ORIGINAL ARTICLE
(CC BY-SA)



UDC: 001.891.5:[37.018.262:616-085 https://doi.org/10.2298/VSP170721002U

Pharmacotherapy literacy questionnaire for parents of pre-school children in Serbia: construction and psychometric characteristics

Upitnik za procenu farmakoterapijske pismenosti roditelja predškolske dece u Srbiji: konstrukcija i psihometrijske karakteristike

Stana Ubavić*, Dušanka Krajnović[†], Nataša Bogavac-Stanojević[‡]

*Medicines and Medical Devices Agency of Serbia, Belgrade, Serbia; University of Belgrade, Faculty of Pharmacy, †Department of Social Pharmacy and Pharmaceutical Legislation, ‡Department of Biochemistry, Belgrade, Serbia

Abstract

Background/Aim. Valid and reliable instruments were emphasized in the studies of pharmacotherapy literacy which is the capacity to obtain, evaluate, calculate, and comprehend basic information about pharmacotherapy and actions necessary to make appropriate medication-related decisions. The aims of this study were: to develop an instrument for assessment of pharmacotherapy health literacy among parents of pre-school children in Serbia (PTHL-SR) and to evaluate psychometric properties. Methods. This study was a four-stage methodological one, conducted from November 2015 to October 2016. The instrument content was established through qualitative and quantitative expert reviews in the first and second phase. Experts had to answer about the clarity and relevance of questions. The Content Validity Ratio (CVR) and index (CVI) were calculated based on the necessity and relevance of questions. Third phase was pre-testing of initial instrument to assess comprehensibility of questions. In the fourth phase, 300 parents completed questionnaire at several kindergartens in Belgrade, to determine questionnaire's reliability through internal consistency, using the Cronbach's alpha coefficient and correlation between classes. Results. The 14-items questionnaire was developed (initial PTHL-SR) and pre-tested on a pilot sample. It had 4 groups of questions about knowledge, understanding, numerical skills and access to medicines-related information. The Content Validity Ratio (CVR = 0.875) was significant and adequate (Lawshe CVR₈ = 0.780). Conclusion. PTHL-SR is a reliable instrument for assessment of pharmacotherapy literacy among parents of pre-school children in Serbia and can be used for the evaluation of understanding, calculating and accessing medicines-related information.

Key words:

drug therapy; parents; child, preschool; knowledge; surveys and questionnaires.

Apstrakt

Uvod/Cilj. Validni i pouzdani instrumenti neophodni su u studijama farmakoterapijske pismenosti koja predstavlja sposobnost dobijanja, procene, izračunavanja i razumevanja osnovnih informacija o farmakoterapiji i radnjama potrebnim za donošenje adekvatnih odluka koje se odnose na primenu lekova. Ciljevi ove studije bili su: da se razvije instrument za procenu farmakoterapijske pismenosti roditelja predškolske dece u Srbiji (PTHL-SR) i da se procene psihometrijske karakteristike ovog instrumenta. Metode. Studija je bila metodološka, u četiri faze, sprovedena od novembra 2015. do oktobra 2016. Sadržaj instrumenta napravljen je kroz kvalitativne i kvantitativne ocene eksperata u prve dve faze. Eksperti su trebali da ocene jasnoću i relevantnost pitanja. Odnos sadržajne validnosti (CVR) i indeks (CVI) izračunati su na osnovu relevantnosti i potrebe za pitanjima. Treća faza bila je pretestiranje inicijalnog instrumenta sa ciljem da se ustanovi razumljivost pitanja. U četvrtoj fazi, 300 roditelja popunilo je upitnik u nekoliko vrtića u Beogradu, da bi se odredila pouzdanost upitnika kroz internu i eksternu konzistentnost, korišćenjem Kronbah-alfa koeficijenta i korelacije između klasa. Rezultati. Konstruisan je upitnik sa 14 pitanja (inicijalni PTHL-SR) i izvršeno je pretestiranje na pilot uzorku. Upitnik sadrži 4 grupe pitanja: o znanju, razumevanju, numeričkim veštinama i pristupu informacijama o lekovima. Odnos sadržajne validnosti (CVR = 0.875) bio je značajan i odgovarajući (Lawshe CVR₈ = 0.780). Zaključak. PTHL-SR je pouzdan instrument za procenu farmakoterapijske pismenosti roditelja predškolske dece u Srbiji i može se upotrebiti za procenu razumevanja, numeričkih veština i pristupa informacija o lekovima.

Ključne reči:

lečenje lekovima; roditelji; deca, predškolska; znanje; ankete i upitnici.

Introduction

According to the definition of the American Medical Association (AMA), health literacy is "the constellation of skills, including the ability to perform basic reading and numerical skills to function in the health care environment".

It is one of the most important social determinants of health which includes competences such as the critical and interactive skills as well as the numerical skills². A person with adequate health literacy is the one who puts its own health and health of his/her family in an appropriate context, understands which factors can affect the health and knows to use health-related information^{3,4}.

It was found that the parents with low health literacy harder understand the importance of vaccination and are not completely able to realize the risks of malnutrition and overweight. They can hardly recognize hazards in the home, which leads to frequent injuries of children ^{4,5–8}.

The parents with low health literacy often have difficulties to understand information given by a doctor as well as information on the baby food and medicine labels. Written information about medicines use are too complex for the parents with low health literacy ^{4,5}. Furthermore, low health literacy among the parents cause difficulties to dose the medicine which is purchased without a prescription (OTC) for a child. Errors in dosing the OTC medicines to children can cause the risk of adverse effects and therapeutic failure ^{6,7}.

According to study conducted in France, oral antibiotic medicines were incorrectly reconstituted by the parents and caregivers in about 50% cases, with a risk of overdosing or underdosing. It was also noted that it is necessary to check if the parents understand the instructions about the use of oral liquid medications for children ⁹.

The level of health literacy may have a significant impact on the way healthcare professionals interact and communicate with the parents of children ¹⁰.

There is an association between low health literacy and misunderstanding of information related to medicines ^{6,7}, and health literacy related to use of medicines, i.e., "pharmacotherapy literacy" is "An individual's capacity to obtain, evaluate, calculate, and comprehend basic information about pharmacotherapy and pharmacy related services necessary to make appropriate medication-related decisions, regardless of the mode of content delivery (e.g., written, oral, visual images and symbols)" ¹¹.

There are several general instruments intended to measure the level of health literacy [the Rapid Estimate of Adult Literacy in Medicine (REALM), the Short Test of Functional Health Literacy in Adults (S-TOFHLA), the Newest Vital Sign (NVS), the Wide Range Achievement Test (WRAT)], as well as specific instruments for evaluation of health literacy in the special patient groups [diabetic patients, nephrology patients, health literacy in dentistry (TOFHLiD), special age (the Rapid Estimate of Adult Literacy in Medicine (REALM-teen), the Health Literacy Weasure for Adolescents (HELMA)] 3, 12-20. None of them is specific for determination of pharmacotherapy literacy in the entire population as well as within parents of pre-school children.

The most of instruments were applied in primary care setting (emergency department, waiting room at primary

care) ^{3, 14, 15–18}. Researchers agree that health literacy is related to the context, and different settings require different assessment tools ³.

Recent review identified 109 different health literacy instruments, 37 were non-English, and 72 were in the English language. It was reported that 47% of instruments were a context/content specific, and there is a growth of context/content specific instruments, as it is recognized that one person may have high level of health literacy tested with general health literacy instrument, but it can exhibit lower level of health literacy in the specific condition and in unfamiliar setting ^{3, 19–21}.

With potential limitations of current health literacy instruments as well as an absence of specific one for pediatric medicines use which has to determine the ability of parents to understand information on pharmacotherapy and medicines, we have intended to develop a pharmacotherapy literacy questionnaire, as a specific instrument for assessment of pharmacotherapy health literacy among the parents of preschool children in Serbia (PTHL–SR) and to evaluate the psychometric properties of this instrument.

Methods

The study was a four-stage methodological one, conducted from November 2015 to October 2016 in Belgrade, Serbia. We decided to make survey in a kindergarten setting as it is the easiest way for an access to the parents, and to make the context specific questionnaire. Kindergarten was chosen as a setting, having in mind that in the context of hospital and pharmacy, the parents are often under the pressure due to medical problems of the child, and have no time to fill-in questionnaire. A person was eligible as a parent if he, or she was related to a child living in the household (at least 18 years of age) as a parent, guardian, or a step-parent, speaking the Serbian language.

Our instrument for the determination of pharmacotherapy literacy of parents was made in order to assess the level of knowledge about the use of medicines for the pediatric population, understanding the information provided on the medicines labels, to determine the numerical skills needed for calculation of dose required for a pediatric therapy as well as access to medicines-related information.

In the first phase, we applied the method of relevant literature research. The literature research involved the examination of PubMed database in order to find publications where the questionnaire was used as an instrument to assess health literacy of parents, or knowledge, and understanding of information about medicines and their use in the pediatric population. Our key words for literature search were: health literacy, parents, caregivers, pediatric patients, questionnaire, medicines, liquid oral medicines.

Based on the literature review, we defined four main domains of pharmacotherapy literacy: health knowledge, understanding of health information (written and spoken), numerical skills and access to information about medicines, as these skills are essential for correct use of medicines for children, as presented in Figure 1.

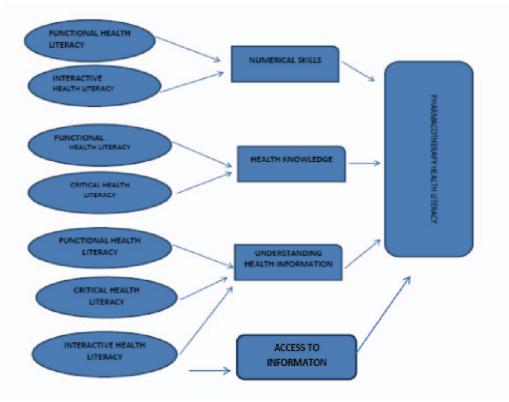


Fig 1. Domains and sub-domains of pharmacotherapy literacy

To determine the qualitative face validity, 10 parents, who were faculty members, were asked to comment about the level of difficulty of items, the obscurity and the proportion of each item.

In the second phase, the content of questionnaire was further defined on the focus group interview ^{22–24}. The focus group had 8 experts who had to determine the face and content validity of questionnaire. The members of focus group were 3 pharmacists working in the Medicines and Medical Devices Agency of Serbia, 2 professors form Faculty of Pharmacy in Belgrade, one pharmacist working in pharmacy, one doctor-pediatrician and one parent of pre-school child without medical education who is also a professor of Serbian language. Each member of the focus group had to grade each question (with the marks from 1-4), a form of questions and the questionnaire, the clarity of graphical pictures in the questionnaire, suitability of information presented in a question and whether the question should be in the questionnaire. The questions that were given score 1 or 2 as the average score were eliminated. The result of the first interview was elimination of 5 questions and modification of expression of all questions and answers in order to be more clear and more precise. On the second focus group interview, using the same methodology, 3 more questions were eliminated. The content validity ratio (CVR) and index (CVI) were calculated based on the necessity and relevance of each question.

Then, based on the Lawshe's table, the items that scored more than or equal to 0.78 were kept in the scale ²⁵.

The CVI was calculated for each question in the questionnaire, which is the percentage of experts that rated the question as 3 or 4 (based on the rating scale from 1 to 4

where 4 represents excellent fit). It was observed that the CVI value of 1.00 was acceptable for panels of 3, or 4 experts, whereas in the case with 8 experts, the acceptable CVI was fixed at 0.80 or $80\%^{25}$.

It was decided that questions meeting the criteria of less than 2 out of 3 methods (66.67% agreement) should be removed. Finally, 16 questions met the criteria of 4 methods fixed for this study, and it was decided to delete 8 questions. After removing the questions, the CVR was calculated.

The CVR is the Content Validity Ratio, and it is zero if a half of experts evaluated the question as essential. Lawshe ²⁵ gave the limit and acceptable values for the CVR related to number of experts (for 8 experts the acceptable CVR is 0.78 and more).

After 2 cycles of focus group interview, our CVR was calculated to be significant 25 and adequate (0.875 > 0.78).

The third phase was pre-testing performed in order to assess the comprehensibility of questions, done in the group of 20 parents who were eligible to fill-in the questionnaire.

In the fourth phase, a quantitative stage, to asses the inter-rater (test – retest) reliability, or consistency among the observational ratings we calculated the Intra-Class correlation (ICC) for the continuous data and Kappa coefficient for the dichotomous data. The Kappa coefficient value was defined by Altman ²⁶. A split-half reliability testing was also performed to test how many errors in the scores were due to the poor test construction. All questions included the dichotomous data and because of that, they were not subjected to the factor analysis. We considered the Kuder-Richardson (KR20) coefficient scores, which provided an estimate of internal consistency for dichotomous variables (items), which

were interpreted like the Cronbach alpha scores ²⁷. Ranging from 0.00 to 1.00, KR20 scores must be greater than 0.60 for a measure to be considered reliable ²⁸. The item difficulty and item discrimination indexes were determined for each question ²⁹. The item difficulty index is the proportion of subjects (parents) who answered an item correctly. The item discrimination explained the ability of an item to distinguish between the parents who had and the parents who did not have the pharmacotherapy knowledge assessed by the questionnaire. It measured a degree of correspondence between the success in each item and in the whole set of items, and can be computed using a point biserial correlation. The correlation values must be above 0.25 for items to be considered sufficiently discriminating ³⁰. We calculated the mean, standard deviation (SD), skewness and kurtosis for each question.

The survey was conducted within 10 kindergartens which were located in different municipalities in Belgrade, between March and October 2016. The survey was distributed by an interviewer (SU) who was trained to distribute the questionnaire and basic information about the survey and research. The printed survey was administered to the parents at the scheduled regular parent-teacher meetings in the kindergarten. The parents were allowed unlimited time to complete the questionnaire (on average 10–15 minutes). As an annex to the PHTL-SR questionnaire, the participants had to answer 12 questions related to socio-demographic characteristics. The socio-demographic questionnaire contained 12 questions with information on age, sex, education, number of visits to a pediatrician within one year, information about breast feeding, smoking, presence of chronic diseases at their children and information on self-assessment of health status of the parents.

Before answering the questionnaire, the respondents gave the informed consent to participate in the study. The study was approved by the Committee for Biomedical Research of the Faculty of Pharmacy (321/2, 15.3.2016.). The subjects were excluded from the study if they reported vision problems, and if they decided to stop filling out the questionnaire. All data were collected and analyzed anonymously, in order to keep the privacy of the respondents, as stated in the procedure approved by the Committee for Biomedical Research at Faculty of Pharmacy, Belgrade.

Results

After the examination of publications, a pool of 50 different questions was found. By removing duplicates and similar questions, we found 24 possible questions to be included in the PHTL-SR questionnaire. We translated questions found in the literature and adapted them to fit to the Serbian language regarding the culture aspects. These questions included the items regarding the dosing devices for children (oral syringes, spoons, etc.), use of analgesic and antipyretics, understanding of usual labeling information on packaging and packaging leaflets, where to find relevant information about medicines and knowledge regarding the use of medicines in the pediatric patients. Some questions (5 ques-

tions) included graphical picture (photo) of the dosing devices or package.

After 2 cycles with the focus group, 8 of 24 questions were removed, based on calculation of CVR ratio (CVR = 0.875). Thus, our initial questionnaire was approved with 16 questions within 4 groups of questions according to the defined domains of pharmacotherapy literacy: knowledge, understanding of health information, numerical skills and access to information about medicines. Of the 16 questions from the PTHL-RS, 3 questions included graphic of the packaging of medicine for the pediatric use, 2 questions were related to the dosing devices for dispensing syrup for children, one question was entirely taken from the PHLAT questionnaire ⁸ and translated, and referred to the data on the label of the pediatric OTC medicine.

In the fourth phase, the purposive sample of 300 parents at the kindergartens completed the initial questionnaire to determine its reliability through the internal consistency. In total, 2/3 of parents who were present at the parent meetings at the kindergartens agreed to fill in the questionnaire. The socio-demographic characteristics of the parents were presented at Table 1.

The answers on the questions are dichotomy variables (the correct answers were coded 1 and the wrong ones were coded 0).

The most of parents who participated in the survey were women (80.7%), aged 30–40 years (75.3%), and married (84%) with 2 children (66%). More than two-third (70%) were non-smokers and 61% estimated their health status as very good and excellent (22%). Moreover, a majority of them (40.7%) reported that their first child was breastfed up to 12 months, and 87% of parents reported absence of chronic diseases in their children.

Firstly, all questions from the initial PTHL-RS were analyzed for the KR 20 calculation. The KR20 score for the knowledge was 0.47. After excluding two items (no. 12 and no. 15) because of the poor item fit parameters, the KR20 was 0.54. Since the KR20 coefficient provides the minimum reliability estimates and the difficulty of items (Table 2) was heterogeneous 31, all 14 items were upheld for future analysis. The difficulty of the knowledge items varied from 41% to 97%, averaging 78%. For items 2, 5, 9, 10, 11 and 16 more than 90% of parents answered correctly, indicating that they were relatively easy for participants to answer, whereas less than 50% of respondents answered items 4 and 14 correctly, suggesting that these items were difficult to answer (Table 2). The mean discrimination value was 0.37, ranging from 0.21 to 0.50. Two questions (2 and 16) had a poor discrimination power, but few questions had high discrimination indexes (items 1, 3, 6, 9, 11, and 13) meaning that they were likely to be answered correctly by those who obtained a high score for all questions. The recalculated Split – half coefficient for the questionnaire with 14 questions, was calculated to be 0.542. The mean values, skewness and kurtosis were presented in Table 3. The most items had negative skewness value, meaning that the item values had a tendency to be left skewed.

Table 1 Socio-demographic characteristics of parents

Characteristics n (%) Sex male 58 (19.3) 242 (80.7) female Age (years) 18–29 17 (5.7) 30-40 226 (75.3) 41-50 46 (15.3) 51 - 6011 (3.8) Number of children one child 85 (28.3) two children 180 (60) three children 32 (10.7) four children 3(1)Marital state 2(0.7)unmarried married 252 (84) divorced 18 (6) widow 4(1.3)common-law 18(6) single parent 6(2)Education 0(0)no school 2(0.7)primary school 81 (27) high school higher school (VI grade) 51 (17) university 159 (53) PhD grade 7(2.3)Employment incapable 1(0.3)unemployed 35 (11.7) 260 (86.7) employed student 3(1) pensioner 1(0.3)Self-estimation of health status 2(0.7)very bad bad 2(0.7)good 47 (15.7) very good 183 (61) excellent 66 (22) Chronic diseases 261 (87) no 39 (13) yes diabetes 1(0.3)5 (1.7) asthma bronchitis 4(1.3)cardiac diseases 3(1.0)orphan diseases 23 (7.7) celiac disease 1(0.3)allergy 1(0.3)other 1(0.3)Smoker 210 (70) 90 (30) yes Breast feeding of a first child \leq 6 months 92 (30.7) < 12 months 139 (46.3) \leq 24 months 35 (11.7) \geq 24 months 4 (1.3) 30 (10) No Annual visits to pediatrician once a year 38 (12.7) 43 (15.7) twice a year 52 (17.3) 3 times a year 4 times a year 46 (15.3) 5 times a year 48 (16.0) 26 (8.7) 6 times a year 8 (2.7) 35 (11.7) 7 times a year 8 times a year and more

Table 2 Difficulty and discriminatory index

| Domain | Difficulty index | Point biserial correlation |
|-------------|------------------|----------------------------|
| Question 1 | 0.76 | 0.431 |
| Question 2 | 0.97 | 0.219 |
| Question 3 | 0.85 | 0.429 |
| Question 4 | 0.4167 | 0.363 |
| Question 5 | 0.9233 | 0.277 |
| Question 6 | 0.8 | 0.495 |
| Question 7 | 0.6433 | 0.399 |
| Question 8 | 0.85 | 0.319 |
| Question 9 | 0.9433 | 0.408 |
| Question 10 | 0.96 | 0.379 |
| Question 11 | 0.91 | 0.488 |
| Question 13 | 0.5367 | 0.402 |
| Question 14 | 0.42 | 0.369 |
| Question 16 | 0.95 | 0.209 |

Table 3 Kappa coefficients for answers in PTHL-SR

| Domain | Mean ± SD | Skewness | Kurtosis | Kappa coefficient (n = 16) |
|-------------|-----------------|----------|----------|----------------------------------|
| Question 1 | 0.76 ± 0.43 | -1.22 | -0.51 | 1 |
| ` | | | | - |
| Question 2 | 0.97 ± 0.16 | -5.90 | 33.10 | 1 |
| Question 3 | 0.85 ± 0.36 | -1.93 | 1.80 | 1 |
| Question 4 | 0.42 ± 0.49 | 0.33 | -1.90 | 1 |
| Question 5 | 0.92 ± 0.27 | -3.19 | 8.30 | 1 |
| Question 6 | 0.80 ± 0.40 | -1.50 | 0.28 | 0.444 |
| Question 7 | 0.64 ± 0.48 | -0.60 | -1.65 | 0.815 |
| Question 8 | 0.85 ± 0.36 | -1.97 | 1.90 | 0.762 |
| Question 9 | 0.94 ± 0.23 | -3.85 | 12.90 | 1 |
| Question 10 | 0.96 ± 0.20 | -4.71 | 20.40 | 1 |
| Question 11 | 0.91 ± 0.29 | -2.87 | 6.30 | 1 |
| Question 12 | 0.19 ± 0.39 | 1.61 | 0.60 | 0.762 |
| Question 13 | 0.54 ± 0.45 | -0.14 | -2.00 | 0.444 |
| Question 14 | 0.42 ± 0.49 | 0.32 | -1.90 | 1 |
| Question 15 | 0.86 ± 0.34 | -2.12 | 2.50 | 1 |
| Question 16 | 0.95 ± 0.23 | -3.99 | 14.00 | 1 |

PTHL-SR - Pharmacotherapy health literacy among parents of pre-school children in Seria; SD - standard deviation.

However, the kurtosis values for 5 questions had the negative value and all other items had the positive values. The inter-rater reliability was demonstrated by the ICC = 0.934 for a variable with a maximum score in the PTHL-RS. As a measure of agreement between the dichotomy variables we used the Kappa coefficient. Eleven answers on the questions showed very good strength of agreement (Kappa = 1), 3 showed good and 2 moderate agreement (Table 2). A split – half coefficient was calculated to be 0.436, which was acceptable. Finally, the questionnaire with the satisfactory psychometric characteristic had 14 questions which are presented at Table 4.

Table 4

Questions included in the final version of constructed questionnaire about pharmacotherapy literacy among parents of pre-school children in Serbia (questions 12 and 15 from the initial version were excluded)

| No | Question | Domain | Correct answer (%) |
|----|--|---------------|--------------------|
| 1 | What is this medicine (ibuprofen) used for? | Knowledge | 76.00 |
| 2 | What does this medicine contain? (picture of paracetamol syrup) | Knowledge | 97.33 |
| 3 | Would you give aspirin to a child of 6 years if it has a fever? | Knowledge | 84.67 |
| 4 | Your child has otitis and pain. Where do you find information on how much medicine for pain relief to give (per kg or per age)? | Knowledge | 41.67 |
| 5 | What is the highest temperature limit after you give antipyretic to a child? | Knowledge | 92.33 |
| 6 | Pharmacist told you to avoid milk and milk products while taking medicine. What does it mean to you? | Understanding | 80.00 |
| 7 | Avoid sun while taking medicine. What does it mean to you? | Understanding | 64.33 |
| 8 | Keep under 25°C. After reconstitution, keep refrigerated up to 14 days. How will you store this medicine after reconstitution? | Understanding | 85.00 |
| 9 | You have to give medicine to a child 2 times a day. If your package has 10 items, how many medicines you will have after 3 days? | Numeracy | 94.33 |
| 10 | To mark the dosage for a child of 13 kg on measuring spoon. | Numeracy | 96.00 |
| 11 | To answer how much medicine is inside the oral syringe. | Numeracy | 91.00 |
| 13 | To calculate a dose of oral syrup for child based on dosage regimen per kg. | Numeracy | 53.67 |
| 14 | To interprete paracetamol dosage chart written on package, per weight. | Numeracy | 42.00 |
| 16 | Where did you get an information how much antipyretic to give to your child? | Access | 94.67 |

Discussion

This is the first effort to design a questionnaire for the evaluation of pharmacotherapy literacy among the parents of pre-school children in Serbia. Recent study in Serbia by Jovic-Vranes and Bjegovic-Mikanovic 32 was the evaluation of health literacy screening tool in the primary care patients which involved the population of adults in a medical setting. This survey is a context specific as it was conducted outside the medical setting, in the kindergartens. This study indicates that the PTHL-SR has the validity and reliability necessary for the determination of parents with difficulties in applying and understanding information related to use of medicines. One of the strengths of PTHL-SR is that, beside functional pharmacotherapy literacy, it also addresses the interactive and critical skills. Another important advantage of this study is that it was done outside of the medical setting, in the kindergartens. As health literacy, as well as pharmacotherapy health literacy is a context-specific, applying the questionnaire out of medical settings overcomes the barriers and anxiety the parents may have in the medical setting.

During the construction of questionnaire we included questions that were necessary when using medicines in case of common health problems of children, which together with all mentioned aspects of pharmacotherapy literacy increased the value of PTHL-SR.

Questionnaires for evaluation of health literacy of parents of pre-school children are not completely unknown. The PHLAT (Parental health literacy activities test) ⁸ is a 20 items questionnaire that covers 3 clinical domains: nutrition-growth/development/ injury-safety, but it is not specific just for pediatric medicines, and it was used in clinical environment. The MedLitRxSE by Sauceda is a general health literacy instrument that assesses skills needed to manage medication

properly, not specific for the parents and caregivers of preschool children because it is also used in clinical setting ²⁰.

The general health literacy instruments (S-TOFHLA, NVS) have limitations as they are not specific and could only serve as the predictive instruments for the assessment of pharmacotherapy literacy of parents. In the study of comparison of NVS and S-TOFHLA ³³ it was found that the S-TOFHLA has a ceiling effect as compared to the NVS.

The HELMA (Health Literacy Measure for Adolescents)³ is a specific questionnaire designed for the special age population from 15–18 years of age, context specific, assessed in non-clinical environment (school). Although age and context specific, it does not include the questions related to the use of medicines. It has 44 items covering 8 different areas.

In comparison to the mentioned specific questionnaires (PHLAT, HELMA, MEDLitRxSE), the factor structure of PHTL-SR is similar to them, as each domain has at least two questions and a reliable construction. It has 4 domains, comparing to the PHLAT which has 3 and the HELMA with 8. In the phase of construction, we used the competences necessary to address the possible cases of use of pediatric medicines and to cover different aspects of medicines use, which increased the validity of PTHL-SR.

As this is the first attempt to construct pharmacotherapy literacy of parents of pre-school children in Serbia, future studies should take into consideration a larger pharmacotherapy group of medicines (not only antipyretics and analgesics) and the parents from rural area as this would lead to the stronger confirmation of psychometric characteristics of PHTL-SR. Having in mind that internet is a frequent source of information for the parents, future studies should also take into consideration the access to reliable information about medicines from the internet.

Limitations

The study was conducted among parents only from the municipalities of the city of Belgrade. The sample was convenient and there was no possibility of data generalization. However, the sample was relatively heterogeneous because parents of different social, cultural, economic and educational environment were included.

Moreover, our questionnaire did not access outcomes of low pharmacotherapy literacy on children's health and this should be addressed in some future studies.

Although the questionnaire had the satisfactory psychometric characteristics, further research has to be performed in the future.

Conclusion

The PHTHL-SR is a reliable instrument for the assessment of pharmacotherapy literacy among the parents of preschool children in Serbia and can be used for the evaluation of different levels of understanding, calculating and accessing different medicines-related information.

Acknowledgements

The work of DK was supported by the Ministry of Education, Science and Technological Development of the Republic of Serbia, Project No. 41004.

REFERENCES

- Weiss BD. Health literacy and patient safety: Help patients understand. Manual for clinicians. 2nd ed. Chicago, IL: AMA Foundation and American Medical Association; 2007. p. 62.
- Sørensen K, Van Den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, et al. Health literacy and public health: A systematic review and integration of definitions and models. BMC Public Health 2012; 12: 80.
- Ghanbari S, Ramezankhani A, Montazeri A, Mehrabi Y. Health Literacy Measure for Adolescents (HELMA): Development and Psychometric Properties. PLoS One 2016; 11(2): e0149202.
- Yin HS, Johnson M, Mendelsohn AL, Abrams MA, Sanders LM, Dreyer BP. The health literacy of parents in the United States: a nationally representative study. Pediatrics 2009; 124 Suppl 3: S289–98.
- Yin HS, Parker RM, Wolf MS, Mendelsohn AL, Sanders LM, Virar KL, et al. Health literacy assessment of labeling of pediatric nonprescription medications: examination of characteristics that may impair parent understanding. Acad Pediatr 2012; 12(4): 288–96.
- Yin HS, Dreyer BP, Foltin G, van Schaick L, Mendelsohn AL. Association of low caregiver health literacy with reported use of nonstandardized dosing instruments and lack of knowledge of weight-based dosing. Ambul Pediatr 2007; 7(4): 292–8.
- Yin HS, Mendelsohn AL, Nagin P, van Schaick L, Cerra ME, Dreyer BP. Use of active ingredient information for low socioeconomic status parents' decision-making regarding cough and cold medications: role of health literacy. Acad Pediatr 2013; 13(3): 229–35.
- 8. Kumar D, Sanders L, Perrin EM, Lokker N, Patterson B, Gunn V, et al. Parental understanding of infant health information: health literacy, numeracy, and the Parental Health Literacy Activities Test (PHLAT). Acad Pediatr 2010; 10(5): 309–16.
- Berthe-Aucejo A, Girard D, Lorrot M, Bellettre X, Faye A, Mercier JC, et al. Evaluation of frequency of paediatric oral liquid medication dosing errors by caregivers: amoxicillin and josamycin. Arch Dis Child 2016; 101(4): 359–64.
- Tran TP, Robinson LM, Keebler JR, Walker RA, Wadman MC. Health Literacy among Parents of Pediatric Patients. West J Emerg Med 2008; 9(3): 130–4.
- King SR, McCaffrey DJ, Bonldin AS. Health literacy in the pharmacy setting: defining pharmacotherapy literacy. Pharm Pract (Granada) 2011; 9(4): 213–20.
- Baker DW, Williams MV, Parker RM, Gazmaraian JA, Nurss J. Development of a brief test to measure functional health literacy. Patient Educ Couns 1999; 38(1): 33–42.

- Baker DW. The meaning and the measure of health literacy. J Gen Intern Med 2006; 21(8): 878–83.
- 14. Davis TC, Wolf MS, Arnold CL, Byrd RS, Long SW, Springer T, et al. Development and validation of the Rapid Estimate of Adolescent Literacy in Medicine (REALM-Teen): a tool to screen adolescents for below-grade reading in health care settings. Pediatrics 2006; 118(6): e1707–14.
- Shih CL, Chang TH, Jensen DA, Chiu CH. Development of a health literacy questionnaire for Taiwanese hemodialysis patients. BMC Nephrol 2016; 17(1): 54.
- Al Sayah F, Williams B, Johnson JA. Measuring health literacy in individuals with diabetes: a systematic review and evaluation of available measures. Health Educ Behav 2013; 40(1): 42–55.
- Gong D.A, Lee JY, Rozier RG, Pahel BT, Richman J.A, Vann WF Jr. Development and testing of the Test of Functional Health Literacy in Dentistry (TOFHLiD). J Public Health Dent 2007; 67(2): 105–12.
- Ubavic S, Krajnovic D, Marinkovic D. Analysis of health literacy instruments which could be used on a primary healthcare level. Arh Farm 2015; 65(1): 1–16.
- Nguyen TH, Park H, Han HR, Chan KS, Paasche-Orlow MK, Haun J, et al. State of the science of health literacy measures: Validity implications for minority populations. Patient Educ Couns 2015. pii: S0738-3991(15)30021-5.
- Sauceda JA, Loya AM, Sias JJ, Taylor T, Wiebe JS, Rivera JO. Medication literacy in Spanish and English: psychometric evaluation of a new assessment tool. J Am Pharm Assoc (2003). 2012; 52(6): e231–40.
- Morrison AK, Schapira MM, Hoffmann RG, Brousseau DC. Measuring health literacy in caregivers of children: a comparison of the newest vital sign and S-TOFHLA. Clin Pediatr (Phila) 2014; 53(13): 1264–70.
- Sharts-Hopko NC. Focus group methodology: when and why? J Assoc Nurses AIDS Care 2001; 12(4): 89–91.
- 23. Nassar-McMillan SC, Borders LD. Use of Focus Groups in Survey Item Development. Qual Rep 2002; 7(1): 1–12.
- 24. Mazur K, Bennett J. Using focus groups to design a choice modelling questionnaire for estimating natural resource management benefits in NSW. Research Report No. 2. (Abstract). Canberra, Australia; Environmental Economics Research Hub Research Reports; 2008.
- Lawshe CH. A quantitative approach to content validity. Pers Psychol 1975; 28(4): 563–75.
- Altman DG. Practical Statistics for Medical Research. London: Chapman & Hall; 1991. p. 403–5.
- Gravetter FJ, Forzano LB. Research methods for the behavioral sciences. 3rd ed. Belmont, CA: Wadsworth Cengage Learning; 2009;

- 28. Wasserman JD, Bracken B.A. Psychometric characteristics of assessment procedures. In: Graham JR, Naglieri JA, editors. Handbook of psychology: assessment psychology. New York: John Wiley and Sons, Inc; 2003. p. 43–66.
- 29. Netemeyer RG, Bearden WO, Sharma S. Scaling procedures. Issues and applications. Thousand Oaks, Ca: Sage Publications, Inc; 2003.
- Kaplan RM, Saccuzzo DP. Psychological testing. Principles, applications, and issues, 7th ed. Belmont, CA: Wadsworth Cengage Learning; 2009.
- 31. *Black TR*. Doing quantitative research in the social sciences. An integrated approach to research design, measurement and statistics. London: SAGE Publications; 1999.
- 32. Jovic-Vranes A, Bjegović-Mikanović V. Evaluation of a health literacy screening tool in primary care patients: evidence from Serbia. Health Promot Int 2014; 29(4): 601–7.
- 33. Sanders LM, Federico S, Klass P, Abrams MA, Dreyer B. Literacy and child health: a systematic review. Arch Pediatr Adolesc Med 2009; 163(2): 131–40.

Received on July 18, 2017. Revised on December 16, 2017. Accepted on January 12, 2018. Online First January, 2018.