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Government's role in shaping public perceptions about clinical research

Over the last decade, Indian clinical research environment has witnessed two forces pulling in opposite directions. The regulatory changes – Indian Good Clinical Practice (GCP) guidelines, Amended Schedule Y, Indian Council of Clinical Research's Ethical Guidelines for Biomedical Research on Human Participants, Clinical Trial Registry of India – all, together with focus on education and training of clinical research professionals in academia and industry, promoted the growth of clinical research and clinical trials. In parallel, frequent media stories of commercialization of clinical research and exploitation of subjects have impeded the growth of clinical research. These stories have been a discussion point for parliament and social activists and could have influenced public perceptions about clinical research in India. This article discusses perceptions of public about the clinical research activities and the role of the government in shaping these perceptions.

PUBLIC PERCEPTIONS

Several American surveys and opinion polls have focused on public perceptions and attitudes about clinical research. [1] Majority of Americans and Europeans considered clinical trials important and believed that clinical research plays an important role in advancing public health. In a survey of 1000 people conducted by The Center for Information and Study on Clinical Research Participation (CISCRP) 2008, 17% felt research studies and trials are very safe, and 51% believed them to be somewhat safe. In contrast, 11% did not believe them to be very safe and 7% did not believe them to be safe at all.[2] According to the survey respondents, the most common reasons why people take part in clinical trials are: a) wanting to make money b) wanting to help mankind c) being sick and having no other option.[2] Fifty seven percent of Americans opined that they would be likely to participate in clinical research, and 40% say they would not.[2] Over 70% of those who took part in clinical trials are likely to do so again.[2]

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In India, there are hardly any surveys on public perspectives on clinical research. According to a study by Gitanjali, only 30% of Indian subjects are likely to consent for a clinical trial.[3] Most patients withheld consent because they did not want to give blood or take a new drug or were afraid of tests. In contrast, the reasons why most patients gave consent were:

- Help medical community
- Relief of pain.

In a meta-analysis of 7 studies covering 904 Indians, Shah et al. explored the reasons why people take part in clinical trials.[4] The factors which favored participation were: personal health benefits, altruism, methods for motivating participation, source of extra income, detailed knowledge about trials, and trust in physicians. The factors serving as barrier to participation in clinical trials were: mistrust on trial organizations, concerns about efficacy and safety of trials, dependency issues, loss of confidentiality, trial burden, psychological reasons and language.

MEDIA INFLUENCE

Media has played an important role in framing the public perceptions. Over the last 5 years, frequent media

reports in leading Indian newspapers have carried stories with alarming headlines focusing on deaths in clinical trials, exploitation of subjects, consent deviations, fraud, regulatory laxity, and compensation for patients. As the medical professionals / academia are not active in creating public awareness of clinical research, the industry avoids media out of fear, and government is a silent spectator; Indian citizens are largely receiving a one-sided education about clinical trial environment from media. However, these stories have made an impact on the Indian parliamentarians. Since 2003, there have been 60 questions in Rajya Sabha on clinical trials.[5] Some of the recurring themes for these questions were: unethical trials, illegal clinical trials, Indian patients as guinea pigs, deaths during clinical trials, compensation, and protection of patients undergoing trials, and monitoring mechanism for clinical trials.

Such media coverage is likely to create distrust in the minds of public. A 2007 Harris Interactive poll among 1,726 adults of United States of America, found that 27% of the public distrusts- 'somewhat' or 'very strongly'- the Food and Drug Administration, and 42% distrust the pharma industry.[1,2] Around 20-25% Americans believed that their doctors would expose them to unnecessary risk in clinical trials.[3] In contrast, the potential Indian participants placed a lot of faith in government endorsement and were more likely to believe that it was safe to participate.[4] They were more inclined to participate, if information on clinical trials was provided through government owned television channels.[4] This emphasizes the central role of government in creating a trustworthy clinical research environment.

GOVERNMENT ROLE

The government has a major role to play in building trust and confidence amongst the public about the need and conduct of clinical trials.

The government must take following actions:
- Clinical Trial Subject Protection measures
- Compliance enforcement
- Communication

CLINICAL TRIAL SUBJECT PROTECTION MEASURES

- The ethics committee (EC) should regularly monitor for the Good Clinical Practice (GCP) compliance of the approved study and report the observations to Central Drugs Standard Control Organization (CDSCO).
- The CDSCO guideline on compensation should be made into a law expeditiously.
- Specific measures to document consent process, e.g. video recording, should be put in place.

COMPLIANCE ENFORCEMENT

- Regulatory Guidance on Clinical Trial Inspection, released in Nov 2010, should be finalized with details of compliance enforcement actions.
- Regulatory inspection to ensure compliance to GCP for investigators sites should be conducted. The number of sites to be inspected could be as per standard audit norms - 20-30% of sites or square root of number of sites for a trial.
- Regulatory inspection should be conducted for Ethics committees, pharma company clinical research departments and clinical research organizations.
- Regulatory inspection findings should be available in public domain on CDSCO website.
- The CDSCO should initiate administrative actions, when significant non-compliance is detected. These enforcement actions should be clearly defined and would include warning letter, suspension of trial, and disqualification of the investigator, and rejection of clinical trial data.
- The CDSCO should initiate process of registration/ certification of all stake holders - investigator sites, ethics committees, pharma company clinical research departments and clinical research organizations.

COMMUNICATION

The government should communicate to the public about:
- clinical research process and its value in improving public health;
- regulatory mechanisms for human subject protection;
- clinical Trial Subject Protection measures; and,
- compliance enforcement actions.

This should be done though all media channels – print, electronic and television.

The current crisis of confidence amongst clinical research participants requires a responsible, responsive and robust regulatory response.

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