PEER REVIEW HISTORY

ARTICLE DETAILS

Title (Provisional)

Thresholds for the Value Judgement of Health Technologies in the United Arab Emirates: A Consensus Approach Through Voting Sessions

Authors

Aldallal, Sara; Farghaly, Mohamed; Fahmy, Sahar; Alnaqbi, Khalid A.; Al Naeem, Wael; Alsaadi, Mouza; Moukarzel, Marleine; Fasseeh, Ahmad; Korra, Nada; Abaza, Sherif; Kalo, Zoltan

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VERSION 1 - REVIEW

Reviewer **1**

Name **Moonesar, Immanuel**

Affiliation **Mohammed Bin Rashid School of Government, Health Policy, Academic Affairs**

Date **16-Jul-2024**

COI **No competing interests from the reviewer.**

Literature review: More literature review inputs are needed since this is a part of the methodology.

Sampling: Justify the sample size representation of the votes.

Clarity in Methodology: While the methodology is robust, more detail on how the structured voting sessions were conducted (e.g., the criteria for selecting participants and the voting process) would enhance transparency.

Economic Justification: Providing a brief rationale for selecting 0.75 times the GDP per capita as the baseline threshold would strengthen the economic argument.

Stakeholder Engagement: More information on how stakeholders' feedback was integrated into the final framework would add depth to the understanding of the collaborative process.

Reviewer **2**

Name	**Nakhi , Wafa Al**
Affiliation	**University of Sharjah, Family and Community Medicien**
Date	**07-Aug-2024**
COI	**No competing interest**

Overall, the research question or study objective is clearly defined with an abstract that is clearly written and completed. However, my comments are mainly around method section, result section and the discussion section.

Method Section

There are different parts of the method sections scattered in the different parts of the manuscripts. It's advisable to have each section of the methods, results, and decision separated. I would recommend having sub heading in the method section for example: study settings and study design, Theme or framework used for the discussion panel, operational definitions of the economic terminologies used in the manuscripts, participant characteristics, survey/voting or measure, analysis, IRB and consent form.

Having headings and sub-sections in the methods section will make the paper more organized. Please make sure to keep enough concise information under each sub-heading. For instance:

study settings and study design:

• How many sessions were conducted for this study? dates of the sessions, duration of each session, online or in person, online which software, if in person where was the location? Are the sessions recorded or not? How is the information kept later for the analysis? did you take notes manually? Did the participant withdraw from the study before or during or after the study and after they were selected to participate?..etc

• Don't you think considering a systematic review with Mesh terms will add more rigor to your study?

• Why did not you consider Delphi method instead of panel discussion in your study?

Theme or framework used for the discussion panel:

• It was not mentioned clearly how the discussion session was guided. Were there themes or framework to ensure the validity of the discussion and there was no drifting away from the main core of the study questions? Every theme should be defined if themes were included in the study.

operational definitions of the economic terminologies used in the manuscripts:

• Please make sure that the terminologies mentioned in the manuscript are defined clearly in the methods section.

• participant or expert's characteristics: You should state your inclusion and exclusion criteria for selecting experts very clearly. What were your clear standards and criteria for selection? For example, state discipline of experts, educational level, years of experience, private vs public sector..etc and any other criteria you used. What is your definition of an internal expert with vast experience in health economics and health policies? Do you mean 5 years, 10 years 20 years? Or more? Please be specific. The characteristics of participants can be listed separately in a table labeled Table x. Demographic characteristics of experts who .. etc., or can be stated in a clear paragraph. Did you assign experts into groups? you should mention that as if you did.

IRB

• Other than consenting participants, did you get an IRB for the study? Did you collect any personal information related to their characteristics?

Findings or Result Section:

• Can you kindly explain what is the difference between Expert Panel Recommendations and Workshop findings?

• Regarding the finding listed in the tables, are you listing all the findings one by one mentioned by each expert, or did you aggregate the recommendations thematically? This should be clearly stated.

• Voting method should be part of the method section not the results (settings, number of participants, sampling methods, software used for analysis) all these should be part of the method section.

• No tables should be illustrated in the method section, all results and experts' opinions and recommendations should be in the findings section. Each table should be labeled clearly and fully.

You presented your results in frequency distribution and percentages while you explained them in writing with median. There should be consistency when reflecting the results from the table in the text in continuous or categorical variables.

Discussion section:

Overall, your references are up to date, however, make sure you organize your paragraph thematically and each paragraph should have a minimum of 1-3 references. Moreover, please make sure that your discussion is rich by comparing your study findings with studies conducted in the region and internationally.

Conclusion:

• Can you name a specific type of study that should follow your current study? Please reference a similar study.

• Can you state at least one policy implication that your study recommends? You can reference as well similar policy.

VERSION 1 - AUTHOR RESPONSE

Reviewer: 1
Dr. Immanuel Moonesar, Mohammed Bin Rashid School of Government
Comments to the Author:

1. Literature review: More literature review inputs are needed since this is a part of the methodology.

Answer:

Based on your comment, **a section for the literature review** in the **methods section** is now added and describes the review as follows:

"Fasseeh et al.'s identified countries that have established CETs by utilizing a comprehensive list of HTA agencies, as compiled by the World Health Organization (WHO). The list was further complemented with data from EUnetHTA and the International Network of Agencies for Health Technology Assessment, including 113 HTA agencies across 63 countries.

The review focused on the threshold values and their underlying basis. Additionally, CETs were classified based on their type—explicit or implicit—and the review considered variations in how these thresholds were reported, such as whether they were presented as a single-point estimate or as a range. This enabled cross-country and regional comparisons, shedding light on the diversity of CET applications.

Moreover, multiple CETs were reviewed focusing on the threshold values, the country specifics, the year of implementation, and the underlying basis for employing multiple thresholds. This comprehensive approach provided a broad understanding of how CETs are applied globally, including the existence of multiple thresholds in certain countries."

2. Sampling: Justify the sample size representation of the votes.

Answer:

The sample size of the votes **included all individuals across the country with relevant knowledge** of HTA and involved as stakeholders. Due to the country's small size population, the number of participants having such criteria is few. We have made it clearer in the methods section and also added a sentence in the limitations section as follows:

Methods section:

"Participants were selected through convenient sampling. Due to the country's small population and the limited proportion of healthcare professionals, particularly those in the public sector, almost all experts in the field were included through invitations extended by local stakeholders. Invited stakeholders were required to possess good knowledge of HTA, belong to the public

sector, have over 10 years of experience, hold senior positions, and be actively involved in the healthcare sector. Participant characteristics are detailed in Table S1 in the appendix."

Limitation section:

"Finally, our study's sample size was constrained by the limited number of participants who possessed both the knowledge of HTA and active engagement as stakeholders."

3. Clarity in Methodology: While the methodology is robust, more detail on **how the structured voting sessions were conducted** (e.g., the criteria for selecting participants and the voting process) would enhance transparency.

Answer:

We have restructured the manuscript so that the methods section now includes subheadings for the national expert panel and voting sessions, such as "**Participant Characteristics"** and **"Process."** These subheadings detail the criteria for selecting participants and outline the process for each voting session and the expert panel.

4. Economic Justification: Providing a brief rationale for selecting 0.75 times the GDP per capita as the baseline threshold would strengthen the economic argument.

Answer:

The selection of 0.75 times the GDP per capita as the baseline threshold was determined through a voting process involving participants with expertise in the field. While this value was collectively agreed upon by stakeholders, the rationale of choosing such baseline of 0.75 can be related to the UAE's economic status. As a high-income country with a **significant and stable** GDP per capita, setting the baseline at 1 might be considered relatively high. Additionally, given that the experts supported the use of multipliers, starting with a 0.75 baseline would not limit reimbursement for high-value interventions as the multiplier will be higher for those interventions.

Moreover, a base multiplier of 0.75 helps to control the maximum attainable thresholds, capping them at 9 times the GDP per capita (12 times 0.75), aligning with international norms (France 6 times its normal threshold, Italy 3 times its normal threshold, USA 10 times its normal threshold, UK 15 times its normal threshold). While a baseline of 1 times GDP per capita would still be acceptable, it would place the UAE among the highest globally, a position that may not be necessary for maintaining balance in reimbursement strategies.

To make it clearer we have enriched the discussion section with the rationale for selecting the 0.75 as baseline threshold as follows:

"The decision to select a baseline threshold of 0.75 times the GDP per capita by experts, rather than 1 times, likely reflects the UAE's economic status with a significant and relatively stable GDP per capita. This baseline helps regulate the maximum thresholds, capping them at 9 times the GDP per capita, aligned with international norms. While a baseline of 1 times GDP per capita would still be acceptable, it would place the UAE among the highest globally, a position that may not be necessary for maintaining balance in reimbursement strategies."

5. Stakeholder Engagement: More information on how stakeholders' feedback was integrated into the final framework would add depth to the understanding of the collaborative process.

Answer:

Stakeholders' feedback was integrated into the CET framework by taking comprehensive notes during the panel discussion by the research team to capture the key points shared by experts, then such notes were consolidated and presented back to experts to consent upon and provide an initial set of recommendations. More information about stakeholders' feedback is now added in the methods section as follows:

"The panel discussion mainly covered three main topics: the basis of the threshold, the application of multiple thresholds, and the underlying basis for adopting these multiple thresholds. During the panel discussion, comprehensive notes were taken to capture the key points shared by the participants. These notes were then consolidated by the research team, who presented them back to participants for review. This process resulted in an initial set of recommendations, which was shared with the participants to confirm consensus on the discussed elements.

Recommendations provided by the expert panel resulted in the creation of a draft CET framework. The draft CET framework was further refined through multiple discussions conducted through a workshop between the research team and local experts in the field. These discussions aimed to further refine and elaborate on the initial recommendations, transforming the draft into a more detailed preliminary framework that would be suitable for the development of CET in the UAE."

Reviewer: 2
Dr. Wafa Al Nakhi, University of Sharjah
Comments to the Author:
Overall, the research question or study objective is clearly defined with an abstract that is clearly written and completed. However, my comments are mainly around method section, result section and the discussion section.

Method Section
There are different parts of the method sections scattered in the different parts of the manuscripts. It's advisable to have each section of the methods, results, and discussion separated. I would recommend having subheadings in the method section for example: study settings and study design, Theme or framework used for the discussion panel, operational definitions of the economic terminologies used in the manuscripts, participant characteristics, survey/voting or measure, analysis, IRB and consent form. Having headings and sub-sections in the methods section will make the paper more organized. Please make sure to keep enough concise information under each sub-heading.

For instance:
Study settings and study design:
1. How many sessions were conducted for this study? dates of the sessions, **duration of each session**, **online or in person**, online which software, **if in person where was the location?** Are the sessions recorded or not? How is the information kept later for the analysis? did you take notes manually? Did the participant withdraw from the study before or during or after the study and after they were selected to participate. etc.

Answer:

We have added a **sub-heading** for study settings and study design, participant characteristics, and process in both the national expert panel and voting sessions inside the methods section. We also added a subheading for "consent form" in the voting sessions section and "panel discussion" section in the national expert panel.

2. Don't you think considering a systematic review with Mesh terms will add more rigor to your study?

Answer:

Thank you for your valuable suggestion. In response to your question, we would like to highlight that **the focus of our study was not the literature review** but on setting the CET for the UAE. Furthermore, in the literature review by Fasseeh et al, a **hierarchical approach** was followed focusing first on data from HTA agencies, which are the primary sources for reporting cost-effectiveness thresholds. This was complemented by information from ministries of health, ISPOR websites, and Google Scholar. Given that the establishment of cost-effectiveness thresholds is typically a national process, we believe that any relevant data would likely be found within these authoritative sources.

Additionally, the literature review by Fasseeh et al identified **multiple thresholds**, providing a comprehensive overview of cost-effectiveness thresholds. Findings of the literature review were presented to experts as the first step in setting the CET in the UAE. We believe that this method yields accurate and relevant outcomes for the topic at hand and does not necessarily require a systematic literature review with MeSH terms.

3. Why **did not you consider Delphi method** instead of panel discussion in your study?

Answer:

Thank you for your valuable suggestion. In response to your question, the panel discussion method was preferred over the Delphi method in the current study due to a number of reasons:

First, panel discussions allow experts to engage in **face-to-face interactions**, fostering a dynamic exchange of ideas. This real-time dialogue is crucial for addressing complex issues where immediate clarification and deeper discussion are needed, which can be more challenging to achieve with the iterative nature of the Delphi method. Second, experts can **directly challenge each other's views** and **collaboratively refine their positions** in a panel discussion allowing for immediate feedback and debate that helps in building a more robust and shared consensus. The Delphi method, while effective in avoiding groupthink through anonymity, lacks the immediacy of such interactive debates, which can be essential when dealing with such topics. the panel discussion format is more time-efficient, facilitating quicker consensus-building compared to the multiple rounds typically required in the Delphi method. Given that the stakeholders involved were of very high caliber and difficult to coordinate for multiple sessions, **a panel discussion was the more practical option**. Thus, the discussion was organized as a satellite event during the EHES conference to optimize their availability and participation.

Theme or framework used for the discussion panel:

4. It was not mentioned clearly how the discussion session was guided. Were there themes or framework to ensure the validity of the discussion and there was no drifting away from the main core of the study questions? Every theme should be defined if themes were included in the

study.
operational definitions of the economic terminologies used in the manuscripts:

Answer:

The discussion session was led by an international professor who presented the findings from the literature review. Following this presentation, the experts engaged in discussions, focusing on three key themes: the basis of the threshold, the application of multiple thresholds, and the rationale for using multiple thresholds. The research team took comprehensive notes throughout the session, which were then consolidated and shared with the experts for their review. This process allowed the group to agree on a set of initial recommendations for the CET draft framework. The methods section now reflects this process clearly as follows:

"The panel discussion mainly covered three main topics: the basis of the threshold, the application of multiple thresholds, and the underlying basis for adopting these multiple thresholds. During the panel discussion, comprehensive notes were taken to capture the key points shared by the participants. These notes were then consolidated by the research team, who presented them back to participants for review. This process resulted in an initial set of recommendations, which was shared with the participants to confirm consensus on the discussed elements.

Recommendations provided by the expert panel resulted in the creation of a draft CET framework. The draft CET framework was further refined through multiple discussions conducted through a workshop between the research team and local experts in the field. These discussions aimed to further refine and elaborate on the initial recommendations, transforming the draft into a more detailed preliminary framework that would be suitable for the development of CET in the UAE."

5.Please make sure that the terminologies mentioned in the manuscript are defined clearly in the methods section.

Answer:

Upon arranging the manuscript, terminologies such as absolute and proportional shortfalls, continuous and categorical approaches are now clearly described in the methods section.

6. participant or expert's characteristics: You should state your inclusion and exclusion criteria for selecting experts very clearly. What were your clear standards and criteria for selection? For example, state discipline of experts, educational level, years of experience, private vs public sector. etc and any other criteria you used. What is your definition of an internal expert with vast experience in health economics and health policies? Do you mean 5 years, 10 years 20 years? Or more? Please be specific.

The characteristics of participants can be listed separately on a table labeled Table x. Demographic characteristics of experts who .. etc., or can be stated in a clear paragraph. Did you assign experts into groups? you should mention that as if you did.
IRB

Answer:

To clarify the participants' characteristics, we have added in the appendix a table with each participant title and affiliation. We have also adjusted the methods section under the sub-

section for participants characteristics for the national expert panel and the voting sessions as follows:

National expert panel

Participants Characteristics:

“Experts were chosen through convenience sampling, adhering to specific inclusion criteria: possessing a solid understanding of HTA, representing various public entities, representing the private sector, having more than 10 years of experience, holding senior positions, and being key influencers within the healthcare system of the Emirates.”

Voting Sessions

Participants Characteristics:

“Participants were selected through convenient sampling. Due to the country’s small population and the limited proportion of healthcare professionals, particularly those in the public sector, almost all experts in the field were included through invitations extended by local stakeholders. Invited stakeholders were required to possess good knowledge of HTA, belong to the public sector, have over 10 years of experience, hold senior positions, and be actively involved in the healthcare sector. Participant characteristics are detailed in Table S1 in the appendix.”

7.Other than consenting participants, did you get an IRB for the study? Did you collect any personal information related to their characteristics?

Answer:

Thank you for your insightful questions regarding the ethical aspects of our study. Our study was primarily focused on the development of a CET framework based on consensus from expert panels and stakeholders within the UAE. The study **did not involve direct patient interaction** or the **collection of personal health data from individuals.** As such, it did not require IRB approval according to local regulations. However, informed consent was obtained from all participants involved in the voting sessions and workshops as they contributed their professional expertise to the consensus-building process. **Furthermore, no personal data** related to participant characteristics, such as demographic information, was collected during the study. The study was designed to ensure that all data was anonymized and aggregated, focusing solely on the consensus outcomes regarding the CET framework rather than on individual participant characteristics.

Findings or Result Section:

8.Can you kindly explain what is the difference between Expert Panel Recommendations and Workshop findings?

Answer:

The national expert panel initially provided broad recommendations for a draft framework of the Cost-Effectiveness Threshold (CET). These recommendations included key elements such as using CET to determine the willingness to pay, linking it to the GDP per capita, and varying the CET based on criteria like severity, rarity, and health gain. They also proposed that rarity should be defined according to FDA or EMA standards and indicated no difference in CET between the public and private sectors. However, these were preliminary recommendations requiring further refinement.

To further refine the framework, additional discussions were necessary to establish more detailed framework. Consequently, a workshop was conducted where representatives elaborated on the framework by assigning specific multipliers for each criterion, setting a cap on the collective multiplier to avoid exceeding internationally observed values, choosing the IRQG method to measure relative health gain, and establishing approaches and measures for disease severity.

In summary, while the national expert panel provided the initial recommendations, the workshop played a crucial role in refining and completing the framework, making it ready for final voting.

To be clearer we will, have adjusted a paragraph in the methods section as follows:

“Recommendations provided by the expert panel resulted in the creation of a draft CET framework. The draft CET framework was further refined through multiple discussions conducted through a workshop between the research team and local experts in the field. These discussions aimed to further refine and elaborate on the initial recommendations, transforming the draft into a more detailed preliminary framework that would be suitable for the development of CET in the UAE.”

9.Regarding the findings listed in the tables, are you listing all the findings one by one mentioned by each expert, or did you aggregate the recommendations thematically? This should be clearly stated.

Answer:

The findings presented in Tables 1 and 2 reflect the recommendations and findings reached through collective discussions among the experts, rather than individual statements from each expert. Table 3, on the other hand, details the voting results, including the number of respondents selecting each option. To be clear we have stated this by an asterisk for tables 1 and 2 as follows:

*Such recommendations reflect the collective consensus of the experts rather than individual opinions.

10.Voting method should be part of the method section not the results (settings, number of participants, sampling methods, software used for analysis) all these should be part of the method section.

Answer:

We have now re-arranged the voting method to be part of the methods section under the name of ‘voting sessions’. We have ensured that all required data are available (settings, number of participants, sampling methods) and added the software used in the analysis as follows:

“Table 3 presents the final survey questions and voting options with the number of participants voting for each option and their proportion. Proportion of participants were calculated using descriptive statistics in Microsoft Excel.”

11. No tables should be illustrated in the method section; all results and experts’ opinions and recommendations should be in the findings section. Each table should be labelled clearly and fully.
You presented your results in frequency distribution and percentages while you explained them in writing with the median. There should be consistency when reflecting the results from the table in the text in continuous or categorical variables.

Answer:

Thank you for your comment. All tables have been moved from the methods section to the results section, as requested.

Regarding the values in the tables, Table 3 presents the number of participants selecting each option for each question, along with their corresponding proportion. In the text, we reported the median value only for the baseline threshold, while all other elements are provided as frequencies. The rationale for presenting the baseline threshold as a median value was explained in the methods section: 'As the base GDP per capita choices were provided on an ordinal scale with equidistant intervals, the median value was utilized to provide a fair representation of the results.'

All other elements have been reported by proportions, consistent with the explanation provided in the methods section: 'The response that received the highest number of votes was designated as the consented response, except for the baseline GDP per capita multiplier, where median values were used.'

To enhance clarity, we have added an asterisk to the question related to the baseline threshold (first question) in Table 3 to indicate that the median value is used.

Discussion section:

12. Overall, your references are up to date, however, make sure you organize your paragraph thematically and each paragraph should have a minimum of 1-3 references. Moreover, please make sure that your discussion is rich by comparing your study findings with studies conducted in the region and internationally.

Answer:

Thank you for your valuable feedback. In response, we have ensured that each paragraph includes a minimum of 1-3 references where applicable (paragraphs where study results are being interpreted did not contain any reference) Additionally, we have enriched the discussion section by comparing our study findings with both international studies (in addition to the regional comparisons in the paper) to provide a more comprehensive analysis as follows:

“Several countries outside the Middle East have also conducted studies to establish national CETs. For instance, Kovács et al. sought to establish a new CET for Hungary by reviewing CETs from 26 European countries [16]. While Kovács et al. utilized the IRQG to account for disease severity, our study primarily relied on the proportional shortfall approach, similar to the method used in the Netherlands [9].”

Conclusion:

13. Can you name a specific type of study that should follow your current study? Please reference a similar study.

Answer:

Thank you for your suggestion to identify a subsequent study that could build on our current research. Based on your suggestion we have added the following paragraph in the discussion section:

“The next logical step would be Conducting CEA of health technologies within the UAE healthcare system. Such a study could leverage the CETs established in our research to evaluate the value of emerging health technologies in a real-world setting. For instance, Drummond et al. performed detailed CEAs using established thresholds to inform healthcare decision-making. A similar approach could be employed in the UAE to validate and refine the CETs proposed in our study, ensuring their applicability and robustness in guiding healthcare resource allocation decisions.”

14. Can you state at least one policy implication that your study recommends? You can reference as well similar policy.

Answer:

Thank you for your valuable suggestion to highlight the policy implications of our study. We have enriched a paragraph in the discussion section to illustrate the policy implications as follows:

“The adoption of the CET framework in the UAE is anticipated to bring about significant improvements in resource allocation, decision-making, transparency, accountability, equitable access to healthcare, and informed policy development. These outcomes would not only promote cost-effective healthcare but also enhance the consistency of reimbursement decisions. This approach has been proven successful in the UK, where the National Institute for Health and Care Excellence (NICE) employs CET to guide decisions on which treatments and technologies should be provided within the National Health Service (NHS) [14].”

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Reviewer: 1
Competing interests of the Reviewer: No competing interests from the reviewer.

Reviewer: 2
Competing interests of Reviewer: No competing interest

VERSION 2 - REVIEW

Reviewer	**2**
Name	**Nakhi , Wafa Al**
Affiliation	**University of Sharjah, Family and Community Medicien**
Date	**15-Sep-2024**
COI	

Thank you for taking the time to address all the reviewers feedback.

VERSION 2 - AUTHOR RESPONSE

Reviewer: 2

Dr. Wafa Al Nakhi , University of Sharjah

Comments to the Author:

Thank you for taking the time to address all the reviewers feedback.

Reviewer: 2

If you have selected ‘Yes’ above, please provide details of any competing interests

Answer:

Competing interests are present in the manuscript and in the submission data.