PEER REVIEW HISTORY

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ARTICLE DETAILS

<table>
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<th>TITLE (PROVISIONAL)</th>
<th>Development and validation of a rurality index for health care research in Japan: A modified Delphi study</th>
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<td>AUTHORS</td>
<td>Kaneko, Makoto; Ikeda, Takaaki; Inoue, Machiko; Sugiyama, Kemmyo; Saito, Manabu; Ohta, Ryuichi; Cooray, Upul; Vingilis, Evelyn; Freeman, Thomas; Mathews, Maria</td>
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GENERAL COMMENTS

REVIEWER Yamashita, Daisuke
Oregon Health & Science University, Department of Family Medicine

REVIEW RETURNED 21-Dec-2022

I appreciate the author's effort in creating the rurality index for Japan. It is crucial to have an index that can be used for future health policy research.

These are my comments.

1. I recommend indicating the four authors participating in the steering team. I am assuming they are MDs who work in Japan. This will provide clarity in the Round 1 section.

2. I recommend providing more detail on the index equation. Most readers are not familiar with the statistical methods, including myself. The equation for pre-conversion RIJ is not intuitive to understand.

   Pre ― conversion RIJ = population density * 0.46 + direct distance to the nearest secondary or tertiary hospital * (—0.3) + remote island * 0.47 + special heavy snowfall areas * 0.3

   I had difficulty understanding why the direct distance to the nearest secondary or tertiary hospital is weighted negatively. The value of the distance should weigh positively. If binary factor or remote island and special heavy snowfall areas are positively weighted. Also, should population density be weighted negatively if that is the case? (higher population density should mean less rural). Please consider providing examples to reduce confusion.

   3. Additional explanation, such as the process and the renewal frequency of the special heavy snowfall area designation will be helpful. Rapidly worsening global warming may impact the validity of the designation if not renewed frequently.

REVIEWER Shankar, Prem
Government Medical College and Super Facility Hospital, Community Medicine

REVIEW RETURNED 10-Feb-2023

Valuable work nicely drafted.

It is advisable to use term 'Gender' rather than 'Sex' when you are considering more than male and female.
**REVIEWER**
Botes, Meghan  
University of the Witwatersrand  
Johannesburg, Nursing Education

**REVIEW RETURNED**
14-Mar-2023

**GENERAL COMMENTS**
Thank you for submitting this very important work in the field of rural health. Your background is well written and clearly defined however lacking in emphasising the significance of having an RI. The main concern is the lack of detail in your methodology - in particular your sampling methods, sample size and rationale/inclusion criteria is not clear for each round of the delphi - the inclusion criteria must be clearly defined as the validity of a delphi study rests on the idea that the chosen sample has expert knowledge in this particular field. The process of analysis of the survey data is also not clear - how the results were analysed and how decisions were made to include/discard or revise items has not been described, and these should have criteria to avoid bias and subjectivity in the process. A discussion is not a valid method of analysis or decision making for a scientific study. The format of the manuscript is also difficult to follow as there are some results presented in the study design/methods and these two sections seem to overlap. The most important figures should be selected and included with a description and interpretation instead of as an annexure to give meaning to the results section. Perhaps consider adding more to your discussion about the significance of the findings and not just its’ comparison to other similar studies - there is an element of interpretation that is missing from your discussion. If the detail on the methodology and clarity on the method of analysis is provided, with some reformatting the manuscript would add great value. There are detailed comments in the attached file for your assistance.

**VERSION 1 – AUTHOR RESPONSE**

Reviewer 1

Thank you very much for your feedback and helpful suggestions. Below and in the manuscript we address all the queries you raised.

Reviewer’s comment #1
I recommend indicating the four authors participating in the steering team. I am assuming they are MDs who work in Japan. This will provide clarity in the Round 1 section.

Response #1
Thank you for reviewing our manuscript and we appreciate your warm comments. The initial Expert Panel consisted of five general practitioners who had practiced in rural areas of Japan. Four were members of the committee of rural and remote medicine in the Japan Primary Care Association. The other was a professor of family medicine and a director of a rural family medicine residency program. To make the Expert Panel more representative, the five physicians, based on their knowledge and existing relationships, recruited the following other members who had engaged in rural practice and had expertise in rural healthcare: a nurse who had worked on a remote island, a public health nurse who practised on a remote island and had educational experience in rural healthcare, and a nurse practitioner who had worked in a rural area. To include patient perspectives, the panel invited a patient who was a leader of a patient group for developing a sustainable healthcare system for rural...
areas. The panel members were recruited from across Japan. Because the description of the steering panel and the panel of key informants are confusing, we unified the expression to “Expert Panel”. We revised the sentences as follows.

(pages 11-12, lines 198-210)
The initial Expert Panel consisted of five general practitioners who had practiced in rural areas of Japan. Four were members of the committee of rural and remote medicine in the Japan Primary Care Association. The other was a professor of family medicine and a director of a rural family medicine residency program. To make the Expert Panel more representative, the five physicians, based on their knowledge and existing relationships, recruited the following other members who had engaged in rural practice and had expertise in rural healthcare: a nurse who had worked on a remote island, a public health nurse who practised on a remote island and had educational experience in rural healthcare, and a nurse practitioner who had worked in a rural area. To include patient perspectives, the panel invited a patient who was a leader of a patient group for developing a sustainable healthcare system for rural areas. The panel members were recruited from across Japan.

Reviewer’s comment #2
I recommend providing more detail on the index equation. Most readers are not familiar with the statistical methods, including myself. The equation for pre-conversion RIJ is not intuitive to understand.
Pre — conversion RIJ = population density * 0.46 + direct distance to the nearest secondary or tertiary hospital * (— 0.3) + remote island * 0.47 + special heavy snowfall areas * 0.3
I had difficulty understanding why the direct distance to the nearest secondary or tertiary hospital is weighted negatively. The value of the distance should weigh positively if binary factor or remote island and special heavy snowfall areas are positively weighted. Also, should population density be weighted negatively if that is the case? (higher population density should mean less rural). Please consider providing examples to reduce confusion.

Response #2
Thank you for pointing it out and sorry for confusing you. The sentence is incorrect. Correct factor loadings are population density: -0.3; direct distance to the nearest secondary or tertiary hospital: 0.46; remote islands: 0.47, and special heavy snowfall areas: 0.3. Our calculation of the RIJ was conducted based on the correct equation. We revised the sentences and the equation.

(page 30, lines 436-440)
Exploratory factor analysis through the Promax rotation revealed the factor loading of each factor as follows: population density: -0.3; direct distance to the nearest secondary or tertiary hospital: 0.46; remote islands: 0.47, and special heavy snowfall areas: 0.3.

Reviewer’s comment #3
Additional explanation, such as the process and the renewal frequency of the special heavy snowfall area designation will be helpful. Rapidly worsening global warming may impact the validity of the designation if not renewed frequently.

Response #3
Thank you for raising this point. The “Act on Special Measures concerning Countermeasures for Heavy Snowfall Areas” started in 1962. The act has been reviewed 10 times and the last review was in 2007. Also, the update was mainly made not for global warming but for the change in administrative districts. According to your suggestion, we added the sentences as follows.
(pages 6-7, lines 108-109) This Act was legislated in 1962, and has been reviewed 10 times, with the last update in 2007.

(page 35, lines 533-534) For example, the special snowfall areas also may change due to global warming.

Reviewer 2
Thank you very much for your feedback. We hope that we addressed the problems you raised.

Reviewer’s comment #1
It is advisable to use term ‘Gender’ rather than ‘Sex’ when you are considering more than male and female.

Response #1
Thank you for reviewing our manuscript and we thank your constructive feedback. According to your suggestion, we changed the term from "sex" to “gender” in Table 1.

Reviewer 3
Thank you very much for your feedback. We hope that we addressed the problems you raised. The reviewer provided general comments in the email and detailed comments in the file of the manuscript. We responded to the comments one by one.

Reviewer’s comment #1
Setting is too broad - it does not give any indication of the setting from which you drew your sample.

Response #1
Thank you for reviewing our manuscript and for your constructive feedback. We developed an Expert Panel. The panel included five rural general practitioners. Four of them were members of the committee of rural and remote medicine in the Japan Primary Care Association. The other was a professor of family medicine and a director of a rural family medicine residency program. The five physicians recruited other members who had engaged in rural practice and had expertise in rural healthcare based on the physicians’ knowledge and existing relationships: a nurse who had worked on a remote island, a public health nurse who practised on a remote island and had education experience in rural healthcare, a nurse practitioner who had worked in a rural area. To adopt the perspectives of patients, the panel included a patient who was a leader of a patient group for developing a sustainable healthcare system for rural areas. The panel members were recruited from across Japan. Also, we gathered survey participants from across Japan. According to your suggestion, we changed the sentence as follows.

(page 3, lines 42-44) The study developed an Expert Panel including healthcare professionals and a patient who had expertise in rural healthcare.

(page 3, line 45) The study recruited survey participants from across Japan.
Reviewer’s comment #2
Your background needs to include the significance on a rurality index - why is it important to have one?

Response #2
Thank you for indicating this important point. Japan’s “rural area” in healthcare policy has been mainly decided based on population and the distance to the nearest medical institution the area is called “non-doctor districts”. However, the indicator is dichotomous: “non-doctor districts” or not and does not describe gradation between rural and urban. Also, because of depopulation in these rural areas, maintaining rural medical facilities has become difficult. Therefore, updating the definition of “rural area” in Japanese healthcare is warranted. Such a rurality index can be indispensable for a country as it can provide healthcare policymakers as well as researchers with a single, consistent operational definition and gradient of rurality by which to assess rural-urban healthcare disparities and to identify rural regions in need of appropriate healthcare services. According to your suggestion, we added the sentence as follows.

(page 8, lines 128-138)
Japan’s “rural area” in healthcare policy has been mainly decided based on population and the distance to the nearest medical institution the area is called “non-doctor districts”. However, the indicator is dichotomous: “non-doctor districts” or not and does not describe gradation between rural and urban. Also, because of depopulation in these rural areas, maintaining rural medical facilities has become difficult. Therefore, updating the definition of “rural area” in Japanese healthcare is warranted. Such a rurality index can be indispensable for a country as it can provide healthcare policymakers as well as researchers with a single, consistent operational definition and gradient of rurality by which to assess rural-urban healthcare disparities and to identify rural regions in need of appropriate healthcare services.

Reference

Reviewer’s comment #3
Name the validation tests conducted

Response #3
Thank you for raising this point. We conducted content, factorial, convergent and criterion-related validity. According to your suggestion, we changed the sentence as follows.

(page 11, lines 190-192)
We subsequently conducted content, factorial, convergent and criterion-related validity assessments on the results as part of Phase 3.

Reviewer’s comment #4
How was this information collected and how was it analysed or used? Was it included as a phase in the study?

Response #4
Thank you for pointing it out. As we described above, the Expert Panel included the leader of the patient group for developing a sustainable healthcare system for rural areas. Also, we invited the
members of the patient group to the Delphi survey. Through the panel and the survey, we included patients’ perspectives. According to your suggestion, we modified the sentences as follows.

(page 12, lines 208-210)
To include patient perspectives, the panel invited a patient who was a leader of a patient group for developing a sustainable healthcare system for rural areas.

Reviewer's comment #5
This process is not clear - who was on the steering team - who initiated the steering team - what was the criteria?

Response #5
Thank you for indicating this important point. The first author initiated the steering team and the criterion for membership for the steering team was healthcare providers who have expertise in rural healthcare. The members were five general practitioners. Four of them were members of the committee of rural and remote medicine in the Japan Primary Care Association. The other was a professor of family medicine and a director of a rural family medicine residency program. To make the Expert Panel more representative, the five physicians, based on their knowledge and existing relationships, recruited the following other members who had engaged in rural practice and had expertise in rural healthcare: a nurse who had worked on a remote island, a public health nurse who practised on a remote island and had educational experience in rural healthcare, and a nurse practitioner who had worked in a rural area. To include patient perspectives, the panel invited a patient who was a leader of a patient group for developing a sustainable healthcare system for rural areas. The panel members were recruited from across Japan. We added the information as follows.

Also, because the description of the steering panel and the panel of key informants are confusing, we unified the expression to "Expert Panel".

(pages 11-12, lines 198-210)
The initial Expert Panel consisted of five general practitioners who had practiced in rural areas of Japan. Four were members of the committee of rural and remote medicine in the Japan Primary Care Association. The other was a professor of family medicine and a director of a rural family medicine residency program. To make the Expert Panel more representative, the five physicians, based on their knowledge and existing relationships, recruited the following other members who had engaged in rural practice and had expertise in rural healthcare: a nurse who had worked on a remote island, a public health nurse who practised on a remote island and had educational experience in rural healthcare, and a nurse practitioner who had worked in a rural area. To include patient perspectives, the panel invited a patient who was a leader of a patient group for developing a sustainable healthcare system for rural areas. The panel members were recruited from across Japan.

Reviewer’s comment #6
Please distinguish between the steering team and the panel - what was the criteria for recruitment of the panel? Why only four members? Justify their input as experts What was your sampling method?

Response #6
Thank you for raising this important point. As we stated above, because the description of the steering panel and the panel of key informants are confusing, we unified the expression to “Expert Panel”. We have described this group, and their activities in the study. The second group consisted of the survey participants who were chosen as experts in rural health care. We revised the sentences as follows.

(pages 11-12, lines 198-210)
The initial Expert Panel consisted of five general practitioners who had practiced in rural areas of Japan. Four were members of the committee of rural and remote medicine in the Japan Primary Care Association. The other was a professor of family medicine and a director of a rural family medicine residency program. To make the Expert Panel more representative, the five physicians, based on their knowledge and existing relationships, recruited the following other members who had engaged in rural practice and had expertise in rural healthcare: a nurse who had worked on a remote island, a public health nurse who practised on a remote island and had educational experience in rural healthcare, and a nurse practitioner who had worked in a rural area. To include patient perspectives, the panel invited a patient who was a leader of a patient group for developing a sustainable healthcare system for rural areas. The panel members were recruited from across Japan.

Reviewer’s comment #7
Was this process purely subjective or based on the scoping review - how was the process carried out? How was this data collected and analysed? Was it a focus group discussion or just a casual discussion? Your methodology is not clear.

Response #7
Thank you for indicating this important point. We combined the results of the scoping review and discussion of the expert panel. We conducted two online meetings. The meetings were held with the Expert Panel on 20th April online. At the first meeting, the initial discussion of the Expert Panel was on the determination of a unit of analysis for the rurality index in Japan. The consensus was to employ the zip code as a minimum unit for the index because the zip code is suitable for describing location information and other administrative districts, such as cities or towns that can include both rural and urban areas in one district. The Expert Panel convened through a video conferencing meeting that was recorded. The meeting was held on 8th July 2021. At the meeting, the first author began with a summary of the scoping review findings. According to our previous scoping review, the frequently used variables in the existing rurality indices are population (size or density), travel distance/time to emergency care and/or referral center, as well as resource availability, such as the number of physicians (primary care physicians and specialists). Subsequently, the Expert Panel reviewed all the factors one by one and discussed other potential factors based on their expertise considering the Japanese healthcare context. According to your suggestion, we added the sentences as follows.

(page 13, lines 217-222)
The first meeting was held with the Expert Panel on 20th April 2021 online. At this meeting, the initial discussion of the Expert Panel was on the determination of a unit of analysis for the rurality index in Japan. The consensus was to employ the zip code as a minimum unit for the index because the zip code is suitable for describing location information and other administrative districts, such as cities or towns that can include both rural and urban areas in one district.

(pages 13-14, lines 227-235)
For Round 2, the Expert Panel convened through a video conferencing meeting that was recorded. The second meeting was held on 8th July 2021. At the meeting, the first author began with a summary of the scoping review findings. According to our previous scoping review, the frequently used variables in the existing rurality indices are population (size or density), travel distance/time to emergency care and/or referral center, as well as resource availability, such as the number of physicians (primary care physicians and specialists). Subsequently, the Expert Panel reviewed all the factors one by one and discussed other potential factors based on their expertise considering the Japanese healthcare context.

Reviewer’s comment #8
Why governement officers? What is their expert knowledge?

Response #8
Thank you for pointing it out. The Expert Panel included local government officers who had been engaged in healthcare policy in rural areas as a stakeholder because perspectives from an administrator in rural areas were important to utilize the index for healthcare policy. According to your suggestion, we added the sentence as follows.

(page 15, lines 254-257)
The Expert Panel also included local government officers who had been engaged in healthcare policy in rural areas as a stakeholder because perspectives from an administrator in rural areas were important to utilize the index for healthcare policy.

Reviewer’s comment #9
What is MK?
Why 100? what was your sampling method or technique for designing your sample - snowball sampling accepted however how did you decide on the number?

Response #9
Thank you for raising this important point. MK is the initial of the first author. We used snowball sampling. The previous literature about the methodology of Delphi described that there is no agreement on the number of survey respondents and many published Delphi employed 10 to 100 or more participants. Therefore, we recruited 100 participants. According to your suggestion, we added the sentences as follows.

(page 14, lines 245-248)
The Expert Panel identified stakeholders who had expertise in rural healthcare. Previous literature on the methodology for the Delphi method provided no agreement on sample size for the survey and many published Delphi studies employed 10 to 100 or more participants. Therefore, in this study, the Expert Panel recruited 100 stakeholders as potential participants.

Reference

We also added the explanation about “MK”.

(pages 15, lines 261-262)
The initial draft of the survey was developed by one of the Expert Panel members (MK)

(page 15, lines 257-258)
Nine Expert Panel members recruited 10 participants each, and one member (MK) recruited 20 participants.

Reviewer’s comment #10
What about the rest of the items - did they not reach 80%?

Response #10
Thank you for pointing it out. As you mentioned, the other items did not reach 80%. To clarify this point, we revised the sentences as follows. Also, to avoid overlapping the methods and the results
section, we moved the sentences from the methods section to the results section. Moreover, we changed Table S1 from a supplementary table to Table 2 because of the importance of the information.

Specifically, at the start of the first survey, 16 factors were listed. Four factors reached 80% agreement and the others did not reach 80% agreement. As shown in Table 2, three of the four factors were related to a remote island issue and were combined into one factor, “remote island”, based on the Expert Panel’s discussion.

Reviewer’s comment #11
Based on discussion - but what were their scores? Why did these items need discussion?

Response #11
Thank you for raising this important point. The other factors did not reach 80% agreement shown in Table S1. Therefore, after the first round, only two factors remained: population density and remote islands. Thus, the expert panel decided further discussion was necessary to modify the other factors’ expression. According to your suggestion, we revised the sentences as follows.

At the end of the first survey round, only two factors remained: population density and remote islands. Thus, the expert panel decided further discussion was necessary to modify the other factors’ expression.

Reviewer’s comment #12
what was the sample therefore in the second round?

Response #12
Thank you for indicating this point. The items of the second round are described in Table 2. According to your suggestion, we added the sentence as follows.

The changes in the items are shown in Table 2.

Reviewer’s comment #13
So the survey changed completely in the third round to two options? What was the response rate and the results?

Response #13
Thank you for raising this important point. In the third survey, the response rate was 84.8% and 71.4% of the participants selected the four-factor model involving distance, island, weather, and population density. According to your suggestion, to clarify the process and the results, we moved the sentences from the Methods section to the Results section and revised the sentences as follows.

After the second survey, three factors reached 80% agreement: direct distance to the nearest secondary or tertiary hospital from the center of each zip code area, remote islands, and whether weather influences access to the nearest secondary or tertiary hospital. The Expert Panel combined “distance to the nearest hospital which provides care for patients with acute stroke” and “Distance to
the nearest hospital which provides care for patients with an acute heart attack” into “Distance to the nearest secondary or tertiary hospital” because it is difficult to know whether each secondary hospital offers care for acute stroke or heart attack from public data. Although population density is the most frequently utilized factor for rurality indices in previous studies, it was not included at that stage. Therefore, the Expert Panel discussed the issue and conducted the third survey. The third survey proposed two models: a three-factor (distance, island, and weather) model and a four-factor model (three-factor model plus population density). In the third survey, we requested the participants to choose either one.

(pages 28-29, lines 409-415)
In the third survey, the response rate was 84.8% and 71.4% of the participants selected the four-factor model involving distance, island, weather, and population density. Therefore, we included the following four factors into the RIJ: population density in each zip code, direct distance to the nearest secondary or tertiary hospital from the center of each zip code area (Euclidean distance), remote islands, and whether weather, such as typhoons or heavy snowfall, influences access to the nearest secondary or tertiary hospital.

Reviewer’s comment #14
It is not clear what the methodological process was for going from a 16 item survey to a two item survey - how were items discarded or combined and on what basis or criteria?

Response #14
Thank you for indicating this important point. The factors that reached 80% agreement were selected. Regarding population density, because this was the most frequently used factor for rurality indices in previous studies based on the scoping review, the expert panel proposed the third survey including two models: a three-factor model that reached 80% agreement and a four-factor model adding to population density. According to your suggestion, to clarify the process and the results, we moved the sentences from the Methods section to the Results section and revised the sentences as follows.

(page 22, lines 377-392)
After the second survey, three factors reached 80% agreement: direct distance to the nearest secondary or tertiary hospital from the center of each zip code area, remote islands, and whether weather influences access to the nearest secondary or tertiary hospital. The Expert Panel combined “distance to the nearest hospital which provides care for patients with acute stroke” and “Distance to the nearest hospital which provides care for patients with an acute heart attack” into “Distance to the nearest secondary or tertiary hospital” because it is difficult to know whether each secondary hospital offers care for acute stroke or heart attack from public data. Although population density is the most frequently utilized factor for rurality indices in previous studies, it was not included at that stage. Therefore, the Expert Panel discussed the issue and conducted the third survey. The third survey proposed two models: a three-factor (distance, island, and weather) model and a four-factor model (three-factor model plus population density). In the third survey, we requested the participants to choose either one.

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In the third survey, the response rate was 84.8% and 71.4% of the participants selected the four-factor model involving distance, island, weather, and population density. Therefore, we included the following four factors into the RIJ: population density in each zip code, direct distance to the nearest secondary or tertiary hospital from the center of each zip code area (Euclidean distance), remote islands, and whether weather, such as typhoons or heavy snowfall, influences access to the nearest secondary or tertiary hospital.
Reviewer's comment #15
In the introduction, the definition and distinction was made clear so this seems like a contradiction.

Response #15
Thank you for pointing it out and sorry for confusing you. Although the administrative distinction between primary, secondary, and tertiary care is defined as described in the Methods section, there is no patient registration system for primary care facilities and a patient can access a secondary care hospital without a referral from a primary care physician. Therefore, from a patient’s perspective, the boundary between primary and secondary/tertiary care is ambiguous and some patients utilize not a clinic but a hospital as their usual source of care. This is one of the characteristics of the Japanese healthcare system. According to your suggestion, we added the sentences in the Introduction section as follows.

(page 7, lines 119-124)
Although the administrative distinction between primary, secondary, and tertiary care is defined above, there is no patient registration system for primary care facilities and a patient can access a secondary care hospital without a referral from a primary care physician. Therefore, from a patient’s perspective, the boundary between primary and secondary/tertiary care is ambiguous and some patients utilize not a clinic but a hospital as their usual source of care.

Reference


Reviewer's comment #16
The main concern is the lack of detail in your methodology - in particular your sampling methods, sample size and rationale/inclusion criteria is not clear for each round of the delphi - the inclusion criteria must be clearly defined as the validity of a delphi study rests on the idea that the chosen sample has expert knowledge in this particular field.

Response #16
Thank you for raising this important point. According to your suggestion, we revised the sentences. Responses #4 to #14 addressed this point. We believe that incorporating your advice into the previous version has made the manuscript better.

Reviewer's comment #17
The process of analysis of the survey data is also not clear - how the results were analysed and how decisions were made to include/discard or revise items has not been described, and these should have criteria to avoid bias and subjectivity in the process.

Response #17
Thank you for indicating this point. According to your suggestion, we revised the sentences. Responses #4 to #14 addressed this point. We really thank your constructive feedback.
Reviewer's comment #18
A discussion is not a valid method of analysis or decision making for a scientific study.

Response #18
Thank you for pointing it out. Based on your feedback, we clarified the method to improve the scientific validity of the study. Also, we revised the Discussion section based on the changes. This is the first study to create a rurality index for healthcare in Japan. The RIJ can be utilized to examine rural-urban disparity and to detect a point on intervention in the Japanese healthcare setting. Also, the RIJ can be used not only for describing the disadvantages of rural practice but also the advantages of it such as comprehensive care or a broader scope of practice. According to your suggestion, we added the sentences in the Discussion section.

(page 33, lines 480-482)
We developed the RIJ using a modified Delphi method. This is the first study to create a rurality index for healthcare in Japan.

(pages 487-490, lines 33)
The RIJ can be utilized to redefine “rural area” in the Japanese healthcare setting and to examine rural-urban disparity. Also, the RIJ can be used not only for describing the disadvantages of rural practice but also the advantages of it such as comprehensive care or a broader scope of practice.

Reviewer's comment #19
The format of the manuscript is also difficult to follow as there are some results presented in the study design/methods and these two sections seem to overlap.

Response #19
Thank you for indicating this important point. According to your suggestion, we moved the sentences from the Methods section to the Results section as mentioned in responses #10, #13 and #14. Also, we changed the Methods section as follows.

(pages 18-19, lines 323-332)
Phase 2: Formulation of the RIJ based on the results of Phase 1
To normalize the included factors, we employed min-max normalization. We also conducted exploratory factor analysis through the Promax rotation using the identified four factors to determine the factor structure. We employed a Scree Plot to determine the number of factors.

Reviewer's comment #20
The most important figures should be selected and included with a description and interpretation instead of as an annexure to give meaning to the results section.

Response #20
Thank you for raising this important point. We think Figure 2, the map with the rurality index, is the most important. In the figures, areas with higher rurality are depicted in red colour. Because “Special Heavy Snowfall Areas” are located in the northern areas of Japan, the part is described in a darker red colour. Also, remote islands without secondary or tertiary hospitals are shown in a darker red colour. Around Tokyo or other big cities are described in a greener colour. The expert panel agreed that the maps were consistent with clinical realities based on the visual inspection. According to your suggestion, we added the sentences as follows.
In the figures, areas with higher rurality are depicted in red colour. Because “Special Heavy Snowfall Areas” are located in the northern areas of Japan, that part is presented in a darker red colour. Also, remote islands without secondary or tertiary hospitals are shown in a darker red colour. Around Tokyo or other big cities are described in a greener colour. The Expert Panel agreed that the maps were consistent with clinical realities based on the visual inspection.

Reviewer’s comment #21
Perhaps consider adding more to your discussion about the significance of the findings and not just its’ comparison to other similar studies - there is an element of interpretation that is missing from your discussion.

Response #21
Thank you for indicating this point. This is the first study to create a rurality index for healthcare in Japan. The RIJ can be utilized to redefine “rural area” in the Japanese healthcare setting and to examine rural-urban disparity. Also, the RIJ can be used not only for describing the disadvantages of rural practice but also the advantages of it such as comprehensive care or a broader scope of practice. According to your suggestion, we added the sentences in the Discussion section.

We developed the RIJ using a modified Delphi method. This is the first study to create a rurality index for healthcare in Japan.

The RIJ can be utilized to redefine “rural area” in the Japanese healthcare setting and to examine rural-urban disparity. Also, the RIJ can be used not only for describing the disadvantages of rural practice but also the advantages of it such as comprehensive care or a broader scope of practice.

Additional comments to the editors and the reviewers
To avoid confusion, we unified the terms “systematic scoping review”, “scoping systematic review”, and “scoping review” to “scoping review” throughout the manuscript.

To clarify the meaning of the sentence, we revised the sentence in the discussion section.

Therefore, such resource availability may not have been identified as a factor of rurality in a Delphi method used in this study.

In the Results section of the first manuscript, we wrote “At the end of the first survey round, only two factors remained: population density and remote islands.” However, it was incorrect. The correct sentence is “At the end of the first survey round, only two factors remained: remote islands and direct distance to the nearest secondary or tertiary hospital.”

We believe that incorporating your advice into the previous version has made the manuscript better. Thank you once again.
GENERAL COMMENTS
Revision made the index description clear and easier to understand. The selection of the review panel participating in the Delphi process is more precise. The index will be helpful in future research in the Japanese rural context.

GENERAL COMMENTS
Thank you for the revised version of your manuscript, there is notable improvement in clarity regarding the methodology of your study. It is also noted that the significance of your study is now well represented. There are still some points of clarity needed in order for the study to be replicable with a clear map to your methodology. These specific issues include:

**ABSTRACT**
1. Please include a short background in your abstract and a more meaningful description of your setting.
2. Unless the demographics had some correlation to the results statistically it is not clear why gender and age are specifically noted in the summary of your results.

**METHODOLOGY:**
1. Your methodology should include setting, sampling, process, collection and analysis for each phase. This is particularly important for phase 1, round 3- How were participants recruited, did the sample represent the various regions across Japan as this was the description used in the abstract. What were the inclusion and exclusion criteria for the recruitment of participants, keeping in mind that selection for Delphi methodology must ensure that participants have knowledge or experience in the field understudy? How did you reach your sample size and what was the sample size calculation method? What was the process for data collection and analysis.

**RESULTS:**
1. In the table depicting demographics it is not clear what "others" refers to under occupation - it is not clear how this subset of the sample is eligible to participate?

The discussion of your findings is well presented however the methodology is not sufficiently described to enable a clear link between your findings and your methodology.

This is an important study and therefore it it important to ensure that the methods are soundly presented.

**VERSION 2 – AUTHOR RESPONSE**

Reviewer 3
Thank you very much for your feedback. We hope that we addressed the problems you raised. We
responded to the comments one by one.

Reviewer’s comment #1
Please include a short background in your abstract and a more meaningful description of your setting.

Response #1
Thank you for reviewing our manuscript and for your constructive feedback. According to your suggestion, we added a short background and a description of the setting. We omitted a few words to keep the abstract within 300 words.

Objectives: Rural-urban health care disparities exist globally. Various countries have utilized a rurality index for evaluating the disparities. Although Japan has many remote islands and rural areas, no rurality index exists. This study aimed to develop and validate a rurality index for Japan (RIJ) for healthcare research.

Design: We employed a modified Delphi method to determine the factors of the RIJ and assessed the validity. The study developed an Expert Panel including healthcare professionals and a patient who had expertise in rural healthcare.

Setting: The panel members were recruited from across Japan including remote islands, mountain areas and heavy snow areas. The Panel recruited survey participants whom the Panel considered to have expertise.

Participants: The initial survey recruited 100 people, including rural healthcare providers, local government staff, and residents.

Primary outcome measures: Factors to include in the RIJ were identified by the Expert Panel and survey participants. We also conducted an exploratory factor analysis on the selected factors to determine the factor structure. Convergent validity was examined by calculating the correlation between the index for physician distribution and the RIJ. Criterion-related validity was assessed by calculating the correlation with average life expectancy.

Results: The response rate of the final survey round was 84.8%. From the Delphi surveys, four factors were selected for the RIJ: population density, direct distance to the nearest hospital, remote islands, and whether weather influences access to the nearest hospital. We employed the factor loadings as the weight of each factor. The average RIJ of every zip code was 50.5. The correlation coefficient with the index for physician distribution was -0.45 (p<0.001), and the correlation coefficients with the life expectancies of men and women were -0.35 (p<0.001) and -0.12 (p<0.001), respectively.

Conclusion: This study developed the RIJ using a modified Delphi method. The index showed good validity.

Reviewer’s comment #2
Unless the demographics had some correlation to the results statistically it is not clear why gender and age are specifically noted in the summary of your results.

Response #2
Thank you for indicating this point. According to your suggestion, we deleted the information on the gender and age of the respondents.

Reviewer’s comment #3
Your methodology should include setting, sampling, process, collection and analysis for each phase. This is particularly important for phase 1, round 3- How were participants recruited, did the sample represent the various regions across Japan as this was the description used in the abstract. What
were the inclusion and exclusion criteria for the recruitment of participants, keeping in mind that selection for Delphi methodology must ensure that participants have knowledge or experience in the field understudy? How did you reach your sample size and what was the sample size calculation method? What was the process for data collection and analysis.

Response #3
Thank you for raising this important point and sorry for confusing you. Inclusion criteria and sample size were described in Round 2 section. We moved the sentences from Round 2 to Round 3 and revised the sentences. The Expert Panel members were recruited from rural areas across Japan including remote islands, mountain areas and heavy snow areas. Although we did not obtain information on the survey participants’ regional demographics in detail, the Expert Panel members had local connections with the participants. Thus, the survey participants would have various regional backgrounds. The inclusion criteria used by the Expert Panel members to identify potential survey participants were that the potential survey participants had enough knowledge and experience in rural healthcare or healthcare policy to respond to the survey. There were no specific exclusion criteria; the reason is that we aimed to include diverse perspectives from not only healthcare providers but also rural residents. According to your suggestion, we revised and added the sentences as follows.

(page 11, lines 189-191)
The panel members were recruited from rural areas across Japan including remote islands, mountain areas and heavy snow areas.

(pages 13-15, lines 234-254)
The Expert Panel recruited stakeholders for the Round 3 survey through snowball sampling. The Expert Panel identified stakeholders who had expertise in rural healthcare. Previous literature on the methodology for the Delphi method provided no agreement on sample size for the survey and many published Delphi studies employed 10 to 100 or more participants. Therefore, in this study, the Expert Panel recruited 100 stakeholders as potential participants. The inclusion criteria for survey participants were rural healthcare providers, government officers and residents that the Expert Panel considered would have opinions about rural health based on their knowledge and experience: e.g. a resident who is a member of a committee for developing a sustainable healthcare system for rural areas. The Expert Panel also included local government officers who had been engaged in healthcare policy in rural areas because perspectives from an administrator in rural areas were important to utilize in the development of the index for healthcare policy. There were no specific exclusion criteria; the reason is that we aimed to include diverse perspectives from not only healthcare providers but also rural residents. Nine Expert Panel members recruited 10 participants each, and one member (MK) recruited 20 participants. The Expert Panel members were recruited from rural areas across Japan including remote islands, mountain areas and heavy snow areas. Although the study did not obtain information on the survey participants’ regional demographics in detail, the Expert Panel members had local connections with the participants. Thus, the survey participants would have various regional backgrounds.

Reviewer’s comment #4
In the table depicting demographics it is not clear what “others” refers to under occupation - it is not clear how this subset of the sample is eligible to participate?

Response #4
Thank you for pointing it out. “Others” includes rural residents, academic faculty etc. We added the
information to Table 1.