



Perspective

Ethics preparedness for infectious disease outbreaks research in India: A case for novel coronavirus disease 2019

In the past decade, India has witnessed several outbreaks/epidemics (such as H1N1, H5N1, avian influenza, Ebola, SARS, Zika and Nipah) which were successfully tackled with appropriate research¹. India with its 1.3 billion population residing in densely populated areas in resource-constrained environments is at constant risk for any emerging outbreaks that can cause rapid spread of infection. There have been considerable investments in preparedness for rapid responses and to create a conducive environment to undertake therapeutic or disease prevention research. Research is needed when the outbreak is ongoing or after it has subsided.

Ethics preparedness refers to the capability of the public health system, to protect and have the ability to quickly respond to by having in place an ethical framework that would build trust and guide measures to recover from health emergencies. This can make science more holistic, sensitive and people centric focussing on local, social and cultural values helping better protection of our population. The outbreaks could be regular and known for which the research preparation is high or these could be first time or novel for which there is no specific research preparation and requires quick adaptation. Over the last several years, the Indian Council of Medical Research (ICMR) has worked with the Department of Health Research (DHR), Ministry of Health and Family Welfare (MoHFW), Government of India, in enhancing the national capacity for early diagnosis of infections that have an epidemic potential by setting up a network of well-equipped Virus Research and Diagnostic Laboratories for managing epidemics that can lead to public health crisis². The network is led by the ICMR-National Institute of Virology, Pune, which is well equipped with capability to handle highly contagious pathogens having a Biosafety Level 4 (BSL4) laboratory to set the stage for prompt action³.

It has also been identified among the 15 laboratories across the world for diagnosis of novel coronavirus infection recently labelled coronavirus disease 2019 (COVID-19) by the WHO Director-General at the media briefing on February 11, 2020⁴. In case of COVID-19, the research areas could be varied ranging from study of disease transmission routes, incubation period, secondary attack, sequelae, susceptibility and isolation containment, *etc.*, or research could be on setting up of diagnostics which may include tools for quick screening or molecular tools for confirmatory diagnosis. Research can also be on treatment or therapeutics because there is no known treatment and ways for protection or it could also be on vaccine candidate molecules. Important research needs in epidemic/outbreaks are given in Table I.

Existing governance structure that helps in ethical preparedness

Provisions that guide the implementation, measures to control, surveillance and ethical conduct of biomedical and health research or of clinical trials for approval of therapeutics in the case of epidemics/outbreaks are as listed below.

Indian Council of Medical Research's (ICMR) national ethical guidelines

The latest version of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants released in October 2017 has, for the first time, included a separate section on research during Humanitarian Emergencies and Disaster conditions and suggested ethical safeguards for any research during an outbreak⁵. This section has identified the need for pre-emptive preparation and suggested a framework for prior planning for dealing with emergency and outbreaks. It discusses how the Ethics Committee (EC) can undertake an

Table I. Types of research requiring ethics preparedness during outbreak investigation

Type of research	Examples
Epidemiological	To explain - where, when, how and who; disease transmission, susceptibility, <i>etc.</i> ; causes, outcome, case control, cohort, clinical trials, operational, implementation research
Vector/agent characterization	Biology, structure, behaviour, resistance, <i>etc.</i>
Diagnostics	Methods, scaling up, validations
Therapeutics	New drugs, indications, dosage, duration, adverse events, efficacy, alternative systems
Prevention	Secondary attack, containment, vaccine development
Storage of biological samples and data	Secondary use of samples and data, privacy and confidentiality, sharing of information/sequences/samples/isolates
Collaboration and partnerships	Regional, national or international, public and private
Monitoring	Research evaluation, surveillance, oversight

expedited review or hold unscheduled meetings in a given time frame or to connect with relevant experts through available channels, such as video or teleconference whenever physical presence may be difficult for ethical review in a time-bound manner. The guidelines provide measures for protection of the affected individuals or populations from harm and ensuring their safety, stigmatization and ostracization, while maintaining their dignity and protect their privacy or any unauthorized use of identifying information, despite the fact that such diseases are to be notified to public health authorities. The need to draft formats and research protocols in advance, including informed consent forms or plans to seek waiver of informed consent, can help speed up the responses when the need arises. A Monitored Emergency Use of Unregistered and Investigational interventions is also suggested and may be implemented with due precautions. Need for thorough scientific review, followed by an ethics review, local oversight, good manufacturing practice compliance/rescue medicines and supportive treatment accessible are some of the other safeguards suggested.

Clinical trial regulations - New drugs and clinical trial rules (NDCT)

The New Drugs and Clinical Trial Rules (NDCT), under the Drugs and Cosmetics Act, 1940, notified in March 2019, have included supportive provisions to enable fast-track approval processes for the use of unapproved Drugs in Public Health Emergencies^{6,7}. Permission can be sought from the Drugs Controller General of India (DCGI) for restricted use of

combination drugs which are expected to be potentially useful against the infection. Therefore, on the regulatory front, there have been major strides and a responsive enabling environment has been created for online fast-track clinical trial registration and approvals, registration of ECs on SUGAM Portal and monitoring and accreditation of ECs through National Accreditation Board for Hospitals and Healthcare Providers (NABH)^{6,8}. The norms for clinical trials are updated and the NDCT Rules regulate all new drugs, investigational new drugs for human use, clinical trials, bioequivalence studies, bioavailability studies and ECs.

Clinical Trials Registry of India (CTRI)

It is a public database to improve accountability and transparency and ensure that every clinical trial can be prospectively registered. Since 15th June 2009, DCGI has made it mandatory to register all clinical trials on Clinical Trials Registry of India (CTRI) Platform run by the National Institute of Medical Statistics (NIMS) under ICMR⁹. The database collects information about the study sites, investigators, sponsors, interventions and patient groups, and registration is mandatory before any participant is enrolled. The registration also requires uploading a copy of the EC approval letter and approval from the Central Drugs Standard Control Organization (CDSCO) for clinical trials. The details are available on the website for public and these registered trials can be searched both on the CTRI and the World Health organization's (WHO's) International Clinical Trials Registry Platform (ICTRP) search portal, as well as from the CTRI¹⁰.

Department of Health Research - Naitik portal

Chapter IV of the NDCT⁷ has made it mandatory for every researcher and EC to follow the ICMR National Ethical Guidelines for research and requires registration of all ECs engaged in review of any biomedical and health research with the DHR on its portal¹¹. This registration is in addition to the requirement for the EC to register with CDSCO for clinical trials⁶. Therefore, since September 2019, an Office for EC Registration has been created at the DHR, which is now registering ECs and will be coordinating and monitoring the activities of the ECs registered with it. This fulfils the existing gap related to the regulation of biomedical and health research apart from clinical trials and has helped create a framework for accountability of every EC in the country.

Integrated disease surveillance programme

This programme was started in 2004 by the MoHFW, Government of India, to strengthen the disease surveillance systems for epidemics/outbreak detection and response. It maintains a rapid response team across several locations of the country and aims to strengthen laboratory systems for early detection and diagnosis of epidemics/outbreaks. It uses a network of IT-enabled systems for quick collection, analysis, reporting on samples and dissemination of results. Policy guidance is, thus, provided to respective local, regional or national health departments¹².

Five specific areas have been identified to focus upon to improve ethics preparedness in dealing with

outbreaks such as COVID-19 and urges all relevant stakeholders to recognize the same and implement various steps to guide better public health outcomes. Table II discusses the areas for ethics preparedness in case of outbreaks⁵.

Building public trust: Protecting societal values, engaging with community and improving communication

Any large public health programme must be based on ethical principles of transparency, accountability and information exchange with the involved population or communities. Along with building appropriate infrastructure for scientific research, training of investigators and field workers, it is also important to simultaneously inform the public about outbreaks and to educate them about their responsibilities to curtail the spread of infection. There is also a need to dispel and clarify about the fake information floating on social and print media related to the use of unproven claims. The importance of community engagement can never be undermined; however, in an outbreak situation, it is very challenging to practically plan it in view of limited time and resources. Simple key public health messages and responsible use of social media platforms can greatly help. Recently, the MoHFW has prepared some frequently asked questions (FAQs) and fact sheets and ICMR has been preparing press statements and posting updates on COVID-19 on its website on a daily basis. The WHO has also developed a lot of educational messages and warned the public about an ongoing infodemic, discussing ways of

Table II. Key areas of ethical preparations for research in case of outbreak/epidemics

Area	Objective	Stakeholders
Building trust and communication	To create better understanding and trust between patients/representatives and healthcare professionals through better communication	Patients, public, researchers, medical professionals, ECs, Regulators, government agencies, sponsors, media, civil society, community representatives
Protection and engagement	To have better transparency, accountability and to plan activities while being sensitive to the needs of the patients/representatives	Patients, families, community, doctors, nurses, field workers
Collaboration and partnership	To plan collaboration across boundaries with public or private entities for more meaningful and timely outcomes	Scientists, medical professionals, State agencies, national agencies, governments, international agencies, pharmaceutical companies
Quality ethics review	To ensure quality ethics review by trained ethics committees in a timely and efficient manner and to guide and monitor the conduct of research	ECs, institutions, accreditors, regulatory bodies
Governance structure	To have a framework for governance of healthcare as well as research for meaningful outcomes	Scientific advisory committees, monitors, DSMB, ministry, departments

EC, ethics committee; DSMB, Data and safety monitoring board
Source: Ref. 5

combating rumours and false information on the internet¹³. Efforts must be in place to gather public support and trust and remove unnecessary anxiety, panic or scare. Media has an important responsibility to report facts in a timely manner and not create false alarms. The ICMR has partnered with the Global Health Strategies to receive guidance on communication and networking activities¹⁴. Nodal communication officers have been appointed in each of the institutes who coordinate with the Communication Unit at ICMR Headquarters office and public relations officers for media-related activities. A social media policy has been released and a few workshops have been held to train scientists on effective communication skills¹⁵. These small initiatives can go a long way in improving communication capabilities and build strong public support. Communication, engagement and consultations with various members of civil society, non-government organization (NGOs), patient and community representatives can greatly improve the understanding of the societal ethical values in planning and make interventions more sensitive to the needs of our population.

Capacity building and protection of patients, research participants, families and health workforce

Constant efforts are required at State, regional or national level to build capacity in diagnostics, infection control, outbreak management and adaptation to the international standards and ensure appropriate training of the workforce. Researchers must make sure that there is a fair selection of patients as research participants, and steps have been taken for risk minimization and equitable distribution of risks and benefits, and approvals from ECs⁵. It may be important to note that some vulnerable persons may become particularly vulnerable due to the disease condition and may need more protection. If a clinical trial is planned, the trial site capacity and country scientific capacity development is essential and local researchers should be involved in the conduct of a trial, especially at planning, review and writing stages. The health professionals and healthcare workers should look at individual needs and make efforts to not only prevent the spread and reduce the severity but also be sensitive to the impact on family or the community. Due care should be provided to treat, give supportive care, and provide comfort in isolation, or quarantine, as well. Informed consent process should be simple and in the language understood by the participant. Depending on circumstances, use of oral

methods for consenting or waiver of consent can be planned with due approval of the EC in line with the sociocultural milieu. Often, research or therapeutic interventions may be using unproven or experimental therapies and there would be unclear benefits or unknown harms, which require due monitoring and follow up on a long-term basis. The researchers must be aware of plans to safely store the collected samples or information, for the specified duration, knowing who can have access, or with whom this may be shared, and for what purpose. This can help avoid any further trauma, stigmatization, discrimination or even ostracization. Any unauthorized disclosure of personal information collected during an outbreak (name, address, diagnosis, family history, caste, community, *etc.*) can expose individuals to additional risk. Use and sharing of non-aggregated surveillance data for research purposes should have the approval of well-trained ECs. Researchers as well as ECs should be alert to the issues of conflicts of interest which could be commercial (monetary gains and patents) or academic (awards, promotion and publications) and manage them. Safety of all healthcare workers should also be top priority in ethical preparedness and they should have access to good-quality basic safety and protection gear, from possible infection in the course of their interactions with infected patients/participants. It is also important to ensure the physical, social and psychosocial support to health workers who take great risk to their own health.

For ethical conduct of public health interventions or research and protection of patients/participants/families and communities ongoing efforts are required to build capacity of the health force and safe work environment for doctors, nurses, field workers or other members of the team.

Collaborations and partnerships - Including sharing samples, biobanking

Collaborations at the level of State, region, national or international level are important to ensure prompt and appropriate responses in outbreak/epidemic situations. Collective knowledge and experiences can guide the situation better and accelerate the scientific efforts to control the spread of infection or develop new therapeutics. Collaboration can be between public agencies or with private partners and in case of COVID-19, following the genome sequence released by China, global efforts were initiated to target diagnostics therapeutics

control and prevention. The WHO plays an important role in coordinating efforts to control the outbreak at the global level and brings the scientific community for various countries together for undertaking critical public health research in therapeutics, diagnostics as well as innovations. Collaborations may also be needed between international partners to closely monitor the outbreak and understand the pathogen better. Preparedness is needed to have policies in place in regard to sharing the data, samples, results of studies when protecting intellectual property and ownership, as well as storage of sample for future use. At present, there is a requirement to obtain a clearance from the Health Ministry's Screening Committee (HMSC) for any research involving international collaboration and the committee looks at the sensitivity of the research and need for collaboration¹⁶. For research on outbreaks/epidemics, there should be appropriate fast-track mechanisms in place to facilitate research in international collaboration. Extensive collaborations at local, regional, national or international level involving public agencies or private entities are needed to multiply efforts to control the spread of infection and develop therapeutics to preserve lives. Ethical Considerations form an important part of the collaborative policies to allow sharing of samples/data and recognize intellectual contributions.

Robust ethical review

All biomedical and health research must undergo ECs review before its conduct in accordance with the National Ethical Guidelines and considering the local ethical values for due protection of research participants. To review clinical trial protocol, ECs are requested to register with CDSCO, whereas others must register with DHR and can review biomedical and health research. There are many ECs that have received accreditation from NABH or even have international recognition from Strategic Initiative for Developing Capacity in Ethical Review¹⁷. Depending on the region of outbreak, the needful ECs in the region can be activated. The ICMR in the last few years has conducted extensive training and dissemination programmes across the country and more than 7000 persons have received an update¹⁸. The copy of national guidelines has been widely shared across medical colleges and research institutions to empower the decisions and functioning of the ECs. ICMR also released a brief handbook summarizing the key take-home messages from the main national

guidelines¹⁹. The ICMR Bioethics Unit at the ICMR-National Centre for Disease Informatics and Research, Bengaluru, has also developed a web portal with all important information and resources²⁰. A good EC would review all documentation looking at both scientific and ethical aspects of the research as it would concern the human participants. Besides reviewing the protocol and informed consent form, it would look at other elements as well, such as management of adverse events, provisions made for isolation, quarantine, travel restrictions, monitoring research teams for any signs and symptoms of infection, availability of appropriate training to work in such challenging situations, *etc.* It would guide payment of compensation in case of injury, look at ways for protection of confidentiality, and prevention from any stigmatization, rapid post-trial access, local roll out and surveillance, benefit sharing with the community, fair and transparent partnerships, international collaboration and publication of results in a timely manner. Ethical values must be upheld during public health emergencies²¹.

Ethical review by well-trained, efficient and accredited ECs in a timely manner can not only protect the safety and well-being of patients/research participants as well as health workers from any undue harm but also improve science and quality of research outcomes. Table III summarizes the ethical issues for consideration⁵.

Appropriate governance and monitoring structure

Dealing with outbreaks and emergencies efficiently and promptly would require a very robust governance mechanism where the roles and responsibilities of each stakeholder are clearly laid out. Research must be responsive to affected communities and the officials must ensure appropriate, expedient and flexible mechanisms²². The framework would also facilitate close oversight, appropriate monitoring to entail activities such as adequacy of informed consent, adherence to approved protocols, collection of adverse events, ensuring the integrity of the collected research data, appropriateness of participant selection. A clear organizational chart defining responsibilities and flow of information with all stakeholders would help clarify right at the beginning, on who conducts, or who reviews the protocol scientifically and who monitors the study, or appoints Data and Safety Monitoring Board to function independently. An enabling network which can share, communicate, support, issue advisories, handle media concerns, reduce panic in the public and be effective

Table III. Ethical issues for consideration during outbreaks/epidemics

Topic	Details
Social value	Public health relevance, importance of using unapproved interventions to save lives, prevent spread of infection in care of outbreaks or epidemics
Scientific design and conduct	Use of unapproved interventions after thorough scientific consultation for trial (placebo/intervention). Clear inclusion exclusion criteria
Benefit risk assessment	Benefit and risks assessed at both individual and population level. Supportive care, adequate monitoring/follow up, management of adverse events, <i>etc.</i>
Selection of study population/recruitment of participants	Fair selection of participants following defined methodology removing the possibility of any bias or discrimination of particular group or individual
Protection of privacy and confidentiality	Identifying information of confirmed cases to be reported to public health authorities but protected from unauthorized access to media or others
Community consideration	Efforts be made to engage with communities to communicate, discuss sensitivities involved. Release timely, accurate updates to remove panic
Qualification and site facilities	Site well equipped to deal with outbreaks/appropriate facility for isolation and quarantine. Investigators and health workers trained/qualified to understand ways of infection control
Informed consent process	Prior approvals with dummy protocol/informed consent forms. EC may be requested to allow oral consent/waiver of consent depending on situation, efforts be made to simplify informed consent in local language
Collaboration	Urgent need to join hands to make collective efforts for infection control. Adequate safeguards needed and sharing data, sample storing for future use, biobanking, <i>etc.</i> , and fast-track systems to facilitate collaboration
Governance mechanism	Well informed, responsive governance mechanism involving all stakeholders who can work towards a common goal of outbreak control and guide research

Source: Ref. 5

in controlling the crisis in a time-bound manner can be of great value in an outbreak situation. It will cover provisions for data collection and analysis while ensuring that the conflicts of interests are managed. Since it is not possible to predict the region for outbreak or its extent in advance to support prior planning, holistic, well informed, and fast-track approaches at the central level are critical. Dealing with an outbreak may require an inter-ministerial master plan involving not only MoHFW but also other Ministries, Departments and Agencies. In ICMR, the Division of Epidemiology and Communicable Diseases has developed action plan in consultation with expert groups. The responsibilities of multiple stakeholders including those of sponsors, industry, NGOs, government and others must be clearly defined²³. A governance framework for rapid response with collaborative planning and coordination can help define responsibilities of each stakeholder, encourage judicious use of resources, better planning and coordination to control the infection²⁴.

An ethically conscious, well informed and updated governance framework which identifies the relevant stakeholders, defines their roles and responsibilities,

lays down an implementation plan and a monitoring strategy, can safeguard the ethical values of the society, promote good science and deliver better outcomes.

Conclusions

Ethics preparedness is an important component of plan for dealing with public health emergencies or outbreaks because it helps ensure best standards and quality of deliverables without any compromise on human safety and the ethical values. Availability of trained health workers with strong psychosocial support, research-enabled environment, good ethics review, prior community needs assessment and possible adoption to the present requirements are measures that can help develop interventions that are robust and at par with the international standards. The preparedness also helps the government initiate immediate response and fulfil the expectations from the public and build their confidence and trust. Along with well-equipped laboratories to tackle highly contagious organisms, appropriate updates on training of health personnel are important. Prior plans for data sharing, storage of samples and biobanking can be developed and the network of laboratories and the governance structure can enable them to initiate timely

action and improve quality of outcomes. Fair and transparent accountable collaborations are important. The strong political support along with preparedness activities can lead to the successful conduct of public health interventions that may be required and pave the way for future trials in the country. Outbreaks stimulate all partners and agencies to collaborate their efforts to establish best socially acceptable responses that ensure ethical safeguard for the population. Together countries can achieve a lot in tackling the outbreaks which need prompt public health action to prevent their spread and save human lives. Ethics preparedness can guide various stakeholders involved in the public health emergency for fair decision-making based on moral reasoning in the best interest of the population and thereby help make outcomes more ethical and acceptable to the public.

Conflicts of Interest: None.

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