza post-hoc je pokazala, da obstajajo statistično značilne razlike v koordinaciji celotnega telesa med skupinama NTT in D ($p = 0,000$) ter med skupinama PTT in D ($p = 0,000$), medtem ko se skupini NTT in PTT v koordinaciji celotnega telesa ne razlikujeta statistično značilno ($p = 0,138$). Rezultati testa Plosk spredaj – zadaj kažejo, da se skupine NTT, PTT in D v hitrosti preprostih gibov razlikujejo statistično značilno ($p < 0,05$); pri tem so otroci iz skupine NTT opravili največ ponovitev, nekoliko manj ponovitev je uspelo otrokom v skupini PTT in najmanj v skupini D. Zanimivo je, da analiza post-hoc ni razkrila statistično značilnih razlik v hitrosti preprostih gibov med posameznimi skupinami. Rezultati testa Sestavljanje kock kažejo, da se otroci iz skupin NTT, PTT in D v vizualno-motorični koordinaciji razlikujejo statistično značilno ($p < 0,05$). Najuspešnejši so otroci iz skupine PTT, nekoliko manj otroci iz skupine NTT, medtem ko so najmanj uspešni otroci iz skupine D, pri čemer nižji rezultat testa pomeni boljši dosežek. Vrednosti standardnih odklonov (SD) so pri vseh treh skupinah merjencev precej visoke, kar kaže na večjo razpršenost rezultatov. Test post-hoc je razkril, da obstajajo statistično značilne razlike v vizualno-motorični koordinaciji med skupinama NTT in D ($p = 0,009$) ter med skupinama PTT in D ($p = 0,030$), medtem ko se skupini NTT in PTT ne razlikujeta statistično značilno ($p = 0,997$).

Tabela 2. *Osnovni statistični pokazatelji testov gibalne učinkovitosti (AS – aritmetična sredina, SO – standardni odklon) in analiza variance glede na status telesne teže.*

Table 2. *Means, Standard Deviations (SD) of physical fitness tests, Results of One-way Analysis of variance (ANOVA) according to weight status.*

Testi gibalne učinkovitosti Physical fitness tests	NTT/ NOW (n = 422)	PTT/OW (n = 95)	D/O (n = 55)	ANOVA	
	AS ± SO Mean ± SD	AS ± SO Mean ± SD	AS ± SO Mean ± SD	F	p
Hoja skozi obroče nazaj (sek.) Backward Polygon (sec)	8,18 ± 2,81	8,85 ± 2,55	11,59 ± 4,41	32,574	0,000
Plosk spredaj-zadaj (št.pon.)/ Hand Clapping (attempts)	26,64 ± 5,14	25,46 ± 6,10	25,11 ± 5,45	3,372	0,035
Sestavljanje kock (sek)/ Cube Insertion (sec)	17,11 ± 10,32	16,99 ± 12,25	22,64 ± 23,78	4,887	0,008
Flamingo test (št. poskusov)/ Flamingo test (no. tries)	18,53 ± 7,74	20,96 ± 8,18	24,02 ± 7,48	14,138	0,000
Skok v daljino z mesta (cm)/ Standing Broad Jump (cm)	125,4 ± 22,79	120,98 ± 21,53	108,36 ± 20,84	14,682	0,000
Tek 300 metrov (sek)/ 300 meters Run (sec.)	84,38 ± 16,05	88,07 ± 18,29	100,58 ± 24,41	21,538	0,000

Rezultati testa Flamingo kažejo, da se skupine NTT, PTT in D v ravnotežju razlikujejo statistično značilno ($p < 0,05$). Najuspešnejši so otroci iz skupine NTT, nekoliko manj uspešni so otroci iz skupine PTT in najmanj otroci iz skupine D. Tudi pri tem testu pomeni nižji rezultat testa boljši dosežek. Analiza post-hoc je pokazala, da obstajajo statistično značilne razlike v ravnotežju med skupinama NTT in PTT ($p = 0,024$) ter med skupinama NTT in D ($p = 0,000$), medtem ko je razlika med skupinama PTT in D na meji statistične značilnosti ($p = 0,069$). Rezultati testa Skok v daljino z mesta kažejo, da se skupine NTT, PTT in D v eksplozivni moči nog razlikujejo statistično značilno ($p < 0,05$). Najdlje skočijo otroci iz skupine NTT, nekoliko manj otroci iz skupine PTT in najmanj otroci iz skupine D. Analiza post-hoc je pokazala, da obstajajo statistično značilne razlike v eksplozivni moči nog med skupinama NTT in D ($p = 0,000$) ter med skupinam PTT in D ($p = 0,004$),

medtem ko se skupini NTT in PTT v eksplozivni moči nog ne razlikujeta statistično značilno (p = 0,211). Rezultati testa Tek 300 metrov kažejo, da se skupine NTT, PTT in D v vzdržljivosti razlikujejo statistično značilno (p < 0,05). Najhitreje so to razdaljo pretekli otroci skupine NTT, nekoliko počasnejši so bili otroci skupine PTT in še nekoliko počasnejši so bili otroci skupine D. Analiza post-hoc je razkrila, da obstajajo statistično značilne razlike v vzdržljivosti med skupinama NTT in D (p = 0,000) ter med skupinama PTT in D (p = 0,000), medtem ko se skupini NTT in PTT v vzdržljivosti ne razlikujeta statistično značilno (p = 0,176).

4 RAZPRAVA

V raziskavi smo ugotavljali razlike v gibalni učinkovitosti med otroki z normalno telesno težo, s prekomerno telesno težo in z debelostjo. Rezultati so potrdili naše predpostavke, saj se je v vseh testih gibalnih sposobnosti pokazala pomembna razlika med skupinami otrok glede na status telesne teže. Najboljše rezultate so dosegli otroci z normalno telesno težo, sledijo otroci s prekomerno telesno težo, izrazito manj uspešni pa so bili otroci z debelostjo.

Dobljeni rezultati so skladni z nekaterimi dozdajšnjimi raziskavami (21, 22), predvsem v tistem delu, ki govori o razlikah v testnih nalogah za merjenje moči, vzdržljivosti in hitrosti gibanja, torej testih, pri katerih je treba premikati telo v prostoru oziroma premagovati lastno telesno težo. Pri omenjenih sposobnostih so odločilnega pomena energijski procesi, ki zagotavljajo energijo za izvajanje posameznih gibalnih nalog (31). Pomembno razliko med obravnavanimi skupinami otrok smo dobili tudi v testih hitrosti gibanja rok in ravnotežja, kar se ujema z raziskavo Karppanen in sod. (19). Poleg tega naši rezultati kažejo pomembne razlike tudi v testih koordinacije gibanja, kar pa v drugih raziskavah ne navajajo. Predvidevamo, da je to lahko posledica dejstva, da so otroci z debelostjo na splošno manj gibalno dejavni (23), zato si pridobijo manj raznolikih gibalnih izkušenj, hkrati pa se jim koordinacijske gibalne sposobnosti ne razvijejo do ravni kot gibalno aktivnejšim vrstnikom. V določeni meri o podobnih ugotovitvah poročajo (26), in sicer da imajo otroci s prevladujočim sedentarnim načinom življenja manj razvito koordinacijo gibanja od gibalno dejavnejših vrstnikov.

Podrobnejša analiza dobljenih rezultatov je pokazala, da v gibalni učinkovitosti v primerjavi z drugima dvema skupinama statistično pomembno odstopajo predvsem otroci z debelostjo. Nasprotno pa med otroki s primerno in prekomerno telesno težo ni statistično pomembnih razlik, razen v ravnotežju. V tem pogledu pa se naša dognanja nekoliko razlikujejo od nekaterih drugih, ki ugotavljajo, da je veliko večja verjetnost, da je raven gibalnih sposobnosti otrok s prekomerno telesno težo na nižji ravni kot raven gibalnih sposobnosti otok z normalno telesno težo (27). Pri tem velja opozoriti, da v raziskavah opredeljujejo status telesne teže na osnovi različnih meril, kar nedvomno vpliva na primerljivost dobljenih rezultatov.

5 ZAKLJUČEK

Najbolj skrb vzbujajoče spoznanje naše raziskave je dejstvo, da so vse gibalne sposobnosti najmanj razvite pri otrocih z debelostjo. Vzroke za slabšo gibalno učinkovitost je mogoče iskati v dejstvu, da za te otroke premagovanje lastne telesne teže predstavlja večje breme kot za primerno težke vrstnike. Po drugi strani pa rezultati podpirajo domnevo, da je nizka gibalna učinkovitost eden izmed vzrokov za pojav debelosti (19, 28), kar posledično pomeni, da imajo otroci z debelostjo manj gibalnih izkušenj, zato so manj uspešni in se posledično manj vključujejo v gibalne dejavnosti. Največji izziv pri raziskovanju odnosov med gibalno dejavnostjo, gibalno učinkovitostjo in debelostjo je prav gotovo opredelitev vzročnosti povezav med temi segmenti (29). Dejstvo pa je, da pogosta in primerno intenzivna gibalna dejavnost omogoča doseganje in ohranjanje primerne ravni gibalne učinkovitosti ter v veliki meri tudi preprečuje nastanek debelosti (30). Slovenske smernice za telesno udejstvovanje (32) priporočajo od 40 do 60 minut trajajočo aerobno vadbo od 3- do 4-krat tedensko pri 85–90 % največje frekvence srca, visoko intenzivno intervalno anaerobno vadbo, pri čemer intenzivnost ne sme biti višja od 90 % največje frekvence srca. Vadbo za moč naj bi izvajali od 2- do 3-krat tedensko, v 2–3 serijah z 8–15 ponovitvami pri obremenitvi 60–85 % 1 RM, medtem ko bi naj vadba za izboljšanje gibljivosti zajemala statične raztezne vaje (32). Gibalna dejavnost skladno z omenjenimi smernicami bi vsekakor v veliki meri pripomogla k izboljšanju gibalne učinkovitosti otrok ter posledično k znižanju prekomerne telesne teže in debelosti.

V prihodnje bi bilo raziskovanje na tem področju smiselno razširiti tudi na proučevanje povezav statusa telesne teže in gibalne učinkovitosti mladostnikov, odraslih in starostnikov. Prav tako bi bilo smiselno podrobneje proučiti vrsto, pogostost in intenzivnost gibalne dejavnosti otrok in mladostnikov iz posameznih skupin glede na telesno težo. Zelo pomembno je, da otrokom s prekomerno težo in debelostjo že v

predšolskem in zgodnjem šolskem obdobju zagotovimo možnosti vključevanja v kakovostno izvedene šolske in zunajšolske gibalne dejavnosti, ki so prilagojene njihovim sposobnostim, saj so izjemnega pomena za otrokovo zdravje ter skladen telesni in psihični razvoj. Hkrati pa bi bilo smiselno proučiti, kako različni intervencijski programi vplivajo na uravnavanje telesne teže od otroštva do pozne starosti.

Zahvala

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COMPARISON OF METHODS FOR DETECTION OF FOUR COMMON NOSOCOMIAL PATHOGENS ON HOSPITAL TEXTILES

PRIMERJAVA METOD ZA DETEKCIJO ŠTIRIH POGOSTIH POVZROČITELJEV BOLNIŠNIČNIH OKUŽB NA BOLNIŠNIČNIH TEKSTILIJAH

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Abstract

Introduction: *Although the most common vehicle for transmission of health-care acquired infections is the person-to-person transmission route, the role of environment should not be ignored and hospital linen may contribute to the spreading of nosocomial infections. The contact plate method and swabbing are common methods for sampling microorganisms on textiles; however, results are available after two days as they are based on incubation followed by phenotype identification. An important alternative is using quick wash-off methods followed by PCR detection, which shortens the identification process from two days to a few hours.*

Methods: *The following test microorganisms at different concentrations were inoculated onto textile swatches and dried overnight: Staphylococcus aureus, Klebsiella pneumoniae, Pseudomonas aeruginosa and Clostridium difficile. RODAC plate sampling as well as a non-destructive wash-off method for capturing microorganisms from the textiles using a Morapex device were used. The elution suspension from the Morapex device was used for two methods. In the first method, classical incubation on selective media followed by phenotypic identification was used and in the second method DNA was extracted from the elution suspension followed by amplification and agarose gel electrophoresis to visualize amplified products.*

Conclusions: *All chosen bacteria were found using all methods. However, the most sensitive proved to be detection using PCR amplification as we detected the sample with initial concentration of 102 cfu/mL inoculated onto the textile surface before drying. The final detectable recovered bacterial concentration on textiles was up to 10 cfu/mL.*

Key words: health care associated infections, hospital textiles, *Staphylococcus aureus, Klebsiella pneumoniae, Pseudomonas aeruginosa, Clostridium difficile,* Morapex

Izvirni znanstveni članek
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Izvleček

Izhodišča: *Čeprav so bolniki ali osebje najpogostejši vir bolnišnično pridobljenih okužb, ne smemo zanemariti vloge okolja, med katere sodijo bolnišnične tekstilije, ki lahko prispevajo k širitvi bolnišničnih okužb. Najpogostejši metodi vzorčenja mikroorganizmov na tekstilijah sta vzorčenje s kontaktnimi ploščami in z brisi, vendar so izsledki na voljo čez dva dni, ker so osnovani na fenotipski identifikaciji po inkubaciji vzorca na gojiščih. Pomembna alternativa so metode eluiranja, ki jim sledi detekcija s PCR-metodo, kar skrajša proces identifikacije z dveh dni na nekaj ur.*

Metode: *Na tekstilne vzorce smo pri različnih koncentracijah nanesli naslednje izbrane mikroorganizme – Staphylococcus aureus, Klebsiella pneumoniae, Pseudomonas aeruginosa in Clostridium difficile – in jih sušili čez noč. Iz tekstilnih vzorcev smo nato zajeli mikroorganizme z vzorčenjem sploščicami RODAC kakor tudi z nedestruktivno metodo eluiranja z aparatom Morapex. Eluirano suspenzijo iz aparata Morapex smo nadalje uporabili za dve metodi. Pri prvi metodi smo eluat inkubirali na selektivna gojišča, čemur je sledila fenotipska identifikacija, pri drugi metodi pa smo iz eluata ekstrahirali DNK in ga pomnožili ter nato s pomnoženimi produkti izvedli agarozno gelsko elektroforezo.*

Zaključki: *Vse mikroorganizme smo zaznali z vsemi metodami, vendar je bila najobčutljivejša metoda pomnoževanje*

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DNK s PCR-metodo, saj smo po inkubaciji zaznali tudi vzorec z začetno koncentracijo 102 cfu/mL bakterijske suspenzije, inokulirane na tekstilno površino pred sušenjem. Končna koncentracija bakterijske suspenzije, ki smo jo zaznali na tekstilnem vzorcu, je bila do 10 cfu/mL.

Ključne besede: bolnišnično pridobljene okužbe, *Staphylococcus aureus, Klebsiella pneumoniae, Pseudomonas aeruginosa, Clostridium difficile*, Morapex

1 INTRODUCTION

In 1920, Charles Winslow defined Public health as the science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of society, public and private organizations, communities and individuals (1) and the basic concept of this definition still stands today. Thus, one of the areas of public health includes preventing diseases transmitted from inanimate surfaces. Such surfaces, which are common in hospital areas, are: metal, glass, plastic, ceramics and textiles.

It has been determined in published literature (2, 3) that the main sources of nosocomial or health-care associated infections are the individual patient, medical equipment or devices, the hospital environment, healthcare personnel, contaminated drugs, contaminated food and contaminated patient care equipment. Although the person-to-person transmission route is the most common, the role of the environment should not be ignored and hospital linen may contribute to the spread of nosocomial infections (4, 5).

Microorganisms are able to survive on environmental surfaces for periods up to several weeks (6), providing a significant biotransfer / crosscontamination / cross-infection potential (7) that should not be overlooked. One of the possible sources of nosocomial pathogens can be inappropriately disinfected textiles (8). Published research shows that hospital textiles have been the possible source for infections of patients or hospital workers (9) with *Staphylococcus aureus* (10), methicilin resistant *Staphylococcus aureus* (MRSA) (11), *Streptococcus pyogenes* (12), vancomycin resistant enterococci (13), *Bacillus cereus* (14), *Salmonella* Typhimurium(15), *Salmonellahadar* (16), antibiotic resistant coliform bacteria (17), hepatitis A virus (18), *Trichophyton interdigitale* (19), *Sarcoptes scabiei* (20), *Microsporum canis* (21) and others. Research has also shown the survival of various microorganisms on textiles after laundering in hospital laundries where the following microorganisms have been detected: aerobic bacteria, total coliforms, *Enterococcus faecium*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Clostridium difficile* spores (22-30).

It is therefore obvious that hospital textiles need to be 'hygienically clean', that is free of pathogenic microorganisms in concentrations sufficient to cause human illness (31). The concentrations or the infectious dose for pathogen bacteria can be from 1 to 100 cells, where the immune status of the individual plays an important role (32), therefore the low detection limit of bacteria is very important.

Until now, the most commons methods used for sampling hospital textiles were: RODAC surface sampling, swabbing and destructive elution method (33). There is a published research (33) that includes a novel non-destructive method for implementing the elution method using aMorapex device. However, all these methods are based on classical incubation methods followed by phenotypic detection of microorganisms, which can take between 2 to 4 days to be completed. A faster and more reliable possibility is to use polymerase chain reaction (PCR) detection of microorganisms (from eluted samples used by the Morapex device). In our study, we compared this method with classical RODAC surface sampling and elution method with the Morapex device followed by cultivation on differential media. We used these three methods for detecting artificially inoculated textiles with various concentrations of potentially pathogenic bacteria: *S. aureus*, *K. pneumoniae*, *P. aeruginosa* and. *C. difficile*.

2 METHODS

2.1 Textile swatches

100% cotton tabby weave textile (thread spacing warp/weft 27 threads/cm; weight 190 g/m^2) cut into square swatches (7x7cm) was used. The swatches were sterilized in an autoclave at 121°C for 15 min and then dried in an oven at 100°C for 2 hours. The swatches were transferred with sterile forceps to labelled petri dishes. Work was conducted in a laminar flow cabinet.

2.2 Microorganisms

48 hour cultures of *S. aureus*, *K. pneumoniae and P. aeruginosa* grown in nutrient broth were used. Before each experiment, viable counts of the cultures were

made to enable the calculation of the number of cells inoculated onto the surfaces. Serial tenfold dilutions and viable plate counting using the appropriate selective mediums noted below for each microorganism were used. All work was carried out in a laminar flow cabinet. For *C. difficile* spore preparation, a five day old culture grown in anaerobic conditions on a blood agar plate was swabbed and resuspended in 1 mL sterile distilled water. This suspension was washed three times with fresh sterile water. The spore suspension was stored at 4°C until use in experiments.

2.3 Selective medium

Selective agars were used as a medium for incubating the microorganisms after retrieving from swatches. For *S. aureus*, the Baird-Parker agar base (Sigma-Aldrich), with added egg-yolk tellurite emulsion (Fluka) (incubation 48 hours at 37°C), was used. For *K. pneumonia*, the HiCrome Klebsiella Selective Agar base (Fluka) (incubation 48 hours at 37°C) was used. Cetrimide agar base (Sigma-Aldrich) with added glycerol (Sigma) (incubation 48 hours at 37°C) was used for the detection of *P. aeruginosa*. Clostridium Difficile Agar Base (Fluka) with added Clostridium difficile Supplement (Fluka) (incubation under anaerobic conditions for 72 hours at 37°C) was used to determine the presence of *C. difficile* spores that were on the textile swatches after overnight drying.

2.4 Application of microorganisms on textile swatches

On each swatch, 2 mL of a prepared suspension of microorganisms was applied. All work was conducted in a biosafety cabinet. Petri dishes with inoculated swatches were left in the laminar flow cabinet for 24 hours to allow the applied suspension to dry. The method has been described previously (8).

2.5 RODAC plate method

The RODAC plates were prepared with selective mediums for each of the chosen bacteria. The RODAC plate was pressed onto the inoculated swatch and held for 3 s, followed by closing and placing into the incubator. After incubation, the colonies were counted and the cfu was calculated.

2.6 Non-destructive elution method using the Morapex device

The swatch was placed between two plates of the Morapex device (33). 20 mL of test liquid (0.9% NaCl +0.2% Tween 80) was pressed through the textile swatch in three cycles of 10 s. The extract was collected in a tube and serial tenfold dilutions were prepared followed by viable plate counting using differential media for each microorganism. After incubation, colonies were counted and the cfu (colony forming units) was calculated.

2.7 DNA detection

DNA extraction: Bacterial genomic DNA was extracted from the suspension of bacteria retrieved from swatches with the elution method using the Morapex device. PrepMan Ultra Sample Preparation Reagent (Applied Biosystems) was used in accordance with the manufacturer's instructions. Extracted DNA was stored at -20^{0}C prior to PCR amplification. A negative control of DNA extraction was also conducted for each experiment. Bacterial genomic DNA extracted from an overnight culture in liquid broth was used as a positive control.

Selection of primers: The target genes for the four chosen bacteria are shown in Table1. The following oligonucleotide primer pairs were used: egcAU (34) for *S. aureus;* ITS(35) for *K. pneumoniae*, *gyrB* (36) for *P. aeruginosa* and CD (37) for *C. difficile*.

DNA amplification: PCR was performed using HotStarTaq DNA polymerase (Qiagen) following the manufacturers' instructions where 9 µL of reaction mix was added to 1 µL of extracted DNA. The reaction mix was separately prepared for each chosen bacteria and consisted of 1 µL 10x PCR buffer with 15 mM $MgCl_2$ (Qiagen), 0.2 mM of each dNTP (Sigma-Aldrich), 0.5 µM of each oligonucleotide primer (Omega) and 2.5 units of HotStarTag polymerase per reaction.

Sensoquest S labcycler was used under the following amplification conditions: initial denaturation at 95°C for 15 min, followed by: 35 cycles for *S. aureus* (denaturation at 94°C for 45 s; annealing at 56°C for 45 s and extension at 72°c for 90 s); 40 cycles for *P. aeruginosa* (denaturation at 94°C for 1 min; annealing at 55°C for 1 min and extension at 72°C for 1 min); 40 cycles for *K. pneumoniae* (denaturation at 94°C for 1 min; annealing at 56°C for 1 min and extension at 72°C for 1 min); and 30 cycles for *C. difficile* (denaturation at 94°C for 45 s; annealing at 52°C for 1 min and extension at 72°C for 80 s). All PCR reactions were concluded with final extension for 10 min at 72°C. Each PCR reaction included positive controls directly from nutrient broths and negative controls containing sterile water.

Detection of PCR amplicons: Agarose gel electrophoresis was performed to visualize amplified products with 1.2 % agarose gel (Sigma) in 0.5 TBE buffer (89 mM Tris base (Sigma), 89 mM Boric acid (Sigma-Aldrich) and 2 mM EDTA (Sigma-Aldrich) stained with SYBR Green I nucleic acid gel stain

(Sigma-Aldrich) with a 100 bp ladder (Promega). Gels were visualized under UV illuminator Transiluminator Super-Bright (VilberLourmat) at 312 nm using a gel images system Doc Print VX2 (VilberLourmat) to confirm the presence of the amplified DNA. Images processed by the Photo-Capt software.

Table 1. *Primers used for PCR amplification.*
Tabela 1. *Začetni oligonukleotidi za pomnoževanje DNK z metodo PCR.*

Target bacteria / tarčna bakterija	Primer/začetni oligonukleotid	Primer 5'-------3'	Product size / velikost baznega produkta (bp)
S. aureus	egcAU (34)	f (5'- CTTCATATGTGTTAAGTCTTGCAGCTT-3')	82
		r (5'-TTCACTCGCTTTATTCAATTGTTCTG-3')	
K. pneumoniae	ITS (35)	f (5'-ATT TGA AGA GGT TGC AAA CGA T-3')	130
		r (5'-TTC ACT CTG AAG TTT TCT TGT GTT C-3')	
P. aeruginosa	*gyrB* (36)	f (5'-CCT GAC CAT CCG TCG CCA CAA C-3')	222
		r (5'-CGC AGC AGG ATG CCG ACG CC-3')	
C. difficile	CD (37)	f (5'-TTG AGC GAT TTA CTT CGG TAA AGA-3')	157
		r (5'- CCA TCC TGT ACT GGC TCA CCT-3')	

3 RESULTS

3.1 Detection of *S. aureus* on textile swatches after 24 hour drying

Figure 1 shows that the detection of *S. aureus* inoculated onto textile swatches at eight different concentrations levels (A to H) in descending order from 10^{10} cfu/mL to 10^{2} cfu/mL yielded positive results after overnight drying for samples A to F (RODAC sampling method with incubation on selective agars); A to H (Morapex sampling method with incubation on selective agars); andA to I (Morapex sampling method with PCR).

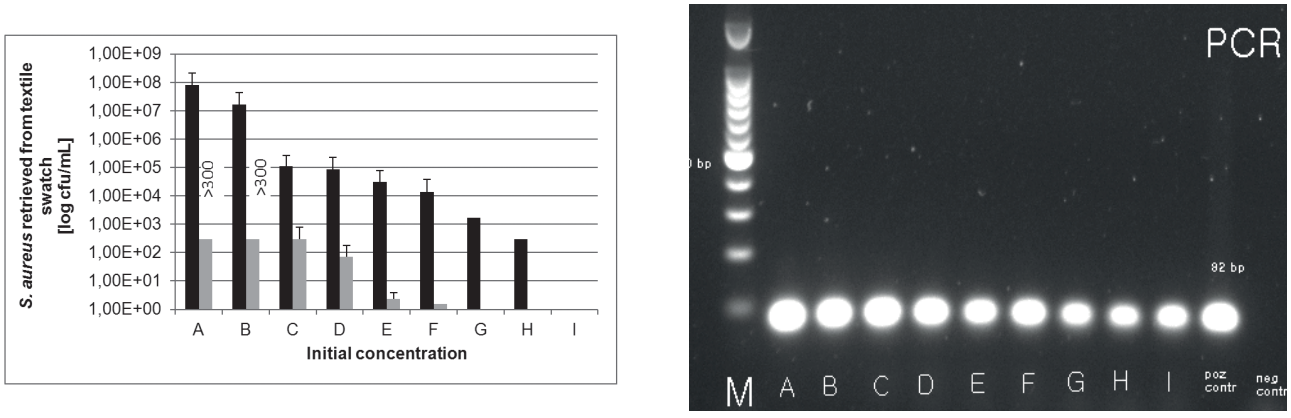
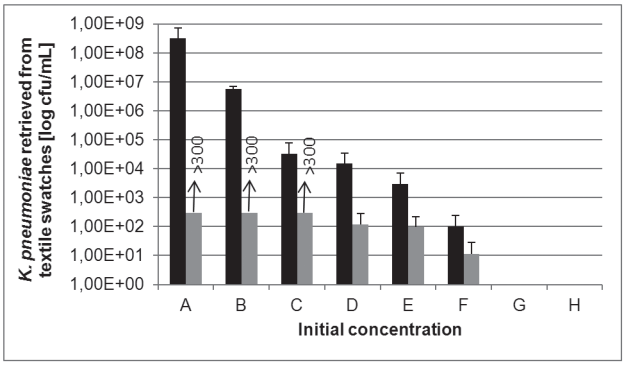


Figure 1. *Detection of different concentrations of S. aureus on textile swatches after 24 hour drying with three methods: RODAC with incubation (grey columns) and parallel Morapex with incubation (black columns) on upper figure and Morapex with PCR on lower figure.*
Slika 1. *Detekcija različnih koncentracij S. aureus na tekstilnih krpicah po 24 urnem sušenju s tremi metodami: RODAC s kultivacijo (sivi stoplci), vzporedno Morapex s kultivacijo (črni stoplci) na zgornji sliki in Morapex s PCR na spodnji sliki.*

Initial bacterial concentration before overnight drying /začetna koncentracija suspenzije bakterij pred sušenjem: A (2.13 x 10^{10} cfu/mL); B (1.64 x 10^{9} cfu/mL); C (1.77 x 10^{8} cfu/mL); D (5.20 x 10^{6} cfu/mL); E (7.73 x 10^{5} cfu/mL); F (1.33 x 10^{5} cfu/mL); G (8.60 x 10^{4} cfu/mL); H (1.05 x 10^{3} cfu/mL); I (2.0 x 10^{2} cfu/mL); M: (size marker / masni označevalec); positive control/pozitivna kontrola. 82 bp.

3.2 Detection of *K. pneumoniae* on textile swatches after 24 hour drying

Figure 2 shows that the detection of *K. pneumoniae*i noculated onto textile swatches at eight different concentrations levels (A to H) in descending order from 10^{10} cfu/mL to 10^{2} cfu/mL yielded positive results after overnight drying for samples A to F (RODAC sampling method with incubation on selective agars and Morapex sampling method with incubation on selective agars) andA to G (Morapex sampling method with PCR).



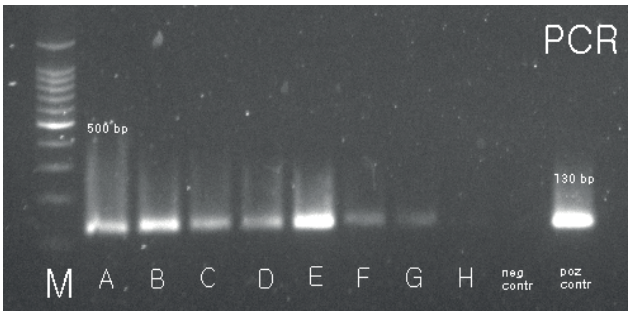


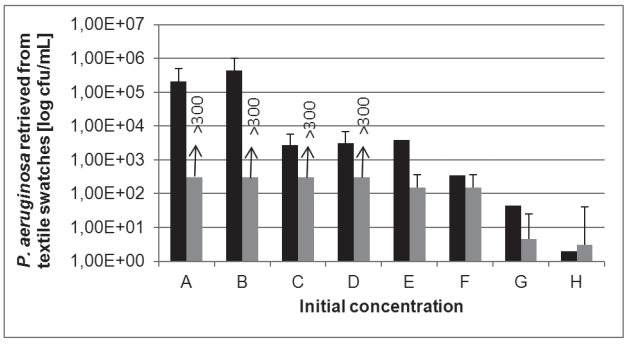
Figure 2. *Detection of different concentrations of K. pneumoniae on textile swatches after 24 hour drying with three methods: RODAC with incubation (grey columns) and parallel Morapex with incubation (black columns) on upper figure and Morapex with PCR on lower figure.*

Slika 2. *Detekcija različnih koncentracij K. pneumoniae na tekstilnih krpicah po 24 urnem sušenju s tremi metodami: RODAC s kultivacijo (sivi stoplci), vzporedno Morapex s kultivacijo (črni stoplci) na zgornji sliki in Morapex s PCR na spodnji sliki.*

Initial bacterial concentration before overnight drying / začetna koncentracija suspenzije bakterij pred sušenjem: A (2.58×10^{10} cfu/mL); B (1.04×10^{9} cfu/mL); C (2.90×10^{7} cfu/mL); D (1.30×10^{6} cfu/mL); E (4.00×10^{5} cfu/mL); F (4.05×10^{4} cfu/mL); G ($9{,}88 \times 10^{3}$ cfu/mL); H (2.00×10^{2} cfu/mL); M: (size marker / masni označevalec); positive control/pozitivna kontrola: 130 bp.

3.3 Detection of *P. aeruginosa* on textile swatches after 24 hour drying

Figure 3 shows that the detection of *P. aeruginosa* inoculated onto textile swatches at eight different concentrations levels (A to H) in descending order from 10^{10} cfu/mL to 10^{5} cfu/mL yielded positive results after overnight drying for samples A to H for all three methods.



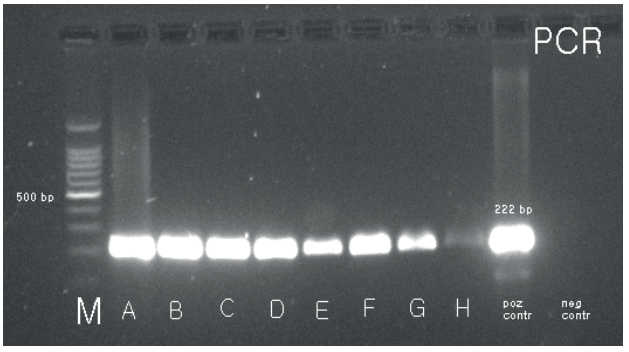


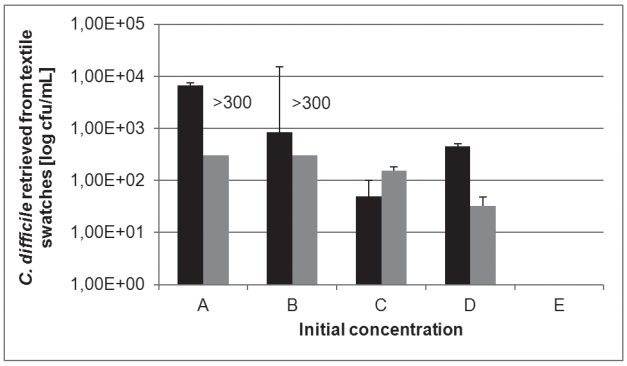
Figure 3. *Detection of different concentrations of P. aeruginosa on textile swatches after 24 hour drying with three methods: RODAC with incubation (grey columns) and parallel Morapex with incubation (black columns) on upper figure and Morapex with PCR on lower figure.*

Slika 3. *Detekcija različnih koncentracij P. aeruginosa na tekstilnih krpicah po 24 urnem sušenju s tremi metodami: RODAC s kultivacijo (sivi stoplci), vzporedno Morapex s kultivacijo (črni stoplci) na zgornji sliki in Morapex s PCR na spodnji sliki.*

Initial bacterial concentration before overnight drying / začetna koncentracija suspenzije bakterij pred sušenjem: A (4.35 x 10^{10} cfu/mL); B (1.06 x 10^{9} cfu/mL); C (1.51 x 10^{8} cfu/mL); D (4.55 x 10^{7} cfu/mL); E (3.50 x 10^{7} cfu/mL); F (1.28 x 10^{6} cfu/mL); G (2.25 x 10^{5} cfu/mL); H (1.92 x 10^{4} cfu/mL); M: (size marker / masni označevalec); positive control/pozitivna kontrola: 222 bp.

3.4 Detection of *C. difficile* on textile swatches after 24 hour drying

The detection of *C. difficile* spores inoculated onto textile swatches noted in figure 4 shows that at five different concentrations levels (A to E) in descending order from 10^{8} cfu/mL to 10^{3} cfu/mL positive results after overnight drying were noted for samples A to D (RODAC sampling method with incubation on selective agars and Morapex sampling method with incubation on selective agars) andA to E (Morapex sampling method with PCR).



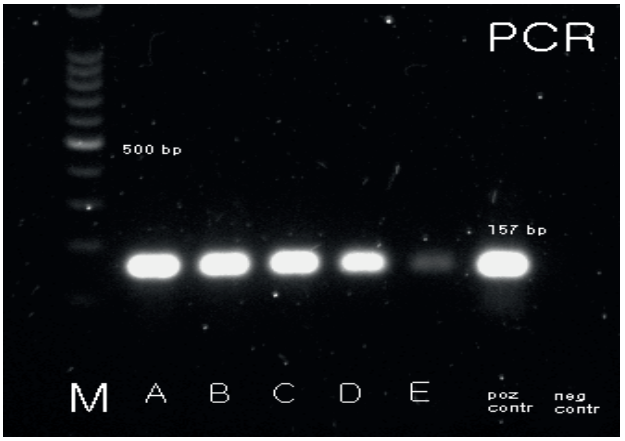


Figure 4. *Detection of different concentrations of C. difficile on textile swatches after 24 hour drying with three methods: RODAC with incubation (grey columns) and parallel Morapex with incubation (black columns) on upper figure and Morapex with PCR on lower figure.*

Slika 4. *Detekcija različnih koncentracij C. difficile na tekstilnih vzorcih po 24 urnem sušenju s tremi metodami: RODAC s kultivacijo (sivi stoplci), vzporedno Morapex s kultivacijo (črni stoplci) na zgornji sliki in Morapex s PCR na spodnji sliki.*

Initial sporal concentration before overnight drying / začetna koncentracija suspenzije bakterijskih spor pred sušenjem: A (2.29 x 10^{8} cfu/mL); B (2.23 x 10^{6} cfu/mL); C (1.57 x 10^{6} cfu/mL); D (1.16 x 10^{4} cfu/mL); E (3.80 x 10^{3} cfu/mL); M: (size marker / masni označevalec); positive control/pozitivna kontrola: 157 bp.

4 DISCUSSION

Quick detection of microorganisms on textiles is important especially in hospital and other healthcare settings where many different kinds of textiles are used such as: bed sheets, blankets, towels, patient apparel, uniforms, gowns, drapes for surgical procedures (38). Contaminated textiles often contain high numbers of microorganisms from body substances, including blood, skin, stool, urine, vomitus and other body tissues and fluids. Although contaminated textiles in healthcare facilities can be a source of substantial numbers of pathogenic microorganisms, reports of healthcare associated diseases linked to contaminated textiles are few; therefore, the overall risk of disease transmission is very low. However, experience encourages infection control teams to take hospital textiles as a possible vehicle for transmission of infection very seriously in outbreaks that seem to have no obvious cause (39). Classical methods for the detection of microorganisms on textiles are RODAC sampling, swabbing or destructive elution methods (33) based on capturing microorganisms followed by incubation on nutrient or selective media to enable phenotypic determination of colony forming units of present microorganisms. In this research (33), it was found that wash-out or elution methods are much more efficient in detecting microorganisms on textiles than surface sampling such as RODAC sampling or swabbing, as these methods do not capture microorganisms that have penetrated into the three dimensional structure of textiles, which can cause false negative results. It takes at least 2 days to achieve results for these methods and in the case of infections in hospital settings, this time is much too long. PCR detection on the other hand yields results in less than four hours, thus being a much more efficient alternative.

In our research, we compared the detection limit of chosen microorganisms (*S. aureus, K. pneumoniae, P. aeruginosa* and *C. difficile*) using three methods: RODAC sampling, elution method using the Morapex device followed by classical incubation on selective agars or by PCR detection. The Morapex device proved to be efficient for eluting microorganisms from textiles (33) without destroying the fabric and is therefore an efficient method for determining the hygiene of laundered hospital textiles. The basic principle is that the textile material is placed between two metal plates; the test liquid is pressed through the material and then collected in a tube. This test liquid was then used for two completely different methods. The first consisted of classical detection consisting of serial tenfold dilutions following the plating on selective medium and incubation, and the second method consisted of DNA extraction followed by PCR amplification and agarose gel electrophoresis. The first method yielded results in two days and the second within four hours, thus significantly shortening detection time. In all our experiments, the PCR method also proved to be the most sensitive method as detection of PCR fragments were positive at the lowest concentrations, while the results for the elution method followed by classical incubation and surface sampling with RODAC plates yielded detectable results at the second or third lowest concentrations, with RODAC plating being the least reliable method. The drying process lowered the concentration of all microorganisms by2 to 4 log steps. The lowest detection limits of our experiments with PCR method were reached at the initial bacterial concentration before overnight drying between 100 and 1000 cfu/mL. After overnight drying, this concentration was at least one log step lower, so the lowest possible concentration of detection with PCR methods was between 10 and 100 cfu/mL for all chosen bacteria. This coincides with results from a similar research (40) where the detection limit for different strains of *Salmonella* species was between 2 and 10^3 cfu/mL depending on the primer pairs used. Our results also prove that appropriate primer pairs for all four microorganisms were chosen. Another important observation is that no inhibition occurred during PCR amplification of high concentrated samples as has occurred in other research (41).

Smith and co-authors (42) found that *P. aeruginosa* and *S.aureus* inoculated and then dried on a woven cotton fibre surface and a blood protein coagulum surface can survive over six months at room temperature. Although the viability was consistently higher on dried blood surfaces, the viability was next highest on cotton strings. For both of these environments, staphylococci appeared to lose viability between three and six months, while *P. aeruginosa* survived longer. The authors importantly conclude that such extended survival on blood and fibre surfaces, as observed in part, explains the difficulty in controlling colonization of patients and spread of these nosocomial pathogens. This conclusion can also be hypothesized for most pathogenic microorganisms. In our research, we found that *P. aeruginosa* was detectable with all three methods at the lowest initial bacterial concentration (10^4 cfu/mL), thus confirming survival on inanimate surfaces. *S. aureus* was also detected at the lowest initial bacterial concentration before overnight drying in sample I (10^2 cfu/mL) with the PCR method. Classical elution with incubation on

selective agar yielded a positive result for sample H, and RODAC plating proved least reliable as the lowest positive result was found in sample F.

Klebsiella spp. are coliform bacteria ubiquitous in nature and natural habitants of environmental waters; they can also survive laundering as well as on inanimate surfaces such as hospital textiles (43-45). In our research, we found that an inoculation of 1000 cfu/mL (sample G) before overnight drying yielded positive results for PCR, while the classical elution method followed by incubation on selective medium yielded positive results after drying of 100 cfu/mL for sample F (initial bacterial concentration 10^4 cfu/mL).

It has been reported that *C. difficile* [46] spores can survive temperatures and chemical treatment of typical hospital laundering cycles and that cross-contamination of *C. difficile* spores can occur on bed linen during a wash cycle. Therefore, the persistent nature of this organism must be considered by infection control personnel when implementing programs for laundering soiled and contaminated hospital linen (47). In our research, PCR yielded the lowest detectable survival of *C. difficile* spores on textiles after overnight drying in sample E with the lowest inoculated concentration before drying of (10^3 cfu/mL). Elution followed by incubation as well as RODAC plating yielded positive results (<50 cfu/mL) for sample (D) with initial concentration before drying of 10^4 cfu/mL.

5 CONCLUSION

The most common microorganisms found on health-care associated textiles are Gram negative bacteria, coagulase negative staphylococci, *Bacillus* sp. and typical skin flora (48).In the study by Catano et al. (49), it was found that a large proportion of textiles in hospital settings (white coats, curtains and ties) as well as computer keyboards and cell phones were contaminated with bacterial pathogens that may act as reservoirs for bacterial pathogens that may be associated with healthcare-associated infections. They concluded that further research is needed to evaluate strategies to minimize the risk of patient-to-patient transmission of pathogens from other contaminated items. One of these strategies is to perform regular sanitary controls of all inanimate surfaces as well as implementing quick methods for the determination of cleanliness and hygiene. Elution of microorganisms using the Morapex device followed by PCR detection on the other hand yield results in less than four hours, thus being a much more efficient alternative than classical incubation followed by phenotypic identification and an important method for the quick detection of microorganisms on textiles and enabling a direction of support in evaluating the cause of hospital acquired infections due tomicroorganisms on inanimate surfaces. However, a limitation of this method is that classical molecular methods are unable to discriminate between live and dead microorganisms, therefore special variants of real-time PCR reaction could be used such as ethidium bromide monoazide (EMA) PCR (50) or propidium monoazide (PMA) PCR (51) that distinguish viable from non-viable cells.

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THE ROLE OF SPORTS CLUBS IN SPORTS ACTIVITY OF STUDENTS

VLOGA ŠPORTNIH KLUBOV PRI ŠPORTNI AKTIVNOSTI ŠTUDENTOV

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Abstract

Objective: *Exercise is a recognised means for improving quality of life. In general, students perform less sports activity than previous generations. In contrast, however, children's participation in competitive sports has increased. The present study therefore aimed to assess how many students participate in sports clubs, how active in sports student (non)members are, and what actual effect sports clubs have on enabling sufficient sports activity.*
Methods: *Students (N=213) in the first year of university studies (19-20 years) were recruited for a study approved by the Slovenian Ethics Committee. They answered a questionnaire on their sports club membership and on their sports activity during organised sports training and/or in their free time. Results were statistically analysed and compared to our previous results obtained from primary and secondary school children (1).*
Results: *Only 16% of students participate in sports clubs, which is less ($p<0.001$) than in primary and secondary school children. The average (SD) sports activity of student sports-club members is 11.7 (6.8) h/week, with students non-members being significantly ($p<0.001$) less active with 4.6 (3.0) h/week. Participation in sports clubs is lower ($p<0.001$) in female (15%) than in male (21%) students, which is similar to children.*
Conclusions: *The results of the study demonstrate that sports clubs in Slovenia are important for promoting sufficient sports activity. Namely, most of the student members participate in sports activity more than the recommended 1 h/day and are more than two times more active than their peers. Females, however, participate less often in sports clubs, which calls for further attention.*

Key words: active lifestyle, students, sports activity, sports clubs, weekly activity

Izvirni znanstveni članek
UDK 614:796-057.875

Izvleček

Uvod: *Športna vadba je danes priznano sredstvo za izboljšanje kakovosti življenja. V splošnem velja, da so študentje manj športno aktivni kot prejšnje generacije. V nasprotju s tem pa se mlajši mladostniki pogosteje vključujejo v tekmovalni šport. Cilj te raziskave je bil zato oceniti, koliko študentov je vključenih v športne klube, kako športno dejavni so študentje ne(člani) in kakšen dejanski učinek imajo športni klubi pri doseganju zadostne športne aktivnosti.*
Metode: *V raziskavo, ki jo je odobrila Komisija Republike Slovenije za medicinsko etiko, so bili vključeni študentje (N=213) prvega letnika univerzitetnih študijev (19–20 let). Izpolnili so vprašalnik o svojem članstvu v športnih klubih ter o svoji športni aktivnosti med organiziranimi športnimi treningi in/ali v svojem prostem času. Rezultate smo statistično analizirali in jih primerjali z rezultati predhodne raziskave, izvedene med osnovnošolci in srednješolci (1).*
Rezultati: *Le 16% študentov je bilo včlanjenih v športne klube, kar je manj ($p<0,001$) kot med osnovnošolci in srednješolci. Povprečna (SD) športna aktivnost študentov članov športnih klubov je bila 11,7 (6,8) h/teden; študentje nečlani so bili s 4,6 (3,0) h/teden značilno ($p<0,001$) manj aktivni. Študentke (15%) so v športne klube vključene redkeje ($p<0,001$) kot študenti (21%), kar je podobno kot pri mlajših mladostnikih.*
Zaključki: *Rezultati raziskave kažejo, da so športni klubi v Sloveniji pomembni pri spodbujanju zadostne športne aktivnosti, saj je večina študentov članov športno aktivna več kot priporočeno 1 h/dan in je tako več kot dvakrat*

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aktivnejša od vrstnikov nečlanov. Dekleta so v nasprotju s fanti v športne klube včlanjena redkeje, kar si zasluži nadaljnjo analitično obravnavo.

Ključne besede: aktiven življenjski slog, športni klubi, študentje, tedenska aktivnost, športna aktivnost

1 INTRODUCTION

Although the capability of prolonged exertion and physical expertise are less important for human survival nowadays than in earlier human populations (2), regular sports activity is a recognised mean for improving quality of life in the contemporary world (2, 3). Regular sports activity has on several occasions been proven beneficial for positive physical and psychological development in children and adults (4-6).

Both, in children and adults, regular sports activity influences their health in a positive manner, as it lowers the level of cardiovascular risks (7). Also, just as a sedentary way of life causes children and adolescents to become overweight and obese (4), regular sports activity helps in successful management of optimal body mass. Sports activity undoubtedly also effects physical development, because active children demonstrate better motor control than their peers (7, 8) as well as better motor skill competence (9). Last, but not least, it seems that sports activity of children increases the probability of active lifestyle in adulthood (7, 10, 11).

It has been demonstrated that apart from the stated positive physiological effects of active lifestyle in childhood and adolescence, regular organised sports activity of children improves their motor, mental and emotional development. For both genders, but for girls in particular, the amount of time spent in organised sports activity correlates closely with their movement skills (12). In addition, organised sports activity involves socialisation of children with their peers, which enables them to learn sports as well as social skills that they can use in their everyday life (7, 13). Regular sports activity has also been demonstrated to positively influence academic outcomes, such as grades (14), test scores and school engagement, to result in higher self-esteem and to reduce depression (4). Better motor coordination has also been positively associated with intelligence in adolescents (15). Lastly, through organised sports activities, which are defined by rules and norms, children can also control aggression (4).

Taking into account all the recognised benefits of sports activity, the U.S. Centres for Disease Control and Prevention recommend that children should be involved in at least 60 minutes of sports activity of moderate intensity most days of the week, preferably daily (16, 17). It is therefore alarming that according to the existing reports, only one third of all young people in Europe and North America are involved in 60 minutes or more of such activity at least five times per week (16). In comparison to younger children, the population of students deals with further obstacles associated with sports activity. Diverse course schedules, higher requirements for learning, and often a significant amount of time spent for traveling from home to the place of study are only a few of the reasons for the lack of time devoted to sports activity in students. Due to regular systematic monitoring of sports activity levels in primary and secondary school children (18, 19), reliable data exist on this issue for Slovenia. In contrast, studies only rarely focus on the student population, with a few of them demonstrating that although student interests have shifted from team to individual sports over the last decades (20), students still perceive sports activity as a positive value (21), which is evident from a rather high percentage of students who perform non-organised sports, thus sports activities in their free time (22), and would at the same time require some adaptation of the existing sports programs to suit them better (23, 24).

If we widen the perspective and take into account not only the student population but also the situation with sports activities in young Slovenian people in general, the following conclusions can be made. Sports education has a long and rather successful tradition in Slovenia, nevertheless some of the new reports suggest that the situation with sports activities in children is fast approaching that of the western world. Namely, as demonstrated by the Slovenian HBSC study performed in 2006 (25), which is recognised as nationally representative within Europe, the number of teenagers in Slovenia who are active in sports for at least one hour daily at least five times per week has decreased by more than 7% in males and almost 3% in females from 2002 (N=3956) to 2006 (N=5130), thus in four years only. Similarly, a recent analysis of trends in sports activity of 11 to 15 year old children in the period of 2002 to 2010 demonstrated that although bidirectional variations between particular years can be detected, on the whole the percentage of children who fulfil the current recommendations for sports activity decreased significantly within the stated period (19). In addition to these observations, our previous work that was performed on 818 primary and secondary school children from the Northern Primorska region (including

the area from towns of Vipava to Bovec) demonstrated that although sports activity levels are decreasing in general, children in Slovenia often participate in sports clubs and, furthermore, that participation in competitive sports seems to have increased (1).

It is worthwhile noting that the organisation of voluntary sports activities in Slovenia is similar to that in Scandinavian countries (7, 26); apart from the extra-curricular school programs, organised sports activities for children are usually being organised by sports clubs, which in Slovenia are members of national sports associations. This is in contrast with the situation in the United States, where the majority of voluntary sports activities are organised by schools and universities. Although the existing organisation of voluntary sports activities in Slovenia has now been functioning for several decades, it has, however, not yet been evaluated, what are the direct effects of sports club inclusion on weekly sports activity levels in students.

The aim of the present study was therefore to assess how many students take part in organised sports activities of sports clubs, how active sports student members or non-members of sports clubs are, and what is the amount of weekly sports activity in student members and non-members. We also aimed to compare the results obtained in students with our previous results obtained in children and adolescents (1) to assess differences between generations.

2 MATERIALS AND METHODS

The study protocol was approved by the National Ethics Committee of the Republic of Slovenia on 19. 3. 2011 (No.: 60/02/11) and the study was performed in Slovenia.

We observed a sample of 20-year old students enrolled in the first year of the Biotechnical Faculty and the Faculty of Education in 2010 and 2011. The students were provided with an anonymous questionnaire, and they could decide voluntarily whether they would participate in the study or not.

The questionnaire included questions about the age and gender of subjects, recent sports club membership, the amount of sports activity in their free time or during organised sports training, and the age of their first enrolment in a sports club.

The completed questionnaires were first digitalised and then analysed. We then compared the obtained information with our previous results on sports activity in younger children, specifically to data from 12 year old children enrolled in the seventh year of primary school and to those from 17 year old adolescents in the third year of secondary school (1). We also calculated the age of first inclusion into a sports-club for different age groups. As the present study was performed three and a half years after our study of primary and secondary school children (1), 17 year old adolescents and 20 year old students were actually born in the same year; therefore, data from these two subject groups were finally joined to calculate the age of first inclusion into a sports-club and were compared to children born 5 years later.

The statistical analysis was performed by a Chi-square test for the nonparametric data (gender, membership) and by a one-way-ANOVA for parametric data (age, weekly sports activity). All parametric results are presented as averages (SD).

3 RESULTS

The results were obtained from 213 students (age: 20 (0.8) years); 169 female and 44 male students participated. Students who participated in organised sports activities of at least one sports club at the time they answered the questionnaire were marked as “Members”. In contrast, students who did not participate in organised sports activities of any sports club at the time of answering were marked as “Non-members”. Students who were members of sports clubs in the past but were no longer engaged in a sports club at the time of answering were counted as “Non-members”.

From 213 students who participated in the study, 16% of subjects (N=35) were members of sports clubs at the time of answering. When we compare this result to results obtained in younger children (1), a large difference in sports-club inclusion can be seen between the age groups and a clear reduction in sports club participation becomes obvious with age. Namely, 42% of children in primary school and 27% of adolescents in secondary school were members of sports clubs (1). The difference in sports club participation between all three age groups is highly significant ($p<0.001$) and is presented in Figure 1.

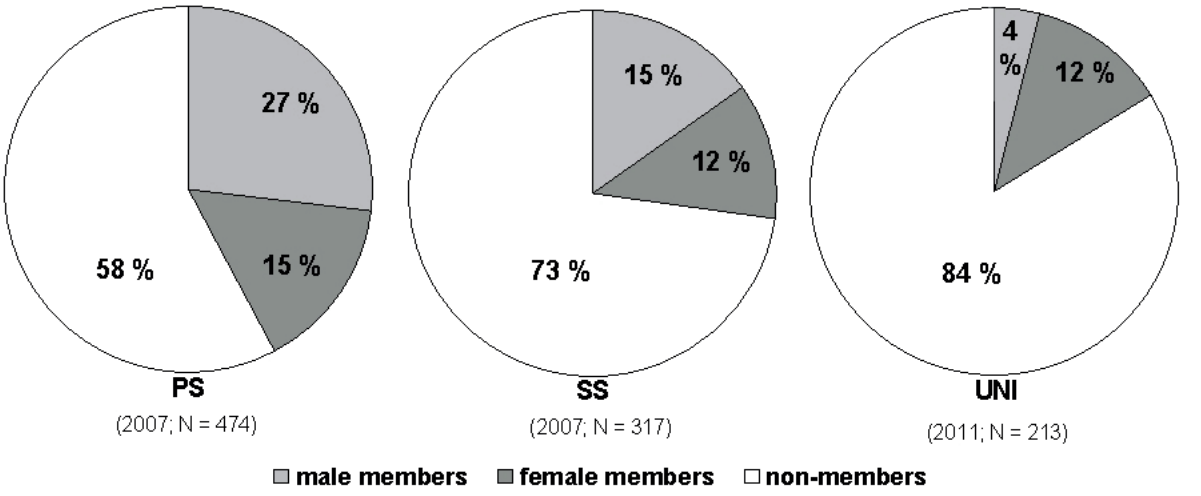

Figure 1. *Participation in sports clubs according to age group and gender. Compared to children, significantly (p<0.001) less students participate in sports clubs. Data for students from the present study, data for primary and secondary school children from (1), year of research study and subject number are presented for each category. PS – primary school children, SS – secondary school children, UNI – university students.*

Slika 1. *Članstvo v športnih klubih glede na starostno skupino in spol. V primerjavi z mlajšimi mladostniki so študenti značilno (p<0,001) redkeje člani športnih klubov. Podatki za študente so iz pričujoče študije, podatki za osnovno in srednjo šolo iz (1), za vsako kategorijo sta predstavljena leto raziskave in število preiskovancev. PS – osnovnošolci, SS – srednješolci, UNI – univerzitetni študenti.*

In addition, the results demonstrate that female students participate less often in sports clubs than male students (p<0.001). Namely, 21% of the male students were included in sports clubs at the time of answering, but only 15% of female students. When we compare these results with younger children, a similar pattern of enrolment can be observed between the genders irrespective of age. Namely, both in primary and secondary school, more males (54% and 38%, respectively) than females (30% and 20%, respectively) participate in sports clubs (1), which is in turn all higher than within students. The differences between and within all three age groups are highly significant (p<0.001).

The amount of weekly sports activity (in hours per week) was calculated for student members and non-members of sports clubs; the results are presented in Table 1. When the groups were compared, sports activity in their free time was used for student non-members, and cumulative sports activity including sports activity in their free time and during organised sports training was used for student members. The results suggest that student non-members performed significantly less (p<0.0001) sports activity than student members. This was also true for primary and secondary school children, where average sports activity of non-members was again significantly lower (p<0.001) than that of members (1). Rather surprisingly, however, student non-members performed more sports activity per week than non-members in primary and secondary school (Table 1).

Furthermore, significant differences were observed in the year of first enrolment of older and younger children. Namely, children born in 1990 first joined sports clubs at the age of 10.1 (3.4) years. Compared to the five year younger children born in 1995, this was both effectively and statistically (p<0.01) later, as the younger group first joined sports clubs already at the age of 8.4 (1.9) years. Thus, in five years only, the age of first enrolment into a sports club decreased by more than 1.7 years (Figure 2).

Table 1. *The amount of weekly sports activity (in hours per week; average (SD)) of student non-members and members of sports clubs (data from the present study), and for primary- and secondary school children (data from (1)); year of research study is also presented for each category.*
Tabela 1. *Količina tedenske športne aktivnosti (v urah na teden; povprečje (SD)) študentov nečlanov in članov športnih klubov (podatki iz pričujoče raziskave) in mlajših mladostnikov iz osnovne in srednje šole (podatki iz (1)); za večjo preglednost je za vsako kategorijo predstavljeno tudi leto raziskave.*

	Age (years)	Non-members of sports clubs (h/week)	Members of sports clubs (h/week)	Significance (non-members vs. members)
Students (2011)	**20 (0.8)**	**4.6 (3.0)**	**11.7 (6.8)**	**p<0.0001**
Secondary school children (2007)	17 (0.6)	2.9 (2.9)	10.6 (4.6)	p<0.001
Primary school children (2007)	12 (0.4)	3.9 (4.1)	8.9 (5.2)	p<0.001

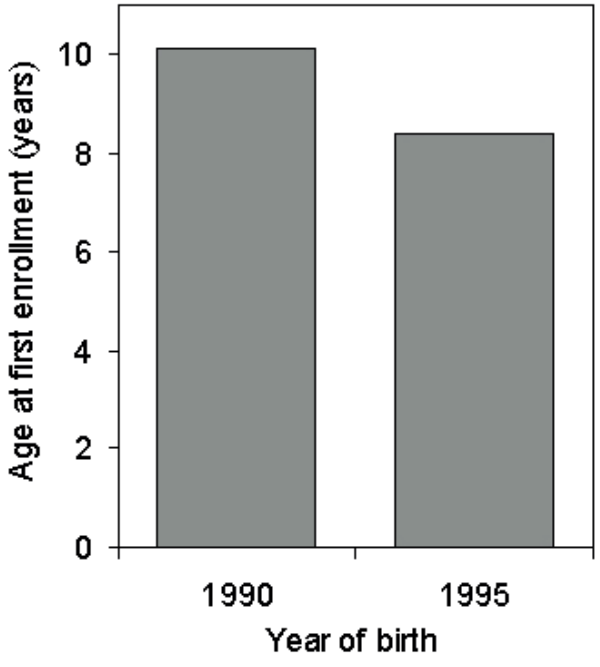

Figure 2. *The age of children at their first enrolment into a sports club according to their year of birth. Data combined from the present study and from (1).*
Slika 2. *Starost mladostnikov ob njihovi prvi včlanitvi v športni klub glede na njihovo leto rojstva. Podatki so kombinirani iz pričujoče študije in iz (1).*

4 DISCUSSION

The present study demonstrated that on average student members of sports clubs are almost two and a half times more active in sports per week than their peers. This difference is similar to that previously reported by other studies (1) in primary school children, namely, of the difference in average weekly sports activity of 12 year old members and nonmembers of sports clubs. The observed difference is somewhat smaller than the difference in weekly sports activity observed between 17 year old children members and non-members, where members were reported to be three and a half times more active than their non-member peers (1).

The combination of the results of the present study and previous results obtained in children and adolescents (1) demonstrates that the majority of sports club members, regardless of age, are active in sports at least one hour per day, which is in line with the existing recommendations (16, 17). In contrast, students and children who are non-members of sports clubs on average fail to fulfil this criterion. This conclusion is valid even considering the fact that the study on children and adolescents (1) was performed in the region of Northern Primorska, which is often believed to be above the Slovenian average for sports activity in children. The present study therefore demonstrates that similar to younger children (1), sports clubs in Slovenia are

important promoters of regular sports activity also in students.

One could speculate on whether sports club members are more active than their peers because they are members of a sport club, or whether they are members of a sports club because they are more active; an almost similar level of free time activity of both members and non-members suggests that the former is indeed true. In addition to the Slovenian HBSC studies performed on a nationally representative sample of 11 to 15 year old children in 2002 and 2010 (6, 27), which demonstrated that younger children more often fulfil the existing weekly criteria for sports activity than older children, our study further extended these results to the student population. Namely, the present study confirmed that the proportion of young individuals that are active in sports significantly decreases with age, as fewer students are included in sports clubs than children in primary and secondary school. This may be a result of the more sedentary lifestyle of students and less free time during university studies than in childhood. It may also be that students participate more often in other types of extracurricular activities that are, for example, more closely associated with their future profession. Furthermore, economic status may also reduce the participation of students in sports clubs. Namely, although studies report that children from families with low income benefit more from extracurricular participation than their peers (4), and although enrolment in sports clubs is usually free of charge as the majority of sports clubs in Slovenia perform their activities on a voluntary basis, organised sports activities outside sports clubs require the payment of monthly fees. Furthermore, higher living costs associated with university studies may reduce the capability of students to purchase specific sports equipment, as compared to children.

The results of the present study also demonstrated that it is worth paying attention to the gender structure of sports club members. Namely, regardless of age, females participated significantly less often in sports clubs than males. This result is in accordance with several cross-national studies within the WHO HBSC scheme (31-33), which detected this issue on different occasions. According to the existing reports (26), females seem to prefer other extracurricular activities more than sports, for example music or language learning. When it comes to sports activities, however, it has also been reported that females prefer to engage in non-competitive sports (26). In contrast to males, who usually report participation in more vigorous exercise activities, both outside of school and during school sports education, as well as higher participation in sports teams, females usually report participation in activity-related lessons and classes (28, 29). Furthermore, in contrast to males, who engage in sport either for social reasons, because they have fun or because they like competition, females seem to place more focus on the shape of their body and self-image (30).

It may therefore be speculated that the existing sports clubs programs are exceedingly competitively oriented and do not provide sufficient learning motivation, which in turn decreases the inclusion of females. It has to be noted that the existing organised sports activities for children were developed in the past by, and consequently for, males (26). This may well be the reason why sports activities remain rather male-dominated, which makes them less attractive for females (26). In order to stimulate the inclusion of young females into sports clubs, it is therefore proposed that sports clubs could and should improve their programs by offering less competitive sports activities for children, which would target and thus more successfully attract females in the juvenile population.

At this point, it seems reasonable to stress that the Biotechnical Faculty and the Faculty of Education, from which the students of the present study were recruited, usually enrol larger numbers of females than males. This resulted in a better representation of females than males in the student sample of the present study. It is thus recommended that future studies are extended to faculties that predominantly enrol males in their study programs in order to improve the representativity of the conclusions for the male student population. In addition, students who participated in the present study came from all over Slovenia and thus had different sports backgrounds. This enabled us to embrace a significant heterogeneity of the student population. Nevertheless, using the same approach as presented above, thus recruiting also students from faculties that enrol predominantly male students to future studies would enable depicting student heterogeneity even further.

In addition, although this was not the aim of the present study and therefore the corresponding data were not collected, other studies (34) have demonstrated that factors such as time of the year may affect the amount of sports activities in children. Namely, children seem to participate more often, both in organised and non-organised sports activities, during spring and summer months, and less often in autumn and winter (34). Thus, apart from gender, other factors including multicomponent combinations, such as school-based interventions and family involvement (35), also need to be considered when planning and developing optimal sports activities for children.

Last, but not least, the age at first enrolment into sports clubs of students was significantly higher than that of younger children. As the number of sports club members was similar in the compared age groups, one can reasonably expect that any selection bias that might have affected this conclusion was avoided. It thus seems that sports clubs aim to attract younger and younger children, likely to improve their selection possibilities, which goes well in line with the competitively oriented programs. This can be, however, rather unfavourable for both the sports development of children, as it can increase the injury rate (36), and for psychological development, because of stimulated rivalry and requirement for victory at a very young age. Furthermore, participation in highly competitive extracurricular activities has already been shown to increase anxiety and stress levels (4).

5 CONCLUSION

The present study demonstrated that the role of sports clubs in promoting sports activity in students is undoubtedly beneficial. At the same time, however, other important issues have been emphasised, namely low percentage of student members of sports clubs, lower inclusion of females, and earlier first enrolment into sports clubs in younger generations.

As the results of the present study demonstrated that the average levels of weekly sports activity are low at university, specifically for sports club non-members, strategies and programs for increasing sports activity at university should be aimed to attract more students. Furthermore, a lower enrolment of females into sports clubs as compared to males suggests that strategies and programs for increasing sports activity among students should be gender specific. It is recommended that participation in sports clubs can be made more attractive for females in particular by planning and emphasising sports activity as healthful and enjoyable social gatherings and not as a competitive, athletic, performance-related program.

Lastly, it is suggested that students should be attracted to multiple activities, which will decrease effectiveness in each particular sports discipline but will also ensure a harmonising development and whole body agility (4). Such a change of programs, however, would also require an alternative scheme of sports clubs funding, as sports clubs are most often funded according to the sponsorship schemes, but the latter are directly related to competitive results of sports club members.

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Conflicts of interest

None declared.

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SELF-ASSESSMENT QUESTIONNAIRE FOR FAMILY DOCTORS' ASSESSMENT OF QUALITY IMPROVEMENT COMPETENCIES: A CROSS-CULTURAL ADAPTATION IN SLOVENIA

VPRAŠALNIK ZA SAMOOCENO KOMPETENC ZDRAVNIKA DRUŽINSKE MEDICINE NA PODROČJU IZBOLJŠEVANJA KAKOVOSTI: MEDKULTURNA PRILAGODITEV V SLOVENIJI

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Original scientific article
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Abstract

Aim: *To perform a cross-cultural adaptation of the Quality Improvement Competency Self Assessment (QICS) questionnaire for family physicians into the Slovenian language and to validate it in a representative sample of Slovenian FPs.*

Methods: *This cross-sectional observational postal survey was conducted in a random sample of 398 Slovenian FPs. We used the QICS questionnaire that was developed on the basis of the new Quality Improvement Competency Framework for family medicine. The QICS questionnaire consists of 37 items included in six domains. The questions can be answered on a five-point Likert scale. The validity of the translation was provided by the backward translation from Slovenian to the English language and by the reference group consisting of experienced FPs in the consensus process. The reliability of the questionnaire was assessed by Cronbach's alpha coefficient and Spearman rho to determine the test-retest reliability (the questionnaire was sent to the physicians in the sample twice in a period of two weeks).*

Results: *The final sample consisted of 100 (25.1%) family physicians, out of which 71 (71.0%) were women. Mean age of the sample was 43.3 ± 9.6 years. Mean score of the QICS questionnaire was 127.0 ± 30.1 points (first round) and 127.8 ± 30.6 points (second round). Cronbach's alpha scores were 0.984 (first round) and 0.988 (second round). Spearman's rho for the summary score of the whole scale was 0.829 with $p < 0.001$.*

Conclusion: *The Slovenian version of the QICS questionnaire proved to be a valid and reliable tool for self-assessment of quality improvement competencies by FPs in terms of continuous professional development.*

Key words: clinical competence, family medicine, self-assessment, quality improvement

Izvirni znanstveni članek
UDK 614.2(497.4)

Izvleček

Namen: *Izvesti medkulturno prilagoditev vprašalnika o samoocenjevanju kompetenc zdravnika družinske medicina na področju izboljševanju kakovosti (vprašalnik QICS) in ga validirati na reprezentativnem vzorcu slovenskih zdravnikov družinske medicine.*

Metode: *Ta presečna opazovalna raziskava je bila izvedena v naključnem vzorcu 398 slovenskih zdravnikov družinske medicine. Uporabili smo vprašalnik QICS, ki je bil razvit na podlagi novega teoretičnega okvira izboljševanja kakovosti v družinski medicini. Vprašalnik QICS je sestavljen iz 37 vprašanj, vključenih v šest področij. Na vprašanja je mogoče odgovoriti po petstopenjski Likertovi lestvici. Veljavnost prevoda je bila zagotovljena z dvosmernim prevodom in s pomočjo referenčne skupine, ki so jo sestavljali izkušeni zdravniki družinske medicine. Zanesljivost vprašalnika smo ocenjevali s pomočjo koeficienta Cronbach alfa in koeficienta Spearman rho za ugotavljanje časovne stabilnosti (vprašalnik je bil poslan zdravnikom v vzorcu dvakrat v razmiku dveh tednov).*

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Rezultati: *Končni vzorec je bil sestavljen iz 100 (25,1 %) zdravnikov družinske medicine, od katerih je bilo 71 (71,0 %) žensk. Povprečna starost vzorca je bila 43,3 ± 9,6 leta. Povprečno število točk na vprašalniku QICS je bilo 127,0 ± 30,1 (prvo pošiljanje) in 127,8 ± 30,6 (drugo pošiljanje). Cronbach alfa je bil 0,984 (prvo pošiljanje) in 0,988 (drugo pošiljanje). Spearman rho je bil 0,829 s p < 0,001.*

Zaključki: *Slovenska različica vprašalnika QICS je zanesljivo in veljavno orodje za samooceno kompetenc zdravnikov družinske medicine na področju izboljševanja kakovosti v sklopu stalnega podiplomskega izobraževanja oz. stalnega strokovnega dograjevanja.*

Ključne besede: klinične kompetence, družinska medicina, samoocenjevanje, izboljševanje kakovosti

1 INTRODUCTION

Self-assessment is the ability of physicians to perform self-rating or use self-audit with a goal of generating summary judgments on their performance to determine their own learning needs and find resources to meet them (1). Self-assessment is an integral part of many appraisal systems and has been proposed as an essential aspect of individual behaviour by several regulatory bodies and those developing learning outcomes for clinical students (2, 3). Self-assessment can be used in various aspects of education and life-long learning such as in achieving credits in continuous medical education (CME), in relicensing process and in assessing professional competencies (1, 4-6).

Competence is viewed as an attainment of a static set of attributes rather than a dynamic process in which physicians continuously use their practice experiences to progress in a competence towards the attainment of expertise (7). Competency-based continuous professional development (CPD) emphasises self-directed learning processes and promotes the role of assessment as a professional expectation and obligation (7, 8). So far, several competency models and frameworks have been developed in order to enhance educational activities in family medicine in different ways and in different levels of education (9). However, the attempts to address the need for family physicians' (FPs) training in quality improvement (QI) have been unevenly spread across countries (10-14).

So far, several tools for physicians' self-assessment have been used (1). Some of them measured basic medical knowledge (15, 16), some basic clinical skills (17, 18) and some specific clinical knowledge and skills (19, 20). None of them was specifically based on the proposed competency framework such as some of the other tools were (21). Also, the results on the physicians' self-assessment have not been externally evaluated to ensure objectivity (1). Namely, previous studies have suggested that physicians have a limited ability to accurately perform self-assessment (1). Also, self-assessment might be dependent on the ability of physicians to determine their own learning needs and therefore can result in the failure of professionals to generate summary judgments of their performance (22).

A recent study on the QI competencies for CPD for European FPs provided a QI competencies framework (QICF) (9). This framework served as the basis for the development of the QI Competencies Self-assessment (QICS) questionnaire for FPs. This questionnaire can be used by FPs, teachers of family medicine, decision makers and patients to identify gaps in competencies of FPs (23, 24).

As this questionnaire has been developed in the English language, the aim of this study was to perform a cross-cultural adaptation of the questionnaire into the Slovenian language and to validate it in a representative sample of Slovenian FPs.

2 METHODS

2.1 Type of study and settings

This was a cross-sectional observational postal survey and was conducted in the representative sample of Slovenian FPs. It was part of an international study (25). The study was approved by the National Ethics Committee (No. 96/05/21).

2.2 Study population

The study population consisted of Slovenian FPs. A representative sample of 398 FPs was drawn randomly from the membership list of Slovenian Family Doctors Society. We aimed at a total of 30% FPs in the final sample. In 2011, there were 937 working FPs in Slovenia (26), out of which 255 (27.2%) were men. Most FPs in 2011 were in the age group 50-59 (313, 33.4%) (26).

2.3 Data collection

Data was collected by a postal survey. We sent out two rounds of mail; the second one was sent for the purposes of obtaining the data for the test-retest reliability. The

mail consisted of the questionnaire (described below), the invitation letter and a pre-stamped return envelope. The first round was sent at the beginning of May 2012. Prior to the first shipment, we sent out an email invitation to all participants in order to increase the response rate. The second round was sent two weeks after the first round. Similarly, it was preceded by an email invitation.
We used the QICS questionnaire that was developed on the basis of the new QICF in family medicine (9). The questionnaire was translated from the original English version into the Slovenian language using the standard procedure (27). First, the English version was translated to the Slovenian language by two independent experts. They discussed the differences and produced a common version that was translated back into the English language by two independent experts. Both versions were then checked for differences and the final Slovenian version was produced.
The QICS questionnaire consists of 37 items included in the following domains: patient care and safety (8 items), effectiveness and efficiency (7 items), equity and ethical practice (8 items), methods and tools (5 items), leadership and management (4 items) and continuing professional development (5 items). The participants were asked to assess their own level of competencies on a five-point Likert scale ranging from 1 ("novice" = I have little or no knowledge/ability, or no previous experience of the competency described and need close supervision or instruction) to 5 ("expert" = I am a primary source of knowledge and information in the medical field). So, the minimum summary score of the whole questionnaire was 37 points and the maximum 185 points. The minimum/maximum summary scores of the domains were 8/40 points for patient care and safety, 7/35 points for effectiveness and efficiency, 8/40 points for equity and ethical practice, 5/25 points for methods and tools, 4/20 points for leadership and management and 5/25 points for continuing professional development. The questionnaire also consisted of demographic factors: sex, age, working period, number of registered patients, type of practice, area of practice, working style, involvement in teaching activities, involvement in research and participation in CME activities.
The QICS questionnaire was piloted in a sample of 10 FPs and adjusted according to their suggestions. Its face validity was provided by experts in family medicine teaching and experienced FPs as the reference group in the consensus process.

2.4 Statistical analysis

Data were analysed using the SPSS 19.0 package (SPSS Inc., Chicago, IL). Descriptive statistics were computed. We calculated the reliability (Cronbach's alpha) coefficient for the composite score of the questionnaire and the Spearman rho to determine the test-retest reliability of the questionnaire. We also calculated the reliability (Cronbach's alpha) coefficients of each competency domain.
For the bivariate analyses, we used a Mann-Whitney test and a Spearman correlation test.
We regarded $p < 0.05$ as statistically significant.

3 RESULTS

3.1 Demographic characteristics

There were 168 (42.2%) FPs in the sample, out of which 68 (40.5%) did not complete both rounds. So, the final sample consisted of 100 (25.1%) FPs, out of which 71 (71.0%) were women. Other demographic characteristics of physicians and practices are presented in Table 1. Mean age of the sample was 43.3 ± 9.6 years. Mean working period was 16.4 ± 9.8 years. Mean number of registered patients per FP was 1,650 ± 815.

Table 1. *Demographic characteristics of respondents and practices.*
Tabela 1. *Demografske lastnosti zdravnikov in ambulant.*

Characteristic/Lastnost	N (%)
Sex/spol	
Male/moški	29 (29.0)
Female/ženska	71 (71.0)
Education status/izobrazba	
Specialist of family medicine/specialist družinske medicine	75 (75.0)
Resident of family medicine(specializant družinske medicine	17 (17.0)
Other specialization/druga specializacija	3 (3.0)
No specialization/brez specializacije	5 (5.0)
Practice status/status ambulante	
Public/javna	69 (69.0)
Private contractor/zasebnik s koncesijo	30 (30.0)
No answer/brez odgovora	1 (1.0)
Practice organization/organizacija dela	
More physicians at the same location/več zdravnikov na eni lokaciji	82 (82.0)
Only physician at this location/sam na eni lokaciji	15 (15.0)
No answer/brez odgovora	3 (3.0)
Practice location/lokacija ambulante	
Urban/urbani predel	65 (65.0)
Rural/ruralni predel	34 (34.0)
No answer(brez odgovora	1 (1.0)
Involvement in education/vključenost v poučevanje	68 (68.0)
Involvement in research/vključenost v raziskovanje	22 (22.0)
Continuous medical education/stalno podiplomsko izobraževanje	
Never/nikoli	12 (12.0)
1-2 times per year/1-2-krat na leto	53 (53.0)
3-4 times per year/3-4-krat na leto	22 (22.0)
No answer/brez odgovora	13 (13.0)

3.2 Reliability of questionnaire

The mean scores of the QICS questionnaire were 127.0 ± 30.1 points (first round) and 127.8 ± 30.6 points (second round). Mean scores of the individual domains for both rounds are presented in Table 2. The temporal stability of the whole questionnaire was good with a Spearman's rho of 0.829 with $p < 0.001$. Data on temporal stability of the individual domains are presented in Table 2.

Table 2. *Scores of the questionnaire and temporal stability.*
Tabela 2. *Dobljene točke na vprašalniku in časovna stabilnost vprašalnika.*

Dimension/dimenzija	Mean score ± standard deviation/ povprečje ± standardna deviacija		Spearman's rho	P
	First round/ prvo pošiljanje	Second round/ drugo pošiljanje		
Patient care & Safety/oskrba in varnost bolnika	27.9 ± 6.6	28.6 ± 6.7	0.813	< 0.001
Effectiveness & Efficiency/učinkovitost in uspešnost	23.7 ± 6.2	23.8 ± 6.0	0.796	< 0.001
Equity & Ethical Practice/pravna in etična oskrba	29.8 ± 6.6	29.5 ± 6.5	0.884	< 0.001
Methods & Tools/metode in orodja	14.4 ± 5.3	15.1 ± 5.2	0.777	< 0.001
Leadership & Management/vodenje in upravljanje	13.7 ± 3.6	13.9 ± 3.8	0.813	< 0.001
Continuing Professional Development/ stalen poklicni razvoj	17.6 ± 4.4	17.5 ± 4.4	0.867	< 0.001
All/skupaj	127.0 ± 30.1	127.8 ± 30.6	0.829	< 0.001

Cronbach's alpha coefficients of the whole questionnaire were 0.984 (first round) and 0.988 (second round). Cronbach's alpha coefficients of the questionnaire's dimensions were 0.941 (first round) and 0.953 (second round) for Patient care & Safety, 0.941 (first round) and 0.949 (second round) for Effectiveness & Efficiency, 0.951 (first round) and 0.958 (second round) for Equity & Ethical Practice, 0.944 (first round) and 0.960 (second round) for Methods & Tools, 0.907 (first round) and 0.928 (second round) for Leadership & Management and 0.939 (first round) and 0.950 (second round) for Continuing Professional Development.

3.3 Competencies' correlations

Older FPs had higher summary scores of the questionnaire (Spearman's rho = 0.529, $p < 0.001$). FPs with more working experiences had higher summary scores of the questionnaire (Spearman's rho = 0.527, $p < 0.001$). Specialists of family medicine had higher summary scores of the questionnaire when compared to others (135.8 ± 24.7 vs. 100.8 ± 29.8, $p < 0.001$). FPs who reported not attending any CPD activity in the last year had lower summary scores of the questionnaire when compared to others (105.3 ± 34.2 vs. 130.1 ± 27.7, $p = 0.012$). FPs involved in education had higher summary scores of the questionnaires when compared to others (131.7 ± 29.3 vs. 118.6 ± 29.2, $p = 0.024$).

4 DISCUSSION

4.1 Summary of main findings

The Slovenian version of the QICS questionnaire proved to be a valid and reliable tool for self-assessment of QI competencies by FPs in terms of CPD. This questionnaire can be used in terms of a whole scale as well as in terms of each separate competency scale. Older FPs, those with longer working experiences, specialists of family medicine and those involved in education assessed their level of competencies higher. On the other hand, those not attending any CME activity assessed their level of competencies lower.

4.2 Contextualisation of the findings

This was the first study in Slovenia that dealt with self-assessment of desired QI competencies in FPs. A recent Slovenian study on medical students' attitudes towards family medicine competencies showed high

validity and reliability of the questionnaire used (28). It also showed that such questionnaires can be used for evaluating changes of students' attitudes towards undergraduate curricula and for prediction of students' preferences regarding their future professional career in family medicine (28).

So far, the QICS questionnaire has been translated into the Albanian language and validated in a sample of FPs (24) and of patients (23). The original English version has not yet been validated. As in our study, the Albanian study in a sample of FPs showed that the Albanian version of the questionnaire was reliable and had high temporal stability (24). However, the temporal stability of the individual competencies in our study was different than in the Albanian one. The latter found the lowest Spearman's rho scores for the leadership and management domain and the highest for the patient care and safety domain (24). In our study, the lowest Spearman's rho scores were found in the methods and tools domain and the highest in the equity and ethical practice domain. Probably, there are organisational and cultural differences between both countries, which could explain the differences in our results (29, 30).

The instrument proved to be a reliable one also in a sample of patients assessing the desired level of given competencies of their FPs (23).

Mean summary score of the questionnaire (127 points) in our study was higher than in the Albanian one (96 points) (24). It seems that Albanian FPs are less confident in their competencies or actually possess less QI knowledge and skills. This might be the consequence of some differences between both countries, especially in terms of primary care organisation in the past. In Slovenia, primary care traditionally has a strong and important role in the health care system (29). Also, family medicine as a discipline and specialisation in family medicine, have existed since the 1960s (31). Trainees have to perform a QI project during a module in specialty training curriculum (14). In Albania, on the other hand, there was not any strong role of primary care and also there was not any formal education in family medicine at any level of education until 1997, when the Department of Family Medicine at the University of Tirana was established (32).

In our study, the highest level of competencies was found in the equity and ethical practice field, which is in line with previous studies in Slovenia that showed high level of awareness about ethical dilemmas and their solving (33, 34).

The finding that older FPs and those with longer work experience assessed their level of competencies higher was expected as through work experience we also gain confidence in our knowledge, skills, and expertise. The result that specialists in family medicine rated their competencies higher is probably a consequence of the fact that specialisation in family medicine in Slovenia follows the European guidelines (35) and is based on family medicine competencies (31). It is also interesting that FPs who did not attend CPD activities rated their competencies lower. Presumably, they have other problems rather than being not interested in education, i.e. lack of time, lack of money. On the other hand, it seems that they are aware of their low competencies, which support the importance and necessity of self-assessment.

However, the question remains whether the self-rated level of competencies will be really that high when assessed by external assessors. Some studies have shown that self-assessment might not be very objective and that external review was necessary (1). But such competencies' assessment might be very time-consuming and therefore difficult to implement. Therefore, the QICS questionnaire might be very useful, as it was developed also for assessing the level of competencies of FPs by patients, teachers and policy makers (9, 23, 24). When comparing their self-perceived level of competencies to the desired ones by patients, teachers and policy makers, FPs might gain an objective view of their real level of competencies and might develop and grasp correct self-educational activities in order to improve the quality of their work. Nevertheless, self-assessment has been accepted as a part of formal assessment that is most important in formative assessment (35).

4.3 Strengths and limitations of the study

The main strength of this study is the fact that the QICS questionnaire is based on a theoretical framework (9), which justifies the content and use of this tool. Also, the process of cross-cultural adaptation of the QICS questionnaire was consistent with the recommended guidelines (27).

The main limitation of this study is the fact that the questionnaire was given only to family physicians and not also to patients and policy makers. Also, the response rate was low but still consistent with the usual response rate achieved with postal surveys (36). The sex distribution in our sample was consistent with the actual one, whereas FPs in our sample were younger when compared to average age of all Slovenian FPs (26). Therefore, the results should be interpreted with care and given further consideration when trying to generalise them to the whole FP population in Slovenia.

4.4 Recommendations for further research

Further studies should validate this tool also in a sample of patients, family medicine teachers and policy makers. Also, the original English version should be validated in a representative sample. A large international study should analyse the level of competences, spot the differences between the countries and plan appropriate educational interventions as a part of CPD in individual countries.

5 CONCLUSION

The Slovenian version of the QICS questionnaire can be used as a self-assessment tool for quality improvement by family physicians. It can also be used by family medicine teachers to assess the gap between the desired and the self-assessed competencies of quality improvement of their students or residents.

Conflict of interests

The authors declare no conflicts of interest.

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ADHERENCE FACTORS TO PAPERLESS PRIMARY HEALTHCARE: A FOCUS GROUP STUDY

DEJAVNIKI ZA SPREJETJE BREZPAPIRNE OSKRBE V OSNOVNEM ZDRAVSTVU: ŠTUDIJA FOKUSNIH SKUPIN

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Abstract

Background: *Information and communication technology (ICT) and paperless practices have been shown to improve "existing processes in the workplace" "as well as being an important component of modern primary healthcare". The aim of our study was to analyse the attitudes of health-care professionals and patients with regard to paperless practice and the most frequently used information and communication technology tools in Slovenian primary healthcare.*
Methods and participants: *Qualitative methodology using focus groups of 22 primary care physicians, 14 nurses and 18 patients.*
Results: *The areas recognised by all participants as important for further information and communication technology development were: computer-supported decision making, accessibility and completeness of personal e-health data, emergency cases, support for chronic disease management, ICT related time savings, e-prescriptions and e-discharge letters. The most important identified barriers impeding the use of ICT were: the heavy workload of primary care physicians and nurses, health insurance reimbursement rules and duplication of work using both paper and electronic health records.*
Conclusions: *This study highlighted a number of strengths of ICT use in primary care as well as numerous areas where changes in procedures and improvement of ICT tools to support them are needed.*

Key words: information and communication technology, primary health care, focus groups, paperless health care

Izvirni znanstveni članek
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Izvleček

Izhodišča: *Informacijsko-komunikacijska tehnologija (IKT) in brezpapirno delo lahko izboljšata obstoječe delovne procese in so pomembna sestavina sodobnega osnovnega zdravstva. Namen študije je bil analizirati stališča zdravstvenega osebja in pacientov glede brezpapirne ambulante in najpogostejše uporabljene informacijsko-komunikacijske tehnologije v slovenskem osnovnem zdravstvu.*
Metode in preiskovanci: *Kvalitativna metodologija fokusnih skupin z 22 zdravniki iz osnovnega zdravstva, s 14 ambulantnimi sestrami in z 18 bolniki.*
Rezultati: *Področja, ki so jih vsi udeleženci prepoznali kot pomembna za nadaljnji razvoj IKT, so: računalniško podprto odločanje, dostopnost in popolnost osebnih zdravstvenih podatkov, nujni primeri, podpora pri obravnavi kroničnih bolezni, prihranki časa z uporabo IKT, e-recept in e-odpustno pismo. Najpomembnejše ovire za uporabo IKT so: velike delovne obremenitve zdravnikov in sester v osnovnem zdravstvu, pravila zdravstvene zavarovalnice, podvajanje dela z uporabo papirnatih in elektronskih zdravstvenih kartotek.*
Zaključki: *Študija je poudarila številne prednosti uporabe IKT v osnovnem zdravstvu in tudi številna področja, na katerih so potrebni spremembe v procesih in izboljšanje podpornih orodij IKT.*

Ključne besede: informacijsko-komunikacijska tehnologija, primarno zdravstveno varstvo, fokusne skupine, brezpapirna zdravstvena oskrba

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1 BACKGROUND

Information and communication technology (ICT), in particular electronic health records (EHRs), is increasingly viewed as a key means of improving the quality, safety and efficiency of health-care systems (1-6). ICT tools improve access to critically important clinical information, can reduce unnecessary repetitions of clinical procedures and provide real-time decision support to clinicians (5-8). It has been shown that their benefits also include: improved disease management and health outcome of patients, increased levels of preventive care, reduction of paper-based tasks and increased collaboration among members of health-care teams (7-11). ICT, which in medical informatics literature generally has the same meaning as "health information technology" (HIT), also has the potential to decrease medical errors (6, 12, 13).

To successfully implement and use various ICT solutions in providing health-care services, it is important to understand the attitudes, expectations and experiences of different user groups. Implementation of new ICT tools or upgrading existing ones has an impact on the workplace processes of medical staff, requiring significant efforts to be invested into managing this change. New types of medical errors or other detrimental outcomes could also result in reduced support for ICT implementation (4, 10, 13).

Patients' and primary care physicians' opinions concerning existing and upcoming ICT solutions have been sought in a number of studies (4, 5, 7-9, 11, 13-15). These studies have seldom analysed opinions and concerns of primary-care nurses, usually the first point of a patient's contact with the health system (4, 5, 16-19).

Primary care provides almost unlimited access to healthcare and deals with a wide array of health problems across a spectrum of age, sex and other characteristics. This diversity stresses the importance of careful planning and evaluation of ICT when it is implemented (14, 20-26).

There are five ICT providers in Slovenia holding a significant market share of about 1,300 primary care practices. Health authority influence on ICT providers and consequently on improving ICT implementation is still minimal. National legislation regarding ICT is deficient – including a shortage of accepted standards, validation and certification processes. Consequently, adoption of modern ICT tools in primary care in Slovenia has been relatively slow (14, 15, 27). Despite the good quality of the ICT infrastructure, the use of computers and eHealth applications in Slovenian primary care was well below the EU average in 2008. The only exception was the storage of administrative patient data (15). Almost all primary care practices own a computer, but less than a quarter of general practitioners actually used it during a consultation with patients. In the same year, about 83% of GP practices were connected to the internet, but transfer and exchange of electronic patient data in primary care was minor (15, 26).

Despite numerous challenges, foreseen ICT benefits led to substantial interest - particularly from health policymakers - to speed up its adoption. In 2006, the Slovenian government created and promoted the National Strategy for eHealth. The national EHR system was planned to be implemented and accomplished by 2010 (15, 26, 29-31).

The aim of this qualitative study was to identify the ICT expectations and needs of its users, adherence factors and the most important obstacles and opportunities for adoption of paperless primary healthcare in Slovenia. Patients, primary health-care physicians and nursing staff were identified and included in the study as the three most relevant groups of ICT users in family medicine. The study was approved by the Slovenian National Board for Medical Ethics, document no. 80/06/07. The study lasted from June 2006 to May 2010.

2 METHODOLOGY

The methodology of the study used focus groups, and this design was chosen for several reasons (4, 8, 32-36). This method allows ideas to emerge from the group rather than the investigator and helps to identify barriers and incentives as they apply to the aims of the research. We used a sampling method that aimed at strategic selection and distribution of respondents. This ensured the collection of adequate material, which provided in-depth information to explore the research questions (34, 37-40).

We used the following inclusion criteria: 25 - 65 years old, no hearing disorders, absence of serious psychiatric illness and adequate communication skills in the Slovenian language. Homogenous groups were formed according to the profile of participants (physicians, nurses, patients).

Physicians and nurses had to fulfil additional criteria: at least five years of active working experience in primary care and basic knowledge of health information technologies. All nurses had to have at least 20 hours a week in ICT - enabled or "computerised" primary care practices (i.e. active use of ambulatory EHR) during the last three years.

Family physicians were chosen on a regional basis from an urban area with more than 100,000 inhabitants and from three semi-rural areas with less than 25,000 inhabitants.
Primary care nurses were recruited from two mid-sized community health centres (between 50 and 200 employees).
Patients were selected from 10 family medical practices in four different regions. We tried to include a diversity of patients as regards age, sex and educational level.

a) Focus groups, data collection and data analysis

After the introduction of participants and before leading the focus group, a 15-minute presentation of the topic was given by the moderator (general information about existing EHRs and paperless work in primary care practices).
The list of seven frame-setting questions, the same for all focus groups, is represented in Table 1. The questions were formed according to data from the literature (1, 4-8, 11, 13, 16-19, 29-33).
Each focus group lasted from 70 to 90 minutes. The moderator and the observer, who took notes in addition to audio-recordings, were present at all group interviews and discussed key topics that arose from conversations immediately after each session.

Table 1. *Main Questions for all Focus Groups.*
Tabela 1. *Glavna vprašanja za vse fokusne skupine.*

ICT experience and current HIT usage/ Izkušnje z IKT in trenutna uporaba IT v zdravstvu	What is your previous experience with computers, internet and other ICT tools?/ Kakšne so vaše predhodne izkušnje z računalniki, internetom in drugimi orodji IKT?
	What is your view on the current state of ICT use in Slovene primary healthcare? / Kaj menite o trenutnem stanju uporabe IKT v osnovnem zdravstvu v Sloveniji?
Internet and eHealth services/ Internet in e-storitve v zdravstvu	What are your attitudes towards the use of: internet health portals, e-prescription, e-appointment, e-referral, etc.?/ Kakšen je vaš odnos do uporabe: spletnih zdravstvenih portalov, e-receptov, e-naročanja, e-napotnic itn.?
	What is your view on e-consultation with primary care physicians, clinical specialists and other health-care professionals?/ Kaj menite o e-svetovanju splošnih zdravnikov, kliničnih specialistov ali drugih zdravstvenih delavcev?
Electronic health records/ Elektronski zdravstveni zapisi	What do you think about existing EHRs and the possible influence of ICT tools on primary health-care professionals' work?/ Kaj menite o obstoječih elektronskih zdravstvenih zapisih in možnih vplivih orodij IKT na delo zdravstvenih delavcev v osnovnem zdravstvu?
	What is your view on electronic personal health records and on accessing EHR online?/ Kakšno je vaše mnenje o elektronskih osebnih zdravstvenih zapisih in o spletnem dostopu elektronskih zdravstvenih zapisov?
Computer decision-making support/ Računalniška podpora procesu odločanja	What is your view on computerised follow-up of the most common chronic diseases and the use of ICT-based decision-making support tools in primary care?/ Kaj menite o računalniško podprti nadaljnji obravnavi najbolj razširjenih kroničnih bolezni in uporabi IKT orodij za računalniško podporo procesu odločanja v osnovnem zdravstvu?

Analysis of the transcribed texts from the focus groups, including the open coding and axial coding processes, was carried out using established standards for qualitative research and according to accepted study guidelines. The authors classified the cited statements by taking into account the connotation of the particular code as it applied to the corresponding theme (37-42). "Quantifying" of qualitative data was derived by counting citations by topics and categories and evaluating them as positive, neutral or negative. Each citation was assessed by two researchers. If the assessments were different, a third researcher was consulted. The results of the analysis were harmonised at meetings organised between researchers RI, MM, DP and TPS.

The most experienced researcher in qualitative analysis (MK) monitored the progress of the study, supervised the methodological accuracy and regularity of focus group analysis and took part in the final revision.

Internal validity of the study was assured by using the triangulation of participants, sources and researchers. Credibility was assessed by regular team debriefings and re-examinations of coding discrepancies (33, 40, 43, 44).

3 RESULTS

We invited 78 physicians, 36 nurses and 48 patients into the study. Seven focus groups with a total of 54 participants in three different Slovenian regions were held.

Each group had six to nine members. Participants' demographic characteristics are represented in Table 2. One of three physician groups consisted of those who had three years or more of active use of electronic health records during office consultation. Two physicians' groups were mixed and including physicians without any experiences in EHR usage.

Two primary care nurse focus groups were conducted. They were gender homogeneous. The first patient group consisted of participants 25 - 45 years of age and the second consisted of participants 45 - 65 years of age. The purpose of placing patients into two age groups was to encourage their active involvement and mutual interaction during sessions.

Table 2. *Characteristics of focus group participants.*
Tabela 2. *Značilnosti udeležencev fokusnih skupin.*

Participant demographics/ Demografija udeležencev	Physicians (σ)/ Zdravniki (σ)	Nurses (σ)/ Medicinske sestre (σ)	Patients (σ)/ Pacienti (σ)	Total (σ)/ Skupaj (σ)
Male/ Moški	7	/	8	15
Female/ Ženske	15	14	10	39
Age/Starost	46.4 (6.1)	43.1 (5.9)	48.7 (12,7)	46.3 (8.9)
Years of internet use/ Leta uporabe interneta	9.1 (3.7)	6.4 (3.0)	4.3 (4.11)	6.8 (4.1)
Primary school or less/ Osnova šola ali manj	/	/	4	4
Secondary school/ Srednja šola	/	10	8	18
Graduate degree/ Visoka dodiplomska izobrazba	2	4	4	10
Postgraduate degree/ Visoka podiplomska izobrazba	20	/	2	22

Legend: σ = standard deviation
Legenda: σ = standardni odklon

20 of 22 physicians were general practitioners/ family doctors; the other two were a paediatrician and a gynaecologist. Among nurses, 10 were from family practices, two from paediatrics and two from gynaecology practices. Practice characteristics are represented in Table 3.

Table 3. *Practice characteristics.*
Tabela 3. *Značilnosti ambulant.*

Practice/ Praksa	Physicians (σ)/ Zdravniki (σ)	Nurses (σ)/ Medicinske sestre (σ)	Total (σ)/ Skupaj (σ)
Average number of registered patients/ Povprečno število registriranih pacientov	1,730 (340.3)	1,240 (476.6)	1,539 (460)
Years of work in primary care/ Delo v osnovnem zdravstvu v letih	17.4 (7.6)	16.7 (7.6)	17.1 (7.5)
Years of EHR use/ Uporaba elektronskih zdravstvenih zapisov v letih	6.4 (3.0)	10.2 (2.5)	8.3
Primary health-care centres/ Zavodi osnovne zdravstvene dejavnosti	18	12	30
Individual contractors/ Zasebni izvajalci	4	2	6

The total numbers of all appraised citations was 1,010, and they were classified into 66 themes and 25 subthemes. Citations were determined and classified by performing a combination of the open coding and the axial coding processes, described in the methodology section of this article. Finally, themes were grouped in 7 categories through the process of constant comparison until saturation was reached. The most cited categories identified through subsequent content analysis were: "User expectations regarding ICT" (n= 168) and "Electronic vs. paper health records" (n=167). The least cited categories were: "ICT influence on practice workflow" (n=116) and "e-consultation" (n=118). The most cited themes/subthemes determined through content analysis were: "e- appointment, e-referral letter" (n=25), "Phone consultation in primary care" (n=25) and "Health insurance reimbursement rules" (n= 23). The least cited themes were: "Experience with new EHR" (n=2) and "Patient education" (n=2). Defined categories with the most typical themes and citations are represented below.

Category: "Health-care system"

The majority of negative comments were related to the themes: "Health Insurance Institute rules" (n = 17) and the "Health insurance electronic card" (n = 11). Nurses were the most critical subset of participants in both cases. The following quotations were typical of the category "Health-care system":

Theme: Primary care office organisation. Subthemes: "ICT equipment", "Administrative tasks in primary care offices", "Number of consultations".

- MD: "I have a feeling that I spend half my time looking for what I wrote somewhere on paper."
- Nurse: "Administrative procedures are becoming more time consuming by the day."

Theme: Health-care system efficacy. Subthemes: "Supervision of National health insurance service", "Waiting list for clinical specialists", "Local vs. EU".

- MD: "Once we have the same number of consultations per day as the physicians in the western EU, we will be able to use e-consultation much more."
- Pt : "It's not right to pay for health insurance for 35 years and then be required to pay extra for a consultation with specialists."

Theme: Health insurance electronic card

- Nurse: "The health insurance cards should show immediately that a patient has been vaccinated against tetanus... "
- MD: "We could not reach agreement on which data to provide on the electronic insurance card. Should it be allergy information, vaccination data, donor status information or something else?"

Theme : Rules of National Health Insurance Institute

- MD: "On the one hand, the doctor is satisfied. On the other hand, he is annoyed because of the Insurance Institute rules. "

Theme: ICT costs

- Pt.: "An average computer costs about 800 euros plus internet and other equipment. It's not a small thing. "

Category: "User expectations regarding ICT"

In this category, the participants emphasised the potential benefits of the wider use of ICT in primary care. The most positive expectations were found in the areas of "Saving time with the use of ICT" (n = 19) and "The integrity and traceability of e-data" (n = 16). The most optimistic on both these issues were patients (respectively, 10 and 7 positive comments). Concerns were expressed primarily regarding "Protection of

electronic medical data" and the "Influence of ICT on the social component of healthcare". The following statements were characteristic of the "User expectations regarding HIT" category:

Theme: Data organisation
- MD: "The need for ICT seems to grow every year. I think the huge increase of diagnostic and treatment procedures caused medical data to become completely nontransparent in paper form. "
- Nurse: "We must get up, walk around and look for all those papers instead of having all the documents in the computer. "

Theme: Availability of e –medical information
- Nurse: "When patients have particular questions, it's easy for me to find related information on the internet."
- Nurse: "We often search information on the internet where a lot of useful options are available."
- MD: "The problem is that the search engines often show you too many relevant articles and you just get lost."

Theme: ICT evaluation and application upgrades
- Nurse: "I miss other EHRs to compare with my own and to say what should be improved."

Theme: Comparison to other professions
- MD: "The tax office also took a long time to deal with my income, despite all these computers... "

Theme: Patient and health-care professional trust in ICT
- MD: "Mistakes are more easily made by a human than a PC."

Theme: Social aspect, human contact
- Pt.: "From a social point of view, I am not convinced of the benefits the computer brings. Look at retail stores – they have become so impersonal – a doctor should not allow this to happen. "
- Nurse: "We would like to have a computer that would enable pressing a button and making the patient or doctor smile."

Category: "ICT influence on practice workflow"

The previous experience of the participants with the use of ICT in primary care was positive, mostly in the following areas: "Preventive tasks, diagnosis and therapy" (n = 16), "Office administration" (n=14) and "Physician and nurse professional tasks" (n=13). Doctors were most optimistic in the first two areas, while patients were the most optimistic in the third one. Most concerns in this category were expressed about the "Impact of ICT on communication with patients". The following statements were characteristic of the "ICT influence on practice workflow" category:

Theme: Control and organisation of medical data
- MD: "I have almost all data stored electronically on my computer!"

Theme: Office administration
- Nurse: "We can't imagine working without a computer - there is just so much administrative work to be done."

Theme: Communication with patients
- Pt : "Perhaps once all these EHRs are further improved (from the point of view of usability), the doctor will be able to engage more with the patient and less with the computer."

Theme: Health-care personnel satisfaction
- Nurse: "My computer does not oppose me."
- MD: "Almost 12 years has passed since I started using a computer, but I still cannot see any substantial progress."
- Nurse: "I think that use of computers is very important for ambulatory teamwork."

Theme: Patient education
- MD: "Just upload the instructions on the screen and show the patient how to carry out spirometry."

Category: "User-centred design of actual ICT"

Participants gave a very bad evaluation to the user friendliness and adaptability of existing ICT, particularly: "Updates of existing EHRs" (n = 12), "Physician and nurse workloads" (n = 18), "Health-care user limitations - age, ICT equipment, acceptance and ability to use ICT" (n = 16), "Response time of ICT" (n = 10) and "Cooperation with software vendors" (n = 9). Most criticism came from the doctors.

The following statements were characteristic of the "User-centred design of actual ICT" category:

Theme: Friendliness of existing ICT. Subthemes: "International Code of Diseases and diagnosis browser", "User interfaces for data acquisition", "Instructions and education of health-care personnel for ICT usage".
- MD: "Why do we have computers if we must still learn the diagnosis codes by heart? This code list is a disaster."

Theme: Physician and nurse skills for ICT
- MD: "I send patients out of the office before taking notes so they don't see how badly I type when entering data into the computer."

Theme: Physician and nurse workloads
- Nurse: "Nurse work overload is the biggest problem. The computer helps, but it is also additional work."

Theme: EHR provider cooperation with health-care professionals
- MD: "We have problems with our EHR providers. They always seem to think they know better what we (physicians) need."

Category: "Electronic vs. paper health records"
Efficiency and transparency of EHRs were assessed positively, but much concern was expressed regarding the entry, availability and completeness of e-health information. The most disturbing for all participants were: "Repeating work with paper and electronic medical records" (n = 14), "Efficiency and reliability of paper records" (n=6) and "Storage, integrity and completeness of paper medical data" (n = 8).
The following statements were characteristic of the "Electronic vs. paper health records" category:
Theme: Storage, integrity and completeness of paper medical data
- Nurse: "The advantage of paper records is that if a computer doesn't work we still have access to all information."

Theme: EHR efficiency.
- MD: "I think that the EHR is fast enough and does not obstruct our work. Earlier, we were afraid it would be disturbing for patients."

Theme: Support for nurses' work
- Nurse: "I miss support for nurse-related tasks, e.g. height, weight, blood pressure and the rest. Since you can't enter these data into an EHR system, you need to write them down on a paper record. EHRs are still insufficient regarding nurse activities."

Theme: Legibility of EHRs
- Nurse: "Electronic notes from physicians are legible. Paper based ones are sometimes hard to read."

Theme: Repeating work with paper and electronic health records
- Nurse: "The use of paper records is intrusive. I like to have all medical data in the computer."
- MD: "We have to type the most important information once again. I need to store the data somewhere. "

Theme: Medical data, storage and updating
- MD: "Patients are very satisfied; the pharmacist as well. I only need one minute for all the administration of a patient. "
- MD: "I have typed all diagnoses and therapy information into my EHR since 2000, and I have these data in electronic format for all patients".

Category: "E-consultation"
In this category, "E-prescription and e-discharge letter" (n = 15) got high and uniform support from all participants, while "Phone consultation" (n = 22) and "E- consultation to family physician and nurse" (n = 18) received more concerns than support. Scepticism mainly came from doctors and nurses. Patients were the most optimistic regarding "E- appointment and e-referral letter", while nurses were the most critical of the same topic. "Physician availability" was identified by the patients as the biggest obstacle to the successful delivery of e-consultation in primary care.
The following statements were characteristic of the "E-consultation" category (theme numbers are in parentheses):
Theme: "E-consultation to family physician/ nurse"
- Nurse: "Responding to e-mails during office consultations seems impossible at a frequency of 60-70 patient visits per day in addition to phone calls."
- MD: "Once you spend an hour or two each day on this, it becomes a big problem."
- Pt.: "A doctor should be available 24 hours a day for e-consultation, which is difficult to provide."

Theme: E-prescription and e-discharge letter
- Pt : "We probably don't even need paper prescriptions."

Theme: E- appointment, e-referral letter
- MD: "I have tried to use the internet for e-referrals. Unfortunately, it took the other provider 14 days to respond. "
- MD: "Actually, we now send huge amounts of referrals, but no one knows what's going on with them or even if anyone reads them at all. "

Theme: E-network and e-communication among health-care personnel and health institutions
- MD: "You cannot browse the internet during the consultation. Patients must be examined correctly, and you cannot do all these tasks simultaneously."

Category: "Computer-supported decision making and accessibility of personal e-health data"
The most positive expectations in this category were related to: "Accessibility of personal e- health data by primary-care physicians and clinical specialists" (n = 25) and "Computer- supported decision making" (n = 25). The first theme was mostly supported by patients (n=13) and physicians (n=9). Computer-supported decision making was largely advocated by physicians.
The following statements were characteristic of the "Computer-supported decision making and accessibility of personal e- health data" category:
Theme: Accessibility of personal e- health data. Subthemes: "Accessibility of personal e- health data to primary-care physicians and clinical specialists" and "Accessibility of personal e- health data to other health-care professionals".
- Pt : "Physicians need to have as much data as possible to provide optimal care."

– MD: “We expected this to allow us to see when and to what specialist or institution each single patient was referred.”

Theme: Accessibility of personal health data for urgent care

– Pt.: “If you have a car accident, the hospital staff should have access to all your relevant medical data in two seconds…”

Theme: Patient summary

– MD: “Diagnoses, allergies, medication lists - that is of most importance. At the moment, no one can access it, not even the emergency room.”

Theme: Computer-supported decision making

– MD: “I am not against computerised decision support. However, I think there are more basic things that need to be implemented first.”
– Nurse: “Now there are no alerts on the computer. You have to remember everything yourself.”

Theme: Accessibility to one’s own personal e-health data

– Pt.: “I would want to have all my personal health data in one place and to have the possibility to access it from time to time.”

Theme: Patient’s consent to personal health data access

– Pt.: “It is difficult for patients to decide which medical information to hide from a specialist…”

Citation appraisal

In additional citation appraisal rounds, each citation was assessed on the three level scale: positive, negative or neutral. The evaluation results, sorted by category and participant subgroup, are represented in Table 4.

Table 4. *Citations by category and participant subgroup.*
Tabela 4. *Citati po kategorijah in podskupinah udeležencev.*

Category/ Kategorija	Physicians/ Zdravniki			Nurses/ Medicinske sestre			Patients/ Pacienti		
	Pos./ Poz.	Neut./ Nevt.	Neg.	Pos./ Poz.	Neut./ Nevt.	Neg.	Pos./ Poz.	Neut./ Nevt.	Neg.
Health-care system/ Sistem zdravstvene oskrbe	8	10	32	5	1	34	2	8	32
User expectations and needs regarding ICT/ Pričakovanja in potrebe uporabnikov v zvezi z IKT	48	7	8	34	5	10	36	6	16
ICT influence on practice workflow/ Vpliv IKT na potek dela v praksi	30	4	3	24	0	11	30	5	11
User-centred design of actual ICT/ Usmerjenost zasnove dejanskih IKT k uporabniku	6	6	56	14	9	41	4	9	20
Electronic vs. paper health records/ Elektronski zdravstveni zapisi v prim. s papirnatimi	44	0	49	31	2	20	13	1	9
E-consultation/ E-svetovanje	20	6	12	18	4	14	25	1	18
Computer-supported decision making and accessibility of personal e-health data/ Računalniško podprt proces odločanja in dostopnost do elektronskih osebnih zdravstvenih podatkov	47	5	3	21	1	4	49	1	7
Total/ Skupaj	203	38	163	147	22	134	159	31	113

Altogether, 404 quotes (40%) were from physician focus groups, 303 (30%) from nurse focus groups and the final 30% were from focus groups of patients. The percentage of positive or negative comments from the three participant subgroups varied by category. Dissatisfaction with the present health-care system was expressed in 64% of citations from physicians and in more than 80% of nurse and patient citations. Positive expectations regarding ICT were found in 76.2% of physician citations and "only" in 62% of citations from patients. A similar ratio between physician and patient positive citations (81.8% vs. 65.2%) was found in the result concerning "ICT influence on practice workflow". Physicians were the most pessimistic subgroup regarding the category "User centred design of actual ICT", with 82.35% having negative comments compared to 64.1% of nurses and 60.6% of patients who were negative. Electronic vs. paper health records was the only category that was supported by two subgroups (nurses had 58.5% positive comments; patients 56.5%) and rejected by the third (physicians had 52.7% negative comments). The category "E-consultation" got mild support, while the category "Computer-supported decision making and accessibility of personal e-health data" got strong support among all three participant subgroups.

4 DISCUSSION

This evaluation of attitudes by the key user subgroups regarding the use of ICT and paperless records in primary healthcare included the qualitative method, which is becoming increasingly popular in health informatics research (1, 4, 8, 13, 31, 45-50).

The methodology applied to the analysis and the additional citation appraisal rounds enabled a more accurate evaluation of the data and consequently improved the quality and validity of the results.

The three-level process (positive, negative, neutral) of appraising citations allowed the researchers to determine participant support for the themes and categories.

The most important areas for further e-Health development identified by all participants were: "Accessibility and completeness of personal e-health data", "Computer-supported decision making" and "E-prescription and e-discharge letter". Through the process of content analysis, these three themes got the highest number of positively-assessed citations in all participants' subgroups.

Physicians also strongly supported "Structured medical data entry", while nurses pointed to "Nurse service support". Patients gave strong support to "Time savings with ICT" and "E- appointment, e-referral letter".

The benefits of patient accessibility to data are clear and got the strongest support by participants in all three subgroups. In other words, there was strong support for access to personal health information by patients and health professionals at various levels within the health-care system. The most important current challenges regarding access to personal health information in Slovenia are related to: lack of an appropriate legislative framework, data storage method (centralised or decentralised) and patient summary architecture (26, 51).

Access to personal health information by others also implies clear rules concerning access and explicit consent of the patient, who is the owner of the data (8, 51, 52, 53, 54). The highest level of support for this theme comes from health authorities and decision makers (26). However, even in large European countries, national or system-wide sharing of patient data was deficient until recently (51).

A standard EHR or EHR-like system usually incorporates an overall patient summary as a fundamental condition for prompt and broad access to the patients' medical data. A summary was defined by the epSOS project as a: "minimum set of a patient's data that would provide a health professional with essential information needed in case of unexpected or unscheduled care (e.g. emergency, accident) but also in case of planned care (e.g. after a relocation, cross-organisational care path)" (52).

Accessibility to the EHR also offers both physicians and patients a sense of seamless communication over time and location (3-5, 15, 32, 48).

Safety of medical data in electronic format was mainly assessed negatively by patients in our study. Some other research papers have indicated that many patients are unprepared to allow distribution of their personal health data for purposes other than clinical care (54-56). This finding implies that the issue of patient consent must be seriously considered in all cases of personal e-health information exchange.

E-prescribing is usually defined as "the process of the electronic capture and transfer of a prescription by a health-care provider to a pharmacy for retrieval of the medicine by the patient and the recording of dispensation in the patient's record" (51). The epSOS project defines ePrescription as a service "made up of electronic prescribing and electronic dispensing" (57). The automation of medication prescriptions provides big benefits to general practitioners, as it addresses

legibility concerns, can be a significant time saver (particularly for repeat prescriptions) and offers the potential to make use of decision-support capabilities (8, 13, 57-59).

E-prescription, as well as the patient summary, have been identified as top e-Health priorities in all EU states since 2006. However, full implementation of these two services at national levels is slow and Slovenia is not an exception (14, 15, 51). E-prescription, e-discharge letter and patient summary were almost equally supported by all three subgroups of participants in our study. Together these three areas got the highest support of all themes that were identified. It seems that the electronic transfer of prescription-related information is acceptable to all eHealth users -- if concerns about patient confidentiality are taken into account and the role of pharmacists in prescription management is extended (55).

"Time savings with ICT" got the fourth highest level of support in our study and was another area highly ranked by all participant subgroups. Patients were the most optimistic subgroup regarding the potential time benefits from ICT.

There are advantages of EHRs over traditional paper-based records as regards legibility, accessibility and automation of repeated tasks. Consequently, there is the potential to increase time spent on direct patient care (1, 53, 55, 58, 60-63). However, some time studies have failed to demonstrate any noticeable increase of the time spent on clinician–patient encounters (64-67).

Computer-supported decision making, which got the third highest support, was most supported by physicians and least by nurses. Based on the literature, physicians want existing computer decision support systems to enhance physician–patient relationships, redirect work among staff, adjust to individual patients and provide time-saving tools (12, 13, 56, 64, 68-73).

The most important recognised barriers impeding the wider use of ICT among physicians are:

"EHR provider cooperation with health-care professionals," "Updates of existing EHRs" (both got 13 negative comments), "Friendliness of existing ICT" (11 negative comments), "Heavy workload and number of consultations" (11 negative comments), "Accessibility and completeness of current e-medical data" (8 negative comments) "Clearness and comprehensiveness of paper medical records" (7 negative comments) and "Repeating work with paper and electronic health records" (7 negative comments).

The biggest obstacles to wider use of ICT, as recognised by nurses, are: "Health insurance service rules" (10 negative comments), "Heavy workload and number of consultations" (10 negative comments), "Administrative tasks in offices" (6 negative comments), "Phone consultation in primary care" (6 negative comments), "Health insurance electronic card" (5 negative comments) and "Repeating work with paper and electronic health records" (5 negative comments).

The major barriers identified by patients are: "Age of the e-Health-care user" (7 negative comments), "Capabilities for e-consultation" (7 negative comments), "Waiting lists for clinical specialists" (6 negative comments), "Safety of medical data in electronic format" (5 negative comments), "Social aspect, human contact" (4 negative comments), "Trust in the health-care system" (4 negative comments) and "ICT costs" (4 negative comments).

The vast majority of recognised obstacles are organisational in nature, which is also confirmed by the highest percentage of negative quotations in the category "Health-care system". This was cited mostly by nurses. Doctors also highlighted user friendliness of existing ICT, while patients also expressed concern about the so-called "Social aspects of ICT usage".

At the aggregate level, organisational issues are critical in national strategies and action plans that ultimately influence the adoption of ICT (4, 14, 16, 51, 63-66, 74-77). These obstacles could be removed or transformed through systematic, well-planned changes in the health-care system, including health insurance and its rules for service reimbursement. Modification of current primary care practice workflow and reduction of the usual physician and nurse workloads should also be a necessary part of these systemic changes. Successful development of eHealth in northern European countries suggests that ICT adoption on a national level depends largely on the maturity and sophistication of eHealth strategies and legislations (51, 78).

Physician and nurse scepticism about user-driven eHealth applications is confirmed by the second lowest rating received by the category "User-centred design of existing ICT". This should be a serious alert for relevant policymakers and not be overlooked.

Patient-centred applications are defined as systems that enable a partnership between practitioners, patients and their families (when appropriate), which ensures that procedures and decisions respect patient needs and preferences. It seems that redistributing ICT tasks between professionals, as well as adapting ICT tools to the needs of users, is crucial for ICT to effectively be used in clinical work (2, 58, 75-82). Therefore, it makes sense to increase the involvement of end-users in the implementation process (2, 17, 41, 62, 79-82). The category "User expectations regarding HIT" could provide a basic list of priorities for ICT implementation in primary care.

The patients highlighted at least four social and demographic themes relevant to full exploitation of ICT. These influences are well known in the literature (4, 8, 31, 70, 83 –86). The proportion of older adults in the population of all EU countries is steadily increasing. Older people generally have less knowledge about health issues and a lower computer literacy, consequently lagging behind in ICT adoption. Some believe the lower level of ICT adoption in this subpopulation will soon change (85, 86). Introduction of patient accessible, location-independent electronic medical records and the promotion of tele-health solutions for chronic diseases could accelerate the process of ICT adoption (17, 84). Lack of human contact or of IT/internet experience and inadequate promotion of primary care eHealth services have been recognised as important barriers in some studies (2, 8, 32, 83, 84). Some environmental factors could also play an important role in the use of ICT by patients. An example might be patient location when using this technology (4). The concepts of patient empowerment and shared decision making could probably offer efficient methods to help solve the social and demographic eHealth barriers and need further exploration (62, 87).

5 CONCLUSIONS

In-depth focus group analysis highlighted the following concerns of key eHealth users in Slovenian primary care:

- high expectations regarding ICT in general, computer-supported decision making and accessibility of personal e- health data;
- Positive attitudes toward the influence of ICT on primary healthcare as well as expected benefits from e-consultation and e-appointments;
- Strong dissatisfaction with the inefficiency of the existed health-care system and with current user-centred design of available ICT in Slovenian primary care.

Recognised barriers, opportunities and organisational weakness require quick and efficient systemic measures aimed at improving cooperation among all groups using eHealth.

The internet and computers are recognised as important social determinants of health in Slovenia (87).

Generalisation comparing different countries is more challenging and requires other evidence-based data.

Authors' contributions

RI: the principle investigator who conducted this research including the study design, data collection and interpretation; manuscript preparation.

MM: study design, data collection and interpretation; manuscript preparation

DP: data interpretation and validation, codes assessment; manuscript preparation

TPS: data interpretation and validation, codes assessment

MK: data validation and study supervision

Conflicts of interests

There are no competing interests.

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IMPACT OF AIR POLLUTION WITH PM_{10} ON PRIMARY HEALTH CARE CONSULTATIONS FOR RESPIRATORY DISEASES IN CHILDREN IN ZASAVJE, SLOVENIA: A TIME-TREND STUDY

VPLIV ONESNAŽENOSTI ZRAKA S PRAŠNIMI DELCI PM_{10} NA ŠTEVILO OBISKOV V PRIMARNEM ZDRAVSTVENEM VARSTVU ZARADI BOLEZNI DIHAL PRI OTROCIH V ZASAVJU: ŠTUDIJA ČASOVNEGA TRENDA

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Abstract

Aim: *The aim of our study was to assess the temporal association between the number of consultations in the primary health care unit due to respiratory diseases in children and the level of particular matter of 10 micrometres in diameter (PM_{10}) pollution in the Zasavje region.*
Methods: *A time-trend ecological study was carried out for the period between 1 January 2006 and 31 December 2011. The daily number of first consultations for respiratory diseases among children in the Zasavje region was observed as the outcome. Poisson regression analysis was used to investigate the association between the observed outcome and the daily PM_{10} concentrations, adjusted to other covariates.*
Results: *The results showed that the daily number of first consultations were highly significantly associated with the daily concentrations of PM_{10} in the Zagorje ($p<0.001$) and Trbovlje ($p<0.001$) municipalities. In the Hrastnik municipality, a significant association was not observed in all models.*
Conclusions: *It can be concluded that evidence of association between the daily PM_{10} concentration and the daily number of first consultations for respiratory diseases among children exists, indicating that there is still a need for public health activities in the sense of reduction of harmful environmental factors in the region. Additionally, on the basis of these results, it can be assumed that with some improvements linkage of existing health and environmental data in Slovenia in general could be feasible in identifying a grounded need for future public health action.*

Key words: outdoor air pollution, PM_{10}, respiratory diseases, children, the Zasavje region, time-trend study

Izvirni znanstveni članek
UDK 616.2-053.2:504.5(497.4 Zasavje)

Izvleček

Namen: *Namen študije je bil oceniti časovno povezanost med številom obiskov v primarnem zdravstvenem varstvu zaradi bolezni dihal pri otrocih in prašnimi delci premera 10 mikrometrov (PM_{10}) v Zasavju.*
Metode: *Ekološka študija časovnega trenda je bila izvedena za obdobje od 1. januarja 2006 do 31. decembra 2011. Opazovani izid je bil dnevno število prvih obiskov zaradi bolezni dihal pri otrocih v Zasavju. Za oceno povezanosti med opazovanim izidom in dnevnimi koncentracijami PM_{10}, standardizirano na preostale pojasnjevalne dejavnike, je bila uporabljena Poissonova regresijska analiza.*
Rezultati: *Rezultati so pokazali močno statistično povezanost med dnevnim številom prvih obiskov in dnevnimi koncentracijami PM_{10} v občinah Zagorje ($p < 0,001$) in Trbovlje ($p < 0,001$). V občini Hrastnik nismo opazili značilne povezanosti pri vseh modelih.*
Zaključek: *Sklenemo lahko, da v Zasavju obstaja povezanost med boleznimi dihal pri otrocih in koncentracijo PM_{10}, kar kaže na to, da je v tej slovenski regiji še vedno prisotna potreba po javnozdravstvenih ukrepih v smislu*

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zmanjševanja škodljivih okoljskih dejavnikov. Dodatno lahko na podlagi rezultatov študije sklepamo, da bi bilo lahko v prihodnje v Sloveniji povezovanje okoljskih in zdravstvenih podatkov z nekaterimi izboljšavami uporabno pri ocenjevanju utemeljenih potreb za javnozdravstveno ukrepanje.

Ključne besede: onesnaženost zunanjega zraka, PM_{10}, bolezni dihal, otroci, Zasavje, študija časovnih trendov

1 INTRODUCTION

Given the scale and widespread distribution of outdoor air pollution, this negative health determinant is considered as one of the major public health concerns of today (1-8). It has been proven to be associated with a variety of adverse health outcomes, however most of the recent evidence focuses mainly on respiratory and cardiovascular effects (1, 6, 8-15). The most susceptible population group to respiratory effects of air pollution is children (16-18). One of the most important reasons is that children have a larger lung surface area per kilogram of body weight than adults and, under normal breathing, breathe in 50% more air per kilogram of body weight than adults. The other is that they have increased exposure to many air pollutants because of higher minute ventilation and higher levels of outdoor physical activity (16-20).

A variety of pollutants can be found in the outdoor air, however one of the most important is particulate matter (PM) of 10 micrometres in diameter (PM_{10}). It can penetrate deep into the bronchial tree and trigger respiratory symptoms. Several studies have consistently demonstrated an association between emergency department visits or hospital admissions due to respiratory diseases and concentration of PM_{10} (1, 6, 8). In the last decade, many studies have applied time-series methods to study the association between air pollution with PM_{10} and its health effects (21-23). These studies mostly rely on routinely available outdoor air pollution and health registry data (24). Many of them have indicated a positive association between a short-term variation in outdoor levels of PM_{10} and daily frequencies of events (e.g. primary health care visits, hospital admissions, deaths) for respiratory diseases (1, 4-6, 8).

In regards to air pollution, Slovenia is no exception. One of the most polluted areas in the country is the Zasavje region (or Zasavje) (Figure 1), which is located in the central part of the country and consists of municipalities Zagorje ob Savi (or Zagorje), Trbovlje and Hrastnik (Figure 2) (25, 26). In this region, there are three narrow valleys located more or less perpendicular to the larger Sava river valley. The main characteristics of Zasavje are coal mines and various different kinds of heavy industry (cement, glass, chemical, etc.) (Figure 2) that were established in Zasavje in the past. Among others, one of the biggest steam power plants in Slovenia is located there, having the highest chimney in Europe (25). This is due to the proximity to the source of energy and the fact that the Sava river valley with the railway line for decades represented one of main transport pathways of Slovenia. Most industrial plants considered as the largest emitters in the region are situated in the Sava river valley or at the intersection of the Zagorje, Trbovlje and Hrastnik valleys and the Sava river valley (Figure 2). Ever since the establishment, this industry has had a huge impact on the outdoor air pollution. The most important pollution in the past has been due to sulphur dioxide (SO_2) and PM_{10}. However, according to the report of the Slovenian Environmental Agency (SEA), the situation in SO_2 has greatly improved, and the national legally defined maximum values are exceeded only occasionally, while measurements of PM_{10} and ozone (O_3) levels show that they constantly exceed the national legally defined maximum values at the existing monitoring stations in Zasavje (26, 27). On the bottoms of the valleys, the temperature inversions are also frequently present in winter and autumn. Unfortunately, only few studies have studied the association between outdoor air pollution and the health of the Zasavje population in the past (28, 29). In the last few years, there have been some new studies carried out. The first study was the study of Eržen et al. (30), which indicated the association between the level of outdoor air pollution and prevalence of chronic respiratory diseases in the Zagorje municipality by using a rough assessment of level of pollution in different parts of the municipality. In the study of Kukec et al. (31), researchers upgraded these research methods with multivariate statistical analyses in all three municipalities in the Zasavje. However, further research is needed in order to bring up evidence to prove the health impact due to the environmental factors.

Figure 1. *Location of the Zasavje region in Slovenia.*
Slika 1. *Lokacija regije Zasavje v Sloveniji.*

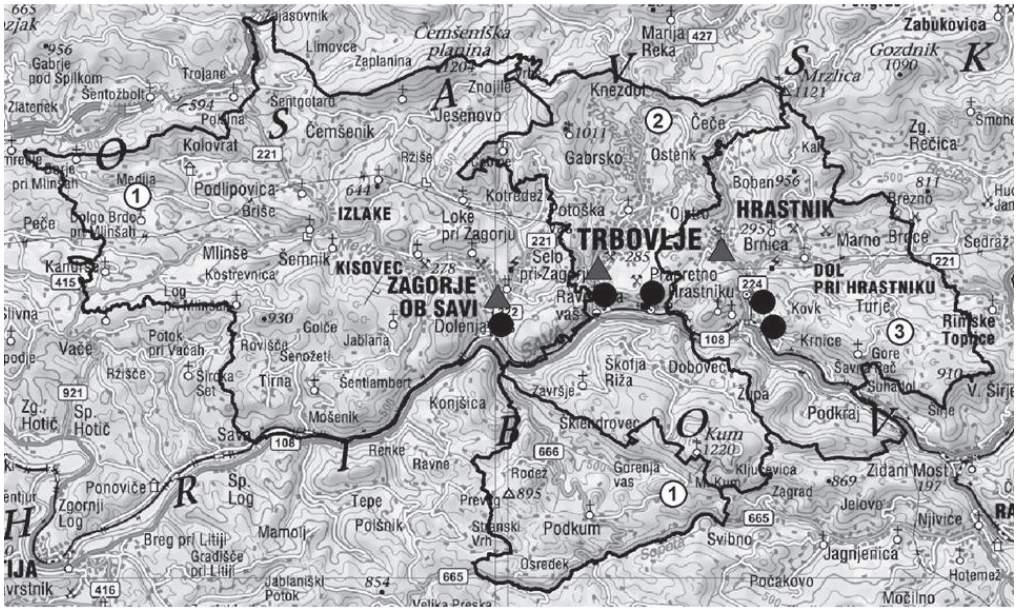

Figure 2. *Zasavje region, Slovenia, map with locations of main point sources of outdoor air pollution in the region. Legend: ① = Zagorje municipality; ② = Trbovlje municipality; ③ = Hrastnik municipality; ● = location of cement, steam power, chemical, and glass plants; ▲ = location of environmental and meteorological data measuring stations;■ = houses/settlements (font size of the settlement name indicate the rough size of the settlement).*

Slika 2. *Lokacija najpomebnejših točkovnih virov onesnaževanja zunanjega zraka v regiji Zasavje, Slovenija. Legenda: ① = občina Zagorje; ② = občina Trbovlje; ③ = občina Hrastnik; ● = lokacija kemične in cementne industrije, termoelektrarne in steklarne; ▲ = lokacija ekoloških in meteoroloških merilnih postaj; ■ = hiše/naselja (velikost črk naselja prikazuje okvirno velikost naselja)*

The so-called linkage methods for environment and health analysis were proposed more than a decade ago by the World Health Organization (WHO) (24, 32). They belong to a wider group of epidemiological methods called ecological studies – a study design in which the relationships between environment and health are studied on population level, by analysing spatial and/or temporal variations in exposure and health outcome (33-35).

The aim of our study was to assess the feasibility of linkage of existing health and environmental data in Zasavje in identifying a grounded need for public health action. The specific goal of the study was to assess the temporal association between the number of consultations in primary health care units due to respiratory diseases in children and the level of PM_{10} pollution in Zasavje. The hypothesis was that a positive temporal relationship between the daily number of first consultations for respiratory diseases and the daily concentration of PM_{10} exists in the municipalities of Zasavje. The study was part of larger project that was performed at the Chair of Public Health, Faculty of Medicine, University of Ljubljana in collaboration with environmental and health experts (36).

2 METHODS

2.1 Study design and study population

The study design was an ecological time-trend study (34). The unit of observation was a single day of the observed period. The study population consisted of all children, aged 1-11 years, residing permanently in Zasavje, who visited the Community Health Centres in (CHC) Zagorje, Trbovlje or Hrastnik due to selected respiratory diseases between 1 January 2006 and 31 December 2011 (37). Altogether, 2,191 days were observed (365 in the years 2006, 2007, 2009, 2010 and 2011 and 366 in the year 2008).

2.2 Data acquisition

2.2.1 Health data

Routinely collected health data were obtained from the health information systems of the CHCs of Zagorje, Trbovlje and Hrastnik. Daily numbers of first consultations due to the following diagnoses according to the WHO International Classification of Diseases, version 10 (ICD-10), were obtained: J00-J06 (acute upper respiratory tract infection), J10-J18 (influenza and pneumonia), J20-J22 (other acute lower respiratory tract infection), J30-J32 (other diseases of upper respiratory tract) and J40-J46 (chronic lower respiratory tract disease).

2.2.2 Environmental data

Immission data on daily PM_{10} concentrations could be obtained at three fixed measuring stations in Zasavje, located in Zagorje, Trbovlje and Hrastnik (Figure 2), which are a part of the National automated network for monitoring air quality operated by SEA. In Zagorje and Trbovlje, the data could be obtained for the entire observation period, while in Hrastnik PM_{10} measurements were only just started on 1 January 2010. Consequently, the observed period in Hrastnik only lasted between 1 January 2010 and 31 December 2011.

Immission data on other important outdoor air pollutants (co-pollutants) in Zasavje: SO_2, O_3 and nitrogen dioxide (NO_2), were obtained as well. Data on daily SO_2 and O_3 concentrations could be obtained at all the measuring stations for the entire observation period, while data on daily NO_2 concentration were only available at the Trbovlje measuring station.

Daily data on meteorological factors: air temperature and relative humidity, could be obtained at all the measuring stations for the entire observation period.

2.2.3 Data on seasonal factors

In the analysis, the following seasonal factors were considered: season of the year (spring, summer, autumn, winter), work day (yes/no), holiday (yes/no) and influenza season (yes/no). Data on influenza season were obtained from annual reports (Epidemiological surveillance of communicable diseases in Slovenia) of the National Institute of Public Health of the Republic of Slovenia (38).

2.3 Statistical analysis

2.3.1 Data description

The distributions of health and environmental data were statistically described by non-parametric typical statistical values (mean, standard deviation, minimum, maximum, 1st, 2nd and 3rd quartile). The temporal patterns of health and environmental data were presented by using sequence plots (33, 34).

2.3.2 Relationship analysis

In the relationship analysis, the daily number of first consultations for all respiratory diseases was considered as the observed outcome, daily concentration of PM_{10} (24-hr average PM_{10} concentration) as the

explanatory factor and co-pollutants (24-hr average SO_2 concentration, 8-hr maximum average O_3 concentration), and 24-hr average NO_2 concentration), meteorological and seasonal factors were considered as covariates. In all pollutants, like in other similar studies (11, 39-44), lags from zero up to five days from exposure to the consultation day (lag 0, lag 1, lag 2, lag 3, lag 4 and lag 5 days respectively) were examined to determine the amount of time between exposure and effect. The association between the observed outcome, explanatory factor and covariates was analysed using Poisson regression models (45, 46). The modelling procedure was performed in three stages. In the first stage, univariate models for lags 0-5 days were built by relating the observed outcome to only the explanatory factor. In the second stage, single-pollutant models for lags 0-5 days were built by adding the explanatory factor to a core covariate model that included seasonal (season of the year, work day/ weekend day, holiday/non-holiday day and influenza season) and meteorological factors (air temperature and relative humidity). In this stage, the best lags for the explanatory factor and co-pollutants were defined. In the third stage, multi-pollutant models were built by including best lags of the explanatory factor and co-pollutants along with the meteorological and seasonal factors. In order to achieve comparability of results for the Zagorje and Trbovlje municipalities, multi-pollutant models that only included SO_2 and O_3 as co-pollutants were built first. Afterwards, an additional model that included SO_2, O_3 and NO_2 was defined only for the Trbovlje municipality. The multi-pollutant model for the Hrastnik municipality was not defined due to the short observation time. The interpretable end result was the incidence rate ratio (IRR) (47). It was presented together with its 95% confidence interval (CI). P-value of 0.05 or less was considered as statistically significant in all the statistical tests.

All statistical analyses were carried out by using SPSS 18.0 software (SPSS Inc., Chicago, IL, USA).

The study protocol was approved by the National Medical Ethics Committee of the Republic of Slovenia.

3 RESULTS

3.1 Data description

Complete health data were available at all three Zasavje CHCs for all 2,191 days of the study period. In the Zagorje municipality, there were 128/2,191 (5.8%) days with no first consultations for all respiratory diseases, and in the municipalities of Trbovlje and Hrastnik, there were 577/2,191 (26.3%) and 685/2,191 (31.3%) such days respectively. A statistical description of the distribution of the daily number of first consultations for all respiratory diseases is presented in Table 1. Temporal patterns of the daily number of first consultations for the observed outcome are presented in Figures 3a, 4a, and 5a. In all three municipalities, the observed outcome was the highest in winter months (from December to February).

Table 1. *Descriptive statistics for the daily number of first consultations for respiratory diseases among children and environmental data in the Zasavje region, Slovenia, for 2,191 days between January 1, 2006 and December 31, 2011.*

Tabela 1. *Opisna statistika dnevnega števila prvih obiskov zaradi bolezni dihal pri otrocih in okoljskih podatkov v regiji Zasavje, Slovenija, za 2.191 dni med 1. januarjem 2006 in 31. decembrom 2011.*

			Typical value/*Tipična vrednost*				
	Mean	**SD**	**Min**	**Q_1**	**Q_2**	**Q_3**	**Max**
	Povprečje	***SD***	***Min***	***Q_1***	***Q_2***	***Q_3***	***Max***
Zagorje municipality/*Občina Zagorje*							
Number of consultations due to respiratory diseases Število *obiskov zaradi bolezni dihal*	4.99	4.0	0.0	2.0	4.0	7.0	29.0
PM_{10} 24-hr average concentration (µg/m^3) PM_{10} *24-urna povprečna koncentracija (µg/m^3)*	40.3	23.9	4.3	23.5	33.8	49.6	231.1
SO_2 24-hr average concentration (µg/m^3) SO_2 *24-urna povprečna koncentracija (µg/m^3)*	5.8	4.6	0.0	2.7	5.1	7.8	47.0
O_3 maximum 8-hr average concentration (µg/m^3) O_3 *maksimalna 8-urna povprečna koncentracija (µg/m^3)*	59.6	31.1	1.2	34.6	58.9	82.3	149.3
Temperature 24-hr average (°C) *24-urna povprečna temperatura* (°C)	11.4	8.0	-10.2	4.9	11.9	18.1	28.3
Relative humidity 24-hr average (%) *24-urna povprečna relativna vlažnost* (%)	73.4	14.6	3.0	65.7	75.1	83.9	98.4
Trbovlje municipality/*Občina Trbovlje*							
Number of consultations due to respiratory diseases Število *obiskov zaradi bolezni dihal*	4.91	4.9	0.0	0.0	4.0	8.0	33.0
PM_{10} 24-hr average concentration (µg/m^3) PM_{10} *24-urna povprečna koncentracija (µg/m^3)*	36.3	21.8	1.3	21.2	30.2	46.0	188.6
SO_2 24-hr average concentration (µg/m^3) SO_2 *24-urna povprečna koncentracija (µg/m^3)*	4.0	4.5	0.0	1.0	3.0	5.6	43.0
O_3 maximum 8-hr average concentration (µg/m^3) O_3 *maksimalna 8-urna povprečna koncentracija (µg/m^3)*	67.3	33.6	1.6	42.5	66.5	91.8	164.0
NO_2 24-hr average concentration (µg/m^3) NO_2 *24-urna povprečna koncentracija (µg/m^3)*	20.0	9.1	1.7	19.6	18.9	25.0	60.5
Temperature 24-hr average (°C) *24-urna povprečna temperatura* (°C)	11.3	8.0	-10.5	4.9	11.9	17.8	27.9
Relative humidity 24-hr average (%) *24-urna povprečna relativna vlažnost* (%)	76.8	11.7	34.2	68.7	77.7	85.7	99.2
Hrastnik municipality/*Občina Hrastnik*							
Number of consultations due to respiratory diseases Število *obiskov zaradi bolezni dihal*	2.61	3.0	0.0	0.0	2.0	4.0	23.0
PM_{10} 24-hr average concentration (µg/m^3) PM_{10} *24-urna povprečna koncentracija (µg/m^3)*	28.0	16.2	3.1	17.3	23.9	34.7	123.4
SO_2 24-hr average concentration (µg/m^3) SO_2 *24-urna povprečna koncentracija (µg/m^3)*	5.8	3.9	0.0	3.0	5.0	8.0	44.0
O_3 maximum 8-hr average concentration (µg/m^3) O_3 *maksimalna 8-urna povprečna koncentracija (µg/m^3)*	73.5	33.1	3.8	48.3	72.8	97.0	178.1

Temperature 24-hr average (°C) *24-urna povprečna temperatura* (°C)	11.1	8.0	-10.4	4.8	11.7	17.6	28.1
Relative humidity 24-hr average (%) *24-urna povprečna relativna vlažnost* (%)	76.2	11.9	34.2	67.9	76.7	85.5	99.9

Legend/*Legenda*: SD -standard deviation/*standardni odklon*; Q_1 - the first quartile/*prvi kvartil*; Q_2 -the second quartile/*drugi kvartil*; Q_3 -the third quartile/*tretji kvartil*; Min/*Min* -minimum/*najnižja vrednost*; Max/*Max* -maximun/*najvišja vrednost*; * = data available only for the period from January 1, 2010 to December 31, 2011/*podatki so dostopni le za obdobje od 1. januarja 2010 do 31. decembra 2011*

Complete data for the daily concentration of PM_{10} were available for 2,135/2,191 (97.4%) days in the Zagorje municipality, 1,985/2,191 (90.6%) days in the Trbovlje municipality, and 730/730 (100%) days in the Hrastnik municipality. Statistical description of the distribution of daily PM_{10} concentration is presented in Table 1. Temporal patterns of daily PM_{10} concentration at all three measuring stations are presented in Figures 3b, 4b, and 5b. The highest daily PM_{10} concentrations were observed in the months from November to February at all three measuring stations.

Complete data for the daily concentration of SO_2 were available for 2,080/2,191 (94.9%) days in the Zagorje municipality, 2,159/2,191 (98.5%) days in the Trbovlje municipality, and 2,132/2,191 (97.3%) days in the Hrastnik municipality. Complete data for the daily concentration of O_3 were available for 2,131/2,191 (97.3%) days in the Zagorje municipality, 2,101/2,191 (95.9%) days in the Trbovlje municipality, and 2,120/2,191 (96.7%) days in the Hrastnik municipality. Complete data for the daily concentration of NO_2 were available for 2,067/2,191 (94.3%) days in the Trbovlje municipality. Statistical description of the distribution of daily co-pollutants (SO_2, O_3 and NO_2) concentration is presented in Table 1.

Complete data for the daily meteorological factors (air temperature and relative humidity) were available for 2,189/2,191 (99.9%) days in the Zagorje municipality, 2,184/2,191 (99.7%) days in the Trbovlje municipality, and 2,170/2,191 (99.0%) days in the Hrastnik municipality. Statistical description of the distribution of daily meteorological factors is presented in Table 1. In the observed period there were in total 541/2,191 (24.7%) winter days, 552/2,191 (25.2%) spring days, 552/2,191 (25.2%) summer days and 546/2,191 (24.9%) autumn days. There were also in total 626/2,191 (28.6%) weekend days and 1,565/2,191 (71.4%) workdays. In the observed period there were in total 1,588/2,191 (72.5%) non-holiday days and 603/2,191 (27.5%) holiday days (school holidays and work-free days). Also, there were in total 1,505/2,191 (68.7%) days without an influenza epidemic and 686/2,191 (31.3%) days with an influenza epidemic.

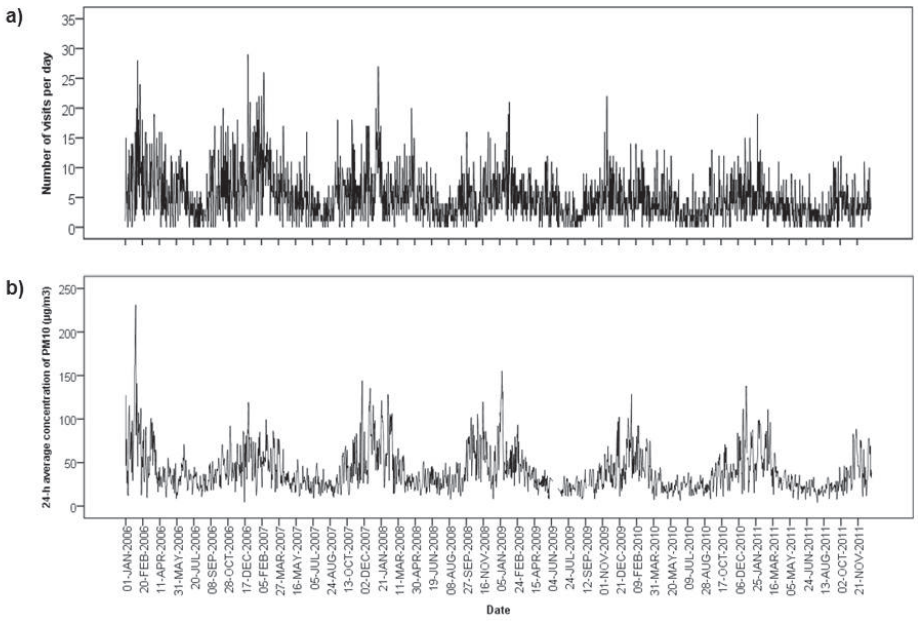

Figure 3. *Temporal pattern of: a) daily number of consultations for respiratory diseases in children, and b) daily 24-hr average concentration of PM_{10} (µg/m³) in the Zagorje municipality, Slovenia, between January 1, 2006 and December 31, 2011.*

Slika 3. *Časovno spreminjanje: a) dnevnega števila obiskov zaradi bolezni dihal pri otrocih in b) dnevne 24-urne povprečne koncentracije PM_{10} (µg/m³) v občini Zagorje, Slovenija, med 1. januarjem 2006 in 31. decembrom 2011.*

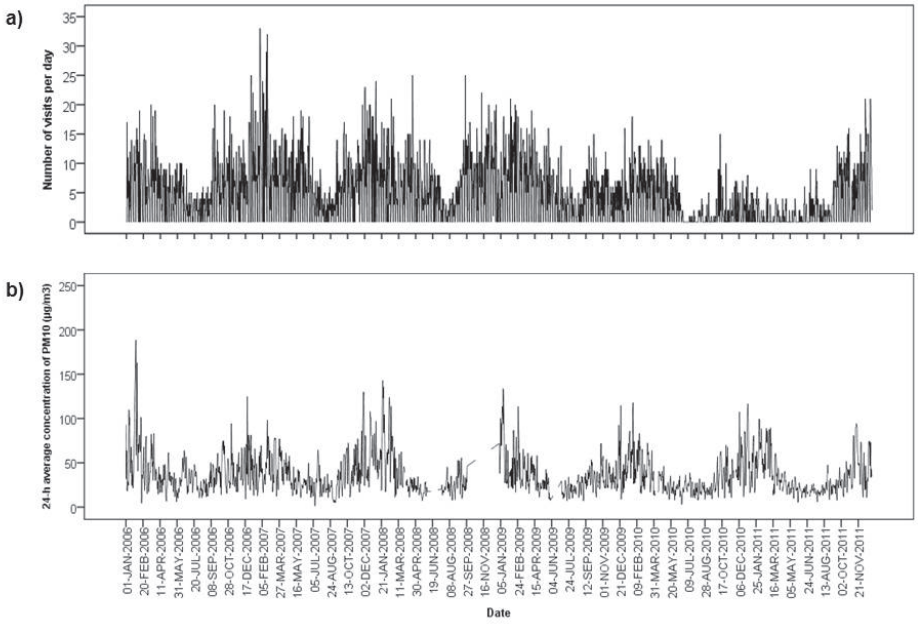

Figure 4. *Temporal pattern of: a) daily number of consultations for respiratory diseases in children, and b) daily 24-hr average concentration of PM_{10} (µg/m³) in the Trbovlje municipality, Slovenia, between January 1, 2006 and December 31, 2011.*

Slika 4. *Časovno spreminjanje: a) dnevnega števila obiskov zaradi bolezni dihal pri otrocih in b) dnevne 24-urne povprečne koncentracije PM_{10} (µg/m³) v občini Trbovlje, Slovenija, med 1. januarjem 2006 in 31. decembrom 2011.*

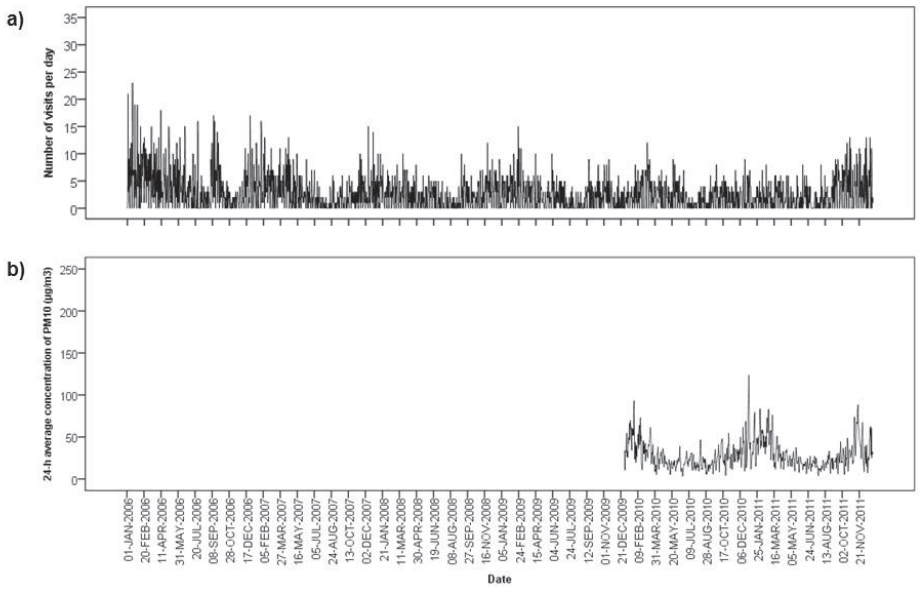

Figure 5. *Temporal pattern of: a) daily number of consultations for respiratory diseases in children, and b) daily 24-hr average concentration of PM_{10} (µg/m³) in the Hrastnik municipality, Slovenia, between January 1, 2006 and December 31, 2011.*

Slika 5. *Časovno spreminjanje: a) dnevnega števila obiskov zaradi bolezni dihal pri otrocih in b) dnevne 24-urne povprečne koncentracije PM_{10} (µg/m³) v občini Hrastnik, Slovenija, med 1. januarjem 2006 in 31. decembrom 2011.*

3.2 Relationship analysis

The results of the univariate analysis showed that the daily number of first consultations for respiratory diseases among children was statistically significantly associated with PM_{10} concentrations in all three municipalities. In all of them, the strongest association was observed in lag 0 (Zagorje municipality - IRR: 1.007, 95% CI: 1.007-1.008; p<0.001; Trbovlje municipality - IRR: 1.010, 95% CI: 1.009-1.011, p<0.001; Hrastnik municipality - IRR: 1.009, 95% CI: 1.006-1.011; p<0.001).

The results of single-pollutant multivariate models once again showed that the daily number of first consultations for respiratory diseases among children in the Zagorje and Trbovlje municipalities was statistically significantly associated with PM_{10} concentrations. In both municipalities, the strongest association was observed in lag 0 (Zagorje municipality - IRR: 1.003, 95% CI: 1.002-1.004; p<0.001; Trbovlje municipality - IRR: 1.003, 95% CI: 1.001-1.005; p<0.001). In the Hrastnik municipality, the association was no longer significant (IRR: 1.000, 95% CI: 0.995-1.005: p=0.969). The results of the multi-pollutant multivariate models with SO_2 and O_3 included as co-pollutants showed that daily number of first consultations for respiratory diseases among children was still significantly associated with PM_{10} concentrations in both the Zagorje and Trbovlje municipalities. The detailed results are presented in Table 2. The results for co-pollutants are presented in the same table as well. In the Trbovlje municipality, the results didn't change much after the inclusion of NO_2 as an additional co-pollutant in the model (IRR: 1.004, 95% CI: 1.002-1.006, p=0.001).

Table 2. *Results of the Poisson regression analysis of association between consultations for respiratory diseases and PM_{10} concentration, controlling for selected covariates between January 1, 2006 and December 31, 2011 in the Zasavje region, Slovenia ($N_{days\ Zagorje}$=1.996); ($N_{days\ Trbovlje}$=1.927).*

Tabela 2. *Rezultati Poissonove regresijske analize povezanosti med obiski zaradi bolezni dihal in PM_{10} standardizirano na izbrane pojasnjevalne dejavnike med 1. januarjem 2006 in 31. decembrom 2011 v regiji Zasavje, Slovenija ($N_{dni\ Zagorje}$=1.996); ($N_{dni\ Trbovlje}$=1.927).*

Explanatory factor/Covariates ***Pojasnjevalni dejavnik/Sopojavi***		**IRR** ***RIS***	**95% CI limits for IRR** ***95 % IZ za RIS*** **Lower** ***Spodnji***	**Upper** ***Zgornji***	**p** ***p***
Zagorje municipality/*Občina Zagorje*					
PM_{10} 24-hr average concentration (µg/m³)		1.003	1.002	1.004	<0.001
PM_{10} *24-urna povprečna koncentracija (µg/m³)*					
SO_2 24-hr average concentration (µg/m³)		0.983	0.976	0.989	<0.001
SO_2 *24-urna povprečna koncentracija (µg/m³)*					
O_3 maximum 8-hr average concentration (µg/m³)		1.002	1.001	1.004	0.003
O_3 *maksimalna 8-urna povprečna koncentracija (µg/m³)*					
Temperature 24-hr average (°C)		0.998	0.991	1.005	0.633
24-urna povprečna temperatura (°C)					
Relative humidity 24-hr average (%)		1.003	1.001	1.005	0.014
24-urna povprečna relativna vlažnost (%)					
Season of the year	Summer/*Poletje*	1.000			
Letni čas	Winter/*Zima*	1.732	1.478	2.030	<0.001
	Spring/*Pomlad*	1.111	1.039	1.188	0.002
	Autumn/*Jesen*	1.092	1.057	1.128	<0.001
Work day	No/*Ne*	1.000			
Delovni dan	*Yes/Da*	2.297	2.125	2.486	<0.001
Holiday	No/*Ne*	1.000			
Počitnice	Yes/*Da*	0.739	0.674	0.809	<0.001
Influenza season	No/*Ne*	1.000			
Sezona gripe	Yes/*Da*	1.260	1.160	1.369	<0.001
Trbovlje municipality/*Občina Trbovlje*					
PM_{10} 24-hr average concentration (µg/m³)		1.004	1.002	1.006	<0.001
PM_{10} *24-urna povprečna koncentracija (µg/m³)*					
SO_2 24-hr average concentration (µg/m³)		0.986	0.977	0.995	0.002
SO_2 *24-urna povprečna koncentracija (µg/m³)*					
O_3 maximum 8-hr average concentration (µg/m³)		0.998	0.996	1.001	0.180
O_3 *maksimalna 8-urna povprečna koncentracija (µg/m³)*					
Temperature 24-hr average (°C)		1.004	0.995	1.014	0.370
24-urna povprečna temperatura (°C)					
Relative humidity 24-hr average (%)		0.996	0.992	1.001	0.132
24-urna povprečna relativna vlažnost (%)					
Season of the year	Summer/*Poletje*	1.000			
Letni čas	Winter/*Zima*	1.805	1.474	2.212	<0.001
	Spring/*Pomlad*	1.207	1.107	1.316	<0.001
	Autumn/*Jesen*	1.100	1.054	1.148	<0.001
Work day	No/*Ne*	1.000			
Delovni dan	Yes/*Da*	5.103	4.436	5.903	<0.001
Holiday	No/*Ne*	1.000			
Počitnice	Yes/*Da*	0.641	0.566	0.724	<0.001
Influenza season	No/*Ne*	1.000			
Sezona gripe	Yes/*Da*	1.148	1.032	1.278	0.012

Abbreviations/okrajšave: IRR/*RIS* – incident rate ratio/*razmerje incidenčnih stopenj*; CI/*IZ* – confidence interval/ *interval zaupanja*; N – number of days/število dni

4 DISCUSSION

The main results of our study have consistently showed that in the Zagorje and Trbovlje municipalities the daily number of first consultations for respiratory diseases among children was significantly associated with the daily concentration of PM_{10}. Only in the Hrastnik municipality was a significant association not observed in all models. This result is clearly in relation to the much shorter time series in this municipality compared to the other two municipalities in Zasavje. The hypothesis that a positive temporal relationship exists between the daily number of first consultations for respiratory diseases and the daily concentration of PM_{10} was thus certainly confirmed in the Zagorje and Trbovlje municipalities. Moreover, these results are consistent with the results of many similar studies (23, 48-50) that also confirmed the positive association between respiratory diseases and PM_{10} concentration.

Our study, in addition to the main results, also provides some additional findings. For example, in the Zagorje municipality, the daily number of first consultations for respiratory diseases among children was also significantly associated with the daily O_3 concentrations. Since the dynamics of this pollutant differ from the PM_{10} dynamics, it would be useful to analyse this problem in depth in a separate study.

Our study has some potential limitations. First, when assessing the usefulness of environmental data for Zasavje as the input data for time-trend studies, we encountered some problems. The results of our study namely showed that all observed pollutants lacked a certain percentage of the measurement. The SEA provided an oral explanation that this was mainly due to the calibration of instruments or filter blockage of the measuring device but certainly not a deliberate shutdown of instrumentation. For the present study, the biggest problem was the lack of PM_{10} data in the Hrastnik municipality. In this municipality, SEA only started with continuous measurements of 24-hr concentrations of PM_{10} from 2010 onwards (26), however it is still not clear whether or not the measurements will continue to be implemented in the future (51-53). An additional problem related to PM_{10} measurements, which must be stressed at this point, is that for now in Slovenia only concentrations of PM_{10} are routinely measured, while concentration of $PM_{2.5}$ are only measured at three locations (Biotechnical Faculty, Ljubljana, Maribor and Maribor centre Vrbanski plateau) (26). Furthermore, the chemical composition of PM_{10} is provided only in individual cases (27). However, these data are crucial for unbiased estimates of the health impact due to the environmental factors. PM_{10} can vary significantly and thus also have different effects on human health. Second, we have to take into account the potential problem with health data that was observed in the larger project that our study was a part of (36). In this project, the usefulness of health data for Zasavje as input data for time-trend studies was assessed, and some potential problems were encountered (36). On one side, there were no problems with the completeness of data collection - at all Zasavje CHCs, data for all days of the observed 6-year period were available. On the other side, certain ambiguities related to the outcome variable were encountered. In the Zagorje municipality, compared to the Trbovlje or Hrastnik municipalities, 1.3 to 1.4 times higher numbers of days were detected with at least one consultation due to respiratory diseases, among which acute respiratory diseases dominated (36). The project assumed that there may be a difference in the encoding of individual diagnoses. However, this problem could only be confirmed if time-trend studies of larger dimensions would be carried out in Slovenia. According to our knowledge, only two studies similar to ours were carried out in Slovenia so far. In both, the researchers observed the association between O_3 concentrations and the number of consultations due to respiratory diseases at CHCs. The first was carried out in the Nova Gorica (54, 55) and the second one in the Koper municipality (56). In both studies, only the data obtained at one CHC were analysed. As a result, the problems that surfaced in our study could not be observed. Third, a potential limitation could be that in our study the association between the observed outcome and explanatory factors was adjusted for covariates that were available in the frame of routinely collected data by SEA in Zasavje. However, we considered most of the generally recommended covariates in similar studies (50, 57, 58). Unfortunately, we could not take confounding factors such as the concentration of pollen into account, because the concentration of pollen is not monitored in the Zasavje region.

On the other hand, this study has several strengths. First, it is still one of the first and few such studies that actually need to become routine in monitoring the health of the population in relation to air pollution. Second, the results of the study indicate a positive association between PM_{10} concentration and the daily number of first consultations for all respiratory diseases among children in Zasavje. Consequently, the study provides important information for further work in the field of public health activities, especially the implementation of environmental health promotion activities in the region. While there has been much done in the Zasavje region

in recent years in the sense of reduction of some air pollutants (for example installation of filter systems to reduce SO_2 emissions in the local cement and steam power plants), some problems still remain. The biggest problem at the moment is certainly the outdoor air pollution with PM_{10}, but the results of our study also indicate a problem of the outdoor air pollution with O_3. Here, new problems related to the chemical composition of PM_{10}, in which a lot of invisible hazards could be hidden, are posing along the old problems related to PM_{10} concentrations. Another important strength of our study is that it showed important deficiencies in the currently available input data for studies that integrate routinely collected health and environmental data in Slovenia. These deficiencies could be eliminated to a large extent and consequently make these kinds of studies in Slovenia more viable and useful in the field of health policy (59).

All issues arising during our study represent a new challenge for future research in the field of linkage of environmental and health data in Slovenia. Since this kind of research is in the beginning stages, there is a lot that has to be done. Although we now have some knowledge in the use of linkage methods for environment and health (24, 32), we first need to make the routinely collected data in both information systems - health and environment – more reliable. Although there will be a lot of difficulties in solving these problems, especially since changes in legislation should be addressed in this process, they are not unsolvable. Certainly, the multidisciplinary approach would be the most appropriate and successful.

5 CONCLUSIONS

In conclusion, we found positive correlation between concentrations of PM_{10} and the daily number of first consultations for all respiratory diseases among children in the Zagorje and Trbovlje municipalities. On the basis of these results, it can be assumed that with some improvements (at least a uniform method to collect health-related data, more air pollution measuring sites in the more polluted areas and more detailed geographical studies), linkage of existing health and environmental data in Zasavje could be feasible in identifying a grounded need for public health action.

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KLOPNI MENINGOENCEFALITIS V SLOVENIJI (1953-2013): OB 60-LETNICI POJAVA

TICK-BORNE ENCEPHALITIS IN SLOVENIA (1953-2013): THE 60TH ANNIVERSARY

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Izvirni znanstveni članek
UDK 614:616.9(497.4)

Izvleček

Uvod: *Leta 2013 mineva 60 let od izolacije virusa klopnega meningoencefalitisa (KME) v Sloveniji. Od takrat se slovenski infektologi, epidemiologi, virologi in drugi strokovnjaki strokovno in znanstvenoraziskovalno ukvarjajo s proučevanjem KME.*
Metode: *Ob jubileju so s historiografskimi metodami analizirali objave skozi ta čas in pripravili retrospektivno študijo pojavljanja te bolezni pri nas.*
Rezultati: *V nekaterih delih Slovenije se je v letih po drugi svetovni vojni začela pojavljati bolezen osrednjega živčevja, ki je do tedaj niso poznali. Leta 1953 so Milko Bedjanič in Slava Rus, oba infektologa, ter virologinja Jelka Vesenjak Zmijanac z osamitvijo virusa iz krvi bolnice dokazali, da je ta bolezen KME. Virologi so v naslednjih letih proučevali povzročitelja KME; številni epidemiologi so raziskovali njegove epidemiološke značilnost, entomologi in ornitologi ekosisteme arbovirusnih okužb, infektologi klinične in laboratorijske značilnosti okužb in potek okužb ter morebitne posledice bolezni. Mikrobiologi so izpopolnjevali možnosti diagnostike te okužbe. Razvili so tudi uspešno cepivo in zakonsko so določene skupine, ki se morajo obvezno cepiti.*
Zaključki: *Bolezen se je pri Slovencih ustalila kot endemski tip KME, ki jo kliniki sicer dobro obvladujejo, a je skupen trud epidemiologov in javnega zdravja usmerjen v zvišanje precepljenosti proti KME, saj je v Sloveniji ta odstotek zelo nizek in se bolezen še vedno prekomerno pojavlja.*

Ključne besede: klopni meningoencefalitis, izolacija virusa, retrospekivna študija, Slovenija, 1953–2013, zgodovina medicine

Original scientific article
UDC 614:616.9(497.4)

Abstract

Introduction: *In the year 2013, we are celebrating the 60th anniversary of the isolation of the tick-borne encephalitis virus (TBE) in Slovenia. Ever since its isolation, Slovenian infectologists, epidemiologists, virologists and other experts have been researching this disease.*
Methods: *For this anniversary, we have historiographically analysed all qualified articles from this period and prepared a retrospective study of the appearance of the disease in Slovenia.*
Results: *In certain parts of Slovenia, in the years following the Second World War, there was an increased presence of previously unknown diseases of the central nervous system. In 1953, Milko Bedjanič, Slava Rus and Jelka Vesenjak Zmijanac isolated a virus in the blood and thereby proved that the disease was indeed TBE. In the years that followed, virologists studied the cause of TBE, many epidemiologists researched its epidemic characteristics, entomologists and ornithologists studied the ecosystems of arboviral infections and infectologists studied the clinical and laboratory features of infections and the course of the disease as well as its possible consequences. Microbiologists perfected the technique of diagnosing this infection. They developed a vaccine and selected the groups that were legally obliged to be vaccinated.*
Conclusion: *the disease has stabilised as an endemic type of TBE that clinicians can control, but the common effort of epidemiologists and the public health service directed towards vaccinating people against this disease has*

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not been very successful and the disease is still too common.

Key words: tick-borne encephalitis, virus isolation, retrospective studies, Slovenia, 1953-2013, history of medicine

1 UVOD

Klopni meningoencefalitis je bolezen, ki jo je prvič leta 1931 opisal avstrijski zdravnik Schneider (1). Etiologija bolezni je ostala nepojasnjena do leta 1937. Takrat je ekipi ruskih znanstvenikov na vzhodu Sibirije uspelo dokazati, da bolezen povzroča virus (2). Pred šestdesetimi leti, leta 1953, so infektologa Milko Bedjanič in Slava Rus ter virologinja Jelka Vesenjak Zmijanac z osamitvijo virusa iz krvi bolnice dokazali, da je bolezen osrednjega živčevja, ki se je začela pojavljati v nekaterih delih Slovenije po drugi svetovni vojni in ki je do tedaj niso poznali, klopni meningoencefalitis (KME).

2 METODE DELA

Retrospektivno študijo smo pripravili s historiografsko analizo različnih medicinskih, epidemioloških in javnozdravstvenih člankov in zapisov, ki z znanstvenim instrumentarijem popisujejo pojav bolezni, podobne seroznemu meningitisu, ki je v začetku petdesetih let 20. stoletja v nekaterih delih Slovenije dobila endemske razsežnosti in so jo strokovnjaki postopoma identificirali za endemski tip klopnega meningoencefalitisa. Opravili smo tudi intervjuje z nekaterimi sopotniki proučevanja KME.

3 REZULTATI

3.1 Prva epidemija meningoencefalitisa pri Slovencih in izolacija virusa

Leta 1953 je izbruhnila velika epidemija obolenj, katerih klinična diagnoza je bila meningoencefalitis. Zboleli in prijavljeni so bili 304 primeri. Infektologinja Slava Rus je na infekcijski kliniki zdravila večje število teh bolnikov, predvsem žensk, ki so bile vse doma iz Kamnika in okolice in ki so vse navajale vbod klopa. Skupaj z Milkom Bedjaničem (Slika 1) sta domnevala, da gre za virusno obolenje osrednjega živčevja in da klop prenaša ta virus (3–5). Njuna domneva je bila pravilna in še isto leto je Jelki Vesenjak Zmijanac s sodelavci uspela izolacija povzročitelja, virusa KME (KMEV), iz krvi bolnice v prvi fazi bolezni (6). Leta 1955 je virolog Miha Likar (1923–2010) (Slika 2) izoliral virus iz klopa vrste *Ixodes ricinus*. (7) Z reakcijo nevtralizacije je bilo ugotovljeno (8), da je izolirani virus zelo soroden virusu rusko spomladansko-poletnega encefalitisa. Poznejše raziskave so potrdile, da je v Sloveniji prisoten evropski podtip KMEV (9).

Slika 1. Infektolog akad. prof. dr. Milko Bedjanič, dr. med. (1904–1976) (fotoarhiv Inštituta za zgodovino medicine MF UL).

Figure 1. Infectologist Academician Milko Bedjanič (1904–1976) (photo archive of the Institute for the History of Medicine Faculty of Medicine University Ljubljana).

Slika 2. *Virolog prof. dr. Miha Likar, dr. med. (1923–2010) (fotoarhiv Inštituta za zgodovino medicine MF UL).*

Figure 2. *Virologist Professor Miha Likar (1923–2010) (photo archive of the Institute for the History of Medicine Faculty of Medicine University Ljubljana).*

3.2 Razširjenost KME po svetu

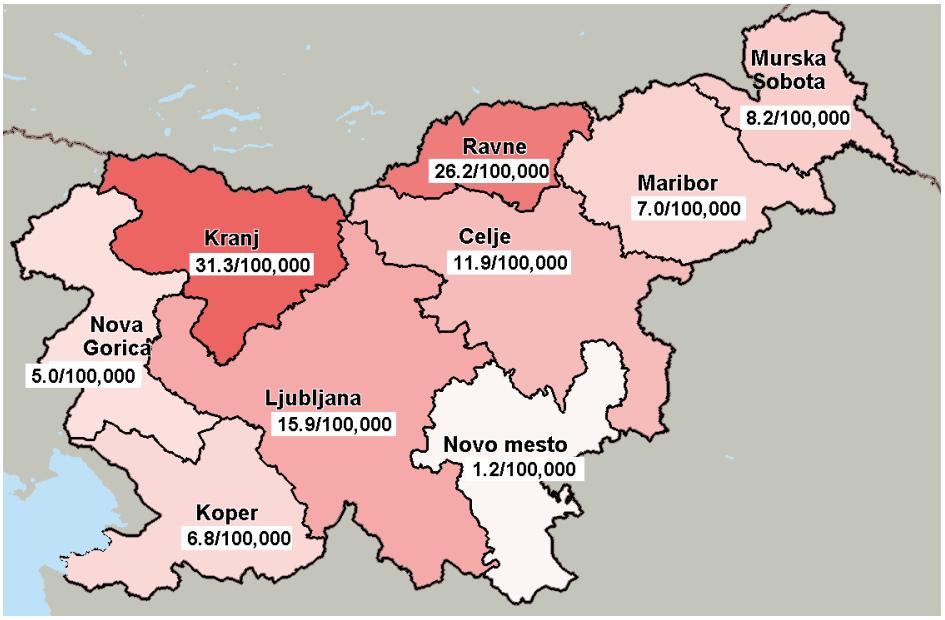
V Evropi je KME endemičen v določenih območjih severne, osrednje, južne in vzhodne Evrope, v Skandinaviji, v državah nekdanje Sovjetske zveze in Daljnega vzhoda. Število prijavljenih primerov se je v zadnjih 30 letih močno povečalo. Primerjava obdobij 1976–1989 in 1990–2007 kaže, da se je število obolelih v Evropi in Rusiji povečalo za približno 300 %, samo v Evropi za več kot 190 % (10–12).
Deloma to pripisujejo podnebnim spremembam, ki pripomorejo k izboljšanju življenjskih pogojev za klope in njihove gostitelje. Pri povišanju pojavnosti obolelih so pomembni tudi socialno-ekonomski dejavniki.

3.3 Značilnosti KME

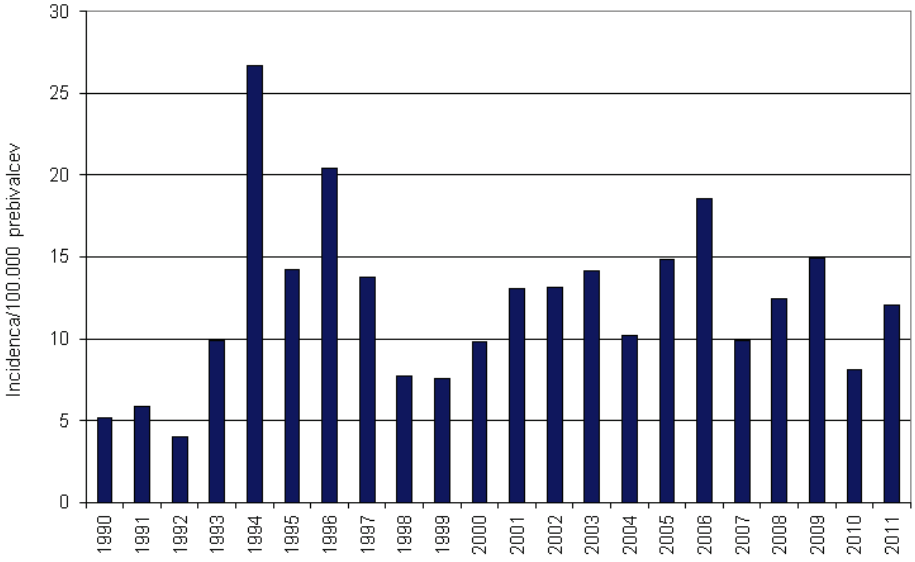
Slovenski epidemiologi dr. Janez Kmet (Slika 3) in drugi so že leta 1954 začeli raziskovati epidemiološke značilnosti KME (13). Identificirali so endemično območje KME, ki je pri nas zemljepisno omejeno in se do pred desetimi leti ni bistveno spreminjalo in povečevalo (14–16), v zadnjih letih pa se širi (17). Omejimo ga lahko s črto, ki poteka od Jesenic čez Škofjo Loko in Postojno do Kočevja, nato proti Litiji in prek Zidanega Mosta ter mimo Celja in Šentjurja na Hrvaško.

Slika 3. *Epidemiolog dr. Janez Kmet, dr. med. (1916–2003) (iz zasebne zbirke družine Kmet).*
Figure 3. *Epidemiologist Dr Janez Kmet (1916–2003) (from the private collection of a family Kmet).*

Največje pojavljanje bolezni je bilo v zadnjih letih na območjih Gorenjske in Koroške pa tudi v ljubljanski regiji; manjše je pojavljanje v koprski, goriški, murskosoboški in v novomeški regiji (18) (Slika 4). Občasni primeri se pojavljajo tudi zunaj znanih endemičnih žarišč. S povprečno stopnjo pojavnosti 18,4 v časovnem obdobju 1960–1966, 7,9 v obdobju 1985–1993 (14) in v zadnjih letih 13,1 na 100.000 prebivalcev sodi Slovenija v sam evropski vrh (18) (Slika 5).



Slika 4. *Povprečne letne prijavne incidenčne stopnje klopnega meningoencefalitisa po zdravstvenih regijah, med leti 2000 in 2009 (z dovoljenjem avtorice M. Grgič-Vitek po ref. 18).*
Figure 4. *Average annual filing TBE incidence rates by health region, between 2000 and 2009 (with the permission of the author M. Grgič-Vitek cited in ref. 18).*



Slika 5. *Prijavne incidenčne stopnje klopnega meningoencefalitisa v Sloveniji med leti 1990 in 2010 (z dovoljenjem avtorice M. Grgič-Vitek povzeto po ref. 17).*

Figure 5. *Registration TBE incidence rates in Slovenia between 1990 and 2010 (with the permission of the author M. Grgič-Vitek cited in ref. 17).*

Tudi stopnja prekuženosti prebivalstva na endemičnih območjih je zelo različna. V nekaterih delih je zelo visoka, tudi do 30- in celo do 80-odstotna (19).

Število obolelih pri nas iz leta v leto niha. Pojavljanje obolenj je odvisno od vremenskih dejavnikov, ki pomembno vplivajo na biološko aktivnost klopa in na številčnost populacije majhnih gozdnih sesalcev. V Sloveniji je vsako leto prijavljenih približno 250–300 primerov KME (13, 17, 18).

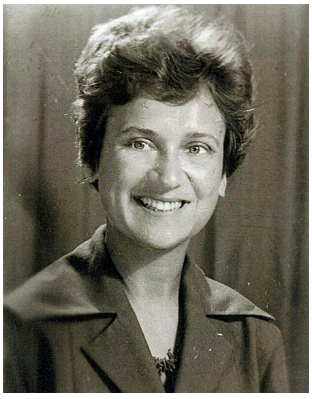
KME se pojavlja sezonsko, med aprilom in novembrom, kar je povezano z biološko aktivnostjo klopov vrste *I. ricinus*, ki ima vrh v mesecih juniju in juliju ter drugega jeseni – septembra in oktobra. Temu z zamikom od 3 do 4 tednov sledi tudi sezonsko pojavljanje okužb s KMEV z vrhoma v juniju in (ali) juliju (14).

V zadnjih letih opažajo, da oboleva vedno več starejših oseb. Obolevnost je najvišja v starostni skupini 55–64 let, tudi deleži obolelih so najvišji v starostni skupini 45–64 let (17). Moški obolevajo pogosteje kot ženske. Največje tveganje za okužbo je pri ljudeh, ki se začasno ali stalno zadržujejo na endemičnih območjih. Med take skupine spadajo predvsem delavci v gozdnem gospodarstvu, lesnih podjetjih, lesnopredelovalni industriji in v gradbeništvu. Tveganje obstaja tudi pri kmečkih delavcih, če so njihova polja blizu gozdov, ki so naravna žarišča bolezni, ali so sredi njih. Opazno je tudi veliko obolelih med ljudmi, ki hodijo v gozd zaradi rekreacije, nabiranja gozdnih sadežev itn.

Nedavna epidemiološka raziskava je predstavila nekatere dodatne in zanimive podatke, ki jih epidemiologi običajno ne objavljajo. Vprašalnik o poteku KME je bil poslan 2.779 osebam, ki so prebolele dokazano okužbo z KMEV. Odgovorilo je 69,5 % vprašanih. Avtorici sta ugotovili, da je imela večina bolnikov več vbodov klopov, da so imeli moški vbode predvsem na hrbtu, ženske na nogah, otroci do predšolskega obdobja pa na glavi in vratu, da je skoraj četrtina (23,5 %) imela klopa prisesanega manj kot 6 ur, da sta 2/3 obolelih uporabljali nekatere profilaktične ukrepe, predvsem pregledovanje telesa in odstranjevanje prisesanega klopa, manj jih je uporabljalo repelente, in da je KMEV prisoten v vseh zemljepisnih delih. Največ obolelih je bilo iz severnih in osrednjih delov Slovenije (20).

3.4 Sistematika in ekologija trdih klopov

Danica Tovornik (1927–2012) (Slika 6), začetnica medicinske entomologije v Sloveniji, je neposredno po osamitvi virusa KME iz klopov začela raziskovati sistematiko in ekologijo trdih klopov ter ugotavljati njihove številne in raznolike vretenčarske gostitelje v Sloveniji in tudi širše na ozemlju nekdanje Jugoslavije.



Slika 6. *Biologinja dr. Danica Tovornik (1927–2012) (vir: Wikipedija).*
Figure 6. *Biologist Dr Danica Tovornik (1927–2012) (source: Wikipedia).*

Samica klopa meri od 3 do 4 mm, samec 2,5 mm. Samica izleže od 500 do 800 jajčec; iz njih se po določenem času razvijejo larve, te se prelevijo v nimfe, te pa v odrasle klope. Vsaka razvojna oblika mora enkrat sesati kri, da se lahko razvije v višjo obliko. Tudi samica izleže jajčeca šele po tem, ko se je napila krvi. Samci navadno ne sesajo krvi, ampak na gostitelju popijejo le nekaj tkivne tekočine. Celotni razvojni krog klopa lahko traja do 8 let, povprečno pa od 2 do 4 let. Klop lahko prezimi v vseh razvojnih obdobjih, če temperatura ni nižja od 0 ^{0}C. Potrebuje tudi ustrezno vlago v zraku (9).
KMEV se med klopi prenaša vertikalno. Prenaša se spolno (z okuženega samca na samico), transovarialno (s samice na jajčeca) in transstadialno (z larve na nimfo in z nje na odraslo žival). Navadno se larve in nimfe okužijo z virusom med sesanjem krvi živali, ki je v obdobju viremije, in ga nato kot nimfe in odrasle živali prenesejo na druga živa bitja, katerih kri sesajo. Velik delež klopov se okuži med sočasnim hranjenjem okuženih in neokuženih klopov na neviremičnem gostitelju. Domače hlevske živali (govedo, konji in ovce) razvijejo viremijo in izločajo virus v mleku, ki se lahko prenese na njihove potomce in tudi na človeka. Način prenosa z mlekom je zelo redek (9).
Virus se v klopu razmnoži in se naseli v vseh njegovih organih. V klopu ne povzroča bolezenskih sprememb, klop pa ostane nosilec virusa vse življenje (9, 21–22).
V Sloveniji živijo klopi v gozdnih kompleksih z značilnimi ekološkimi pogoji. V takih delih se ljudje najlažje okužijo in jih označujemo kot naravna žarišča KME.
Klop za svoj razvoj potrebuje primerno okolje: sesalce, ptiče in plazilce, ki so njegovi gostitelji v vseh razvojnih oblikah. Klopi živijo na določenih mestih v gozdu, kjer je ugodna sestava tal in rastlinstva. Klop vrste *I. ricinus* ima več kot 100 različnih gostiteljev. Najpomembnejša sta gozdna voluharica in rumenogrla gozdna miš. V Sloveniji je rumenogrla miš (*Apodemus flavicolis*) primarni gostitelj KMEV. Pri miši traja obdobje viremije daljši čas. Človek ni pomemben niti kot gostitelj klopa niti kot vir njegove okužbe. Pri njem se kroženje virusa konča (9, 21–23).
Analiza genetskih značilnosti virusov klopnega meningoencefalitisa, ki je bila narejena z neposrednim sekveniranjem vzorcev bolnikov, klopov in glodavcev, je pokazala precejšnjo heterogenost virusov in da se virusi z enakimi genetskimi karakteristikami kopičijo zemljepisno, ne pa glede na gostitelja. Posebna vrednost raziskave je vpogled v veliko (do zdaj največje) število virusov, pridobljenih iz krvi bolnikov s KME (24).
V naravnih žariščih je stopnja okuženosti klopov od 0,1- do 5-odstotna in niha glede na endemsko območje. V Sloveniji ni natančnih podatkov o deležu s KMEV okuženih klopov. Ocenjujejo, da je v endemskih delih okužen približno vsak tisoči klop (21–22). V nedavni slovenski raziskavi pa so ugotovili, da je bilo s KMEV okuženih 0,47 % pregledanih klopov (25).
Infektologi so v številnih kliničnih raziskavah ugotovili, da se človek okuži na več načinov: z vbodom odraslega okuženega klopa ali katere izmed njegovih razvojnih oblik, z uživanjem okuženega mleka – kozjega, ovčjega, kravjega – in mlečnih proizvodov, ki se pripravljajo iz neprekuhanega ali nepasteriziranega mleka. V koroški regiji je bilo v letu 2012 nekaj primerov (3) prenosa KMEV s kozjim mlekom (26).
Mogoča je tudi laboratorijska okužba.

3.5 Patogeneza

Patogeneza KME je podobna veliko drugim virusnim okužbam. Virus se razmnožuje na mestu vboda klopa (ali v črevesni sluznici, če virus zaužijemo), nato se razširi v lokalno in sistemsko mezgovnično tkivo. Na vstopnem mestu v dendritičnih celicah kože se virus KME razmnožuje, razširi se v bližnje bezgavke, pride v limfo, nato v kri in s krvjo v razne organe. S krvjo pride virus v endotelne celice možganskih kapilar in vstopi v parenhim možganov. Nekateri domnevajo, da virus lahko pride v osrednje živčevje po živčni poti iz okuženih perifernih živcev ali z okužbo dovzetnih vohalnih živcev. Pri razvoju bolezni pa zelo verjetno sodelujejo tudi imunopatološki mehanizmi (27–28).
Že v šestdesetih letih prejšnjega stoletja so infektologi natančno opisali simptome in znake okužbe s KMEV, značilni klinični potek bolezni, posledice po preboleli bolezni in značilne laboratorijske preiskave; virologi pa so razvili različne diagnostične metode za dokazovanje okužbe.

Okužba s KMEV lahko poteka brez simptomov ali kot lahka vročinska bolezen z neznačilnimi kliničnimi znaki. Menijo, da je pri dveh tretjinah okuženih okužba neopazna. Seroepidemiološke študije KMEV v endemičnih delih Evrope in tudi pri nas dokazujejo, da se pojavljajo asimptomatske infekcije oz. abortivne infekcije s KMEV (29).

3.6 Klinična slika

Inkubacija KME je navadno od 7 do 14 dni (od 2 do 28 dni). Bolezen poteka v več kot dveh tretjinah dvofazno. Prvo obdobje je posledica viremije in poteka z neznačilnimi in gripi podobnimi simptomi. Prvi fazi sledi prosto obdobje, ki traja od 1 do 20 dni. Drugo obdobje bolezni se kaže z znaki prizadetosti osrednjega živčevja. Klinične oblike so odvisne od stopnje in lokalizacije prizadetosti osrednjega živčevja.

Bolezen poteka kot *meningitis*, ki se kaže z vročino, glavobolom, z bruhanjem, ali kot *encefalitis,* ki se pridruži meningitisu in se kaže z zaspanostjo, s tremorjem rok in ali jezika, lahko tudi s hujšimi motnjami zavesti, govora, z vedenjskimi motnjami in motnjami ravnotežja ter motnjami v delovanju vegetativnega živčevja. Žariščni encefalitis z znaki lateralizacije, parezami, lokalnimi ali z generaliziranimi krči so redke pojavne oblik KME.

Bolezen lahko poteka kot *meningoencefalomielits,* ki se kaže z ohlapnimi parezami in ohromitvami različnih mišičnih skupin, predvsem mišic ramenskega obroča in predela kolkov ter proksimalnih mišic zgornjih in spodnjih udov. Pareze se pojavljajo asimetrično. Motenj v senzibiliteti ni. Posebno nevarna je bulbarna oblika, zlasti če sta prizadeta vazomotorni in dihalni center. KME lahko poteka tudi kot *meningoencefaloradikulitis,* ki se kaže s simptomi in z znaki meningoencefalitisa z znaki prizadetosti in vnetja hrbteničnih živcev. KMEV lahko okvari obrazni živec po perifernem tipu, ki ga spremlja radikularna bolečina (30).

Mogoča je tudi oralna okužba s KMEV. Potek bolezni po zaužitju okuženega mleka se nekoliko razlikuje od poteka bolezni po vbodu klopa. Inkubacijska doba je krajša, traja 2 do 3 dni. Potek je dvofazen. Kratki neznačilni in gripi podobni vročinski bolezni sledi prosto obdobje. Čez 6–10 dni sledi druga faza bolezni, ki se kaže s kliničnimi simptomi in z znaki meningitisa pa tudi encefalitisa. Parez pri tej obliki niso opazili. Ozdravljenje je popolno, brez trajnih posledic (31–32).

Virus prizadene tudi miokard, jetra in druge organe. Na srcu povzroča miokarditis, ki se klinično kaže z motnjami srčnega ritma (5, 16, 27–28, 33).

Med viremijo v krvni sliki laboratorijsko ugotovijo levkopenijo (5, 16, 27–28), trombocitopenijo in včasih nenormalne jetrne funkcijske teste (34). Ko se KMEV razseje po osrednjem živčevju, je v likvorju povečana koncentracija limfocitov in beljakovin. V periferni krvi je lahko navzoča zmerna levkocitoza, prevladujejo mononuklearne celice. Hitrost sedimentacije eritrocitov je normalna. V elektrokardiogramu so lahko prisotne spremembe. Elektroencefalogram pri nekaterih bolnikih pokaže žariščne ali difuzne spremembe (28, 35).

3.7 Prospektivna študija

Zelo pomembna je bila prospektivna klinično-epidemiološka multicentrična raziskava o KME v Sloveniji v letu 1994, ki je obravnavala 492 bolnikov. V študiji je sodelovalo vseh osem slovenskih infekcijskih oddelkov. Raziskava je ugotovila, da je pri slovenskih bolnikih prizadetost osrednjega živčevja potekala kot meningitis (pri 35,8 % bolnikov), meningoencefalitis (pri 59,8 % bolnikov), meningoencefalomielitis (pri 3 % bolnikov) ali meningoencefaloradikulitis (pri 1,4 % bolnikov) in da je 73,9 % bolnikov ozdravelo brez posledic, 25,9 % jih je imelo še po šestih mesecih težave, najpogosteje glavobol (22,6 %), utrujenost (21,7 %), motnje koncentracije (15,2 %), različne bolečine (11,2 %), tremor prstov rok (10,2 %) in znojenje (5,5 %) (28). Raziskava je dokazala tudi statistično značilno povezavo med starostjo bolnikov in resnostjo bolezni; v starosti nad 60 let je bilo statistično značilno več primerov z neugodnim potekom (35).

3.8 Potek in posledice KME pri obolelih

V osemdesetih letih in začetku devetdesetih let 20. stoletja so menili, da poteka KME pri otrocih blago (16, 36). V letu 1994 so pediatri na Kliniki za infekcijske bolezni in vročinska stanja v Ljubljani opazovali izrazito hud potek KME pri otrocih (37). Od 25 otrok, ki so jih v tem letu zdravili, se jih je kar pet (20 %) zdravilo v intenzivni enoti, pet otrok je potrebovalo umetno predihavanje in kar 60 % otrok je imelo bolj ali manj izražene encefalitične simptome. V zadnjih letih so opazovali kar pri eni tretjini otrok s KME žariščne spremembe v EEG ali vsaj asimetrijo. Vendar pa je nekajletno proučevanje kliničnega poteka KME pri otrocih (38) in odraslih bolnikih pokazalo, da poteka bolezen pri otrocih blažje kot pri odraslih (39) in da zlasti hudo poteka okužba pri odraslih, starih nad 60 let (40). Zanimivi sta tudi raziskavi o poteku bolezni in morebitnih posledicah po preboleli bolezni. Pri bolnikih, ki so jih zdravili na infekcijski kliniki v Ljubljani med letoma 1974 in 1975, je bolezen potekala večinoma blago; povprečno so težave trajale 10 dni. Pri bolnikih, ki so jih zdravili v letu 2011, je bolezen potekala blago pri 25 %

bolnikov, srednje hudo pri 57,1 % bolnikov in hudo pri 17,9 % bolnikov (41). Pri bolnikih, ki so jih zdravili v letih 1974–1977, so se pareze pojavile pri 6,9 % (42), pri bolnikih, ki so jih zdravili v letu 2011, pa so se pareze pojavile pri 5,0 % (41).
Umrljivost je bila pri odraslih od 1- do 2-odstotna; pri otrocih je majhna.
Po preboleli bolezni imajo nekateri bolniki – tudi 35–58 % – dolgotrajne posledice, ki lahko pomembno vplivajo na kakovost življenja. Težave so poimenovali postencefalitisni sindrom. Različni avtorji so ugotavljali predvsem glavobol, motnje spomina in/ali koncentracije, razdražljivost, motnje ravnotežja, okvare sluha, tresenje in ohromelost posameznih mišičnih skupin (35, 42–43).

3.9 Mikrobiološka diagnostika

Klinična slika KME ni dovolj značilna; diagnoza temelji na dokazovanju specifičnih protiteles (44–45). V zadnjih letih uporabljajo encimsko-imunsko metodo, ki je hitra in občutljiva ter omogoča dokaz specifičnih protiteles razredov IgM in IgG, ki so v serumu bolnikov večinoma prisotni od začetka druge faze bolezni. Tvorbo specifičnih protiteles lahko dokažejo tudi v likvorju, vendar nekoliko pozneje in v nižjih koncentracijah (9).
V prvem obdobju bolezni lahko okužbo potrdijo z neposrednim dokazom virusa ali virusne RNA. Za neposredno dokazovanje okužb s KMEV večinoma uporabljajo molekularne metode RT-PCR za dokaz virusne RNA v krvi bolnika v prvi fazi bolezni (46). Dokaz virusne RNA v likvorju bolnika v drugi fazi bolezni uspe le izjemoma. Uporaba molekularnih metod je v rutinski diagnostiki okužb s KMEV omejena. Tudi poskus osamitve virusa iz kužnin bolnika je časovno zamudna, tehnično zahtevna in razmeroma nevarna metoda, zato za hitro diagnostiko okužb ni primerna (9).

3.10 Akademska obravnava KME pri Slovencih

Svoje ugotovitve so slovenski virologi, epidemiologi, kliniki in medicinska entomologinja objavili v uglednih strokovnih revijah in predstavili na različnih strokovnih srečanjih. Nekatera srečanja so bila posvečena le obravnavi KME. Prvi simpozij o KME je bil v Sloveniji na Golteh leta 1973, kjer so pregledali delo, opravljeno do tega leta, in ustanovili komisijo za proučevanje aktualnih vprašanj KME, ki jo je vodil Milko Bedjanič (16, 21, 47). Tudi na Bedjaničevem simpoziju leta 1993 v Dobrni je bila osrednji tema obravnava raziskav o KME (48–49). Svoje izkušnje so slovenski infektologi nadalje predstavili na italijansko-jugoslovanskem srečanju *III Convegno Italo-Jugoslavo di Malattie Infettive* leta 1973 v Radencih (50), na simpoziju o arbovirusih v mediteranskih deželah *Arboviruses in the Mediterranean countries* leta 1979 na dalmatinskem otoku Braču (51), na simpoziju o okužbah osrednjega živčevja leta 1983 na Dunaju in še na nekaterih drugih uglednih strokovnih srečanjih.

3.11 Izdelava cepiva

Pomemben mejnik v zgodovini KME je bil izdelava cepiva proti KME ter s tem možnost učinkovitega in varnega preprečevanja okužbe.
Na trgu je več inaktiviranih cepiv proti KME. V Sloveniji je cepljenje proti KME po programu cepljenja od leta 1986 obvezno za posebej ogrožene skupine prebivalcev, torej tiste, ki so pri svojem delu izpostavljeni okužbi z KMEV, od leta 1990 pa tudi za dijake in študente, ki so med šolanjem in pri praktičnem pouku izpostavljeni mogoči okužbi (14). Kljub povečanemu številu cepljenih v zadnjih letih je delež cepljenih proti KME v Sloveniji še vedno nizek, le okoli 12 % (18).
Infektologi in epidemiologi priporočajo cepljenje vsem osebam, ki živijo na endemskem območju ali tja prihajajo.

4 ZAKLJUČEK

Natančno, vztrajno in predano raziskovalno delo epidemiologov, infektologov, medicinskih entomologov in mikrobiologov je znanje in vedenje o tej bolezni postopoma, iz leta v leto, izpopolnjevalo in dopolnjevalo. Dosežek njihovega dela je današnje znanje o KME. V Sloveniji se še vedno pojavljajo bolniki s KME; številni od teh se zdravijo na Kliniki za infekcijske bolezni in vročinska stanja v Ljubljani. Infektologi skrbno spremljajo te bolnike in ugotavljajo nekatere nove in zanimive podrobnosti v kliničnem poteku KME.

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PREDICTABILITY OF SMOKING ONSET AMONG ROMANIAN ADOLESCENTS

PREDVIDEVANJE ZAČETKA KAJENJA MED ROMUNSKIMI MLADOSTNIKI

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Abstract

Objectives: *Research identifying reliable and country-specific predictors of smoking is needed in order to develop effective adolescent smoking prevention programmes. The objective of this study was to assess the cognitive and socio-demographic factors associated with smoking onset among Romanian teenagers, using both cross-sectional and longitudinal data.*

Methods: *The data were obtained from a two-wave, one-year longitudinal study carried out among 316 senior high school non-smokers from Cluj-Napoca, Romania.*

Questionnaires assessed smoking behaviour, attitudes, social influence, self-efficacy and intention regarding smoking (motivational variables) as well as different sociodemographic features.

Results: *The cross-sectional analyses showed that socio-demographics and motivational variables were strongly associated with smoking behaviour; the explained variance was 76%. The longitudinal analyses revealed that four variables explained 33% of the variance in change of status from non-smoking to regular smoking over a period of one year. Regular smoking onset after one year was predicted by baseline low self-efficacy in refraining from smoking in different situations, having more smoking friends and playing truant from school. Having a brother was a protective factor.*

Conclusion: *The results suggest that smoking prevention programmes in Romania should strengthen self-efficacy beliefs and resistance against peer modelling and help Romanian young people to develop skills and action plans to cope with pressure to smoke and challenging situations.*

Key words: smoking predictors, Romanian adolescents, smoking prevention

Izvirni znanstveni članek
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Izvleček

Namen: *Za razvoj učinkovitih programov za preprečevanje kajenja med mladostniki je potrebna raziskava, ki bi opredelila zanesljive dejavnike začetka kajenja, značilne za posamezno državo. Cilj te študije je bil oceniti kognitivne in socialno-demografske dejavnike, povezane z začetkom kajenja med romunskimi mladostniki, in sicer na podlagi presečnih in vzporedno primerljivih podatkov.*

Metode: *Podatki so bili pridobljeni z enoletno študijo, ki je vzporedno potekala v dveh vejah in je vključevala 316 dijakov zadnjih letnikov, ki niso kadili, iz romunskega mesta Cluj-Napoca. Z vprašalniki so se ocenjevali kadilsko vedenje, odnos do kajenja, družbeni vpliv, samoučinkovitost in namera v povezavi s kajenjem (motivacijske spremenljivke) ter razni socialno-demografski podatki.*

Rezultati: *Analiza presečnih podatkov je pokazala, da so bile socialno-demografske in motivacijske spremenljivke močno povezane s kadilskim vedenjem; navedena varianca je bila 76-odstotna. Analiza vzporedno primerljivih podatkov pa je razkrila, da so štiri spremenljivke pojasnile 33 odstotkov variance v spremembi statusa od nekadilca do rednega kadilca, in to v obdobju enega leta. Začetna nizka samoučinkovitost pri vzdržnosti od kajenja v različnih situacijah, večje število prijateljev kadilcev in izostajanje od pouka so nakazovali začetek rednega kajenja po enem*

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letu. Pri mladostnikih/-cah, ki imajo brata, se je ta sorodstvena vez pokazala kot zaščitni dejavnik.
Zaključki: *Izsledki kažejo, da bi morali programi za preprečevanje kajenja v Romuniji okrepiti prepričanje o samoučinkovitosti in upiranje vzorčnemu vedenju med vrstniki ter pomagati mladim v Romuniji razviti sposobnosti in načine ukrepanja, s katerimi bodo lahko obvladovali pritiske, ki jih napeljujejo h kajenju, in druge zahtevne situacije.*

Ključne besede: dejavniki kajenja, romunski mladostniki, preprečevanje kajenja

1 INTRODUCTION

In countries in South-East Europe, such as Romania, smoking is an important public health problem (1). Research identifying reliable and country-specific predictors of smoking is needed. This information can be used to develop effective, country-specific adolescent smoking prevention programmes. Thus, the present study aims to identify the socio-demographics and motivational factors that predict smoking onset in Romanian adolescents aged 15 to 17. Both cross-sectional and longitudinal outcomes are presented.

Current smoking prevention programmes are characterised by the use of comprehensive theories (2, 3) such as the Integrated Model of Change (the I-Change Model) (4). This model as well as its predecessor (Attitude-Social Influences-Self Efficacy Model) has proven to be a useful tool in assessing the determinants of smoking as well as developing and evaluating smoking prevention programmes in several European countries (5-10). Based on these positive European experiences, we adopted the model to guide our Romanian study.

The I-Change Model, like other social-cognitive health behaviour models (11, 12, 13), assumes that an important determinant of behaviour is behavioural intention, which is in turn influenced by three proximal factors: individuals' overall evaluations of the behaviour (attitude), their beliefs about the beliefs and behaviours of significant others (social influence) and the control that they perceive themselves to have over performing a behaviour (self-efficacy). Distal factors such as demographics (e.g. age, gender) and psychological factors (e.g. self-esteem) are assumed to influence behaviour via these proximal factors (5).

Our present study has the following objectives. First, we aim to cross-sectionally and prospectively assess the importance of socio-demographic factors as well as attitudinal, social, self-efficacy and intentional beliefs in predicting smoking onset among Romanian adolescents. Based on the assumptions from the I-Change Model and findings from previous studies (14-19), we expect that more favourable attitudes to smoking, more social influences in favour of smoking from peers and family, lower self-efficacy beliefs in refraining from smoking in different situations and stronger intention to smoke in the future will predict smoking onset. Second, we compare the outcomes and amount of variance explained when using a cross-sectional compared to a longitudinal design.

2 METHODS

2.1 Sample and procedure

In spring 2004, five senior high schools from Cluj-Napoca, a city in north-west Romania with approximately 330,000 inhabitants and 39 high schools, were randomly chosen and approached to participate in a survey about adolescent smoking behaviour. Time and financial constraints limited the inclusion of more schools in the study. The principals of the five schools were informed about the survey during individual meetings with the research team; all principals agreed to participate, and all first-year classes from the five schools were involved in the survey. Consent was obtained from the school administration only, in line with standard procedure in Romania.

Data were gathered in two waves. A baseline measurement was conducted in May–June 2004 (T1) among students from 19 first-year senior high school classes (aged 15 to 17), and a follow-up measurement was performed 12 months later (T2).

The students were not informed in advance about the date on which the assessment would take place. The research team administered the questionnaires to each class; classroom completion of the questionnaire took approximately 50 minutes.

Students were asked to read an introductory letter. They were assured that the researchers would treat their questionnaires confidentially and that they could refuse to participate by leaving the questionnaire blank. They put their completed questionnaires in an envelope, sealed it and wrote their names on the envelope and then the researchers collected the envelopes. No refusals were recorded; non-participation was exclusively due to absence of students on the day of assessment. The questionnaires were filled in by 473 students at T1 and 482 students at T2. A total of 416 students participated in both measurements; 66.5% of these were girls.

2.2 Questionnaire

An existing questionnaire based on the I-Change Model (5) was translated from the version used for OCTOPUS, a European three-country study (23), and for the European Smoking Prevention Framework Approach (ESFA), a collaboration of six European countries (7). It was designed to be sensitive to changes in smoking levels in primary and high school settings and has shown satisfactory scale reliability and item homogeneity (3, 7, 9). It assesses smoking behaviour, motivational factors regarding smoking (attitudes, social influences, self-efficacy expectations, intention) and several socio-demographic items, which are described in more detail below.

In a pilot test, the instrument was given to 30 Romanian first-year senior high school students to evaluate item clarity. The students' comments revealed no lack of clarity in the wording of the items about motivational factors and showed completeness of most relevant items. Adaptations were needed of only a few items on socio-demographic characteristics such as ethnicity, religion and pocket money spent per month.

Smoking behaviour was assessed by a combination of five questions. First, students were asked to choose a statement that best described their smoking behaviour (e.g. 'I smoke less than weekly'; 'I smoke at least once a week'). The responses were cross-validated using an algorithm of concepts measuring current smoking (smoking in the last month, the last week and the last 24 hours) and lifetime smoking (number of cigarettes smoked during lifetime). The adolescents were then categorised into two groups: regular smokers and non-smokers. Regular smokers were defined in line with the definition of the Centre for Disease Control and Prevention's Behavioural Risk Factor Surveillance System (21) and other international studies (5) as smoking at least one cigarette per week or smoking less than weekly but having smoked more than 100 cigarettes during their lifetime. The remaining respondents were classified as non-smokers, in line with another European study (5).

Attitudes were measured on a seven-point scale using 12 items. The answer categories ranged from 'I totally disagree' (= –3) to 'I totally agree' (= +3). A factor analysis on the attitudes was conducted using oblimin rotation and two scales were created: pros (six items referring to the expected positive outcomes of smoking such as 'It helps to calm my nerves'; Cronbach's α = .75 at T1;α = .77 at T2) and cons of smoking (six items referring to the perceived negative outcomes such as 'It's bad for my health'; Cronbach's α = .62 at T1; α = .69 at T2).

To assess social influences, we measured perceived social norms, perceived social pressure and perceived smoking behaviour. Social norms were measured by a 7-point scale assessing adolescents' perceptions of whether their parents (α = .64 at T1; α = .67 at T2), siblings (sister and brother; α = .45 at T1; α = .49 at T2) and peers (best friend, other friends and people in the same school year; α = .60 at T1; α = .72 at T2) thought they should smoke or not (e.g. 'My best friend thinks I definitely should smoke' (+3) to 'should not smoke' (–3). Social pressure was assessed using items with five answer categories on perceived pressure from parents (mother and father; α = .82 at T1; α = .78 at T2), siblings (sister and brother; α = .40 at T1; α = .60 at T2) and peers (best friend, other friends, people in the same school year; α = .77 at T1; α = .78 at T2) (e.g. 'Have you ever felt pressure from your mother to smoke?' where never = 0 and very often = +4). For both social norms and social pressure, the three scales regarding parents', siblings' and peers' influences were created based on the results of the factor analysis using oblimin rotation. Perceived behaviour was measured by asking whether those in their social circles (mother, father, sister(s), brother(s) and best friend) smoked (no = 0, yes = 1) as well as how many friends and people in the same school year smoked, with five answer possibilities (nobody = 0; everybody = 4). Because these items are not assumed to be one-dimensional, perceived behaviour was analysed separately for each measured person in the social environment.

Self-efficacy expectations to avoid smoking were measured by 12 items on a 7-point scale. The items measured the adolescents' perception of their ability to refrain from smoking when pressured by others (e.g. when with friends who smoke), when under emotional strain (e.g. when feeling upset) or when undertaking daily routines (e.g. when watching TV). Answer categories ranged from 'I'm sure I will smoke (= –3) to 'I'm sure I won't smoke' (= +3). Factor analysis revealed one factor for self-efficacy; consequently one scale was created (α = .95 at T1; α = .97 at T2).

Intention was measured by one question on a 7-point scale and evaluated adolescents' intention to smoke in the next year (+3 = definitely yes; –3 = definitely not).

For each motivational concept, we calculated the mean of the scale items.

The assessed demographic variables included: age, gender, religious background, ethnic background and family structure. The literature had indicated that the following risk factors influence smoking behaviour: spending pocket money, school performance, choice of leisure time location, involvement in several health-risk

behaviours (14, 16, 17, 22, 23). Pocket money spent per month by adolescents was measured using eight response categories ranging from nothing per month to the equivalent of more than €25/month; previous studies showed that smoking was statistically significantly more frequent among Romanian adolescents who spent more than €15 per month than among those who spent less money (24). Analyses were carried out using a dichotomous variable: spending less than €15/month (0) and at least €15/month (1); the €15 represents around twice the monthly governmental scholarship received by each Romanian high school student. Perceived school performance in the previous year was assessed as follows: 0 = in the bottom third of their class, 1 = in the middle third, 2 = in the top third. Each student also had to choose three places where they frequently spent their leisure time (home, friends' houses, street, shops, bars/discos/parties, sport clubs, youth clubs, and work) (23). Involvement in other risk behaviours (using alcohol, marijuana and other drugs, gambling, playing truant from school, physically fighting with other people, stealing, destroying things) was measured with eight items on a 5-point scale ranging from never (= 0) to at least once a week (= 4).

An identification code was used in the data file for each questionnaire for data connection; researchers replaced the names of students before the data were entered.

2.3 Analyses

A logistic regression analysis was used to compare participating and non-participating subjects in the second measurement, with data from the first measurement as predictors of dropout.

The sample consisted of students who participated at both measurements and were non-smokers at T1 (N = 316). Due to the limited sample size, the analyses were performed for the whole sample and not for boys and girls separately.

The prevalence of different socio-demographic characteristics and risk behaviours was assessed for the non-smokers at T1 at baseline and at follow-up; chi^2 tests were used to compare the results from the two waves.

Mean scores and standard deviations were calculated for the motivational concepts. Bivariate correlation was used to assess both cross-sectional and longitudinal association between smoking onset at T2 and motivational factors measured at T2 and T1 respectively. Differences between the new regular smokers (n = 44) and those who remained non-smokers (n = 272) at T2 were tested using cross-sectional logistic regression analyses. The independent variables as measured at the second wave were entered in four blocks. Demographic variables were included in block 1: gender, family structure and pocket money spent per month. Several risk behaviours (school achievement, use of alcohol on a monthly basis, playing truant from school at least once a month, frequently spending free time in bars/discos/parties) were added in block 2. Attitudes, social influence and self-efficacy items were included in block 3, while intention to smoke in the future was added in block 4. Forward method was used within the first three blocks and enter method applied in the last block.

To gain deeper insight into the process of transition from non-smoking to smoking between the two waves, multiple logistic regression analyses were also conducted for the longitudinal data with the aim of assessing the association between smoking onset at T2 and explanatory variables measured at T1. The logistic regression analyses used the same procedure as described above.

Data analysis was performed with the SPSS-12 statistics programme. Significant results are reported at $p < 0.05$.

3 RESULTS

3.1 Characteristics of the sample

A total of 416 students participated in both measurements. The dropouts (N = 57) did not differ significantly from the rest of the sample in terms of gender, smoking behaviour or other risk behaviours such as alcohol use or frequently spending their free time in bars or discos.

Among the 416 students who participated in both measurements, regular smoking at T1 was 24% (N= 100). The non-smokers in the first wave (N = 316) represented the base for this study. The mean age of the non-smokers was 15.9 (SD = 0.3; range 15–17 years) at T1; 69.9% were female. Table 1 presents the socio-demographic characteristics as well as several health-risk behaviours of the non-smokers at T1. It reveals that all risk behaviours increased from T1 to T2. A percentage of 13.9% of the non-smokers at T1 became regular smokers at T2 (N = 44).

Table 2 indicates the mean scores of the motivational concepts measured at both T1 and T2.

Table 1. Socio-demographic characteristics and risk behaviours of the sample.
Tabela 1. Sociodemografske značilnosti in tvegane oblike vedenja.

Variables/ Spremenljivke	T1 % N=316	T2 % N=316
Family structure/ Družinska struktura		
Living with the mother/ Živi z materjo	90.5	89.9
Living with the father/ Živi z očetom	80.1	79.4
Living with the brother(s)/ Živi z bratom/-oma/-i	33.5	34.2
Living with the sister(s)/ Živi s sestro/-ama/-ami	32.1	29.4
Spending ≥15 Euros/month/ Poraba ≥15 evrov/mesec	4.1[a]	9.3
Risk behaviours/ Tvegane oblike vedenja		
Playing truant from school at least once/month/ Izostanek od pouka vsaj enkrat/mesec	20.1	25.6
Bad school achievements last year/ Slab lanskoletni šolski uspeh	1.9[a]	5.4
Using alcohol at least once/month/ Uživanje alkohola vsaj enkrat/mesec	19.9[a]	29.8
Spending time in bars/discos/parties/ Preživljanje časa v barih/ diskotekah/zabavah	16.6[a]	22.9

Statistically significant difference between T1 and T2 variables at chi^2 test ($p<0.05$)
a- Statistično pomembna razlika med spremenljivkami T1 in T2 pri hi-kvadrat preizkusu ($p<0.05$)

Table 2. Mean scores of cognitive variables/scales at T1 and T2 and their bivariate correlations with smoking onset at T2.
Tabela 2. Srednje vrednosti kognitivnih spremenljivk/lestvic pri T1 in T2 in njihovih bivariatnih korelacij z začetkom kajenja pri T2.

Variables/Scales/ Spremenljivke/ lestvice	Mean (SD) of T1 variables/ Srednja vrednost (SD) spremenljivk T1	Mean (SD) of T2 variables/ Srednja vrednost (SD) spremenljivk T2	Associations between smoking onset at T2 and T1 variables[i] / Povezave med začetkom kajenja pri T2 in spremenljivkami T1[i]	Associations between smoking onset at T2 and T2 variables[i] / Povezave med začetkom kajenja pri T2 in spremenljivkami T1[i]
Pro smoking attitude (-3 to +3)[b] / Pozitiven odnos do kajenja (-3 do +3) [b]	0.37(0.56)	0.36(0.55)	NS	0.31
Con smoking attitude (-3 to +3) [b] / Negativen odnos do kajenja (-3 do +3) [b]	2.02(0.75)	1.81(0.85)	-0.25	-0.45
Social norms parents (-3 to +3) [c] / Socialne norme staršev (-3 do +3) [c]	-2.49(0.81)	-2.42(0.86)	0.20	0.27
Social norms siblings (-3 to +3) [c] / Socialne norme bratov, sester (-3 do +3) [c]	-0.99(1.07)	-1.00(1.08)	0.13	0.21
Peer social norms (-3 to +3) [c] / Socialne norme vrstnikov (-3 do +3) [c]	-1.32(0.97)	-1.30(1.13)	0.11	0.31
Mother smokes (0 to 1) [d] / Mati kadilka (0 do 1) [d]	0.37(0.48)	0.36(0.48)	0.10	0.12

Father smokes (0 to 1) [d] / Oče kadilec (0 do 1) [d]	0.44(0.49)	0.43(0.49)	NS	NS
Brother smokes (0 to 1) [d] / Brat kadilec (0 do 1) [d]	0.15(0.35)	0.18(0.39)	NS	NS
Sister smokes (0 to 1) [d] / Sestra kadilka (0 do 1)[d]	0.08(0.27)	0.09(0.29)	NS	0.15
Friends smoke (0 to 4) [e] / Prijatelji kadilci (0 do 4)[d]	1.48(1.31)	1.65(1.36)	0.20	0.29
Best friend smoke (0 to 1)[d] / Najboljši prijatelj kadilec (0 do 1) [d]	0.18(0.38)	0.24(0.43)	NS	0.25
People in the same school year smoke (0 to 4) [e] / Dijaki v istem letniku, ki so kadilci (0 do 4) [d]	1.47(1.22)	1.89(1.27)	0.15	0.11
Parents pressure (0 to 4) [f] / Pritisk staršev (0 do 4) [f]	0.05(0.33)	0.06(0.34)	NS	0.10
Siblings pressure (0 to 4) [f] / Pritisk bratov, sester (0 do 4) [f]	0.10(0.38)	0.09(0.37)	NS	0.11
Peer pressure (0 to 4) [f] / Pritisk vrstnikov (0 do 4) [f]	0.59(0.66)	0.62(0.67)	0.12	0.12
Self-efficacy (-3 to +3) [g] / Samoučinkovitost (-3 do +3)[g]	2.47(0.77)	2.20(1.17)	-0.33	-0.71
Intention to smoke in the next year (-3 to +3) [h] Namerava kaditi v naslednjem letu (-3 do +3) [h]	-2.20(1.83)	-1.83(1.65)	0.23	0.64

b-(-3)= I totally disagree to (+3)= I totally agree
c-(-3) = I definitely should not smoke to (+3)= I definitely should smoke
d-0=no; 1=yes
e-0=nobody; 4=everybody
f-0=never; 4=very often
g-(-3)=I am sure I will smoke to(+3) =I am sure I won't smoke
h-(-3)=I am sure I will not smoke to(+3) =I am sure I will smoke
i-All correlations with depicted correlation coefficient are significant: P<0.05
NS=Non-significant
b-(-3) = Sploh se ne strinjam do (+3) = Povsem se strinjam
c-(-3) = Zagotovo ne bi smel/-a kaditi do (+3)= Zagotovo bi moral/-a kaditi
d-0 = ne; 1 = da
e-0 = nihče; 4 = vsi
f-0 = nikoli; 4 = zelo pogosto
g-(-3) = Prepričan/-a sem, da bom kadil/-a do (+3) = Prepričan/-a sem, da ne bom kadil/-a
h-(-3) = Prepričan/-a sem, da ne bom kadil/-a do (+3) = Prepričan/-a sem, da bom kadil/-a
i – Vse korelacije s prikazanim korelacijskim koeficientom so pomembne: P < 0,05.
NS = Ni statistično pomembno.

3.2 Cross-sectional correlates of regular smoking

Table 2 shows the cross-sectional bivariate correlations of cognitive variables measured at T2 with smoking behaviour at the second wave (smoking onset N=44; non-smokers N= 272). All variables except the perceived behaviour of father and brother were significantly correlated with regular smoking. Low self-efficacy and high intention to smoke in the future correlated most strongly with smoking behaviour.

Table 3 presents the results of the cross-sectional regression analyses. Adolescents with lower self-

efficacy and stronger intention to smoke in the next year were more likely to smoke. So, too, were those who frequently spent their free time in bars/discos and who had less strong attitudes against smoking and a higher proportion of smoking friends. The model variables explained 76% of the variance in smoking behaviour at the second wave.

3.3 Longitudinal predictors of regular smoking onset

Table 2 also presents the results of the longitudinal bivariate correlation analysis. It shows that the variables measured at T1 associated with smoking onset at T2 were less distinct attitudes against smoking, lower social norms against smoking, more perceived behaviour of the mother, friends and colleagues, more perceived peer pressure towards smoking, lower self-efficacy and higher intention to smoke in the next year. The associations of the baseline factors with behaviour one year later were generally lower when longitudinal associations were evaluated than when cross-sectional associations were assessed. Baseline self-efficacy and baseline cons of smoking correlated most strongly with smoking onset one year later.

Table 4 shows the results of the longitudinal regression analysis. Socio-demographic and health-risk behaviours predicted 15% of the variance in regular smoking onset. When the cognitive variables were also included, self-efficacy explained 13% of the variance of adolescents' smoking behaviour, while the smoking behaviour of their friends added 5% of explained variance. The inclusion of intention in the model made no significant contribution. The final model shows that the transition to regular smoking over a period of one year was predicted by low self-efficacy in refraining from smoking in different situations, having more smoking friends at first measurement and playing truant from school. Having a brother was a protective factor.

Table 3. *Results of T2 independent variables in the cross-sectional logistic regression model for those who remained non-smokers at T2 and those who became smokers at T2 (N =299 [a]).*

Tabela 3. *Rezultati neodvisnih spremenljivk pri T2 v presečnem logistično-regresijskem modelu za tiste, ki so pri T2 ostali nekadilci, in za tiste, ki so pri T2 postali kadilci (N = 299 [a]).*

		Model 1		Model 2		Model 3		Model 4	
	Variables / scales at T2 [b] / Spremenljivke/ lestvice pri T2[b]	OR	R^2 Change/ sprememba	OR	R^2 Change/ sprememba	OR	R^2 Change/ sprememba	OR	R^2 Change/ sprememba
1	Spending ≥15 Euros/month/ Poraba ≥15 evrov/mesec	6.23	0.09	-		-		-	
2	Using alcohol at least once/ month/ Uživanje alkohola vsaj enkrat/mesec			5.84	0.16	-		-	
	Spending time in bars/discos/ parties/ Preživljanje časa v barih/ diskotekah/zabavah			7.33	0.10	6.37		6.03	
	School achievement/ Šolski uspeh			11.52	0.07	-		-	
3	Con smoking attitude/ Negativen odnos do kajenja					0.38	0.02	0.41	
	Modelling friends smoke/ Prijatelji, ki jih posnema, kadijo					2.09	0.03	1.87	
	Self-efficacy/ Samoučinkovitost					0.14	0.28	0.24	
4	Intention/ Namera							1.65	0.01
	R^2 of the model/ R^2 modela		0.09		0.42		0.75		0.76

a - Due to missing values on several variables the population was reduced to 299

b - All variables/scales with depicted OR are significant: P<0.05

a – Zaradi manjkajočih vrednosti pri več spremenljivkah je bila populacija zmanjšana na 299.

b – Vse spremenljivke/lestvice s prikazanim razmerjem obetov (OR) so pomembne: P < 0,05.

Table 4. Results of the T1 independent variables in the longitudinal logistic regression model for those who remained non-smokers at T2 and those who became smokers at T2 (N =298[a]).
Tabela 4. Rezultati spremenljivk, neodvisnih od T1, v longitudinalnem logistično-regresijskem modelu za tiste, ki so pri T2 ostali nekadilci, in za tiste, ki so pri T2 postali kadilci (N = 298 [a]).

	Variables / scales at T1[b] /Spremenljivke/lestvice pri T1[b]	Model 1		Model 2		Model 3		Model 4	
		OR	R^2 change	OR	R^2 change	OR	R^2 change	OR	R^2 change
1	Living with the father/ Živi z očetom	0.43	0.03	0.44		-		-	
	Living with the brother/ Živi z bratom	0.36	0.04	0.27		0.16		0.16	
2	Spending time in bars/discos / parties/ Preživljanje časa v barih/diskotekah/zabavah			3.00	0.05	-		-	
	Playing truant from school at least once/month/ Izostanek od pouka vsaj enkrat/mesec			2.53	0.03	3.64		3.64	
3	Modelling friends smoke/ Prijatelji, ki jih posnema, kadijo					1.59	0.05	1.58	
	Self-efficacy/ Samoučinkovitost					0.27	0.13	0.28	
4	Intention/ Namera							-	
	R^2 of the model/ R^2 modela		0.07		0.15		0.33		0.33

a - Due to missing values on several variables the population was reduced to 298
b- All variables/scales with depicted OR are significant: P<0.05
a – Zaradi manjkajočih vrednosti pri več spremenljivkah je bila populacija zmanjšana na 298.
b – Vse spremenljivke/lestvice s prikazanim razmerjem obetov (OR) so pomembne: P < 0,05.

4 DISCUSSION

Several findings from this study provide important information on the process of smoking initiation among Romanian adolescents. As in other studies (25), playing truant from school predicted regular smoking onset. This underlines the fact that preventing truancy among Romanian adolescents may also have important benefits on smoking prevention.

Regular smoking onset was also predicted by baseline low self-efficacy expectations to avoid smoking. Other studies also found this to be an important predictor of smoking initiation (6, 16, 26).

As regards social influences, the longitudinal results confirmed the strong influence of smoking friends on adolescents' smoking behaviour. The results of other international studies also showed important influences of friends in explaining smoking uptake (14, 15, 18).

Having a brother was a protective factor. Other studies have also found some support for family bonding in influencing smoking behaviour (14, 18, 27). Since no information was recorded on the age of the brother or bonding between the siblings, no further interpretation of this finding is possible. Yet, why the study did not find a similar impact of having a sister remains unclear. Although one interpretation may be that brothers may serve as a more important role model or bonding factor, more in-depth research is needed to further explain this result.

The influence of smoking parents on the smoking behaviour of Romanian adolescents aged 15 to 17 was not confirmed by our results. Several studies from other countries also showed that when controlling for peer influence, the effect of parental smoking behaviour has non-significant results (14, 15). According to other studies (28-31) parental smoking can also be a strong predictor of the transition to regular smoking. Our study population had recently transitioned to senior high school; this may have prompted feelings of increasing maturity among the students, which caused them to turn away from parental influence and towards the influence of their friends' smoking behaviour.

Contrary to our hypothesis, attitudes to smoking did not predict smoking initiation after one year. Several studies showed that more positive attitudes toward smoking were associated with an increased likelihood of smoking among adolescents. However, other studies have found that such attitudes did not predict smoking uptake in the presence of other socio-demographic, environmental and behavioural factors (14). It is conceivable that teenagers alter their attitudes and intention and start smoking over a short period of time, and that longitudinal studies with several months between the waves do not capture this process (19). As other studies also suggested (19, 32), another explanation is, however, that for adolescents at this age smoking related attitudes follow behaviour instead of predicting it; our finding that the cons of smoking were cross-sectionally associated with smoking behaviour may support this.

While some studies found intention to smoke in the future to be an important predictor of smoking onset (33, 34*)*, others did not (35). In our study, intention did not predict smoking initiation among Romanian adolescents. It is not quite clear why we did not find a predictive role of intention, as one would have expected according to the notions of the Theory of Planned Behaviour (36). It is, however, conceivable that intention for Romanian adolescents at this age is quite unstable and thus does not predict behaviour but, as with attitudes, follows behaviour.

Several studies have argued that smoking initiation among adolescents is unplanned behaviour (32). Romanian young people were widely exposed to tobacco product advertisement and promotional activities (37-39) before 2007, when these activities were banned in Romania (40). They also frequently see many adolescents and adults smoking and are exposed to passive smoking in public places or even in the home, as the smoking prevalence in Romania is high and the law prohibiting smoking in public places is poorly enforced (37-39, 41). Under these circumstances, it is not unexpected that some Romanian young people start to feel unable to refrain from smoking in different situations and at certain moments start smoking regularly, even if this was not their intention.

As in other studies (6, 19), the cross-sectional findings showed that much of the variance in smoking behaviour could be explained by demographic and cognitive variables. Nevertheless, these variables could explain only 33% of the variance between becoming regular smokers and remaining non-smokers in the longitudinal logistic regression analysis; this may be explained in terms of the long interval (one year) between the two waves. The explained variance found by other prospective studies over a period of one year was similar (6, 19, 42) and decreased when the interval between the measurements increased (6). Many studies have demonstrated that social cognitive models explained behaviour in cross-sectional studies well, but that the explained variance of these models to predict behaviour might be more limited (43, 44). Nevertheless, even small effect sizes can have theoretical and practical utility (45). Thus, although the explained variance of our longitudinal study implies that much remains unknown about why Romanian children start smoking, it still offers some tools for prevention efforts.

The most important finding of this study is that in a society with high social acceptability of smoking such as Romania, even if intention might not predict smoking onset, self-efficacy beliefs play an important role in smoking initiation. The results imply that smoking prevention programmes should strengthen self-efficacy beliefs and resistance against peer influences and help Romanian young people to develop skills as well as action plans to cope with pressure to smoke and with challenging situations; these findings are similar to those from other international studies (6, 14, 16, 18, 26, 27).

This study is subject to certain limitations. First, we included only first-year high school students from Cluj-Napoca. Moreover, despite the fact that the schools offered diverse curricula, which should attract girls and boys, the percentage of girls in each class was generally higher. This meant our sample unexpectedly consisted of more girls. Second, the sample size limited the performing of analyses separately for boys and girls. Future Romanian studies should include a nationally representative sample of adolescents and analyse subpopulations based on age and gender. Third, like other studies (5, 19), we classified smoking behaviours in just two categories: non-smokers and regular smokers. The results from another European study have identified five stages of smoking initiation (46); future Romanian studies should also use more categories. Information on siblings' age and smoking behaviour as well as the bond between siblings could be also useful in further explaining smoking onset. Fourth, the results are based on adolescents' self-reports of smoking behaviour. Several studies, however, have found high correlations between self-reports and biochemical assessments of adolescent smoking behaviour when confidentiality of responses is assured (47, 48) (as it was in our study).

In short, this study presents similar patterns of smoking onset among Romanian adolescents as other European and international studies (6, 14, 16, 18, 26, 27),

showing that the smoking prevention programmes to be developed in Romania can benefit from the extensive experience in this field from other countries.

Conflict of interest

None

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VALIDATION OF SLOVENIAN VERSION OF JEFFERSON SCALE OF EMPATHY FOR STUDENTS

VALIDACIJA SLOVENSKE RAZLIČICE JEFFERSONOVE LESTVICE EMPATIJE ZA ŠTUDENTE

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Abstract

Objective: *Empathy is the most frequently mentioned humanistic dimension of patient care and is considered to be an important quality in physicians. The importance of fostering the development of empathy in undergraduate students is continuously emphasised in international recommendations for medical education. Our aim was to validate and adapt the Slovenian version of the Jefferson Scale of Empathy– Students version (JSE-S) on a sample of first-year medical students.*

Methods: *First-year students of the Medical faculty in Ljubljana participated in the research. JSE-S version, a self-administered 20-item questionnaire, was used for collecting the data. Descriptive statistics at the item level and at the scale level, factor analysis, internal consistency and test-retest reliability (two weeks after the first administration) of the JSE-S were performed.*

Results: *234 out of 298 (response rate 78.5%) students completed JSE-S. The mean score for the items on the 7-point Likert scale ranged from 3.27 (SD 1.72) to 6.50 (SD 0.82). The mean score for the scale (possible range from 20 to 140) was 107.6 (from 71 to 131, SD 12.6). Using factor analysis, we identified six factors, describing 57.2% of total variability. The Cronbach alpha as a measure of internal consistency was 0.79. The instrument has good temporal stability (test-retest reliability ICC = 0.703).*

Conclusion: *Findings support the construct validity and reliability of JSE-S for measuring empathy in medical students in Slovenia. Future research is required to evaluate factors contributing to empathy.*

Key words: empathy, Jefferson scale of empathy, students, validation, Slovenia

Izvirni znanstveni članek
UDK 61:37.015.3(497.4)

Izvleček

Namen: *Empatija je najpogosteje omenjena človeška lastnost v odnosu do bolnika in predstavlja pomembno vrednoto v zdravniškem poklicu. Krepitev empatičnega odnosa pri študentih medicine je pogosto poudarjena v mednarodnih smernicah za medicinsko izobraževanje. Namen raziskave je bil validacija in adaptacija slovenske variante študentske različice Jeffersonove lestvice za merjenje empatije na vzorcu študentov prvega letnika medicine.*

Metode: *V raziskavo so bili vključeni študentje prvega letnika Medicinske fakultete v Ljubljani. Podatke smo zbrali s pomočjo študentske različice Jeffersonove lestvice – vprašalnika z 20 vprašanji, ki so ga izpolnili študentje. Naredili smo osnovno statistično analizo posameznih vprašanj, analizo celotne lestvice, faktorsko analizo ter analizo notranje konsistentnosti in časovne stabilnosti lestvice štirinajst dni po prvem izpolnjevanju.*

Rezultati: *234 od skupno 298 študentov je sodelovalo v raziskavi in izpolnilo vprašalnik. Povprečna vrednot za posamezno vprašanje na 7-stopenjski Likertovi lestvici se je gibala od 3,27 (SD 1,72) do 6,50 (SD 0,82). Povprečna vrednost celotne lestvice (mogoč razpon od 20 do 140) je bila 107,6 (od 71 do 131, SD 12,6). S faktorsko analizo smo prepoznali šest faktorjev, s katerim smo pojasnili 57,2 % celotne variabilnosti. Cronbach alfa kot merilo notranje konsistentnosti je znašal 0,79. Potrdili smo časovno stabilnost lestvice (ICC = 0,703).*

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Zaključek: *Potrdili smo veljavnost in zanesljivost slovenske variante študentske različice Jeffersonove lestvice za merjenje empatije. Potrebno bo nadaljnje raziskovanje, ki bo pojasnilo dejavnike, ki prispevajo k empatiji.*

Ključne besede: empatija, Jeffersonova lestvica empatije, študentje, validacija, Slovenija

1 INTRODUCTION

Patient care is becoming more and more complex, and modern medical technology is not a replacement for a professional physician-patient relationship. Empathy is the most frequently mentioned humanistic dimension of patient care and an essential component of the physician-patient relationship. An extensive review of the literature on empathy by Morse describes the four components of the multidimensional concept of empathy. These include emotive - the ability to subjectively experience and share another person's psychological state or intrinsic feelings, moral - an internal altruistic force that motivates the practice of empathy, cognitive - the helper's intellectual ability to identify and understand another person's feelings and perspective from an objective distance and behavioural - communicative response to convey understanding of another person's perspective (1).

A frequently used definition of empathy is that of Hojat and colleagues: Empathy is a predominantly cognitive (rather than emotional) attribute that involves an understanding (rather than feeling) of experiences, concerns and perspectives of the patient combined with the capacity to communicate this understanding. Verbal and non-verbal communication of the physician results in a helpful therapeutic action (2- 4).

Empathy must not be confused with sympathy. Empathic and sympathetic orientations toward patient care are two different measurable entities. The distinction between the terms "empathy" and "sympathy" has been summarised in this way: empathic physicians share their understanding, while sympathetic physicians share their emotions with the patients (5, 6).

Empathy has many positive effects on patient care. The patients of physicians who are able to provide empathic communication report more on their symptoms and concerns and receive more illness-specific information. An empathic relationship also increases patients' participation and enablement and improves patients' adherence to treatment and satisfaction (7).

The aim of medical education is transforming individuals from medical students with broad clinical knowledge to professional physicians with the ability to use a bio-psycho-social model of patient care, taking into account cultural and existential dimensions (8). Medical students' values appear to change slightly during medical education, but the medical education process is associated with changes in certain students' qualities and attributes, among them being also students' empathy (2,9,10).

Entrance criteria for medical schools in Slovenia are heavily science-oriented. Students enter medical school just after graduation from high school at the age of 18 or 19 years. Besides teaching clinical knowledge, it is necessary for medical schools to educate students about the importance of empathy as an integral part of professionalism in medicine (11-13), which is necessary in enabling holistic approach as a main concept of patient care (8).

The first step in teaching for improvement of the level of empathy is assessment of empathy. 36 instruments for measuring empathy have been recognised. Eight of them demonstrate evidence of reliability, internal consistency and validity (14); six of them are self-rated measures. One of the most frequently used instruments for the measurement of empathy is the Jefferson Scale of Physician Empathy (JSE), which describes empathy as a multidimensional concept (15, 16).

The Jefferson scale has been translated into 42 languages, including also the Slovenian language for a students' version of the JSE, and used in more than 50 countries around the world (15, 17). In several academic medical centres, it is used as a major research instrument. The fostering of development of empathy in undergraduate students is continuously emphasised in international recommendations for medical education. In European countries (18,19) and worldwide (20-23), students' empathy has been already measured and followed. Besides, there have been attempts to adapt curricula to influence the students' empathy (24-26).

We have not measured the empathy of medical students in Slovenia yet. The first step in the measurement of empathy is validation of the instrument for measuring empathy (JSE-S) in the Slovenian language. The aim of our study was to validate and adapt the Slovenian version of JSE-S.

2 METHODS

2.1 Study population

Of the 298 first-year medical students of the Medical faculty in Ljubljana, 234 (response rate 78.5%)

voluntarily completed the JSE-S. We defined students who declined to participate or failed to answer at least 16 questions (80%) in the questionnaire as non-responders. In a sample of 80 students, we tested the test-retest reliability two weeks after the first admission. The study was conducted in academic year 2011/12; data were gathered between 30 November and 24 December 2011.

2.2 Instrument

The student version of JSE (S-version) used in this study includes 20 items answered on a seven-point Likert scale (1 - strongly disagree, 7 - strongly agree). To decrease the confounding effect of the "acquiescence response style" (e.g. the tendency to constantly agree or disagree: yea-, naysayers), 10 of the statements in the questionnaire had positive and 10 of them had negative connotation.

The total score of the scale ranges from 20 to 140, with higher value indicating a higher degree of empathy. In calculation of the total score, we inverted the scale for the answers to questions with a negative connotation. Original JSE is a three-dimensional instrument with the following three dimensions: compassionate care, standing in the patient's shoes and perspective taking (3).

We used the back translation method for translating the original English version of the questionnaire into Slovenian (27). The JSE-S was first translated into the Slovenian language by two independent translators with medical knowledge. Using the back translation procedure, three independent translators familiar with both languages translated the questionnaire back to English. The fourth person checked the three back translated versions in order to detect inconsistencies. Any differences were resolved by consensus. The back translated English version was compared with the original English version to ensure that no loss of meaning or context occurred during the translation process.

Students completed the questionnaire individually in the classroom. We explained to them that the instrument was a questionnaire about empathy and that we would like to use the results for a research project.

In a sample of 80 students, we assessed the test-retest reliability two weeks after the first admission in order to test whether the results for the same individual on different occasions are the same.

2.3 Analysis of the data

We calculated the mean value and the standard deviation (SD) for each item, the item to total correlation and the total scale if item deleted. The total score as the sum of all items based on the JSE scoring algorithm was calculated. We also presented SD, range and quartiles. To compare empathy score for male and female students, we applied the t-test for two independent samples. The level of significance was set to $p<0.05$.

We calculated the Cronbach alpha to assess the internal consistency aspect of reliability of the instrument. Usually, a reliability of 0.70 is required for analysis at the group level and values of 0.85 and higher at the individual level (28). The test-retest reliability was calculated two weeks after the first admission using the ICC coefficient.

Validity of the JSE-S was examined by confirmatory factor analysis (principal component analysis with varimax rotation). Factors with eigenvalue greater than 1 were retained.

All calculations were conducted using IBM SPSS Statistics version 21 for Windows.

2.4 Ethical approval

The research protocol was approved by the national ethical committee on 31 January 2011. Number of approval was 143/02/11.

3 RESULTS

3.1 Descriptive analysis at the item level

Descriptive analysis at the item level

234 out of 298 (response rate 78.5%) students completed the JSE-S. There were 162 female (69.2%) and 72 male (30.8%) students. The average age of the students was 19.3 years (from 18 to 46 years, SD 2.3 years, skewness 7.6). The mean score of the items ranged from 3.27 (SD 1.72) for item "Health care providers should not allow themselves to be influenced by strong personal bonds between patients and their family members" to 6.50 (SD 0.82) for item "Patients feel better when their health care providers understand their feelings". Table 1 presents descriptive analysis at the item level.

Table 1. *Descriptive analysis at the item level. SD is standard deviation, ITC is the item to total correlation and SID is the total scale if item deleted.*

Tabela 1. *Deskriptivna statistika posameznih vprašanj. SD je standardna deviacija, ITC je korelacija med posamezno spremenljivko in celotno lestvico, SID pa je vrednost lestvice, če odstranimo posamezno spremenljivko.*

No. Št.	Item Vprašanje	Mean Povprečje	SD	ITC	SID
1	Physicians' understanding of their patients' feelings and the feelings of their patients' families does not influence medical or surgical treatment. Če zdravnik razume čustva svojih bolnikov in čustva njihove družine, to ne vpliva na medicinsko ali kirurško zdravljenje.	5.20	1.76	0.26	102.39
2	Patients feel better when their physicians understand their feelings. Bolniki se bolje počutijo, če zdravniki razumejo njihova čustva.	6.50	0.82	0.40	101.05
3	It is difficult for a physician to view things from patients' perspectives. Za zdravnika je težko videti stvari z bolnikovega stališča.	4.65	1.27	0.08	102.96
4	Understanding body language is as important as verbal communication in physician-patient relationships. Razumevanje govorice telesa je pri odnosu zdravnik-bolnik prav tako pomembno kot besedno sporazumevanje.	5.87	1.32	0.34	101.71
5	A physician's sense of humour contributes to a better clinical outcome. Zdravnikov smisel za humor prispeva k boljšemu kliničnemu izidu.	3.89	1.78	0.23	103.70
6	Because people are different, it is difficult to see things from patients' perspectives. Ker se ljudje razlikujemo, je težko videti stvari z bolnikovega stališča.	4.75	1.40	0.23	103.33
7	Attention to patients' emotions is not important in history taking. Pri anamnezi upoštevanje bolnikovih čustev ni pomembno.	5.66	1.38	0.50	101.92
8	Attentiveness to patients' personal experiences does not influence treatment outcomes. Upoštevanje bolnikovih osebnih izkušenj ne vpliva na izid zdravljenja.	5.42	1.50	0.50	102.11
9	Physicians should try to stand in their patients' shoes when providing care to them. Zdravniki bi se morali pri obravnavi bolnikov poskusiti postaviti v njihov položaj.	5.24	1.24	0.45	102.27
10	Patients value a physician's understanding of their feelings which is therapeutic in its own right. Bolniki cenijo zdravnikovo razumevanje čustev, kar je samo po sebi terapevtsko.	5.73	1.20	0.35	101.79
11	Patients' illnesses can be cured only by medical or surgical treatment; therefore, physicians' emotional ties with their patients do not have a significant influence on medical or surgical treatment. Bolnikove bolezni lahko pozdravi le zdravljenje z zdravili ali ali kirurško zdravljenje; zato čustvene vezi med zdravniki in njihovimi bolniki nimajo pomembnega vpliva na zdravljenje z zdravili ali kirurško zdravljenje.	5.85	1.43	0.54	101.66
12	Asking patients about what is happening in their personal lives is not helpful in understanding their physical complaints. Spraševanje bolnikov o dogajanju v njihovem zasebnem življenju ne pomaga pri razumevanju njihovih telesnih težav.	5.90	1.24	0.34	101.62

13	Physicians should try to understand what is going on in their patients' minds by paying attention to their non-verbal cues and body language. Zdravniki bi morali z upoštevanjem bolnikovih nebesednih znakov in govorice telesa poskusiti razumeti, kaj se dogaja v bolnikovem umu.	5.31	1.58	0.49	102.17
14	I believe that emotion has no place in the treatment of medical illness. Mislim, da čustva ne sodijo v zdravljenje bolezni.	5.93	1.31	0.52	101.60
15	Empathy is a therapeutic skill without which the physician' s success is limited. Empatija je terapevtska veščina, brez katere je uspeh zdravnika omejen.	5.71	1.37	0.58	101.86
16	Physicians' understanding of the emotional status of their patients, as well as that of their families is one important component of the physician-patient relationship. Zdravnikovo razumevanje čustvenega stanja bolnikov in njihovih družin je pomemben del odnosa zdravnik-bolnik.	5.94	1.17	0.46	101.63
17	Physicians should try to think like their patients in order to render better care. Zdravniki bi morali poskusiti razmišljati kot njihovi bolniki, kar bi jim omogočilo nuditi boljšo oskrbo.	4.65	1.44	0.43	102.87
18	Physicians should not allow themselves to be influenced by strong personal bonds between their patients and their family members. Zdravniki si ne bi smeli dovoliti, da nanje vplivajo tesne osebne vezi z bolniki in njihovimi družinskimi člani.	3.27	1.72	0.04	104.31
19	I do not enjoy reading non-medical literature or the arts. Ne prebiram rad nemedicinske literature in ne uživam v umetnosti.	6.45	1.18	0.19	101.07
20	I believe that empathy is an important therapeutic factor in medical treatment. Mislim, da je empatija pomemben terapevtski dejavnik pri zdravljenju.	6.10	1.16	0.61	101.43

3.2 Data analysis at the scale level

209 (89.3%) students answered all the items. The mean score for the scale with possible range from 20 to 140 was 107.6 (from 71 to 131, SD 12.6). Table 2 shows the descriptive statistics for the JSE-S.

Table 2. Descriptive statistics for the JSE-S.
Tabela 2. Deskriptivna statistika za JSE-S.

Statistics/Statistika	Value Vrednost
Mean / Povprečje	107.6
Range / Interval	71-131
Standard error of mean / Standardna napaka povprečja	0.868
25th percentile / 25. percentil	100.5
50th percentile / 50. percentil	109.0
75th percentile / 75. percentil	117.0
Alpha reliability estimate / Ocena zanesljivosti Alfa	0.79
ICC (test-retest reliability) / ICC (zanesljivost "test-retest")	0.703

Distribution of students based on the total score on the JSE-S is presented in Figure 1.

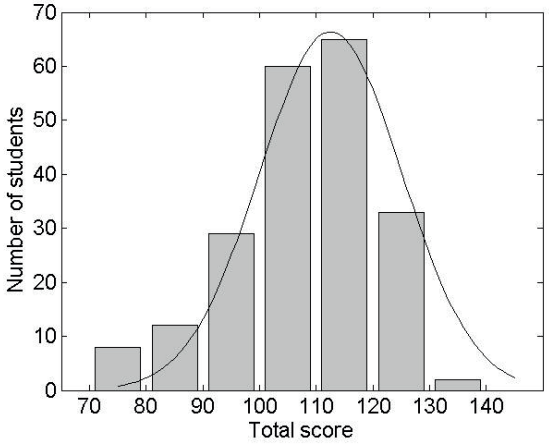

Figure 1. *Students' empathy assessed by the Jefferson scale. Higher total score means more empathic behaviour of the students.*

Slika 1. *Empatija študentov na osnovi Jeffersonove lestvice. Višji rezultat pomeni bolj empatično obnašanje študentov.*

We found that the level of empathy was higher for female than male students (109.2 vs. 103.5, difference 5.7, standard error of difference 1.9, t-test, p=0.003).

3.3 Factor analysis

Using factor analysis (principal component analysis for extraction) with varimax rotation, we described 57.2% of the total variance using six factors with eigenvalues of at least 1.0. Table 3 shows factor loadings on the JSE-S. The items belonging to the particular factor are bolded. The values of all bolded items are greater than 0.35. We labelled the factors as follows:

Factor 1: Perspective taking - 1
Factor 2: Perspective taking - 2
Factor 3: Compassionate care
Factor 4: Standing in the patient's shoes
Factor 5: Interpersonal relationship
Factor 6: Miscellaneous

Table 3. *Loadings of factors with eigenvalues of at least 1.0. Eigenvalues at the bottom of the table are taken after varimax rotation.*

Tabela 3. *Uteži faktorjev z lastnimi vrednostmi vsaj 1.0. Lastne vrednosti na dnu tabele so vzete po rotaciji varimax.*

No. Št.	Item Vprašanje	Factor 1 Faktor 1	Factor 2 Faktor 2	Factor 3 Faktor 3	Factor 4 Faktor 4	Factor 5 Faktor 5	Factor 6 Faktor 6
		Perspective taking - 1 Razumevanje bolnikovega videnja – 1	Perspective taking - 2 Razumevanje bolnikovega videnja - 2	Compassionate care Sočutna oskrba	Standing in the patient's shoes Sposobnost postaviti se v vlogo bolnika	Interpersonal relationship Medosebno razmerje	Miscellaneous Razno
11	Patients' illnesses can be cured only by medical or surgical treatment; therefore, physicians' emotional ties with their patients do not have a significant influence on medical or surgical treatment. Bolnikove bolezni lahko pozdravi le zdravljenje z zdravili ali ali kirurško zdravljenje; zato čustvene vezi med zdravniki in njihovimi bolniki nimajo pomembnega vpliva na zdravljenje z zdravili ali kirurško zdravljenje.	0.662	0.132	0.185	0.103	0.160	-0.018

12	Asking patients about what is happening in their personal lives is not helpful in understanding their physical complaints. Spraševanje bolnikov o dogajanju v njihovem zasebnem življenju ne pomaga pri razumevanju njihovih telesnih težav.	0.698	-0.023	-0.057	-0.107	0.176	-0.092
14	I believe that emotion has no place in the treatment of medical illness. Mislim, da čustva ne sodijo v zdravljenje bolezni.	0.745	0.147	0.198	0.061	-0.061	-0.054
15	Empathy is a therapeutic skill without which the physician' s success is limited. Empatija je terapevtska veščina, brez katere je uspeh zdravnika omejen.	0.543	0.347	0.161	0.168	0.046	0.266
16	Physicians' understanding of the emotional status of their patients, as well as that of their families is one important component of the physician-patient relationship. Zdravnikovo razumevanje čustvenega stanja bolnikov in njihovih družin je pomemben del odnosa zdravnik-bolnik.	0.443	0.434	-0.153	-0.112	0.364	0.173
20	I believe that empathy is an important therapeutic factor in medical treatment. Mislim, da je empatija pomemben terapevtski dejavnik pri zdravljenju.	0.556	0.334	0.159	0.104	0.191	0.324
2	Patients feel better when their physicians understand their feelings. Bolniki se bolje počutijo, če zdravniki razumejo njihova čustva.	0.116	0.535	-0.052	0.167	0.405	0.020
4	Understanding body language is as important as verbal communication in physician-patient relationships. Razumevanje govorice telesa je pri odnosu zdravnik-bolnik prav tako pomembno kot besedno sporazumevanje.	0.076	0.419	0.269	-0.055	0.029	0.395
9	Physicians should try to stand in their patients' shoes when providing care to them. Zdravniki bi se morali pri obravnavi bolnikov poskusiti postaviti v njihov položaj.	0.290	0.663	0.075	0.128	-0.082	-0.051

13	Physicians should try to understand what is going on in their patients' minds by paying attention to their non-verbal cues and body language. Zdravniki bi morali z upoštevanjem bolnikovih nebesednih znakov in govorice telesa poskusiti razumeti, kaj se dogaja v bolnikovem umu.	0.412	0.445	0.187	-0.027	-0.002	0.221
17	Physicians should try to think like their patients in order to render better care. Zdravniki bi morali poskusiti razmišljati kot njihovi bolniki, kar bi jim omogočilo nuditi boljšo oskrbo.	0.011	0.799	0.194	-0.023	0.116	-0.120
1	Physicians' understanding of their patients' feelings and the feeling of their patients' families does not influence medical or surgical treatment. Če zdravnik razume čustva svojih bolnikov in čustva njihove družine, to ne vpliva na medicinsko ali kirurško zdravljenje.	0.110	0.045	0.727	-0.070	-0.056	-0.026
7	Attention to patients' emotions is not important in history taking. Pri anamnezi upoštevanje bolnikovih čustev ni pomembno.	0.102	0.239	0.701	0.109	0.212	0.157
8	Attentiveness to patients' personal experiences does not influence treatment outcomes. Upoštevanje bolnikovih osebnih izkušenj ne vpliva na izid zdravljenja.	0.295	0.141	0.505	0.122	0.356	-0.130
3	It is a difficult for a physician to view things from patients' perspectives. Za zdravnika je težko videti stvari z bolnikovega stališča.	-0.037	-0.038	-0.044	0.843	0.093	0.089
6	Because people are different, it is difficult to see things from patients' perspectives. Ker se ljudje razlikujemo, je težko videti stvari z bolnikovega stališča.	0.120	0.137	0.080	0.806	-0.041	-0.068

5	A physician's sense of humour contributes to a better clinical outcome. Zdravnikov smisel za humor prispeva k boljšemu kliničnemu izidu.	-0.001	-0.026	0.252	-0.120	0.748	-0.045
10	Patients value a physician's understanding of their feelings which is therapeutic in its own right. Bolniki cenijo zdravnikovo razumevanje čustev, kar je samo po sebi terapevtsko.	0.224	0.128	-0.029	0.145	0.619	0.083
18	Physicians should not allow themselves to be influenced by strong personal bonds between their patients and their family members. Zdravniki si ne bi smeli dovoliti, da nanje vplivajo tesne osebne vezi z bolniki in njihovimi družinskimi člani.	0.194	-0.032	0.221	-0.067	-0.051	-0.705
19	I do not enjoy reading non-medical literature or the arts. Ne prebiram rad nemedicinske literature in ne uživam v umetnosti.	0.312	-0.174	0.257	-0.049	-0.053	0.600
	Eigenvalue Lastna vrednost	2.86	2.36	1.77	1.56	1.55	1.36
	% of explained variance % pojasnjene variance	14.31	11.72	8.83	7.80	7.75	6.78

We confirmed the multidimensionality of the concept of empathy by finding six dimensions. Our first-year medical students recognise all three dimensions of the original three-dimensional structure of the JSE-S, but they also recognised an additional two dimensions: "positive perspective on patient care" and "bio-medical perspective".

4 DISCUSSION

The findings of this study support the construct validity of the Slovenian translation of the JSE-S. Using factor analysis, we confirmed the multidimensionality of the concept of empathy; six factors explain understanding of the concept of empathy in Slovenian students. The reliability of the Slovenian version is comparable to other translated versions and is only slightly smaller than the original version. The instrument is now available for measuring empathy in medical students.

The mean values of items ranged from 3.27 to 6.50 on the seven-point Likert scale. The finding indicates that the respondents tend to be skewed toward the upper end of the scale (negative skewness). The item with the highest value was "Patients feel better when their physicians understand their feelings" (in the original version of Jefferson scale it belongs to the component named "perspective taking"), which is the most cognitive dimension of empathy, while the item with the lowest value was "Physicians should not allow themselves to be influenced by strong personal bonds between their patients and their family members", which belongs to the component named "compassionate care" in the original version of JSE (3).

Empathy in first-year medical students in Slovenia is similar to that in some other European countries such as Austria (18) and Portugal (19), slightly higher than in Japan (20), Iran (23) and Kuwait (29) and lower than in the United States (3,25) and Brazil (21). Cultural

differences seem to have impact on the level of empathy in medical students at the beginning of their medical education (30). It seems that the emotional component of care is highly valued in America but less in Europe or in Asia.

The Slovenian version of the JSE-S has an acceptable level of internal consistency and test-retest stability. Internal consistency of our scale was slightly lower than internal consistency of the original questionnaire, which was 0.89 (3), and similar to most of the translations (16, 20,2 3).

As in most other studies, we confirmed higher level of empathy in females than in males (3, 4, 20, 25, 30). The gender differences in empathy should be explained with intrinsic biological factors and also with extrinsic factors, e.g. gender role expectations (3).

Our first-year medical students recognised empathy as a multidimensional concept. Six factors were recognised; the last three of them consisted of only two items. Similar results were found in Japan, where students recognised five factors (20).

Factor 1, which explains 14.3% of the variance, is a major component that could be labelled as "perspective taking". It contains six items with factor coefficients greater than 0.40. The second most important factor, which explains 11.7% of the variance and consists of five items, might also be labelled as "perspective taking". With both factors that belong to the component "perspective taking", we explained 26% of the variance (almost half of all explained variance). The "perspective taking" component has been described as a major dimension of empathy in patient care (3).

Factor 3, which explains 8.8% of variability and contains three items, might be labelled as "compassionate care". All items belonging to this component are also a part of the component "compassionate care" in the analysis made by Hojat et al. (3).

Factor 4 might be labelled as "standing in the patient's shoes". Items 3 and 6 were recognised to be a part of the domain "standing in the patient's shoes" also in the studies made by Hojat et al. (3), Tavakol et al. (16) and Kataoka et al. (20).

Factor 5 could be labelled as "interpersonal relationship". Students at the beginning of medical education seem to be very enthusiastic and try to have positive relationship to people who are their potential patients. They found humour as an important element in communication, which is helpful in establishing a good doctor-patient relationship (13).

Items of factor 6 do not have anything in common and cannot form a separate factor. It seems that students were confused when they had to answer a question asking them about their opinion about art.

The findings generally confirm the three factors of "perspective taking, compassionate care and ability to stand in the patient's shoes" that had appeared in American students (3).

The differences in understanding of empathy between Slovenian and American students might be explained by cultural differences and values in different societies. Another reason for differences in understanding of empathy might be the criteria for entering medical school, which are extremely science-oriented. High school students who are going to enter medical school tend to concentrate heavily on studying science, and they do not have much time for extracurricular activities for development of humanistic skills related to physician's professionalism.

4.1 Strengths and limitations of the study

The study was conducted on a representative sample of first-year medical students. The response rate was high. We took into account all the recommendations for validation of the instrument recommended by the authors of JSE, and our results are in line with the results published by other authors.

Our study also has some limitations. We had included only students of one out of the two medical faculties in the country. Due to similar cultural background and similar requirements for entering the medical schools in the country, we do not expect that the students of two medical schools would have different levels and understanding of empathy at the beginning of the study. Due to the cross-sectional design of the study, we did not have to estimate some important aspects of reliability and validity, including responsiveness to changes.

Our measurement of empathy using the JSE-S was self-reported. It measures a medical student's orientation to empathy, but it does not measure the student's behaviour. However, a research by Hojat and co-authors demonstrated a correlation that supports a predictive value of the JSE-S for empathic behaviour (31).

4.2 Implications for practice

Teachers should structure curricula in a way to combine professional knowledge with broad concept of humanistic personal development. Curricula that include time dedicated to discuss students' reactions to patients' care and enable participation in service activities are believed to enhance the level of students' empathy (11, 32).

It has been reported that assessed level is related to the future professional career. Empathy in "people-oriented" specialities is higher than empathy in technology-oriented specialities. The highest mean scores of empathy were found in psychiatrists, but family medicine specialists also belong to the specialities with the highest empathy scores (3). The level of empathy should be included as a part of election process of candidates for residency in family medicine.

4.3 Implications for future research

It would be interesting to know how the empathy varies from the first to the sixth year of the medical study. We believe that our curricula, especially after the Bologna changes with the implementation of early patient contact into medical teaching (13), stimulate development of humanistic values in medical students and positively influence students' empathy. In a systematic review of studies, especially those with longitudinal data, it was found that the empathy decline during the medical study and residency compromised striving toward professionalism and may threaten health care quality (33), but there were also other reports claiming that empathy can be preserved or increased through the educational process at the medical school (11, 19, 26, 34).

An important question is also whether the self-reported empathy assessed by JSE-S is related to empathic behaviour of students and later on also to the behaviour of residents and physicians in practice (30, 35). A longitudinal observation of self-reported empathy and empathic behaviour of the cohort of students from the first year of the undergraduate study to their specialist exam would be interesting.

5 CONCLUSION

Our findings provide support for the construct validity and reliability of the Slovenian translation of the student version of the Jefferson scale of empathy (JSE-S). The instrument is now available for use in national and cross-cultural studies in medical education. Further research is required to find out whether the changes in medical curricula according to the Bologna declaration have a positive impact on students' empathy. A longitudinal cohort study is needed to test variations in students' empathy throughout the medical school. It would be also beneficial to know the relationship between empathy and career preferences as well as between empathy and clinical behaviour.

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CURRENT REGULATORY AND MARKET ENVIRONMENT FOR BIOSIMILARS IN SERBIA

TRENUTNO ZAKONODAJNO IN TRŽNO OKOLJE NA PODROČJU PODOBNIH BIOLOŠKIH ZDRAVIL V SRBIJI

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Abstract

Background: *Biosimilars are currently a reality of the pharmaceutical market in the European Union. This paper describes the current regulatory policy for approving biosimilars both in the European Union and in Serbia, which is not a Member State. Also, a comprehensive analysis on biosimilars consumption data on the Serbian market has been performed.*

Methods: *The European Medicines Agency has established a series of biosimilar scientific guidelines that comprises a regulatory policy for biosimilars in the European Union. This has enabled different biosimilar products to be marketed, making the European Union biosimilar market the most developed one globally. In the paper, this regulatory environment has been analysed, emphasising all relevant biosimilar guidelines as well as marketed biosimilar medicines. Also, an analysis is performed on Serbian regulatory requirements for approving and marketing biosimilars, analysing the Serbian regulatory authority's consumption data as well as data available from the National Health Insurance Institution.*

Results: *In the paper, the comprehensive analysis of the current European Union as well as Serbian regulatory environment has been presented, with a special emphasis on the Serbian market potential for biosimilar medicines. Detailed consumption data has been analysed for the period 2007-2011.*

Conclusion: *Serbia has good potential for biosimilar products, which is supported by national health insurance policy and the general trend of cutting the reimbursement costs for prescription medicines. Five year consumption data for biosimilars in Serbia shows that the Serbian biosimilars market is very small in terms of market share values, especially comparing to other large European biosimilar markets.*

Key words: biosimilar, medicine regulatory authority, consumption, Serbia, marketing authorisation

Izvirni znanstveni članek
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Izvleček

Uvod: *Podobna biološka zdravila so trenutno realnost farmacevtskega trga v Evropski uniji. Članek opisuje trenutno zakonodajno politiko pridobitve registracij podobnih bioloških zdravil v državah Evropske unije in v Srbiji, ki ni članica EU. Izvedena je bila tudi podrobna analiza porabe podobnih bioloških zdravil na srbskem trgu.*

Metode: *Evropska agencija za zdravila je uvedla vrsto znanstvenih smernic za registracijo bioloških zdravil, ki veljajo za zakonodajo na tem področju v Evropski uniji. To je omogočilo registracijo številnih podobnih bioloških zdravil in farmacevtski trg v državah Evropske unije velja za enega izmed najrazvitejših na svetovni ravni. V članku je opisano zakonodajno okolje s poudarkom na vseh pomembnih regulatornih smernicah in tudi analiza registriranih podobnih bioloških zdravil. Prav tako je narejena analiza predpisanih regulatornih zahtev za pridobitev registracij in trženje podobnih bioloških zdravil v Srbiji; izvedena je bila tudi analiza porabe registriranih zdravil v Srbiji prek podatkov srbske agencije za zdravila in zavoda za zdravstveno zavarovanje.*

Rezultati: *V članku je predstavljena celovita analiza trenutnega zakonodajnega okolja v državah Evropske unije in v Srbiji s poudarkom na tržnem potencialu podobnih bioloških zdravil v Srbiji. Prav tako je podana podrobna analiza porabe bioloških zdravil za obdobje 2007–2011.*

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Zaključek: *Srbija ima dober potencial za podobna biološka zdravila, ki so podprta z nacionalno zdravstveno politiko zavarovanja in s splošnim trendom zmanjševanja povračil stroškov za zdravila na recept. Petletni podatki o porabi podobnih bioloških zdravil v Srbiji kažejo, da je srbski trg zelo majhen v njihovi porabi, še posebej v primerjavi z drugimi večjimi evropskimi trgih podobnih bioloških zdravil.*

Ključne besede: podobno biološko zdravilo, agencije za zdravila, poraba zdravil, Srbija, registracija zdravil

1 INTRODUCTION

The biopharmaceutical industry has expanded dramatically over the last 30 years since the first successes of recombinant DNA technology. Biotechnology derived medicinal products, which comprise cytokines, hormones, clotting factors, monoclonal antibodies and vaccines, are presently the best characterised biologicals with considerable production and clinical experience and have revolutionised the treatment of some of the most difficult-to-treat diseases. Considering that during the period 1995-2007, the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) approved 174 biologic products, at present over 450 are under development (1). While in 2000 they represented 11% of the market, it is expected they will reach 44% in 2012 (2).

Nowadays, the patent and regulatory data protection periods for the first and second waves of biopharmaceuticals based on recombinant proteins have started to expire, opening the way for other manufacturers to place follow-on products on the market. This has occurred for many years for conventional medicines containing small-molecule active substances. In the latter case, regulations for generic products allow for abbreviated approval based on proof of therapeutic equivalence demonstrated by analytical as well as usually by bioequivalence studies (3). Generics' manufacturers do not have to bear the cost of medicine discovery, do not need to prove the safety and efficacy of their medicines through costly clinical trials and are not subject to significant project attrition during development. Consequently, generic medicines can be offered at a significantly lower price than the innovator's medicine (4).

Meanwhile, it has been recognised by all stakeholders – politicians, regulators, the innovative and generics pharmaceutical industry, payers, physicians, pharmacists and patients that there are fundamental differences between conventional small-molecule based medicines and biopharmaceuticals. This has led to the adoption of distinct legal and regulatory frameworks for follow-on products to biopharmaceuticals ("biosimilars") in various parts of the world.

Fundamental differences between small-molecule based (chemical) medicines and biopharmaceuticals are especially evident in the manufacturing process. Recombinant DNA technology enabled the manipulation of genes and cells to produce structurally complex medicines that would have been impossible to manufacture through chemical synthesis or to purify from natural sources. These medicines are produced through highly controlled manufacturing processes including bacteria, yeast, plant or mammalian cells acting as the "manufacturing facility". The development and manufacturing of recombinant protein products include:

- cloning the coding DNA sequence into a suitable DNA vector;
- transfecting this vector into a host cell;
- screening for the cell that forms the product in the desired quality and required quantity;
- subcloning and developing this cell further concerning expression yield, growth properties, etc. into a master and working cell bank respectively from which all subsequent production runs are performed;
- growing the recombinant cell in large bioreactor vessels (up to, and even exceeding, 10,000 L scale) depending on the supply needs;
- purifying the target protein using a multi-step downstreaming process; and finally
- bringing it into a formulation and device suitable for transport, storage and application to the patients.

The whole process has to be run under strictly controlled, validated conditions in closed systems to ensure consistency and avoid any contamination and in accordance with Good Manufacturing Practice (GMP) requirements. A second manufacturer aiming to replicate a protein product independently has to run through an analogous procedure as above but will not be able to reproduce it in an identical way. Transfection of the host cell represents a unique event that cannot be identically replicated, resulting in a manufacturing cell line with different properties (3). Therefore, for biopharmaceuticals it is often said that "the process is the product", emphasising that the result

of the replicated manufacturing process would be a manufacturing cell line with different properties.
On the other hand, small-molecule based medicines are typically manufactured through chemical synthesis, which means that this is made by combining specific chemical ingredients in an ordered process. Chemical medicines generally have well-defined chemical structures and a finished medicine can usually be analysed to determine all its various components. By contrast, it is very difficult, and sometimes impossible, to characterise a complex biologic medicine using testing methods available in a laboratory and some of the components of a finished biologic may be unknown. It has been recognised by the regulatory authorities that differences in the manufacturing process of biopharmaceuticals necessarily will lead to differences in the product attributes that cannot be fully assessed by analytical characterisation. Therefore, not only physicochemical-biological testing, but also the manufacturing process ("process equals product" paradigm), was made part of the determination of the product quality, emphasising the importance of process control, process validation and product testing. As a consequence, therapeutic proteins derived from independent manufacturing processes can never be identical but can at least be "similar", i.e. possessing the same clinical safety and efficacy profile in spite of not being "the same" molecule.
Like in other European countries, in the past decade biosimilars have entered the Serbian market. This paper gives an overview of the regulatory framework for biosimilars in the European Union as well as a general consideration of regulatory requirements for authorising biosimilars in Serbia. Also, the paper presents analysis of biotechnology medicines consumption data on the Serbian market for the past five years both for authorised innovative biotechnology medicines and biosimilars. Additionally, comparison of market share value for Serbian and some selected European biosimilars markets has been presented.

2 METHODS

The literature review was undertaken by the authors in PubMed, MEDLINE and EMBASE for the retrieval of documents pertaining to pharmaceutical legislation for biotechnology medicines, analysis of regulatory processes in the European Union, manufacturing of biologics and reimbursement policies and analysis of relevant market data using key words. These were "biosimilar", "pharmaceutical legislation, biosimilars", "reimbursement, biosimilars", "biosimilar market share". The focus was on relevant articles on biosimilars published before January 2013. For regulatory documents pertaining to the processes of the approval of biosimilars, biologics and generics, a search for legislative decisions, briefing summaries, concept papers, guidance, reports and evaluations of approved and rejected applications for biosimilars published by the World Health Organisation, European Medicines Agency (EMA), Medicines and Medical Devices Agency of Serbia and National Health Insurance Institution of Serbia was conducted. Whenever possible, data from the primary literature were reviewed. Where no data were available in the primary literature, regulatory and other publications (available in the public domain) were cited.
Following the comprehensive literature review, biosimilars regulatory guidelines were summarised in Table 1 and described in section 3. Also, data on biosimilars authorised in Serbia as well as biosimilars consumption data available from the Serbian medicines regulatory authority and National Health Insurance Institution were analysed and compared to data from other European Union markets.

3 EUROPEAN UNION REGULATORY FRAMEWORK FOR BIOSIMILARS

In the EU, technologically advanced medicinal products, such as those developed by means of a biotechnological process (e.g. recombinant DNA technology), can be placed on the market only after a marketing authorisation has been issued by the Community in accordance with the provisions of Regulation (EC) No. 726/2004 (5) (centralised procedure). The difference between conventional generics and biosimilar products has been acknowledged in Article 10 (4) of EU directive 2001/83/EC as amended by directive 2004/27/EC (6). Based on this legislation, the European Union became the first region globally to introduce a particular regulatory framework for biosimilars developed by EMA's Committee for Medicinal Products for Human Use (CHMP). It consists of an overarching guideline as well as more general guidelines concerning the product quality and other clinical and non-clinical issues. Product-specific guidelines are also available, and the EMA is in the process of developing additional product-specific guidelines and is planning to update these guidelines as new information comes to light (Table 1).

Table 1. *European Medicines Agency guidelines for biosimilars (7).*
Tabela 1. *Smernice za podobna biološka zdravila izdana s strani Evropske agencije za zdravila (7).*

Guideline reference number/ Referenčna številka smernic	Guideline title/ Naslov smernic	Effective date/ Datum začetka veljavnosti	Remarks/ Opombe
Overarching guideline/ Nadrejene smernice			
CHMP/437/04 Rev.1	Similar biological medicinal product (concept paper)/ Podobna biološka zdravila (koncept)		Released for consultation May 2013/ predložene v posvetovanje maja 2013 Deadline for comments 31 October 2013/ rok za pripombe 31. oktober 2013
CHMP/437/04	Similar biological medicinal products (adopted guideline)/ Podobna biološka zdravila) (sprejete smernice)	October/ oktober 2005	
Quality issues guidelines/ Smernice o kakovosti			
EMA/CHMP/ BWP/247713/2012	Similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues/ Podobna biološka zdravila, ki kot zdravilno učinkovino vsebujejo biotehnološko pridobljene beljakovine: vprašanja kakovosti (concept paper)/ (koncept)		Released for consultation May 2012 predložene v posvetovanje maja 2012 / Deadline for comments 30 November 2012/ rok za pripombe 30. november 2012
EMEA/CHMP/ BWP/49348/2005	Similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues/ Podobna biološka zdravila, ki kot zdravilno učinkovino vsebujejo biotehnološko pridobljene beljakovine: vprašanja kakovosti (adopted guideline)/ (sprejete smernice)	June/ junij 2006	
CPMP/ICH/5721/03	Comparability of medicinal products containing biotechnology-derived proteins as active substance - Quality issues/ Primerljivost zdravil, ki kot zdravilno učinkovino vsebujejo biotehnološko pridobljene beljakovine – vprašanja kakovosti (adopted guideline)/ (sprejete smernice)	December 2003	Superseded by / nadomeščene s CPMP/ICH/5721/03
Non-clinical and clinical issues guidelines/ Smernice o nekliničnih in kliničnih vprašanjih			
EMA/CHMP/ BMWP/572828/2011	Revision of the guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues / Sprememba Pregled smernic o podobnih bioloških zdravilih, ki kot zdravilno učinkovino vsebujejo biotehnološko pridobljene beljakovine: neklinična in klinična vprašanja (concept paper)/ (koncept)		Released for consultation October 2011/ predložene v posvetovanje oktobra 2011 Deadline for comments 31 December 2011/ rok za pripombe 31. december 2011
EMA/CHMP/ BMWP/86289/2010	Immunogenicity assessment of monoclonal antibodies intended for in vivo clinical use/ Ocena imunogenosti monoklonskih protiteles, namenjenih za klinično uporabo in vivo (adopted guideline)/ (sprejete smernice)	December 2012	

EMEA/CHMP/ BMWP/14327/2006	Immunogenicity assessment of biotechnology-derived therapeutic proteins/ Ocena imunogenosti biotehnološko pridobljenih terapevtskih beljakovin (adopted guideline)/ (sprejete smernice)	April 2008	
EMEA/CHMP/ BMWP/101695/2006	Comparability of biotechnology-derived medicinal products after a change in the manufacturing process - non-clinical and clinical issues (adopted guideline)/ Primerljivost biotehnološko pridobljenih zdravil po spremembi v proizvodnem procesu – neklinična in klinična vprašanja (sprejete smernice)	November 2007	
EMEA/CHMP/ BMWP/42832/2005	Similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues/ Podobna biološka zdravila, ki kot zdravilno učinkovino vsebujejo biotehnološko pridobljene beljakovine: neklinična in klinična vprašanja (adopted guideline)/ (sprejete smernice)	June/junij 2006	
EMEA/CPMP/3097/02	Comparability of medicinal products containing biotechnology-derived proteins as drug substance: non-clinical and clinical issues/ Primerljivost zdravil, ki kot zdravilno učinkovino vsebujejo biotehnološko pridobljene beljakovine: neklinična in klinična vprašanja (adopted guideline)/ (sprejete smernice)	June 2004	Superseded by/ nadomeščene s CHMP/BMWP/101695/06
Product-specific guidelines/ Smernice, ki se nanašajo na posamezna zdravila			
CHMP/ BMWP/671292/2010	Similar biological medicinal products containing recombinant follicle stimulation hormone/ Podobna biološka zdravila, ki vsebujejo rekombinantni folikle spodbujajoč hormon (adopted guideline)/ (sprejete smernice)	1 September 2013	
CHMP/ BMWP/652000/20100	Similar biological medicinal products containing interferon beta/ Podobna biološka zdravila, ki vsebujejo interferon beta (adopted guideline)/ (sprejete smernice)	1 September 2013	
EMA/CHMP/ BMWP/403543/2010	Similar biological medicinal products containing monoclonal antibodies: non-clinical and clinical issues/ Podobna biološka zdravila, ki vsebujejo monoklonska protitelesa: neklinična in klinična vprašanja (adopted guideline)/ (sprejete smernice)	1 December 2012	
EMEA/CHMP/ BMWP/301636/08	Similar biological medicinal products containing recombinant erythropoietins/ Podobna biološka zdravila, ki vsebujejo rekombinantne eritropoetine (adopted guideline)/ (sprejete smernice)	30 September 2010	

EMEA/ CHMP/945626/2005	Annex to guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues - Guidance on similar medicinal products containing recombinant erythropoietins/Dodatek k smernicam o podobnih bioloških zdravilih, ki kot zdravilno učinkovino vsebujejo biotehnološko pridobljene beljakovine: neklinična in klinična vprašanja – Navodila za podobna zdravila, ki vsebujejo rekombinantne eritropoetine (adopted guideline)/ (sprejete smernice)	July/julij 2006	Superseded by/ nadomeščene z EMEA/CHMP/BMWP/301636/08
EMEA/CHMP/ BMWP/118264/2007 Rev. 1	Non-clinical and clinical development of similar biological medicinal products containing low-molecular-weight heparins/ Nekliničen in kliničen razvoj podobnih bioloških zdravil, ki vsebujejo heparine z nizko molekulsko maso (concept paper) / (koncept)		Released for consultation January 2013/ predložene v posvetovanje januarja 2013 Deadline for comments 31 July 2013/ rok za pripombe 31. julij 2013
EMEA/CHMP/ BMWP/118264/2007	Similar biological medicinal products containing low-molecular-weight heparins/ Podobna biološka zdravila, ki vsebujejo heparine z nizko molekulsko maso (adopted guideline) / (sprejete smernice)	October / oktober 2009	
EMEA/CHMP/ BMWP/102046/2006	Non-clinical and clinical development of similar medicinal products containing recombinant interferon alpha/ Nekliničen in kliničen razvoj podobnih zdravil, ki vsebujejo rekombinantni interferon alfa (adopted guideline)/ (sprejete smernice)	April 2009	
EMEA/CHMP/ BMWP/31329/2005	Annex to guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues - Guidance on biosimilar medicinal products containing recombinant granulocyte-colony stimulating factor/Dodatek k smernicam o podobnih bioloških zdravilih, ki kot zdravilno učinkovino vsebujejo biotehnološko pridobljene beljakovine: neklinična in klinična vprašanja – Navodila za biološko podobna zdravila, ki vsebujejo rekombinantni dejavnik, ki spodbuja nastajanje kolonij granulocitov (adopted guideline)/ (sprejete smernice)	June/junij 2006	
EMEA/CHMP/ BMWP/94528/2005	Annex to guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues - Guidance on similar medicinal products containing somatropin/Dodatek k smernicam o podobnih bioloških zdravilih, ki kot zdravilno učinkovino vsebujejo biotehnološko pridobljene beljakovine: neklinična in klinična vprašanja – Navodila za podobna zdravila, ki vsebujejo somatropin (adopted guideline)/ (sprejete smernice)	June/junij 2006	

EMEA/CHMP/ BMWP/32775/2005	Revision of the guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues/ Sprememba Pregled smernic o nekliničnem in kliničnem razvoju podobnih bioloških zdravil, ki vsebujejo rekombinantni humani inzulin in analoge inzulina (concept paper) / (koncept)		Released for consultation December 2012/ predložene v posvetovanje decembra 2012 Deadline for comments 30 June 2013/ rok za pripombe 30. junij 2013
EMEA/CHMP/ BMWP/32775/2005	Annex to guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues - Guidance on similar medicinal products containing recombinant human insulin/Dodatek k smernicam o podobnih bioloških zdravilih, ki kot zdravilno učinkovino vsebujejo biotehnološko pridobljene beljakovine: neklinična in klinična vprašanja – Navodila za podobna zdravila, ki vsebujejo rekombinantni humani inzulin (adopted guideline)/ (sprejete smernice)	June 2006	

In the case of biosimilar medicinal products, because the active substance is similar but not identical to those in the reference product, the requirements for marketing authorisation are based on the demonstration of the similar nature of the two biological products through comparability studies, named the 'comparability exercise'. The comparability exercise is needed to generate evidence substantiating the similar nature in terms of quality, safety and efficacy of the new similar biological medicinal product and the chosen reference medicinal product authorised in the EU (8).

The results of the comparative studies done at the quality level may allow a reduction in the non-clinical and clinical data requirements compared to a full dossier. The clinical studies should be designed to demonstrate equivalence rather than non-inferiority, i.e. "better" outcome is not an option because it indicates lack of similarity. Efficacy and safety have to be justified or demonstrated separately for each claimed indication.

The selected reference product will need to be the same throughout the comparability programme. Such comparability studies involve a thorough process starting by the comparison in terms of product quality and manufacturing process consistency, as the safety and efficacy profile of the product is closely linked to its manufacturing method. Currently, due to the state of the art in science, it is almost impossible to prove that two biologic medicines have the same qualitative and quantitative composition. In order to prove that there are no relevant differences between both medicines, in most, if not all cases, comparison to the reference product has to be performed at a non-clinical level. In all cases, there should be pharmacokinetic/pharmacodynamic comparison of a biosimilar and reference product, and in some cases clinical therapeutic equivalence trials are requested to show similar efficacy and safety, at least in one clinical situation (9).

The European system for biosimilar approval devotes special attention to concerns over potential immunogenicity of a biosimilar and to post-marketing testing and surveillance to detect any potential safety issues. Unfortunately, the immunogenicity of biosimilars often cannot be fully predicted using preclinical studies, and clinical immunogenicity studies are thus required before approval. Therefore, safety data will be needed before marketing authorisation and will also be required post marketing.

It is also worth mentioning that the granting of approval does not mean that the biosimilar product can be automatically substituted for the reference product and vice versa. This decision should only be taken after obtaining the opinion of a qualified health professional. Several countries, such as France, Spain, Italy, the Netherlands, the UK and Sweden, have established legislative measures to prohibit the automatic substitution of these products (10).

Announced revision of biosimilar guidelines will probably solve some of the most critical issues during biosimilars' marketing authorisation, which were especially raised by the pharmaceutical industry. On

the basis of the experience gained since the release of the initial guideline, the revision intends to:

- provide clarification with regards to terminology for biosimilars;
- give better clarity on the principles of biosimilarity, including on safety and efficacy aspects;
- clarify requirements regarding the posology, route of administration and formulation of biosimilars.

The revision will also cover global development aspects, including the choice of the reference product when conducting non-clinical and clinical studies. With the aim of facilitating the global development of biosimilars and to avoid unnecessary repetition of clinical trials, the revised guideline explains that it may be possible for an applicant to compare its biosimilar in certain clinical studies and *in vivo* non-clinical studies with a comparator authorised outside of the European Economic Area (EEA). This comparator will need to be authorised by a regulatory authority with similar scientific and regulatory standards to those of the EMA. It will then be the applicant's responsibility to establish that the comparator is representative of the reference product authorised in the EEA. Therefore, it is expected that the revised biosimilar guideline will speed up the authorisation process in the future and the clinical trials costs will be significantly reduced, which will introduce some biosimilar medicines, authorised on other markets, to European Union patients.

4 BIOSIMILARS ON EUROPEAN UNION MARKET

So far, the EMA has granted 14 marketing authorisations for biosimilar products in the EU, including biosimilars to recombinant human growth hormone, granulocyte-colony stimulating factor and erythropoietin (Table 2), i.e. somatropin, filgrastim and epoetin respectively, as their recombinant versions. Approved biosimilars have been compared with reference products in terms of composition and primary structure, higher order structure conformation, post translational modifications, polarity, charge, isoforms, size, detection of aggregates, binding and biological activity (11). Clear regulatory guidelines (Table 1) and tight control are essential in order to guarantee efficacy and safety to patients.

Table 2. *Biosimilar products currently present in the EU market.*
Tabela 2. *Podobna biološka zdravila na trgu EU.*

INN	Name/Ime	Company/ Proizvajalec	Reference product/ Podoben izdelek	CHMP opinion/ mnenje	EU approval/ sprejem
Somatropin	Omnitrope	Sandoz	Genetropin (Pfizer)	January 2006	April 2006
Somatropin	Valtropin (withdrawn)	BioPartners	Humatrope (Lilly)	February 2006	April 2006
Epoetin alfa	Binocrit	Sandoz	Eprex/Erypro (JnJ/ Amgen)	June 2007	August 2007
Epoetin alfa	Epoetin alfa Hexal	Sandoz (Hexal)	Eprex/Erypro (JnJ/ Amgen)	June 2007	August 2007
Epoetin alfa	Abseamed	Medice	Eprex/Erypro (JnJ/ Amgen)	June 2007	August 2007
Epoetin zeta	Retacrit	Hospira	Eprex/Erypro (JnJ/ Amgen)	October 2007	December 2007
Epoetin zeta	Silapro	Stada	Eprex/Erypro (JnJ/ Amgen)	October 2007	December 2007
Filgrastim	TevaGrastim	Teva	Neupogen (Amgen)	February 2008	September 2008
Filgrastim	Filgrastim Ratiopharm (withdrawn)	Ratiopharm	Neupogen (Amgen)	February 2008	September 2008
Filgrastim	Biograstim	CT Arzneimittel	Neupogen (Amgen)	February 2008	September 2008
Filgrastim	Filgrastim Hexal	Hexal	Neupogen (Amgen)	October 2008	February 2009
Filgrastim	Zarzio	Sandoz	Neupogen (Amgen)	October 2008	February 2009
Filgrastim	Nivestim	Hospira	Neupogen (Amgen)	March 2010	June 2010

As occurred with the introduction of equivalent medicines (generic), the approval of biosimilars could be cost saving for health care providers. It has been suggested that an initial wave of biosimilars could generate cost savings equivalent to over 2 billion USD for European health care providers (12). At launch, medicines approved in the EU (Table 2) were offered with about 15-35% lower price vs. the list prices of the innovator products (depending on the product, country and package size). An example was the price reduction of erythropoietin in Germany, where a biosimilar entered the market with a significantly lower price than the reference medicine, and the price of the reference medicine was reduced accordingly, with an overall 33% price reduction of the initial price of the medicine (13). The rising pressure of cost-containment in all major markets is driving the uptake of generics and also creates a demand for biosimilars. However, the cost and duration of development for biosimilars are much greater than for small-molecule generics and present a significant barrier to entry and a resistor of biosimilars market growth (14).

The EU presents the most advanced market for biosimilars, accounting for 80% of global spending on these molecules. However, despite a strong legislative foundation, to date only a few manufacturers have launched biosimilars in the region. These include a mixture of existing generics houses, the generics arms of major companies and new ventures, most notably Sandoz/Novartis, Stada, Hospira, Medice and Ratiopharma (Teva). Biosimilars are established in three therapy areas in Europe: epoetins for treating anaemia caused by renal dialysis, filgrastim for lowered white blood cell counts after chemotherapy and somatropin. The penetration of biosimilars varies by country, reflecting local pricing and reimbursement policies, stakeholder influence and attitudes towards their adoption and use. Across markets, filgrastims have generally achieved the highest penetration by value and somatropin the lowest (25% and 4% class uptake respectively). The lower penetration of somatropin has been largely driven by the greater element of patient choice and discrimination over devices and convenience. Original brand Genotropin, for example, is available in a form that does not require refrigeration, whereas this is a prerequisite for the biosimilar version. Cautious prescribing has also played a role, with physicians hesitant to use biosimilar somatropin given the time it takes to show an effect; with filgrastims, the impact of treatment is more readily apparent, enabling physicians to change course in a faster timeframe if required. In the case of epoetins, uptake is more driven by payer than patient concerns, given the lack of any discernible difference in the patient experience as a result of switching to a biosimilar. Uptake also varies across countries when therapy areas are considered according to type, being significantly lower in differentiated markets where the stakeholder landscape is extremely complex, the value proposition is high and the market is driven by price (e.g. somatropin), versus commodity markets where access is mostly controlled by payers and the product has limited intrinsic value (e.g. filgrastims and epoetins) (15).

5 BIOSIMILARS ON SERBIAN MARKET – REGULATORY AND MARKET ASPECTS

Placing a medicinal product on the Serbian market requires a marketing authorisation, granted on the basis of an application. Since Serbia is still not an EU Member State, European legislation is transposed one by one, which means that a marketing authorisation in the EU does not automatically mean the recognition of the approval with Serbia's competent authority. Rather, the authorisation procedure is carried out by criteria as harmonised as possible with those in EU. When Serbia becomes a full EU Member State, then the principle of European legislation that extends to the new Member State will start to be applied in full. The Serbian medicines regulatory authority - Medicines and Medical Devices Agency of Serbia – is therefore performing a *national procedure* of medicines authorisation, ensuring that authorised medicine is meeting the criteria of quality, safety and efficacy. An additional measure in ensuring better access to medicines on the Serbian market is the introduction of the *fast track marketing authorisation procedure,* which represents a necessary harmonisation step in Serbian legislation, ensuring that medicines authorised by centralised procedure by EMA could be available to patients in Serbia in a shorter period of time, i.e. 150 days. This also reflects the growing capacity of Serbia's competent authority to assess these types of applications and to prepare for future participation in other European procedures (mutual recognition procedure and decentralised procedure) (16).

In line with intensive negotiations with the European Union as well as preparation for the future World Trade Organisation (WTO) membership, Serbian pharmaceutical legislation has been fully harmonised with the current EU directives. The major principle is to establish the same evaluation criteria for medicine

applications submitted in Serbia as for those in EU regulatory authorities in order to achieve the same quality, efficacy and safety of medicines marketed in Serbia. Having this principle in mind, the Serbian regulatory authority is assessing applications for biosimilar medicines on the grounds established in the relevant EMA guidelines (Table 1), which means that there are no additional or less requirements for marketing authorisation of biosimilars in Serbia. Comparability exercise data are required based on the comparison to reference biotechnology products marketed in the EU on the basis of full dossier. The deadline for issuing marketing authorisation for biosimilar medicine is 210 days on the basis of a complete medicine application.

Having in mind all national measures taken in order to harmonise with the EU legislation and to transpose all the requirements set in EU pharmaceutical directives, the Serbian pharmaceutical market has been growing steadily. While the market is small in terms of absolute numbers, relative per capita spending on medicines is expected to improve over the long term. As Serbia continues its economic convergence with developed Europe, medicine consumption is also expected to rise. However, financial inefficiencies within the health insurance system mean that the National Health Insurance Institution is unable to always meet its obligations on time, leaving patients to pay for formerly reimbursed medicines or hospitals having to cover the difference. Pharmaceuticals expenditure is rising from RSD75.70bn (US$1.03bn) in 2011 to RSD81.44bn (US$0.92bn) in 2012 (+7.6% in local currency terms and -11.0% in US dollar terms, which was due to an unfavourable inflation rate of 13 percent in 2012) (17).

The public fund for healthcare in Serbia mainly originates from salary contributions to the compulsory health structures, and private or complementary voluntary health insurance is not well developed and not well integrated with existing public schemes. The Serbian compulsory health insurance fund includes a positive medicine list (PML) as a benefit of the scheme and listing is typically crucial for achieving a significant share in the Serbian market.

There are multiple PMLs in Serbian healthcare system (List A, A_1, B, C and D) with varying reimbursement levels. In order to avoid the risk of exceeding predefined budget, physicians are encouraged to adjust their prescribing accordingly.

Despite continued underfinancing of healthcare in Serbia and the intensification of cost-containment measures by authorities, a number of new, expensive medicines have been included in the PMLs in recent years. It is important to recognise that behind these observations lie some of Serbia's first experiences with patient access, financial and even risk-sharing agreements. Manufacturers' first attempts to partner with payers in Serbian market were exclusively financial in nature and included agreements such as straightforward hidden discounts, classic price-volume contracts or portfolio agreements, where the positive listing of a new drug is conditional on a price decrease for an already marketed product. For example, in order to enable inclusion on the Serbian PML, manufacturers of three oncology drugs (INN: bevacizumab, cetuximab and rituximab) agreed to offer rebates of 25% in 2008 and 11% in 2009 on the reimbursed price (18).

By the end of 2012, several innovative biotechnological medicines were authorised by the Serbian medicines regulatory authority, mainly various forms of epoetin, somatropin and filgrastim. The first market authorisations were issued in 2006 for epoetin beta and darbepoetin alfa, after which filgrastim and somatropin were authorised in 2007 and 2008 respectively. On the other hand, only one biosimilar product has been authorised for the Serbian market, namely epoetin zeta by local pharmaceutical manufacturer Hemofarm AD.

After its authorisation, careful consumption data for epoetin, somatropin and filgrastim medicinal products have been collected by the Serbian medicines regulatory authority; these are presented in Annual medicine consumption reports (19-23). The data were summarised as presented in Table 3, which presents consumption data both for innovative biotechnological medicines and biosimilars that are marketed in Serbia. Also, Table 3 indicates the brand names of registered products in Serbia.

Table 3. *Epoetins, somatropin and filgrastim consumption data on the Serbian market for the period 2007-2011.*

Tabela 3. *Podatki o porabi epoetinov, somatropina in filgrastima na srbskem trgu za obdobje 2007-2011.*

CONSUMPTION DATA OF INNOVATIVE BIOTECHNOLOGICAL MEDICINES/ PODATKI O UPORABI INOVATIVNIH BIOTEHNOLOŠKIH ZDRAVIL											
ATC Code	INN/ Dosage form, strength and package/ marketed product/ INN/farmacevtska oblika, jakost zdravila in pakiranje/zdravilo z dovoljenjem za promet	Amount/packages sold/ Število prodanih pakiranj					Total price (in 000 RSD)/ Skupna cena (v 000 RSD)				
		2007	2008	2009	2010	2011	2007	2008	2009	2010	2011
B03XA01	Epoetin alfa Inj. 6x2000 i.j./0.5ml/EPREX®, Cilag	no MA	no MA	9100	6320	4227	/	/	90.548	67.326	42.767
	Epoetin alfa Inj. 6x2000 i.j./ml/ EPREX®, Cilag	15300	22130	0	0	0	155.539	224.973	0	0	0
	Epoetin beta Inj. 6x2000 i.j./0.3ml/ RECORMON®, Roche Diagnostic GmbH	0	28357	23420	16867	23323	0	272.383	211.986	163.449	213.589
	Darbepoetin alfa Inj. 1x10mcg/0.4ml/ ARANESP®, Amgen Europe B.V.	8972	0	110	14762	30988	16.224	0	8.324	27.798	54.867
	Darbepoetin alfa Inj. 1x20mcg/0.5ml/ ARANESP®, Amgen Europe B.V.	11122	0	0	26292	32219	40.226	0	0	98.713	112.115
	Darbepoetin alfa Inj. 1x30mcg/0.3ml/ ARANESP®, Amgen Europe B.V.	7808	0	0	11310	24338	42.359	0	0	63.520	126.591
	Darbepoetin alfa Inj. 1x60mcg/0.3ml/ ARANESP®, Amgen Europe B.V.	no MA	no MA	no MA	1353	1611	/	/	/	15.155	17.215
H01AC01*	Somatropin Inj. 5x5.3 mg/ml/*	1130	1436	2198	1157	2112	72.126	91.657	150.179	84633	132.683
	Somatropin Inj. carp.1x1.5ml/10mg (pen) /*	1909	1118	795	912	1773	51.748	30.306	25.006	30.712	56.764

	Somatropin Inj. carp.1x1.5ml/15mg (pen) /*	2783	6015	6951	7850	9105	116.037	250.796	336.307	406.617	360.968
L03AA02	Filgrastim Inj. 1x0.5ml/48 M i.j./NEUPOGEN®, F.Hoffman-La Roche LTD	11947	14492	13559	15590	14994	140.750	155.504	168.829	207.824	161.426
	Filgrastim Inj. 1x0.5ml/30 M i.j. /NEUPOGEN®, F.Hoffman-La Roche LTD	883	1626	1898	2176	1468	8.268	10.738	14.545	17853	10.104
B03XA01	Epoetin zeta Inj. 6x2000 i.j./0.6ml/ EQRALYS, Hemofarm AD	no MA	0	5320	3389	2874	/	0	57.329	39.098	24.616

Legend: no MA – medicine had no Marketing Authorisation (MA),
*- Somatropins with marketing authorization in Serbia (innovative medicines): GENOTROPIN®-Pfizer, HUMATROPE®-Lilly France S.A.S, NORDITROPIN® NORDILET-Novo Nordisc, NORDITROPIN® SIMPLEXX®-Novo Nordisc.
Legenda: brez DP – zdravilo nima dovoljenja za promet (DP)
*– Somatropini z dovoljenjem za promet v Srbiji (inovativna zdravila): GENOTROPIN®-Pfizer, HUMATROPE®-Lilly France S.A.S, NORDITROPIN® NORDILET-Novo Nordisc, NORDITROPIN® SIMPLEXX®-Novo Nordisc.

Based on consumption data presented in Table 3, it can be concluded that although Serbia's medicine market is open to biosimilar medicines, with a favourable regulatory environment that is in accordance with EU pharmaceutical legislation, only innovative biotechnology medicines are marketed. Also, there is one approved biosimilar product, but consumption data indicate that physicians are generally in favour of innovative medicines. General consumption data, available from the National Health Insurance Institution database, indicate that the relative market share of biotechnology medicines has a value of less than 1% throughout the analysed period 2007-2011. This value is calculated for innovative biotechnology medicines, whereas market value of the approved biosimilar in Serbia is of no significance. However, when analysing the market share of biotechnology medicines by ATC code groups in which they are classified (Table 3: B – drugs for blood and blood forming organs, H – systemic hormonal preparations, excluding sex hormones and insulins, L – antineoplastic and immunomodulating agents) for the same period, the following data were obtained (24):

- market share of approved epoetins in Serbia is approximately 6% comparing to other marketed medicine products from ATC group B;
- somatropin shows constant market share growth from 27.36% to 34.53% of all marketed products from ATC group H, from 2007 to 2011 respectively;
- as for filgrastim, the market share value is very low (approximately 2% throughout the analysed period) comparing to other marketed medicines of the same ATC group.

The small size of the biosimilar market in Serbia is additionally emphasised when compared with other large markets in Europe such as in Germany and France. In these markets, biosimilars have already achieved strong market share positions in terms of units sold. Currently, Germany and France account for half of the biosimilars market by value in the region with a 34% and 17% share respectively across Europe. Germany is the largest pharmaceutical market in Europe, with a history of high consumption of small molecule generics thus supporting a strong presence of the generic medicines industry; physicians and their patients accept and have confidence in generic/biosimilar medicines due to well-known company branding of generic/ biosimilar medicines. The systems of reference pricing and incentives for physicians to prescribe generics are well-established in Germany. Furthermore, there is a relatively high reimbursement price for marketed medicines in Germany, which motivates generics pharmaceutical companies to provide more resources and information to increase physician awareness of

competing therapeutic options of biosimilars; with regard to the high uptake of biosimilar epoetins, the implementation of quotas has played an effective role. France, for example, applies the same discounts on biosimilars as on generics, thus making the biomsimilars' price more or less equal to the brand-name's price (25).

As for the reimbursement policy in Serbia, the National Health Insurance Institution is trying to cut the costs for prescription medicines as much as possible, giving favour to generic medicines for every indication possible. Having in mind the clinical significance of approved innovative biotechnological products as well as the fact that only one biosimilar is approved in Serbia, all approved innovative biotechnological and biosimilar medicines in Serbia were placed on the last Positive Medicine List, which is approved and available from 25.12.2012. Various forms of epoetins are on List C, which is the list for medicines with special regime and with full reimbursement by National Health Insurance Institution; medicines with somatropin and filgrastim as INNs are on List A and List B respectively, for prescribed medicines for which patients pay only a symbolic participation price (50 RSD, equivalent to 0.5 EUR) (24).

6 CONCLUSION

Biosimilars have the potential of lowering prices and thus reducing the cost of treatments, improving access and reducing expenditures. Payers and reimbursing authorities have some tools to promote the uptake of biosimilars (e.g. to support the availability of information to doctors and patients on the effectiveness and safety of biosimilars, to provide incentives to doctors to prescribe biosimilars when this is an effective and safe option), although the scope for biosimilars penetration is relatively more limited than for conventional generics for technical reasons, e.g. the restricted substitutability and interchangeability of biosimilars and reference products. The future role of biosimilars in the biotech market looks, in principle, promising since the number of biological products reaching patent expiry in the coming years and the growing cost pressure will certainly create a sound basis for a promising development of biosimilars. They will certainly not produce reductions in the price of biological medicines when exclusivity periods expire in the same relative amounts that conventional generics do. Health authorities assume that biosimilars have the potential of lowering prices and thus reducing the pressures on pharmaceutical expenditure, as happens with generics in the small molecule medicines markets. The limited existing evidence suggests, however, that the relative rates of market share uptake and impact on prices are much lower for biological medicines than for small-molecule medicines. Although it has been constantly growing since 2007, by 2010 biosimilars had only a 15% market share of the aggregate products market. Relative high risk in research and development with high investment is accountable for lower price reductions, but given the high annual costs for originator biologicals, any price reduction will bring considerable savings.

In general, biosimilar medicines have enjoyed limited success in the EU to date. The market accessibility of biosimilars is inhibited by many factors: (1) the difficulties and expenses involved in manufacturing biosimilars; (2) the high cost of fulfilling regulatory requirements to obtain marketing authorisation; (3) the limited number of companies that are able to manufacture and commercialise biosimilars; (4) the brand loyalty of physicians and patients to reference biopharmaceutical medicine; (5) the prohibition against substituting a biosimilar for a reference biopharmaceutical medicine; (6) the life cycle management strategies of companies that are marketing reference biopharmaceutical medicines (e.g. developing second-generation reference biopharmaceutical medicines) (26).

Uptake of biosimilars in Europe is slowly increasing according to a new report published by the European Commission's Enterprise and Industry Directorate-General (27). Biosimilars still account for a relatively small segment of the EU pharmaceutical market, but they do have strong annual growth despite the fact that automatic substitution by pharmacists is not permitted in most countries. For the 12-month period from July 2010 to June 2011, biosimilars represented 19 million of a total market estimate of 175 million defined daily doses – approximately 11% by total patient volume. Although in Germany pharmacists may substitute a biosimilar, currently no country has explicitly authorised the substitution of biologicals from different manufacturers, and a number of EU Member States have gone as far as banning this practice.

The uptake of biosimilars also differed between different countries, with differences across European Member States being attributed to differences in national healthcare systems, structures and processes. Some issues that were seen to have an impact on biosimilars' uptake were:

- physicians' perception of biosimilars,
- patients' acceptance of biosimilars,
- local pricing and reimbursement regulations,
- procurement policies and terms.

Therefore, it is a general opinion that in order to increase the use of biosimilars in Europe it is essential that physicians and patients have a thorough understanding of biological medicines, including biosimilar medicines. This would then increase their confidence in using both biological and biosimilar therapies (27).

The Serbian national medicines authority and National Health Insurance Institute will try to strike an acceptable balance between the objectives of protecting patients' health and providing the industry with appropriate incentives for innovation on the one hand and the objectives of reducing treatment costs and ensuring sufficient incentives for the generics/biosimilars industry on the other. The biosimilars market in Serbia is small, struggling not only with physicians' and patients' low confidence in these types of medicines but also with a serious economic crisis that is reflected in the National Health Insurance Institute's inability to cover all costs. Therefore, it is justifiable to expect that the Serbian biosimilars market would not be able to keep up with the constant growth as in other EU Member States, since an additional burden on biosimilars manufacturers is repetition of authorisation procedures in Serbia as a non-EU Member State, even if the product has already been authorised in the EU.

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PRESEČNA RAZISKAVA STALIŠČ RAVNATELJEV O UMEŠČANJU ŠOLSKE MEDICINSKE SESTRE V SLOVENSKI ŠOLSKI PROSTOR

CROSS-SECTIONAL RESEARCH OF SCHOOL PRINCIPALS' VIEW ON PLACEMENT OF SCHOOL NURSES IN SLOVENIAN SCHOOLS

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Izvleček

Izhodišča: *V šoli otroci preživijo velik del dneva, zato ima šola pomembno vlogo pri zdravju otrok in mladostnikov pa tudi pri sodelovanju z zdravstvenimi službami.*
Namen: *Ugotoviti stališče ravnateljev o pomenu, smotrnosti in o možnosti umestitve šolske medicinske sestre v osnovne šole.*
Preiskovanci in metode: *Podatki so zbrani s strukturiranim anketnim vprašalnikom. Vzorec zajema 55,6 % (n = 266) celotne populacije ravnateljev osnovnih šol. Uporabljena je deskriptivna statistika. Soodvisnost je analizirana z multiplo regresijsko in dimenzije odvisne spremenljivke s faktorsko analizo.*
Rezultati: *Na osnovnih šolah najpogosteje ukrepajo zaradi akutnega bolezenskega stanja (PV = 3,48), psihosomatskih (PV = 3,42) in kroničnih bolezni (PV = 3,22) (lestvica 1–6). Ravnatelji prepoznavajo potrebo po nalogah šolske medicinske sestre iz promocije zdravja in zdravstvenih storitev, saj je 11 od 13 predlogov dobilo v povprečju oceno nad 4 (lestvica 1–5). Najprimernejšo umestitev šolske medicinske sestre vidijo deloma v zdravstvenem domu, deloma v šoli (60,2 %); najprimernejši delodajalec je zdravstveni dom (59,4 %). Mnenja se ne razlikujejo glede na velikost šole in vključitev v mrežo Zdravih šol. Ravnatelji s šol, v katerih je telesnih poškodb učencev več, izražajo značilno večjo potrebo po šolski medicinski sestri (b = 0,208, p < 0,014), kar velja tudi za ravnatelje z mnenjem, da je usposabljanje učiteljev za prepoznavanje in ukrepanje ob zdravstvenih težavah v odgovornosti zdravstvenega doma (b = 0,270, p < 0,000).*
Zaključki: *Ravnatelji menijo, da se v šolah srečujejo z zdravstvenimi težavami učencev, a učitelji za ukrepanje nimajo dovolj znanja niti kompetenc. Pozitivno prepoznavajo umestitev šolske medicinske sestre v šolo.*

Ključne besede: šolska medicinska sestra, osnovna šola, zdravstvene težave, vzgoja za zdravje

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Abstract

Background: *Children spend most of their days in schools, therefore schools play an important role in children's inter-institutional health care.*
Objectives: *To identify views of school principals on the importance, relevance and possible placement of school nurses in Slovenian schools.*
Methods: *A structured questionnaire was used. The sample consisted of 55.6% (n=266) of the total population of elementary school principals; descriptive statistics was used. Interdependence was analysed with multiple regression, while dependent variable dimensions were obtained with factor analysis.*
Results: *The most frequent interventions in schools are the result of acute medical conditions (M=3.48), psychosomatic disorders (M=3.42) and chronic diseases (M=3.22) (1-6 scale). Principals ranked the need for suggested services of school nurses highly, as 11 out of 13 suggestions received a mean value of over 4 (on a 1-5 scale), not only in health promotion/education but also in other medical services. The most appropriate work location*

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of school nurses is partly in primary health centres and partly in schools (60.2%); the most appropriate employer is the primary health centre (59.4%). Opinions of principals do not differ according to the size of school or participation in the network 'Schools for health'. Principals of schools with a higher number of interventions due to children's injuries expressed a significantly higher need for school nurse services in the school (b=0.208, p<0.014); the same also goes for principals who feel that training teachers to recognise and act upon children's health problems has to be organised by a primary health centre (b=0.270, p<0.000).

Conclusions: *In school principals' view, schools are faced with children's health problems but teachers do not have enough knowledge or competences to take appropriate measures. They positively recognise the placement of school nurses in schools.*

Key words: school nurse, elementary school, health problems, health education

1 UVOD

Za zdrav in vsestranski razvoj otroka in mladostnika sta potrebna medsektorsko sodelovanje in povezovanje. Resolucija o nacionalnem planu zdravstvenega varstva 2008–2013 nalaga, da bo v ukrepe za ohranjanje in krepitev zdravja poleg zdravstvenega dejavno vključenih več resorjev, predvsem pa šolski, socialni, kmetijski, okoljski in prometni (1).

V nekaterih tujih državah je v šolski prostor tradicionalno vpet zdravstveni kader (2–6). Šolska medicinska sestra izpolnjuje številne potrebe otrok s kroničnimi ali z akutnimi stanji (7). Ima vlogo pri nemotenem zagotavljanju celostnega zdravstvenega varstva otrok in mladostnikov (8, 9). Njene vloge in odgovornosti pomembno vplivajo na celotno zdravje učencev, blagostanje in učni uspeh (7–12). V Sloveniji je delo diplomirane medicinske sestre v zdravstvenem varstvu šolskih otrok in mladine vezano na tim šolskega zdravnika, katerega vodja je zdravnik. Resolucija o nacionalnem planu zdravstvenega varstva 2008–2013 v enem izmed ciljev izpostavlja povečanje vloge medicinskih sester pri prevzemanju novih in samostojnih vlog pri obravnavi kroničnih bolnikov (1). Tudi Svetovna zdravstvena organizacija v svojem poročilu o zdravju in zdravstvenih sistemih v Evropi za leto 2009 izpostavlja nov pristop v primarnem zdravstvenem varstvu, t. i. k ljudem usmerjeno oskrbo kot rešitev na spremenjene potrebe populacije ter kadrovske obremenitve z vedno zahtevnejšo populacijo, s pomanjkanjem časa za svetovanje, večanje administrativnih bremen, pomanjkanjem časa za klinične inovacije itn. ter tudi pomanjkanje zdravnikov (13).

V Sloveniji obseg nalog diplomirane medicinske sestre zajema naloge s področja zdravstvene nege pri kurativnih obiskih in preventivnih obiskih ter aktivnosti izvajanja preventivnega programa. Deluje na lokaciji zdravstvenega doma; v šolski prostor vstopa izjemoma, predvsem z namenom izvajanja vzgoje za zdravje. Iz pregleda slovenske literature je samo iz dveh člankov razvidno (14, 15), da v enem izmed ljubljanskih zdravstvenih domov redno izvajajo tudi programirano zdravstveno vzgojo, ki je z Navodilom za izvajanje preventivnega zdravstvenega varstva na primarni ravni sicer predpisana za vso Slovenijo (16). To je zdravstvena vzgoja, ki se izvaja dodatno, torej ne v sklopu sistematskih pregledov, in navadno poteka v šoli. V omenjenem zdravstvenem domu so medicinske sestre nosilke dejavnosti zdravstvene vzgoje in so pri svojem delu samostojne; skrbijo za načrtovanje, organizacijo, koordinacijo in za izvedbo programov, ki zajemajo splošne zdravstvene in zobozdravstvene vsebine, delo pa izvajajo v vrtcih ter v osnovnih in srednjih šolah (14).

Namen raziskave je bil ugotoviti stališča ravnateljev glede potreb po delovanju šolske medicinske sestre, kot jo poznajo ponekod v tujini, ter o možnosti in smotrnosti umeščanja tega kadra v šole z namenom povečati dostopnost do zdravstvenih storitev in tako zmanjšati razlike v zdravju.

2 METODE

Uporabili smo kvantitativni raziskovalni pristop.

2.1 Instrument

Vprašalnik smo razvili na podlagi pregleda literature, ki je navedena v nadaljevanju. Dva sklopa vprašanj (*Praksa ukrepanja* in *Usposobljenost učiteljev*) sta bila večinoma oblikovana na podlagi razgovorov s petimi učitelji iz različnih šol, saj gre za področje, ki v literaturi ni opisano, navedeno literaturo pa smo uporabili le v delu, ki se nanaša na prvo pomoč. Vprašalnik vsebuje pet demografskih vprašanj, devet vprašanj zaprtega tipa in enega odprtega.

Zanesljivost vprašalnika smo preverjali v več fazah. Pri nastajanju vprašalnika smo se povezali s posameznimi učitelji v redni osnovni šoli in osnovni šoli s prilagojenim programom ter sproti testirali vprašanja. Nato smo

vprašalnik dali izpolniti petim učiteljem iz različnih šol in takrat večino nejasnih in nesmiselnih vprašanj izpustili oz. preoblikovali. Zanesljivost smo preverjali z analizo notranje konsistentnosti na pilotni študiji, ki smo jo izvedli med naključno izbranimi 47 ravnatelji osnovnih šol po Sloveniji, in dobili vrnjenih 32 vprašalnikov oz. 68 %. Rezultate testa zanesljivosti, kjer vrednost koeficienta Cronbach alfa nad 0,8 pomeni visoko zanesljivost, predstavljamo v nadaljevanju. Pozneje vprašalnika nismo spreminjali.

Strukturna predstavitev vprašalnika:

Zdravstvene težave (17–19, 7)

Ugotavljali smo pojavnost zdravstvenih težav pri učencih v šoli in pogostost učiteljevih ukrepanj ob posamezni težavi.

Praksa ukrepanja (20)

Kakšna je praksa ukrepanja na šolah ob akutni bolezni učenca, poslabšanju kronične bolezni oz. poškodbe, smo ugotavljali s šestimi trditvami, do katerih so se anketiranci opredeljevali s 5-stopenjsko lestvico pogostosti. Ugotavljali pa smo tudi, kdo in kako pogosto poskrbi za učenca ob zgoraj opisanih težavah.

Usposobljenost učiteljev (20)

Usposobljenost učiteljev za prepoznavanje težav glede zdravja učencev in ukrepanje ob problemih smo ugotavljali s pomočjo 11 trditev, do katerih so se anketiranci opredeljevali s 5-stopenjsko lestvico strinjanja.

Sodelovanje s šolskim dispanzerjem (9, 19, 14)

Sodelovanje šole in šolskega dispanzerja smo ugotavljali z osmimi trditvami, do katerih so se anketiranci opredeljevali s 5-stopenjsko lestvico strinjanja. Stopnjo zanesljivosti smo testirali na petih trditvah, ki merijo strinjanje glede sodelovanja (Cronbach alfa 0,802).

Predlogi izvajanja nalog šolske medicinske sestre (17, 18, 21, 7, 22, 10)

S trinajstimi trditvami smo ugotavljali potrebe po izvajanju nalog, ki jih v tujini izvaja medicinska sestra na šoli. Do trditev so se anketiranci opredeljevali s 5-stopenjsko lestvico potrebe. Trditve smo razdelili v dva sklopa, ki smo ju poimenovali *Predlogi izvajanja nalog šolske medicinske sestre – zdravstvene storitve* in *Predlogi izvajanja nalog šolske medicinske sestre – promocija zdravja*. Stopnja zanesljivosti za prvi sklop je 0,917 in za drugega 0,948.

Delovanje diplomirane medicinske sestre na šoli (3, 14, 16, 10)

Možnost vključevanja diplomirane medicinske sestre iz obstoječega šolskega dispanzerja v šolski prostor smo preverjali s sedmimi trditvami, do katerih so anketiranci strinjanje izražali s 5-stopenjsko lestvico (Cronbach alfa 0,956).

2.2 Populacija

Vključili smo populacijo ravnateljev osnovnih šol v Sloveniji. V šolskem letu 2011/12 je bilo 478 osnovnih šol, 450 z rednim in 28 s prilagojenim programom (23). Vrnjenih smo dobili 267 vprašalnikov, v obdelavo pa vključili 266 izpolnjenih, kar predstavlja 55,6 % celotne populacije. En vprašalnik se je vrnil neizpolnjen. Več kot polovica anketiranih šol (149 ali 56 %) je vključenih v Slovensko mrežo zdravih šol (SMZŠ), kar je približno enako kot siceršnji delež vključenih osnovnih šol (57 %).

2.3 Potek raziskave in obdelava podatkov

Ravnateljem smo po redni pošti poslali anonimne vprašalnike. Vabilo za izpolnjevanje so dobili enkrat, ponovno pa jih k sodelovanju nismo vabili. Sodelovanje ravnateljev je bilo prostovoljno. Dovoljenje za izvedbo raziskave je podala Komisija za magistrske zadeve Visoke šole za zdravstveno nego Jesenice. Raziskava je potekala v okviru priprave magistrskega dela prve avtorice članka. Izpolnjene poštne vprašalnike smo zbirali od 6. do 23. marca 2012. Podatke smo analizirali s programom SPSS, različica 18. Uporabili smo deskriptivno statistiko. Večina rezultatov je bila predstavljena na podlagi povprečnih vrednosti in standardnih odklonov. Analize odvisnosti spremenljivk smo naredili z multiplo regresijsko analizo (metoda najmanjših kvadratov, OLS) s stopnjo pomembnosti pod 5 %. S faktorsko analizo smo preverili dimenzije odvisne spremenljivke.

3 REZULTATI

Ravnatelji so poročali o tem, ali je bil v šolskem letu 2011/12 v šolo vključen učenec, ki ima oz. je imel posamezno zdravstveno težavo ali bolezen. Rezultati so pokazali, da je 234 anketirancev (88 %) odgovorilo, da je vključen učenec s kronično boleznijo (s sladkorno boleznijo, z astmo, alergijo, s celiakijo, z epilepsijo itn.), enako jih je 234 (88 %) navedlo, da so se pojavile telesne poškodbe, povzročene med poukom (npr. zvini, zlomi, rane, udarci itn.). 223 (83,8 %) ravnateljev je v šolskem letu 2011/12 med učenčevim prebivanjem na šoli zaznalo pojav ušivosti, 220 (82,7 %) pojav akutnega stanja (poviš. tel. temperatura, glavobol, bolečine v trebuhu, epi. napad, akutna alergijska reakcija, hiper-/hipoglikemija itn.) ter 215 (80,8 %), da je vključen učenec s psihosomatsko boleznijo (glavobol/migrena, bolečine v trebuhu, tesnoba, omedlevica itn.). Manj anketirancev, 76 (28,6 %), je poročalo o tveganem vedenju (raba alkohola/tobaka/drog, neodgovorno

spolno vedenje, namerne poškodbe itn.). V povprečju (lestvica 1–6) na šolah najpogosteje ukrepajo zaradi akutnega bolezenskega stanja (3,48), psihosomatskih (3,42) in kroničnih bolezni (3,22).

Na vprašanje, ali ima šola napisan postopek ukrepov za primer ogroženosti zdravja učenca, je 172 (64,7 %) anketirancev odgovorilo, da ga ima in 75 (28,2 %), da ne. Pogostost prakse ukrepanja so ravnatelji potrjevali prek šestih trditev s 5-stopenjsko lestvico. Najpogosteje se dogaja, da ob ogroženosti zdravja učencev šola obvesti starše in učenec pod nadzorom šolskega osebja počaka v šolskem prostoru (PV 4,51), manj pogosto pa se dogaja, da šola obvesti zdravstveni dom in starše, nekdo od šolskega osebja pa učenca odpelje v zdravstveni dom (2,56); redkeje se dogaja, da osebje iz zdravstvenega doma na poziv šole pride po učenca na šolo (1,87). Ob poškodbi zelo pogosto (4,45) šolsko osebje nudi učencem prvo pomoč. Ob poslabšanju kronične bolezni da šolsko osebje učencu pogosteje predpisana zdravila oz. kako drugače ukrepa po navodilu staršev učenca (2,73) kot po navodilu zdravnika (2,17).

Zanimalo nas je mnenje ravnateljev o tem, ali so učitelji in strokovni delavci šole usposobljeni za prepoznavanje težav glede zdravja učencev in za ukrepanje ob težavah ter kako, kar smo merili z 11 trditvami na 5-stopenjski lestvici. Anketirani so se s povprečno stopnjo strinjanja 3,76 opredelili, da jih ukrepanja ob poslabšanju stanja pri kroničnih bolnikih običajno naučijo starši učencev; s 3,63, da se učitelji na njihovih šolah redno izobražujejo za nudenje prve pomoči; s 3,25, da se učitelji redno izobražujejo zaradi prepoznavanja zdravstvenih problemov učencev; s 3,05, da učitelji znajo dajati zdravila učencem s kroničnimi boleznimi. Obenem so izrazili strinjanje s trditvijo, da prepoznavanje zdravstvenih težav učencev ne more biti kompetenca učiteljev (3,87) ter da dajanje zdravil v nobenem primeru ne bi smela biti odgovornost učitelja (3,85). Opredelili so se tudi do mnenja, da bi za usposabljanje učiteljev glede prepoznavanja zdravstvenih težav učencev in ukrepanja ob tem morala biti odgovornost zdravstvenega doma – tima šolskega zdravnika (4,13), ne strinjajo pa se, da bi za tovrstno usposabljanje morala biti odgovorna šola (2,23).

Sodelovanje šole in službe za zdravstveno varstvo šolskih otrok in mladine smo preverjali z osmimi trditvami na 5-stopenjski lestvici. Rezultati kažejo, da se ravnatelji sorazmerno visoko strinjajo (4,19), da bi bil lahko zdravstveni delavec tesneje povezan s šolo in bi del storitev opravljal na lokaciji šole. V povprečju se strinjajo (3,8), da s timom šolskega zdravnika v večini primerov sodelujejo le za izvedbo sistematskih pregledov, a hkrati, da tim šolskega zdravnika poznajo in z njim tesno sodelujejo pri zagotavljanju zdravstvenega varstva učencev (3,4) ter da ob zdravstvenih težavah učenci iščejo pomoč v šolski svetovalni službi, ki se nato poveže s šolskim dispanzerjem (3,34). Kljub temu pa se anketiranci strinjajo, da zdravstvene informacije o učencih, ki so pomembne za varno prebivanje otroka v šoli, pridobivajo od staršev (4,25), manj se strinjajo, da informacije poda šolska zdravstvena služba (2,89). V povprečju se srednje strinjajo (3,28), da tim šolskega zdravnika sodeluje pri razvoju in izvedbi programov s področja zdravja in zdravstvene vzgoje na šoli, ter se ne strinjajo (2,81), da je diplomirana medicinska sestra iz šolskega dispanzerja prisotna na šoli za izvajanje zdravstvene vzgoje.

Predloge nalog, ki jih v tujini opravlja šolska medicinska sestra na šoli, smo preverjali s 13 trditvami na 5-stopenjski lestvici potrebe (Tabela 1). Potreba po nalogah, povezanih s promocijo zdravja, je bila ocenjena v povprečju z oceno 4,21, potreba po nalogah, povezanih z zdravstvenimi storitvami, pa s 4,03.

Tabela 1. Potreba po izvajanju predlaganih nalog šolske medicinske sestre v šoli.
Table 1. Need for implementation of suggested school nurses' duties in schools.

	Stopnja potrebe / Scale 1 - 5	Standardni odklon/ Std. deviation
	PV mean	SO SD
Izvajanje izobraževanj krepitve zdravja in preprečevanja bolezni za učence, starše, učitelje. Health promotion and health education for pupils, parents, teachers	4,36	0,847
Spremljanje učencev s kronično boleznijo in posebnimi zdravstvenimi stanji. Caring for children with chronic diseases and specific health conditions.	4,33	0,881
Vodenje zdravstvenovzgojnih programov in programov promocije zdravja na šoli. Running health education and health promotion programs.	4,30	0,901
Ključna povezave med šolo in šolskim dispanzerjem (timom šolskega zdravnika). The key link between the school and primary health care center.	4,29	0,897
Vključenost v šolski tim in aktivno sodelovanje pri politiki zdravja v šoli. Being part of the school team and active participation in school health policy.	4,26	0,907
Ukrepanje ob nujnih stanjih učencev (poškodbe, poslabšanje kroničnih bolezni ipd.). Interventions due to pupil's emergency health conditions.	4,22	0,892
Tesno sodelovanje s starši in učitelji pri krepitvi zdravja in preprečevanju bolezni. Cooperation with parents and teachers at promoting health and preventing diseases.	4,22	0,936
Prepoznavanje problemov v zvezi z zdravjem v času bivanja učenca na šoli. Recognizing problems relating to pupil's health during staying at school.	4,21	0,960
Povezovanje šole, zdravstva in lokalne skupnost na področju krepitve zdravja. Linking school, health care and local community in health promotion activities.	4,14	0,926
Oskrbovanje učencev z zdravstvenimi storitvami v času pouka. Provide health services to students during school time.	4,08	1,056
Ob spremembah zdravstvenega stanja naročanje in spremljanje učencev v zdravstveni dom. Directing and attending pupils to primary health care center (by changed health status).	4,02	1,097
Sodelovanje pri pripravi uravnoteženih jedilnikov. Participation in the preparation of healthy diets.	3,98	1,017
Izvajanje določenih presejalnih testov na šoli in usmerjanje učencev na nadaljnje preglede. Implementing screening tests and directing pupils to further treatments.	3,90	1,163

Diplomirana medicinska sestra iz zdravstvenega varstva šolskih otrok in mladine ima tudi v Sloveniji v šolskem prostoru možnost delovanja na številnih področjih, zato nas je zanimalo mnenje ravnateljev glede področij, na katerih bi tovrstni kader deloval na šoli. Anketiranci so se opredeljevali s 5-stopenjsko lestvico strinjanja do sedmih področij. Za vsa področja so se v povprečju strinjali z oceno nad 4: individualno svetovanje in podpora učencem in staršem s področja zdravja (4,24); promocija zdravja, zdravstvena vzgoja in izobraževanje s področja zdravja v okviru pouka (4,23); sodelovanje pri oblikovanju in realizaciji šolske politike zdravja (4,21); delo s šolskim osebjem (izobraževanje s področja zdravja) (4,19); vodenje interesnih dejavnosti (4,18); sodelovanje v pedagoškem timu – medpredmetno povezovanje (4,15); vodenje podpornih skupin (npr. za kronične bolnike) (4,06).

Ravnatelje smo vprašali tudi, kakšna oblika zaposlovanja in lokacija delovanja diplomirane medicinske sestre, ki v okviru zdravstvenega varstva šolskih otrok in

mladine skrbi za zdravje učencev, je po njihovem mnenju najprimernejša za naše okolje. Več kot polovica anketiranih (160 ali 60,2 %) se je opredelila za kombinirano lokacijo, deloma zdravstveni dom, deloma šola. Dobra četrtina (70 ali 26,3 %) ravnateljev meni, da je najprimernejša lokacija delovanja takega kadra v celoti šola, šele na tretje mesto se je uvrstila možnost, da naj medicinska sestra v celoti deluje v zdravstvenem domu, kar je izbralo 30 (11,3 %) anketirancev.

Na vprašanje, kdo naj tovrstni kader zaposluje, se jih večina, 158 (59,4 %), strinja, da zdravstveni dom, 40 (15 %) jih je kot delodajalca izbralo šolo, 25 (9,4 %) regionalni zavod za zdravstveno varstvo in 14 (5,3 %) občino. Nekaj ravnateljev (22 oz. 8,3 %) je navedlo druge možnosti, v sklopu katerih so se v večini opredeljevali za kombinacijo: šola – zdravstveni dom oz. zdravstveni dom – regionalni zavod za zdravstveno varstvo.

Želeli smo analizirati, kaj vpliva na potrebo po tem, da bi šolska medicinska sestra delovala na šoli in izvajala naloge, povezane s promocijo zdravja ter s preventivo in kurativo bolezni. Faktorska analiza (metoda glavnih osi) mnenj anketiranih ravnateljev o predlogih izvajanja nalog šolske medicinske sestre je pokazala, da se vsi indikatorji (13 predlogov nalog šolske medicinske sestre) z visokimi utežmi uvrščajo v en faktor (vrednosti uteži od 0,897 do 0,741). Faktor, ki smo ga uporabili v nadaljnji statistični obdelavi, smo poimenovali »Potreba po izvajanju nalog šolske medicinske sestre v šoli«. Predlogi, zajeti v faktorju, pojasnjujejo 69,61 % variance faktorja.

Ugotavljali smo odvisnost med nekaterimi mnenji ravnateljev in močjo potrebe po izvajanju nalog šolske medicinske sestre. Multipla regresijska analiza je pokazala, da le mnenje glede odgovornosti zdravstvenega doma za izobraževanja učiteljev za prepoznavanje in ukrepanje ob zdravstvenih težavah značilno vpliva na stopnjo izražene potrebe po nalogah šolske medicinske sestre (b = 0,270, p < 0,000) (Tabela 2).

Tabela 2. *Rezultati multiple regresijske analize vpliva mnenj ravnateljev na potrebo po izvajanju nalog šolske medicinske sestre v šoli.*

Table 2. *Multiple regression analysis of the impact of principals' opinions on the need for school nurses' duties.*

Potreba po izvajanju nalog šolske med. sestre v šoli The need for school nurses' duties	Mnenje/ Opinion	b	Beta	t	p
prilag. R^2=0,045 F=4,933 **p=0,002**	Konstanta/ Constant	-0,895		-2,671	0,008
	Dajanje zdravil ne sme biti odgovornost učitelja. Administer medicines should not be the responsibility of the teacher.	-0,035	-0,041	-0,516	0,606
	Prepoznavanje zdravstvenih težav ne more biti kompetenca učiteljev. Recognizing health problems can not be teachers' competence.	-0,022	-0,025	-0,306	0,760
	Usposabljanje učiteljev za prepoznavanje zdr. težav in ukrepanje je odgovornost ZD. Training teachers to recognize health problems and measure is the responsibility of the health care center.	0,270	0,244	3,833	**0,000**

Nato smo želeli ugotoviti, ali tiste šole, na katerih učitelji pogosteje ukrepajo zaradi kroničnih bolezni učencev, akutnih bolezenskih stanj in telesnih poškodb, izražajo večjo potrebo po izvajanju nalog šolske medicinske sestre. Ugotovili smo, da šole, ki pogosteje ukrepajo zaradi telesnih poškodb učencev, izražajo značilno večjo potrebo po delovanju šolske medicinske sestre na lokaciji šole (b = 0,208, p < 0,014), pogostost ukrepanja ob kroničnih boleznih in pogostost ukrepanja ob akutnih stanjih pa s tem nista povezani (Tabela 3).

Tabela 3. Rezultati multiple regresijske analize vpliva pogostosti ukrepanja ob zdravstvenih težavah na potrebo po izvajanju nalog šolske medicinske sestre v šoli.
Table 3. Multiple regression analysis of the impact of interventions' friquency for acute health conditions on the need for school nurses' duties.

Potreba po izvajanju nalog šolske med. sestre na lokaciji šole The need for school nurses' duties	Značilnosti/ Characteristic	b	Beta	t	p
prilag. R^2=0,021 F=2,495 p=0,061	Konstanta/ Constant	-0,630		-2,168	0,031
	Pogostost ukrepanja ob kroničnih boleznih Frequency of interventions due to chronic diseases	0,031	0,057	0,795	0,428
	Pogostost ukrepanja ob akutnih stanjih Frequency of interventions due to emergency condition	-0,003	-0,004	-0,052	0,959
	Pogostost ukrepanja ob telesnih poškodbah Frequency of interventions due to children's injuries	0,208	0,173	2,485	**0,014**

Zanimalo nas je, ali posamezne značilnosti šol vplivajo na izraženo potrebo ravnateljev po delovanju šolskih medicinskih sester. Multipla regresijska analiza je pokazala, da velikost šole glede na število učencev (b = 0,000, p < 0,710), vključenost v Slovensko mrežo zdravih šol (b = –0,018, p < 0,896), napisan postopek ukrepov ob nujnih stanjih (b = 0,073, p < 0,619), redno izobraževanje učiteljev iz prve pomoči (b = 0,032, p < 0,675) in prepoznavanja zdravstvenih težav (b = 0,058, p < 0,426) ne vplivajo na moč potrebe po izvajanju nalog šolske medicinske sestre v šoli.

4 RAZPRAVLJANJE

Rezultati raziskave kažejo, da se po mnenju ravnateljev na osnovnih šolah pojavljajo različne težave glede zdravja učencev z različno pogostostjo; najpogosteje se strokovni delavci na šolah srečujejo z akutno bolnimi učenci, s psihosomatskimi težavami učencev in s kroničnimi bolniki, poročajo pa tudi o telesnih poškodbah, ki se v povprečju dogajajo nekajkrat letno. Tuji avtorji v rednih šolskih programih opisujejo povečanje števila učencev s kroničnimi stanji (7, 22). Podobno ugotavljajo slovenski strokovnjaki, ki od kroničnih bolezni v ospredje postavljajo alergijske bolezni, ki so v porastu, zlasti astma, alergijski dermatitis in alergijski nahod, pa tudi porast sladkorne bolezni tipa 1. Dodatno slovenski strokovnjaki izpostavljajo še bolezenske posledice slabih prehranjevalnih navad in nezadostne telesne dejavnosti (24).

V slovenskih šolah je učitelj tisti, ki je ves čas ob učencu, in zato tudi najpomembnejša oseba, ki se mora ob nujnem stanju učenca ustrezno odzvati in sprejeti odločitve glede ukrepanja. Iz te raziskave je razvidno, da ob poškodbi zelo pogosto učitelji nudijo učencem prvo pomoč, ob poslabšanju kronične bolezni pa pogosteje učencu dajo predpisana zdravila oz. kako drugače ukrepajo po navodilu staršev kot po navodilu zdravnika. V tujini za to skrbi šolska medicinska sestra, saj v šoli izvaja vrsto aktivnosti, ki vključujejo tudi aplikacijo zdravil, izvajanje negovalnih intervencij, opravljanje presejalnih pregledov, zagotavljanje z zdravjem povezanih napotitev (7–9, 2, 25).

Analiza je pokazala, da se ravnatelji v povprečju slabše strinjajo s trditvami, da se učitelji redno izobražujejo iz prve pomoči in prepoznavanja zdravstvenih problemov ter da učitelji znajo dajati zdravila učencem s kroničnimi boleznimi. Iz tega bi lahko sklepali, da učitelji niso kompetentni in dovolj usposobljeni za obvladovanje zdravstvenih težav učencev v šoli. Slaba tretjina ravnateljev tudi izraža, da nimajo pisnega postopka ukrepov za primer ogroženosti zdravja učencev. Šolam bi bila prav gotovo v pomoč priporočila za ukrepanje ob nujnih stanjih in nenadnih nastalih boleznih po vzoru priporočil, ki jih je Inštitut za varovanje zdravja RS izdal za vrtce (19). Skrb vzbujajoča je ugotovitev raziskave, da učitelji najpogosteje prejmejo navodila

za kronične bolnike od staršev, ki so običajno tudi edini vir izobraževanja za prepoznavanje zapletov in ukrepanja ob poslabšanjih. Ravnatelji se opredeljujejo, da dajanje zdravil ne sme biti odgovornost učitelja, da prepoznavanje težav ni kompetenca učiteljev in da je usposabljanje učiteljev za prepoznavanje zdravstvenih težav ter ukrepanje ob tem odgovornost zdravstva.
Ravnatelji v raziskavi na splošno pozitivno prepoznavajo pomen zdravstvenega kadra in se jim njihova umestitev v šole zdi smiselna. Ne izražajo samo potreb po izvajanju nalog s področja promocije zdravja/zdravstvene vzgoje, ampak tudi s področja bolj t. i. zdravstvenih storitev, ki se v obstoječi praksi trenutno izvajajo v zdravstvenih domovih (npr. presejanja, aplikacija terapije, skrb za kronične bolnike itn.). Analiza rezultatov nakazuje tudi visoko stopnjo strinjanja ravnateljev s tem, da bi obstoječa diplomirana medicinska sestra iz šolskega dispanzerja lahko že zdaj intenzivneje delovala na šoli na številnih področjih, povezanih s promocijo zdravja. To se ujema s študijo v ljubljanskih šolah, ki je pokazala, da učitelji medicinske sestre, ki v šolah izvajajo zdravstveno vzgojo, doživljajo pozitivno ter da njihove aktivnosti ocenjujejo kot potrebne in sodelovanje zelo dobro, želeli pa bi si še več obiskov v razredih in dodatnih vsebin (14).
Dve tretjini ravnateljev navajata, da je najprimernejša lokacija delovanja diplomirane medicinske sestre iz šolskega dispanzerja kombinacija šole in zdravstvenega doma, presenetljivo jih dobra četrtina navaja, da v celoti šola, in le desetina, da v celoti zdravstveni dom, kot je trenutna praksa v Sloveniji. Pričakovano je veliko ravnateljev izbralo zdravstveni dom kot najprimernejšega delodajalca omenjenega kadra, a jih je presenetljivo kar 15 % navedlo, da bi bil najprimernejši delodajalec kar šola sama. Vse to potrjuje, da na anketiranih šolah obstaja potreba po vključevanju zdravstvenega kadra v šolo, in to ne glede na velikost šole ali vključenost v mrežo zdravih šol ali drugo značilnost. Z določenimi zadržki (zelo šibka pojasnjevalna moč regresijskih modelov) ugotavljamo le dvoje: ravnatelji s šol, v katerih je telesnih poškodb učencev več, ter ravnatelji z mnenjem, da je usposabljanje učiteljev za prepoznavanje in ukrepanje ob zdravstvenih težavah v odgovornosti zdravstvenega doma, izražajo značilno večjo potrebo po šolski medicinski sestri.
Vloga diplomirane medicinske sestre je v skrbi za zdravstveno varstvo otroka in mladostnika žal premalo poudarjena. Njeno delo je vezano na zdravnika, saj deluje v timu, katerega nosilec je zdravnik (16); ocenjujemo, da ni ustrezno usmerjeno v pacienta. Tudi drugi avtorji ugotavljajo, da imamo npr. kakovostno specializacijo družinske medicine, medicinska sestra v splošni medicini ostaja administratorka, ki ji zaradi preobremenjenosti primanjkuje časa za delo z bolnikom (26). V ambulanti družinske medicine so se z uvedbo referenčne ambulante sicer že pojavile spremembe, ki so lahko dober model tudi za šolsko zdravstveno varstvo. Diplomirana medicinska sestra prevzema naloge s področja preventivne dejavnosti in spremljanja parametrov urejene kronične bolezni (27).
V Sloveniji je treba vlogo diplomiranih medicinskih sester znotraj sistema zdravstvenega varstva šolskih otrok in mladostnikov preoblikovati. Predvsem je treba povečati vlogo promocije zdravja in zdravstvene vzgoje, ki jo diplomirana medicinska sestra lahko samostojno načrtuje, koordinira, vodi in izvaja. Iz ugotovitev raziskav namreč izhaja, da šolski sektor prepoznava pomen vloge zdravstvenega kadra pri izvajanju nalog v šolskem prostoru, saj se s spreminjanjem načina življenja mladih in družbe kot celote spreminjajo tudi potrebe učencev znotraj šolskega prostora.
Izpostaviti želimo tudi omejitve raziskave. Z vprašalnikom smo sicer nagovorili celotno populacijo ravnateljev, sodelovali pa so tisti, ki so želeli. Tudi vsi trije regresijski modeli imajo izjemno šibko pojasnjevalno moč, kar pomeni, da na mnenja ravnateljev na potrebo po izvajanju nalog šolske medicinske sestre vplivajo tudi druge stvari, ki jih v tej raziskavi nismo merili. Dobrodošlo bi bilo o tej temi podrobneje pridobiti tudi mnenja relevantnih političnih in strokovnih odločevalcev na ravni države ter tudi zdravstvenega kadra, učiteljev in uporabnikov, kar bi bila lahko osnova za sistematičen pristop k preoblikovanju vloge diplomirane medicinske sestre v zdravstvenem varstvu šolskih otrok s ciljem zmanjševanja neenakosti v zdravju.

5 ZAKLJUČEK

Po mnenju osnovnošolskih ravnateljev se učitelji srečujejo z različnimi zdravstvenimi težavami učencev, ob katerih morajo ukrepati, primanjkuje pa jim znanja in kompetenc. To se kaže tudi v tem, da ravnatelji izražajo močno potrebo po delovanju zdravstvenega kadra v osnovnih šolah. Šola je prostor, v katerem otroci preživijo veliko časa, zato ima pomembno vlogo pri zdravju otrok in mladostnikov pa tudi pri sodelovanju z zdravstvenimi službami. Skrb za zdravje zajema dejavnosti s področja krepitve zdravja in preventive pred boleznimi pa tudi s področja zdravljenja in zdravstvene nege akutno in kronično bolnih. Na konceptualni ravni se krepitev zdravja loči od preventive pred boleznijo in še bolj od kurative, a v praksi to pogosto poteka povezano. Ravno tako se povezujejo in prepletajo

potrebe zdravega šolarja in šolarja, ki zboli. V tujini strokovnjak, kot je šolska medicinska sestra, pozna učenca z vsemi posebnostmi in s trenutnim zdravstvenim stanjem, zato zanj lahko skrbi celovito. Tudi v Sloveniji bi bila lahko diplomirana medicinska sestra, dodatno izobražena s področja javnega zdravja in drugih relevantnih področij, pomembna povezava med krepitvijo zdravja, preprečevanjem bolezni, zdravljenjem in izobraževanjem, kar bi pozitivno vplivalo na rast in razvoj otrok in mladostnikov ter na uspešnost pri učenju. Raziskava stališč ravnateljev je lahko osnova za testiranje različnih modelov in morebitne spremembe na tem področju v prihodnje.

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