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THE APISS QUESTIONNAIRE: A NEW TOOL TO ASSESS THE EPIDEMIOLOGY OF SYSTEMIC ALLERGIC REACTIONS TO BEE VENOM IN BEEKEEPERS

VPRAŠALNIK APISS: NOVO ORODJE ZA EPIDEMIOLOŠKO OCENO SISTEMSKIH ALERGIJSKIH REAKCIJ PO PIKU ČEBELE MED ČEBELARJI

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ABSTRACT	Aim: To develop and validate a comprehensive questionnaire to be used as an instrument in cross-sectional studies among beekeepers.				
Keywords: Hymenoptera Hypersensitivity Beekeeping Questionnaire	Methods: A comprehensive questionnaire in Slovenian was validated by an expert panel (n=13) for content relevance and a rater panel (n=14) for clarity and comprehensibility. The content validity indices (an item-level content validity index and scale-level content validity index based on the average and universal agreement method) and item-level face validity index were calculated in accordance with the recommended number of both the review panels with their implications on the acceptable cut-off scores. Piloting was performed in a sample (n=50) of the target population (N=1.080) using telephone interviews.				
	Results: The item-level content validity index and scale-level content validity index based on the average method exhibited excellent content validity (0.97), while the scale-level content validity index based on the universal agreement method reached a value of 0.72. The item-level face validity index of 1.00 indicated that all items were clear and comprehensive.				
	Conclusions: The new instrument may be considered valid and feasible for use in nationwide population-based studies among Slovenian beekeepers and eventually in other populations.				
IZVLEČEK	Namen : Razviti celostni vprašalnik in preveriti njegovo veljavnost na način, da bo uporaben kot orodje v presečnih raziskavah med čebelarji.				
Ključne besede:	Metode: Celostni vprašalnik v slovenskem jeziku smo oblikovali na podlagi sistematičnega pregleda literature.				
kožekrilci	Protokol za sistematični pregled literature smo predhodno registrirali v mednarodni prospektivni register za				
preobčutljivost	sistematične preglede in pri pripravi upoštevali Prednostna poročila za sistematične preglede in metaanalizo (2022). Vsebinsko veljavnost vprašalnika smo ugotavljali na podlagi strinjanja skupine strokovnjakov različnih				
čebelarjenje	strok (n = 13), zdravorazumsko veljavnost pa znotraj skupine čebelarjev laikov (n = 14). Indekse vsebinske				
vprašalniki	veljavnosti (indeks vsebinske veljavnosti na ravni postavke, indeks vsebinske veljavnosti na ravni lestvice izračunan z metodo povprečnega in splošnega soglasja) in indeks zdravorazumske veljavnosti na ravni postavke smo izračunali glede na priporočeno število oseb obeh skupin, ki sta bili vključeni v preverjanje veljavnost vprašalnika. Pilotno testiranje vprašalnika smo izvedli na vzorcu (n = 50) ciljne populacije čebelarjev (N = 1.080, z metodo telefonskega intervjuja.				
	Rezultati : Indeks vsebinske veljavnosti na ravni postavk in indeks vsebinske veljavnosti na ravni lestvice, izračunana z metodo povprečnega soglasja, sta znašala 0,97; indeks vsebinske veljavnosti na ravni lestvice, izračunan z metodo splošnega soglasja, pa 0,72. Vrednost indeksa zdravorazumske veljavnosti na ravni postavke 1,00 nakazuje, da so vse postavke jasne in razumljive.				
	Zaključki: Rezultati potrjujejo veljavnost in primernost razvitega orodja, ki bi ga lahko uporabili v nacionalnih populacijskih raziskavah med slovenskimi čebelarji. Prevod vprašalnika v angleški jezik nakazuje možnost njegove širše uporabe na mednarodni ravni.				

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1 INTRODUCTION

Allergic reaction to Hymenoptera (bees, wasps, and hornets) is an important public health problem, with a large local reaction (LLR) and systemic allergic reaction (SAR) as the two main clinical presentations. LLR is defined as local swelling exceeding 10 cm in diameter, increasing within 24-48 hours after the sting, and lasting longer than 72 hours, while SAR involves one or more organs and consists of various grades, depending of the classification used (1).

Stinging Hymenoptera are amongst the most common causes of SAR (2), with bees of the family Apidae and wasps of the family Vespinae as the main perpetrators of a Hymenoptera venom allergy (HVA) in developed countries (3). The prevalence of the self-reported SAR to Hymenoptera venom in the adult general population across different European countries over a 20-year period ranges from 0.9 to 8.9% (4). The rates are the highest among beekeepers due to their unavoidable seasonal or all-year-round exposure to the elicitors of a HVA, bees in particular. However, epidemiological observational studies worldwide published between 1996 to 2018 have shown significant differences in the prevalence of the selfreported SAR, with estimates ranging from 2.1 (5) to 37.6% (6). The factors accounting for the degree of variability have been attributed to the degree of exposure, data collection technique used, definition of allergic reaction, climate and geographical location (7).

To the best of our knowledge, to date no comprehensive and validated questionnaires exist for assessing epidemiological data on the self-reported SAR to bee venom and the risk factors for SAR among beekeepers.

Therefore, this study aims to address this gap through the development and validation of a comprehensive questionnaire to be used as an instrument in crosssectional studies among Slovenian beekeepers. The first objective of the study is to describe the questionnaire's development process and assess its validity. The second objective is to pilot-test the final version of the tool to verify its feasibility for the proposed research approach.

2 METHODS

2.1 Questionnaire development

2.1.1 Domain identification and item generation

Initially, a systematic literature review (data not published yet) was carried out using the methodology previously reported in a protocol paper (8), aiming to identify the observed outcome (questionnaires) of the relevant surveys to generate a comprehensive new instrument, making it possible, through the targeted environmental history, to address epidemiological public health aspects of the selfreported SAR to bee venom and the risk factors for SAR among beekeepers to provide a more complete information in the process of assessing clinical aspects and diagnosis of HVA. Providing evidence-based data, the following objectives were: a) assessing the prevalence of the selfreported SAR to Hymenoptera venom in beekeepers worldwide, b) exploring the impact of environmental differences worldwide on the prevalence rates, and c) updating the principal risk factors for SAR. In total, of 442 studies identified, seven original articles were included and used for developing a comprehensive guestionnaire in the Slovenian language. Preliminary data show the prevalence of the self-reported SAR to bee venom ranging from 2.1 to 37.6%. Several risk factors were identified that either increase, decrease risk or no association was proven. The identification of pertinent content domains and item generation were initially carried out by the first author based on two main sources: descriptions of studies' questionnaires and a copy of a German questionnaire (Questionnaire for the Assessment of Beekeepers' Health, QABH) obtained on request (9). The pool of domains and items were reviewed and refined by the consensus group, comprising the three authors of this paper, until complete agreement on the domains/items was achieved, resulting in a first draft of the study questionnaire. An example of the refinement is the question about current smoking status (smoking status domain). The predefined responses were refined according to the World Health Organization Countrywide Integrated Noncommunicable Diseases Intervention (CINDI) programme, more specifically according to the CINDI Health Monitor Questionnaire (10).

2.2 Validity assessment

2.2.1 Expert panel selection and recruitment

A panel of 15 experts from different fields (public health, sanitary engineering, clinical medicine, veterinary medicine, biology, microbiology and beekeeping), was nominated and selected based on the criteria presented by Fernandez-Gomez (11). All of these individuals were knowledgeable about the subject, either because of their professional knowledge/academic background or because of their epidemiological and/or clinical work experience. The recruitment period lasted from 5th to 10th September 2021. Each nominee was individually and confidentially contacted through email and invited to be a part of the expert panel. The experts who indicated their willingness to participate were emailed again and provided with all the documents needed to conduct the validity process (i.e., an informed consent form attached to an explanatory cover letter, a first version of the questionnaire, a brief demographic questionnaire (i.e., on gender, age, statistical region, place of residence), and a content validation form). The cover letter included a short description of the study's purpose, a description of the content review instrument with instructions, a

rating score to help guide the experts with regard to the scoring method and the reasons for their (the experts') nomination (12).

2.2.2 Content validity

For qualitative validity, members of the expert panel were asked to critically review each item of the targeted domain prior to scoring its relevance. Following the experts' assessment, domains and items were revised by the consensus group and, if necessary, modified upon their agreement.

For the quantitative assessment of the content validity, a panel of experts was asked to rate the instrument items in terms of their relevance. A four-point Likert scale based on a criterion propounded by Davis (13) was used as follows: 1 = not relevant to the measured domain; 2 = somewhat relevant to the measured domain; 3 = quite relevant to the measured domain; and 4 = highly relevant to the measured domain. The scale was recoded into dichotomised relevant (rating of 3 and 4) and non-relevant (rating of 1 and 2) values prior to calculating the content validity indices (CVIs) (14).

Quantitative data were analysed by the computing CVIs at the item (item-level content validity index, I-CVI) and scale levels (scale-level content validity index, S-CVI), the latter being calculated using two methods, i.e., the average (Ave, S-CVI/Ave) and the universal agreement (UA, S-CVI/UA) (15). Calculations were made using the following equations (1-3):

Equation 1	$I-CVI = \frac{agreed\ item}{number\ of\ expert}$
	I = item CVI = content validity index
Equation 2	$\frac{S-CVI}{Ave} = \frac{sum \ of \ I-CVI \ scores}{number \ of \ item}$
	S = scale CVI = content validity index Ave = average
Equation 3	$\frac{S-CVI}{UA} = \frac{sum of UA \ scores}{number \ of \ item}$
	S = scale CVI = content validity index UA = universal agreement

In relation to the number of experts, items and using the questionnaire as a tool, the cut-off scores of I-CVI ≥ 0.78 (13) and S-CVI/Ave ≥ 0.90 , respectively, were considered to be acceptable (16), while for S-CVI/UA a value of ≥ 0.80 was accepted as good (17, 18).

2.2.3 Pre-piloting: study participants and recruitment

Pre-piloting was performed among a sample of the target population, beekeepers (n=14) of any age, registered with the Slovenian Beekeepers' Association (SBA), according to which a beekeeper is a member of the SBA who undergone through a standardized educational and training system in the framework of a lifelong learning, led by the SBA, regardless beekeeping status (professional or amateur). This includes training under a supervisor (mentor) who is well educated in beekeeping, has long experience of beekeeping, uses the principles of good beekeeping practice, performs beekeeping nearby and in the same hive system, and is willing to share knowledge and experience in order to help the new beekeeper with the initial steps on their beekeeping path. The SBA includes 207 beekeeping societies and 14 regional beekeeping associations, with a total of about 7,500 amateur and professional beekeepers (19). The following exclusion criteria were applied: stings caused by Hymenoptera species other than bees (e.g., wasp, hornet); toxic reaction; acute or chronic conditions that prevent the beekeeper from participating in the study; refusal to participate after obtaining informed consent. The recruitment period took place from 25th to 29th September 2021 using an online approach - a Google form published on the SBA website. Participants willing to take the survey marked their informed consent and expressed their preferred time and date to conduct the survey using a face-to-face method. The physical location for the in-person meetings was determined individually and tailored to the participant's request.

2.2.4 Response process validation

For the quantitative assessment of the response process validation, the members of the rater panel were requested to rate the instrument items in terms of clarity and comprehensibility. The same scoring and the same recoding procedure were applied as for the CVIs. The item-level face validity index (I-FVI) was computed as the number of agreed items divided by the number of raters (Equation 4). Items with FVI values above 0.83 were considered to be accepted (20).

Equation 4 I-FVI = $\frac{agreed \ items}{number \ of \ rater}$ I = item FVI = face validity index

2.3 Piloting

The validated questionnaire was piloted among a group of beekeepers of any age, registered with the SBA, to assess its feasibility for the planned research approach. The same recruitment process and the same exclusion criteria were applied as for the response process validation with the data collection period from 15th to 29th October 2021. We included the first 50 beekeepers who filled out an online informed consent form, a number that was chosen based on a consensus among all authors of this paper. Due to the health risks posed by the COVID-19 pandemic and the associated restrictions, we were forced to switch our survey methodology from face-to-face to telephone. A telephone-to-paper method was used with the guestions administered to the respondent during a phone call; the data were simultaneously recorded on a paper version of the questionnaire. The interviews were carried out by the same researcher with expertise in conducting telephone interviews.

The Slovenian version of the questionnaire was translated into English using the forward-backward translation method. A copy of this version of the questionnaire is available from the first author.

2.4 Statistical analysis

Descriptive statistics were used to describe the sociodemographic characteristics of the study participants, including the frequencies for categorical variables, and median values and their respective interquartile ranks (IQRs) for continuous variables. Data are shown in both graphic and tabular form. IBM SPSS (version 27) was used for the data analysis.

3 RESULTS

3.1 Questionnaire development and validation

3.1.1 Domain identification and item generation

A synthesis of the data resulted in the identification of seven domains, as follows: 1) socio-demographics, 2) beekeeping, 3) self-reported SAR to bee venom, 4) treatment, 5) comorbidities, 6) smoking, and 7) beekeeping among family members. An initial pool of 46 items was reviewed iteratively until the consensus group reached agreement on 39 items. The instrument was named APISS-Q, based on the genus name Apis for "bee", the letter "S" for "Slovenia" and "Q" for "questionnaire".

3.2 Validity assessment

3.2.1 Sociodemographic profile of the panel experts

Of the 15 experts selected and invited to participate in the study, 13 responded to the mailed request (response rate: 86.7%). The panel experts were aged between 24 and 66 years (mean age 46.7 years) with a slight female

predominance (seven of 13; 53.9%). The vast majority came from the Central Slovenia statistical region (eight of 13; 61.5%), followed by Gorenjska (two of 13; 15.4%), while Goriška, Savinjska, and Podravska statistical regions each had one participating expert (one of 13; 7.7%).

3.2.2 Sociodemographic profile of the pre-test study participants

Out of 14 study participants, 11 were male and three were female, and they were aged between 34 and 71 years (mean age 54.7 years). The vast majority came from the Central Slovenia statistical region (six of 14; 42.9%), followed by the Goriška (three of 14; 21.4%) and Primorsko-notranjska (two of 14; 14.3%). Jugovzhodna, Gorenjska and Podravska statistical regions each had one pre-test study participant (one of 14; 7.1%).

3.2.3 Content validity and response process validation

The APISS-Q in its final form contained 50 items under the following domains: 1) socio-demography (i.e., gender, age, bodyweight, etc.), 2) beekeeping (i.e., type of beekeeping - amateur, professional; type of protective clothing while beekeeping, etc.), 3) self-reported SAR to bee venom (i.e., SAR grading system with the description of typical symptoms for each grade, the number of bees causing SAR, etc.), 4) treatment modalities of the self-reported SAR to bee venom (i.e., medical services accessed after the first SAR to bee venom, allergy specialist review after the first SAR to bee venom, etc.), 5) comorbidities and regular drug therapy (i.e., symptoms of atopy or other allergic diseases, other comorbidities, etc.), 6) behavioural risk factors (smoking status), and 7) beekeeping among family members/close blood relatives.

The relevance ratings of the 13 experts with regard to the item scale are shown in Table 1. All 50 items met the I-CVI threshold of \geq 0.78. An average item quality expressed by the S-CVI/Ave was 0.97, indicating a high content validity of the questionnaire. The S-CVI/UA method, reflecting the proportion of items in the tool that achieved a rating of three or four by all the panel members, was below the value accepted as good (0.72). An item level of the response process validity index of 1.00 indicated clarity and comprehensibility for all items of the APISS-Q. The flow chart of the questionnaire development and validation process is shown in Figure 1.

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 Table 1. The relevance ratings of the 13 experts with regard to the item scale.

Legend: I-CVI - item-level content validity index; S-CVI/Ave - scale-level content validity index based on the average method; S-CVI/UA - scale-level content validity index based on the universal agreement method; UA - universal agreement; SAR - systemic allergic reaction; Q - question.

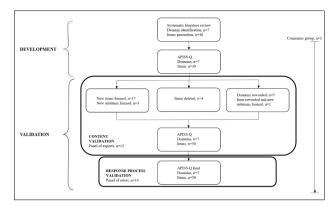


Figure 1. Flow chart of the questionnaire development and validation. Legend. APISS-Q - Apis for "bee", the letter "S" for "Slovenia" and "Q" for "questionnaire".

3.3 Piloting

3.3.1 Demographic profile of the pilot study participants

All beekeepers who filled out an online consent form responded to the survey (100% response rate). On average, it took a little more than 10 minutes to complete the telephone interview, with all participants finding the length to be acceptable. Out of 50 study participants, 43 were male, and seven were female, aged between 18 and over 61 years (mean age 51.1 years). The vast majority came from the Central Slovenia statistical region (20 of 50; 40.0%), followed by the Goriška (nine of 50; 18.0%); Gorenjska (eight of 50; 16.0%), Savinjska (seven of 50; 14.0%), and Jugovzhodna (two of 50; 4.0%). Zasavska, Pomurska, Obalno-kraška and Primorsko-notranjska statistical region each presented had one study participant (one of 50; 2.0%).

4 DISCUSSION

The overriding aim of this study was to develop and validate a comprehensive questionnaire, making it possible, through the targeted environmental history, to collect epidemiological data about the self-reported SAR to bee venom and the risk factors for SAR among beekeepers, all vitally important for future clinical assessment in order to formulate a correct diagnosis and the related treatment, including counselling. Our findings have demonstrated the high calculated CVIs (I-CVI, S-CVI/Ave) and FVI (I-FVI) values, indicating the excellent validity of the tool. Subsequent piloting among beekeepers with no further adjustments suggests that this questionnaire is feasible for use for its intended purpose in public health and clinical settings. Translation into English may additionally contribute to its wider international use.

There have been few published studies in this field of science. To the best of our knowledge, the only available study questionnaire to date is the German one (QAHB), provided by the author on our request (9). The QAHB was designed after gathering information from previous research among beekeepers and includes a large number of domains with some very detailed data. The whole instrument (QAHB and the Inventory for the Measurement of Bodily Negative Affectivity (INKA-h) questionnaire) was piloted in 10 volunteers prior to the survey to ensure its intelligibility. In addition, the authors included a reference group to rule out any potential biases between the responders and non-responders. However, the QAHB is rather long (13 pages), which may contribute to an experience of fatigue or a loss of motivation to complete it, albeit length per se is not the only measure of the effort needed to answer all the items. From the methodological point of view, the major limitation of the QABH lies in its development, as the questionnaire was no validated. The same is true for the questionnaires covering different types of allergies, as none of the questionnaires used were tested for content validity, using either systematic or nonsystematic approaches (21). This is important, as content validity, vital to support the validity of the assessment tool (14), in addition to the response process validity (20), are both needed to assess how far a survey instrument measures the intended idea, and thus is a high-quality assessment tool (22). In addition, with regard to the mode of delivery neither home interviewing nor personal delivery were used, both of which have been shown to be preferable methods of the tool distribution in terms of response rate (23). Taken together, the aforementioned factors may have contributed to the lowest response rate (3%) among the surveys included in our systematic literature review that provided the data. Among these studies, with the exception of Annila et al. (24), a rather low response rate (i.e., below 60%) has also been reported by a number of authors (5, 7, 25), and this has been found across all epidemiological designs in recent years (26). Despite not being recognized as evidence of study quality and validity alone, a low response rate may reduce the statistical power and prevent generalization to the wider community, thus representing an important component of the overall survey problems (27).

Our study has potential limitations that need to be addressed. Firstly, it could be argued that including both professional and amateur beekeepers is a weakness, since the latter are generally less educated about beekeeping. However, this is not the case in Slovenia, due to rigorous unified entry and the lifelong SBA educational and training system for all beekeepers, as explained in the methods section (19). Moreover, when developing the APISS-Q the specific characteristics of the Slovenian beekeeping were taken into account (28). Next, although data were collected by face-to-face and telephone interviews with a medical doctor, making it possible to clarify certain clinical concerns, we are aware that the questioners, if using the APISS-Q, might not have appropriate knowledge to distinguish between different clinical types of AR. Therefore, prior its use they should be well educated by a medical doctor. Next, switching questionnaire delivery mode during the study due to COVID-19 pandemic might have impacted the pilot phase. However, the epidemiological measures had to be respected and we firmly believe that this change did not have a major impact on the results. Nonetheless, the preferred mode for delivery is definitely face-to-face. Next, one of the major weaknesses of the scale used might be the lack of a "don't know" answer. However, offering neutral options could allow experts and study participants in prepiloting to move on without giving careful thought to the domain and item investigated. In addition, apart from Yussof (14, 20), the use of a four-point Likert scale in the content validity was suggested (29) and used by several other authors (15, 30), and Chang (31), who compared four- and six-point Likert scales, reported that the former have greater reliability. Next, although several other consensus methods to evaluate interrater agreement for content validity purposes could be used (i.e., T, rWG, r*WG, content validity ratio (CVR)), the widely used CVI has advantages with regard to ease of computation, understandability, focus on agreement of relevance rather than agreement per se, focus on consensus rather than consistency, and provision of both item and scale information when compared it to alternative indexes (32). One weakness is its failure to adjust for chance agreement that can be in future solved by translating I-CVIs into values of a modified kappa statistic. Still, several recent studies (14, 20) established the content validity using the same CVI and FVI as we did to support the validity of an assessment tool. Next, a further shortcoming of the study is the value of S-CVI/UA, which was below the threshold of \geq 0.80, considered to show excellent content validity (33). Nonetheless, the UA calculation method was not used to evaluate the overall instrument as it may underestimate its content validity due to the reciprocal relationship between the probability that the experts would all agree on relevance and the number of experts (17). In other words, the higher the number of experts, the more difficult to achieve acceptable values for S-CVI/UA. Based on the literature, most studies avoid using the S-CVI/ UA approach, and thus a more flexible method for the overall instrument-CVI calculation is preferred (i.e., S-CVI/ Ave) (34). Next, it could be claimed that the differences between respondents and non-respondents regarding some characteristics (e.g. gender, age, education level and regional distribution) were not studied and shown. Unfortunately, due to the EU General Data Protection Regulation, the SBA could not provide us with a list of registered beekeepers with general demographic characteristics, hence we were forced to address the request for this to the presidents of the individual beekeeping societies. As a result, there were no data

available to compare respondents and non-respondents regarding their socio-demographic characteristics. However, given how the SBA takes care of the education of each new member, we felt that this would not adversely affect the survey results. Finally, we are aware that the detailed description/reporting of all specific questions within each domain and their refinement after the first draft would enhance the transparency and replicability of the study. Unfortunately, this was not possible due to journal limitations. However, all interested readers can get an insight into the questionnaire and its development stages in the Slovenian language from the first author upon request.

5 CONCLUSIONS

This may be the first study providing an evidence-based assessment tool and determining its validity using selected validity assessment indices. Numerous panel members with different fields of expertise, enabling the inclusion of all the relevant public health and clinical aspects across content domains, and the panel raters, randomly selected from the target group of the population, all reduce the effect of a chance agreement on the results. Piloting among beekeepers using a telephone approach suggested the tool to be feasible for its epidemiological use among beekeepers. The data gathered could have substantial benefits for clinicians, public health experts and policymakers that aim to mitigate the risk of SAR to bee venom among beekeepers and in the wider community.

CONFLICTS OF INTEREST

The authors have no competing financial interests or personal relationships to declare.

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ETHICAL APPROVAL

The study was approved by the National Medical Ethics Committee of the Republic of Slovenia (No. 0120-423/2020-3, academic research). All participants gave written, informed consent prior to survey participation.

AVAILABILITY OF DATA AND MATERIALS

The questionnaire and information on its development stages in Slovenian are available from the first author upon request. When the entire methodological process is fully completed, the English version of the questionnaire will also be available from the first author upon request.

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