Original article

A missing factor in the reporting of medical research outcomes: Geographic classification of participants

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Abstract
Background: It is known that rurally-residing individuals are often at a significant health disadvantage when compared to urban peers. Improving the health of rural residents has been directly identified as a key priority across the world; however, as models of healthcare are primarily derived from evidence-based research, any failure by the researcher base to consider rural needs may result in a poor alignment of health services against actual need. This paper reviews how consistently participants' geographic classification is identified and considered as a factor in research reported in a leading medical journal, *The Lancet*.

Method: Using a predetermined definition of rurality as being locations with a population below 100,000 people, 300 eligible articles were reviewed retrospectively from *The Lancet*'s 2015-2017 editions. The purpose was to establish if the methodology and findings of these 300 research papers actively considered the geographic classification of participants.

Results: In approximately 60% of the 300 reviewed studies it was not possible to accurately determine participants' geographic classification. Only 2% of papers focused on rural participants in isolation, with 18% using solely urban residents. The remaining 20% of papers had both rural and urban participants.

Conclusion: This sample of *The Lancet* articles indicates minimal attention has been paid to participants' geographic classification. This failure to consider the relevance of location as a factor in outcomes potentially limits the applicability of research findings to a significant proportion of the community, and raises concerns about using such evidence bases for determining national health frameworks and practice guidelines.

Keywords: geographic classification, health disadvantage, urban, rural.

Introduction

In both developed and developing countries around the world there is a substantial proportion of people living outside of large cities; it is estimated by the United Nations that 46% of the world's population reside outside urban areas[1]. While there is no one world-wide standard definition of what constitutes a rural setting versus an urban one,[2] using different developed country's own definitions reveal substantial proportions of the population living in rural areas. Approximately 20% of the United States of America (USA) population, around 60 million people, reside in a rural location.[3] The United Kingdom (UK) is similar, with 17% of the population, or 9.3 million people, living in a rural area.[4] In Australia, the distribution of rural to urban residents is slightly different, with approximately 70% of the population living in the major urban locations.[5] The remaining 30% of Australia's population represents over 6.8 million rural people,[6] which, to provide a context, is around 35% bigger than Australia's most populous city of Sydney.

It is known that individuals who live in rural and remote areas are often at a significant social and health disadvantage when compared to urban peers within the same country. Rurality in a number of developed countries, including Australia, USA, UK, New Zealand, and Canada, is linked to socioeconomic disadvantage, reduced health and basic service access, lowered employment opportunities, and poor public transportation.[7] Life expectancy for rural residents in countries such as Australia and the USA are lower than for urban dwellers, and the gap is widening,[8,9] with contributing factors including higher death rates from diseases such as cancer.[10] Rural residents can expect to face higher levels of unemployment, reduced access to essential services and support including housing, education, transport, and healthcare, and have an overall lower socioeconomic status.[11-15]

Improving the health of rural residents has been directly identified as a key priority over the past decade in key centres including, but not limited to, Europe,[16] the USA,[17] UK,[18] Australia,[19] and China.[20] If new models of healthcare, best practice guidelines and government health policies are derived from evidence-based research, any failure to proactively consider medical outcomes specifically for rural residents may result in a poor alignment of health care services against actual need in certain locations. The goal of this paper was therefore to review how consistently the geographic classification of participants is identified and considered as a factor when reporting the outcomes of medical research. No similar geographically focused reviews of research articles in *The Lancet* have been identified.

Method

Definition of Rurality

For the purpose of the current investigation, a consistent divide between rural and urban was required and it was determined that a location would be classified as rural if it had a population below 100,000 people. The rationale and methodology used to establish this figure has been published previously.[21] It is acknowledged that the cut-off

mark of 100,000 is arbitrary, but the numerous different and sometimes contradictory classifications of 'rural' and 'urban' across the world[22-24] meant that any other single definition will be equally open to argument.

Review process

The Lancet was chosen as the target journal for this review, both due to its longstanding excellence and its scope of international medical research that would include countries with a range of rural and urban locations. A figure of 300 original research article reviews was nominated prior to commencement in order to establish a large sample of research.

The author was responsible for data extraction from the 300 original research articles. The Abstract, Methods and Results section of each paper was read initially to attempt to determine the geographic classification of the study's participants. If this information could not be determined, the entire paper was then read in an attempt to establish any further information that could accurately identify participant locations. In-text referrals to previously published papers for additional information were not pursued, unless it was explicitly stated that geographic information was available. If the article nominated a location for the research, an online search was conducted when appropriate to determine the population of the site.

Exclusions for the search included all Editorials, Comments, World Reports, Perspectives or Viewpoints, Correspondence, rejoinders, systematic or literature reviews, meta-analyses, purely theoretical frameworks or models, reviews of policy documents, book reviews, opinions and perspectives, Department of Error, and any Retracted Articles. The review started with Volume 390, Number 10090, p95-202 [8 July 2017], and worked sequentially backwards through all eligible research articles until the pre-nominated target of 300 articles was reached in Volume 386 Number 10002 p1419-1508 [10 October 2015].

The classification system used to assess the 300 papers was: solely rural, solely urban, both urban and rural, or not specified/unable to determine. All data were recorded on a spreadsheet. Research that was 'solely rural' or 'solely urban' provided sufficient detail for the reader to establish a population-based location for participants. Research was categorized as 'both urban and rural' if the paper specified that recruitment and participation covered entire regions with both urban and rural areas (for example, questionnaires sent to all medical practitioners in the state of New South Wales). However, imprecise regions (for example, those located in South-East England) were considered unspecified. Other examples of research that were defined as being 'not specified/unable to determine' featured vague descriptors such as 'three hospitals in Kenya' or 'select health services in Southern Ontario'.

Results

Table 1 provides a summary of the 300 papers and how each study's participants were categorized geographically. The sample included studies undertaken in Europe, Asia, Northern America, Southern America, Africa, and Oceania, although precise numbers for each area were not able to be established as research regularly covered multiple countries and continents, or failed to identify a place of origin. Of the 300 papers, 188 (63%) derived at least part of their data from one or more randomised control trials.

Table 1. Breakdown of Geographic Classification of Research Papers

Article Categories	N (%)
Solely Rural Participants	6 (2)
Solely Urban Participants	55 (18.3)
Rural and Urban Participants	60 (20)
Not Specified / Unable to Determine	179 (59.7)
Total research articles	**300 (100)**

Solely Rural Participants

A total of six eligible papers in *The Lancet* between 10 October 2015 and 8 July 2017 were found to focus solely on rurally based participants (Table 1). The general theme amongst these papers was a specific focus to examine medical and health-care issues within lowly populated areas. It was commonplace within the Introduction section of these articles to include a justification of why the researchers purposely chose that location. An example of a rurally focused paper was that of Downs *et al.*[25]

Solely Urban Participants

Just below 20 percent of the reviewed articles, such as the 2017 article by Chow *et al*[26], were focused solely on participants from urban locations. Within these urban-focused research articles, the authors rarely justified why they had chosen to concentrate upon urban participants, and often simply noted the location.

Rural and Urban

Twenty percent of all eligible reviewed papers did include participants from both rural and urban locations. The 2017 paper by Chen *et al*[27] was an example of a paper that specifically considered both rural and urban residents. Many of the papers in this category were often large-scale questionnaires and surveys, and while they reported on other comparative factors, such as sex, age, education etc, geographic classification was seldom an area of specific interest.

Not Specified/Unable to Determine

The largest category in this research was 'not specified/unable to determine'. It was not possible to determine the geographic classification of participants in approximately 60% of all the 300 reviewed articles. Papers within this category did not provide the reader with sufficient detail to allow accurate identification of where the study's

participants resided, and geographic classification was not considered as a factor within any analysis. There were six papers in which the reader would not have been able to confidently nominate the country in which the participants were located. While a general location could often be conjectured by reviewing the affiliations of the researchers or the body providing ethical approval, this method could not be considered as being definitive, and was particularly problematic when reviewing research with multiple collaborating authors across different locations. Papers that reported on data from multiple countries were the most likely not to feature more in-depth geographic details; while inter-country comparisons were common, they rarely also included examination of intra-country issues.

Discussion

Of the 300 research papers reviewed from 10 October 2015 to 8 July 2017 in *The Lancet*, only 2% focused solely on rural participants in comparison to the 18% of articles that reported on purely urban-based participants. This disparity represents a potential bias as it is considerably different from what the world-wide rural population data[1,3,4,6] would indicate as being proportionate. In 60% of the reviewed articles there was not sufficient data to allow the reader to know whether the participants resided in a rural or urban location, or included participants from both.

The high proportion of *Lancet* papers in this study in which it was not possible to determine a precise location is concerning. Common statements in the Methodology sections would note demographic and methodological generalisations, such as 'In this double-blind, multicentre, randomised trial done at 912 clinical centres in 44 countries'. The data was often compared between different countries, but was rarely then further stratified to allow the reader to understand any internal geographic differences. This approach could be leading to an artificially high picture of national health outcomes if all the research sites are located in major urban areas, rather than also including rural and remote locations.

These unclassified studies often used descriptors for the research location that were vague and ambiguous. Phrases such as 'undertaken in four hospitals situated in the state of …', or 'GP clinics in western ….' were common, and failed to provide the reader with any understanding of the actual location of participants. Papers would report in considerable detail on other key demographic factors (for example age, sex, race, BMI, education, physical activity, alcohol and drug use, number of people living in the house, history of hypertension, number of visits to the doctor in the past 12 months, and so on), but overlook the geographic classification. Even if the overarching definition of rurality was changed, the failure to report on participants' residential site would still result in these articles remaining unclassifiable, and leave the reader unable to determine whether the location could be a factor.

There are reasons why research does not report on geographic classification. In some studies, where the participants live will genuinely be irrelevant to the treatment provided or healthcare outcomes. Similarly, reporting on the geographic classification of participants' residence may breach the ethical guidelines to ensure confidentiality. However, neither of these reasons would seem to totally explain the imbalance between urban and rurally focussed research, or why a large proportion of studies did not nominate geographic classification. One contributing factor to these results may be related to the location of large hospitals and universities. The majority of base hospitals and universities, and by extension the majority of medical researchers, are located in urban locations.[28,29] It is perhaps not surprising that most researchers will use a sample that is easily accessible through their normal workplace. However, if researchers do consistently use this approach, it may be partially responsible for the observed skewed research base towards urban participants.

Approximately 63% of the reviewed articles reported data obtained from randomised controlled trials (RCTs). This high number of RCTs is not surprising, as RCTs have been long considered the gold standard for assessing treatment outcomes and cost effectiveness,[30] and their results are considered the highest level of evidence[31]. However, there is a potential problem if the results from RCTs are then extrapolated by third parties, such as government policy makers, to cover groups not included in the original research. The 300 reviewed research papers reported on a wide variety of health issues and situations, but by failing to either report on or consider geographic classification, the use of these data in developing wider health frameworks, treatment recommendations, practice guidelines and government policies must be questioned. Without recognizing the potential disadvantages or advantages that location may have had on the participants, reported results within medical research must be considered carefully before applying them to other contexts.

There were numerous examples whereby it appeared that the research team, at best, simply overlooked reporting the participants' geographic classification, or, at worst, did not appear to consider whether the location could have any impact. This failure to actively recognize the role of rurality therefore removes important context from the findings of the research, and potentially limits understanding of what factors may have led to the outcomes being reported. If such data are then used to establish national government policies and best practice guidelines, there is a risk of unintended and unforeseen health consequences for rural residents.

This research has a number of limitations that require acknowledgement. It examined 300 sequential eligible original research papers of *The Lancet*, and it is recognised that a larger sample of papers might result in different findings. Likewise, as reputable as *The Lancet* is, research articles within this one journal cannot be considered representative of either specific medical research or the general health service sector. Using the same methodology to undertake a comprehensive review

of at least ten discipline-disparate health journals would be an appropriate mechanism to start to provide a greater understanding of how the wider sector has considered geographic classification.

Also, a different definition of rurality would possibly result in different findings. It is recognised that using a set population figure does not take into account potential differences between a very remote village of 20 people and a large regional city with a population of 99,000 people. Similarly, other important factors, including geographic isolation from other population centres,[32] were not considered as that level of analysis was beyond the scope of this paper. A future solution to this issue could be the identification, where possible, of the home country for each separate piece of research, and to then apply that country's specific definition of rurality to that paper. However, such an approach was also beyond the scope of this paper.

For researchers, it is recommended that any impact that the geographic classification of a project's participants may have on outcomes is actively considered and evaluated prior to commencement. If it is perceived that location may have an impact, the project methodology needs to then be developed to incorporate both rural and urban participants. Collaboration with rurally located universities, who often have specific expertise in this area, could successfully overcome the potentially identified issue associated with the urban-bias of researchers' own residence.

The second recommendation is for journal editors and article reviewers. While there remains no requirement by journals for articles to nominate participant's geographic classification, this issue will continue to occur. A possible solution is to mandate in the 'Information for Authors' section that all potential articles must provide adequate information in the Methodology section to allow readers to accurately identify the geographic classification of the study participants. Reviewers could then be reminded to ensure every article has these prerequisite data during the initial review process.

Finally, it is worth recognizing that many of the readers of *The Lancet* are health practitioners and policy makers, rather than pure researchers. It is recommended that all papers and reported outcomes are read with due attention to the research population in question. Findings and recommendations need to be viewed with appropriate consideration to whether the data are from a location that is relevant to the setting in which the reader is working.

The findings of this study indicate that insufficient attention has been paid to the impact of geographic classification in medical research in one leading journal. These findings are concerning, as research outcomes from journals such as *The Lancet* underpin evidence-based practice across the world. If such research does not appropriately include, examine and report on outcomes for a substantial proportion of the world's population, the specific needs of this group will not be met through existing and future healthcare systems, and the health of rural residents will continue to lag behind their urban counterparts.

References

1 United Nations. World's population increasingly urban with more than half living in urban areas. 2014. https://esa.un.org/unpd/wup/ (accessed 9 September 2016).

2 United Nations Statistical Division. Population density and urbanization. 2016. http://unstats.un.org/unsd/Demographic/sconcerns/densurb/densurbmethods.htm (accessed 9 September 2016).

3 United States Census Bureau. How many people reside in urban or rural areas for the 2010 Census? What percentage of the U.S. population is urban or rural? 2016. https://ask.census.gov/faq.php?id=5000&faqId=5971 (accessed 13 July 2017).

4 Gov. UK. Official Statistics. Rural population and migration statistics. 2016. https://www.gov.uk/government/publications/rural-population-and-migration/rural-population-201415 (accessed 13 July 2017).

5 Baxter J, Hayes A, Gray M. Families in Regional, Rural and Remote Australia. Canberra: Australian Government, Australian Institute of Family Studies, 2011.

6 Australian Bureau of Statistics. Regional Population Growth, Australia, 2013-2014. 2016. http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/3218.02013–14?OpenDocument (accessed 12 September 2016).

7 Smith KB, Humphreys JS, Wilson MGA. Addressing the health disadvantage of rural populations: How does epidemiological evidence inform rural health policies and research? *Australian Journal of Rural Health* 2008; 16(2): 56–66.

8 Singh GK, Siahpush M. Widening Rural–Urban Disparities in Life Expectancy, U.S., 1969–2009. *American Journal of Preventive Medicine* 2014; 46(2): e19–e29.

9 Australian Institute of Health and Welfare. Rural Health Life Expectancy 2017. http://www.aihw.gov.au/rural-health-life-expectancy/ (accessed 13 July 2017).

10 Henley S, Anderson R, Thomas C, Massetti G, Peaker B, Richardson L. Invasive Cancer Incidence, 2004–2013, and Deaths, 2006–2015, in Nonmetropolitan and Metropolitan Counties — United States. *Morbidity and Mortality Weekly Report (MMWR) Surveillance Summaries* 2017; 66(No. SS-14): 1–13.

11 AIHW. Rural, regional and remote health: A study of mortality. Canberra: Australian Institute of Health and Welfare, 2003.

12 Alston M, Kent J. Social Impacts of Drought: A report to NSW Agriculture. Wagga Wagga: Centre for Rural Social Research, Charles Sturt University, 2004.

13 Francis K. Health and health practice in rural Australia: Where are we, Where to from here? *On-line Journal of Rural Nursing and Health Care* 2005; 5(1): 28–36.

14 Stutz F. Tackling rural disadvantage. *Independent Education* 2015; 45(1):18–19.

15 Winterton R, Warburton J. Does place matter? Reviewing the experience of disadvantage for older people in rural Australia. *Rural Society* 2011; 20(2):187–197.

16 World Health Organization. Rural poverty and health systems in the WHO European Region. Copenhagen: WHO Regional Office for Europe 2010.

17 Mackinney AC, Mueller KJ, McBride TD. The march to accountable care organizations-how will rural fare? *Journal of Rural Health* 2011; 27(1):131–137.

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References

1 Marušić A. Discussing predatory journals – EASE at the 5th World Conference on Research Integrity. *European Science Editing* 2017;43(1):2,6.

2 Butler D. Investigating journals: The dark side of publishing. *Nature* 2013;495(7442):433–435.

3 Shen C, Björk B-C. 'Predatory' open access: A longitudinal study of article volumes and market characteristics. *BMC Medicine* 2015;13:230.

4 Beninger PG, Beall J, Shumway S E. Debasing the currency of science: The growing menace of predatory open access journals. *Journal of Shellfish Research* 2016;35(1):1–5. DOI: http://dx.doi.org/10.2983/035.035.0101.

5 Reynolds RR. The predatory publishing phenomenon: dead end or just an inconvenience on the road to a new scholarly publishing landscape? *Insights* 2016;29(3):233–238. DOI: http://dx.doi.org/10.1629/uksg.325.

6 Anderson R. Should we retire the term 'predatory publishing'? Available at: https://scholarlykitchen.sspnet.org/2015/05/11/should-we-retire-the-term-predatory-publishing/ (accessed 20 July 2017).

7 Berger M, Cirasella J. Beyond Beall's list: Better understanding predatory publishers. *College & Research Libraries News* 2015;76(3):132–135.

8 Shamseer L, Moher D. Thirteen ways to spot a 'predatory journal' (and why we shouldn't call them that). *Times Higher Education* 2017; issue 2300 (April 6):42–43.

9 Dadkhah M, Borchardt G. Hijacked journals: An emerging challenge for scholarly publishing. *Aesthetic Surgery Journal* 2016;36. DOI: https://doi.org/10.1093/asj/sjw026.

10 Federal Trade Commission. FTC charges academic journal publisher OMICS group deceived researchers. Complaint alleges company made false claims, failed to disclose steep publishing fees. Available at: https://www.ftc.gov/news-events/press-releases/2016/08/ftc-charges-academic-journal-publisher-omics-group-deceived (accessed 20 July 2017).

11 The American Association of Neurological Surgeons v. Austin Publications, LLC. Available at: https://www.plainsite.org/dockets/2nyxwlchv/illinois-northern-district-court/the-american-association-of-neurological-surgeons-v-austin-publications-llc/ (accessed 20 July 2017).

12 Eriksson S, Helgesson G. The false academy: Predatory publishing in science and bioethics. *Medicine, Health Care and Philosophy* 2017;20(2):163–170.

13 Gillis A. Beware! Academics are getting reeled in by scam journals. Available at: http://www.universityaffairs.ca/features/feature-article/beware-academics-getting-reeled-scam-journals/ (accessed 20 July 2017).

14 Silver A. Controversial website that lists 'predatory' publishers shuts down. Available at: https://www.nature.com/news/controversial-website-that-lists-predatory-publishers-shuts-down-1.21328 (accessed 20 July 21 2017).

15 Silver A. Pay-to-view blacklist of predatory journals set to launch. Available at: https://www.nature.com/news/pay-to-view-blacklist-of-predatory-journals-set-to-launch-1.22090 (accessed 20 July 2017).

16 Wager E. Why we should worry less about predatory publishers and more about the quality of research and training at our academic institutions. *Journal of Epidemiology* 2017;27(3):87–88.

17 Eriksson S, Helgesson, G. Where to publish and not to publish in bioethics — the 2017 list. Available at: https://ethicsblog.crb.uu.se/2017/05/09/where-to-publish-and-not-to-publish-in-bioethics-the-2017-list/ (accessed 20 July 2017).

18 McLeod A, Savage A, Simkin M G. The ethics of predatory journals. *Journal of Business Ethics* 2016. DOI: https://doi.org/10.1007/s10551-016-3419-9.

19 Pulla P. In India, elite institutes in shady journals. *Science* 2016;354(6319):1511–1512.

20 Caplan A. L. The problem of publication-pollution denialism. Mayo Clinic Proceedings 2015;90(5):565–566.

Continued from page 79

18 National Health Services Scotland. Delivering for Remote and Rural Healthcare: The Final Report of the Remote and Rural Workstream. NHS Scotland, Edinburgh 2007.

19 Brooke F. Championing the National Strategic Framework for Rural and Remote Health. *Australian Journal of Rural Health* 2017; 25(2):134.

20 Wagstaff A. Reforming China's rural health system. World Bank Publications; 2009.

21 Wark S. Does intellectual disability research consider the potential impact of geographic location? *Journal of Intellectual and Developmental Disability* 2017; Early On-line, 1-8. http://dx.doi.org/10.3109/13668250.2017.1310826

22 United States Census Bureau. Urban and rural classification. 2015. https://www.census.gov/geo/reference/urban-rural.html.

23 Gov. UK. Urban Rural Classification. 2016. https://www.gov.uk/government/collections/rural-urban-classification (accessed 12 September 2016).

24 Statistics Canada. Rural Areas. 2015. https://www12.statcan.gc.ca/census-recensement/2011/ref/dict/geo042-eng.cfm (accessed 12 September 2016).

25 Downs JA, Mwakisole AH, Chandika AB, *et al.* Educating religious leaders to promote uptake of male circumcision in Tanzania: a cluster randomised trial. *The Lancet* 2017; 389 (10074):1124–1132.

26 Chow CK, Thakkar J, Bennett A, *et al*. Quarter-dose quadruple combination therapy for initial treatment of hypertension: placebo-controlled, crossover, randomised trial and systematic review. *The Lancet* 2017; 389 (10073):1035–1042.

27 Chen H, Kwong JC, Copes R, *et al.* Living near major roads and the incidence of dementia, Parkinson's disease, and multiple sclerosis: a population-based cohort study. *The Lancet* 2017; 389 (10070):718–726.

28 Universities Australia. Australian University Profiles. 2016. https://www.universitiesaustralia.edu.au/australias-universities/university-profiles#.WA1UYHqRag4 (accessed 24 October 2016).

29 The Complete University Guide. University Profiles. 2016. http://www.thecompleteuniversityguide.co.uk/universities/ (accessed 24 October 2016).

30 Sibbald B, Roland M. Understanding controlled trials: Why are randomised controlled trials important? *BMJ* 1998; 316 (7126):201.

31 Murad MH, Asi N, Alsawas M, Alahdab F. New evidence pyramid. *Evidence Based Medicine* 2016; 21:125–127

32 Wark S, Ryan P, Parmenter T, *et al*. Supporting end-of-life care across geographic diversity: What works and what needs to change? *Journal of Intellectual Disability Research* 2016; 60 (7/8):760.