Correspondence

Undertaking Research in Other Countries: Further Considerations

Adamson Muula

The article by Skene [1] has touched on an important topic in as far as global health research is concerned. Skene's barometer is certainly a critical contribution to the discourse in research ethics that could be used in both extra-territorial and intra-territorial research. There are, however, several areas where I feel a different opinion would enrich the discussion.

My first concern is that the author presents this barometer with the slices of the pie having sharp demarcations. To the reader, this may suggest that there are clear-cut transitions from one area of the barometer to the other. In reality, however, issues in ethics are less well demarcated. For instance, a research area in itself may fit more in one color zone, but the participants chosen may move it towards the next color zone. Another researcher studying the same research area but different participant groups may be in a different color zone. In general, however, gradations with one color merging into the other, rather than clear-cut demarcations, would be more likely to be observed in practice. The fact that a different scheme could present reality more clearly is exemplified by the author's use of the "green zone", where research on competent adults, research on vulnerable populations, and research on children have all been grouped under one "roof". Skene's barometer may also be modified if one considers that vulnerability can be determined on a categorical basis (all persons in that category are vulnerable) versus on a situational basis [2]. For example, why should all persons under sentence of capital punishment be considered vulnerable? Do we assume that these people cannot make informed decisions which are so central in research ethics? Are we worried about coercion or constraining factors?

It is of interest that Skene's barometer has research on stored human tissue and observing people in a public place as neither associated with any laws and no requiring ethics oversight. Did the author mean that a researcher intending to video tape (which is by the way observational) in a restaurant not require ethics oversight? I would argue that stored human specimens should also be associated with ethical oversight. Mfutso-Bengo and I have made a case for continued ethical oversight on stored specimens in international collaborative research [3]. This view has been supported by Ndebele, who has advocated for materials transfer agreements [4]. Although we have made arguments based on actual specimens, we have not argued in support of agreements on use of data that emanates from international research.

The author also writes, "research that imposes severe suffering on animals, especially for a cosmetic rather than scientific purpose, would be widely condemned as well as unlawful in Australia". I do understand that the author writes from an Australian standard point, but the statement implicitly suggests that research conducted for cosmetic improvements cannot be for "scientific purposes". What is the author's definition of science? It would certainly make a difference if what the author actually meant was research for cosmetic purposes or gains versus research for treatment of diseases (although cosmetics can also be a treatment for disfiguring human diseases).

It is interesting that the author also suggests that research on cloning "would be unlawful in Australia and almost universally regarded as ethically unacceptable". This certainly brings into question the thesis that research ethics are universal. I guess in the next decades, the world will grapple with the ethical conduct of research in space. Who has jurisdiction when research occurs in outer space? These questions and others will certainly confront humanity, if not in this century, perhaps in the next.

Finally, because of the use of specific examples and situations, Skene's barometer may be applicable to Australia but not so much to the wider world. I guess the tool will undergo transformations where general algorithms and principles will be considered such that the barometer will be used beyond Australia. ■

Adamson Muula (muula@email.unc.edu)
University of Malawi
Blantyre, Malawi

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Undertaking Research in Other Countries: Author's Reply

Adamson Muula [1] rightly observes that demarcation between the "zones" of Skene's barometer is unclear. Certain activities may fall in one zone or another, depending on the circumstances. A research project does not fall within a particular zone solely because of its type. One must consider the project in operation. Muula mentions the treatment of participants in trials, particularly whether they are properly informed before the trial starts. One could add other factors such as the way participants are recruited, personal information held, or adverse incidents reported. Thus "research involving competent adults", which I have in the green zone (permitted with ethical oversight), would move to the yellow or orange zones (permitted under national laws with ethical oversight; or prohibited by national laws) if participants were coerced or duped into entering a trial; or if their personal details were revealed without their consent

or other lawful authority; or if researchers did not inform the appropriate authority during the trial that other participants had suffered serious and unexpected injury. Similarly, "medical research involving children" would fall within the green zone only if there is minimal harm to the child and full parental consent.

I suggested in my original article that the sensitivity of research could be "measured" on the barometer by its nature and by how it is legally regulated. I then gave examples, such as medical research involving competent adults and research on genetically modified crops. That is, of course, only the first step. I intended to designate research of that kind that is "properly conducted". The zones are less clear when one considers a variation of the initial research activity.

This is illustrated by Muula's examples. In Australia, there is no general legal restriction on observing people in a public place, or even photographing or videotaping them for research. I therefore placed those activities in the white zone on the Australian barometer (no specific laws or oversight). Australian law does not recognize a general legal right to "privacy". However, those activities could appear in another zone in certain circumstances. It is an offence to "stalk" people, or to photograph them so as to suggest they are acting unlawfully or to defame them.

Similarly, in Australia, it is not unlawful to collect human bodily material that has been "discarded" by other people, even if they have not consented and do not know about it. A scientist who picks up a tissue with a person's blood on it, in a public place, and does research on the blood would commit no offence even if he or she knew the identity of the person concerned. No ethics committee approval is needed. The scientist would breach the law only if personal information derived from the research was revealed without lawful authority. The same argument applies to research on bodily materials that are discarded by hospitals or pathology laboratories as garbage. The position of the research on the barometer moves according to the circumstances. If the bodily material is specifically sought from a hospital or laboratory, ethics approval would be needed, and possibly also consent from the people concerned, though that can be waived in certain circumstances.

The barometer is always based on local laws, which are a measure of the sensitivity of the community regarding particular conduct. The barometer reading may indicate that community opinion is divided or not so opposed to particular activities that they could not be accepted in another country, especially where they are undertaken with appropriate ethical surveillance. If other countries choose to use the barometer, they must substitute their own local laws and they may, of course, reach a different conclusion. Research ethics are not universal, but there may be more agreement than is commonly thought. ■

Loane Skene (l.skene@unimelb.edu.au)
University of Melbourne
Melbourne, Australia

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Natural Ventilation for Prevention of Airborne Contagion: Conclusions Overgeneralized

Hal Levin

This article and editor's summary give the impression that the tuberculosis infection rate was actually reduced by opening windows [1]. A careful reading of the article clearly states that while ventilation rates were measured, infection rates were merely calculated using the Wells-Riley equation. This is old news. While it is important to take into account the adequacy of the ventilation rate provided by mechanical ventilation systems, the ventilation rate through open windows is a function of window size, number, and location in a room as modified by indoor–outdoor temperature differences and wind direction and velocity.

Not every case will result in the differences observed in the Peruvian hospitals studied. One must be careful not to overgeneralize the results.

A new article, "Role of ventilation in airborne transmission of infectious agents in the built environment—A multidisciplinary systematic review" by Yuguo Li et al., is a thorough review of infectious disease transmission and ventilation just published in the February 2007 issue of the journal *Indoor Air*, the International Journal of Indoor Environment and Health, available at http://www.blackwell-synergy.com/toc/ina/17/1 [2]. ■

Hal Levin (hal.levin@buildingecology.com)
Building Ecology Research Group
Santa Cruz, California, United States of America

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Natural Ventilation for Prevention of Airborne Contagion: Authors' Reply

We would like to thank the correspondents for their thoughtful contributions to this important public health topic [1]. As our abstract and article state, we measured natural and mechanical ventilation and then calculated the effects of these ventilation rates on estimated tuberculosis (TB) infection rates using a mathematical model of airborne infection. This appears to be the first published assessment

of natural ventilation rates in health-care settings, and the novel conclusions of our article are that extremely high rates of dilutional ventilation can be achieved through natural ventilation at very little cost by simply opening windows and doors. Indeed, this natural ventilation was far in excess of even the best maintained mechanical ventilation systems used in health-care settings. Importantly, this natural ventilation greatly reduced the calculated risk of airborne infection.

Measuring TB transmission itself is difficult, as rates in staff are confounded by exposures outside the workplace, and mechanical air sampling techniques have had limited success. We have established a guinea pig air sampling facility to directly measure TB transmission in a hospital ward in Lima, Peru [2] and have used this model to evaluate the effects of upper room ultraviolet light and negative air ionization on TB transmission. We plan to use this facility to further study natural ventilation, and its effect on actual TB transmission.

The results of the current study cannot be generalized to regions too cold to tolerate enhanced natural ventilation and not every room may be as amenable to natural ventilation as the Peruvian rooms that we studied. However, the key conclusions are clear: high rates of natural ventilation were achieved even on days with little wind and even rooms without high ceilings and large windows were well ventilated, such that natural ventilation significantly exceeded mechanical ventilation.

It is therefore clear that natural ventilation has an important role to play in the fight against institutional TB transmission in resource-limited settings. Mechanical ventilation is expensive to install, requires costly ongoing maintenance, may be dangerous if poorly maintained (for example, delivering positive instead of negative pressure), and is clearly inappropriate for the great majority of resource-limited settings where the burden of TB is highest. TB infection control is an urgent priority, underscored by the emergence of extreme drug-resistant TB strains and the increasing congregation in potentially high-risk overcrowded settings of persons living with HIV through the roll-out of enhanced HIV care. When infectious TB patients share rooms with others, opening windows and doors to enhance natural ventilation is a simple, inexpensive, and effective strategy in the fight against nosocomial TB transmission. ■

Adrian Roderick Escombe (rod.escombe@imperial.ac.uk)

David A. J. Moore

Jon S. Friedland

Carlton A. Evans

Imperial College London

London, United Kingdom

Robert H. Gilman

Johns Hopkins Bloomberg School of Public Health

Baltimore, Maryland, United States of America

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