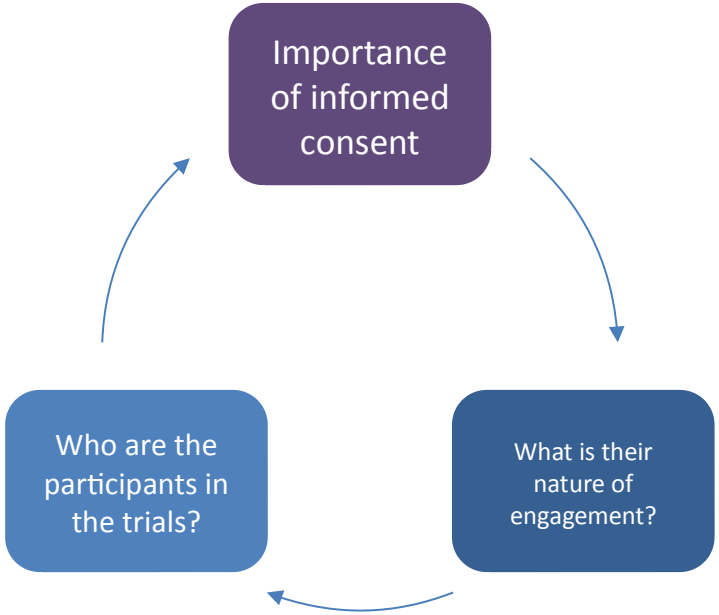
A WEBINAR SERIES: Ethical and Leal Challenges in Research in preventive vaccines and in making approved vaccines available

SCIENTIFIC AND ETHICAL ISSUES IN COVID VACCINE TRIALS

NATURE OF PUBLIC ENGAGEMENT AND INFORMED CONSENT

WEBINAR 1: 7 November 2020

Nature of public engagement and informed consent



Participants and their involvement

Participants

- Healthy participants, not exposed to COVID
- 18-65 years/up to 80/85 years, children 12 years and above.
- Screening – inclusion & exclusion criteria – recruit participants
- Poor, vulnerable, HCW, students?
- Shouldn't people with co-morbidities also be enrolled in the trials?

Their involvement

- Call through advertisement/ word of mouth - Wrong messages can induce participants or bring an attitude to do it "for the nation"
- Screening visit
- Vaccination visit(s)
- Follow up visits / telephonic follow up
- Providing blood samples
- Testing for coronavirus
- Fill up a diary of side-effects
- End of study visit
- Paid some amount per visit

Basic Principles of Consent

- Right to autonomy and bodily integrity
- "Every adult being of sound mind, has a right to determine what should be done with her body…"
- Informed consent – person is able to weigh the risks and benefits, the options, and then take a decision
- Are people signing up for the trials based on media and political messages, and are they truly understanding what are the risks? Are they truly altruistic, or motivated by fear or other influences?
- Where no consent – assault/ battery

- Contractual agreement – "same thing in the same sense"
- Consent has to be free and voluntary
- It should be free from coercion, undue influence, mistake, fraud, misrepresentation
- Coercion – force, threat to harm, etc.
- Undue influence – person in position of power takes advantage over another person – would vitiate consent
- Simple, in a language understood by the participant

Content of consent form

Purpose of trial, design, number of arms in trial, sponsor(s), who to contact – PI and EC

- Risks involved, known risks, unknown, reporting of side-effects, alternatives. Confidentiality.

Duration of trial, number of participants, number of visits, withdrawal, refusal, stop of trial for varied reasons, compensation payable

- Consent to enter trial, collect & use anonymized data, store samples for future, etc. Those in placebo arm to get vaccine, if proven to be effective post-trial.

Legal and Ethical considerations

Just signing on a document is not enough. Participant should also understand.

Rules and Guidelines – audio visual consent for new chemical entities. But, in fast track mode – may not be done in some trials.

Electronic consent accepted – due to COVID. But, some may not have access to electronic devices

- Monitoring of trial done by Sponsor and EC
- ICD - signatures, thumb impressions, date, signature of PI, signature of impartial witness, etc. EC can even call participants about the process and understanding of the trial
- Check detailed notes of the IC process
- Check AV consent – if participant is understanding, asking questions, etc.

Importance of Informed Consent

- IC is a continuous process – relevant and complete information, competence of participant, comprehension and voluntariness
- Participant involved in the research actively
- Understands and helps researcher by noting adverse events and serious adverse events
- Understands the importance of follow up
- Participant becomes an equal partner in the research process – is not a mere “subject”

Public Engagement

On the one hand – more than 30,000 people have signed up as volunteers to enter trials – 'One day sooner'

On the other hand more than 50-60% of people say they will not take the vaccine even if available

Important to involve the communities and public in the entire process
ICMR COVID-19 guidelines (2.7) – community engagement

There is vaccine hesitancy and mistrust due to the haste at which the vaccines are being developed

Importance of engaging the public

- ICMR portal https://vaccine.icmr.org.in/covid-19-vaccine has information on the vaccine trials – currently 3 of them in India – BB – Covaxin, SII – Covishield, ZC – ZyCoV-D

  It Has CTRI details, updates on the status of the trials and the stage of the trials, DCGI approvals
- Give out honest, complete and correct information
- What is meant by Emergency Use Authorization of the vaccine? Provide complete information
- Not a miracle cure or quick fix, will not be available to all immediately, need to continue with standard preventive measures

- Develop trust that DCGI will objectively assess the data and safety concerns and not be driven by the notion of being "the first to find a vaccine", or be persuaded by the pharma cos., or corruption, or other concerns of the people – should be transparent and open in the decision making process.
- Involve the public in developing guidelines not just for conducting the trials, but also for prioritising the distribution of the vaccine in certain populations
- Not to have a top down approach, but a participatory approach

Public's role in COVID-19 vaccine

Understand & inform public's expectations about vaccine – benefits, risks, and supply

Earn public's confidence on equitable and just vaccine allocation and availability

Vaccine available in safe, convenient and familiar places

Communicate meaningful, relevant information

Instill confidence of public – ownership of vaccine

- John Hopkins – centre for health security

Carry out context specific research – involving communities, participants – ethical, political, economic, legal and religious dynamics – concerns and barriers to participation

Identify community dynamics and patterns of trust

Engagement and trust – open data and ensure full transparency

Integrate community perspective

Open dialogue through advisory groups and community consultations

Not only misinformation to be identified, but also sources of mistrust

- Social Science in Humanitarian Action Platform

African Union aims to scale up COVID-19 vaccine trials by engaging communities while designing and executing vaccine trials. Use Participatory Research tools, prepare communities.

- **Opinion: Vaccine trials start and end with the Community**
  - Githinji Gitahi, Lolem Ngong, George Kimathi

Conclusion

- Important for governments, donors, public health experts, scientific community, policy makers to involve the public at every step of the development of the vaccine(s)
- Government should be open and transparent in their functioning and dealings about the vaccine trials, development and distribution
- Responsibility and accountability needs to be emphasized. Compensation should be payable.
- Informed consent and participant comprehension are important medical, ethical and legal standards
- Right to autonomy, right to health and right to life of people needs to be upheld in the public health discourse of vaccine trials

- Thank You