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# Development and validation of a rurality index for health care research in Japan: A modified Delphi study

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Development and validation of a rurality index for health care research in Japan:

A modified Delphi study

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Abstract

Objectives: Rural-urban health care disparities exist globally. Although Japan has many remote islands and rural areas, there is no rurality index. This study aimed to develop and validate a rurality index in Japan (RIJ) for healthcare research.

Design: We employed a modified Delphi method to determine the factors of the RIJ and we assessed the validity.

Setting: Japan

Participants: The initial survey targeted 100 people, including rural health care providers, local government staff, and residents.

Primary outcome measures: We also conducted an exploratory factor analysis 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% (median age: 47.5, male: 51.8%). From the Delphi surveys, four factors were selected for 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, remote islands, and whether weather influences access to the nearest secondary or tertiary hospital. We employed the factor
loadings as the weight of each factor and created the RIJ. 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.

**Strengths and limitations of this study**

- This is the first study to develop a rurality index for use in Japanese healthcare research.
- The index showed good validity.
- The index can utilize both at the zip code level and municipality level overall Japan.
- We did not consider the availability and frequency of public transportation, such as ships or airplanes because of the difficulty of gathering the information.
Rural-urban health care disparities exist globally, regardless of a country's level of development. These disparities pose challenges to policymakers, healthcare providers, and the public. People who live in rural areas have more chronic diseases compared to those living in urban areas\(^1\). Furthermore, rural areas have fewer health care providers owing to difficulties in recruiting and retaining a workforce\(^1,2\). In response to these issues, various countries have developed a rurality index for evaluating rural-urban health disparities and developing evidence-based policies\(^1,3\).

Rurality indices, such as the Rurality Index of Ontario (RIO)\(^4\) in Canada and the Modified Monash Model in Australia\(^5\) have been used successfully in clinical research and policymaking. There are no universal measures or approaches for developing a rurality index because rurality is significantly context-specific\(^6\). For instance, RIO was developed using population density, time to the nearest basic referral center, and time to the nearest advanced referral center. However, remote islands were not considered\(^4\).

Subsequently, the clinical peripherality index in Scotland considers remote islands because Scotland has several remote islands\(^7\). Therefore, each country or region must develop a rurality index based on their contexts\(^6\).

Japan has many remote islands in which 683,000 people (0.5% of the overall population) live\(^8\). Additionally, 11 million people live in rural areas called “depopulated
Japan has some areas that experience heavy snowfall, and people living in these areas have limited access to healthcare during the winter months. There is no existing multifaceted index of rurality that considers population density, distance to medical facilities, and climate. Therefore, developing a rurality index for Japan that is specific to Japan’s unique rural areas is crucial for a highly accurate assessment of Japanese rural healthcare.

As a first step toward developing a rurality index in Japan (RIJ) for healthcare research, we conducted a scoping systematic review in 2020. The review revealed frequently used variables, methods for calculating indices, and validation measures in previous rurality indices over the past 30 years. In this study, we aimed to develop and validate a RIJ based on the results of our scoping systematic review and the consensus of healthcare providers, policymakers, and residents.

**Aims**

The study aimed to develop and validate a RIJ for use in Japanese health care research.

**Methods**

**Study Design**
We employed a modified Delphi method to conduct sequential surveys of targeted stakeholders and we also assessed validity. The Delphi method is suitable for establishing consensus for the research problem, which can benefit from subjective judgments on a collective basis. The Delphi method facilitates anonymity in responses, gathers expert opinions, employs sequential questionnaires without face-to-face discussions, and uses frequency distributions to identify patterns of the agreement through two or more rounds of surveying. The approach is used widely in medical and health services research. The modified Delphi method, unlike the original Delphi, offers a research team the opportunity to discuss opinions between survey rounds. In Round 1 of Phase 1, we developed a steering team to identify members of the panel of key informants. In Round 2, the steering team and the panel listed potential factors for the RIJ. In Round 3, the steering team and the panel recruited 100 stakeholders and conducted surveys. In Phase 2, we developed the formulation of the RIJ based on the results of Phase 1. We also conducted validation tests as part of Phase 3.

Setting

**Healthcare system in Japan:** In Japan, the governance of medical care is under the Ministry of Labor, Health and Welfare, which is responsible for policy setting and administration. Local governments are responsible for the delivery of primary,

Tertiary care plays a significant role in providing advanced medical care, such as organ transplantation or surgical procedures for rare congenital diseases. Primary care service areas comprise approximately 1,700 districts (e.g., cities, towns, and villages), secondary care service areas comprise 344 jurisdictions, and tertiary care service areas comprise 52 areas. The provisioning system for emergency care is essentially based on the population of each secondary care service area.

Definition of rural area in Japan: Apart from the medical care service areas mentioned above, there are several definitions of “rural” in Japan used mainly for deciding the national government’s subsidy to residents and local governments.

“Depopulated area” is determined by the municipality’s income, demand, and population decline rate. “Disadvantaged area” is defined similarly to the depopulated area or several acts of legislation addressing remote islands or areas that experience heavy snowfall, such as the “Remote Islands Development Act” and the “Act on Special Measures concerning Countermeasures for Heavy Snowfall Areas.” The Act on Special Measures concerning Countermeasures for Heavy Snowfall Areas determines heavy snowfall areas and special heavy snowfall areas. “Special Heavy Snowfall
Areas,” which account for approximately 20% of all land in Japan, represent areas in which heavy snow can hinder transportation and disrupt the daily lives of the residents\textsuperscript{16,17}.

**Patient and public involvement**

This study invited patients and residents in rural areas as stakeholders and participants of the Delphi survey. The patients and residents were invited to comment on the study design and consulted on the relevance of the research.

**Procedure and statistical analysis**

Figure 1 shows the flow chart of the process of development and validation of the RIJ.

**Phase 1: Modified Delphi methods for identifying the factors that should be included, and their relative importance:**

**Round 1: Identifying stakeholders**

As the first step, we developed a steering team. The steering team comprised five authors of this manuscript. Four of the steering team were members of the committee of rural and remote medicine in the Japan Primary Care Association. The steering team discussed who should be involved in the panel of key informants for Round 2 and the
unit of analysis. The members of team recruited four members of the panel: a nurse, a public health nurse, a nurse practitioner, and a resident/patient in rural areas. In terms of the unit of analysis, the steering team employed 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.

Round 2: Identifying the crucial factors for the RIJ through the panel of key informants based on their expertise and our systematic scoping review

The steering team and the panel of key informants identified the vital factors to include in the RIJ. According to our previous literature 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). Moreover, the steering team considered the Japanese context. For example, Japan has many remote islands, and sometimes, a patient can only access a secondary hospital through a ship or an airplane. Additionally, in Japan, secondary hospitals play a significant role as referral centers, and they provide out-of-hours care for patients who potentially require
admission after hours\textsuperscript{18}. Therefore, travel distance or time to a secondary hospital must be considered. Access to medical facilities may also be affected by the weather. After the discussion, the steering team and the panel members developed a list of potential factors for the RIJ. They assessed content validity through discussions on domains and subdomains to be included in the survey\textsuperscript{19,20}. Additionally, the steering team and panel members recruited stakeholders for Round 3 through snowball sampling.

**Round 3: Online surveys (modified Delphi Methods)**

An expert panel method was used to develop the survey. The initial draft of the survey was developed by one of the authors (MK), and the steering team as well as the panel of key informants reviewed and revised subsequent versions of the survey. Three consecutive online surveys were conducted from August 2021 through October 2021 to obtain a consensus on the factors included in the RIJ. The steering team and the panel recruited 100 stakeholders as potential participants. The inclusion criteria were rural healthcare providers, government officers and residents that the steering team and panel members 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. Nine people (five steering team members...
and the four key informant panel members) recruited 10 participants each, and one steering team member (MK) recruited 20 participants. The participants of the online survey received an email invitation from each member of the steering team or the key informant panel members. The email invitation contained a link to the online survey. Participants were asked to rate the importance of each factor using a six-point Likert scale (1 = not important at all; 6 = extremely important) and offer written feedback/suggestions. Consensus on factors that should be included in the rurality index was set a priori and defined as at least 80% agreement (we regarded 5 or 6 as agreement) based upon recommendations and consensus levels used in the previous Delphi studies\textsuperscript{21,22,23}. At the start of the first survey, 16 factors were listed. Four factors reached 80% agreement and three of them about the remote island were combined into one factor “remote island” based on the steering team’s discussion. At the end of the first survey round, the research team discussed whether factors that did not reach 80% agreement needed to be modified. Through steering team members’ discussion, the expression described in legal terms such as disadvantaged areas and heavy snow falls areas were changed because the meaning of the terms might be difficult to understand for the participants. In the second round of surveying, only participants who had completed the first round were asked to complete the second survey round. 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 steering team 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 grasp 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 steering team 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).

We requested the participants to choose either one.

The demographic characteristics of the survey participants and the level of consensus for each factor were examined using descriptive statistics, including frequencies and percentages. Comments/suggestions on survey items were transcribed into a single report for review and discussed by the steering team.
Phase 2: Formulation of the RIJ based on the results of Phase 1

Four factors were identified through the three surveys: population density (continuous variable), distance to the nearest secondary or tertiary hospital (continuous variable), remote islands (dichotomous variable), and whether weather influences access to the nearest secondary or tertiary hospital (dichotomous variable: heavy snow fall area or not). We first employed min-max normalization to normalize the included factors. We also conducted exploratory factor analysis through the Promax rotation using the identified four factors to determine the factor structure\textsuperscript{24}. We employed a Scree Plot to determine the number of factors. We utilized the calculated value from the factor loading as the weight of each factor\textsuperscript{25}.

Phase 3: Validation test

Factorial validity was verified using the results obtained from the exploratory factor analysis conducted in Phase 2. Convergent validity was examined by calculating the Pearson correlation coefficient between the index for physician distribution per 100,000 people\textsuperscript{26} and the developed rurality index. The index for physician distribution was developed from the standardized number of physicians and the population and standardized consultation ratio in each region\textsuperscript{26}. This index has been used to describe
the uneven distribution of doctors in secondary or tertiary healthcare service areas. Therefore, in this study, we evaluated the correlation between the RIJ and the index for physician distribution in each secondary healthcare service area. Criterion-related validity was assessed by calculating the correlation between average life expectancy in each municipality and the rurality index. Because the previous study reported rurality is negatively correlated with life expectancy and there are no other suitable rurality indices in Japan to evaluate criterion-related validity, we employed life expectancy for evaluating criterion-related validity. We also calculated the cut-off of the RIJ using “depopulated area” and “disadvantaged area,” which are the existing definitions of rurality in Japan, as the reference standards. The cut-off was determined using the Youden index. All statistical analyses were conducted using StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC

Ethics approval

The study protocol was performed following the Declaration of Helsinki, reviewed and approved by the Ethics Committee of Yokohama City University (approval number: B210100001). Informed consent was obtained from all study participants.
Results

In Phase 1, out of 100 potential participants, 85 responded to the survey (response rate: 85%, median age: 45 years, males: 55.3%, females: 43.5%, and prefer not to answer: 1.2%). The participants’ demographic characteristics in the first, second, and third surveys are shown in Table 1. The response rate of the third round was 84.8%.

Table S1 shows the list of potential factors determined by the steering team/the panel of key informants and through the results of the first and second surveys. The changes in the potential factors determined by the steering team are also described in Table S1.

Table 1. Participants’ demographic characteristics

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<td>22 (33.3)</td>
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<td>70-79</td>
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Although the participants who did not join the second survey were not invited to the third survey, in some categories (e.g. 60-69 years old), the number of participants in the third survey was higher than that in the second survey. This might be explained by the wrong input of the participants.

In the third survey, 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. Because the line between secondary and tertiary care is ambiguous in Japan and because the respondents...
regarded care for acute diseases, such as stroke, heart attacks, and obstetrical delivery, as important, we included both secondary and tertiary hospitals. We also defined a remote island as an island other than the four main islands in Japan (Hokkaido, Honshu, Shikoku, and Kyushu) and an island without a secondary or tertiary hospital.

Additionally, the steering team defined areas in which “access to a secondary or tertiary hospital is affected by the weather” as “special heavy snowfall areas” based on the Act on Special Measures concerning Countermeasures for Heavy Snowfall Areas because in Japan, access to healthcare services in such areas is mainly hindered by typhoons and heavy snowfall, and typhoons may already be accounted for by the factor of “remote islands.” The steering team regarded the zip code areas in special heavy snowfall areas and those without a secondary or tertiary hospital as the areas in which “access to a secondary or tertiary hospital is affected by the weather.”

For all the 113,952 zip codes in Japan, we considered population density and direct distance to the nearest secondary or tertiary hospital. We identified every zip code associated with a remote island and special heavy snowfall areas. Two common factors were extracted based on the initial explanatory factor analysis. Factor loadings were rotated using the Promax rotation to interpret the factors. Therefore, population density and special heavy snowfall areas were classified into one group labelled
“population/climate factors.” In addition, direct distance to the nearest secondary or tertiary hospital and remote islands were grouped as “distance factors.” Exploratory factor analysis through the Promax rotation revealed the factor loading of each factor as follows: population density: 0.46; direct distance to the nearest secondary or tertiary hospital: -0.3; remote islands: 0.47, and special heavy snowfall areas: 0.3. We employed the factor loadings as the weight of each factor and created a pre-conversion RIJ as follows:

\[
\text{Pre-conversion RIJ} = \text{population density} \times 0.46 + \text{direct distance to the nearest secondary or tertiary hospital} \times (-0.3) + \text{remote island} \times 0.47 + \text{special heavy snowfall areas} \times 0.3
\]

We calculated the pre-conversion RIJ and converted the score into integers. The total scores were ranked on a scale of 1–100, and they were used as the RIJ. Higher scores represented increased levels of rurality.

The average rurality index for every zip code in Japan was 50.5 (standard deviation (SD): 28.9), and the average rurality index in depopulated areas was 75.7 (SD: 20.6), and that in disadvantaged areas was 66.9 (SD: 24.9). We also calculated the rurality index for every municipality and secondary healthcare service area using an average of the pre-converted RIJ for each area. We created the maps based on the RIJ for every zip code, municipality, and secondary care service area. The maps are shown in Figures 2(a), 2(b), and 2(c).
We also examined the correlation between the RIJ and the index for physician distribution in each secondary healthcare service area or the average life expectancy in each municipality. The correlation coefficient of the RIJ through the index for physician distribution was -0.45 (p<0.001). The correlation coefficients of the RIJ through the life expectancies of men and women were -0.35 (p<0.001) and -0.12 (p<0.001), respectively. The scatter plots are shown in Figures 3(a), 3(b), and 3(c).

We used receiver operating characteristic (ROC) curves to plot the sensitivity (true positive rate) against the specificity (false positive rate) of the pre-conversion RIJ using the depopulated areas and disadvantaged areas as the reference standards. The Youden value indicates the optimal cut-off value. The cut-off value of the pre-conversion RIJ for depopulated areas is 0.00197, the sensitivity at the cut-off is 0.65, the specificity at the cut-off is 0.84, and the area under the curve at the cut-off is 0.83. For disadvantaged areas, the cut-off value is 0.00147, the sensitivity at the cut-off is 0.74, the specificity at the cut-off is 0.79, and the area under the curve at the cut-off is 0.84. The ROC curves are shown in the supplementary files: Figures S1(a) and S1(b).

Discussion

Summary of the findings
We developed the RIJ based on discussions by the steering team, the panel of key informants, and the stakeholders, including rural residents. The index comprises four factors: population density in each zip code, direct distance to the nearest secondary or tertiary hospital from the center of each zip code area, remote islands, and whether weather, such as typhoons or heavy snowfall influences access to the nearest secondary or tertiary hospital. The RIJ showed good factorial, convergent, and criterion-related validities.

Comparison with existing literature

Two of the included factors, population density, and distance to the nearest secondary or tertiary hospital, were consistent with previously developed rurality indices in other countries or regions. Our previous scoping review revealed that population density is the most frequently used factor, whereas distance and time are the second most frequently used factors\(^6\). Another common factor is resource availability, such as the number of physicians, including primary care physicians and specialists, or the physician/population ratio\(^6,30,31,32\). However, in Japan, the boundary between primary care and secondary care is unclear, and defining a primary care provider is difficult\(^14,33\). Therefore, such resource availability may not have been identified in the modified Delphi method used in this study.
Inherently, rurality is dependent on the context of each country or region. The remaining two factors, remote islands, and weather might reflect the Japanese context. Similarly, Scotland includes remote islands in their rurality index\textsuperscript{7}, and as such, their index might be similar to that used in Japanese contexts. Moreover, because the recent climate change can affect access to healthcare\textsuperscript{34}, including weather in a rurality index might become important for other countries.

The RIJ showed acceptable validity. We assessed factorial, convergent, and criterion-related validities. In previous studies, only 29\% of all indices examined validity\textsuperscript{6}. Content validity is crucial owing to its context-specific nature\textsuperscript{6}, and conducting validation using different aspects is a major strength of our study.

Implication of the study

This study revealed that the RIJ negatively correlates with physician distribution and life expectancy among men and women. Because there is currently no index for describing the degree of rurality in Japan, the RIJ can be utilized to evaluate rural-urban discrepancies related to health outcomes and the workforce. The RIJ can also be used to determine the required scope of practice in each rurality level, as is the case in Australia\textsuperscript{35}.
Limitation of the study

This study has some limitations. First, we employed direct distance rather than actual distance to assess the distance from each zip code to the nearest hospital owing to the difficulty of measuring the actual distance. However, direct distance and actual distance are relatively correlated\(^{36}\). Therefore, the use of direct distance should not skew the index. Second, we did not consider the availability and frequency of public transportation, such as ships or airplanes. These factors are important for rural residents, especially islanders. However, because information on the availability and frequency of public transportation might change often, employing it in the rurality index for all of Japan is difficult, and it may result in inconsistencies over time. However, in Japan, public transportation is mainly utilized in metropolitan areas compared to rural prefectures\(^{37}\). Therefore, the lack of or the frequency of public transportation, as they pertain to the RIJ, might not affect most rural areas. Third, the figures for the included factors may change over time. Therefore, we shall update the data and share the new RIJ on our website to ensure easy access for researchers and policymakers.

Conclusions

In this study, we developed a rurality index in Japan (RIJ) using a modified Delphi
method. The index showed good factorial, convergent, and criterion-related validities.

The RIJ can be a useful tool for assessing rural-urban disparity, workforce recruitment and retention policies, as well as accessibility to other health care resources in rural areas throughout Japan.

Declarations

Acknowledgements

We thank the members of the committee of rural and remote medicine in the Japan Primary Care Association. We also thank Kenichi Takeshita, Tokyo Map Research Inc. and Tsugio Kote, Daylight Co., Ltd. for their support in creating the maps. We would like to thank Editage (www.editage.com) for English language editing.

Funding

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Competing interest

There are no potential competing interests to be declared relevant to this work.

Contributors

MK designed the study and participated in the implementation, data collection, data analysis, and writing of the manuscript. MK also serves as the guarantor. MI, KS, MS, RO, UC, EV, TRF, and MM contributed to the design of the study and critically reviewed the manuscript. MK and TI analyzed the data and drafted the manuscript. All authors had full access to the data and take responsibility for the integrity of the data and the accuracy of the analysis.

Transparency

All authors had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity and accuracy of the data analyses. The lead author affirms that the manuscript is reliable and accurate and provides a transparent account of the study being reported, that no important aspects of the study have been omitted, and that any discrepancies from the study as planned have been explained.

Data sharing: The datasets are available from the corresponding author on reasonable request.
References


11. Fitch K, Bernstein SJ, Aguilar MD et al. The RAND/UCLA Appropriateness


15. The Ministry of International Affairs and Communication, Japan. Requirements for depopulated area. 2019. Available:


Figure legends

Figure 1. Flow chart of the process of development and validation of the Rurality Index for Japan.

Figure 2(a). The Rurality Index for Japan by zip code.

Figure 2(b). The Rurality Index for Japan by the municipality.

Figure 2(c). The Rurality Index for Japan by secondary healthcare service area.

Figure 3(a). Scatter plot of the Rurality Index for Japan and the index for physician distribution.

Figure 3(b). Scatter plot of the Rurality Index for Japan and life expectancy of men.

Figure 3(c). Scatter plot of the Rurality Index for Japan and life expectancy of women.

Figure S1(a). Receiver Operating Characteristic (ROC) curves of the Rurality Index for Japan.
Japan for predicting depopulated areas

Figure S1(b). Receiver Operating Characteristic (ROC) curves of the Rurality Index for Japan for predicting disadvantaged areas
### Phase 1: Modified Delphi method

<table>
<thead>
<tr>
<th>Round 1: Identifying the panel of key informants</th>
<th>The steering team decided the panel of key informants.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Round 2: Identifying the important factors for a Rurality Index (RIJ)</td>
<td>The panel of key informants developed the list of factors for the RIJ.</td>
</tr>
<tr>
<td>Round 3: Online surveys</td>
<td>Three consecutive online surveys were conducted on 100 potential participants.</td>
</tr>
</tbody>
</table>

### Phase 2: Development of formulation of the RIJ

- **To normalize the included factors**: Mini-max normalization
- **To determine the factor structure and weight**: Exploratory factor analysis

### Phase 3: Validation test

- **Content validity**: Discussion on domains by the steering team and the panel
- **Factorial validity**: Factor analysis
- **Convergent validity**: Correlation between the RIJ and the index for physician distribution
- **Criterion-related validity**: Correlation between the RIJ and average life expectancy
- **Determining cut-off value**: Receiver Operating Characteristic curve and Youden index
Rurality Index for healthcare research in Japan (zip code): 1 to 100

- 91 - 100
- 81 - 90
- 71 - 80
- 61 - 70
- 51 - 60
- 41 - 50
- 31 - 40
- 21 - 30
- 11 - 20
- 1 - 10
Rurality Index for healthcare research in Japan (municipality): 1 to 100

- 91 - 100
- 81 - 90
- 71 - 80
- 61 - 70
- 51 - 60
- 41 - 50
- 31 - 40
- 21 - 30
- 11 - 20
- 1 - 10

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Rurality Index for healthcare research in Japan (secondary healthcare service area): 1 to 100

- 91 - 100
- 81 - 90
- 71 - 80
- 61 - 70
- 51 - 60
- 41 - 50
- 31 - 40
- 21 - 30
- 11 - 20
- 1 - 10

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Table S1. Percentages of agreement in potential factors for the RIJ

<table>
<thead>
<tr>
<th>Potential factors</th>
<th>First survey</th>
<th>Second survey</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population density</td>
<td>77.6</td>
<td>68.2</td>
<td>Third survey</td>
</tr>
<tr>
<td>Distance to the nearest secondary or tertiary hospital</td>
<td>83.5</td>
<td></td>
<td>Included</td>
</tr>
<tr>
<td>Distance to the nearest hospital which provides care for patients with acute stroke</td>
<td>74.1</td>
<td>83.4</td>
<td>Combined into “distance to the nearest secondary or tertiary hospital”</td>
</tr>
<tr>
<td>Distance to the nearest hospital which provides care for patients with an acute heart attack</td>
<td>76.5</td>
<td>86.4</td>
<td>Combined into “distance to the nearest secondary or tertiary hospital”</td>
</tr>
<tr>
<td>Distance to the nearest hospital which provides care for pregnant women for delivery</td>
<td>72.9</td>
<td>77.3</td>
<td>Rejected</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Disadvantaged Area</td>
<td>57.6</td>
<td>Changed into “population decline rate” †</td>
<td></td>
</tr>
<tr>
<td>Heavy Snowfall area</td>
<td>49.4</td>
<td>Combined with “Whether weather such as heavy snow influences access to the nearest secondary or tertiary hospital”</td>
<td></td>
</tr>
<tr>
<td>Remote island</td>
<td>90.6</td>
<td>Included</td>
<td></td>
</tr>
<tr>
<td>Remote island with a clinic or hospital</td>
<td>92.9</td>
<td>Combined into “remote island”</td>
<td></td>
</tr>
<tr>
<td>Service</td>
<td>Approval Rate</td>
<td>Rejection Rate</td>
<td>Decision</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>----------------</td>
<td>----------------</td>
<td>----------</td>
</tr>
<tr>
<td>Bridge between remote island and main island</td>
<td>81.2</td>
<td>18.8</td>
<td>Included</td>
</tr>
<tr>
<td>Whether weather such as heavy snow influences access to the nearest secondary hospital</td>
<td>75.2</td>
<td>24.8</td>
<td>Included</td>
</tr>
<tr>
<td>Availability of public transportation to the nearest secondary hospital</td>
<td>70.6</td>
<td>29.4</td>
<td>Rejected</td>
</tr>
<tr>
<td>Availability of emergency helicopter to the nearest secondary hospital</td>
<td>65.9</td>
<td>34.1</td>
<td>Rejected</td>
</tr>
<tr>
<td>Availability of house call</td>
<td>41.2</td>
<td>58.8</td>
<td>Rejected</td>
</tr>
<tr>
<td>Community General Support Center</td>
<td>27.1</td>
<td>72.9</td>
<td>Rejected</td>
</tr>
<tr>
<td>Availability of care management for elderly</td>
<td>34.1</td>
<td>65.9</td>
<td>Rejected</td>
</tr>
</tbody>
</table>

Additional factors from the second survey by the steering team
discussion

<table>
<thead>
<tr>
<th>Population decline rate</th>
<th>54.5</th>
<th>Rejected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of people aged 65 years and over</td>
<td>68.2</td>
<td>Rejected</td>
</tr>
<tr>
<td>Proportion of people aged 15-29 years</td>
<td>59.1</td>
<td>Rejected</td>
</tr>
</tbody>
</table>

Comments

Distance to the nearest pharmacy

Availability of CT/MRI

Physician/population ratio

† The definition of the disadvantaged area included the population decline rate.

Community General Support Center: The center provides community-based-integrated care, including living arrangements, social care, and daily life support services.28

Care management: Care management means coordination by licensed care managers of the different services provided by different providers to accommodate geographically dispersed home settings.29
Sensitivity: 0.65
Specificity: 0.84

Area under ROC curve = 0.8279
## STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item #</th>
<th>Recommendation</th>
<th>Reported on page #</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td>1, 3</td>
<td><em>(a)</em> Indicate the study's design with a commonly used term in the title or the abstract</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>(b)</em> Provide in the abstract an informative and balanced summary of what was done and what was found</td>
<td>3</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td>2</td>
<td>Explain the scientific background and rationale for the investigation being reported</td>
<td>5, 6</td>
</tr>
<tr>
<td><strong>Objectives</strong></td>
<td>3</td>
<td>State specific objectives, including any prespecified hypotheses</td>
<td>6</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study design</td>
<td>4</td>
<td>Present key elements of study design early in the paper</td>
<td>7</td>
</tr>
<tr>
<td>Setting</td>
<td>5</td>
<td>Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection</td>
<td>7-15</td>
</tr>
<tr>
<td>Participants</td>
<td>6</td>
<td><em>(a)</em> Give the eligibility criteria, and the sources and methods of selection of participants</td>
<td>9-12</td>
</tr>
<tr>
<td>Variables</td>
<td>7</td>
<td>Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable</td>
<td>13, 14</td>
</tr>
<tr>
<td>Data sources/measurement</td>
<td>8*</td>
<td>For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group</td>
<td>13-15</td>
</tr>
<tr>
<td>Bias</td>
<td>9</td>
<td>Describe any efforts to address potential sources of bias</td>
<td>7-15</td>
</tr>
<tr>
<td>Study size</td>
<td>10</td>
<td>Explain how the study size was arrived at</td>
<td>7-12</td>
</tr>
<tr>
<td>Quantitative variables</td>
<td>11</td>
<td>Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why</td>
<td>13, 14</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>12</td>
<td><em>(a)</em> Describe all statistical methods, including those used to control for confounding</td>
<td>13-15</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>(b)</em> Describe any methods used to examine subgroups and interactions</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>(c)</em> Explain how missing data were addressed</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>(d)</em> If applicable, describe analytical methods taking account of sampling strategy</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>(e)</em> Describe any sensitivity analyses</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### Notes

- This checklist is updated periodically by the STROBE initiative to ensure it remains relevant to modern research practices.
- The criteria are designed to help researchers enhance the transparency and quality of their reporting, facilitating a more informed and critical assessment by readers and reviewers.
- Compliance with these recommendations can help improve the reproducibility and reliability of research findings.

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<table>
<thead>
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<th>Category</th>
<th>Item</th>
<th>Description</th>
<th>Page</th>
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</thead>
<tbody>
<tr>
<td>Participants</td>
<td>13*</td>
<td>(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Give reasons for non-participation at each stage</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(c) Consider use of a flow diagram</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Descriptive data</td>
<td>14*</td>
<td>(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders</td>
<td>16-18</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Indicate number of participants with missing data for each variable of interest</td>
<td>16-18</td>
</tr>
<tr>
<td>Outcome data</td>
<td>15*</td>
<td>Report numbers of outcome events or summary measures</td>
<td>16-19</td>
</tr>
<tr>
<td>Main results</td>
<td>16</td>
<td>(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included</td>
<td>16-22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Report category boundaries when continuous variables were categorized</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Other analyses</td>
<td>17</td>
<td>Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Discussion</td>
<td>18</td>
<td>Summarise key results with reference to study objectives</td>
<td>22</td>
</tr>
<tr>
<td>Limitations</td>
<td>19</td>
<td>Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias</td>
<td>23,24</td>
</tr>
<tr>
<td>Interpretation</td>
<td>20</td>
<td>Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence</td>
<td>22-24</td>
</tr>
<tr>
<td>Generalisability</td>
<td>21</td>
<td>Discuss the generalisability (external validity) of the study results</td>
<td>23,24</td>
</tr>
<tr>
<td>Other information</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Funding</td>
<td>22</td>
<td>Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based</td>
<td>26</td>
</tr>
</tbody>
</table>

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.
Development and validation of a rurality index for health care research in Japan: A modified Delphi study

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<th>BMJ Open</th>
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<td>Date Submitted by the Author:</td>
<td>25-Apr-2023</td>
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<tr>
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<td>Kaneko, Makoto; Yokohama City University, Department of Health Data Science Ikeda, Takaaki; Yamagata University; Tohoku University, Inoue, Machiko; Hamamatsu University School of Medicine Sugiyama, Kemmyo; Tohoku University Graduate School of Dentistry School of Dentistry Saito, Manabu; Teuchi Clinic Ohta, Ryuichi; Unnan City Hospital Cooray, Upul ; Tohoku University Graduate School of Dentistry School of Dentistry, Department of International and Community Oral Health Vingilis, Evelyn; Western University, Department of Family Medicine Freeman, Thomas; Western University, Department of Family Medicine Mathews, Maria; Western University, Department of Family Medicine</td>
</tr>
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<tr>
<td>Secondary Subject Heading:</td>
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</tr>
</tbody>
</table>
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Development and validation of a rurality index for health care research in Japan:
A modified Delphi study

Makoto Kaneko* MD, M ClinSci (Family Medicine), PhD; Takaaki Ikeda PhD, Machiko Inoue MD, MPH, PhD, Kemmyo Sugiyama MD, PhD; Manabu Saito MD, PhD; Ryuichi Ohta MD, MHPE, PhD; Upul Cooray BDS, Msc; Evelyn Vingilis PhD; Thomas Robert Freeman MD, M ClinSci (Family Medicine), CCFP, FCFP; Maria Mathews PhD

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Tel: +81 45 787 2311

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Word count: 4,299
Abstract

**Objectives:** Rural-urban health care disparities exist globally. Although Japan has many remote islands and rural areas, there is no rurality index. This study aimed to develop and validate a rurality index in Japan (RIJ) for healthcare research.

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

**Setting:** The study recruited survey participants from across Japan.

**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% (median age: 47.5, male: 51.8%). From the Delphi surveys, four factors were selected for 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, remote islands, and whether weather influences access to the nearest secondary or tertiary hospital. We employed the factor loadings as the weight of each factor and created the RIJ. 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.

Strengths and limitations of this study

- This is the first study to develop a rurality index for use in Japanese healthcare research.
- The index showed good validity.
- The index can utilize both at the zip code level and municipality level in Japan.
- We did not consider the availability and frequency of public transportation, such as ships or airplanes because of the difficulty of gathering the information.

Introduction
Rural-urban healthcare disparities exist globally, regardless of a country's level of development. These disparities pose challenges to policymakers, healthcare providers, and the public. People who live in rural areas have more chronic diseases compared to those living in urban areas\(^1\). Furthermore, rural areas have fewer healthcare providers owing to difficulties in recruiting and retaining a workforce\(^1,2\). In response to these issues, various countries have developed a rurality index for evaluating rural-urban health disparities and developing evidence-based policies\(^1,3\). Rurality indices, such as the Rurality Index of Ontario (RIO)\(^4\) in Canada and the Modified Monash Model in Australia\(^5\) have been used successfully in clinical research and policymaking. There are no universal measures or approaches for developing a rurality index because rurality is context-specific\(^6\). For instance, RIO was developed using population density, time to the nearest basic referral center, and time to the nearest advanced referral center. However, remote islands were not considered\(^4\). Yet, Scotland’s rurality index, “clinical peripherality”, considers remote islands because Scotland has several remote islands\(^7\). Therefore, each country or region must develop a rurality index based on their specific contexts\(^6\).

**Definitions of rural area in Japan**

Japan has many remote islands in which 683,000 people (0.5% of the overall...
population) live. Additionally, 11 million people live in rural “depopulated areas” (11% of the overall population and 58% of all the areas). Japan has some areas that experience heavy snowfall, and people living in these areas have limited access to healthcare during the winter months. As a consequence, Japan developed several definitions of “rural”. “Depopulated area” is determined by the municipality’s income, demand, and population decline rate. “Disadvantaged area” is defined similarly to the depopulated area or by several acts of legislation addressing remote islands or areas that experience heavy snowfall, such as the “Remote Islands Development Act” and the “Act on Special Measures concerning Countermeasures for Heavy Snowfall Areas”.

The Act on Special Measures concerning Countermeasures for Heavy Snowfall Areas determines heavy snowfall areas and special heavy snowfall areas. “Special Heavy Snowfall Areas,” which account for approximately 20% of all land in Japan, represent areas in which heavy snow can hinder transportation and disrupt the daily lives of the residents. This Act was legislated in 1962 and has been reviewed 10 times, with the last update in 2007. However, the above definitions of “rural” have been used mainly for deciding the national government’s subsidy to residents and local governments but not for Japan’s healthcare system.

Healthcare system in Japan
In Japan, the governance of medical care is under the Ministry of Labor, Health and Welfare, which is responsible for policy setting and administration. Local governments are responsible for the delivery of primary, secondary, and tertiary care. Generally, in Japanese settings, primary care means patient care in the outpatient setting, and secondary care refers to hospitalized care. Tertiary care plays a significant role in providing advanced medical care, such as organ transplantation or surgical procedures for rare congenital diseases. 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.

Primary care service areas comprise approximately 1,700 districts (e.g., cities, towns, and villages), secondary care service areas comprise 344 jurisdictions, and tertiary care service areas comprise 52 areas. The provisioning system for emergency care is essentially based on the population of each secondary care service area. Japan’s “rural area” in healthcare policy has been mainly 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.

### Aims

The aim of this study was to develop and validate a rurality index in Japan (RIJ) for use in Japanese healthcare policy development and research. As a first step
toward developing a RIJ, we conducted a scoping review in 2020. The review
identified frequently used variables, methods for calculating indices, and validation
measures used in previous rurality indices over the past 30 years. In this study, we
developed and validated a RIJ based on the results of our scoping review and the
consensus of healthcare providers, policymakers, and residents using the Delphi
method.
Methods

Study Design

We employed a modified Delphi method in this study. The Delphi method is suitable for establishing consensus for the research problem, which can benefit from subjective judgments on a collective basis. The Delphi method facilitates anonymity in responses, gathers expert opinions, employs sequential questionnaires without face-to-face discussions, and uses frequency distributions to identify patterns of agreement through two or more rounds of surveying. The approach is used widely in medical and health services research. The modified Delphi method, unlike the original Delphi, offers a research team the opportunity to discuss opinions between survey rounds.

Procedure and statistical analysis

Figure 1 shows the flow chart of the process of development and validation of the RIJ. This study included three Phases and three Rounds of data collection under Phase 1. Briefly, in Phase 1, Round 1, we convened an Expert Panel. In Round 2, the
Expert Panel identified potential factors for the RIJ based on a previously conducted scoping review. In Round 3, the Expert Panel developed a survey including the identified potential factors. They recruited 100 participants with expertise in rural healthcare and conducted three sets of surveys. In Phase 2, we developed the formulation of the RIJ based on the results of Phase 1. We subsequently conducted content, factorial, convergent and criterion-related validity assessments on the results as part of Phase 3. These Phases are described in detail below.

Phase 1: Modified Delphi methods for identifying and rating factors to be considered in RIJ:

Round 1: Developing an Expert Panel

The first step was to identify and convene an Expert Panel to oversee all aspects of the study. 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.

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.

Round 2: Identifying the crucial factors for the RIJ through the Expert Panel based on the scoping review and their expertise.

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)⁶. Subsequently, the Expert Panel reviewed all the factors one by one and discussed other potential factors based on their expertise considering the Japanese healthcare context⁶. For example, Japan has many remote islands⁶, and sometimes, a patient can only access a secondary hospital by travelling by a ship or an airplane. Additionally, in Japan, secondary hospitals play a significant role as referral centers, and they provide out-of-hours care for patients who potentially require admission after hours¹⁹. Therefore, travel distance or time to a secondary hospital must be considered. Access to medical facilities may also be affected by the weather. After the discussion, the Expert Panel developed a list of potential factors for the RIJ. They assessed content validity through discussions on domains and subdomains to be included in the survey²⁰,²¹. During this Round, the Expert Panel also 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. Nine Expert Panel members recruited 10 participants each, and one member (MK) recruited 20 participants.

Round 3: Online surveys (modified Delphi Methods)

An Expert Panel method was used to develop the survey. The initial draft of the survey was developed by one of the Expert Panel members (MK), and the Expert Panel reviewed and revised subsequent versions of the survey. Three consecutive online surveys were conducted from August 2021 through October 2021 to obtain a consensus on the factors included in the RIJ. The participants of the online survey received an
email invitation from a member of the Expert Panel. The email invitation contained a link to the online survey. Participants were asked to rate the importance of each factor using a six-point Likert scale (1 = not important at all; 6 = extremely important) and offer written feedback/suggestions. Consensus on factors that should be included in the rurality index was set a priori and defined as at least 80% agreement (we regarded 5 or 6 as agreement) based upon recommendations and consensus levels used in the previous Delphi studies\(^{24,25,26}\).

The demographic characteristics of the survey participants and the level of consensus for each factor were examined using descriptive statistics, including frequencies and percentages. Comments/suggestions on survey items were transcribed into a single report for review and discussed by the Expert Panel. There were three surveys. Following the first survey, the expert panel reviewed the results and feedback from survey participants. The second survey retained the factors that had met the 80% agreement threshold, and proposed factors that had been revised based on the feedback. Only participants who responded to the first survey were invited to complete the second survey. The third survey incorporated the results and feedback from the second survey. Participants who responded to the second survey were invited to complete the third survey.
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. We utilized the calculated value from the factor loading as the weight of each factor.

Phase 3: Validation test

Factorial validity was verified using the results obtained from the exploratory factor analysis conducted in Phase 2. Convergent validity was examined by calculating the Pearson correlation coefficient between the index for physician distribution per 100,000 people and the developed rurality index. The index for physician distribution was developed from the standardized number of physicians and the population and standardized consultation ratio in each region. This index has been used to describe the uneven distribution of doctors in secondary or tertiary healthcare service areas.

Therefore, in this study, we evaluated the correlation between the RIJ and the index for physician distribution in each secondary healthcare service area. Criterion-related
validity was assessed by calculating the correlation between average life expectancy\textsuperscript{30} in each municipality and the rurality index because a previous study reported that rurality is negatively correlated with life expectancy\textsuperscript{31} and there are no other suitable rurality indices in Japan by which to evaluate criterion-related validity. We also calculated the cut-off of the RIJ using “depopulated area” and “disadvantaged area,” which are the existing definitions of rurality in Japan, as the reference standards. The cut-off was determined using the Youden index. All statistical analyses were conducted using StataCorp 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC

**Ethics approval**

The study protocol was performed following the Declaration of Helsinki, reviewed and approved by the Ethics Committee of Yokohama City University (approval number: B210100001). Informed consent was obtained from all study participants.

**Results**

In Phase 1, out of 100 potential participants, 85 responded to the survey (response rate: 85%, median age: 45 years, males: 55.3%, females: 43.5%, and prefer
not to answer: 1.2%). The participants’ demographic characteristics in the first, second, and third surveys are shown in Table 1. Table 2 shows the list of potential factors determined by the survey participants and through the results of the first and second surveys. The changes of the term or combining the factors determined by the Expert Panel are also described in Table 2. 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. At the end of the first survey round, only two factors remained: remote islands and direct distance to the nearest secondary or tertiary hospital. Thus, the Expert Panel decided further discussion was necessary to modify the other factors’ expression. Through the Expert Panel members’ discussion, legal terms such as ‘disadvantaged areas’ and ‘heavy snowfall areas’ were changed because the meaning of the terms might be difficult to understand for the participants. The changes in the items are shown in Table 2. In the second round of surveying, only participants who had completed the first round were asked to complete the second survey round. 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.

Table 1. Participants’ demographic characteristics

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
<th>First survey</th>
<th>Second survey</th>
<th>Third survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=85</td>
<td>N=66</td>
<td>N=56</td>
<td></td>
</tr>
<tr>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Response rate (%)</td>
<td>85</td>
<td>77.6</td>
<td>84.8</td>
</tr>
<tr>
<td>Age (year)</td>
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</tbody>
</table>

Page 19 of 50
<table>
<thead>
<tr>
<th>Age Group</th>
<th>Male</th>
<th>Female</th>
<th>Prefer not to answer</th>
<th>Others</th>
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<td>20-29</td>
<td>4 (4.7)</td>
<td>3 (4.6)</td>
<td>2 (3.6)</td>
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</tr>
<tr>
<td>30-39</td>
<td>30 (35.3)</td>
<td>22 (33.3)</td>
<td>14 (25.0)</td>
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</tr>
<tr>
<td>40-49</td>
<td>28 (32.9)</td>
<td>21 (31.8)</td>
<td>16 (28.6)</td>
<td></td>
</tr>
<tr>
<td>50-59</td>
<td>12 (14.1)</td>
<td>11 (16.7)</td>
<td>10 (17.9)</td>
<td></td>
</tr>
<tr>
<td>60-69</td>
<td>5 (5.9)</td>
<td>4 (6.1)</td>
<td>56 (10.7)</td>
<td></td>
</tr>
<tr>
<td>70-79</td>
<td>6 (7.1)</td>
<td>5 (7.6)</td>
<td>8 (14.3)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Education</th>
<th>High school</th>
<th>College</th>
<th>University</th>
<th>Masters</th>
<th>Doctorate</th>
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</thead>
<tbody>
<tr>
<td>Male</td>
<td>7 (8.2)</td>
<td>11 (12.9)</td>
<td>46 (54.1)</td>
<td>16 (18.8)</td>
<td>5 (5.9)</td>
</tr>
<tr>
<td>Female</td>
<td>5 (7.6)</td>
<td>10 (15.2)</td>
<td>38 (57.6)</td>
<td>11 (16.7)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>1 (1.2)</td>
<td>1 (1.5)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Others</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Occupation

<table>
<thead>
<tr>
<th>Occupation</th>
<th>First survey</th>
<th>Second survey</th>
<th>Third survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>43 (50.6)</td>
<td>33 (50)</td>
<td>28 (50)</td>
</tr>
<tr>
<td>Nurse</td>
<td>8 (9.4)</td>
<td>7 (10.6)</td>
<td>4 (7.1)</td>
</tr>
<tr>
<td>Public health nurse</td>
<td>4 (4.7)</td>
<td>3 (4.5)</td>
<td>3 (5.4)</td>
</tr>
<tr>
<td>Local government staff</td>
<td>2 (2.4)</td>
<td>1 (1.5)</td>
<td>2 (3.6)</td>
</tr>
<tr>
<td>Not employed</td>
<td>7 (8.2)</td>
<td>6 (9.1)</td>
<td>8 (14.3)</td>
</tr>
</tbody>
</table>

Although the participants who did not join the second survey were not invited to the third survey, in some categories (e.g. 60-69 years old), the number of participants in the third survey was higher than that in the second survey. This might be explained by the wrong input of the participants or participant aging between surveys.

Table 2. Percentages of agreement in potential factors for the RIJ

<table>
<thead>
<tr>
<th>Potential factors</th>
<th>First survey</th>
<th>Second survey</th>
<th>Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population density</td>
<td>77.6</td>
<td>68.2</td>
<td>Third survey</td>
</tr>
<tr>
<td>Service</td>
<td>Distance 1</td>
<td>Distance 2</td>
<td>Decision</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>------------</td>
<td>------------</td>
<td>----------</td>
</tr>
<tr>
<td>Distance to the nearest secondary or tertiary hospital</td>
<td>83.5</td>
<td>Included</td>
<td></td>
</tr>
<tr>
<td>Distance to the nearest hospital which provides care for patients with acute stroke</td>
<td>74.1</td>
<td>83.4</td>
<td>Combined into “distance to the nearest secondary or tertiary hospital”</td>
</tr>
<tr>
<td>Distance to the nearest hospital which provides care for patients with an acute heart attack</td>
<td>76.5</td>
<td>86.4</td>
<td>Combined into “distance to the nearest secondary or tertiary hospital”</td>
</tr>
<tr>
<td>Distance to the nearest hospital which provides care for pregnant women for delivery</td>
<td>72.9</td>
<td>77.3</td>
<td>Rejected</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Changed into</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disadvantaged Area</td>
<td>57.6</td>
<td>“population decline rate” †</td>
</tr>
<tr>
<td>Heavy Snowfall area</td>
<td>49.4</td>
<td>Combined with</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“Whether weather such as heavy snow influences access to the nearest secondary or tertiary hospital”</td>
</tr>
<tr>
<td>Remote island</td>
<td>90.6</td>
<td>Included</td>
</tr>
<tr>
<td>Remote island with a clinic or hospital</td>
<td>92.9</td>
<td>Combined into “remote island”</td>
</tr>
<tr>
<td>Bridge between remote island and main island</td>
<td>81.2</td>
<td>Combined into “remote island”</td>
</tr>
<tr>
<td>Whether weather such as heavy snow influences access</td>
<td>75.2</td>
<td>83.3</td>
</tr>
<tr>
<td>Service</td>
<td>Score 1</td>
<td>Score 2</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>Availability of public transportation to the nearest secondary hospital</td>
<td>70.6</td>
<td>59.1</td>
</tr>
<tr>
<td>Availability of emergency helicopter to the nearest secondary hospital</td>
<td>65.9</td>
<td>78.8</td>
</tr>
<tr>
<td>Availability of house call management for elderly</td>
<td>41.2</td>
<td>53.0</td>
</tr>
<tr>
<td>Community General Support Center</td>
<td>27.1</td>
<td>50.0</td>
</tr>
<tr>
<td>Availability of care management for elderly</td>
<td>34.1</td>
<td>78.8</td>
</tr>
<tr>
<td>Population decline rate</td>
<td>54.5</td>
<td></td>
</tr>
<tr>
<td>Proportion of people aged 65 years and over</td>
<td>68.2</td>
<td></td>
</tr>
</tbody>
</table>
Proportion of people aged 15-29 years

<table>
<thead>
<tr>
<th>Proportion</th>
<th>59.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rejected</td>
<td></td>
</tr>
</tbody>
</table>

Comments

Distance to the nearest pharmacy

Availability of CT/MRI

Physician/population ratio

† The definition of the disadvantaged area included the population decline rate.

Community General Support Center: The center provides community-based-integrated care, including living arrangements, social care, and daily life support services.\(^{32}\)

Care management: Care management means coordination by licensed care managers of the different services provided by different providers to accommodate geographically dispersed home settings.\(^{32}\)

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. Because the line between secondary and tertiary care is ambiguous in Japan and because the survey participants regarded care for acute diseases, such as stroke, heart attacks, and obstetrical delivery, as important, we included both secondary and tertiary hospitals. We also defined a remote island as an island other than the four main islands in Japan (Hokkaido, Honshu, Shikoku, and Kyushu) and an island without a secondary or tertiary hospital. Additionally, the Expert Panel defined areas in which “access to a secondary or tertiary hospital is affected by the weather” as “special heavy snowfall areas” based on the Act on Special Measures concerning Countermeasures for Heavy Snowfall Areas because in Japan, access to healthcare services in such areas is mainly hindered by typhoons and heavy snowfall, and typhoons may already be accounted for by the factor of “remote islands.” The Expert Panel regarded the zip code areas in special heavy snowfall areas and those without a secondary or tertiary hospital as the areas in which “access to a secondary or tertiary hospital is affected by the weather.”

For all the 113,952 zip codes in Japan, we calculated population density and direct distance to the nearest secondary or tertiary hospital. We identified every zip code
associated with a remote island and special heavy snowfall areas. Two common factors were extracted based on the initial explanatory factor analysis. Factor loadings were rotated using the Promax rotation to interpret the factors. Therefore, population density and special heavy snowfall areas were classified into one group labelled “population/climate factors.” In addition, direct distance to the nearest secondary or tertiary hospital and remote islands were grouped as “distance factors.” 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. We employed the factor loadings as the weight of each factor and created a pre-conversion RIJ as follows:

\[
\text{Pre-conversion RIJ} = \text{population density} \times (-0.3) + \text{direct distance to the nearest secondary or tertiary hospital} \times 0.46 + \text{remote islands} \times 0.47 + \text{special heavy snowfall areas} \times 0.3
\]

We calculated the pre-conversion RIJ and converted the score into integers. The total scores were ranked on a scale of 1–100, and they were used as the RIJ. Higher scores represented increased levels of rurality.

The average rurality index for every zip code in Japan was 50.5 (standard deviation (SD): 28.9), and the average rurality index in depopulated areas was 75.7 (SD: 20.6), and that in disadvantaged areas was 66.9 (SD: 24.9). We also calculated the
rurality index for every municipality and secondary healthcare service area using an average of the pre-converted RIJ for each area. We created the maps based on the RIJ for every zip code, municipality, and secondary care service area. The maps are shown in Figures 2(a), 2(b), and 2(c). 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.

We also examined the correlation between the RIJ and the index for physician distribution in each secondary healthcare service area or the average life expectancy in each municipality. The correlation coefficient of the RIJ through the index for physician distribution was -0.45 (p<0.001). The correlation coefficients of the RIJ through the life expectancies of men and women were -0.35 (p<0.001) and -0.12 (p<0.001), respectively. The scatter plots are shown in Figures 3(a), 3(b), and 3(c).

We used receiver operating characteristic (ROC) curves to plot the sensitivity (true positive rate) against the specificity (false positive rate) of the pre-conversion RIJ using the depopulated areas and disadvantaged areas as the reference standards. The
Youden value indicates the optimal cut-off value. The cut-off value of the pre-conversion RIJ for depopulated areas is 0.00197, the sensitivity at the cut-off is 0.65, the specificity at the cut-off is 0.84, and the area under the curve at the cut-off is 0.83. For disadvantaged areas, the cut-off value is 0.00147, the sensitivity at the cut-off is 0.74, the specificity at the cut-off is 0.79, and the area under the curve at the cut-off is 0.84. The ROC curves are shown in the supplementary files: Figures S1(a) and S1(b).

Discussion

Summary of the findings

We developed the RIJ using a modified Delphi method. This is the first study to create a rurality index for healthcare in Japan. The index comprises four factors: population density in each zip code, direct distance to the nearest secondary or tertiary hospital from the center of each zip code area, remote islands, and whether weather, such as typhoons or heavy snowfall influences access to the nearest secondary or tertiary hospital. The RIJ showed good factorial, convergent, and criterion-related validities. 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.

Comparison with existing literature

Two of the included factors, population density, and distance to the nearest secondary or tertiary hospital, were consistent with previously developed rurality indices in other countries or regions. Our previous scoping review revealed that population density is the most frequently used factor, whereas distance and time are the second most frequently used factors. Another common factor is resource availability, such as the number of physicians, including primary care physicians and specialists, or the physician/population ratio. However, in Japan, the boundary between primary care and secondary care is unclear, and defining a primary care provider is difficult. Therefore, such resource availability may not have been identified as a factor of rurality in a Delphi method used in this study.

Inherently, rurality is dependent on the context of each country or region. The remaining two factors, remote islands, and weather might reflect the Japanese context. Similarly, Scotland includes remote islands in their rurality index, and as such, their index might be similar to that used in Japanese contexts. Moreover, because climate change can affect access to healthcare, the inclusion of weather in a rurality index might become important for other countries.
The RIJ showed acceptable validity. We assessed factorial, convergent, and
criterion-related validities. In previous studies, only 29% of all indices examined
validity\(^6\). Content validity is crucial owing to its context-specific nature\(^6\), and
cconducting validation using different aspects is a major strength of our study.

Limitations of the study

First, we employed direct distance rather than actual distance to assess the
distance from each zip code to the nearest hospital owing to the difficulty of measuring
the actual distance. However, direct distance and actual distance are relatively
correlated\(^38\). Therefore, the use of direct distance should not skew the index. Second, we
did not consider the availability and frequency of public transportation, such as ships or
airplanes. These factors are important for rural residents, especially islanders. Because
information on the availability and frequency of public transportation might change
often, employing it in the rurality index for all of Japan is difficult, and it may result in
inconsistencies over time. However, in Japan, public transportation is mainly utilized in
metropolitan areas compared to rural prefectures\(^39\). Therefore, the lack of or the
frequency of public transportation, as they pertain to the RIJ, might not affect most rural
areas. Third, the figures for the included factors may change over time. For example, the
special snowfall areas also may change due to global warming. Therefore, we shall
update the data and share the new RIJ on our website to ensure easy access for
researchers and policymakers.

Implication of the study

As expected, this study revealed that the RIJ negatively correlates with
physician distribution and life expectancy among men and women. Because there is
currently no index for describing the degree of rurality in Japan, the RIJ can be utilized
to evaluate rural-urban discrepancies related to health outcomes and the health
workforce. The RIJ can also be used to determine the required scope of practice in each
rurality level, as is the case in Australia\textsuperscript{40}.

Conclusions

In this study, we developed a rurality index in Japan (RIJ) using a modified Delphi
method. The index showed good factorial, convergent, and criterion-related validities.
The RIJ can be a useful tool for assessing rural-urban disparity, workforce recruitment
and retention policies, as well as accessibility to other health care resources in rural
areas throughout Japan.
Declarations

Acknowledgements

We thank the members of the committee of rural and remote medicine in the Japan Primary Care Association. We also thank Kenichi Takeshita, Tokyo Map Research Inc. and Tsugio Kote, Daylight Co., Ltd. for their support in creating the maps. We would like to thank Editage (www.editage.com) for English language editing.

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Competing interest

There are no potential competing interests to be declared relevant to this work.

Contributors

MK designed the study and participated in the implementation, data collection, data
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Figure legends
Figure 1. Flow chart of the process of development and validation of the Rurality Index for Japan.

Figure 2(a). The Rurality Index for Japan by zip code.

Figure 2(b). The Rurality Index for Japan by the municipality.

Figure 2(c). The Rurality Index for Japan by secondary healthcare service area.

Figure 3(a). Scatter plot of the Rurality Index for Japan and the index for physician distribution.

Figure 3(b). Scatter plot of the Rurality Index for Japan and life expectancy of men.

Figure 3(c). Scatter plot of the Rurality Index for Japan and life expectancy of women.

Figure S1(a). Receiver Operating Characteristic (ROC) curves of the Rurality Index for Japan for predicting depopulated areas

Figure S1(b). Receiver Operating Characteristic (ROC) curves of the Rurality Index for Japan for predicting disadvantaged areas
### Phase 1: Modified Delphi method

#### Round 1: Identifying the Expert Panel
The Expert Panel was convened from across Japan.

#### Round 2: Identifying the important factors for a Rurality Index for Japan (RIJ)
The Expert Panel developed the list of factors for the RIJ.

#### Round 3: Online surveys
Three consecutive online surveys were conducted on 100 survey participants.

---

### Phase 2: Development of formulation of the RIJ

#### To normalize the included factors
Mini-max normalization

#### To determine the factor structure and weight
Exploratory factor analysis

---

### Phase 3: Validation test

#### Content validity
Discussion on domains by the Expert Panel

#### Factorial validity
Factor analysis

#### Convergent validity
Correlation between the RIJ and the index for physician distribution

#### Criterion-related validity
Correlation between the RIJ and average life expectancy

#### Determining cut-off value
Receiver Operating Characteristic curve and Youden index
Sensitivity: 0.65
Specificity: 0.84

Area under ROC curve = 0.8279
### STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item #</th>
<th>Recommendation</th>
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</table>
| Title and abstract     | 1,3    | *(a)* Indicate the study’s design with a commonly used term in the title or the abstract  
*(b)* Provide in the abstract an informative and balanced summary of what was done and what was found | 1,3                |
<p>| Introduction           | 2      | Explain the scientific background and rationale for the investigation being reported | 5,6                |
| Objectives             | 3      | State specific objectives, including any prespecified hypotheses                   | 6                  |
| Methods                |        |                                                                                 |                    |
| Study design           | 4      | Present key elements of study design early in the paper                            | 7                  |
| Setting                | 5      | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 7-15              |
| Participants           | 6      | <em>(a)</em> Give the eligibility criteria, and the sources and methods of selection of participants | 9-12              |
| Variables              | 7      | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 13,14             |
| Data sources/ measurement | 8*  | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 13-15             |
| Bias                   | 9      | Describe any efforts to address potential sources of bias                           | 7-15              |
| Study size             | 10     | Explain how the study size was arrived at                                          | 7-12              |
| Quantitative variables | 11     | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 13,14             |
| Statistical methods    | 12     | <em>(a)</em> Describe all statistical methods, including those used to control for confounding | 13-15             |
|                        |        | <em>(b)</em> Describe any methods used to examine subgroups and interactions               | Not applicable    |
|                        |        | <em>(c)</em> Explain how missing data were addressed                                       | Not applicable    |
|                        |        | <em>(d)</em> If applicable, describe analytical methods taking account of sampling strategy | Not applicable    |
|                        |        | <em>(e)</em> Describe any sensitivity analyses                                            | Not applicable    |
| Results                |        |                                                                                 |                    |</p>
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<tr>
<td>Participants</td>
<td>13*</td>
<td>(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed</td>
<td>16</td>
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<td>(b) Give reasons for non-participation at each stage</td>
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<td>(c) Consider use of a flow diagram</td>
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<tr>
<td>Descriptive data</td>
<td>14*</td>
<td>(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders</td>
<td>16-18</td>
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<td>(b) Indicate number of participants with missing data for each variable of interest</td>
<td>16-18</td>
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<tr>
<td>Outcome data</td>
<td>15*</td>
<td>Report numbers of outcome events or summary measures</td>
<td>16-19</td>
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<td>Main results</td>
<td>16</td>
<td>(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included</td>
<td>16-22</td>
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<td>(b) Report category boundaries when continuous variables were categorized</td>
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<td>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period</td>
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<tr>
<td>Other analyses</td>
<td>17</td>
<td>Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses</td>
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<tr>
<td>Discussion</td>
<td>18</td>
<td>Summarise key results with reference to study objectives</td>
<td>22</td>
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<tr>
<td>Limitations</td>
<td>19</td>
<td>Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias</td>
<td>23,24</td>
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<tr>
<td>Interpretation</td>
<td>20</td>
<td>Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence</td>
<td>22-24</td>
</tr>
<tr>
<td>Generalisability</td>
<td>21</td>
<td>Discuss the generalisability (external validity) of the study results</td>
<td>23,24</td>
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<td>Other information</td>
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<td>Funding</td>
<td>22</td>
<td>Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based</td>
<td>26</td>
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.
# Development and validation of a rurality index for health care research in Japan: A modified Delphi study

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Development and validation of a rurality index for health care research in Japan:

A modified Delphi study

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Word count: 4,422
Abstract

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.

**Strengths and limitations of this study**

- This is the first study to develop a rurality index for use in Japanese healthcare research.
- The index showed good validity.
- The index can utilize both at the zip code level and municipality level in Japan.
- We did not consider the availability and frequency of public transportation, such as...
ships or airplanes because of the difficulty of gathering the information.

**Introduction**

Rural-urban healthcare disparities exist globally, regardless of a country's level of development. These disparities pose challenges to policymakers, healthcare providers, and the public. People who live in rural areas have more chronic diseases compared to those living in urban areas. Furthermore, rural areas have fewer healthcare providers owing to difficulties in recruiting and retaining a workforce. In response to these issues, various countries have developed a rurality index for evaluating rural-urban health disparities and developing evidence-based policies. Rurality indices, such as the Rurality Index of Ontario (RIO) in Canada and the Modified Monash Model in Australia have been used successfully in clinical research and policymaking. There are no universal measures or approaches for developing a rurality index because rurality is context-specific. For instance, RIO was developed using population density, time to the nearest basic referral center, and time to the nearest advanced referral center. However, remote islands were not considered. Yet, Scotland’s rurality index, “clinical peripherality”, considers remote islands because Scotland has several remote islands. Therefore, each country or region must develop a rurality index based on their specific contexts.
Definitions of rural area in Japan

Japan has many remote islands in which 683,000 people (0.5% of the overall population) live. Additionally, 11 million people live in rural “depopulated areas” (11% of the overall population and 58% of all the areas). Japan has some areas that experience heavy snowfall, and people living in these areas have limited access to healthcare during the winter months. As a consequence, Japan developed several definitions of “rural”. “Depopulated area” is determined by the municipality’s income, demand, and population decline rate. “Disadvantaged area” is defined similarly to the depopulated area or by several acts of legislation addressing remote islands or areas that experience heavy snowfall, such as the “Remote Islands Development Act” and the “Act on Special Measures concerning Countermeasures for Heavy Snowfall Areas”.

The Act on Special Measures concerning Countermeasures for Heavy Snowfall Areas determines heavy snowfall areas and special heavy snowfall areas. “Special Heavy Snowfall Areas,” which account for approximately 20% of all land in Japan, represent areas in which heavy snow can hinder transportation and disrupt the daily lives of the residents. This Act was legislated in 1962 and has been reviewed 10 times, with the last update in 2007. However, the above definitions of “rural” have been used mainly for deciding the national government’s subsidy to residents and local governments but
not for Japan’s healthcare system.

**Healthcare system in Japan**

In Japan, the governance of medical care is under the Ministry of Labor, Health and Welfare, which is responsible for policy setting and administration. Local governments are responsible for the delivery of primary, secondary, and tertiary care. Generally, in Japanese settings, primary care means patient care in the outpatient setting, and secondary care refers to hospitalized care. Tertiary care plays a significant role in providing advanced medical care, such as organ transplantation or surgical procedures for rare congenital diseases. 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. Primary care service areas comprise approximately 1,700 districts (e.g., cities, towns, and villages), secondary care service areas comprise 344 jurisdictions, and tertiary care service areas comprise 52 areas. The provisioning system for emergency care is essentially based on the population of each secondary care service area. Japan’s
“rural area” in healthcare policy has been mainly based on population and the distance to the nearest medical institution; the area is called “non-doctor districts”\textsuperscript{15}. 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.

Aims

The aim of this study was to develop and validate a rurality index for Japan (RIJ) for use in Japanese healthcare policy development and research. As a first step toward developing a RIJ, we conducted a scoping review in 2020\textsuperscript{6}. The review identified frequently used variables, methods for calculating indices, and validation measures used in previous rurality indices over the past 30 years\textsuperscript{6}. In this study, we developed and validated a RIJ based on the results of our scoping review\textsuperscript{6} and the
consensus of healthcare providers, policymakers, and residents using the Delphi method.

Methods

Study Design

We employed a modified Delphi method in this study. The Delphi method is suitable for establishing consensus for the research problem, which can benefit from subjective judgments on a collective basis. The Delphi method facilitates anonymity in responses, gathers expert opinions, employs sequential questionnaires without face-to-face discussions, and uses frequency distributions to identify patterns of agreement through two or more rounds of surveying. The approach is used widely in medical and health services research. The modified Delphi method, unlike the original Delphi, offers a research team the opportunity to discuss opinions between survey rounds.

Procedure and statistical analysis

Figure 1 shows the flow chart of the process of development and validation of
This study included three Phases and three Rounds of data collection under the RIJ. Briefly, in Phase 1, Round 1, we convened an Expert Panel. In Round 2, the Expert Panel identified potential factors for the RIJ based on a previously conducted scoping review. In Round 3, the Expert Panel developed a survey including the identified potential factors. They recruited 100 participants with expertise in rural healthcare and conducted three sets of surveys. In Phase 2, we developed the formulation of the RIJ based on the results of Phase 1. We subsequently conducted content, factorial, convergent and criterion-related validity assessments on the results as part of Phase 3. These Phases are described in detail below.

Phase 1: Modified Delphi methods for identifying and rating factors to be considered in RIJ:

Round 1: Developing an Expert Panel

The first step was to identify and convene an Expert Panel to oversee all aspects of the study. 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 rural areas across Japan including remote islands, mountain areas and heavy snow areas.

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.

Round 2: Identifying the crucial factors for the RIJ through the Expert Panel
For Round 2, the Expert Panel convened through a video conferencing meeting that was recorded. The second meeting was held on 8\textsuperscript{th} 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)\textsuperscript{6}. 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\textsuperscript{6}. For example, Japan has many remote islands\textsuperscript{8}, and sometimes, a patient can only access a secondary hospital by travelling by a ship or an airplane. Additionally, in Japan, secondary hospitals play a significant role as referral centers, and they provide out-of-hours care for patients who potentially require admission after hours\textsuperscript{10}. Therefore, travel distance or time to a secondary hospital must be considered. Access to medical facilities may also be affected by the weather. After the discussion, the Expert Panel developed a list of potential factors for the RIJ. They assessed content validity through discussions on domains and subdomains to be included in the survey\textsuperscript{20,21}. 

Based on the scoping review\textsuperscript{6} and their expertise.
Round 3: Online surveys (modified Delphi Methods)

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. An Expert Panel method was used to develop the survey. The initial draft of the survey was developed by one of the Expert Panel members (MK), and the Expert Panel reviewed and revised subsequent versions of the survey. Three consecutive online surveys were conducted from August 2021 through October 2021 to obtain a consensus on the factors included in the RIJ. The participants of the online survey received an email invitation from a member of the Expert Panel. The email invitation contained a link to the online survey. Participants were asked to rate the importance of each factor using a six-point Likert scale (1 = not important at all; 6 = extremely important) and offer written feedback/suggestions. Consensus on factors that should be included in the rurality index was set a priori and defined as at least 80% agreement (we regarded 5 or 6 as agreement) based upon recommendations and consensus levels used in the previous Delphi studies.

The demographic characteristics of the survey participants and the level of consensus for each factor were examined using descriptive statistics, including
frequencies and percentages. Comments/suggestions on survey items were transcribed into a single report for review and discussed by the Expert Panel. There were three surveys. Following the first survey, the expert panel reviewed the results and feedback from survey participants. The second survey retained the factors that had met the 80% agreement threshold, and proposed factors that had been revised based on the feedback. Only participants who responded to the first survey were invited to complete the second survey. The third survey incorporated the results and feedback from the second survey.

Participants who responded to the second survey were invited to complete the third survey.

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. We utilized the calculated value from the factor loading as the weight of each factor.

Phase 3: Validation test
Factorial validity was verified using the results obtained from the exploratory factor analysis conducted in Phase 2. Convergent validity was examined by calculating the Pearson correlation coefficient between the index for physician distribution per 100,000 people and the developed rurality index. The index for physician distribution was developed from the standardized number of physicians and the population and standardized consultation ratio in each region. This index has been used to describe the uneven distribution of doctors in secondary or tertiary healthcare service areas.

Therefore, in this study, we evaluated the correlation between the RIJ and the index for physician distribution in each secondary healthcare service area. Criterion-related validity was assessed by calculating the correlation between average life expectancy in each municipality and the rurality index because a previous study reported that rurality is negatively correlated with life expectancy and there are no other suitable rurality indices in Japan by which to evaluate criterion-related validity. We also calculated the cut-off of the RIJ using “depopulated area” and “disadvantaged area,” which are the existing definitions of rurality in Japan, as the reference standards. The cut-off was determined using the Youden index. All statistical analyses were conducted using StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC.
Patient and public involvement

This study invited residents in rural areas as stakeholders and participants of the Delphi survey. The residents were invited to comment on the study design and consulted on the relevance of the research.

Ethics approval

The study protocol was performed following the Declaration of Helsinki, reviewed and approved by the Ethics Committee of Yokohama City University (approval number: B210100001). Informed consent was obtained from all study participants.

Results

In Phase 1, out of 100 potential participants, 85 responded to the survey (response rate: 85%, median age: 45 years, males: 55.3%, females: 43.5%, and prefer not to answer: 1.2%). The participants’ demographic characteristics in the first, second, and third surveys are shown in Table 1. Table 2 shows the list of potential factors determined by the survey participants and through the results of the first and second surveys. The changes of the term or combining the factors determined by the Expert Panel are also described in Table 2. 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. At the end of the first survey round, only two factors remained: remote islands and direct distance to the nearest secondary or tertiary hospital. Thus, the Expert Panel decided further discussion was necessary to modify the other factors’ expression. Through the Expert Panel members’ discussion, legal terms such as ‘disadvantaged areas’ and ‘heavy snowfall areas’ were changed because the meaning of the terms might be difficult to understand for the participants. The changes in the items are shown in Table 2. In the second round of surveying, only participants who had completed the first round were asked to complete the second survey round. 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.

Table 1. Participants’ demographic characteristics

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
<th>First survey</th>
<th>Second survey</th>
<th>Third survey</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=85</td>
<td>N=66</td>
<td>N=56</td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Response rate (%)</td>
<td>85</td>
<td>77.6</td>
<td>84.8</td>
</tr>
<tr>
<td>Age (year)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-29</td>
<td>4 (4.7)</td>
<td>3 (4.6)</td>
<td>2 (3.6)</td>
</tr>
<tr>
<td>30-39</td>
<td>30 (35.3)</td>
<td>22 (33.3)</td>
<td>14 (25.0)</td>
</tr>
<tr>
<td>40-49</td>
<td>28 (32.9)</td>
<td>21 (31.8)</td>
<td>16 (28.6)</td>
</tr>
<tr>
<td>50-59</td>
<td>12 (14.1)</td>
<td>11 (16.7)</td>
<td>10 (17.9)</td>
</tr>
<tr>
<td>60-69</td>
<td>5 (5.9)</td>
<td>4 (6.1)</td>
<td>§ 6 (10.7)</td>
</tr>
<tr>
<td></td>
<td>70-79</td>
<td>20-79</td>
<td>50+</td>
</tr>
<tr>
<td>----</td>
<td>-------</td>
<td>-------</td>
<td>------</td>
</tr>
<tr>
<td>Male</td>
<td>47 (55.3)</td>
<td>36 (54.5)</td>
<td>29 (51.8)</td>
</tr>
<tr>
<td>Female</td>
<td>37 (43.5)</td>
<td>29 (43.9)</td>
<td>27 (48.2)</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>1 (1.2)</td>
<td>1 (1.5)</td>
<td>0</td>
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<tr>
<td>Others</td>
<td>0</td>
<td>0</td>
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**Gender**

**Education**

<table>
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<th>20-79</th>
<th>50+</th>
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<tbody>
<tr>
<td>High school</td>
<td>7 (8.2)</td>
<td>5 (7.6)</td>
<td>4 (7.1)</td>
</tr>
<tr>
<td>College</td>
<td>11 (12.9)</td>
<td>10 (15.2)</td>
<td>11 (19.6)</td>
</tr>
<tr>
<td>University</td>
<td>46 (54.1)</td>
<td>38 (57.6)</td>
<td>31 (55.4)</td>
</tr>
<tr>
<td>Masters</td>
<td>16 (18.8)</td>
<td>11 (16.7)</td>
<td>7 (12.5)</td>
</tr>
<tr>
<td>Doctorate</td>
<td>5 (5.9)</td>
<td>2 (3)</td>
<td>3 (5.4)</td>
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**Occupation**

<table>
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<th>20-79</th>
<th>50+</th>
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</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>43 (50.6)</td>
<td>33 (50)</td>
<td>28 (50)</td>
</tr>
<tr>
<td>Nurse</td>
<td>8 (9.4)</td>
<td>7 (10.6)</td>
<td>4 (7.1)</td>
</tr>
<tr>
<td>Public health nurse</td>
<td>4 (4.7)</td>
<td>3 (4.5)</td>
<td>3 (5.4)</td>
</tr>
</tbody>
</table>
Although the participants who did not join the second survey were not invited to the third survey, in some categories (e.g. 60-69 years old), the number of participants in the third survey was higher than that in the second survey. This might be explained by the wrong input of the participants or participant aging between surveys.

Table 2. Percentages of agreement in potential factors for the RIJ

<table>
<thead>
<tr>
<th>Potential factors</th>
<th>First survey</th>
<th>Second survey</th>
<th>Decision</th>
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<tr>
<td>Population density</td>
<td>77.6</td>
<td>68.2</td>
<td>Third survey</td>
</tr>
<tr>
<td>Distance to the nearest secondary or tertiary hospital</td>
<td>83.5</td>
<td></td>
<td>Included</td>
</tr>
<tr>
<td>Distance to the nearest</td>
<td>74.1</td>
<td>83.4</td>
<td>Combined into</td>
</tr>
<tr>
<td>-------------------------</td>
<td>------</td>
<td>------</td>
<td>--------------</td>
</tr>
<tr>
<td>hospital which provides care for patients with acute stroke</td>
<td>“distance to the nearest secondary or tertiary hospital”</td>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Distance to the nearest</th>
<th>76.5</th>
<th>86.4</th>
<th>Combined into</th>
</tr>
</thead>
<tbody>
<tr>
<td>hospital which provides care for patients with an acute heart attack</td>
<td>“distance to the nearest secondary or tertiary hospital”</td>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Distance to the nearest</th>
<th>72.9</th>
<th>77.3</th>
<th>Rejected</th>
</tr>
</thead>
<tbody>
<tr>
<td>hospital which provides care for pregnant women for delivery</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Disadvantaged Area</th>
<th>57.6</th>
<th>Changed into</th>
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<tbody>
<tr>
<td>“population”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feature</td>
<td>Decline Rate (%)</td>
<td>Notes</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>Heavy Snowfall area</td>
<td>49.4</td>
<td>Combined with</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Whether weather such as heavy snow</td>
</tr>
<tr>
<td></td>
<td></td>
<td>influences access</td>
</tr>
<tr>
<td></td>
<td></td>
<td>to the nearest secondary or tertiary hospital&quot;</td>
</tr>
<tr>
<td>Remote island</td>
<td>90.6</td>
<td>Included</td>
</tr>
<tr>
<td>Remote island with a clinic or hospital</td>
<td>92.9</td>
<td>Combined into &quot;remote island&quot;</td>
</tr>
<tr>
<td>Bridge between remote island and main island</td>
<td>81.2</td>
<td>Combined into &quot;remote island&quot;</td>
</tr>
<tr>
<td>Whether weather such as heavy snow influences access</td>
<td>75.2 83.3</td>
<td>Included</td>
</tr>
</tbody>
</table>
### Availability of Public Transportation to the Nearest Secondary Hospital

<table>
<thead>
<tr>
<th>Availability of Public Transportation</th>
<th>70.6</th>
<th>59.1</th>
<th>Rejected</th>
</tr>
</thead>
</table>

### Availability of Emergency Helicopter to the Nearest Secondary Hospital

<table>
<thead>
<tr>
<th>Availability of Emergency Helicopter</th>
<th>65.9</th>
<th>78.8</th>
<th>Rejected</th>
</tr>
</thead>
</table>

### Availability of House Call

<table>
<thead>
<tr>
<th>Availability of House Call</th>
<th>41.2</th>
<th>53.0</th>
<th>Rejected</th>
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</thead>
</table>

### Community General Support Center

<table>
<thead>
<tr>
<th>Community General Support Center</th>
<th>27.1</th>
<th>50.0</th>
<th>Rejected</th>
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</thead>
</table>

### Availability of Care Management for Elderly

<table>
<thead>
<tr>
<th>Availability of Care Management for Elderly</th>
<th>34.1</th>
<th>78.8</th>
<th>Rejected</th>
</tr>
</thead>
</table>

### Additional Factors from the Second Survey by the Steering Team

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<th>Factor</th>
<th>Value</th>
<th>Rejected</th>
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</thead>
<tbody>
<tr>
<td>Population decline rate</td>
<td>54.5</td>
<td>Rejected</td>
</tr>
<tr>
<td>Proportion of people aged 65 years and over</td>
<td>68.2</td>
<td>Rejected</td>
</tr>
<tr>
<td>Proportion of people aged 15-29 years</td>
<td>59.1</td>
<td>Rejected</td>
</tr>
</tbody>
</table>
Comments

Distance to the nearest pharmacy

Availability of CT/MRI

Physician/population ratio

† The definition of the disadvantaged area included the population decline rate.

Community General Support Center: The center provides community-based-integrated care, including living arrangements, social care, and daily life support services.\(^3\)

Care management: Care management means coordination by licensed care managers of the different services provided by different providers to accommodate geographically dispersed home settings.\(^3\)

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. Because the line between secondary and tertiary care is ambiguous
in Japan and because the survey participants regarded care for acute diseases, such as stroke, heart attacks, and obstetrical delivery, as important, we included both secondary and tertiary hospitals. We also defined a remote island as an island other than the four main islands in Japan (Hokkaido, Honshu, Shikoku, and Kyushu) and an island without a secondary or tertiary hospital. Additionally, the Expert Panel defined areas in which “access to a secondary or tertiary hospital is affected by the weather” as “special heavy snowfall areas” based on the Act on Special Measures concerning Countermeasures for Heavy Snowfall Areas because in Japan, access to healthcare services in such areas is mainly hindered by typhoons and heavy snowfall, and typhoons may already be accounted for by the factor of “remote islands.” The Expert Panel regarded the zip code areas in special heavy snowfall areas and those without a secondary or tertiary hospital as the areas in which “access to a secondary or tertiary hospital is affected by the weather.”

For all the 113,952 zip codes in Japan, we calculated population density and direct distance to the nearest secondary or tertiary hospital. We identified every zip code associated with a remote island and special heavy snowfall areas. Two common factors were extracted based on the initial explanatory factor analysis. Factor loadings were rotated using the Promax rotation to interpret the factors. Therefore, population density
and special heavy snowfall areas were classified into one group labelled “population/climate factors.” In addition, direct distance to the nearest secondary or tertiary hospital and remote islands were grouped as “distance factors.” 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. We employed the factor loadings as the weight of each factor and created a pre-conversion RIJ as follows:

\[
\text{Pre-conversion RIJ} = \text{population density} \times (-0.3) + \text{direct distance to the nearest secondary or tertiary hospital} \times 0.46 + \text{remote island} \times 0.47 + \text{special heavy snowfall areas} \times 0.3
\]

We calculated the pre-conversion RIJ and converted the score into integers. The total scores were ranked on a scale of 1–100, and they were used as the RIJ. Higher scores represented increased levels of rurality.

The average rurality index for every zip code in Japan was 50.5 (standard deviation (SD): 28.9), and the average rurality index in depopulated areas was 75.7 (SD: 20.6), and that in disadvantaged areas was 66.9 (SD: 24.9). We also calculated the rurality index for every municipality and secondary healthcare service area using an average of the pre-converted RIJ for each area. We created the maps based on the RIJ for every zip code, municipality, and secondary care service area. The maps are shown...
In Figures 2(a), 2(b), and 2(c). 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.

We also examined the correlation between the RIJ and the index for physician distribution in each secondary healthcare service area or the average life expectancy in each municipality. The correlation coefficient of the RIJ through the index for physician distribution was -0.45 (p<0.001). The correlation coefficients of the RIJ through the life expectancies of men and women were -0.35 (p<0.001) and -0.12 (p<0.001), respectively. The scatter plots are shown in Figures 3(a), 3(b), and 3(c).

We used receiver operating characteristic (ROC) curves to plot the sensitivity (true positive rate) against the specificity (false positive rate) of the pre-conversion RIJ using the depopulated areas and disadvantaged areas as the reference standards. The Youden value indicates the optimal cut-off value. The cut-off value of the pre-conversion RIJ for depopulated areas is 0.00197, the sensitivity at the cut-off is 0.65, the specificity at the cut-off is 0.84, and the area under the curve at the cut-off is
0.83. For disadvantaged areas, the cut-off value is 0.00147, the sensitivity at the cut-off is 0.74, the specificity at the cut-off is 0.79, and the area under the curve at the cut-off is 0.84. The ROC curves are shown in the supplementary files: Figures S1(a) and S1(b).

Discussion

Summary of the findings

We developed the RIJ using a modified Delphi method. This is the first study to create a rurality index for healthcare in Japan. The index comprises four factors: population density in each zip code, direct distance to the nearest secondary or tertiary hospital from the center of each zip code area, remote islands, and whether weather, such as typhoons or heavy snowfall influences access to the nearest secondary or tertiary hospital. The RIJ showed good factorial, convergent, and criterion-related validities. 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.

Comparison with existing literature

Two of the included factors, population density, and distance to the nearest
secondary or tertiary hospital, were consistent with previously developed rurality indices in other countries or regions. Our previous scoping review revealed that population density is the most frequently used factor, whereas distance and time are the second most frequently used factors. Another common factor is resource availability, such as the number of physicians, including primary care physicians and specialists, or the physician/population ratio. However, in Japan, the boundary between primary care and secondary care is unclear, and defining a primary care provider is difficult. Therefore, such resource availability may not have been identified as a factor of rurality in a Delphi method used in this study.

Inherently, rurality is dependent on the context of each country or region. The remaining two factors, remote islands, and weather might reflect the Japanese context. Similarly, Scotland includes remote islands in their rurality index, and as such, their index might be similar to that used in Japanese contexts. Moreover, because climate change can affect access to healthcare, the inclusion of weather in a rurality index might become important for other countries.

The RIJ showed acceptable validity. We assessed factorial, convergent, and criterion-related validities. In previous studies, only 29% of all indices examined validity. Content validity is crucial owing to its context-specific nature, and
conducting validation using different aspects is a major strength of our study.

Limitations of the study

First, we employed direct distance rather than actual distance to assess the distance from each zip code to the nearest hospital owing to the difficulty of measuring the actual distance. However, direct distance and actual distance are relatively correlated. Therefore, the use of direct distance should not skew the index. Second, we did not consider the availability and frequency of public transportation, such as ships or airplanes. These factors are important for rural residents, especially islanders. Because information on the availability and frequency of public transportation might change often, employing it in the rurality index for all of Japan is difficult, and it may result in inconsistencies over time. However, in Japan, public transportation is mainly utilized in metropolitan areas compared to rural prefectures. Therefore, the lack of or the frequency of public transportation, as they pertain to the RIJ, might not affect most rural areas. Third, the figures for the included factors may change over time. For example, the special snowfall areas also may change due to global warming. Therefore, we shall update the data and share the new RIJ on our website to ensure easy access for researchers and policymakers.
Implication of the study

As expected, this study revealed that the RIJ negatively correlates with physician distribution and life expectancy among men and women. Because there is currently no index for describing the degree of rurality in Japan, the RIJ can be utilized to evaluate rural-urban discrepancies related to health outcomes and the health workforce. The RIJ can also be used to determine the required scope of practice in each rurality level, as is the case in Australia.40

Conclusions

In this study, we developed a rurality index in Japan (RIJ) using a modified Delphi method. The index showed good factorial, convergent, and criterion-related validities. The RIJ can be a useful tool for assessing rural-urban disparity, workforce recruitment and retention policies, as well as accessibility to other health care resources in rural areas throughout Japan.

Declarations

Acknowledgements
We thank the members of the committee of rural and remote medicine in the Japan Primary Care Association. We also thank Kenichi Takeshita, Tokyo Map Research Inc. and Tsugio Kote, Daylight Co., Ltd. for their support in creating the maps. We would like to thank Editage (www.editage.com) for English language editing.

**Funding**

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**Competing interest**

There are no potential competing interests to be declared relevant to this work.

**Contributors**

MK designed the study and participated in the implementation, data collection, data analysis, and writing of the manuscript. MK also serves as the guarantor. MI, KS, MS, RO, UC, EV, TRF, and MM contributed to the design of the study and critically reviewed the manuscript. MK and TI analyzed the data and drafted the manuscript. All
authors had full access to the data and take responsibility for the integrity of the data and the accuracy of the analysis.

Transparency

All authors had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity and accuracy of the data analyses. The lead author affirms that the manuscript is reliable and accurate and provides a transparent account of the study being reported, that no important aspects of the study have been omitted, and that any discrepancies from the study as planned have been explained.

Data sharing: The datasets are available from the corresponding author on reasonable request.

References

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37. Bernard SM, Samet JM, Grambsch A, Ebi KL, Romieu I. The potential impacts of climate variability and change on air pollution-related health effects in the


Figure legends

Figure 1. Flow chart of the process of development and validation of the Rurality Index for Japan.

Figure 2(a). The Rurality Index for Japan by zip code.
Figure 2(b). The Rurality Index for Japan by the municipality.

Figure 2(c). The Rurality Index for Japan by secondary healthcare service area.

Figure 3(a). Scatter plot of the Rurality Index for Japan and the index for physician distribution.

Figure 3(b). Scatter plot of the Rurality Index for Japan and life expectancy of men.

Figure 3(c). Scatter plot of the Rurality Index for Japan and life expectancy of women.

Figure S1(a). Receiver Operating Characteristic (ROC) curves of the Rurality Index for Japan for predicting depopulated areas

Figure S1(b). Receiver Operating Characteristic (ROC) curves of the Rurality Index for Japan for predicting disadvantaged areas
Phase 1: Modified Delphi method

Round 1: Identifying the Expert Panel
The Expert Panel was convened from across Japan.

Round 2: Identifying the important factors for a Rurality Index for Japan (RIJ)
The Expert Panel developed the list of factors for the RIJ.

Round 3: Online surveys
Three consecutive online surveys were conducted on 100 survey participants.

Phase 2: Development of formulation of the RIJ

To normalize the included factors
Mini-max normalization

To determine the factor structure and weight
Exploratory factor analysis

Phase 3: Validation test

Content validity
Discussion on domains by the Expert Panel

Factorial validity
Factor analysis

Convergent validity
Correlation between the RIJ and the index for physician distribution

Criterion-related validity
Correlation between the RIJ and average life expectancy

Determining cut-off value
Receiver Operating Characteristic curve and Youden index
Sensitivity: 0.65
Specificity: 0.84

Area under ROC curve = 0.8279
Sensitivity: 0.74
Specificity: 0.79

Area under ROC curve = 0.8397
### STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item #</th>
<th>Recommendation</th>
<th>Reported on page #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title and abstract</td>
<td>1</td>
<td>(a) Indicate the study's design with a commonly used term in the title or the abstract</td>
<td>1,3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Provide in the abstract an informative and balanced summary of what was done and what was found</td>
<td>3</td>
</tr>
<tr>
<td>Introduction</td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Background/rationale</td>
<td>2</td>
<td>Explain the scientific background and rationale for the investigation being reported</td>
<td>5,6</td>
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<tr>
<td>Objectives</td>
<td>3</td>
<td>State specific objectives, including any prespecified hypotheses</td>
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<td>Methods</td>
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<td>Study design</td>
<td>4</td>
<td>Present key elements of study design early in the paper</td>
<td>7</td>
</tr>
<tr>
<td>Setting</td>
<td>5</td>
<td>Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection</td>
<td>7-15</td>
</tr>
<tr>
<td>Participants</td>
<td>6</td>
<td>(a) Give the eligibility criteria, and the sources and methods of selection of participants</td>
<td>9-12</td>
</tr>
<tr>
<td>Variables</td>
<td>7</td>
<td>Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable</td>
<td>13,14</td>
</tr>
<tr>
<td>Data sources/ measurement</td>
<td>8*</td>
<td>For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group</td>
<td>13-15</td>
</tr>
<tr>
<td>Bias</td>
<td>9</td>
<td>Describe any efforts to address potential sources of bias</td>
<td>7-15</td>
</tr>
<tr>
<td>Study size</td>
<td>10</td>
<td>Explain how the study size was arrived at</td>
<td>7-12</td>
</tr>
<tr>
<td>Quantitative variables</td>
<td>11</td>
<td>Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why</td>
<td>13,14</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>12</td>
<td>(a) Describe all statistical methods, including those used to control for confounding</td>
<td>13-15</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Describe any methods used to examine subgroups and interactions</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(c) Explain how missing data were addressed</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(d) If applicable, describe analytical methods taking account of sampling strategy</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(e) Describe any sensitivity analyses</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>Item</td>
<td>Details</td>
<td></td>
</tr>
<tr>
<td>----------------------------------</td>
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<td></td>
</tr>
<tr>
<td>Participants</td>
<td>13*</td>
<td>(a) Report numbers of individuals at each stage of study—e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Give reasons for non-participation at each stage</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(c) Consider use of a flow diagram</td>
<td></td>
</tr>
<tr>
<td>Descriptive data</td>
<td>14*</td>
<td>(a) Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Indicate number of participants with missing data for each variable of interest</td>
<td></td>
</tr>
<tr>
<td>Outcome data</td>
<td>15*</td>
<td>Report numbers of outcome events or summary measures</td>
<td></td>
</tr>
<tr>
<td>Main results</td>
<td>16</td>
<td>(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders were adjusted for and why they were included</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(b) Report category boundaries when continuous variables were categorized</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period</td>
<td></td>
</tr>
<tr>
<td>Other analyses</td>
<td>17</td>
<td>Report other analyses done—e.g. analyses of subgroups and interactions, and sensitivity analyses</td>
<td></td>
</tr>
<tr>
<td>Discussion</td>
<td>18</td>
<td>Summarise key results with reference to study objectives</td>
<td></td>
</tr>
<tr>
<td>Limitations</td>
<td>19</td>
<td>Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias</td>
<td></td>
</tr>
<tr>
<td>Interpretation</td>
<td>20</td>
<td>Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence</td>
<td></td>
</tr>
<tr>
<td>Generalisability</td>
<td>21</td>
<td>Discuss the generalisability (external validity) of the study results</td>
<td></td>
</tr>
<tr>
<td>Other information</td>
<td>22</td>
<td>Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based</td>
<td></td>
</tr>
</tbody>
</table>

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.