

SECOND ASIA-PACIFIC REGIONAL MEETING for NATIONAL ETHICS/BIOETHICS COMMITTEES

Reducing Inequities through Solutions-Orientated Bioethics

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Literature Summaries

Indigenous Populations and Equity – Key Points

Overall, most of the literature explores ethics in relation to the indigenous populations in Australia and New Zealand. There is limited literature available in other countries within the Western Pacific Region. Outside of this region, Canada, the United States of America, and Sweden have an equally substantial body of indigenous ethics literature. There is a clear delineation in terms of the availability of indigenous ethics literature between developed and developing countries. In addition, there is a limited amount of literature where equity and ethics are explored together.

Indigenous research ethics

Much of the literature describes the importance of acknowledging and incorporating **indigenous perspectives** when designing and conducting research. This is particularly important for ethics committees and the broader governance structures of research processes.

The main concerns for many indigenous peoples in research revolve around respect for their **indigenous rights, control over research** processes and reciprocity within research relationships to ensure that equitable benefits are realized within indigenous groups. The relevance of the Treaty of Waitangi (in a New Zealand context) to research ethics is important to incorporating the range of ethical issues that Maori have expressed as important.

Implementation science research, especially when using participatory and **co-design approaches**, raises unique challenges for research ethics committees. Co-design is considered best practice, for example, in research involving indigenous peoples in New Zealand, Australia and Canada. A comprehensive approach to ethical research involving indigenous peoples requires significant ongoing expenditure of effort and resources with implications for project development, management and funding.

Much of the literature highlighted the issue of the **underrepresentation of indigenous peoples in research**. In Australia, this was largely due to past failures to engage and recruit Aboriginal communities, research fatigue and the use of culturally inappropriate methods. In order to successfully engage indigenous people in health studies, researchers need to build rapport with communities, have a community presence, be respectful and collaborative, utilize incentives, and employ flexible and adaptive methodologies of reasonable length. Oral interviews are preferred to self-completed information. The use of more mixed methods methodologies was suggested when quantitative data collection is necessary. Communities expect presentations about research findings.

There is consensus that evidence-based approaches to health care have been difficult to achieve in Indigenous populations across the world, a situation which has contributed to the **significant health disparities** found in this group. One reason for this is that empirical knowledge tends to be organised around professional disciplines that are grounded in Western ways of knowing. Researchers and ethics committees alike should acknowledge the significant disparities that affect Indigenous people and the role of researchers in addressing this issue.

When conducting research with Indigenous populations **consent** should be sought from both individual participants and the local community. International, national and local ethical guidelines stress the importance of upholding Indigenous values but fail to specify methods for engaging communities or obtaining individual consent. Understanding research participants' motivations about taking part in research is important. This is particularly relevant for Indigenous communities where there is a reported history of research abuse leading to mistrust. This understanding can lead to research practice that is more respectful and responsive to the needs of Indigenous communities and abides by the values of Indigenous communities. Moreover, it can lead to more ethical and respectful research practice for all.

Indigenous bioethics

Issues relating to indigenous populations and bioethics have become more prominent in literature over the past decade.

Much of the literature explores the possibility of constructing a bioethics grounded in **traditional indigenous knowledge**. Contemporary bioethics recognises the importance of the culture in shaping ethical issues, yet in practice, a process for ethical analysis and decision making is rarely adjusted to the culture and ethnicity of involved parties. There is a generally need for further engagement with a variety of indigenous moral teachings and traditions, as this could improve health care involving indigenous patients and communities, and enrich the discipline of bioethics.

The intersection of **bio-banking** and indigenous populations is a topical issue across the literature. Public participation in medical research and biobanking is considered key to advances in scientific discovery and translation to improved health care. **Cultural concerns** relating to blood have been found to affect the participation of indigenous peoples and minorities in research, but such concerns are rarely specified in the literature. There is an empirical basis for researchers and bioethicists to develop culturally grounded strategies to boost the participation of indigenous peoples in biomedical research. This was a prominent theme in Australian Aboriginal literature, alongside a Native Hawaiian study that developed six guiding principles for biobanking (Governance, Re-consent, Education, Accountability, Transparency, Research priorities).

Direct-to-consumer (DTC) genetic ancestry was an issue highlight in several pieces of research. This relates to DTC companies having rapidly increased in popularity, with top testing services maintaining

genetic databases of several million consumers. In particular, many companies claim to be able to determine Indigenous (e.g. Native American) heritage, claims that are not supported by the state of the science and may have significant cultural and political consequences for tribal communities, particularly in the US. Research around the role of DTC in the Western Pacific Region and potential impact on indigenous populations is needed, as there are issues of indigenous identity and sovereignty.

Although human **genetic research** promises to deliver a range of health benefits to the population, genetic research that takes place in Indigenous communities has proven controversial. Indigenous peoples have raised concerns, including a lack of benefit to their communities, a diversion of attention and resources from non-genetic causes of health disparities and racism in health care, a reinforcement of "victim-blaming" approaches to health inequalities, and possible misuse of blood and tissue samples.

Indigenous global and public health ethics

Some studies highlight the need to increase public health research for indigenous populations in low- and middle-income countries. Where there is data available, a 'health divide' exists between indigenous and non-indigenous populations living in these countries. Despite the limited available evidence suggesting that indigenous populations have high levels of health needs, there is **limited research on indigenous health, especially in Africa, China and South Asia**. Pursuing is difficult however, due to prior negative experiences that indigenous populations have had with researchers. Global health researchers, including ethics committees, can contribute to improving the health of indigenous populations.

Public health research is important not only to address the health inequities experienced by Indigenous populations, but also to build knowledge and confidence and to inform practice in indigenous community-controlled health organisations. This is particularly important when determining ethics approaches to indigenous public health research.

Indigenous clinical ethics

In Australian literature, perspectives on confidentiality in Aboriginal communities included issues of social justice, the importance of public demonstrations of confidentiality, and the challenge of protecting all relationships when staff have multiple roles. Incorporation of community perspectives into the teaching of confidentiality may help doctors to understand the responsibilities of practising **confidentiality** in certain communities.

Racism – at an interpersonal and institutional level – was highlighted as a key ethical issue for Indigenous healthcare in some studies. Along with overt experiences of interpersonal racism, Indigenous people with health care needs are confronted by systemic racism in the shaping of institutional structures, hospital policies and in resource allocation decisions. Anti-racism policies and principles should be adopted by clinicians and researchers.

Climate Change - Key Points

Climate change is now well established as a global problem; however, the Asia-Pacific region is expected to experience particularly pronounced effects, with low-income and island nations being the most vulnerable. There is now a significant amount of literature on the health impacts of climate change, but relatively little on the indirect effects, and proportionately less in less developed areas. The impacts of climate change are expected to both exacerbate existing ethical issues of relevance to bioethics committees, and to create new ones.

Health Burden

Both Pacific Islands and Southeast Asia (particularly the Mekong Delta) are identified as areas that are particularly vulnerable to the impacts of climate change. The **Asia-Pacific** area already accounts for 84% of all climate-related deaths, and women (particularly poor women) are significantly more vulnerable than men. **Pacific Islands** are vulnerable due to their small size, and are expected to become increasingly dependent on external economic support as they suffer from loss of land, extreme weather and declining agricultural yields and fish stocks. **Southeast Asia** will have increased flooding, cyclones and heatwaves, exacerbating already existing health problems.

It has been argued that as climate change will have health costs, **policies to protect against climate change should have a specific public health focus**. Some problems, such as air pollution and waste management, can be mitigated with effective policies; others, such as floods and drought, will be unavoidable. It follows that strategies to address the latter problems should focus on adaptation and strengthening of emergency response systems. It has also been argued that poverty is a primary driver of vulnerability to climate change; and therefore, that climate-change policies should focus on reducing poverty and inequality, as well as improving the resilience of vulnerable populations.

Politics

It is noted throughout the literature that low-income countries, and particularly small low-income countries such as the Pacific Island nations, have less institutional capacity to adapt their health systems to the consequences of climate change. For this reason, it has been argued that **developed countries** like Australia and Japan **should assist their regional neighbours** in implementing climate change policies.

Across all countries there is evidence of weak institutional coordination between agencies charged with disaster response and those charged with climate change planning.

Ethics of water

Climate change is expected to both **reduce water availability** and to **increase the incidence of flooding**, thereby putting stress on water systems, reducing water availability and increasing the transmission of water-borne diseases. Ethicists have presented arguments for increased protection of water and water quality both on the basis of the common good of neighbouring countries as well from an eco-centric point of view. Due to the public interest in water, some have argued that ethics review should be at the community level.

The **Mekong Delta Basin** is identified as an area that is particularly prone to flooding, low water quality and water-borne diseases, however there are few studies that have focused on the effects of climate change in this region.

Researching in post-disaster contexts

Research in post-disaster contexts poses a particular challenge to ethics committees, and with the onset of climate change effective ethics oversight in disaster contexts will become increasingly important.

It is generally agreed that, due to the vulnerability of participants in disaster contexts, **a higher bar should be set** for the approval of research. However, it is also acknowledged that there is also a **large social value** of such research.

The Ebola outbreak in West Africa has been particularly informative in learning how clinical ethics review should be conducted in disaster contexts. Various recommendations for ethics review in disaster contexts have been made by both the WHO ethics committee and by other researchers following the outbreak. Most notably, it is suggested both ethics committees and researchers should be more involved in the review process, with ethics committees providing assistance to researchers, and an ongoing exchange of information between researchers and the ethics committee being fostered.

A number of questions still remain, such as:

1. How should "exceptional circumstances" and "unproven interventions" be defined?
2. To what degree should research focus on individual versus collective interests?
3. To what degree do adaptive trial designs have a place in the disaster context?
4. How should compassionate use be understood with unproven interventions?

Data sharing

Although more information on the effects of climate change and health is needed, **the information that exists is under-utilised** and there is need for greater information-sharing, particularly for less-developed countries.

Climate information increasingly needs to be accessed not only by the research community, but also by policy-makers. This creates a responsibility for researchers to share climate data in useful format. However, around half of the international climate modelling groups are currently restricted from sharing digital climate model data beyond the research community. International agreements are needed to eliminate data restrictions.

The International Research Institute for Climate and Society's climate data library provides an example of climate change data being used to support practical action on climate change. Through the library, that information is shared in a way that has helped interdisciplinary researchers understand climate change's impacts on society and health around the world.

Non-communicable diseases

While there is a significant amount of research on the effect of climate change on non-communicable diseases, relatively few of those focus on the effects for countries in the Asia-Pacific region. However, the following points are of note.

Air pollution is identified in the literature as the largest environmental health risk of the 21st century, as well as the second-highest risk factor for non-communicable diseases after tobacco.

Pacific Island and Southeast Asian nations face the **dual risk of both malnutrition and obesity**, as food shortages, exacerbated by climate change, force poorer residents to turn to less nutritious food sources.

Increased heat stress and poor air quality due to climate change pose particular challenges for the **cardiopulmonary system** and the **gastrointestinal tract**, as well as by increasing the prevalence of asthma and other allergic respiratory conditions.

Ethics of Emerging Technologies in Health– Key Points

Overall, popular research on emerging health technologies in the Asia-Pacific region is focussed on data, artificial intelligence, health devices, tissue storage and public engagement with emerging technologies. Outside of the Asia-Pacific region, topics are wide-ranging: topics found in the Asia-Pacific region are reflected here, and are supplemented with research on governance and infrastructure, gene editing, neuroscience and more.

Privacy protection and accessibility were common ethical themes raised in the Asia-Pacific-based research. However, a relative paucity of literature focussing on ethics, equity and governance demonstrates the speed of advancement of health technologies, and the difficulty that both academics and regulators have with maintaining pace with the industry.

Clinical Ethics & Emerging Technologies

In the Asia-Pacific region, clinical applications of emerging technologies often focussed on the implementation of **wearable health devices** or smartphone apps designed to improve health outcomes. Wearable health devices can monitor key health indicators, alert health professionals to medical emergencies, and allow those who cannot safely visit healthcare centres to engage with their health system. This is an important part of emerging healthcare technology, as increasing numbers of people in both developed and developing countries have access to devices with high-capacity connectivity.

Key issues from the research on devices were **reliability, equity, whether health technology solutions can be generalised**, and whether health consumers **trust** and **engage** with device-based healthcare.

The issue of reliability was raised in multiple articles. This can be unpacked into two categories: reliability of the **device** itself, and reliability of the **infrastructure** supporting that device. Device reliability is an important consideration for regulators, as accuracy is essential to the adoption of health devices as legitimate diagnostic tools that improve health outcomes. Reliable connectivity of these devices is also an important consideration for ethicists, as regional inconsistencies in network coverage may result in inequitable benefits to health consumers.

Possible solutions to these issues include ensuring policy is in place for **robust quality control** and **regulation** of these devices, in addition to **working with stakeholders** to ensure that any rollout of health devices is fully supported by existing infrastructure.

Equity was another issue apparent in the literature. Health technologies can aide in clinical and community health settings, as a means of engagement with health professionals that may not have been practical otherwise. For example, **groups that may face stigma as a result of visiting a clinic can still engage with online resources from the safety of their own home**. Individuals who face physical barriers to accessing healthcare (due to health issues or geography) would similarly find themselves able to connect with their health professionals.

However, these benefits do not come without ethical challenges. Low socio-economic status is known to be linked to poor health outcomes, and **those who stand to benefit the most from the use of medical devices (rural communities, ethnic and gender minorities, disabled and older populations) may find that cost is the most significant barrier** to engaging with health technologies.

Many devices and technological solutions for improving clinical outcomes are designed with specific problems in mind. For example, an app may be designed specifically for the elderly to report on their health and wellbeing but may only gather data on health indicators relevant to those over a certain

age. Similarly, a device used to monitor cardiac arrhythmia may not be easily applied to monitor other types of heart conditions. **Generalisability of devices and technological health solutions** was an issue commonly seen in recent articles, wherein a specific health problem was addressed and solved through purpose-built technology, but that technology has few applications outside of the specific purpose for which it was built. Researchers and clinicians should look to maximise the clinical benefits of the development of health devices, with breadth of applications being a design priority for researchers and developers.

Further articles in clinical research investigated **consumer trust and engagement** in healthcare devices and technologies. Researcher has found that public perceptions of wearable health devices and mobile technologies were generally positive, despite the recognition of several issues. These issues included a lack of engagement with target populations in the development phase of technologies, which could result in solutions that do not take cultural and social factors into account, in addition to possible tensions between groups who have received targeted health technologies versus those who have not.

Despite these challenges, researchers have generally found the public to lack a strong opinion about the increased use of personal health devices. This is an important consideration for bioethicists, as **the apparent ambivalence towards health devices may be due to an ignorance of data collection and storage practices**, leading to health consumers consenting to their data and information being used in ways that they are not informed of.

Machine learning, and the big data its algorithms rely on, depends on the collection of broad swathes of health and related data to operate accurately. Health and technology literacy are therefore not the only important considerations for obtaining informed consent from health consumers; an **understanding of data, privacy, and a person's rights regarding both, are central to informed consent in this area.**

Research Ethics & Emerging Technologies

Research into emerging health technologies is expansive; some areas of research fall strictly within the domain of clinical or public health, while others may have started out with therapeutic intentions, but have evolved into novel, non-therapeutic technologies, where ethical issues have the potential to become increasingly complex. Common themes in therapeutic research included **predictive diagnoses based on genetic and behavioural data**, as well as the development of **artificial intelligences and machine learning algorithms**, particularly with regards to **the safe and responsible storage and use of the data** that is fed into those algorithms. Novel technologies without therapeutic intentions (but with possible health applications) include non-therapeutic **altering of DNA using the CRISPR-Cas technique**, and the development of **brain-to-brain interfaces** to influence decision-making.

Genetic information can be used to predict some diseases; research has been done to investigate whether this is practical or ethical to implement in multiple settings. Similarly, recent research has investigated **whether an individual's tracked smart device usage can predict health outcomes, including life expectancy**. In addition to this, researchers are increasingly **testing the capabilities of artificial intelligences and machine learning algorithms to model health outcomes**. These algorithms are fed large and complex datasets; concerns have been raised by academics regarding **adequate governance and safety protocols surrounding these datasets**, particularly if they are used to model diagnoses at an individual level. Ethical issues resulting from such research include **balancing the potential harm and potential benefits of a person knowing their predicted health outcome** (including life expectancy), the **accuracy** of that estimate, **safe and responsible data management practices** and risks associated with **computer models potentially finding a "problem" with an apparently healthy individual**.

Researchers and ethicists should find **solutions** to these issues in **national and international research guidelines** that address a person's right to health information about themselves. Such guidelines would also ensure robust research protocols are followed, and that risks are mitigated or managed so that harm is minimised at an individual and societal level.

Finally, some academics have adopted emerging health technologies for **research with novel, non-therapeutic applications**. Such research has tangential connections to bioethics in the context of health but should be acknowledged as a part of the wider research community that investigates the many applications of emerging health technologies.

Public Health Ethics & Emerging Technologies

Issues relating to public health and the ethics of emerging technologies focussed primarily on **governance** (or lack thereof) and **the role of regulators in the evolution of health technologies**. Common themes in the literature included **population modelling, data sharing** and **policy-making strategies**.

The use of **public health data to predict health outcomes** appeared as a recurring theme in the literature. Examples included using individual caches of device data to **predict life expectancy** and using population health data to **model disease outcomes**. Using predictive analysis to determine health outcomes is useful at a public health level, **but ethical issues arise from individuals learning about what an algorithm has determined to be the outcome of their illness**. Public health regulators should balance the potential harms and benefits of a person knowing this information, with that person's right to information about themselves.

Data sharing was also an issue of interest in research. Many smaller, developing countries are investigating sharing health data with neighbouring countries, to **build stronger datasets** and subsequently better inform public health decision making. However, issues arise where **databases significantly differ across borders**, making data difficult to reconcile. The risks here involve datasets becoming inaccurate due to errors or issues with reconciling different systems, as well as data security protocols with varied levels of sophistication resulting in an increased risk of privacy breaches.

These potential risks should be addressed and mitigated before countries share health data, either **through data being standardised** through a specialised regulatory body, or through the implementation of a **unified health database**, that all participating nations are required to use.

Robust and well-informed **policy** and **governance** is one of the key solutions to many of the issues raised with emerging health technologies. Recent papers suggest that a **principled approach**, that conscientiously balances value-based and evidence-based decision-making, should be adopted when researching and writing policy on ethical research and practice of new and emerging health technologies. The global and interconnected nature of technology demands a **unified approach** that promotes the **continued development** of new technologies, while also ensuring **equitable accessibility and outcomes for all**.