

Genome Editing for Human Benefit: Ethics, Engagement and Governance

Singapore, 12 – 13 November 2019



Case study: Public engagement towards eliciting public views and promoting dialogues on genomic research in India

Manjulika Vaz, Social Scientist, Division of Health and Humanities, St. John's Research Institute, Bangalore, India

Brief description of the research project

While the focus of engagement in high-income countries (HICs) is presently on gene editing, the context of India is different. For the vast majority of the Indian population, researchers have little insight into their understanding of genes, genetic identity and genetic research. Nationalist sentiments and a push for speedy scientific advancement have compelled the Indian government to formulate and present to the Parliament, a DNA Technologies Bill (2019). It is important for any legislation and ethical regulation, especially for contentious and novel areas of research to be responsive to the concerns of its citizens and those most likely to be affected by the research.

Public engagement involves understanding perceptions, expectations and concerns not necessarily based on scientific knowledge but on people's beliefs, customs and life experiences. Sociological studies in other contexts have shown that issues such as genetic privacy, genetic confidentiality and "genetic exceptionalism" (arising from the uniqueness of one's genes) give rise to complexities that are greater than in other kinds of research.¹ People-centred regulatory frameworks and governance of such research is essential to ensure that scientists and researchers are aware and responsive to the sentiments of the public who stand to benefit from such research. Deliberative mechanisms and dialogue are required mechanisms for community engagement and indeed preferred to the delivery of awareness programmes involving one-way communication.

Engagement with communities helps to enhance people's understanding of the methods and tools of genomic research and to negotiate boundaries and arrive at a shared understanding which balances biomedical explanations of illness and traditional culturally sensitive belief systems.²

In 2014-2015, a qualitative study was conducted in the south Indian city of Bengaluru, to understand perceptions of the general public, the research community and ethics committee members to the ethics of biobanking research.³ An unfolding case vignette was used as a tool to help elicit public views on these questions, with scenarios and prompts for people to engage. Drawing from this experience and the findings that emerged, can inform how the research community perceives and conducts engagement with others with respect to novel research like gene drives for health research.

While members of the general public had broad concerns ranging from fears of misuse, eugenics, of manipulating nature, and commercial exploitation; they were on the whole positive about the possibilities of genetic research helping society and helping their children to prevent diseases in the future. They however wished to be informed that such research was underway, particularly to ensure that the researcher was held accountable and that they themselves had a voice. In the words of one participant, "They should inform us if they are doing genetic research... it is not about us understanding or objecting... but making them know that we matter".

In the context of genome editing and genomic research in a developing country, it is vital the locus of information control is not the researcher, funder or regulator but that the engagement is people-centred and includes the views and responses from the public. In the absence of this, participants in newer areas of research are unlikely to be aware of the ethical dimensions of their participation. This runs contrary to the spirit of "informed consent".

A research study is currently underway in Bengaluru, India, to explore mechanisms for people-centred oversight and monitoring of stored samples for genetic research. Rather than following a reductionist approach to eliciting public perceptions and public engagement in the context of genomic research, we have devised an alternative approach.

Fundamental to our approach is the recognition that the public is not a fixed body of individuals; it is composed of persons interested in an issue, and can affect it only by supporting or opposing the actors.⁴ Instead of immediately engaging individual stakeholders, we chose to facilitate a deliberation among a heterogenous group of members with praxis expertise (i.e. of those with interest in people-centred advocacy and governance mechanisms in their respective fields). This approach allows the raising of multiple perspectives, while allowing the group to be small enough to conduct a meaningful deliberation. A more focussed engagement will be completed with key 'stakeholders' and key 'influencers' – each having different interests and needs.

Background – relevant facts about the host country India

Earlier work of the author has shown that health literacy in India is low, not just among the least educated but among people in general.^{3,5} However, in recent years, mistrust of the health system by the public and mistrust of medical research and the assumed exploitative nexus between research and industry has left people cynical and sceptical. At the same time, mainstream and social media has provided people with information about medical advancements, successful novel treatments and sensational, novel experiments including the Chinese case of gene editing of human babies for HIV prevention.⁶

India is culturally pluralistic with diverse belief systems and religious traditions which influence people's views and practices. Social activists and non-governmental organisations are active and vocal on the introduction of new schemes, projects and socio-political-ethical issues.

The 2017 Ethical Guidelines by the Indian Council of Medical Research⁷ allows use of somatic cells for therapy and gene therapy with some conditions subject to Rules 1989 of Environment Protection Act 1986, however there is uncertainty regarding India's regulatory capacity to enforce ethical standards for CRISPR use.⁸ Bengaluru is the hub of biotechnologists and medical scientists in India who are engaged with genomic research and CRISPR use. This community does not want to be left behind in global advancements in gene editing and clinical trials to address medical conditions.

Ethical issues

The ethical issues are that of:

Social justice: Social inclusion and discrimination – Gene editing has the potential to aggravate the socio-cultural problems of India in regard to perceptions of dark skin, short stature, the girl child and worsen pre-existing injustice and inequality.

Public engagement and trustworthiness: In the absence of credible country specific guidance on the ethical parameters on genomic research in India and with the present climate of distrust and scepticism of medical research, it would be an ethical imperative to engage with the public and various stakeholders and arrive at appropriate guidelines and best practices including sustained community involvement.

Conclusions

Within the background of India, the advancements in medical science and the nascency of regulations and laws, understanding the views of the public is critical. Our research suggests that structured, facilitated multi-stakeholder engagement is required to take place to understand people's perceptions, expectations and concerns of genomic research and to negotiate boundaries and develop appropriate guidelines.

References

1. Palsson G, Hardardottir KE. For whom the cell tolls: debates about biomedicine. *Current Anthropology*. 2002;43(2):271–301.
2. Tindana P, Campbell M, Marshall P, et al. Developing the science and methods of community engagement for genomic research and biobanking in Africa. *Glob Health Epidemiol. Genom.* 2017;2:e13. Published 2017 Sep 4. doi:10.1017/gheg.2017.9
3. Vaz M, Vaz M & Srinivasan K. Listening to the Voices of the General Public in India on Biomedical Research – An Exploratory Study. *Indian J Med Ethics*. 2015 Apr-Jun;12(2):68-77
4. H. Gottweis, H. Chen & J. Starkbaum. Biobanks and the Phantom Public. *Hum Genet* 2011; 130: 433.
5. K.C. O'Doherty, A.K. Hawkins & M.M. Burgess. Involving Citizens in the Ethics of Biobank Research: Informing Institutional Policy through Structured Public Deliberation. *Soc Sci Med*. 2012; 75(9):1604-11.
6. Rana P. How a Chinese Scientist Broke the Rules to Create the First Gene-Edited Babies. *The Wall Street Journal*. May 10, 2019. <https://www.wsj.com/articles/how-a-chinese-scientist-broke-the-rules-to-create-the-first-gene-edited-babies-11557506697>
7. Indian Council of Medical Research, Department of Biotechnology. (2017) National Guidelines for Stem Cell Research. Available from : https://www.icmr.nic.in/sites/default/files/guidelines/Guidelines_for_stem_cell_research_2017.pdf
8. Udwadia F, Singh S. Starting the conversation: CRISPR's role in India. *Ind J Med Ethics*. April 18, 2019. DOI: 10.20529/IJME.2019.016. <https://ijme.in/articles/starting-the-conversation-crisprs-role-in-india/?galley=print>