Strengthening India's Medical Research

This editorial is based on "Trials, medical ethics and the orbit of power" which was published in The Hindu on 04/07/2024.The article brings into picture allegations of ethical violations in Bharat Biotech's Covaxin clinical trials and highlights systemic issues in India's medical research ethics.

India's medical research landscape stands at a critical juncture. On one hand, the nation possesses undeniable assets: a **burgeoning pool of talented researchers,** a richly diverse population ideal for clinical trials, and a growing emphasis on scientific and technological advancement.

However concerns like Ethical lapses in medical research cast a long shadow over India's aspirations in healthcare innovation. Recent controversies, such as the **alleged irregularities in the** Covaxin **trial in Bhopal,** have brought to light systemic issues in clinical trials and drug development processes. Furthermore, the allegation on the dysfunctional state of **institutional ethics committees,** which are meant to be the primary safeguards against ethical violations.

There is an urgent need for comprehensive reform in India's medical research and clinical trial landscape. This should **encompass building expertise in clinical development**, and ensuring strict adherence to ethical guidelines, particularly in obtaining informed consent from vulnerable populations.

Which are the Key Organizations Involved in Medical Research in India?

- **Department of Health Research (DHR)**: The apex body under the Ministry of Health and Family Welfare, responsible for promotion and coordination of basic, applied and clinical research including clinical trials and operational research in areas related to medical, health, biomedical and medical profession.
- Indian Council of Medical Research **(ICMR):** The Indian Council of Medical Research is the apex body in India for the formulation, coordination and promotion of biomedical research
- Drugs Controller General of India **(DCGI):** The national regulatory authority responsible for approving clinical trials of new drugs and vaccines in India.

What are the Recent Advancements in Medical Research in India?

- **Rise of Specialized Research Institutes**: India is establishing dedicated institutes for advanced medical research, **fostering innovation in specific fields of medical science**. These institutes are accelerating progress in cutting-edge areas of healthcare.
    - **Example:** The **Translational Health Science and Technology Institute (THSTI) in Faridabad** has been instrumental in developing and validating **diagnostic kits for** Covid-19, showcasing India's growing capabilities in biotechnology research.
- **Improved Focus on Indigenous Health Challenges**: Researchers are increasingly targeting health issues specific to India, addressing local needs and developing solutions tailored to the population.
    - This approach is leading to breakthroughs in areas previously neglected by global research.
    - **Example:** The **development of** ROTAVAC, an affordable rotavirus vaccine by Bharat Biotech, specifically addresses a **major cause of diarrhea in Indian children**, demonstrating the country's ability to solve local health problems.
- **AI and Big Data in Healthcare**: The integration of artificial intelligence and big data analytics is revolutionizing medical research in India.
    - These technologies are enabling more accurate diagnostics, personalized treatments, and efficient healthcare delivery.
    - **Example: Niramai Health Analytix** has developed an AI-based breast cancer screening tool that's non-invasive and cost-effective, potentially improving early detection rates in resource-limited settings.
- **Genomics Revolution**: India is participating in large-scale genomic studies, contributing to a better understanding of genetic diversity and its impact on health.
    - This research is paving the way for personalized medicine approaches tailored to the Indian population.
    - **Example:** The GenomeAsia 100K project, **which includes a significant Indian cohort,** aims to create a comprehensive genetic database that will inform future medical research and treatments specific to Asian populations.
- **Telemedicine and Remote Healthcare Research**: The rapid adoption of telemedicine is not only improving healthcare access but also generating valuable data for research.
    - This trend is **enabling studies on healthcare utilization patterns** and outcomes across diverse Indian populations.
    - **Example: Practo,** a leading telemedicine platform in India, has been leveraging its vast user data to provide insights into disease patterns and healthcare-seeking behaviors, contributing to public health research.

What are the Major Challenges Related to Medical Research in India?

- **Ethical Concerns in Clinical Trials:** India faces ongoing issues with ensuring ethical conduct in clinical trials, particularly **regarding informed consent and protection of vulnerable populations.**
    - These concerns can hinder research progress and damage public trust in medical studies.
    - **Example:** The recent controversy surrounding the **Covaxin trial in Bhopal, where allegations of ethical violations and exploitation of vulnerable groups emerged.**
- **Inadequate Funding and Outdated Infrastructure:** Despite improvements, many research institutions in India still struggle with **insufficient funding and outdated infrastructure**, limiting their ability to conduct cutting-edge research.
    - India's expenditure on R&D hovers around 0.6% of Gross Domestic Product (GDP).
        - The Ministry of Science and Technology, the Council of Scientific and Industrial Research, and the Indian Council of Medical Research garnerse about 20% of it.
    - In **China, Japan, South Korea and the U.S,** the private sector contributed **70% of the research expenditure.**
        - However, Only 36% of India's research expenditure came from the private sector in 2019-20.
- **Brain Drain and Lack of Talent Retention**: India continues to lose skilled researchers to institutions abroad, where better facilities, funding, and career prospects are often available.
    - This exodus of talent impacts the country's research capacity and innovation potential.
    - **Example: Dr. Rahul Purwar,** who developed a novel CAR-T cell therapy for cancer

treatment at IIT Bombay, moved his research to the USA due to better facilities there.
- **Regulatory Hurdles and Bureaucratic Colostral:** Complex and often slow regulatory processes can **delay research projects and clinical trials,** discouraging both domestic and international investment in Indian medical research.
  - **Example**: The development of the indigenous Covid-19 vaccine, Covaxin, faced initial setbacks due to regulatory challenges in obtaining approvals for human trials.
- **Limited Research on Non-communicable Diseases**: It is estimated that the proportion of deaths due to Non-Communicable Diseases (NCDs) in India have increased from 37.9% in 1990 to **61.8% in 2016.**
  - Despite the rising burden of NCDs in India, research funding and focus remain disproportionately skewed towards infectious diseases.
- **Neglect of Practical Clinical Applications:** While India produces valuable medical research, there's often a disconnect between research findings and their practical implementation in healthcare settings.
  - **Example**: Despite numerous studies on the effectiveness of community health workers (like ASHAs) in improving maternal health outcomes, the implementation of **evidence-based practices for ASHA training** and support remains inconsistent across states, limiting the real-world impact of this research.
- **Inadequate Research on Traditional Medicine Integration**: Despite the prevalence of traditional medicine use in India, there's insufficient rigorous research on integrating these practices with modern medicine.
  - **Example:** While the use of **Ayurvedic herbs like** Ashwagandha **is widespread**, there's a lack of well-designed clinical trials to establish its efficacy and safety in combination with conventional treatments for conditions like **anxiety disorders.**

What are the Major Government Initiatives for Promotion of Medical Research?

- Ayushman Bharat Health Infrastructure Mission: It is an Centrally Sponsored Scheme with an objective of the scheme is to fill critical gaps in health infrastructure, surveillance and **health research**- spanning both the urban and rural areas
- National Policy on Research and Development and Innovation in Pharma Medtech Sector: It aims to encourage Research & Development (R&D) in pharmaceuticals and medical devices and to create an ecosystem for innovation in the sector in order for India to become a leader in drug discovery
- **MedTech Product Development Acceleration Gateway of India (mPRAGATI)**: It is a National Centre under the Medical Device and Diagnostics Mission Secretariat (MDMS), sponsored by Indian Council of Medical Research (ICMR) and Department of Health Research (DHR) for **development of medical devices and technology.**
- **Champion Service Sector Scheme:** Ministry of AYUSH has developed the Champion **Services Sector Scheme for Medical Value Travel t**o promote medical tourism in traditional medicine.

What Measures can be Adopted to Enhance Medical Health Research?

- **Blockchain-based Research Collaboration Platform**: Develop a national, blockchain-powered platform for research collaboration, ensuring transparent data sharing, credit attribution, and cross-institutional project management.
  - Implement a system similar to **Ethereum** for smart contracts, but tailored for research protocols.
  - This could enable seamless collaboration between institutions like **AIIMS Delhi and CMC Vellore on multicentric studies**, with automatic tracking of contributions and data integrity.
- **AI-driven Research Prioritization**: Utilize artificial intelligence to analyze health data, research outputs, and funding patterns to identify underserved research areas and optimize resource allocation.
  - **Example**: Develop an AI system that combines data from the National Health Mission, **academic publications, and global health trends** to suggest high-impact research priorities, similar to how **Netflix algorithms predict viewer preferences** but for medical

- **Quantum Computing for Drug Discovery:** Invest in quantum computing capabilities specifically for accelerating drug discovery and molecular modeling.
  - Establishing a national quantum computing facility, similar to **IBM's Quantum Network**, but focused on solving complex pharmaceutical challenges like **protein folding and drug-target interactions** for diseases prevalent in India.
- **Mandatory Research Sabbaticals for Clinicians**: Implement a system where practicing clinicians are required to take **periodic research sabbaticals, bridging the gap between clinical practice and research.**
  - Establishing a program where every five years, **clinicians spend 2-3 months fully devoted to research projects**, similar to the academic sabbatical system but tailored for healthcare professionals.
- **Vernacular Medical Research Network**: Develop a national platform for conducting and disseminating medical research in regional languages to **increase participation and knowledge sharing among non-English speaking healthcare professionals.**
  - Launch a multilingual journal and research database to contribute valuable clinical observations and access cutting-edge research in their native language.
- **Tribal Knowledge Integration Program:** Create a systematic program to document and scientifically validate traditional medical knowledge from India's diverse tribal communities and integrate it with **Ayush Next Database.**
  - Establishing research stations in areas like the Nilgiris, partnering anthropologists with medical researchers to study unique **Toda tribe healing practices,** potentially uncovering novel compounds for pain management or wound healing.

> ### _Drishti Mains Question:_
>
> India's burgeoning medical research sector holds immense promise. However, translating potential into reality requires addressing critical roadblocks. Discuss.

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