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Clinical Trials and Medical Ethics

In a letter to Prime Minister, members of Civil Society have alleged irregularities and ethical violations in the conduct of the clinical trial for Bharat Biotech's Covaxin (a COVID-19 vaccine) by the People's Hospital in Bhopal, Madhya Pradesh and the resultant exploitation of trial participants belonging to vulnerable groups demanding stoppage, punishment and compensation.

Why are clinical trials important?

- Clinical trials are the backbone of medical progress. They rigorously test new drugs, therapies, or medical devices to determine their safety and effectiveness.
- They help identify potential side effects and adverse reactions to new treatments.
- The data gathered from trials is essential for regulatory approval and for informing healthcare decisions for patients

Why are medical ethics important in clinical trials?

- Medical ethics ensure that clinical trials are conducted in a way that protects the rights, safety, and well-being of participants.
- They also maintain the integrity of the research process and the validity of the results

What are some key ethical principles in clinical trials?

- **Informed Consent:** Participants must be fully informed about the trial's purpose, procedures, potential risks and benefits, and their right to withdraw at any time.

- **Beneficence:** The trial should maximize benefits and minimize risks for participants.
- **Non-Maleficence:** Researchers must avoid causing harm to participants.
- **Justice:** The selection of participants should be fair and equitable, without discrimination.
- **Respect for Autonomy:** Participants should have the right to make their own decisions about participating in the trial.
- **Role of Ethics Committee:** Also known as Institutional Review Boards (IRBs), they review and approve trial protocols to ensure they meet ethical standards and protect participants' rights.

What are some ethical challenges in clinical trials?

- **Vulnerable Populations:** Ensuring adequate protection for vulnerable populations such as children, pregnant women, and individuals with impaired decision-making capacity.
- **Informed Consent in Emergency Situations:** Obtaining informed consent can be challenging in emergency situations where immediate action is required (like in case of COVID-19 Pandemic).
- **Conflicts of Interest:** Financial interest of pharmaceutical company developing the drug can compromise the objectivity of the trial.
- **Post-Trial Access to Treatment:** Ensuring participants have access to potentially beneficial treatments after the trial ends.
- **Effective functioning of Ethics Committees:** These committees act as primary guardrails that are supposed to be a check on abuse of medical ethics but often times fail to discharge their duties due to corruption, nexus with private sector & lack of competency.

What is the way ahead?

- **Stringent Regulations:** Clinical trials are subject to strict regulations and oversight by regulatory authorities.
- **Transparency:** Researchers are increasingly making trial protocols and results publicly available.
- **Independent Review:** Independent ethics committees scrutinize trial protocols.
- **Patient Advocacy Groups:** Patient advocacy groups play a role in ensuring ethical conduct and protecting participants' rights.
- **Supporting Ethical Research:** The public can advocate for ethical research practices and support organizations that promote ethical clinical trials.

Can you answer the following question?

The COVID-19 pandemic has accelerated the development of vaccines and treatments through clinical trials. In this context, examine the ethical dilemmas faced by researchers and policymakers in conducting clinical trials.

Factory Accidents and Inspection Reform

Recent Industrial Accident, involving reactor explosion in Dombivli Mumbai caused loss of lives, injuries, and damage

- Unregistered boiler, highlighting lack of adherence to safety regulations & **poor inspection regime**.
- Similar accidents occurred in 2016, 2018, 2020, and 2023
- Maharashtra government failed to relocate 156 chemical factories as decided in 2022

What are the challenges with labour inspection in India?

- **Poor Inspection rate:** Maharashtra inspected only 23.89% of hazardous factories and 8.04% of registered factories.
 - Similar low rates in Tamil Nadu and Gujarat, with an all-India average of 14.65% and 26.02%.
- **Shortage of inspectors** and high workload (499 factories per inspector per year) contribute to inadequate inspections.
- **Low prosecution rate** (6.95% in Gujarat, 13.84% in Maharashtra, 14.45% in Tamil Nadu) weakens the deterrent effect.
- **Current reforms** (self-certification, randomized inspections, etc.) are inadequate and violate ILO's Labour Inspection Convention (081), 1947.
- **Recurrence of similar disasters** indicates lack of learning and accountability. State has failed to perform its duty to ensure a safe working and living environment.

What is the way forward?

- Focus should be on strengthening labor market governance by implementing ILO Convention provisions.
- Increase number of qualified inspectors
- Allow inspectors to enter establishments freely without prior notice
- Focus on both inspection and facilitation of compliance
- Establish a penal system for enforcers (government and labour department officials)
- Ensure efficient and ethical labour inspectorate

Can you answer the following questions?

"Industrial safety in India is compromised by inadequate inspection and lax enforcement of regulations." Critically examine this statement in light of recent industrial accidents and propose measures to improve safety standards.

"The frequent occurrence of industrial accidents in India points to systemic failures in governance and regulation." Analyze this statement and suggest a roadmap for preventing such disasters in the future.

"Self-certification and randomized inspections have weakened the labour inspection system in India." Do you agree? Substantiate your answer with suitable examples and suggest alternative approaches to improve industrial safety.