

# Ethical issues arising in research with people with mental health conditions

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## Case study

### The need for integration of health benefits as an ethical challenge in mental health research among low resource populations in India

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#### Brief description of the research project

The objective of this project was to develop a cohort (n=1526) of participants among children of coal mine workers ages 6 to 23 years belonging to low socio-economic groups from rural and semi-urban areas, including populations from West Bengal, Bihar, Uttar Pradesh, as well as a tribal population. This project was part of a larger neurodevelopmental cohort “Consortium on Vulnerability to Externalizing Disorders and Addictions” (cVEDA) (2016 – 2020) carrying out detailed assessment of behavioural, neuropsychological, neuroimaging and environmental exposures.<sup>1</sup> This case study examines the ethical implications of our experience that receiving tangible health benefits is perceived as the most important motivation for participation in community based mental health research in low resource settings in India.

#### Background

Our cohort comprised children of coal mine workers engaged in manual labour (skilled/semi-skilled/unskilled) as well as other children living in the mining neighbourhood. The cohort was drawn from a population of approximately 6,000 workers engaged in 16 coal mines in the Asansol – Raniganj area of West Bengal, approximately 150 km from the nearest metropolitan city of Kolkata. Male workers in this population have been known to have a high prevalence of alcohol problems. Local co-ordinators were engaged to assist research staff in participant recruitment. Following administration of informed consent all participants underwent detailed neuropsychological assessment and biological samples were collected. Neuroimaging was carried out in a sub-set of eligible participants who consented for the procedure. Neuroimaging was carried out in a government funded imaging centre in Kolkata, and travel arrangements for the participants were made from the project funds.

#### Ethical issues with commentary on each

Mental health issues are globally important public health problems across countries in different stages of economic development, and community based mental health research is essential to understand the growing burden of mental illness in developing countries. In low resource settings community based mental health research faces key ethical challenges, including:

##### *Conceptualisation of mental health*

Our early realization was that for this population group living in low socio-economic conditions there is no clear understanding about mental health.

During our past and ongoing population based studies a consistent observation has been a very low level of awareness about the existence of mental illnesses in this population, which poses an ethical challenge in the implementation of such research. Mental health issues related to personality, temperament and behaviour are, perhaps, perceived as social deviations rather than initiation of a disease process. We explained to participants that such deviations may result in diagnosable mental health issues in the future, which need to be addressed at a very early stage

to prevent more complex problems developing. One of the possible reasons for poorer understanding about mental health could be because this population struggle with receiving adequate physical health care.

#### *Participant recruitment*

As a result of the concept of mental health remaining obscure, mental health conditions are not perceived as a “disease” and people do not come forward to participate in research on this topic.

Although it is desirable that the population has some understanding about mental health before initiation of the study, in the current situation a more pragmatic approach is to convey the concept of mental health during explanation about the study and the consenting process. Therefore, we understood that alternate strategies are required to engage this population. For example, considering a high prevalence of alcohol problems in this worker population we initiated a screening and management of alcohol problems at primary care level among workers, and then encouraged them to bring their families to participate in the study. This strategy was introduced in an effort to engage the local population, to provide an idea about mental health, and finally to assist in engaging more families to participate in the study.

#### *Adequacy of and collaboration with local health services*

The inadequacy of primary physical and mental health care remains a deterrent in implementing mental health studies in this population.

During this project participants also raised physical health issues and expected some treatment advice and medication. We perceived that the reason for this could be the inadequacy of primary care service, which is unable to cater to basic health needs in this population. Therefore, we collaborated with physicians of Eastern Coalfields Ltd. and referred participants with physical treatment needs for consultation. Further, to facilitate retention we also provided all participants with a complete hemogram and routine urine report from biological samples collected for research purposes free of cost. Based on reports we tried to provide basic medicines at no cost through government health programs. We also encountered challenges due to the poor provision of mental health services at primary care level. Participants with a provisional diagnosis of a mental health problem always seek psychiatrist consultation. Considering the existing treatment gap for mental health services in India, it is difficult to arrange such services for this population at the primary care level. At the same time it is unethical for a participant with a provisional diagnosis to remain uncared for. Therefore, in a country like India, for implementation of community based mental health studies availability of standardized mental health services at the primary or secondary care level is a necessary pre-requisite for ethical research. To address this need arrangements were made for participants who screened positive for mental health problems to be seen by a qualified psychiatrist on site on designated days.

#### *Research benefits*

We also felt that in low resource population settings possible benefits of research and advancement of knowledge are intangible, and people are more concerned with receiving direct health benefits.

Whilst some family members having children with obvious mental health issues (e.g., suicidality) were keen to participate, the primary motivation of participants remained in receiving physician consultation and medications. One of the main reasons people from low income countries refuse to participate in health research is due to lack of benefits from the study.<sup>2</sup> However, it needs to be emphasized that whilst minority population groups face a greater disease burden, they are known to be under-represented in health research.<sup>3</sup> Lack of research based evidence creates an inequality of distribution of health resources, which results in a gross disparity of social justice. Ethically sound population based research creates a strong evidence base to provide *locally* relevant and effective treatments for underprivileged populations. Our experience suggests that when participants are offered more information, awareness and necessary services, it creates a bond of trust between the researchers and the population. The sustainable relation between participants and researchers is built around understanding the health needs of the population in

their socio-economic context, empathising with their needs, and acting to deliver meaningful research benefit that meets their needs. When this trust is ensured there is greater community advocacy about the study ensuring more spontaneous participation; which ultimately improves the quality of the study, as a whole. This is an essential mechanism to generate reliable evidence base on mental health priorities among underprivileged communities, which can assist in more equitable allocation of health resources.

### **Conclusions**

This case study illustrates how mental health research in low resource settings of developing countries is constrained by ethical challenges from the very outset. Principles of ethics need to be looked at differently based on socio-cultural contexts in case of community based mental health research in low socio-economic populations of India. As the health needs in such communities are not met by currently available services such research needs to coordinate their research with local services to create a bond of trust between researchers and the community, encouraging willful participation. Research participation shall result in awareness about mental health issues, so far, not acknowledged at the community level. If we consider that the ultimate objective of research is to directly benefit participants, and provide future benefits to the population at large.

### **Recommendations**

1. Engagement – Awareness, information and knowledge and strategies to engage community are essential to encourage participation in mental health studies.
2. Maximization of benefits – Integration of health service including basic mental health service inbuilt with the research agenda is critical to recruit and retain participants from low socio-economic conditions.

### **References**

1. Sharma, E., Vaidya, N., Iyengar, U., Zhang, Y., Holla, B., Purushottam, M., . . . Benegal, V. (2020). Consortium on Vulnerability to Externalizing Disorders and Addictions (cVEDA): A developmental cohort study protocol. *BMC Psychiatry*, 20(1), 2. doi:10.1186/s12888-019-2373-3
2. Mfutso-Bengo, J., Masiye, F., Molyneux, M., Ndebele, P., & Chilungo, A. (2008). Why do people refuse to take part in biomedical research studies? Evidence from a resource-poor area. *Malawi Med J*, 20(2), 57-63. doi:10.4314/mmj.v20i2.10958
3. Redwood, S., & Gill, P. S. (2013). Under-representation of minority ethnic groups in research-call for action. *Br J Gen Pract*, 63(612), 342-343. doi:10.3399/bjgp13X668456

**This case study was prepared for GFBR 2021, which took place virtually. Further details are available at [www.gfbr.global](http://www.gfbr.global).**