Public communication about CHIM: What is the role of the media?

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Abstract

The possibility of introducing the Controlled Human Infection Model of research into India is being discussed by some Indian scientists in order to develop biomedical technologies such as vaccines. CHIM studies involve the deliberate introduction of an infectious agent into a healthy person in order to observe the development and progression of the disease, or test potential treatments. This idea will be alarming to the Indian public who will demand the assurance that CHIM is needed and safe.

Health communication is viewed by researchers as vital to getting communities on board in public health programmes. The role of the media, however, is to provide information and analysis that represents the public's interests, and enables the public to make informed decisions.

The starting point for journalists will be the environment in which CHIM would be conducted in India: poor healthcare, poverty, vulnerabilities of various kinds, ethical violations, weak regulation, and industry's impunity. They will also consider that research agendas may be driven by a focus on technological solutions to complex problems, and promote unnecessary vaccines that subsidise the private sector vaccine industry.

When talking to the media about its interest in conducting human challenge trials, the research community will have to be honest about its plans, transparent in its functioning, and also ready to admit the possibility that we should not introduce this technology in India.

Introduction

The Controlled Human Infection Model or CHIM, that is being discussed by a section of the Indian scientific community, is described as a research method essential to the development of certain biomedical technologies, including new vaccines. It may, for instance, be used to test vaccine candidates for malaria (1), a disease which affects millions of Indians.

The basic premise of CHIM is that the deliberate introduction of an infectious agent into a healthy person permits the researcher to observe the development and progression of the disease, or test potential treatments for (or vaccines against) that disease. The idea that a researcher would deliberately infect a trial volunteer will obviously be alarming to the general public. Before it can even be considered for introduction in India, there is a need for public discussion on whether this research model is needed. Even if the Indian public is persuaded of the importance of CHIM, it will certainly demand assurance that the use of this method will pose no risks to volunteers or the larger community, especially so given the weak regulation of medical research in India.

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Arguments for using the controlled human infection model in India

It has been pointed out that CHIM will immensely benefit the research enterprise both in terms of the science and the costs. For example, at present the process of developing a vaccine against a disease requires promising vaccine candidates to be tested on animals which have been deliberately infected. This is in order to see which of the vaccine candidates – if any – is safe, and effective. Those proven to have some efficacy in animals are then tested on human volunteers for efficacy against a naturally acquired infection.

But not all diseases have good animal models. A vaccine candidate that is effective on a mouse may turn out not to work as well on humans. And even if they do, the process of ruling out ineffective vaccine candidates is long, as researchers must wait for the volunteers to get infected naturally (2).

Researchers say they could use CHIM to test vaccine candidates and rule out the ineffective ones. The vaccine candidate would be given to a small group of human volunteers. Then (after a period of time during which it is hoped that the volunteers develop immunity), the volunteers would be deliberately infected with the pathogen and monitored for a specified period. If the vaccine candidate works, the volunteers won't fall ill. This would reduce the number of people in large trials exposed to what may turn out to be ineffective vaccine candidates. It would speed up research at the early stages, as ineffective vaccine candidates can be eliminated early in development. There is also no need to wait for the volunteers to become infected naturally. All this would bring down research costs.

Researchers would also learn much more about the disease itself. For example, our knowledge of malaria infection comes from patients after they experience symptoms severe enough to warrant seeking health services. CHIM would allow one to learn about pre-symptomatic stages of the disease.

Those proposing the introduction of CHIM in India also suggest that it should be conducted in those countries for

whom such technologies are being developed. It is possible that a vaccine candidate that works well in one part of the world might work differently on the Indian population (2). It has been suggested that there are ethical reasons as well. Referring to the testing of the typhoid vaccine candidate in the UK, it has been asked: "…just [as] we say that we do not want drugs tested on Indians that will benefit richer populations before they benefit us, is it right, (perhaps taking typhoid as an example), that vaccines for diseases that affect us should be tested in people who will never get the disease in their own countries?" (3).

Finally, in order to reassure the public, it is stated that the CHIM model would be used only in specific circumstances. The disease strain used must not cause more than mild infection. Second, the disease being researched must have effective treatments so that the infection would be treated before the volunteer experiences severe illness. Third, volunteers would receive extensive counselling before being admitted into a study. And fourth, the studies would be conducted by highly trained scientists using sophisticated and well-run research facilities, and be carefully monitored (2).

Researchers will presumably make these arguments in public communication on the use of CHIM in India.

Public communication in health and science

Indeed, health communication is an integral part of getting communities on board in public health programmes. The World Health Organization's 2017 document "Strategic communications framework for effective communications" states that the purpose of such communication is to "provide information, advice, and guidance to decision-makers (key audiences) to prompt action that will protect the health of individuals, families, communities and nations." Such communication is often for education, such as on good feeding practices and hygiene, and information and protective action against disease outbreaks (4).

For example, in the case of immunisation programmes, a UNICEF working paper's suggestions include that the government programme work with communication professionals to answer general questions about vaccine safety, respond fast to any cases of illness or death following immunisation (which would include investigating the incident, making full findings public and taking the appropriate action) have a plan on how to deal with rumours, develop long-term "partnerships" with the media, and overall build public trust in immunisation (5).

Science communication is also a way for (government and private) research institutions to share their work with the general public through the media, to alert them about new information and technologies that could improve their lives and the health of communities. For example, research on how cancerous cells multiply could help in the development of more effective treatments (6). Research on drug-resistant organisms should prompt changes in infection control practices and antibiotic protocols (7). The science journalist, who makes science accessible to the public, is a key intermediary between the research institution and the reading (or viewing) public. Like all specialised media practitioners, science journalists are expected to acquire the technical knowledge in the subject, necessary for communicating it accurately to their readers.

Communicating complexity and controversy

The task of the journalist is to equip the public with the information needed to take decisions according to their needs and circumstances. The media is expected to make subtle and highly technical details accessible to the public. For example, when studies on the use of hormone replacement therapy and heart attacks arrive at conflicting conclusions, journalists must explain why this is the case (8). If a study finds a link between hormone replacement therapy and an increased risk of breast cancer, the journalist must explain how significant the risk, as opposed to the benefits (9).

The media is also likely to face different, sometimes competing narratives on a public health intervention, such as a vaccine. It is necessary to study, understand and explain not only the public health justification for a vaccine in the government's programme but also the debates on it within the research and public health communities.

This could mean that parents should be informed that the Pulse Polio campaign may be responsible for a few children developing vaccine associated polio paralysis (10). And parents should be informed that some countries have compensation programmes for vaccine-related injury or death – but India, with the largest child immunisation programme in the world, does not have such a programme.

Likewise, the science journalist must accurately convey the debate on the pentavalent vaccine where questions have been asked about the quality of adverse event reporting and investigation. Parents need this information in order to decide whether their children should be given the vaccine, or possibly oppose a government order to vaccinate. Vaccines should be questioned with reasoned arguments, not supported unconditionally.

Of course, the media has a heavy responsibility when questioning the programme – to be sure of the facts, to put criticisms in perspective for readers, to report differing opinions accurately, and to be aware of the consequences of questioning mainstream views.

Need for transparency in health programmes

Just as the media has these responsibilities, the government has the responsibility to be transparent, and engage the community in its plans. Unfortunately, the government often fails on this count. In the case of immunisation programmes, it must promptly investigate all reports of illness or death following immunisation, make its findings public, and take the appropriate action. But the government's kneejerk response to crises in immunisation programmes is well documented.

For example, in 2000, researchers analysed the government's response to reports of children falling ill or dying after receiving the oral polio vaccine. They found that the government tended to dismiss the parents' concerns. If the community demanded a medical inquiry, the government sent a combined police and medical team, treating it as a "law and order" issue (11).

Almost two decades later, the government's approach has not changed. The recent vaccine drive to administer the measles rubella vaccine to a whopping 3.5 crore children in a three-week period was met with parental pushback, and with good reason. Parents were given very little information on, for example, why a child who had already received the vaccine should be given a repeat dose. Without such information, parents might have been more likely to believe rumours being circulated in the social media (12, 13). The situation exacerbates an already low level of confidence in such public health programmes.

In India, the 2009 H1N1 pandemic is one example of where health authorities' poor communication worsened the crisis created by an inadequate public health response. Hospitals were overwhelmed by an anxious public while the seriously ill sometimes did not receive life-saving treatment (14). Thoughtless and inaccurate media coverage increased public panic (15).

Communication of CHIM and the role of the media

In the case of CHIM, one objective of public communication would be to tell the public what it consists of, what it would be used for, and what precautions would be taken to prevent harm to individual participants and the community, in order to get public support.

But as noted earlier, the journalist should and will demand more. The media's role is not to convince the public of the need for CHIM – or any other research model. The media must provide information and analysis that represents the public's interests, and enable the public to make informed decisions.

Challenges for the research community

The starting point for journalists in India writing about CHIM is the environment in which it would be conducted in India: poor healthcare infrastructure, poverty, and vulnerabilities of various kinds. In medical research, there are extensively documented ethical violations, weak regulation, and industry's impunity.

The research community can expect some measure of general distrust of CHIM in India, given that many sections of the public are likely to have a fear and distrust of the larger research enterprise. The term "medical research" is likely to recall images of research violations, such as unethical testing of provider-controlled contraceptives on poor women who did not give informed consent (16), the HPV vaccine being administered to thousands of tribal children without their parents' consent (17), or hundreds of patients dying in drug trials (18).

Researchers considering CHIM will also have to contend with the concern that research agendas are driven by funding organisations which focus on technological solutions to complex problems. Such emphasis on technology "can detract attention from the social determinants of health while promoting an approach to health that is heavily dependent on clinical technologies. The support of vertical, disease-based programmes can undermine coherent and long-term development of health systems…" (19). The public-private model for vaccine research has been criticised for developing and promoting unnecessary vaccines and subsidising the private sector vaccine industry (20).

Finally, the research enterprise is largely out of public view, privy to regulators and members of research ethics review boards; the rest of us learn of research violations only when they are revealed by advocacy groups and the media. The general public knows almost nothing of what goes on in medical research on humans, who participates in these trials, their socioeconomic backgrounds, their motivations, and so on. The journalist will write about CHIM in the context of all this research.

Among the questions that journalists will ask are: What is the scientific necessity of this technique in medical research? Why has it come up for discussion in India now? What exactly does it involve and what are the different uses? What risks could the use of this research model pose to individual volunteers, and to the community? Who are the potential participants, and what measures will be taken to protect them? What steps will be taken to ensure that the research is properly regulated? Who will be conducting CHIM-related research? Will the design and data from the research be in the public domain? If a vaccine or other technology is developed using CHIM, will it be available to all who need it?

The media must also promote discussion on ethical arguments in favour of CHIM, for instance, is it really unfair if CHIM is used in the UK to develop a vaccine for Indians?

Finally, we should also consider why, from the point of view of the research community, there is a need to engage in public discussion of this particular research technology but not others. What is special about CHIM, when other forms of research have never been taken before the general public? Is there any more need for public communication on CHIM in India than there is on other aspects of research – such as, for example, phase 1 trials of cancer drugs on terminally ill people, or conducting research on patients in intensive care? Or public health research on low cost interventions? Is public communication on CHIM just a caution to be taken when introducing a new method, given the public distrust of research? Or is it time for us to promote better public communication of all health research?

When talking to the media about its interest in conducting human challenge trials, the research community will have to be ready to be honest about its plans, transparent in its functioning, and also ready to admit the possibility that we should not introduce this technology in India.

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References

1. Koshy J. Central labs moot 'human first' approach to test malaria vaccine. *Thehindu.com.* 2017 Jul 27[cited 2018 Oct 19]. Available from: http://www.thehindu.com/sci-tech/health/central-labs-moot-human-first-approach-to-test-malaria-vaccine/article19235713.ece accessed on 2018 Apr 22.
2. Vora P. Interview: What safeguards does India need before it can move to a faster way of developing drugs? *Scroll.in* 2018 Feb 15 [cited 2018 Apr 22]. Available from: https://scroll.in/pulse/868784/interview-is-india-ready-to-safely-adopt-a-faster-way-of-developing-medicines
3. Kang G. Left shifting vaccine development. Website of the Department of Biotechnology, Ministry of Science and Technology. Available from: http://www.dbtindia.nic.in/left-shifting-vaccine-research-and-development/
4. Department of Communications, World Health Organization. WHO Strategic communications framework for effective communications. Geneva:WHO: 2017[cited 2018 Oct 20]. Available from: http://www.who.int/mediacentre/communication-framework.pdf
5. UNICEF Regional Office for South Asia. Building trust and responding to adverse events following immunisation in South Asia: using strategic communication. Working Paper. Kathmandu, Nepal: UNICEF ROSA;2005 Apr [cited 2018 Oct 20]. Available from: https://www.unicef.org/cbsc/files/Immunisation_report_17May_05(final_editing_text).pdf
6. Filipp FV. Sure, cancer mutates, but it has other ways to resist treatment. *The Conversation*, 2018 Apr 4 [cited 2018 Oct 20]. Available from; https://theconversation.com/sure-cancer-mutates-but-it-has-other-ways-to-resist-treatment-93633
7. AFP. Drug-resistant superbug spreading in hospitals: study. *Thehindu.com*. 2018 Sep 4[cited 2018 Oct 20]. Available from: https://www.thehindu.com/sci-tech/science/drug-resistant-superbug-spreading-in-hospitals-study/article24857593.ece
8. Kolata G. Hormone studies: What went wrong? *nytimes.com*. 2003 Apr 22[cited 2018 Oct 20], Available from:https://www.nytimes.com/2003/04/22/science/hormone-studies-what-went-wrong.html
9. MacKenzie D. Why do women keep taking HRT despite breast cancer risks? *newscientist.com* 2016 Aug 23[cited 2018 Oct 20].Available from: https://www.newscientist.com/article/2102063-why-do-women-keep-taking-hrt-despite-breast-cancer-risks/
10. Pulla P. The lowdown on pulse polio. *Thehindu.com*. 2018 Feb 4[cited 2018 Oct 21]. Available from: https://www.thehindu.com/todays-paper/tp-national/the-lowdown-on-pulse-polio/article22647714.ece
11. Coutinho L, Bannerjee N. Social production of blame: OPV-related deaths in West Bengal: *Econ Pol Wkly* 2009 Feb 26. 35(8-9): 709-17.
12. Rao M, Govindarajan V. Whatsapp rumours about vaccinations hamper India's drive to halt measles and rubella. *scroll.in* 2017 Feb 24[cited 2018 Oct 21]. Available from: https://scroll.in/pulse/830129/rumours-about-measles-rubella-vaccine-hit-coverage
13. Thiagarajan K. What Tamil Nadu has failed to communicate to parents about measles-rubella vaccine. *scroll.in*. 2017 Mar 11[cited 2018 Oct 21]. Available from: https://scroll.in/pulse/831478/what-tamil-nadu-has-failed-to-communicate-to-parents-about-the-measles-rubella-immunisation-drive
14.. Phadke A. Response to an epidemic of novel H1N1 flu in Pune: need for public introspection. *Indian J Med Ethics*. 2009 Oct-Dec;6(4):176-8. Available from: http://ijme.in/articles/response-to-an-epidemic-of-novel-h1n1-flu-in-pune-need-for-introspection/?galley=html
15. Srinivasan S. Panic pandemic. *Infochange News & Features*. 2009 Aug [cited 2018 Oct 21] Available from: http://infochangeindia.org/urban-india/112-public-health/analysis/7871-panic-pandemic
16. Sarojini NB, Murthy L. Why women's groups oppose injectable contraceptives. *Indian J Med Ethics*. 2005 Jan-Mar;2(1): 8-9. Available from: http://ijme.in/articles/why-womens-groups-oppose-injectable-contraceptives/?galley=html
17. Jayaraman KS. Pressure mounting on India to explain 'irregularities' in HPV vaccine trials. *Nature India*. 2013 Sep 11[cited 2018 Oct 21]. Available from: https://www.natureasia.com/en/nindia/article/10.1038/nindia.2013.122
18. Legal correspondent. SC shocked at clinical trial deaths. t*elegraphindia.com*. 2014 Mar 11[cited 2018 Oct 21]. Available from: https://www.telegraphindia.com/india/sc-shocked-at-clinical-trial-deaths/cid/202243#.VNNDOZ2UeQw
19. McCoy D, Kembhavi G, Patel J, Luintel A. The Bill & Melinda Gates Foundation's grant-making programme for global health. *Lancet*. 2009 May;373(9675): 1645–53.
20. Madhavi Y, Raghuram N. National vaccine policy in the era of vaccines seeking diseases and governments seeking public private partnerships. *Curr Sci*. 2012 Feb 25;102 (4):58.