



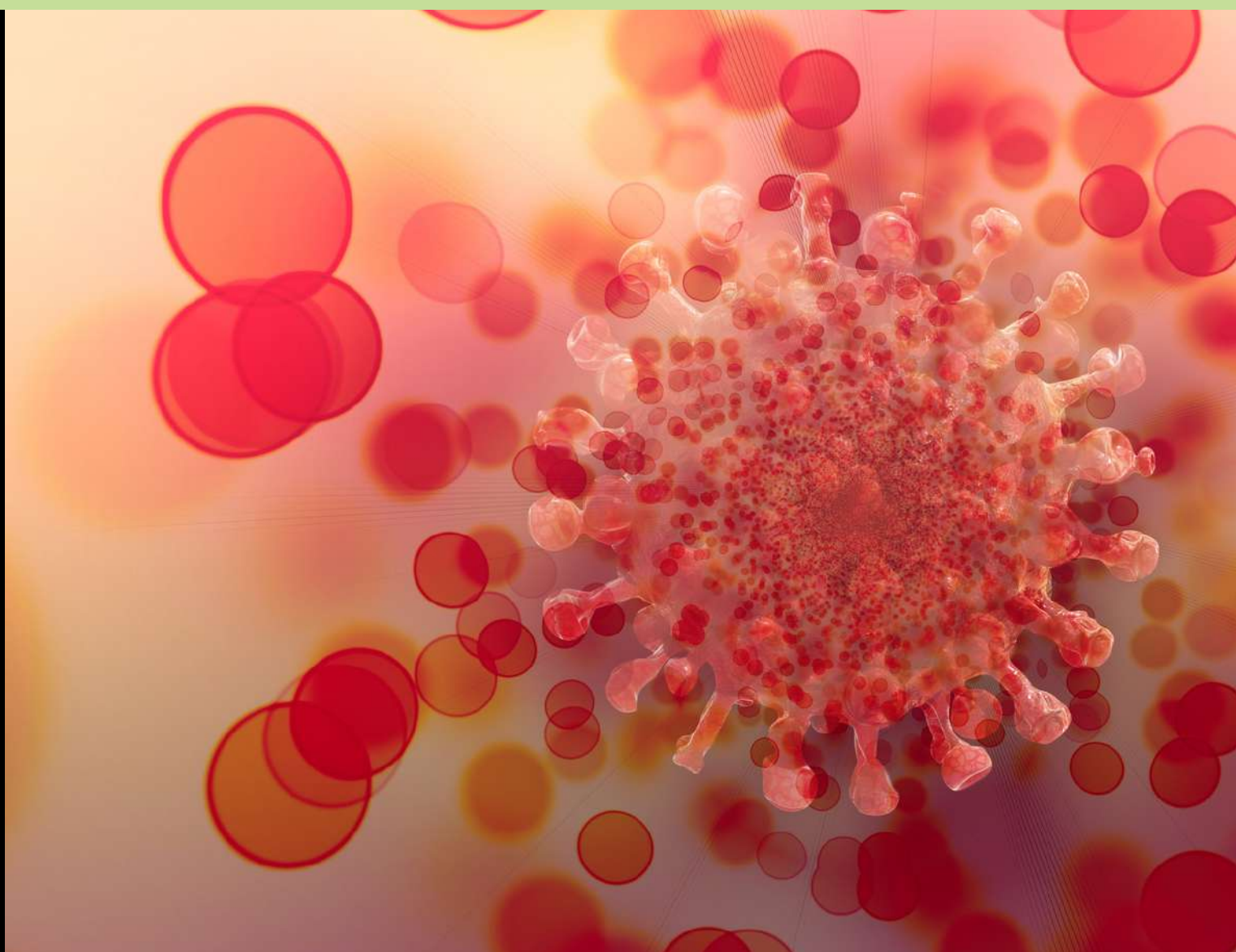
FERCICON 2020-21

**8TH NATIONAL CONFERENCE OF FORUM FOR
ETHICS REVIEW COMMITTEES IN INDIA**
HYBRID MODE: 21st-23rd October, 2021

SOUVENIR

Theme of the conference

“Experience and lessons learnt from COVID-19 Pandemic”



Organized By:

**North Eastern Indira Gandhi Regional Institute of Health and Medical
Sciences, (NEIGRIHMS) Shillong, India**

8th NATIONAL CONFERENCE OF FORUM FOR ETHICS REVIEW COMMITTEES IN INDIA

Program Highlights

PRE-CONFERENCE WORKSHOP

- Registration & accreditation of Ethics Committees
- New Drugs, Biomedical research and Clinical Trial Rules, 19, March, 2019
- Role of regulatory bodies like DCG(I), NABH & ICMR in Ethical conduct of clinical research
- Regulation of different medical devices 2021
- Publication ethics

MAIN CONFERENCE

- Experience and lessons learnt by different stakeholders
- Evolution of diagnostics & other interventions during the pandemic
- Epidemiological studies and disease surveillance
- Role of community engagement in tackling the pandemic
- Indian experience in Vaccine development
- International perspectives in collaborative research

Registration Fees:

	<u>Early Bird Up to 30th Sept. 2021</u>	<u>Up to 18th Oct. 2021</u>	<u>Spot Registration</u>
FERCI Member	750 INR	1000 INR	1250 INR
Non FERICI Member	1000 INR	1250 INR	1500 INR
Industry Delegate	1500 INR	1750 INR	2000 INR
Student*	500 INR	750 INR	1000 INR
Institutional FERICI Members (Max. Nominated members 5)	750 INR	1000 INR	1250 INR

* Student ship to be certified by the concerned Head of the Institution.

Account Details

A/C Holder: M/S FERICON 2019
Bank Name: Bank of Baroda
Account No.: 30270200000098 (Current)
IFSC Code: BARBOMAWDIA
Branch Name: MAWDIANGDIANG MEGHALAYA

FERCI Organizing Members



Dr. Vasantha Muthuswamy
President, FERICI



Dr. Nandini R. Kumar
Vice-President, FERICI



Dr. Urmila Thatte
Secretary, FERICI



Dr. Sandhya Kamat
Treasurer, FERICI



Dr. Roli Mathur
ICMR Bioethics Unit



Prof. Bikash Medhi
PGIMER, Chandigarh

Local Organizing Team



Prof. (Dr.) Nalin Mehta
Director, NEIGRIHMS



Prof. Asima Bhattacharyya
Dean, NEIGRIHMS



Prof. Chayna Sarkar
Professor & HOD, NEIGRIHMS



Dr. D. K. Brahma
Associate Professor, NEIGRIHMS

For Registration Click on:

<https://forms.gle/dRrge527g9UmuMD69>

FERCICON 2020-21



HYBRID MODE
21st-23rd October, 2021

PRE-CONFERENCE WORKSHOP
21st October 2021
10.30 am to 2.00 pm

Main FERICON 2020-21
22nd to 23rd October 2021
10.30 am to 4 pm

Important Dates

Early Bird Registration: 30th September, 2021
Last date for Abstract Submission: 13th October, 2021
Last date of Registration: 18th October, 2021
Spot Registration is also available

PRE-CONFERENCE WORKSHOP

- NDCT Rules 2019
- An update on ethics committee Registration & Accreditation
- Publication ethics

THEME FOR FERICON- 20-21

Experience and lessons learnt from COVID-19 pandemic

Organized By:

North Eastern Indira Gandhi
Regional Institute of Health and
Medical Sciences, (NEIGRIHMS)
Shillong, India

Contact:

Dr. Dhriti K. Brahma
Department of Pharmacology
NEIGRIHMS, Shillong
Email: dbdhrity168@gmail.com
Ph. No.: 8794706170

Prof. Bikash Medhi
Email Id: drbikashmedhi@gmail.com
Mob. no.: 9815409652



FERCICON 2020-21

**8th NATIONAL CONFERENCE OF FORUM
FOR ETHICS REVIEW COMMITTEES IN
INDIA**

Scientific Programme



Theme of the conference
**Experience and lessons learnt from COVID-19
Pandemic**

HYBRID MODE: 21st-23rd October, 2021

PRE-CONFERENCE WORKSHOP

21st October 2021

Main FERCICON 2020-21

22nd to 23rd October 2021



FERCICON 2020-21
Pre-Conference Workshop
 NDCT Rules 2019, An update on ethics committee
 Registration &
 Accreditation, Publication ethics



Day- 1, 21st October, 2021

Time: 11:00 AM to 02:00 PM

Organized by: NEIGRIHMS, SHILLONG

Chairpersons: Dr. Vasantha Muthuswamy & Dr. Nandini K Kumar

11:00 AM – 11:15 AM	Welcome & Introduction FERCI video & NEIGRIHMS video	Dr. Vasantha Muthuswamy Prof. Nalin Mehta Prof. Bikash Medhi
11:15 AM – 11:45 AM	ICMR National Ethical Guidelines and COVID-19 guidelines for EC members	Dr. Roli Mathur, ICMR NCDIR, Bengaluru
11:45 AM – 12:15 PM	NDCT Rules,2019	Dr. Urmila Thatte, Emeritus Professor, KEM, Mumbai
12:15 PM – 12:45 PM	Registration of ECs – CDSCO & DHR	Dr. Abhidnya Desai, TMH, Mumbai
12:45 PM – 01:15 PM	Accreditation of ECs and Good Clinical Practice Professional Certification Scheme (GCPPCS)	Dr. Sucheta Banerjee Kurundkar, CDSA, DBT, Delhi
01:15 PM – 1:45 PM	Publication Ethics	Prof. Bikash Medhi, PGIMER, Chandigarh
01:45 PM – 02:00 PM	Closing session	Dr. Chayna Sarkar Prof. & HOD Dr. Dhriti Brahma, NEIGRIHMS, Shillong



FERCICON 2020-21
Main Conference Schedule
Experience and lessons learnt from COVID-19 pandemic



Day- 2, 22nd October, 2021

Time: 11:00 AM to 04:45 PM

Organized by: NEIGRIHMS, SHILLONG

11:00 AM – 11:30 AM	Welcome & Introduction NEIGRIHMS video FERCI Video Inauguration of the Conference Inaugural address	Prof. Prabha Shankar Shukla Vice- Chancellor, NEHU Dr. Vasantha Muthuswamy, FERCI, President Prof. Nalin Mehta, Director, NEIGRIHMS Dr. Vinod K Paul NITI AYOJ
11:30 AM – 11:50 AM	Key Notes Address Ethics in COVID-19 Pandemic-WHO experience	Dr. Katherine Littler, WHO, Geneva
Session I: Experience and lessons learnt by different stakeholders during Pandemic		
Chairpersons: Dr. Vasantha Muthuswamy & Dr. Nandini K Kumar		
11:50 AM – 12:10 PM	Sponsor Perspective	Dr. Sanish Davis, ISCR, Mumbai
12:10 PM – 12:30 PM	Researcher Perspective	Dr Tulika Seth AIIMS, New Delhi
12:30 PM – 12:50 PM	Ethics Committee (EC) Perspective	Dr. Padmavathy Menon, Chairman KEM/TATA Memorial Hospital
Session II: Evolution of diagnostics & other interventions during the pandemic		
Chairpersons: Prof. Y. K. Gupta & Dr. M. Narendranathan		
12:50 PM – 1:10 PM	Diagnostics	Dr. Priya Abraham, Director, NIV, Pune
01:10 PM – 01:30 PM	Repurposed drugs	Dr. Rubina Bose, CDSCO, Delhi
01:30 PM – 01:50 PM	Vaccines	Dr. N K Arora, INCLN, New Delhi
01:50 PM – 02:10 PM	Public health interventions	Dr. Anand Krishanan, AIIMS, New Delhi
02:10 PM – 02:30 PM	Potential innovations to treat chronic disease in the post COVID era	Dr. Prabhakaran Dorairaj PHFI New Delhi
02:30 PM – 02:45 PM	LUNCH BREAK	

Session III: Panel Discussion**Chairpersons: Dr. Pradeep Kumar Goswami & Dr. S L Hoti, Moderator: Dr. Urmila Thatte**

02:45 PM – 03:30 PM	Experience from different health care systems AYUSH & Modern medicine	Dr. N Srikant (Ayurveda) / Dr. Raghavendra (Yoga)/ Dr. Anil Khurana (Homeopathy)/ Dr. Asim Ali Khan (Unani)/ Dr. Meenakshi Sundaram (Siddha)/ Dr. Padma Gurmet (Sowa Rigpa)/ Dr. Nandini Kumar, DSMB AYUSH/ Dr. PK Bhattacharya (Modern Medicine)
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FREE PAPER PRESENTATION**Chairpersons: Dr. Sandhya Kamat & Dr. S K Tripathi**

03:30 PM – 03:40 PM	Finding Solace in the Mid of Inequality: Lessons from the Pandemic	Dr Ankita Kar NCDIR-ICMR
03:40 PM – 03:50 PM	SARS-CoV-2 Vaccine Research & Administration In Vulnerable Population: A Systematic Review Of Scientific & Ethical Challenges	Dr. Shreya Gupta PGIMER, Chandigarh
03:50 PM – 04:00 PM	Knowledge and Awareness of Ethics Committee members about Functioning of Ethics Committee during COVID -19 pandemic	Dr. Ganesh Dakhale, AIIMS Nagpur
04:00 PM – 04:10 PM	An observational study of the common errors made by the principal investigator and lacunae found in Informed consent during submission to the ethics committee in a tertiary care Hospital in the eastern Uttar Pradesh region.	Dr. Kiran Rajendra Giri, Banaras Hindu University, Varanasi
04:10 PM – 04:20 PM	Clinical and laboratory findings in COVID-19 Adult hospitalized patients in Southern Assam	Dr. Neeraj Sinha, Silchar medical College and hospital, Silchar
04:20 PM – 04:30 PM	Vaccine hesitancy and its associated factors in COVID vaccination among a tribal community of Meghalaya: A mixed methods study	Dr. Joanna Devi Ningombam, NEIGRIHMS, SHILLONG
04:30 PM – 04:40 PM	Insights from a survey-based study on India Ethics Committee functioning during COVID-19	Dr. Priyadarshini Arambam Batra Hospital and Medical Research Centre, New Delhi
4.40 PM to 5.30 PM	GBM for all FERCI members	



FERCICON 2020-21
Main Conference Schedule
Experience and lessons learnt from COVID-19 pandemic



Day- 3, 23rd October, 2021

Time: 11:00 AM to 04:00 PM **Organized by: NEIGRIHMS, SHILLONG**

11:00 AM – 11:30 AM	Key note address Experience of Single Joint Ethics Review of Multicenter Research in Philippines	Dr. Jacinto Blas V. Mantaring, Overall Chair of EC of University of Philippines, Manila
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Session IV: Epidemiological studies and Public Health

Chairpersons: Dr. Shalini Bharat & Dr. Brogen Singh

11:30 AM – 11:50 AM	Implementation of Public health Interventions	Dr. Raman Kutty, Amala Cancer Research Center, Thrissur
11:50 AM – 12:10 PM	Gender Issues	Dr. Ravi Verma ICRW, New Delhi
12:10 PM – 12:30 PM	Mental Health issues	Dr Sunita Simon Kurpad, St John's, Bangalore
12:30 PM - 12:50 PM	Environmental issues	Dr. Uma Rajarathnam, WHO-SEARO, New Delhi

Session V: Vaccine Related Issue

Chairpersons: Prof. Bikash Medhi & Dr. Roli Mathur

12:50 PM - 1:10 PM	Global Perspective	Dr. Ross Upshur, University of Toronto, Canada
1:10 PM – 1:30 PM	Public perspective from India	Dr. Anant Bhan, SANGATH, Bhopal

01:30 PM – 02:00 PM **LUNCH BREAK**

Free paper presentation

Chairpersons: Dr. Bini Toms & Dr. Medha Joshi

02:05 PM – 02:15 PM	Ethical challenges in Telephonic Data Collection for assessing impact of COVID-19 on Maternal and Child health services through the public health system in Maharashtra	Dr. Ragini Kulkarni ICMR-National Institute for Research in Reproductive Health (NIRRH), Parel, Mumbai
02:15 PM- 02:25 PM	The impact of the COVID-19 pandemic on attention deficit hyperactivity disorder drug therapy - a snapshot'	Dr. Rahul Das Nil Ratan Sircar Medical College, Kolkata

02:25 PM – 02:35 PM	Association of type of funding and conflicts of interest to outcome reported amongst the published studies of Covid-19	Dr. Snehalata Gajbhiye AIIMS Nagpur
02:35 PM – 02:45 PM	Covid-19 pandemic: A wake-up call on the significance of capacity-building and protection of research participants.	Dr. Sri Chandana Tanguturi ICMR-NCDIR
02:45 PM – 02:55 PM	Perceptions about Ethics of Public Health Behavioral Interventions during the Covid 19 Outbreak	Dr. Yashashri Shetty Seth GSMC & KEMH, Mumbai,
02:55 PM – 03:05 PM	Drug use pattern during covid-19 pandemic in cardiology in-patient department: a cross sectional study	Dr. Manali Saha Nil Ratan Sircar Medical College, Kolkata
03:10 PM – 03:30 PM	Valedictory address	Dr. Vinod K Paul NITI AYOJ Dr. Vasantha Muthuswamy, FERCI, President
03:30 PM – 04:00 PM	Closing SESSION Announcement of Prizes Views of participants Announcement of next conference & Vote of Thanks	



ABOUT THE CONFERENCE

The Forum for Ethics Review Committees in India (FERCI) is a registered society (Maharashtra State, Reg No. 865/2006 200 GBBSD) set up as the national chapter of FERCAP (Forum for Ethics Review Committees in the Asia Pacific), the latter being an initiative undertaken by WHO TDR.

The idea that such a national forum was needed in India to improve understanding and implementation of ethical review of biomedical research in India, with relevance to local cultural values, was crystallized at Agra on December 19, 2002, as the Indian Chapter of FERCAP during a historical workshop held by FERCAP to write standard operating procedures for the functioning of ethics committees.

FERCI operates in close collaboration with important institutions like the World Health Organization (WHO), the Indian Council of Medical Research (ICMR), the Central Drugs Standard Control Organization (CDSCO), FERCAP, SIDCER (Strategic Initiative for Development of Committees for Ethics Review), etc.

Membership of FERCI is open to everyone involved with ethics review committees and those interested in the process of ethics review of biomedical research in India.

This year 2021 FERCI have given NEIGRIHMS, Shillong the opportunity and responsibility of hosting the 8th National Conference titled **FERCICON 2020-21** with the *theme: "Experienced and Lesson learned from CoVID-19 pandemic"*



ABOUT NEIGRIHMS

Established in 1987, NEIGRIHMS has been intended to be a postgraduate medical institution like AIIMS, New Delhi, and PGIMER, Chandigarh. It was the first postgraduate medical institution in the North-Eastern region, and the third in the Country established by the Ministry of Health and Family Welfare, Government of India. It was registered as a Society on the 12th of January, 1987 by the Registrar of Societies, Meghalaya, Shillong as:

“North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences”.

The North-Eastern region of India has a population of about 46 million which is about 3.7% of the Indian population in an area of about 2.6 Lakh square km covered by about 400 hospitals where the doctor population ratio is approximately 1: 5000 against a national figure 1:2000, with an overall 50% deficiency in medical manpower and overall, 60% in the health sector. NEIGRIHMS has been envisaged as the most vital asset to address the shortage in the North Eastern Region in terms of Health care delivery as well as Human Resource Development.

Destined to be the Pride of the North Eastern Region, NEIGRIHMS, the Island of Excellence bears the mission of an apex coordination center to guide the health care policy of the Central Government, to potentially coordinate with international health organizations like WHO, UNICEF, World Bank and so on, in the activities of the health sector with a Vision of developing an apex seat of learning cum health care delivery and capacity building as also to develop a self-sustainable resource center of Health and Medical Sciences through the trinity of training, services and research.

Satya Pal Malik
Governor



RAJ BHAVAN
SHILLONG - 793001
MEGHALAYA
INDIA



MESSAGE

I am happy to learn that the Department of Pharmacology, NEIGRIHMS, Shillong is organising a 3 (three) days National Conference of "Forum For Ethics Review Committees in India (FERCI)" in Hybrid Mode to be held at NEIGRIHMS, Shillong from 21st to 23rd October, 2021 with the title "**FERCICON 2020-21**" on the theme "**Experience learned from COVID-19 pandemic**" and an e-souvenir is being brought out to mark the occasion.

I extend my best wishes for the success of the Conference.

(Satya Pal Malik)

Phone : +91 3642223001, +91 3642223487

Fax : +91 3642224902

E-mail : maliksatyapal@hotmail.com

rajbhavan-meg@gov.in

Biswanath Somadder
Chief Justice
HIGH COURT OF MEGHALAYA



10th October, 2021

MESSAGE

I have been informed that the Department of Pharmacology, NEIGRIHMS, is going to organise a 3 (three) days National Conference of “FORUM FOR ETHICS REVIEW COMMITTEES IN INDIA (FERCI)” *in Hybrid Mode to be held at NEIGRIHMS, Shillong from 21st to 23rd October, 2021, with the title “FERCICON 2020-21.”* The theme for this event is “*Experience learned from CoVID-19 pandemic*”.

I wish the ensuing Conference all success and may the participants get all positive benefits from the deliberations that will take place during the 3 (three) days of the Conference.

Conrad K. Sangma
Chief Minister
MEGHALAYA



Office : 0364-2224282
PABX : 2200
FAX : 0364-2227913
(R) 2522752

MESSAGE

It gives me immense pleasure to know that the department of Pharmacology, NEIGRIHMS, is organising a three day National Conference of the 'Forum for Ethics Review Committees in India (FERCI)', in Shillong this month.

I convey my best wishes to the organisers and all the participants of the conference and wish 'FERCICON 2020-21' a grand success.



(Conrad K. Sangma)



पूर्वोत्तर पर्वतीय विश्वविद्यालय
पू० प० विवि० परिसर, शिलांग-७९३०२२ (मेघालय)
North-Eastern Hill University
NEHU Campus, Shillong - 793 022 (Meghalaya)



Prof. P.S. Shukla
Vice-Chancellor

Tel. Nos 0364-2550101/2721003/4(O)
e-mail: vcnehu@nehu.ac.in

With the arrival of COVID-19 our lives have abruptly changed. This year has been the most challenging due to the second wave of the pandemic. Looking into these circumstances, I feel honoured to write this souvenir message for the 3-day conference of **Forum for Ethics Review Committees in India (FERCI)** in hybrid mode organized by Department of Pharmacology, NEIGRIHMS, Shillong titled **“FERCICON 2020-21”** with the event theme **“Experience learned from Covid-19 pandemic”**.

We are currently in the midst of a worldwide trial that has changed our lives beyond recognition. Bioethics is a matter of growing international concern which has implications for many areas of our lives. Biomedical research is multidisciplinary in nature and involves various stakeholders; like the principal investigators, medical practitioners, the sponsors, the pharmaceutical industry, drug control regulators, researchers and ethics committees. Each stakeholder confronts ethical dilemmas which need to be resolved with appropriate clinical practices. There is a need to unite all the stakeholders with diverse interests in a single forum. The FERCICON has been providing such an active platform for such consensus.

Covid-19, has challenged clinicians' professional commitment to their communities and to humanity, accompanied by a sacrifice of their own safety and safety of their near and dear ones. In this context, the Holy Granth **“Bhagavad Gita”** is more relevant than ever, especially now in the midst of the Covid-19 pandemic. Recently an article in **The European Heart Journal, a peer-reviewed journal of cardiology published by Oxford University**, has equated **“Prince Arjuna” to healthcare workers and the Kurukshetra battlefield to hospitals**. The great Arjuna, the Mahabharata War Hero's only duty was to fight and **“not worry who he was fighting or the outcome of the war,”** that **resonates the idea** to do what is needed without becoming attached to the result is the way of living a skilful life. With these lessons in mind during the pandemic, I would urge everyone to live an ethical life, addressing difficult questions that continuously arise from our changing circumstances.

Today, we are witnessing the globalization of health research, the spread of **'health tourism'** and the diminishing importance of national boundaries in the fight against corona virus. All these demonstrate that bioethics has an important international dimension. It is therefore important to identify common grounds around which constructive discussion can take place during FERCICON deliberations.

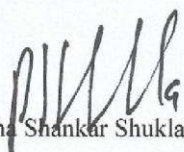
To quote the great sloka from Acharya Chanakya's Neeti Sastra

“अधीत्येदंयथाशास्त्रंनरोजानातिसत्तमः। धर्मोपदेशविख्यातकार्याकार्यशुभाशुभम्॥”

(That man who by the study of these maxims from the sastras acquires a knowledge of the most celebrated principles of duty, and understands what ought and what ought not to be followed, and what is good and what is bad, is most excellent”)

In that spirit, I extend my warmest wishes for organisers who are conducting an interesting and constructive conference.

Let's be ethical. JAI HIND!


(Prabha Shankar Shukla)



MESSAGE

I am glad to know that the Department of Pharmacology, NEIGRIHMS is organizing a National Conference of “Forum for Ethics Review Committees in India (FERCI)” in Hybrid mode to be held at NEIGRIHMS, Shillong from 21st to 23rd October, 2021 with the theme ‘**Experience learned from CoVID-19 pandemic**’. This will be a platform where Speakers and Stakeholders will share and deliberate on the different aspects of CoVID-19 which in turn would be beneficial to all stakeholders.

I convey my best wishes to the Organizers and all participants and wish the Conference a success.


19/10/2021
Director of Health Services (MI)
Meghalaya, Shillong

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences
(An Autonomous Institute)



Dr. Nalin Mehta
Director
NEIGRIHMS



Tel: 0364 2538013 (O)
Fax: 0364 238003
Website: <http://www.neigrihms.gov.in/>
Email: info.neigrihms@nic.in

MESSAGE

It gives me immense pleasure to note that NEIGRIHMS is organizing “**FERCICON 2020 – 21**”, a 3-day National Conference for “*Forum for Ethics Review Committees (FERCI) via Hybrid Mode*” from 21st to 23rd of October, and a Souvenir/E- Souvenir is being brought out to commemorate the occasion.

The conference theme, “**Experiences and lessons learned from Covid-19 pandemic**”, appears to have been very carefully chosen to make sure we can benefit from our experiences during the pandemic and ensure better preparedness and awareness by gaining from the experiences of various stakeholders, getting an insight into the evolution of diagnostics and other interventions related to the pandemic, its epidemiology and surveillance strategies, exploring avenues by which the community can be involved in tackling the pandemic in addition to the vast Indian experience in vaccine development and exploring international perspective for collaborative research.

The importance of Ethics committee and their role in review process of biomedical and clinical research protocol to safeguard the dignity, rights, safety and well-being of research participants etc. cannot be overemphasized.

It is heartening to see that some very crucial issues are being taken up in the pre-conference workshops, while the main conference in itself promises to be a scholastic extravaganza addressing highly pertinent and timely topics, with a strong bearing on the Indian context. I am sure the proceedings will be of tremendous help to all the attendees and will assist them in establishing the highest standards of research ethics in their institutions for the larger good of the community, the nation and for promotion of quality scientific enquiry.

It is also heartening to know that speakers from WHO-Geneva, NITI-Ayog, ICMR, CDSCO, NIV and eminent national-level experts in their concerned fields will be deliberating in this conference.

On behalf of the faculty and staff of NEIGRIHMS, I welcome all the attendees of FERCICON 2020-21 to the beautiful city of Shillong, and extend my gratitude to the experts who have so graciously agreed to be the Resource Persons. FERCI, a national forum has the mandate to improve understanding and implementation of ethical review of biomedical research in India, with relevance to local cultural values. At this conference let us introspect over what we, as a professional community, have accomplished. Furthermore, let us not forget that our dream is to create even greater value globally. The academic program is highly exciting and I am sure it will encourage you all to reflect upon critical issues, commemorate your accomplishments, renew friendships and spread your networks to explore and refine present and future research focuses.

I wish the organizers the very best of success and hope this conference will go a long way in establishing NEIGRIHMS as a leader in the field for promoting Bioethics.


Director
NEIGRIHMS



**Presidential address for FERCICON 2020-21
on 21st October, 2021**

Dear Prof. Nalin Mehta, Director, Dr. Chayna Sarkar, Prof. & HOD, NEIGRIHMS, Dr. Dhriti Brahma, and Prof. Bikash Medhi, Organising Chairmen, the invited international and national speakers, all the registered participants, a very warm good morning and welcome to the 8th National Conference of the Forum for Ethics Review Committees in India commonly known by all of you as FERCICON. The COVID 19 pandemic and its impact has forced us to organise this as a Hybrid conference and I am grateful to Dr. Dhriti Brahma & Prof. Bikash Medhi for accepting the challenge of organising this hybrid mode event at a short notice, one more challenge to the innumerable ones we are all facing as public health and research community.

All of you just now saw the genesis and the decadal activities of FERCICON in the preceding video and its close collaboration with FERCAP and SIDCER in the last 20 years. All of us are stakeholders in biomedical and health research in one role or the other, responsible for good research practices leading to efficient and effective public health interventions borne out of good science and good ethics with the ultimate aim of safety and protection of all research participants. Most of us are familiar with the national and international guidelines to carry out scientifically valid and ethically appropriate clinical research and the onus of human participant protection is entrusted to the Ethics Review Committee members and we are also aware that most of us are not adequately trained to carry out this responsibility.

Realising this essential gap in the research armamentarium, multiple fora were established in 2000 onwards and in the last 20 years Capacity building of EC members and other stakeholders has been the main mandate around the world. FERCICON has taken up this responsibility in India by adapting different strategies including annual conferences to update the research community on the prevalent and changing global perspectives on research and ethical requirements. This year, naturally the theme we have chosen is related to COVID 19 pandemic which is having a crippling effect on the physical and the economic health of the entire world population. The global research community is pushed to come out with effective interventions through innovative strategies in the shortest timeframe. The global response has been tremendous in this regard to tackle the challenges by collaborating with each other to bring us all back to normalcy in the near future, adding a real meaning to our concept of “Vasudaiva Kutumbakam” – the whole world is my family. New approaches have emerged in the conduct as well as review of research giving new insights in tackling the ethical requirements which may become the new norms in the coming years. We are very happy at FERCICON for the overwhelming response from all the invited international and national speakers to share their experiences at the conference which will be a great learning experience for one and all.

My thanks are also due to the enthusiastic participants who are eager to share their perspectives with all of us. We are sorry, we are not able to allot time to all of you due to constraints of time. I am sure the next three and a half day sessions are going to be an intellectual feast for us listening to the best in the field about the global and national initiatives to tackle the challenges posed during the pandemic so that we are better prepared for future such challenges.

This conference has the blessings of Dr. Vinod K Paul, Member, NITI Ayog for delivering the Valedictory address, proof to the importance and relevance of the theme of the Conference to biomedical and health research and his appreciation to the initiatives taken by FERCICON.

I wish all of you an enriching experience on behalf of Team FERCICON and the Organising committee.

Dr. Vasantha Muthuswamy
President, FERCICON

21/10/2021

MESSAGE FROM THE EDITORIAL BOARD

It is a very proud moment for us to be a part of the long-awaited FERCICON, 2020-21. During this pandemic situation, we have adapted in various ways to combat the situation. Changes have also occurred in the research field with the requirement for novel treatment protocols, vaccine-related research etc. But in search of new remedies against COVID-19 in a short period of time, we should not ignore the moral rights of the study population, i.e. the ethical issues. The theme of the conference has also been set or the same, "Experience from pandemic COVID-19". We are blessed to get an opportunity to conduct FERCICON 2020-21, in a hybrid mode with such a timely topic, which will obviously enlighten the path for various researches without violating the ethical issues.

Thanking all

**EDITORIAL COMMITTEE
FERCICON, 2020-21
NEIGRIHMS**



Section 1
8th NATIONAL CONFERENCE OF FORUM FOR ETHICS REVIEW
COMMITTEES IN INDIA
Speaker's Abstract

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3.	Dr. Sucheta Banerjee Kurundkar, CDSA, DBT, Delhi	Accreditation of ECs and Good Clinical Practice Certification Scheme (GCPPCS)	4
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5.	Dr. Katherine Littler, WHO, Geneva	Ethics in COVID-19 Pandemic- WHO experience	5
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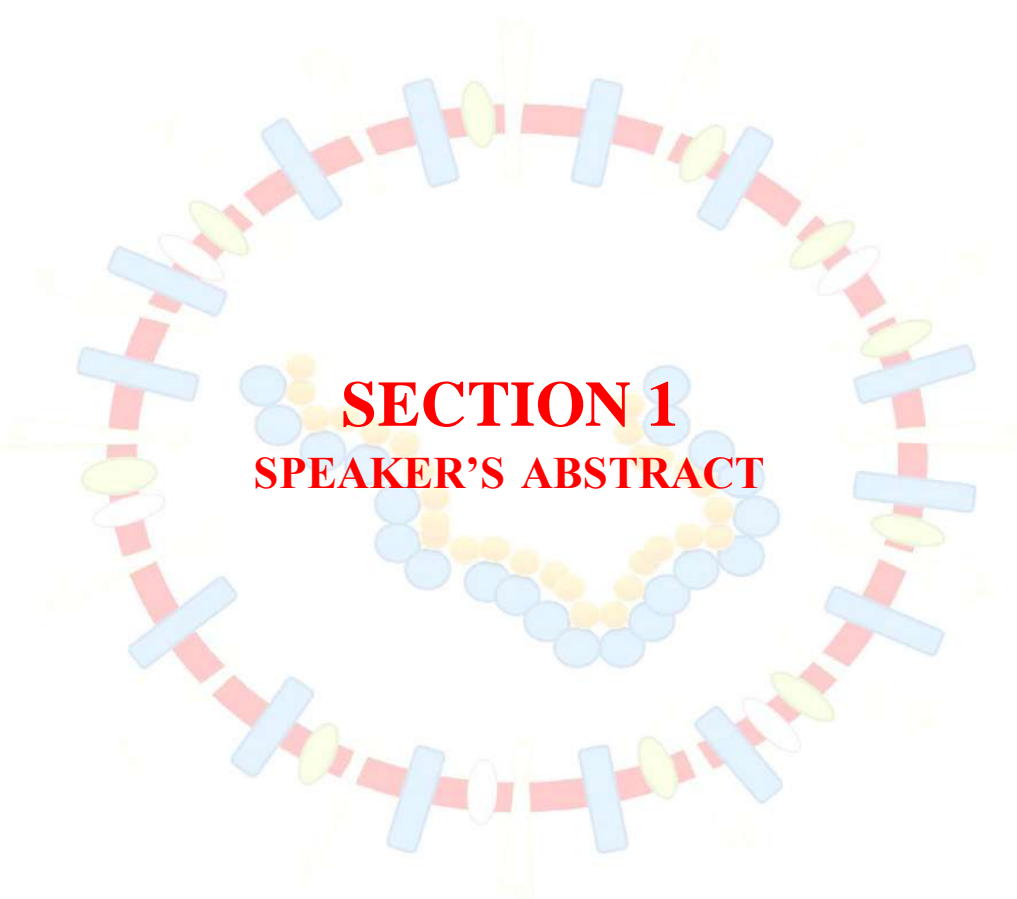
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ABSTRACT 1



Title: ICMR National Guidelines for Ethics Committees reviewing research during COVID-19 Pandemic

Author Name: Dr. Roli Mathur

Affiliation: Scientist F and Head, ICMR Bioethics Unit, NCDIR, Bengaluru

Abstract:

ICMR as an apex institution has always been at the forefront bringing out national ethical guidelines from time to time. With the onset of the pandemic and the lockdown situation, a need was felt to bring out detailed guidance to guide the ethics committees to conduct online reviews through virtual meetings. The latest guidelines for EC review of research during pandemics were amongst the first in the world to be published as early as April 2020. These have discussed how ethics committees can work efficiently to facilitate robust ethics reviews and support quality research which is much needed at this hour. It has highlighted ways to ensure participant protection on one hand and encourage the use of new innovative methodologies and promote the use of digital platforms for research. It suggests how electronic informed consent can be adopted and used for research. Further, the guidelines highlight the newer provisions such as common review of multicentre research, use of ICMR Common forms for ethics committees, adopting Standard Operating Procedures for an emergency review of research recently prepared and released by ICMR and posted on the website (<https://ethics.ncdirindia.org/>).

Further, the guidelines have provided useful suggestions related to improving communication and engagement with the local communities, being sensitive to their needs, safeguarding privacy while making mandatory disclosures to public health authorities, protecting societal values, and building trust. The guidelines discuss ways of protecting those who may be more vulnerable such as those who belong to high-risk groups such as senior citizens or people with co-morbidities or those who are marginalized and others. The need to ensure the psychosocial well-being and safety of health care workers has been highlighted as well.

It is time to integrate ethical reasoning into policymaking and put in place frameworks that encourage ethics preparedness which is critical to finding humane solutions and fair decision making in the best interest of the population. These guidelines have been widely downloaded not only in India but by more than 50 countries across the world and reported in many international newsletters. All biomedical research in the country must follow the National Guidelines to ensure quality ethics review for safeguarding the research participants.



ABSTRACT 2

Title: Registration of Ethics Committees–Central Drugs Standard Control Organization (CDSCO)& Department of Health Research (DHR)

Author Name: Mrs. Abhidnya Desai

Affiliation: Administrator, TMH, Mumbai

Abstract:

Ethics Committees reviewing biomedical and health research should register with the authority designated by the Central Government in the Ministry of Health and Family Welfare, Department of Health Research (DHR). With effect from 6th October 2021 onwards, the requirement of hard copies submission to NECRBHR, and DHR for login registration at the Naitik portal has been removed and is replaced with the eHastaakshar authentication system. EC registration is required to establish transparency and control over the constitution and functioning of the Ethics Committee, to maximize regulatory oversight over the regional IEC and clinical trials in India, and to the accountability of the clinical trials approved or reviewed by the IEC.

Who should register?

- Ethics Committees reviewing and approving clinical trials should register with CDSCO
- Ethics Committees reviewing biomedical and health research should register with the authority designated by the Central Government in the Ministry of Health and Family Welfare, Department of Health Research (DHR)

What can delay your registration?

- Incomplete checklist
- Lack of all EC SOPs
- Lack of SOP for vulnerable population
- Incomplete Membership documents
- Lack of training certificates or evidence for training in GCP/NDCT rules/ICMR/SOPs

CDSCO registration shall remain valid for a period of 05 years from the date of its issue unless suspended or cancelled by the Central Licensing Authority. Application for renewal of registration - 90 days prior to the date of the expiry of the registration.

DHR Provisional registration will remain valid for 02 years. Apply for final registration and the final registration granted by DHR shall remain valid for a period of 05 years from the date of its issue unless suspended or cancelled by the designated FERCICON 2020-21 authority at DHR.



ABSTRACT 3



Title: Accreditation of ECs and Good Clinical Practice Certification Scheme (GCPPCS)

Author Name: Dr. Sucheta Banerjee Kurundkar

Affiliation: Director Training, CDSA, THSTI, DBT

Abstract:

Ethics committees play a crucial role in clinical trials as important stakeholders. They continually review before, during, and after the clinical trials to ensure that the rights, safety, and well-being of all study participants are protected, and the data generated during the process are credible and accurate. There are various (3 are known) accreditation schemes for ECs. They are provided by NABH (QCI), SIDCER (FERCAP, WHO), and AAHRPP. Accreditations are voluntary in nature. There is no doubt that accreditation brings great benefits not only to the EC but to all the clinical trials stakeholders. This presentation describes in detail each one of them thereby raising interest and facilitating quality enhancement through accreditation awareness. Clinical Development Services Agency (CDSA), Translational Health Science and Technology Institute (THSTI) under the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India, after several years of involvement in the development and training in GCP (Good Clinical Practice), decided to leverage its strength to create an ecosystem for enhancing the quality of GCP professionals (clinical trials/research) at the global level by bringing in a scheme for certifying training as well as individual professionals using international best practices like ISO 17024 to support regulation of clinical trials as well as promote acceptance of Indian training and professionals abroad. GCPPCS is the first-in-the globe that such a certification scheme, based on the growing global trend of evaluation of competence of the GCP professionals, has been launched. To gain international acceptance, the newly launched scheme relies on the accreditation of third-party personnel certification bodies by the national accreditation body, the National Accreditation Board for Certification Bodies (NABCB), a constituent Board of the Quality Council of India (QCI), who have attained international equivalence for its accreditation. This presentation gives an overview of what is GCPPCS and the pathway to achieving the personnel certification.

ABSTRACT 4



Title: Publication Ethics

Author Name: Prof. Bikash Medhi

Affiliation: Professor, Department of Pharmacology, PGIMER, Chandigarh

Abstract:

Underpinning good and ethical laboratory practices is the uncompromising emphasis paid to quality. When ICMR-NIV announced the first positive cases of SARS-CoV-2 in India, this



was done after testing the same samples in two laboratories independently. The second laboratory was blinded to the results of the first laboratory and noting concurrence in findings, the results were released. Thirteen laboratories of the VRDL network in India were initially trained to do the RT-PCR for SARS-CoV-2. By constant hand-holding in terms of sending reagents, standard operating protocols, and troubleshooting through video calls, we were able to expand this network to the entire network of 107 laboratories. Every batch of reagents that was sent out was quality-checked by scientists and technicians from other groups within the Institute.

Of volition, ICMR–NIV participated in international quality assurance testing organized by the WHO and National Institute for Biological Standards and Control (NIBSC, UK), both for RT-PCR as well as antibody testing. This gave us confidence in the laboratory tests that we were doing for the nation.

Many indigenous RT-PCR and antibody detection assays were sent to us for validation. The ones that were just falling short of validation standards were assisted in improving the quality of the product. Those that were clearly sub-standard were flagged as unsatisfactory, despite the immense pressure even from influential companies and persons. Likewise, even when it came to testing compounds with claimed anti-viral properties, ICMR-NIV scientists did a methodical job providing correct results, even in the face of many pressures.

Our efforts in pre-clinical trials for Covaxin were challenging too. Especially procuring non-human primates to do virus challenge studies was very difficult during the national lockdown. Despite that, we persisted with our efforts after getting all the necessary permissions from the forest authorities.

Scientists and technical staff worked in a war mode to complete the necessary studies on time. Every study was conducted only after IBSC, IAEC, and IEC approvals, where appropriate. MOUs/MOAs were vetted in the Institute and then sent to ICMR for final approval.

This pandemic has taught us that we can do much as a team and no matter what the pressures may be, there is no justification to cut corners.

ABSTRACT 5

Title: Ethics in COVID-19 Pandemic-WHO experience

Author Name: Dr. Katherine Littler

Affiliation: Technical Officer, Co-lead, Global Health Ethics and Governance Unit, WHO, Geneva

Abstract:

This talk focuses on two key areas of the work of the WHO Ethics and Governance Unit during the COVID-19 pandemic.

The first focuses on activities largely associated with the WHO's COVID-19 Ethics Working Group, in terms of the development of normative guidance and policy papers but also discusses





some of the outreach activities undertaken by the Unit. The second half of the talk, discusses work on research ethics oversight, both from the establishment of emergency SOPs, to starting to think about what lessons we can learn from our experience of reviewing research in COVID-19.

ABSTRACT 6

Title: Experience and lessons learned by different stakeholders during a pandemic

Author Name: Prof. Tulika Seth

Affiliation: Researcher, Dept of Haematology, AIIMS, New Delhi



Abstract:

The havoc created by this new virus is something that was unimaginable, even in our well-connected and advanced society it leads to serious disruptions of work and healthcare. The other major impact of the pandemic was to divert scientific and pharmaceutical attention to only COVID 19. This was at the cost of neglecting work on other important diseases.

Medical research is of paramount importance to find cures and improve the treatment of patients. Research strategies and different phases of trials are performed as advances reach different stages before application in routine medical care. Medical research can be in the form of pure basic science lab work, laboratory work requiring patient samples, animal and translational work, clinical trials, and other clinical research like a cohort, case series, etc.

Disruptions occurred due to the lockdown and transport interruptions and post the second wave- decreased footfall to hospitals, as many were converted to COVID care hospitals. Short- and long-term patient impact due to fear and stress of SARS CoV-2 among patients, problems with medicine access and non-compliance and hesitancy, misconceptions- about medicines and their effect on immunity. The Research Staff- transport problems, had to work in shifts and suffered from family, childcare, and other problems. Psychological impact on students engaged in research, and other research staff and faculty. The faculty too had difficulties – new responsibilities due to COVID-19, shifting to online classes, new ways of doing clinical rounds, coping with student and own stress. Most clinical trials paused new enrolment. Many halted or could not function- leading to dropouts/ protocol violations or the need for amendments to the protocol. In India, the poor and marginalized public have been most affected. Similarly smaller labs, less funded projects, and poorer students are most affected.

Though many research agencies have made compassionate and pragmatic attempts to help. As research disruptions threaten the careers of physician-scientists, many of whom have had to shift efforts from research to patient care. The faculty carry the burden of their lab staff salaries. Hence the implementation of allowances- to support salaries & grants, and relaxed timelines



to protect research in progress, residents' research projects have also been allowed relaxation in numbers as fewer patients enrolled due to the pandemic.

Difficult times have led to newer ways of doing clinical research like giving patients E diaries and allowing online patient updates. Shipping of study drugs directly to patients and giving instructions via video call. Even a new option for remote video consenting has been allowed.

ABSTRACT 7



Title: Ethics Committee (EC) -Perspective

Author Name: Dr. Padmavathy S Menon

Affiliation: Consultant Endocrinologists, Jupiter Hospital, Thane

Abstract:

COVID caught the entire world unexpectedly with its morbidity, mortality, and type of spread. It is very clear that the whole world was unprepared when it happened. It is necessary to promote research to understand this infection mainly to be prepared to face a future infection /epidemic of a similar kind as preparedness is of utmost importance in dealing with this kind of disease.

The problems of IEC KEM faced several situations: meetings became virtual, there was a shortage of staff working for EC due to Lockdowns, the number of deviations was of different kinds, and the participants in Covid clinical trial being admitted, an acute awareness of vulnerability was observed. The being admitted were willing to grasp any straw after death due to respiratory syndrome was described as the main cause of mortality. It is in the light of these facts that the ECS had to work looking at the safety of the participants by confirming all ethical aspects such as informed consent, risk-benefit assessment, and Adverse events reporting and management. It became easier when ICMR guidelines for COVID were available, but still had grey areas to be solved. Some will be discussed.

The IEC at KEM and NIRRH, both of which are chaired by me soon adapted to the online meetings, and all data for the meetings were electronically sent. The data of KEM IEC was analyzed during a period of 2 years: before and during Covid. The number of meetings and the number of projects did not change from pre covid time. The IEC took an undertaking from all PIs that the Covid protocol as given by the government from to time will be followed – like distance, masks, PPE, etc. One of the main problems in the ongoing studies was deviations caused by not coming for follow-up visits at the appropriate time by the participant due to lockout, moving to their village, or being too scared to venture travel (also there were no train or bus service during this period). Hence some of the patients dropped out. There was also the inability of samples processed due to the shutting down of airports in one of the clinical trials. Most protocols submitted were for studies to start after COVID.



In the Covid studies, we did have problems with informed consent. There was an increase in amendments for the Covid studies. In these studies, there was a challenge to weigh risks and benefits, especially in clinical trials. These will be discussed.

ABSTRACT 8

Title: Evolution of diagnostics during the pandemic

Author Name: Prof. Priya Abraham

Affiliation: Director, NIV, Pune

Abstract:

Underpinning good and ethical laboratory practices is the uncompromising emphasis paid to quality.

ICMR-NIV announced the first cases of SARS-CoV-2 in India, after parallel testing of the same samples in two laboratories. The second laboratory was blinded to the results of the first laboratory and noting concurrent results, they were released. Thirteen laboratories of the VRDL network in India were initially trained to do the RT-PCR for SARS-CoV-2. By constant hand holding in terms of sending reagents, standard operating protocols, and troubleshooting through video calls, we expanded this to the network of 107 laboratories. Every batch of reagents was quality checked by scientists/technicians from other groups within the Institute. Of volition, ICMR–NIV participated in WHO quality assurance testing and National Institute for Biological Standards and Control (NIBSC, UK), both for RT-PCR and antibody testing. Many indigenous assays were sent to us for validation. The ones that were just falling short of validation standards were assisted in improving the product quality. Those that were clearly sub-standard were flagged as unsatisfactory, despite the immense pressure of influential companies and persons. Likewise, even when it came to testing compounds with claimed anti-viral properties, ICMR-NIV scientists did a methodical job in providing correct results, even in the face of many pressures.

Our efforts in pre-clinical trials for Covaxin were challenging too. Especially procuring non-human primates to do virus challenge studies was very difficult during the national lockdown. Despite that, we persisted with our efforts after getting all the necessary permissions from the forest authorities.

Scientists and technical staff worked in a war mode to complete the necessary studies on time. Every study was conducted only after IBSC, IAEC and IEC approvals, where appropriate. MOUs/MOAs were vetted in the Institute and then sent to ICMR for final approval.

This pandemic has taught us that we can do much as a team and no matter what the pressures may be, there is no justification to cut corners.





ABSTRACT 9



Title: Repurposed drug during the pandemic

Author Name: Dr. Rubina Bose

Affiliation: Deputy Drugs Controller, CDSCO, Delhi

Abstract:

Drug repurposing is the application of known drugs and compounds to treat new indications (i.e., new diseases or conditions). Also known as drug repositioning, re-profiling, re-tasking, or therapeutic switching. Repurposing generally refers to studying drugs that are already approved to treat one disease or condition to see if they are safe and effective for treating other diseases. During the pandemic outbreak of COVID 19, various actions were taken by MOHFW and CDSCO as a regulatory response to the pandemic. Notice was issued for the stakeholders indicating modalities & pathways for fast-track approval of all products for COVID-19 clinical trial /approval of new drugs including vaccines, rDNA-derived products, and in-vitro diagnostic kits. Any firm having a Drug/Vaccine under development for COVID-19 can directly approach DCG(I) through Public Relations Office for seeking guidance for the regulatory pathway. Any firm or research institute having a protocol for repurposing existing drugs/vaccines for the treatment of COVID-19 will also be given priority for review and approval. New Drugs and Clinical Trial Rules 2019 provide the regulatory tools for such approval in all cases. Some of the drugs approved as repurposed include Favipiravir, Baricitinib, Itoluzumab, Pegylated Interferon alfa-2b, etc

ABSTRACT 10



Title: Vaccines during the pandemic

Author Name: Prof (Dr) Narendra K Arora

Affiliation: Executive Director, INCLIN, New Delhi

Abstract:

COVID-19 vaccines are given Emergency Use Authorization. The first mass vaccination campaign began in early December 2020, and the COVID-19 dashboard displays the number of immunisation doses provided on a daily basis. The FDA approved three COVID-19 vaccines (Pfizer, Moderna, and Johnson & Johnson) to provide an immediate need for protection against the coronavirus pandemic, which was (and continues to be) a public health emergency. And not every vaccine that has been licenced is entirely approved. The CDC, for example, modified its recommendations in December 2021 in response to the possibility of blood clots following delivery of the Johnson & Johnson vaccination. The CDC stated that the Pfizer and Moderna mRNA vaccines are preferable over the Johnson & Johnson vaccine, which is still available



for those who prefer it and in specific conditions. However, in India we have COVISHIELD and COVAXIN in initial phases of emergency approval.

Guidelines on Emergency Use Listing Procedure of WHO

- What is the scope of the EUL?
- Can WHO member states use the EUL as the basis to authorize the use of an unlicensed vaccine/medicine/In Vitro Diagnostics at the national level?
- How is the EUL procedure different from Prequalification?
- Does the listing of a product assessed under the EUL procedure ensure the safety, efficacy & performance of the product?
- Is emergency use approval required in the country of manufacture?
- For how long can a product assessed under the EUL remain listed?

The vaccine recommendation requires stringent pathways to follow from sponsor to ethics committee to subject expert committee and regulatory DCGI and National Technical Advisory Group on Immunisation (NTAGI). In India vaccination emergency use authorization comply with the three Emergency response India phases i.e. phase I -III.

ABSTRACT 11

Title: Ethical Considerations in Designing Public Health Interventions for future pandemics

Author Name: Dr. Anand Krishnan

Affiliation: Professor, Centre for Community Medicine, AIIMS, New Delhi

Abstract:

Pandemics are characterized by many unknowns which constrain our response to them including disease epidemiology and the effectiveness of interventions. There is often immense time pressure and resource constraint to act and this results in situations that can be viewed as conflicts – between individuals, or with the state and often with international ramifications. This calls for a consultative and participatory approach to knowledge generation, balancing individual safety and urgency, as well as the need to share research gains more equitably. In this uncertain situation, trust in science, the system, and the government is critical. Open transparent communication is essential to ensure this, though this is not easy in the given social and political context. A fair process for allocating scarce resources must promote certain ethical values of transparency, inclusiveness, consistency, and accountability. Resources available in the private sector should be harnessed for an effective response and credible mechanisms need to be built for them. Pandemics impact inequities in a big way not only due to pre-existing socio-political context but also through new pathways that control access to information, basic amenities, health and financial services. There is a need for legal protection for people who make many of these difficult decisions. Simultaneously, it is also important to protect human





rights from States overreach. Having the right balance between the two is the challenge of governance. It was also noted during this pandemic that international governance mechanisms were not successful in ensuring access to resources, treatment, and vaccines in poor countries. We need to design a multisectoral collaboration model to achieve transformative change in our systems of governance. Unless we start addressing inequities during non-emergency times, it is difficult to mitigate them during an emergency. Putting equity at the center of public health interventions during a pandemic is critical for its success. It is up to ALL of us to decide how we want to move ahead based on lessons learnt from the pandemic.

ABSTRACT 12



Title: Potential innovations to treat chronic disease in the post COVID era

Author Name: Dr. Prabhakaran Dorairaj

Affiliation: Vice President (Research & Policy), Public Health Foundation of India, PHFI, New Delhi

Abstract:

Closures of healthcare institutions, a lack of public transportation, or service reductions hampered the delivery of regular and routine comprehensive care for chronic patients. How patients with chronic care were affected by the pandemic, healthcare utilisation services, and available prospects for better chronic disease treatment in resource-constrained settings during the pandemic COVID-19 can infect persons of all ages, however, it is most common among the elderly. Furthermore, those with underlying co-morbidity and immunosuppression appeared to be more vulnerable to becoming extremely unwell and dying. Patients with co-morbidity and weekend immunity, according to the World Health Organization (WHO), should be better protected from infection without discrimination. Patients with asthma and chronic obstructive pulmonary disease (COPD) are more likely to have varying levels of severe COVID-19, which could be linked to ACE2 receptor activation. Chronic disease patients require good and timely access for better outcomes and monitoring. Patients with chronic diseases also require ongoing monitoring in order to manage their condition. Patients with asthma and chronic obstructive pulmonary disease (COPD) are more likely to have varying levels of severe COVID-19, which could be linked to ACE2 receptor activation. Chronic disease patients require good and timely access for better outcomes and monitoring.

As a result, unique and novel solutions are required to meet the crucial demands of COVID-19 patients as well as other persons in need of healthcare. Technological advancements have opened up new possibilities in this regard. Although the final COVID-19 solution will be multidimensional, it is one of the most effective methods to employ existing technologies to promote optimal service delivery while reducing the risk of direct person-to-person exposure. The use of telemedicine during epidemic conditions (such as the COVID-19 pandemic) has the potential to improve epidemiological research, disease control, and clinical case management.



Telehealth is the delivery of healthcare services by healthcare professionals over long distances using information and communication technology (ICT) for the exchange of accurate and authentic data. Real-time or video or store-and-forward strategies are used to deliver telehealth services. Because of the rapid innovation and downsizing of portable electronics, most families now have at least one digital device, such as smartphones and webcams, that allows patients and healthcare providers to communicate. Telehealth/Video conferencing becomes a basic necessity for the general public, health care providers, and COVID-19 patients, especially when people are under quarantine, allowing patients to seek guidance on their health problems in real time through communication with a health care provider. The goal of this study was to identify and evaluate the role of telehealth services in disease prevention, diagnosis, treatment, and control during the COVID-19 outbreak.

ABSTRACT 13

Title: Experience learned from COVID-19 Pandemic: Ayush Systems

Author Name: Dr. N Srikanth

Affiliation: Deputy Director-General, Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH

Abstract:

The outbreak of the COVID-19 pandemic has accentuated the need to strengthen health systems and accelerate research and development programs. The Ministry of Ayush (MoA), Government of India has undertaken several public health and R&D initiatives to harness the potential of AYUSH systems to contain the impact of the COVID-19 pandemic. The MoA issued various guidelines and advisories to improve immunity and advised simple home remedies easily accessible to the general public. The MoA constituted an interdisciplinary AYUSH R&D Task Force consisting of scientists from premier organizations and research institutions. The MoA collaborated with several research organizations and premier medical institutions such as Council of Scientific and Industrial Research (CSIR), DBT institutes such as Regional Centre for Biotechnology, Faridabad; and Translational Health Science and Technology Institute, Faridabad; All India Institute of Medical Sciences (AIIMS), New Delhi; AIIMS, Jodhpur; King George Medical University, Lucknow; Institute of Medical Sciences, Banaras Hindu University, Varanasi; Government Medical College, Nagpur; Datta Meghe Institute of Medical Sciences, Wardha; King Edward Memorial Hospital, Mumbai etc. to encourage, promote and advance evidence-based research on Ayush systems. Total 127 clinical studies and basic experimental studies have been initiated at approximately 152 centers by Research Councils and National Institutes under the Ministry through the Intra-mural and collaborative research mode. The core outcomes of these studies demonstrated good prophylaxis against COVID-19, early clinical recovery, achieving early negative RT-PCR assay results, reduction in the duration of hospital stay, prevention in further progress to severe





stage and complications, and improvement in quality of life. A cross-sectional analysis of the data generated through a mobile application ‘AYUSH Sanjivani’ highlighted that a good proportion of the representative population has utilized AYUSH measures across different regions of the country, during the COVID-19 pandemic and have considerable benefits in terms of general well-being and reduced incidence of COVID-19. AYUSH pharmaceutical industry also witnessed significant growth during the pandemic especially for immunity and wellness products. The proactive initiatives taken by the Ministry contributed in creating awareness in the society regarding improving immunity and health through simple Ayush measures during the COVID-19 pandemic. The MoA is committed for evidence-based integration of AYUSH systems for the public health delivery system in the best interest of general public.

ABSTRACT 14



Title: Experience learned from COVID-19 Pandemic: Ayush Systems

Author Name: Prof. Asim Ali Khan

Affiliation: Director-General, CCRUM and Advisor, Ministry of Ayush. Govt. of India

Abstract:

Unani Medicine is a comprehensive medical system, which meticulously deals with the various states of health and disease. According to Unani medicine, the environment plays an important role in the health of human beings. It advocates the maintenance of a proper ecological balance and keeping air, water, and food free from pollution and pathogens.

There is a growing awareness among the scientific community and the general public about the vast potential of our traditional systems of medicine in meeting the health challenges that the world is facing due to the COVID-19 Pandemic. The Ayush systems of medicine, including Unani medicine, offer various immunity-enhancing measures which may help in limiting the spread of the pandemic.

Common preventive approaches of Unani medicine for a healthy lifestyle including a healthy diet, clean air, adequate sleep, and physical activity, and avoidance of disease-causing factors are being reiterated to create awareness amongst the public for adopting these measures to enhance their immunity.

CCRUM has brought out advisories for improving immunity during the pandemic. As per Unani classical wisdom, improving immunity is one of the key approaches to the prevention of disease and maintenance of health. The guidelines for qualified Unani Medicine practitioners provide information on measures to be advised during the Pandemic.



The pandemic also presented an important opportunity for generating credible evidence. The Council has also launched a population-based interventional study on the impact of Unani prophylactic intervention for the prevention of COVID-19 infection in a high-risk population in six cities across India. Add-on studies have also been conducted at a COVID-19 management facility at A & U Tibbiya College, Karol bagh, New Delhi, and at Safdarjung Hospital, New Delhi.

ABSTRACT 15

Title: Experiences gained in controlling COVID 19 through the Siddha system of medicine

Author Name: Prof. M. Meenakshi Sundaram¹, Dr. R. Meenakumari²

Affiliation: ¹Professor & HoD, ²Director, National Institute of Siddha, Chennai

Abstract:

Siddha is a unique system of traditional medicine in India, which has its origin in the Tamil-speaking land, Tamil Nadu. Being a system of Medicine, Siddha Medicine is aiming at the healthy livelihood of the living organisms on this Globe. Though COVID – 19 is a novel infective disease of the respiratory system of human beings, the Siddha system of medicine approaches this pandemic condition as one of the 64 types of suram (fever) as explained in classic Siddha literature. With this foundation, the line of treatment for COVID-19 disease was designed according to the presenting signs and symptoms, Siddha pathogenetic factors wherein repurposing of Siddha formulations indicated for Kabasuram was suggested by legendary Siddha Physicians. Kabasura kudineer, a decoction indicated for a Kabasuram type of fever, was repurposed for treating this novel SARS-COV-2 infection. In addition to this decoction, the other Siddha drugs were repurposed which had proved its efficacy not only in accelerating the recovery from the disease and the viral load but also in reducing the mortality. The gasping for oxygen was prevented from taking the Siddha regimen irrespective of their ages. The Post COVID health assessment of the Siddha-treated people showed quality livelihood despite their comorbidities. Kabasura Kudineer and Nilavembu Kudineer formulations took the Siddha system of medicine across the country and the globe, unfurling the greatness of ancient Scientists, Siddhars.

National Institute of Siddha conducted 4 Clinical studies (incl. 2 RCTs) on COVID patients and High-risk Populations in Containment zones. The outcome of these studies showed the efficacy of Siddha Medicines in the containment of the COVID disease and reduction of Mortality in patients. The studies were done in collaboration with ICMR, Chengalpattu Govt. Medical College and SRM Institute of Science & Technology. The Institute has conducted a COVID Care centre in collaboration with Chengalpattu District administration with 200 bedded facilities treating mild COVID cases in SRM Engineering College campus and Govt. Arts College at Vyasarpadi, Chennai in collaboration with Greater Chennai Corporation. In





2021 NIS has operated 2 COVID Care Centres at NIS and at Vaishnav College, Chromepet catering to more than 500 mild and moderate COVID patients in coordination with the Chengalpattu District Administration. A prophylactic population-based COVID Studies covered more than 20000 high and Moderate risk COVID contacts with Kabasura Kudineer in 2020. The documentation of Siddha medication usage by general public by recommending the installation of AYUSH Sanjeevani app in more than 20000 members. Apart from these, the Institute has distributed Kabasura Kudineer and Nilavembu Kudineer prophylactic kits to frontline workers, Police personnel including Delhi Police force, people in various containment zones, NGOs etc., both during first and second wave of COVID – 19 crisis. The pandemic COVID 19 has thrown lights on Siddha principles of healthy living which emphasizes personal hygienic practices as detailed by Sage Theraiyar in his Treatise on methods of prevention of diseases.

ABSTRACT 16



Title: Experiences and lessons learnt from COVID-19 Pandemic

Author Name: Dr. Nandini K Kumar

Affiliation: Former Deputy Director-General Sr. Grade (ICMR), Vice President, Forum for Ethics Review Committees in India

Abstract:

The Data Safety Monitoring Board (DSMB) comprised statisticians, clinical experts, clinical pharmacologists and ethicist was set up by the Ministry of Ayush for monitoring progress of 26 research proposals on use of Ayush formulations for the treatment of COVID-19. Out of these 2 proposals never got submitted to the Data Safety Monitoring Board set up by the Ministry of Ayush to review the data generated by these trials. 24 proposals were approved by the site ethics committees. Out of this 24 only 14 were submitted to DSMB for review. Of the 10 proposals not submitted to DSMB four had completed the study. Out of the 14 proposals that were submitted to DSMB, seven were advised to go ahead with manuscript writing for publication of the trial. The remaining seven were asked to correct certain observations both on ethical grounds and methodology and return the findings or provide clarifications to DSMB but they were not submitted subsequently.

ABSTRACT 17



Title: Experience of Single Joint Ethics Review of Multicentre Research in the Philippines

Author Name: Jacinto Blas V. Mantaring III¹, Edlyn B. Jimenez²



Affiliation: ¹Professor of Clinical Epidemiology and Chair of the Department of Clinical Epidemiology of the University of the Philippines College of Medicine, ²Coordinator of the University of the Philippines Manila Research Ethics Board (UPMREB)

Abstract:

The Single Joint Research Ethics Board (SJREB) was conceptualized in 2015 and became operational in 2018 with the following objectives: 1) To streamline the review process of health-related protocols to be conducted in multiple sites in the Philippines, 2) To harmonize the results of ethics review among various site RECs through joint review, 3) To strengthen the ethics review capacity of PHREB Level 3 RECs to review different types of protocols that are conducted at their sites, and 4) To shorten the turn-around time of ethics review of multi-site protocols. The success of its organization may be attributed to the organizational and administrative support provided by the Philippine Department of Health.

The number of protocols submitted to the SJREB increased progressively in the succeeding years as more and more hospitals, research institutes, and sponsors became convinced of the advantages of the system. The process includes parallel submissions to the SJREB and the participating sites; organization of the full board meeting, SJREB recommendation, site reviews, and site approvals.

In 2020, The World Health Organization (WHO) issued a policy brief entitled, “Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D,” which highlighted the “...ethical imperative to conduct research during public health emergencies...”. The WHO emphasized that “...as in any other public health emergency, COVID-19 can only be adequately investigated while the pandemic is ongoing...”.

The challenges related to the review of COVID -19 research include: 1) addressing the increased volume of COVID - 19 research; 2) ensuring high-quality review at the shortest possible turnaround time; 3) coordinating the central with the site reviews; 4) monitoring implementation; and 5) addressing conflicts of interest among investigators with several studies.

How these challenges are being addressed is discussed in this lecture. Similarly underscored in this presentation are lessons learned as well as the initiative of the ethics review system to adapt its practices to adjust to the emerging COVID-19 landscape, as the pandemic unfolds.

ABSTRACT 18



Title: Implementation of public health interventions Ethical challenges

Author Name: Dr. V. Raman Kutty

Affiliation: Research Director, Amala Cancer Research Centre, Thrissur

Abstract:

‘Public Health interventions’ are those actions, mostly by the government or some other institution of authority, which are implemented across the board to everyone without exception,



with a view to producing a health outcome in the population. Policies that affect everyone without exception- such as the helmet law and the ban on alcohol below a certain age- can also be considered public health interventions. Usually, public health interventions are needed when there are ‘externalities’- i.e., when what an individual does affects not only himself or herself, but a large number of other people too. So usually, public benefit or public harm is an important consideration. Public health interventions are also adopted when something can bring in disproportionately large benefits for comparatively little cost. The ethical foundation of any public health intervention is based on the assumption that anything that brings net benefit to society is good. So, for any intervention to be accepted, if you sum up all the benefits that accrue to people and reduce the costs that they have to pay, there should be something positive. One problem with PH interventions is that these are applied to everyone without ascertaining their consent. This is why many people argue that interventions such as vaccines should not be mandatory- that everyone should be able to decide whether they need it or not. People who criticize mass interventions such as immunizations point out that for most individual medical interventions, a patient’s consent is mandatory. Strictly from a rights perspective, there is a violation of rights in measures such as lock-downs and mandated social distancing. Government actions sometimes threaten privacy and confidentiality, such as contact tracing. The benefits of PH interventions may accrue to a particular group of people and the harm to another group. The ethical aspects of public health interventions need to be discussed before intervention becomes policy.

ABSTRACT 19

Title: Conducting Research in the Times of Gendered Humanitarian Crisis – The COVID 19

Author Name: Dr. Ravi Verma

Affiliation: International Center for Research on Women (ICRW), New Delhi

Abstract:

COVID 19 has created unprecedented humanitarian crisis. The adverse impacts of accompanied macro-economic processes, undifferentiated policy responses and health system breakdowns were severe on vulnerable people including women, children and those on the margins of development. Conducting research during this time necessitated the need for an elevated level of safeguards to protect the safety, interests, privacy and confidentiality needs of women and girls and marginalized populations and communities. It was also necessary to ensure that those not accessing mobile phones are not excluded from the study. Institutional Review Boards (IRBs) or the ethical review committees had to be extra vigilant in case studies proposed in-person data gathering, to ensure that the COVID-19 safety protocols are adhered to.





Some of the specific review provisions made by the IRBs included, identification and presentation of clear risk mitigation strategies in the research protocols; stating upfront the risk of transmission of COVID beforehand in the consent forms and acknowledging a risk of transmission despite taking all precautions and putting a plan in place should such a situation arise; submission of an additional request to a special committee which approves in-person interactions and provision of an additional review soon after initiation of field work to assess and review the processes before it is too late; ensuring that the compliance with the COVID 19 appropriate behaviour is adhered to not only by the research staff, but also for partner staff or field facilitators and community members; and excluding respondents who were COVID positive or had other COVID positive cases in their household. For this purpose, development of a COVID screening tool was required, which included few questions around COVID 19 exposure and vaccination used by the research team to determine whether potential respondent could take part in the study or not.

Training and orientation of the research team on COVID 19 appropriate behaviours; and community consultations to assess feasibility, access and mitigation strategy prior to data gathering were made mandatory.

ABSTRACT 20

Title: Mental health issues and research: Experience and lessons learned from Covid 19 pandemic

Author Name: Dr. Sunita Simon Kurpad

Affiliation: Professor, Department of Psychiatry, Professor & Head, Department of Medical Ethics, St. John's Medical College and Hospital, Bengaluru, India

Abstract:

The bidirectional effect of mental illness and Covid makes research in persons with mental illness (PMI) an ethical requirement as they too need evidence-based care. As they are a vulnerable group, there are some core ethical questions that should answer by EC (Ethics Committee) members while evaluating the research. These include ascertaining if the research is necessary for this group and are the PMI's rights are being protected. The role of a subject expert is important as the vulnerability of PMI is neither uniform nor static. The nature of mental illness and its course are factors to be borne in mind. Informed consent and issues around the risk-benefit ratio have special implications in India. Other issues like assent, informed consent, role of nominated representatives, legal guardians, voluntary and involuntary patients, and the Indian Mental Health Care Act (2017) need to be noted. The treating doctor is likely to have an important role in protecting the PMI's interests.

The additional challenges for research in the PMI during the Covid era have been due to pandemic and disaster issues. There is a need to keep research scientifically valid, get EC





approval for changes to protocol and take measures to keep research participants and investigators safe. A particular emphasis is on ensuring informed consent and privacy of data with the use of online/telephone methods of data gathering. Despite a lot of ‘wasteful research’, innovative methods have ensured useful research has also been possible in the Covid era. There is a need to audit ongoing research. Whistleblowing, should it occur should be handled ethically to ensure fairness to all, safety, and ideally transparently to reduce the risk of damaging professional relationships. Some references to further reading material on the topic of ethics in research in PMI are suggested.

ABSTRACT 21



Title: Vaccine related issue: Global Perspective

Author Name: Dr. Ross Upshur

Affiliation: Professor, Department of Family and Community Medicine and DLSPH, University of Toronto

Abstract:

Pandemics occur unpredictably, but frequently enough, to have shaped and influenced the moral landscape globally. However, despite public health and infectious disease experts around the globe anticipating a major pandemic, the global community was unprepared for the SARS-CoV-2/COVID-19 pandemic. This is surprising given recent experiences with H1N1 Influenza A, Ebola, and Zika virus and indicates failure at the highest level to take public health preparedness seriously.

The pandemic response is critically dependent on understanding the ethical issues and values that will inform and shape the response of governments, communities, and citizens. While the rapid production of effective vaccines against COVID-19 has justifiably been hailed as a success, the rollout of vaccines has exposed and reinforced the inequitable distribution of resources with the capacity to save lives. At the time of the presentation, there was a conspicuous and unjustifiable disparity in the number of vaccines available and administered in high-income countries in contrast to low and middle-income countries.

The Director-General of the World Health Organization, Dr. Tedros Adhanom Ghebreyesus has drawn attention to vaccine equity as “the challenge of our time” and argued that solidarity is required in order for the global community to successfully respond to the challenge of COVID-19. Stating that no one is safe until everyone is safe, is an effective slogan to reinforce the equal moral worth of each person and illustrates that all should have access to effective vaccination without distinction of race, religion, political belief, economic, or any other social condition.

Sadly, the initial response to the vaccine rollout has failed to uphold these values, and high-income countries have not lived up to their pledges to the COVAX facility, indicating that in their minds, not all people have equal moral worth.





Code: 100

Sub code: 101

Ref. no.: FERCICON/21/OP-001

Reg. no.: FERCICON 2021/195

Title: Finding Solace in the Mid of Inequality: Lessons from the Pandemic

Author name: Dr. Ankita Kar

Affiliation: Project Consultant, ICMR-NCDIR

Email id: ankitarguhs92@gmail.com

Abstract

The coronavirus disease 2019 (COVID-19) pandemic has led to massive social and economic disruptions around the world, impacting mental health.

Health inequity is those inequalities in health considered unfair and unjust. Inequity in mental health exists in access to care, use, and outcomes of care (e.g., morbidity and mortality) and can occur by geographical region (rural/urban), gender, socioeconomic status, racial or ethnic background, and sexual orientation among other things. The consequences of mental health inequalities include continued unnecessary suffering and premature deaths, increased stigma and marginalization, lack of investment in the mental health workforce and infrastructure, and limited or lack of treatment for people suffering from these conditions.

Mental health promotion is an integral part of health promotion theory and practice where persons with mental illness need affordable, available, accessible, and appropriate sustainable mental health services for them to continue education (children and youth) or remain in an economic sustaining livelihood (employment).

Thus, mental health programs may have an important role to play to help those most vulnerable to social inequality in coping with the COVID-19 pandemic, but these mental health responses should be tightly interwoven with socially and culturally adapted interventions that take into account their reality. As ongoing studies have shown that in addition to anxiety and fear, a high prevalence of depression, insomnia, and other mental health problems have been observed in those affected by the current crisis. During this critical time, contact with mental health professionals should be facilitated to help those who are struggling to cope. To do this, it is important to use innovative approaches to reach the most vulnerable.

However, with the paradigm shift from offline to online consultations with professionals, the privacy and confidentiality of individuals may get affected. Therefore, ethical principles of beneficence, autonomy, respect for persons, and non-maleficence for people living with mental disorders should be followed, protecting human dignity, and promoting human rights and social justice.

So, the author of this presentation highlights the issues of mental health inequity and the psychological burden amidst the current pandemic.



Sub code: 102

Ref. no.: FERCICON/21/OP-002

Reg. no.: FERCICON 2021/173

Title: SARS-CoV-2 Vaccine Research & Administration In Vulnerable Population: A Systematic Review Of Scientific & Ethical Challenges

Author name: ¹Dr. Shreya Gupta, ²Dr. Ajay Prakash, ³Dr. Bikash Medhi

Affiliation: ¹DM Resident, Clinical Pharmacology, ²Associate Professor, ³Professor Department of Pharmacology, PGIMER, Chandigarh

Email id: em.shreya@gmail.com

Abstract

Introduction: COVID-19 pandemic has been one of the most challenging feats of the 21st century, and has been instrumental in teaching us valuable lessons in scientific, legal and humanitarian arenas. In fact, as we reflect upon our understanding of the pandemic, the importance of ethical issues takes precedence amidst all the confusion that still clouds the management and prevention of the disease, especially while including the vulnerable population in vaccine research and administration.

Methods: A systematic review of the various scientific and ethical challenges surrounding vaccine research and administration in the vulnerable factions of our society was conducted. The search string was constructed with the following terms combined with the Boolean operators AND/OR, with the keywords, “COVID-19”, “coronavirus”, “SARS-CoV-19”, “ethics”, “acceptance”, “risks”, “vulnerable”, “pregnant”, “lactating”, “child”, “children”, “tribal”, “psychiatric illness”, “mental illness”.

Results: Data will be collected as per the keywords mentioned, till 15th October 2021. The analysis included categorization of the vulnerable population into 5 sub-groups, i.e., pregnant/lactating women, children, elderly, tribal population, and those having a mental illness or cognitively impaired/affected individuals. Ethical issues pertaining to each group will be discussed in the following sub-thematic areas: inclusion in vaccine trials, informed consent process, acceptance of vaccines, and benefits and risks of vaccine administration.

Conclusion: Multiple ethical issues surround the vulnerable groups, especially with regard to inclusiveness in the vaccine trials, which subsequently lead to a dearth of safety and efficacy data in these sub-groups. Further, acceptance and autonomy towards COVID-19 vaccines and safety concerns during vaccine administration also need to be adequately addressed to ensure uniform vaccine coverage for all and to enforce the ethical principles of justice, beneficence, and non-maleficence.

Keywords: COVID-19, ethics, pregnant, children, elderly, tribals, mental illness



Sub code: 103

Ref. no.: FERCICON/21/OP-003

Reg. no.: FERCICON 2021/119

Title: Knowledge and Awareness of Ethics Committee members about Functioning of Ethics Committee during COVID -19 pandemic

Author name: ¹Dr.Ganesh Dakhle, ²Dr.Mrunalini Kalikar, ³Dr.Akhil Giradkar

Affiliation: ¹Professor and HOD, Pharmacology, AIIMS Nagpur, ^{2, 3}M.D., GMC, Nagpur,

Email id: gndakhle@rediffmail.com

Abstract

Introduction: Ethics Committee (ECs) have a vital role in the efficient review of Covid-19 studies and the need for immediate action to contain an infectious disease outbreak may make it difficult to stick on to the usual timeframes for research ethics. Research proposals involving more than minimal risk to human participants require critical review by the full board of the Ethics Committee (2). Ethics committees have to deal with operational challenges like conducting virtual meetings, online circulation of project-related documents, and absence of standard operating procedures (SOPs) for emergency research review (3). The present study is planned to know about the knowledge and awareness of EC members regarding the functioning of EC during the COVID 19 Pandemic.

Methods: This study was a cross-sectional, questionnaire-based survey conducted online through google forms. The respondents were Ethics committee members of various Government, Institutional, and Private Ethics committees across India. The study instrument was a self-developed, pre validated, semi-structured questionnaire consisting of open and close-ended items circulated online. Data were analyzed as a percentage

Results: A total of 82 responses were received. As per the response from the participants, ECs have shifted from only a paper-based review process to either digitalized or a combination of both during covid times (39% paper-based before covid vs 5% paper-based after covid). Though 58% of participants were comfortable with the digitalized working of EC, audio/visual problems and frequent disconnections were reported by more than 65% of respondents. The majority of the participants experienced pressure from stakeholders for expedited review (80%).

Conclusion: The present study suggests that most of the EC have shifted from paper-based review systems to digitalized after COVID. One of the most important challenges faced by EC members was disconnections and audio/ visual problems.

Key Words: Knowledge, Awareness, Ethics Committee members, COVID -19 pandemic



Sub code: 104

Ref. no.: FERCICON/21/OP-004

Reg. no.: FERCICON 2021/118

Title: An observational study of the common errors made by the principal investigator and lacunae found in Informed consent during submission to the ethics committee in a tertiary care Hospital in the eastern Uttar Pradesh region.

Author name: ¹Dr. Kiran Rajendra Giri, ²Dr. Kamlesh M. Palandurkar

Affiliation: ¹Associate Professor, Department of Pharmacology, Institute of Medical Sciences, Banaras Hindu University, ²Associate Professor, Department of Biochemistry, Institute of Medical Sciences, Banaras Hindu University

Email id: drkirangiri@gmail.com

Abstract

Conducting research plays a critical role morally and ethically to combat public health emergencies like COVID 19 Pandemic. Informed consent is the key pillar of any research. Seeking Informed consent is challenging during a Pandemic. 1 Valid and voluntary consent is essential for the Ethical Conduct of any research. 2 We as Institution Ethics Committee, Institute of Medical Sciences, BHU had witnessed alternative modes of informed consent like Telephonic consent, recorded Audio-visual consent, and electronic consent via email and through Google form in questioner-based survey studies. As multiple courses are running in our Medical Institute, we receive multiple projects from diversified courses from MBBS to DM/MCH and Ph.D.

Objective of this study was to analyze the different types of Informed consent submitted to The Institutional Ethics committee during the period of January 2021 to June 2021. To identify the common errors in informed consent submission and its impact on study approval process at IEC.

Method: This was a Retrospective Observational Study. Studies submitted and approved within the study period of 6 months (Jan-June 2021), were included. The data collected was entered in an MS-Excel file. The frequencies and their respective percentages were calculated for different categories and these were further utilized for the analysis.

Result: The percentage of COVID-related projects during the study period was 23.2. An electronic medium for consent was utilized in 13.3% of studies. Incomplete information of the Principal Investigator in the consent form was one of the common errors observed. Incomplete details of procedure and risk involved were also observed in many. Inappropriate use of English words in the local language was also observed.

Conclusion: The significance of this study is to guide the formulation of the strategy for an effective informed consent process for education, communication, and guidelines. The Social scientist and legal expert play an important role to check and confirm the voluntary and noninductive involvement of participants and the protection of their rights. Formulation of an informed consent form involving elements of Electronic and Audiovisual consent is needed of the hour. The involvement of electronic data cells for safety and anonymity is suggested.



Keywords: Informed consent, Electronic Consent, COVID 19, Retrospective

Sub code: 105

Ref. no.: FERCICON/21/OP-001

Reg. no.: FERCICON 2021/179

Title: Clinical and laboratory findings in COVID-19 Adult hospitalized patients in Southern Assam

Author name: Dr. Neeraj Sinha

Affiliation: Department of Pharmacology, Silchar medical College and hospital, Silchar

Email id: sinhaneeraj123@gmail.com

Abstract

Introduction: After the outbreak of COVID-19 in Wuhan province of China, COVID-19 has spread throughout the world causing respiratory and other related problems. It has led to increased mortality among the adult and old-age populations. Many studies have been done related to COVID-19. However, studies relating to clinical symptoms and laboratory findings are limited.

Methods:

Time period: The study was conducted from 1st January 2021 to 31st March 2021.

Eligibility criteria: Patients with confirmed SARS-CoV-2 with or without symptoms.

Data collection: The symptoms and laboratory findings of 114 COVID-19 patients were evaluated.

Results:

Demographic characteristics: The total number of patients analysed was 114. The mean age of the patients across the studies was 48.9 years and males comprised 71.06% of the population.

Clinical manifestations: The clinical manifestations of patients diagnosed with COVID-19 included fever 76.31%, cough 65.78%, dyspnoea 27.19%, headache 16.6%, diarrhoea 5.26% and vomiting 3.5%. There was decrease in oxygen saturation (< 93%) among 25.43% of the patients, while increase in respiratory rate (> 33 beats/min.) in 0.035% of the patients.

Co-morbidities: The most prevalent comorbidity being hypertension 35.08%, followed by diabetes 23.68%, coronary heart disease (CHD) 4.38%, CKD and PTB both being 3.5%.

Covid-19 status and Treatment profile: 38.59% of the patients were of moderate covid-19, while 30.7% suffered from mild covid-19. 31.57% of the patients were given Remdesivir, 32.45% of the patients were given Enoxaparin while 35.08% of the patients were given Streptokinase. 16.66% of the patients required oxygenation, while 14.91% of the patients were admitted in ICU.

Laboratory findings: The result of this random-effects showed that the most prevalent laboratory findings were increased CRP (47.36%), increased LDH (50.87%), increased AST (61.4%), increased ALT (26.31%), increased PCT (61.4%), increased D-dimer (28.94%) and increased NLR ratio (50.87%). There was decrease in Hb% (58.77%), albumin (22.8%) and platelet count (35.96%).



Conclusion: Patients infected with the COVID-19 coronavirus had a wide clinical presentation with non-specific symptoms and laboratory findings. There is need of more studies related to clinical and laboratory findings of COVID-19 patients.

Keywords: COVID-19; SARS-CoV-2; Clinical features; Epidemic; Laboratory findings

Sub code: 106

Ref. no.: FERCICON/21/OP-006

Reg. no.: FERCICON 2021/116

Title: Vaccine hesitancy and its associated factors in COVID vaccination among a tribal community of Meghalaya: A mixed methods study

Author name: ¹Joenna Devi Ningombam, ²Shanthosh Priyan S, ³Gajendra Kumar Medhi, ⁴Vizovonuo Visi, ⁵Markordor Lyngdoh,

Affiliation: ^{1,4,5}Senior Resident, ²Assistant Professor, ³Professor and HoD, Department of Community Medicine, NEIGRIHMS, Shillong

Email id: ningjoenna@gmail.com

Abstract

Background: Vaccine hesitancy is a matter of concern in midst of the pandemic and it poses various pragmatic issues coupled with pragmatic issues. Hence the study was planned to determine the prevalence of hesitancy to COVID vaccination and to explore the factors contributing to the same.

Methods: A community based mixed method study was conducted among the adult tribal population in the rural field service area of NEIGRIHMS, Ri-Bhoi district. A predefined proforma was used to collect the socio-demographic and COVID vaccination characteristics. The facilitators and barriers for vaccination was explored through In-Depth Interviews and Key Informant Interviews. The codes and themes were derived using thematic analysis and interpreted using Health Belief model. Ethics approval was obtained from Institute Ethics Committee (IEC).

Results: A total of 76 individuals were interviewed, among which 36 (47.4%) participants were hesitant to vaccination. Among the participants with hesitancy, 11.2% participants were initially hesitant and 36.2% participants were having refusal for vaccination. On thematic analysis, the facilitators and the barriers to vaccination were divided into the following themes: Individual related factors, disease related factors, vaccine related factors, healthcare system and provided related factors and socio-cultural & religious factors, with confusion, mistrust, doubts on efficacy and side effects of vaccine along with religious belief as the major barrier and the fear of severity and infection among the other family members with persistent health communication as the major potentiators.

Conclusion and recommendations: Vaccine hesitancy in the sampled population is relatively higher with higher percentage of refusal. Lack of awareness along with religious belief is found



to be major barrier for the same. Hence, Information, Education and Communication regarding the benefits of vaccination in the effective control of the pandemic should be incorporated.

Keywords: Vaccine hesitancy, In-depth interview, Key Informant interview

Sub code: 107

Ref. no.: FERCICON/21/OP-007

Reg. no.: FERCICON 2021/226

Title: Insights from a survey-based study on India Ethics Committee functioning during COVID-19.

Author name: ¹Priyadarshini Arambam, ²Sharmila Rani, ³Jayanti Gupta, ⁴Rakesh Dadhania
⁵Dr. Ashish Indani

Affiliation: ¹General Manager, Academic and Research Department, Batra Hospital and Medical Research Centre, New Delhi, ²Project Manager, JSS Medical Research India Pvt. Ltd., ³NishKash Consulting, ⁴Quinary Clinical Research, ⁵Stryker Global Technology Center

Email id: priyadarshini.arambam@gmail.com

Abstract

Background: While ECs are entrusted responsibilities of participant safety and wellbeing, the other stakeholders of research viz. sponsor (often manufacturer), the investigators and the regulators are accountable for the same, in addition to their scientific responsibility. However, with unprecedented operational limitations imposed by COVID-19 pandemic protocols including lockdown, the functioning of ECs faced a major setback and required many transformations. Hence, this study was conducted among ECs in India to explore and substantiate pandemic effect and impact on the ECs functioning.

Methods: This survey initially included ECs of 50 Indian hospitals, which has now been expanded to 80. This study is a questionnaire-based survey that was designed to quantify disruption to key activities such as submission of dossiers, conduct of meetings, query resolution and turnaround timelines caused by the pandemic protocols.

Results: Among the surveyed ECs, the majority (82%) continued to require physical dossier while only 18% accepted online or electronic submissions. Despite the lockdown, 78% of the ECs managed to conduct SOP-scheduled meeting. In all the ECs raised, seventy-one queries of which most (70%) were resolved by the sites within the stipulated timelines. Despite this, the approval TAT of 75% ECs was over a month after the submission and query process completion.

Conclusion: The Indian ECs require to undergo quantum leap in their operations to support the clinical research process in view of improvement of healthcare in the country.

Way forward:

- collaborative working in relatively sublime space by embracing technologies like digital twins and hologram-virtual and virtual meetings
- Collective training efforts for medical devices, software and telemedicine



- creation of a platform for sharing negative and positive experiences, grievance, ideas and concerns and the best practices, to develop uniform review standards that helps ECs to focus mainly on local context, inclusion and diversity, comprehensibility, Intelligibility and readability of the study documents vis a vis scientific messaging for its audience
 - Centralized submission and monitoring platform for EC processing
- Keywords:** COVID-19 pandemic, Ethics Committee, clinical research in India, lockdown measures, Operational Delay, Process Improvement, Ethical Review, Good Clinical Practice, Ethical Review and submission platform.

Sub code: 108

Ref. no.: FERCICON/21/OP-008

Reg. no.: FERCICON 2021/178

Title: Ethical challenges in Telephonic Data Collection for assessing impact of COVID-19 on Maternal and Child health services through the public health system in Maharashtra.

Author name: ¹Dr. Ragini Kulkarni, ²Dr. Shahina Begum, ³Dr. Suchitra Surve, ⁴Dr. Ranjan Kumar Prusty, ⁵Dr. Saurabh Sharma, ⁶Dr. Sumit Aggrawal, ⁷Dr. M Vishnu Vardhan Rao

Affiliation: ¹Scientist E, Department of Operational Research, ²Scientist E & Head, Department of Biostatistics, ³Scientist C, Department of Clinical Research, ⁴Scientist 'B', Department of Biostatistics, ICMR-National Institute for Research in Reproductive Health (NIRRH), ⁵Scientist 'D', ⁶Scientist 'C', ⁷Director, ICMR-National Institute of Medical Statistics, New Delhi.

Email id: kulkarnir120@gmail.com

Abstract

Introduction: ICMR-NIRRH was one of the participating centres in an ICMR multicentre study conducted across six centres in India during September 2020 to January 2021. The main objective of the study was to assess the impact of the COVID-19 epidemic on the Maternal and Child health (MCH) services in India. The present paper describes ethical issues and challenges in the consent process and conduction of telephonic interviews among participants and how the researchers addressed these challenges.

Methods: Institutional Ethics Committee approval was obtained before initiation of the study. Eligible women with their contact numbers were randomly selected from the list obtained from Auxiliary Nurse Midwives (ANMs) and Accredited Social Health Activists (ASHAs). Telephonic interviews were conducted after obtaining verbal consent from 90 pregnant women and women having children less than two years in three districts (Thane, Nasik and Wardha) of Maharashtra. All of them consented for recording verbal informed consent and interview.

Results: A total of 240 women were contacted to meet the sample size of 90. Out of total contacts, 150 women could not be enrolled due to various reasons (Mobile numbers were switched off/ wrong numbers/invalid/out of service [n=140], call was not answered for five attempts [n=20] and women could not be contacted as husbands had mobile phones [n=17]. There were nine refusals; five were at contact level; out of which three women refused as they



were admitted for delivery. Remaining four did not give verbal consent as their husband was not willing for their participation in the study. Overall, the refusal rate was 7.8% (09/116).

Conclusion: In COVID-19 pandemic times, it was feasible to take verbal informed consent and conduct telephonic interviews. Number of eligible participants should be kept around three times of the desired sample size considering the challenges in contacting them for conducting telephonic interviews.

Key words: COVID-19, Ethical, challenges, MCH, Maharashtra

Sub code: 109

Ref. no.: FERCICON/21/OP-009

Reg. no.: FERCICON 2021/122

Title: The impact of the COVID-19 pandemic on attention deficit hyperactivity disorder drug therapy - a snapshot

Author name: ¹Das Rahul, ²Mandal Ananya, ³Ghosh Sayanti, ⁴Biswas Supreeti

Affiliation: ¹Post Graduate Trainee, ²Associate Professor, ³Associate Professor, ⁴Professor & Head of The Department, Department of Pharmacology, Nil Ratan Sircar Medical College, Kolkata, West Bengal.

Email id: dr.rd9960@gmail.com

Abstract

Introduction: The novel coronavirus (COVID-19) pandemic is causing widespread concern, fear and stress around the world. Individuals with neurodevelopmental disorders like attention-deficit hyperactivity disorder (ADHD) are particularly vulnerable to the distress caused by this pandemic and physical distancing measures and they might display increased behavioural problems. The study was conducted to determine the changes in prescription pattern in ADHD patients.

Methods: This cross-sectional observational comparative study was conducted between April'20 to September'20 among 64 patients up to 17 years of age who came for follow up in Child Psychiatry Out Patient Department (OPD) Nil Ratan Sircar Medical College & Hospital (NRSMCH), Kolkata. The data was collected from the prescriptions in predesigned and pretested case record form. For each of the drugs prescribed Daily Define Dose (DDD) was estimated and a comparison was made between their use before and after the first wave of COVID-19 cases in 2020. The results were analyzed from case record form using appropriate statistical tests. The limitations of our study include the small study population and the study was conducted over a shorter period.

Results: Daily use for Methylphenidate, Clonidine and Fluoxetine showed highly significant changes whereas for Risperidone the change was significant. Daily defined dose (DDD) for all the used drugs was increased except Atomoxetine. Dose of Trihexyphenidyl increased. The requirement of behavioural therapy also rose.

Conclusions: There was a significant transition in medication use noted during the ongoing pandemic. Methylphenidate use increased signifying the adverse impact of the pandemic on



ADHD patients. Fluoxetine use rose implying unmasking of childhood depression or denovo depression during this pandemic among children. Trihexyphenidyl use increased due to rising anticholinergic adverse drug reactions associated with other ADHD medications.

Keywords: Covid-19, Children and adolescents, ADHD, Childhood depression, Change in prescription pattern.

Sub code: 110

Ref. no.: FERCICON/21/OP-010

Reg. no.: FERCICON 2021/162

Title: Association of type of funding and conflicts of interest to outcome reported amongst the published studies of Covid-19

Author name: Gajbhiye SV, Chindhalore CA, Gupta A, Dakhale GN

Affiliation AIIMS Nagpur

Email id: dr.ssborkar@gmail.com

Abstract

Introduction: The entire world is carrying out studies to understand the pathophysiology, clinical features, diagnosis and treatment of COVID 19 studies. It is of interest to investigate whether the type of funding and the competing interests affect the outcome reported in the clinical trials. Thus, we decided to evaluate the published clinical trials. The aim of our study is to find the association of outcome of clinical trials in the area of Covid 19 with the type of funding and conflict of interest (COI).

Methodology: The studies were searched with the keywords 'clinical trial' AND 'Covid 19' or 'Corona' on PubMed. The filters were used to select only papers with English language and species 'Human'. Published study protocols, trials with single arm, observational/analytical studies, studies on medical education on COVID-19 and non-drug trials, diagnostic studies were excluded.

Results: There are 1,007 total studies retrieved after the search from PubMed. The data collection is ongoing. Out of 600 studies, 121 (20%) studies have satisfied selection criteria. There is significant association between the presence of COI and association of positive outcomes (Chi-square value 91.727; p value<0.001). We are analysing the rest of the data.

Statistical Analysis: The association of outcome with presence or absence of pharmaceutical funding and COI will be done using a Chi square test

Conclusion: There is a significant association between conflict of interest and the type of outcome among the published studies of Covid-19.

Keywords: Covid-19, non-drug trials.



Sub code: 111

Ref. no.: FERCICON/21/OP-011

Reg. no.: FERCICON 2021/191

Title: Covid-19 pandemic: A wake-up call on the significance of capacity-building and protection of research participants

Author name: Dr. Sri Chandana Tanguturi

Affiliation: Project Scientist-B (Medical), ICMR-NCDIR

Email id: Drchandana87@gmail.com

Abstract

COVID-19 pandemic has caused an immeasurable loss to social and personal lives on a global scale since 2020, particularly in densely populated countries like India. The pandemic demonstrated the importance of having research capacity in place as a key component of pandemic preparedness. Outbreaks in countries with little research capacity resulted in a higher death toll due to delays in diagnosis, treatments, and vaccinations than outbreaks in countries that are equipped with established research capacities. The race for the invention and development of diagnostics, treatments, and vaccines may jeopardize the quality and reliability of the research, which could have disastrous consequences on the research participants. It is the responsibility of the researcher as well as other stakeholders to protect the rights, safety, and well-being of the research participants, and the necessity to do so increases in a pandemic situation, amid chaos and urgency. Health care providers and workers should consider individual requirements and make efforts to not only avoid the spread of disease and minimize its severity but also to consider the impact of the research study on family and community. All the research studies should have clear protocols of risk assessment, a fair selection of patients as research participants, equitable risk and benefits distribution, extra protection for vulnerable people. The studies should also include mitigation strategies to ensure potential mental health impacts on research participants and researchers considering conditions like trauma, stigmatization, discrimination, or ostracization of the affected individuals. Ethics, integrity, and transparency have to be the core principles of any study so that the objective of the study does not cross regulatory hoops. Continuous efforts are required to build the capacity of the health force and create a safe environment for the research participants to conduct ethical research studies and to build trust in the community. The purpose of this presentation is to emphasize the need for capacity building and research participant protection during the COVID -19 pandemic.

Keywords: COVID-19 pandemic, Ethics, Capacity building, Pandemic preparedness, Vulnerable.



Sub code: 112

Ref. no.: FERCICON/21/OP-012

Reg. no.: FERCICON 2021/154

Title: Perceptions about Ethics of Public Health Behavioral Interventions during the Covid 19 Outbreak

Author name: ¹Yashashri Shetty, ²Sudha Ramalingam, ³Medha Rajappa, ⁴Vinita Agarwal, ⁵Gaurav Narula, ⁶Urmila Thatte

Affiliation: ¹Associate Professor, Dept of Pharmacology & Therapeutics, Seth GSMC & KEM H, Mumbai, ²Professor, Dept of Community Medicine, PSGIMSR, Coimbatore, ³Professor, Dept of Biochemistry, JIPMER, Puducherry, ⁴Professor, Dept of Pathology, SGPGIMS, Lucknow, ⁵Professor, Dept of Medical Oncology, TMH, Mumbai, ⁶Emeritus Professor, Dept of Clinical Pharmacology, Seth GSMC & KEM H, Mumbai.

Email id: yashashrirajit@gmail.com

Abstract

Introduction: Covid 19 has affected a large number of people in various countries including India. The study conducted was to find the implications of the Covid behavioural interventions by the government on individual human rights.

Methodology: The objective was to describe the perception of relevant social sectors about the ethical dimensions of public health interventions during the Covid 19 outbreak. It was a cross-sectional validated questionnaire-based study. The 5 study sites were KEMH, JIPMER, SGPGIMS, PSGIMSR, TMH. After IEC permission at respective sites, different stakeholders consenting to participate (Researcher, Hospital administrator, Patients, public officials, General public and/or community outside the hospital and IEC member) 3 to 15 each of these stakeholders were administered the questionnaire. The study duration was for 6 months. Descriptive statistics applied. Open-ended questions were evaluated by Interpretational analysis.

Results: Of the total 450 participants, PSGIMSR (108), KEMH (90), JIPMER (90), SGPGIMS (21) and TMH (18). The age group of respondents was 18-30 yrs (mean age - 54.5 with SD \pm 6) and there was equal gender distribution. The majority (65%) of them accepted the measures taken by the state for the general public, health workers and research except a few (28%) felt India does not have the adequate facility and the measures taken are also insufficient. 24% of participants said that Covid intervention has violated basic human rights, and 8% mentioned Health facility is affected the most. 15% suggested that there should be mass testing, severe punishment for the violation of guidelines and well-equipped hospitals with an adequate number of health workers.

Conclusion: The perception of different social sectors regarding public health interventions during the Covid outbreak was varied.

Keywords: ethics, covid, mask, handwash, human rights



Sub code: 113

Ref. no.: FERCICON/21/OP-013

Reg. no.: FERCICON 2021/129

Title: Drug Use Pattern During Covid-19 Pandemic in Cardiology In-Patient Department: A Cross-Sectional Study

Author name: ¹Saha Manali, ²Mandal Ananya, ³Biswas Supreeti, ⁴Sharma Ranjan kumar

Affiliation: ¹Post graduate trainee, ²Associate Professor, ³Professor & Head of The Department, Department of Pharmacology, ⁴Professor & HOD, Department of Cardiology, Nil Ratan Sircar Medical College, Kolkata, West Bengal.

Email id: manalisaha93@gmail.com

Abstract

Introduction: Surge in mortality and morbidity due to cardiac issues during the COVID-19 pandemic is a growing concern. The objective of the current study was to evaluate use of medication and subsequently adverse drug reactions among admitted heart disease patients during the COVID-19 pandemic.

Methods: This cross-sectional study was conducted among 38 patients who were admitted in cardiology department, of a tertiary care medical college in Kolkata, between 1st to 7th April 2021. A pretested and validated questionnaire was given to them to be filled anonymously. The results were analyzed from the filled in questionnaires.


Results: Average age of the study patients was 58 ± 14 years. Of these, 52.63% patients were diagnosed as a case of MI. 76.32%, 63.15% and 7.8% patients were treated with Aspirin, Clopidogrel and others respectively. We noted that 36.84% patients received LMWH and 5.2% patients were thrombolised. Study shows that Ramipril was given to 68.42% patients with dose of 2.69 ± 0.91 mg and Beta blockers to 65.78% patients with dose of 32.14 ± 11.5 mg to reduce mortality. Also 71.05% patients were given Atorvastatin to reduce the chance of CAD with dose of 58.51 ± 25.37 mg. When assessed on bed side management, 26.31% patients received injectable diuretics (Furosemide) and 31.57% were given oral diuretics. The limitation of our study is that the study database is small and could be considered as snapshot study.

Conclusions: Our study shows adequate management of MI, heart failure and other heart diseases following the standard treatment guideline (STG). The use of anti-platelet drugs is predominant followed by anti-coagulants. Beta-blockers and ACE-inhibitors were used for survival benefit. The study concluded that there is no alternation in the drug use pattern during the COVID-19 pandemic, as no adverse drug reactions or deaths were observed among the study patients.

Key words: Heart failure, heart disease, MI, Drug utilization study, COVID-19 pandemic



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First Prize	
 <p>Dr. Priyadarshini Arambam Batra Hospital & Medical Research Center, New Delhi</p>	<p>Insights from a survey-based study on India Ethics Committee functioning during COVID-19</p>
Second Prize	
 <p>Dr. Yashashri Shetty Seth GSMC & KEMH, Mumbai</p>	<p>Perceptions about Ethics of Public Health Behavioral Interventions during the Covid 19 Outbreak</p>
Third Prize	
 <p>Dr. Ningombam Joanna Devi NEIGRIHMS, Shillong</p>	<p>Vaccine hesitancy and its associated factors in COVID vaccination among a tribal community of Meghalaya: A mixed methods study</p>



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S.No.	Name	Registration Id	Organization
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2.	Dr. Narendra Kr Sharma	FERCICON 2021/102	NEIGRIHMS
3.	Rajiv Ranjan Das	FERCICON 2021/103	Rims Ranchi
4.	Dr Kaustuv Dutta	FERCICON 2021/104	NEIGRIHMS
5.	Dr. Madhavrao C	FERCICON 2021/105	All India Institute of Medical Sciences [AIIMS], MANGALAGIRI
6.	Dr. Mythili Bai K	FERCICON 2021/106	Dr. Pinnamaneni Siddhartha Institute of Medical Sciences & Research Foundation [PSIMS]
7.	Butchi Raju Akondi	FERCICON 2021/107	IBN Sina National College for Medical Studies
8.	Dr. Joonmoni Lahon	FERCICON 2021/108	Dr RMLIMS, Lucknow
9.	Dr Sudha MJ	FERCICON 2021/109	S S Medical College
10.	Jeyalalitha Rathinam	FERCICON 2021/110	Government Medical College, The Nilgiris
11.	Chandrashekar Janakiram	FERCICON 2021/111	Amrita School Of Dentistry
12.	Dr.Linga Devi Thanasekaran	FERCICON 2021/112	SRIHER
13.	Dr. M. Venugopal Reddy	FERCICON 2021/113	Kurnool Medical College
14.	Parvathy B	FERCICON 2021/114	Amrita School Of Dentistry
15.	Veeraju Rondi	FERCICON 2021/115	M/S Life cell International Pvt Ltd
16.	Ningombam Joanna Devi	FERCICON 2021/116	NEIGRIHMS
17.	Ratinder Jhaj	FERCICON 2021/117	All India Institute of Medical Sciences Bhopal
18.	Kiran Rajendra Giri	FERCICON 2021/118	Institute Of Medical Sciences, BHU
19.	Dr Ganesh Dakhale	FERCICON 2021/119	AIIMS Nagpur
20.	Rohan Sen	FERCICON 2021/120	Nilratan Sircar Medical College and Hospital
21.	Nagavishnu Kandra	FERCICON 2021/121	Santhiram Medical College and General Hospital
22.	Dr. Rahul Das	FERCICON 2021/122	Nil Ratan Sircar Medical College
23.	Dr. Sanjeev Gupta	FERCICON 2021/123	GMC & Ah Rajouri J&K
24.	Dr. Sandhiya Selvarajan	FERCICON 2021/124	Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER)



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26.	Rajamohan K Pillai	FERCICON 2021/126	School Of Public Health, KUHS, Trivandrum
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28.	Dr Ch Rama Krishna Prasad	FERCICON 2021/128	All India Institute of Medical Sciences,
29.	Manali Saha	FERCICON 2021/129	Nil Ratan Sircar Medical College and Hospital
30.	Prof. Pinaki Chakravarty	FERCICON 2021/130	Tezpur Medical College and Hospital
31.	Dr. Sahid Aziz	FERCICON 2021/131	Jorhat Medical College
32.	Dr. Riruparna Phukan Ray	FERCICON 2021/132	Jorhat Medical College & Hospital
33.	Prof. (Dr.) Meghali Chaliha	FERCICON 2021/133	Jorhat Medical College & Hospital
34.	Dr. Purnima Bordoloi	FERCICON 2021/134	Gauhati Medical College and Hospital
35.	Dr.RIDHI MEHRA	FERCICON 2021/135	Saraswathi Institute of Medical Sciences, Hapur, U.P.
36.	Dr. Lavita Hazarika	FERCICON 2021/136	Jorhat Medial College and Hospital
37.	Christina Zosangpuii	FERCICON 2021/137	Regional Institute of Medical Sciences
38.	Bajanai Lamare	FERCICON 2021/138	NEIGHRIMS, College of Nursing
39.	Geetanjali Ningthoujam	FERCICON 2021/139	Regional Institute of Medical Sciences
40.	Wandarica Tham	FERCICON 2021/140	College Of Nursing, NEIGRIHMS
41.	Swagata Datta	FERCICON 2021/141	Regional Institute of Medical Sciences, Imphal
42.	Changhorla Awungshi	FERCICON 2021/142	College Of Nursing, NEIGRIHMS
43.	Urmila Das	FERCICON 2021/143	College Of Nursing, NEIGRIHMS
44.	Roshi	FERCICON 2021/144	SDH Akhnoor Jammu
45.	Naina Thakuri	FERCICON 2021/145	College Of Nursing, NEIGRIHMS
46.	Dr Sandhya Kurup	FERCICON 2021/146	MOSC Medical College, Kolenchery, Kerala
47.	Darifica Pde	FERCICON 2021/147	Con NEIGRIHMS
48.	Armelinda B.D. Lyngdoh	FERCICON 2021/148	College Of Nursing, NEIGRIHMS



49.	Meenakshi Devi	FERCICON 2021/149	College Of Nursing, NEIGRIHMS
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64.	Dr. Sarajita Barman	FERCICON 2021/164	Silchar Medical College and Hospital
65.	Gobinath V	FERCICON 2021/165	Regional Institute of Medical Sciences, Imphal
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70.	Nameirakpam Meena Devi	FERCICON 2021/170	Regional Institute of Medical Sciences, Imphal
71.	Dr Sobina Moirangthem	FERCICON 2021/171	Regional Institute of Medical Sciences
72.	Dr. Karabi Adak	FERCICON 2021/172	Tezpur Medical College and Hospital
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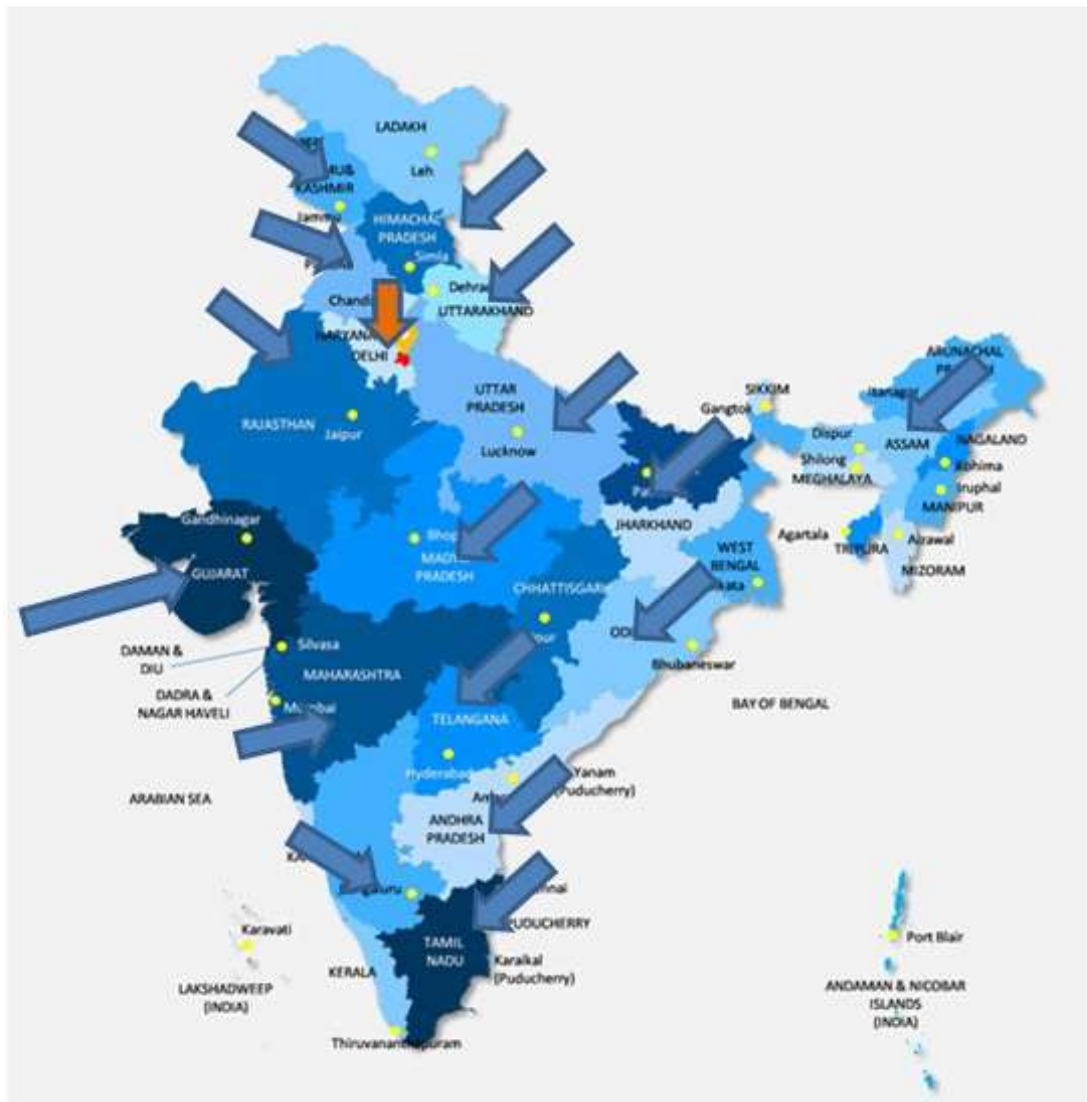


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82.	Dr. K. Jayanthi	FERCICON 2021/182	Associate Professor, Department Of OBG, GMC, The Nilgiris
83.	Sumathi.K	FERCICON 2021/183	Government Medical College, The Nilgiris
84.	Veena	FERCICON 2021/184	Seth GS Medical College and KEM Hospital
85.	Medha Joshi	FERCICON 2021/185	National Cancer Grid, TMC, Mumbai
86.	Dileep G	FERCICON 2021/186	ICMR
87.	Dr.N.J.Rajan	FERCICON 2021/187	Retired/Private Practitioner
88.	Dr Gunajit Das	FERCICON 2021/188	Silchar Medical College & Hospital
89.	Dr Babul Kumar Bezbaruah	FERCICON 2021/189	Silchar Medical College & Hospital
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92.	Manikandan S	FERCICON 2021/192	ICMR-National Institute For Disease Informatics And Research, Bangalore
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95.	Dr. Ankita Kar	FERCICON 2021/195	NCDIR-ICMR
96.	Kingshuk Lahon	FERCICON 2021/196	Veer Chandra Singh Garhwali Govt Medical College Srinagar Garhwal Uttarakhand
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98.	Dr. Supriya Dhakne Palwe	FERCICON 2021/198	Dr. Vasantrao Pawar Medical College, Hospital and Research Centre, Nashik, Maharashtra
99.	Krupa N C	FERCICON 2021/199	ICMR- NCDIR



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120	Yasmeen Hynniewta	FERCICON 2021/220	NEIGRIHMS Hospital
121	Tohrin Seltol	FERCICON 2021/221	NEIGRIHMS
122	Dr Diptimayee Devi	FERCICON 2021/222	Gauhati Medical College
123	Fasty Lyting	FERCICON 2021/223	NEIGRIHMS Hospital
124	Maj. Donna Wanda Mary Khyriem	FERCICON 2021/224	Army Hospital
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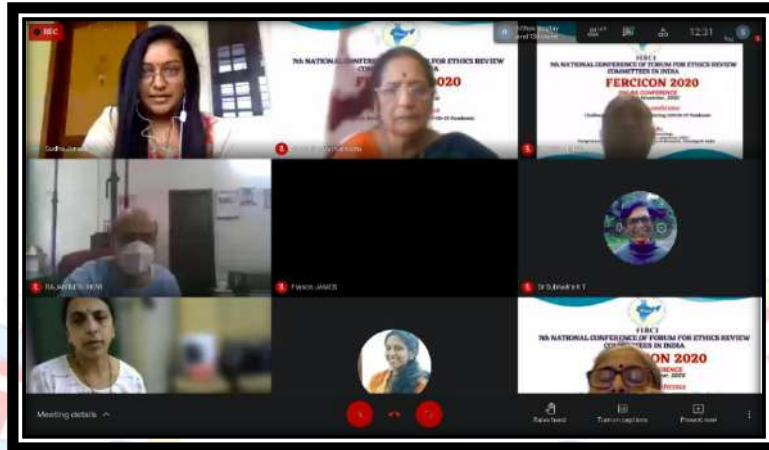
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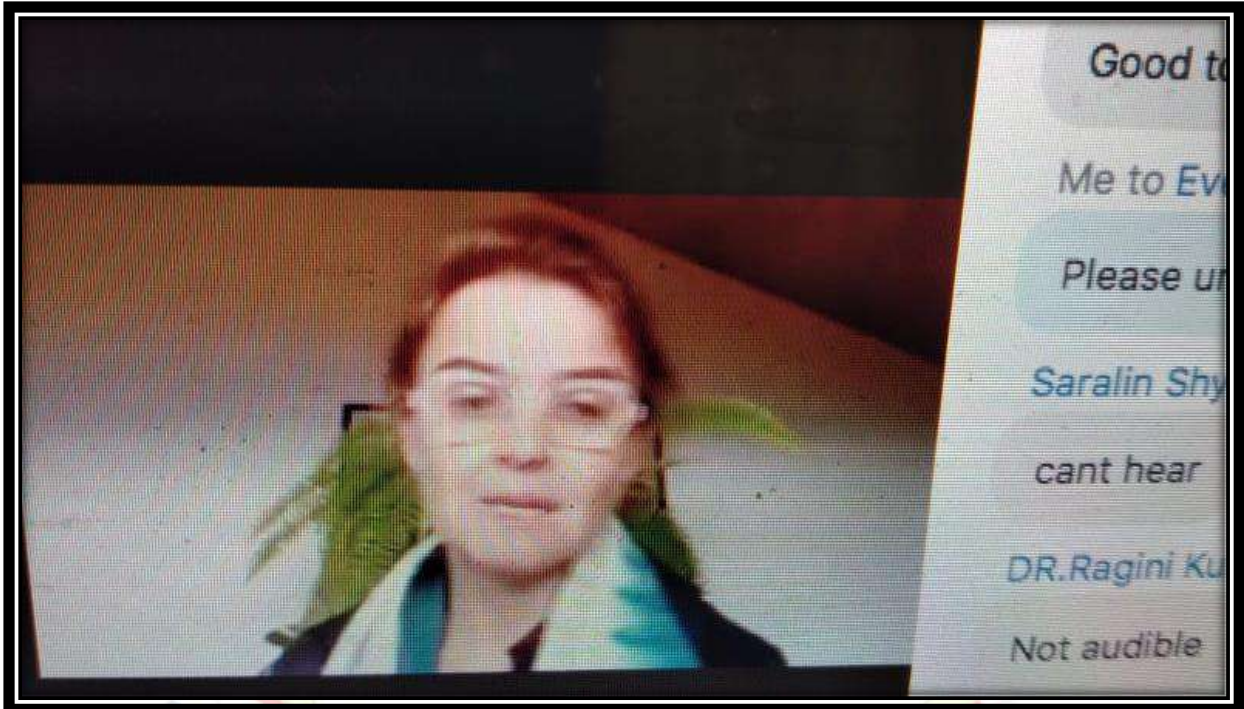


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