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Original Article

Assessment of the Suitability of the Delphi Method for Assessing the Needs of Pharmacoeconomic Studies in the Decision-Making Process

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ABSTRACT

Background: Increasing need for control in healthcare spendings and for publicly available services, opens new areas and topics that needs to be discussed. The aim of this paper is assessment of the technic adequacy for evaluation of knowledge level in the subject territory. **Materials and Methods:** Systematic review has been performed with electronic database PubMed and MEDLINE. The SPIDER model (Sample, Phenomenon of Interest, Design, Evaluation, Research Type) was used to create the search strategy, which is more suitable for qualitative research. **Results:** After the initial check by title and the introductory part of the abstract, 1,282 published articles were eliminated due to inadequate study design. 249 articles that were checked by abstract with a focus on methodology and sample went for additional checking. During this step, 50 articles were selected for checking the complete research, i.e., the published content. Given results has enabled us insight in Delphi method with assessment of advantages and disadvantages.

Keywords: Delphi method, Qualitative methods, Pharmacoeconomic, Decision-making.

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INTRODUCTION

Costs for medicines and health interventions are increasing rapidly, but more and more new medicines and new approaches to treatment are becoming available on the market. It is necessary to consider the introduction of new approaches in decision-making related to medicines, especially in developing countries such as Bosnia and Herzegovina. According to WHO accessibility has three main goals, including physical availability, economic affordability or accessibility, and information availability.[1] Physical availability refers to the availability and geographic accessibility of medicines to those in need of rational use. Affordability refers to the ability of people to pay for medicines without financial difficulties, while the availability of information is the right to request, receive and transmit important information.[1-4] Most healthcare systems strive to ensure the availability of the necessary quantities of safe, effective, and high-quality medicines at acceptable costs.[5] To ensure the continuous supply and availability of medicines, tools,[6] that can ensure control are needed.

One of the methods that could establish control and ensure all of the above is the application of pharmacoeconomic models in the decision-making process in the health system.

Pharmacoeconomics is defined as the "description and analysis of the costs of drug therapy to health care systems and society". Pharmacoeconomic studies identifies, measure, and compare costs (i.e., resources consumed) and consequences (i.e., clinical, economic, humanistic).[7] Economic evaluations assess the value of health care,[8] and should be a powerful tool for evidence-based decision-making.[9,10]

The Delphi method, developed by Dalkey and Helmer in 1950, and later amended in 1962,[11] has been widely applied and accepted to achieve harmonized opinion in terms of current state- of-the-art in a specific field. The Delphi method is designed as a group communication process that aims to conduct detailed investigations and discussions on a specific issue to set goals, research policy, or predict the occurrence of future events.[12]

According to the definition of Dalkey and Helmer, Delphi is a technique created "to obtain the most reliable consensus of a group of experts [...] through a series of intensive questionnaires with controlled responses". Based on the goals of the Delphi method, Häder, in addition to finding consensus, singled out three more methodological types: (1) collecting ideas, (2) creating future events, and, (3) determining expert opinions.[13] It

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studies phenomena that are difficult to quantify and for which objective statistical regularities cannot be derived. It implies a scientific approach through the process of surveying and discussing participants through two or more rounds, whereby the collected data between each round is processed and delivered to the participants for further consideration and evaluation to reach a consensus in assessment, decision-making, and prediction, or generate new ideas about the subject of research.[14] It is designed to encourage genuine debate, regardless of the personalities of the experts involved in the process.[15]

One of the primary characteristics and advantages of the Delphi method is anonymity, which can contribute to reducing the effect of dominant individuals, which is usually a concern in group-based processes used to collect information.[12] It is mainly used when an assessment of long-term difficulties/problems is needed. Since it is a procedure that enables the identification of statements (topics) that are relevant for the future, tacit and complex knowledge is reduced to a single statement and enables judgment.[16] There is an effort to apply pharmacoeconomic methods in the decision-making process related to medicines, but due to incomplete regulations and limited knowledge, the application is limited in Bosnia and Herzegovina. Further research will be focused on examination the level of knowledge in pharmacoeconomic with questionnaire developed with Delphi method. Based on received results adequate methodologies will be proposed. The most important step should be a consensus with experts involved in the decision-making process regarding the questionnaire required to evaluate the level of knowledge and readiness of all parties included (pharmaceutical industry, competent Ministries, etc.).

This paper aims to verify the application of the Delphi method for the development of a questionnaire for examining the level of readiness and knowledge for the introduction of pharmacoeconomic methods in the decision-making process in the health system.

MATERIALS AND METHODS

The research was conducted using a systematic literature review. In this paper we used PRISMA to facilitate transparent and complete reporting of systematic reviews.

Eligibility criteria were related to the development of a pharmacoeconomic evaluation questionnaire using the Delphi method, multidisciplinary panel expert, qualitative or mixed method. Exclusion criteria included any other type of qualitative research used in the development of a pharmacoeconomic evaluation questionnaire.

Furthermore, the exclusion criterion was also the topic to which the research refers, so if the topic is limited only to certain diseases, the intervention or condition was not included in further consideration. The reason for this is an inadequate tested sample, e.g. only certain groups of patients or their guardians were examined, or only certain narrower professions were involved-oncologists, surgeons, etc.

The search was limited for literature published in the period from 2011 to 2021 and in English.

Information source and search strategy

The search was done in the PubMed and MEDLINE databases. The SPIDER model (Sample, Phenomenon of Interest, Design, Evaluation, Research Type) was used to create the search strategy, which is more suitable for qualitative research. SPIDER as a tool has additional advantages that are more suitable for mixed methods and the search strategy of qualitative research is possible due to the addition of "Research type".[17]

Keywords that are combined according to the SPIDER model (Appendix 1):

- Sample: Policymakers, health care, new medicine, decision-makers.
- The Phenomenon of Interest: Pharmacoeconomic, economic evaluation, cost-benefit, cost-minimization, cost-utility, cost-effectiveness.
- Design: Delphi method, multidisciplinary panel expert, expert consensus, questionnaire.
- Evaluation: Experience, opinion.
- Research: Qualitative, mixed-method.

Data collection and selection process

The collection and selection of the searched data were done by two authors, and if there were any disagreements, consensus was applied.

The data selection was related to the research methodology and topic. First, the search results were checked by title, then was reviewed by abstract, and finally, if the literature met the inclusion criteria by abstract, it was included in the review and evaluated as the full article. During the search, no suitable Systematic Review articles were found that would meet the inclusion criteria.

The publication was not considered, if the following was determined:

- Lack of development of questionnaires/interview questions,
- The questionnaire was developed by the research team,
- A pilot study was conducted on the respondents based on which the interview questionnaire was developed,
- The questionnaire was created based on a literature search.

Some articles were excluded because they included occurrences in clinical trials. Published literature that contained the application of methodologies such as:

- Development of questionnaires/interview questions based on a panel discussion with experts,
- Development of polling stations using the Delphi method or,
- Mixed methods for the development of questionnaires, frameworks, or criteria for testing the wider population were included in further research.

Topics that met the inclusion criteria focused on pharmacoeconomic methods, models, and their application, that is, assessment and evaluation of pharmacoeconomic methods. The above-mentioned methodology was applied in the decision-making process related to new drugs, essential drug lists, and health care.

Synthesis methods

During the review and verification of articles, a defined question was used and thus determined number of articles meet the criteria.

During the check, the expansion of the research question was considered, given that a very small number of articles met the minimum requirements criteria. However, it was not possible to expand the criteria within the given phenomena and samples, so the proposal was rejected by the reviewer.

RESULTS

A total of 1,531 articles were found in electronic databases.

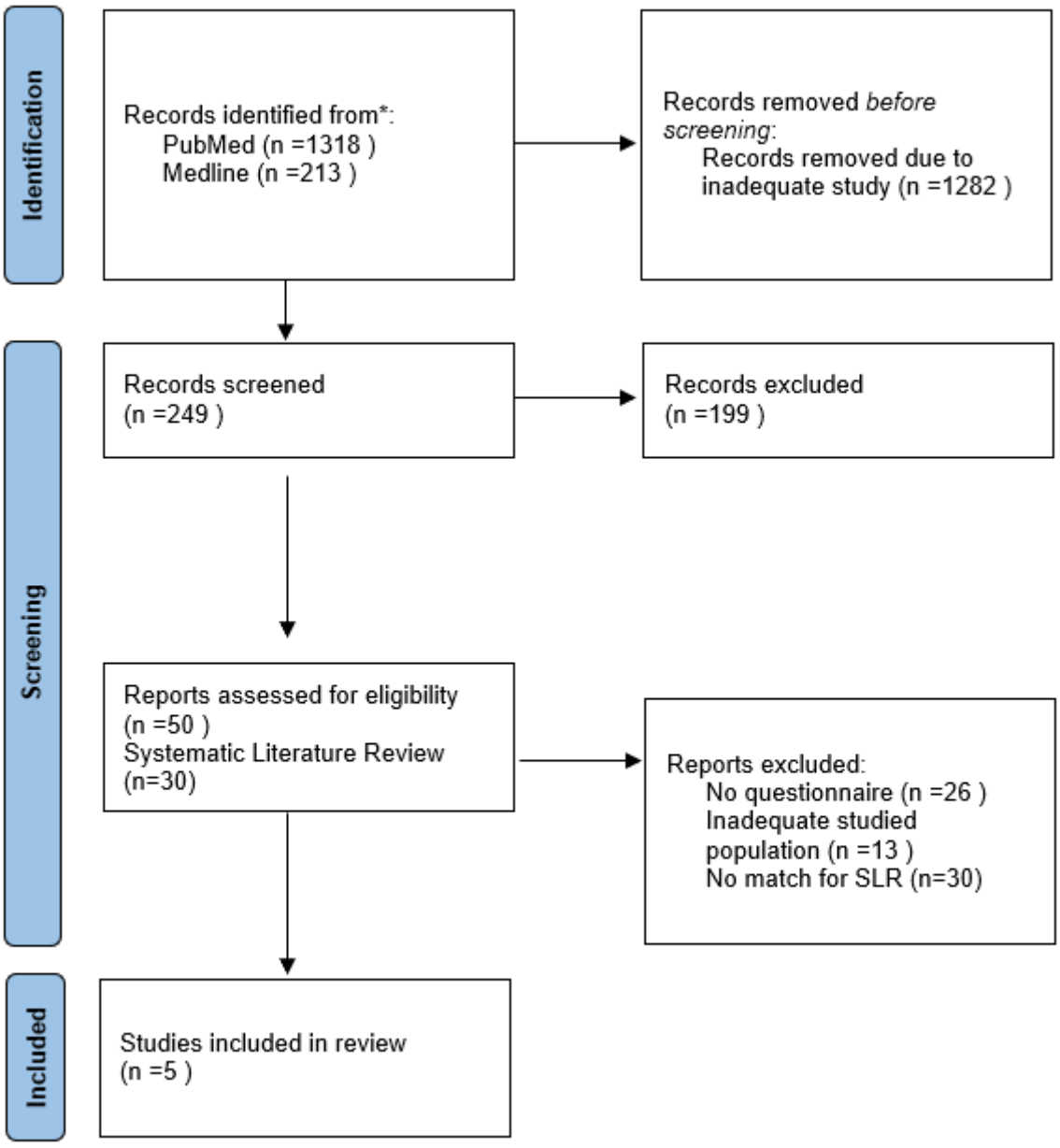

Figure 1: Flow diagram – paper search strategy and selection.

After the initial check by title and the introductory part of the abstract, 1,282 published articles were eliminated due to inadequate study design. 249 articles that were checked by abstract with a focus on methodology and sample went for additional checking. During this step, 50 articles were selected for checking the complete research, i.e., the published content.

During the search, 30 additional publications related to Systematic Literature Review (SRL) was found, but they did not meet the eligibility criteria. The review included 5 articles that met the eligibility criteria (Figure 1).

A checklist for qualitative studies was used to evaluate the included publications. The checklist included an assessment of Credibility Measures and Data collection method through 10 questions. All 5 studies met the criteria of qualitative studies (Appendix 2).[18,19]

The application of pharmacoeconomic indicators in the decision-making process is evaluated in selected studies/publications. Various methods were used, mostly qualitative but also mixed methods. Brief summary of study characteristics and main results of included publications are showed in Table 1.

The article by Kaltenthaler *et al.* referred to health economic models applied for reporting to decision-makers in the process of deciding whether an intervention represents good value for money. This qualitative study looked more closely at the assessment and identification of information used to develop such models. A qualitative study was conducted with focus groups in which experts from the field were involved. This methodology proved to be the most acceptable for collecting data and assessing the degree of consensus among experts. As a result, six topics were identified that were openly discussed by the experts. Framework analysis was used to develop a thematic framework, and qualitative data were classified and organized into key topics and sub-topics.

Study by J. Guzman *et al*. refers to the development of a framework for the implementation of economic evaluation of therapy (in this case, occupational therapy) as part of health care. Two clear goals have been set that should be considered in the economic evaluation, which relates to defining key resources (costs) and outcomes (consequences) and defining how to include them in the framework. The conducted study is a mixed, qualitative, and quantitative method. A literature search was included, then the framework proposal was evaluated with the working group; after that, the Delphi method was applied. The Delphi method was used to rank the outcomes according to their importance when used in the decision-making process. In the first phase after the literature review, authors of this paper observed that the published journals have methodological flaws and that they provide correct to satisfactory evidence of the cost-benefit of individual interventions. From the interviews with decision-makers, a discrepancy in terminology was observed, cost and consequence, and the adopted terminology was resources and outcome. The Delphi method showed some minor differences in the order of resources, but significant differences concerning the ranking of outcomes.

The third article which met the criteria, Iglesias *et al*., published in 2016, refers to model-based economic evaluation and model-based cost-effectiveness analysis, which play a key role in informing decision-makers regarding reimbursement decisions. A two-round Delphi method was conducted to generate criteria for two types of study designs most commonly used to incorporate expert judgment into the model-based economic evaluation of health interventions. The Delphi process was conducted in two rounds and only part of the respondents agreed to participate in the expert panel in the second round.

The fourth article, was an examination of Canadian stakeholder responses to the proposed recommendations for updating the guidelines for Budget Impact Analysis (BIA) issued by the Patented Medicine Prices Review Board. The examination refers to the stakeholder's perspective on the proposals, and a mixed-method study was applied. The opinion and views of policy-makers were collected through one-on-one interviews, and the opinion and views of the industry and their advisors were collected through the platform. The results related to three parts: (1) The response of policymakers (BIA reviewers) (2) Feedback from manufacturers or their consultants (BIA creators) and (3) A comparative analysis between policymakers and manufacturers/consultants. When examining the policymaker group, 4 main areas were identified: BIA can be very useful in drug reimbursement decisions and price adjustments, connecting ICER and BIA, and finally BIA key elements (e.g., timeline) including additional recommendations for improving metrics. The results of the written platform carried out with manufacturers/consultants gave results for each area individually in different proportions. Time frame, population, additional indirect costs that are not related to therapy, and the introduction of total and incremental impact on the budget (cost analysis for all new and existing indications) but without including inflation and discounting were examined.

The final article that met the criteria refers to the original article by Karyan *et al*, where a mixed method was used but with the application of a Discrete Choice Experiment (DCE). This article was included because the survey was conducted on a large group of insured, end users, so it is interesting to consider the application of DCE as a method for examining attitudes and opinions related to healthcare. The study was conducted in Iran, which represents a middle-income country, which makes it suitable for extrapolation of results. The study includes 4 phases of the DCE method. First, attributes and levels were determined through interviews with experts as well as a literature review. After that, 36 experts evolved and evaluated the proposed list of health insurance attributes. D-efficiency criteria were used to make choices and select the most important attributes to be included in the final experiment. The final design contains 24 sets of choice

Table 1: Study characteristics and main results.

Author, year	Country	Study group	Study type	Study methodology	Study aim	Conclusion
Kaltenthaler E., 2014.[21]	UK[21]	Focus group, HTA experts.[21]	Qualitative[21]	Focus group[21]	This study present findings from research with focus group where were explored some unclarities related to identification and checking the proof used in development of cost-effectiveness model.[21]	The results of this research provide an overview of the questioning of the evidence used in cost-effectiveness models. This consideration helps to make the model development more understandable and simpler to apply in the decision-making process.[21]
J. Guzman *et al.*, 2015.[22]	Canada[22]	The working group (managers, unions, healthcare professionals, and researchers), key informant interviews (decision makers within healthcare).[22]	Mixed-qualitative and quantitative.[22]	Interviews and Delphi panel.[22]	The project related to the development of the economic assessment framework for the occupational health and safety program was carried out in cooperation with the participants of the public health in the Canadian province. The project aimed to define key resources and outcomes that should be taken into account in economic evaluation and define how to integrate them into a comprehensive framework.[22]	There is a need to develop guidelines for application of economic evaluation using good practice that includes resources and outcomes.[22]
C.P. Iglesias, 2016.[24]	International[22]	Expert.[24]	Qualitative.[24]	Delphi method.[24]	The aim of the study is to develop reporting criteria for two design types used to identify expert judgement for the application of Delphi method based CEA.[24]	The results of this study are guidelines for reporting for two types study design in EE: an elicitation study with 16 criteria and a Delphi method comparing the opinions of experts with 11 criteria.[24]

Author, year	Country	Study group	Study type	Study methodology	Study aim	Conclusion
N. Foroutan., 2020.[30]	Canada[30]	Ministry of Health, PMPRB, CADTH, pCPA, NIHBP, and private payers.[30]	Mixed-qualitative and quantitative.[30]	Interviews and questionnaire[30]	Results of a qualitative and quantitative analysis on the proposal to update of Budget Impact Analysis guidelines of the Canadian Patented Medicine Prices Review Board (PMPRB).[30]	The study collected opinions and comments or recommendations by reviewing the literature and national guidelines.[30]
Kalyani A.K., 2019.[25]	Iran[25]	Expert[25]	Mixed method using DCE.[25]	DCE[25]	The aim of the research was to find out what are the most important preferences of the Iranian Heath system by applying the DCE method. The results are of great importance for the health system and the creation of package with all benefits for the population of Iran.[25]	Findings can contribute to the improvement of the health care system and increase the usefulness of the individuals and participation in health insurance.[25]

*Abbreviation: HTA – Health Technology Assessment; OHS – Occupational health and safety; CEA – Cost effectiveness analysis; EEs – Economic evaluations; PMPRB – Patented Medicine Prices Review Board; BIA – Budget Impact Analysis; CADTH – Canadian Agency For Drugs And Technologies In Health; pCPA – Pan-Canadian Oncology Drug Review; NIHBP – Non-Insured Health Benefits Program; DCE – Discrete Choice Expert.

(choice set) divided into 3 blocks. Each block has 8 sets of choices consisting of Plan A and Plan B. After that, a questionnaire was created, which was further distributed and based on which the insured were questioned.

DISCUSSION

All published articles showed one common intent in the early phase of the introduction of pharmacoeconomic methods–higher transparency and reduction of possible errors. Additionally, Kaltenthaler *et al.* in their research, highlighted the lack of formal guidelines for best practices in this area.[20]

Guzman and colleagues in their study, emphasize the importance of creating a framework, and methodological guidelines for economic evaluation in the health sector. Authors analyzed outcomes from literature, and concluded that it should be expanded in real environment. The article showed that the application of the framework should increase the quality of the economic evaluation, and with minor adaptations, the framework can be useful in other public service sectors as well, beside OHS.[21] Iglesisas *et al.*, in their article discusses the challenges posed by the use of the Delphi method. Primarily, the development of a standardized toolkit for the design and implementation of Delphi research can be problematic because Delphi is not exclusively a single method. Also, it is not clear whether it is a qualitative or quantitative technique. If it is used to collect opinions (e.g., qualitative expression of expert assessment) it can support the qualitative paradigm. If it is used as a means of collecting a certain phenomenon/behavior (used in the context of generating parameter values for model-based economic evaluation), then it can support the quantitative paradigm. In a conclusion, the authors point out that the review of the Delphi study was by the guidelines of Sullivan and Payne,[22] who propose the Delphi method as the most suitable for identifying the qualitative expression of expert opinion.[23]

In contrast to the articles that applied Delphi, the article by Karyani *et al.* applies the DCE to assess preferences for health insurance in Iran. The authors concluded by reviewing the literature that a specific examination of the preferences of a certain nation related to the coverage of health care is more convenient to do with a DCE analysis.[24] As a reference, research in

the Netherlands related to the examination of preferences related to different health insurance plans,[25] and the determination of different preferences of certain groups in Thailand[26,27] are mentioned. The method is suitable for this type of examination, but since the focus of this literature review is the application of the Delphi method and pharmacoeconomic analysis, this article entered into a more detailed review. During the review of the literature, there was a need to check and take into consideration all mixed methods.

The DCE method is based on three theories, Random Utility Theory (RUT), Lancaster's characteristic demand theory, and the standard microeconomic theory of consumers. The design and implementation of DCE include the following steps: concept of the selection process, selection of attributes and level I, experimental design, questionnaire design, pilot testing, sampling and sample size, data collection, data coding, econometric analysis, validity, interpretation, social welfare, and policy analysis. DCE is based on the elicitation technique, asking respondents to choose between two or more alternatives.

Given that the Delphi method enables the generation of expert opinions and is used to create questionnaires necessary for examining knowledge and attitudes about a certain phenomenon, in this case, it is more suitable for the application. The Delphi method seems like a simple process that can be applied very easily. Some of the common causes for failure are:

- Imposing the researcher's views and preconceptions about the problem on the research group, over-specifying the Delphi structure, and not allowing the contribution of other perspectives related to the problem.
- The assumption that Delphi can be a substitute for any other form of human communication in a given situation.
- The lack of a technique for summarizing and presenting the group's responses and enabling a common interpretation of the assessment scale used.
- Ignoring and not exploring disagreements, which is discouraging and dissidents give up and an artificial consensus is reached.
- Underestimating the demanding nature of Delphi and the fact that respondents should be recognized as consulates respecting their time if it is not an integral part of their work.[28]

Therefore, it is necessary to follow each test round very carefully and precisely to minimize possible errors.

On the other hand, N. Foroutan *et al.*, apply a mixed method to examine the views of stakeholders regarding the updating of guidelines for budget-impact analysis. The Delphi method was not used, but an interview, which is one part consisted of 14 closed questions that the respondents evaluated according to the Likert's scale, and in this way the degree of consensus among the respondents for certain proposals was assessed.[29]

In this systematic review it was not considered usage of PE methods in decision making process related to medicines and introducing new therapies. One of the reason is that we would have a very reduced number of articles that will meet the criteria. Focus was on applying of qualitative and quantitative methods suitable for testing, identifying expert opinions, and reaching a consensus for the identified proposals, in this case pharmacoeconomic methods.

Since pharmacoeconomic became mandatory for decision making related to medicines in most countries[30] it will be very useful to have clear status of knowledge and readiness for full introduction of pharmacoeconomic in Bosnia and Herzegovina. Usage of pharmacoeconomic methods in Bosnia are very limited. Reason for that is probable due to lack of clear guidelines and methods created based on level of knowledge. Further research will be focused on development of questionnaire with Delphi method. Developed questionnaire will be used wider for assessment of level of knowledge and readiness for introduction this type of decision-making process.

CONCLUSION

From this systematic review of the literature, it can be concluded that the Delphi method is suitable for testing, identifying expert opinions, and reaching a consensus for the identified proposals. Also, as part of the methodology of research and identification and generation of expert opinion from a certain field, an interview (structured or semi-structured) was very often used.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

B&H: Bosnia and Herzegovina; **WHO:** World Health Organization; **HTA:** Health Technology Assessment; **OHS:** Occupational health and safety; **CEA:** Cost effectiveness analysis; **EEs:** Economic evaluations; **PMPRB:** Patented Medicine Prices Review Board; **BIA:** Budget Impact Analysis; **CADTH:** Canadian Agency For Drugs And Technologies In Health; **pCPA:** Pan-Canadian Oncology Drug Review; **NIHBP:** Non-Insured Health Benefits Program; **DCE:** Discrete Choice Expert; **SPIDER:** Sample, Phenomenon of Interest, Design, Evaluation, Research Type.

SUMMARY

Increasing need for update and for introducing the new technologies in healthcare system leads us to search proper qualitative methods. The main goal was to review publications and to assess how the Delphi method will be suitable for use during the evaluation and preparation of legislation changes. From total 1531 article (from MEDLINE and PubMed), based on eligibility criteria, 5 article were analyzed. Focus was on reviewing the use of the Delphi method for creating the questionnaire in the process of assessing the level of knowledge about pharmacoeconomic methods. Other methods, also applicable, are found but given that the Delphi method enables the generation of expert opinions and is used to create questionnaires necessary for examining knowledge and attitudes about a certain phenomenon, in this case, it is more suitable for the application. This systematic review were very helpful for further research that will be directed to develop of questionnaire by Delphi method. Developed questionnaire will be used for assessment of level of knowledge and readiness for introducing new methods in decision making process in Bosnia and Herzegovina.

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APPENDIX

Appendix 1: Search strategy.

Sample: "Decision making" OR "Policy makers" OR "New medicine" OR "Healthcare"
The phenomenon of Interest: "Pharmacoeconomic" OR "Economic evaluation" OR "cost-benefit" OR "cost-minimization" OR "cost-utility"
Design: "Delphi method" OR "multidisciplinary panel expert" OR "expert consensus" OR "questionnaire"
Evaluation: "experience" OR "opinion"
Research: "qualitative" OR "mixed method"

Combination of the keywords [S AND Pof I] AND [(D OR E) AND R]

Appendix 2: Credibility measures for qualitative studies

Credibility measure	J. Guzman *et al.*	Kalthenthaler *et al.*	C.P. Iglesias *et al.*	N. Foroutan *et al.*	A.K. Karyani *et al.*
1. Qualitative Research Design	D	D	D	A	D
a) *Ethnography*					
b) *Grounded Theory*					
c) *Case study*					
d) *Action research*					
2. Triangulation (select all that apply): documentation of methods used to establish trustworthiness and credibility are specific and clear.	A and B	B	B	A	A and D
a) Data triangulation					
b) Investigator triangulation					
c) Theory triangulation					
d) Methodological triangulation					
3. Member checks: having participants review and confirm the accuracy (or inaccuracy) of interview transcriptions or observational field notes.	A	A	A	A	A
a) taking transcriptions to participants prior to analyses and interpretations of results or taking analyses and interpretations of data to participants (prior to publication) for validation of (or support for) researchers' conclusions.					
4. Disconfirming evidence: also known as negative or discrepant case analysis.	A	A	A	A	A
a) after establishing preliminary themes/categories, the researcher looks for evidence inconsistent with these themes (outliers, for example individual interview results that say the opposite of the majority of responses).					

Credibility measure	J. Guzman *et al.*	Kalthenthaler *et al.*	C.P. Iglesias *et al.*	N. Foroutan *et al.*	A.K. Karyani *et al.*
5. Researcher reflexivity: being forthright about position/perspective.	A	A	A	A	A
a) researchers attempt to understand and self-disclose their assumptions, beliefs, values, and biases.					
6. Thick, detailed description, particularizability.	A	A	A	A	A
a) reporting sufficient quotes and field note descriptions to provide evidence for researchers' interpretations and conclusions, so readers can determine the degree of transferability to their own situations.					
7. *Data Analysis:* were data sorted, coded, and integrated in a systematic and meaningful way?	C	A and C	B and C	C	B and C
a) Coding schema are explained.					
b) Sufficient rationale is provided for what was (or was not) included in the report.					
c) Conclusions are substantiated by sufficient quotations from participants, field notes of observations, and evidence of documentation inspection.					
DATA COLLECTION METHOD					
8. Interview Study *(or interview components of study).*	A	A and B	A and B	A and B	A and B
a) Appropriate participants were selected: (Purposefully identified, effectively recruited, adequate number, representative of the population of interest).					
b) Interview questions are reasonable (clearly worded, not leading, appropriate and sufficient for exploring domains of interest).					
9. Observation Study *(or observation components of study).*					
10. Document Analysis.	N/A	N/A	N/A	N/A	N/A
a) Meaningful documents (e.g., texts, artifacts, objects, pictures) are found and their relevance is established.					