The Suno India Show

Are controlled human infection studies for a COVID 19 vaccine ethical? A bioethicist explains why not

In human challenge studies you infect people but do it in a very controlled manner. The argument was that, in any case, in Phase 1 clinical trials people do get somewhat exposed to this. So here we are exposing them to the risk, not of the original infection, but an infection which is weakened in such a manner that it produces a reaction in the body without harming the body too much. And you have treatment for the disease, so that even if a person develops the infection, that person is treated. “The argument in COVID is that you have large numbers of candidate vaccines in the laboratory, and they want to bring them into human trials. The best thing is to first test them out in CHIM studies and then decide whether there is a need to do large studies in the communities or in the field. That way they would like to decrease the time taken for developing new vaccines. It will also be cheaper to develop as compared to doing large scale clinical trials.”

“When you are deliberately causing infection you are doing it on a healthy human being with a promise that nothing will happen to that person or it will be minimum that will happen to the person. That means you either have to have a good treatment available or you have a disease, which is self limiting, and post infection that does no big damage to the person. Now, this is another area where COVID does not qualify for CHIM. The reason is very simple: we don't have treatment available.”

“A number of volunteers are ready to undergo CHIM, I don't know why either they're misinformed or they are so altruistic that they want to sacrifice themselves. But whether a scientist or a doctor I would not like to take advantage of people coming forward.

When infection is even prevalent in the developed countries, why should they try CHIM? They can easily do [a field trial] so that maybe it may cost slightly more, but the findings will be very generalizable. And you don't have to again carry out a field trial if you have done because of this whole emergency and people being panicked about what is happening, there are a large number of people who have come forward. There is a website called onedaysooner.org, you will find that more than 30,000 people have volunteered to be on [a COVID-19] CHIM and they come from hundred and forty countries. Now when there is a desperation, there is undermining of volunteerism in the informed consent.”

“In the high income countries large number of students participate. Because they are under debt to get higher education. And this gives them good enough cash money...Now, in COVID kind of situation, I think that type of undue inducement which may cloud people's judgement about risk that they're taking.”

“India has a checkered history of using poor people for this kind of work. If CHIM is not regulated in the manner as it is required, then there is a possibility that there may be misuse of it.”

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Sandhya Srinivasan: *It has been over four months since the WHO declared COVID-19 to be a pandemic; since then millions of people worldwide have been infected, and more than half a million have died of this disease. While today the best response may be to track, test, track, isolate and treat, many public health communities believe that the virus is not going to go away without a vaccine. This may be true, however it will take years to develop a vaccine, developing a vaccine means moving from the lab to testing them for safety and efficacy, getting regulatory approval manufacturing at scale and finally reaching it to all the people who need it. Despite what the Indian Council of Medical Research has indicated, and then later denied, vaccines don't go from the lab to the shot in your arm in six weeks. The process of research into vaccine development also raises some very important ethical issues.*

Hi, I am Sandhya Srinivasan, consulting editor of the Indian Journal of Medical Ethics and the host of this episode of The Suno India Show. This episode is part of a special COVID Science series where we bring in discussions with leading scientists, virologists among others.

In the previous episode with Dr Shahid Jameel, we discussed various steps involved in vaccine development and India's race to find a vaccine. However, we need to talk about what the ethical challenges are involved in the research and development of vaccines. Our guest today Dr Amar Jesani will answer this question and more.

Dr Amar Jesani is a senior bioethicist and editor of the Indian Journal of Medical Ethics. He has been in a number of national and international research ethics review boards for drug And vaccines. During the 2014 Ebola epidemic, he was on the board of the international relief organization Doctors Without Borders, which was involved in testing an Ebola vaccine in a state of emergency.

Sandhya Srinivasan: *Thank you for being here, Dr Jesani. Before you discuss the ethics of human challenge trials which is the subject of our discussion today, would you lay out the key ethical considerations in research on vaccines?*

Dr Amar Jesani: Vaccine in a pandemic like this is to be used on a large number of people, millions or billions of people will be taking it once the vaccine is approved. That means the community becomes very, very important when you do the clinical trial for the discovery of the new vaccine, how will the community understand what kind of work that you want to

carry out for the testing? how good community engagement and participation is necessary? Another reason why community is important is that vaccines are given to people who are not having the infection against which it is to be tested. You people are very concerned because a healthy person would not like to take any kind of vaccine, which may go out of control and may create some problems. So, they would like at the testing stage, some kind of reassurance that there is a very well supported system, where people will be taken care of when they volunteer to get tested. And the last thing is, is that when the vaccine is ready for in after testing and after the approval, the government may have to make a big outlay of the fund because there is a captive market. Government introduces it in the vaccine immunization program. So, there is a concern that the company in order to get a big market should not be cutting any corners, should not be cutting corners on science as well as ethics while developing it. And it caps the price at a reasonable rate. The other thing is, what happens when the trial is on? What kind of standard of care of the volunteers who participate? The volunteers have agency of their own. They do give informed consent, but at the same time those who carry out research, they have an obligation to take care of them. If in this kind of vaccine trial against COVID while the vaccine trial is on if a person COVID infection, will the researchers take care of the person? Sometimes, when the trial is on a person they will have some other infection or other problem like say malaria or typhoid, will the researcher take care of them-that is called ancillary care. So, what standard of care will be provided to all these people is important in Phase 1 clinical trial, which is first time use of the vaccine in the human being, they have to have a very good institutional arrangement, which is very well equipped, because you don't know first time you are using you are not able to anticipate any kind of adverse events of the vaccine to the person. So it has to be valid. It should be able to provide state-of-the-art-care in case an emergency arises. There should be very well qualified and experienced doctors available to save the person if there is an adverse event there. The third is, is that in case this despite all efforts, that is made to provide a high standard of care if somebody gets injured because of the adverse event or dies, will there be compensation available, what kind of compensation will be given? Those things are very, very important. Otherwise, you know, people do come as volunteers out of altruism, to do so service for humanity. And when they suffer, there is nobody to take care of them. It is very, very important how the compensation mechanism will be worked out. It should be very clear to the society that nobody is being forced or being induced to participate. It should be very clear that the vaccine that is being tested has been looked at its protocol has been been looked at by a large number of experts and who concur with the with the good scientific quality of the protocol. So, transparency of having protocols available in the public domain, getting more information about how the vaccine trial is proceeding. This is very, very important. And the last thing is that when you start a vaccine trial, you have to have some kind of MoU or contract with the company which is owning the vaccine, having its patent or whatever, and the researcher and the institution that once the vaccine turns out to be successful, how will it be made available to everybody? Will it be treated as a public good without any profit? It will be purchased by the state and distributed to everybody. Or if there are other costs involved will it be effort for the state as well as the

individuals who need it? So, these are a wide range of concerns, ethical concerns, which are scientific as well as value base. All of them need to be taken into consideration and kept in mind when vaccine trials are carried out.

Sandhya Srinivasan: *You have identified a number of major ethical considerations for research on vaccines. Vaccine research raises special concerns because vaccines are used on healthy people to prevent them from getting sick, rather than on sick people to make them well. And they will be given to large groups of people. I'm listing some of these considerations: any vaccine trial must engage the community to ensure that it has their support. Researchers must ensure participants' informed consent. The trial protocol must be scientifically sound and it must be available in the public domain. The research set-up must be high quality in order to get the best data and to minimise the risk to participants. There must be arrangements to take care of participants who fall sick during the trial, and compensation for any injuries or deaths in the trial. And, finally, if the vaccine is proved to be safe and effective it must be made available to all who need it, at a reasonable rate. Now, vaccines take years to develop. In situations when a vaccine is urgently needed, there are processes by which the research process can be fast-tracked. This includes the use of a human challenge study, or controlled human infection model, which reduces the time and money involved in vaccine research. Could you tell us about the human challenge model and its history?*

Dr Amar Jesani: Well, if you see the history of vaccines starting from Edward Jenner, who had you know used the cowpox to infect the his gardener's son or nephew, in order to show that after the cow pox is inoculated in the child, when that person that child is exposed to the to the smallpox, a child does not get it, but he was trying to establish what is called proof of the concept that this way one is one is able to prevent the infection at the time, you know, there was no there was no understanding about the about the bacteria and virus and that kind of stuff. Thing is science does not develop at that level, but this came from clinical practice. So, that was the kind of, you know, deliberately infecting a human being, in order to test a hypothesis of the scientists. Now this has been used in the history by many, many people, that there are researchers who have, you know, taken a new drug or new vaccine on you know and experimented on themselves before they are going to do the experiment.

Sandhya Srinivasan: *There are many instances of researchers infecting people in the name of scientific study. For example - Nazis doctors infected concentration camp inmates with malaria to study the disease. American researchers injected syphilis into sex workers. Children have been infected with hepatitis – all to learn the natural history of the disease. There are many, many such instances of vulnerable people being given a disease without their knowledge, without their consent, in the name of research. It was only in the late 1960s that there was an uproar on such ethical violations and about other unethical research on humans.*

Dr Amar Jesani: And as a consequence, there are more regulations that were brought up. This kind of clinical trial gradually shifted to the academic universities. You infect people but do it in a very controlled manner. The argument was that, in any case, when you do clinical trials, Phase 1 clinical trials people do get somewhat exposed to this. So here we are exposing them to the risk, not of the original infection, but an infection which is weakened in such a manner that it produces the kind of reaction of the body without harming the body too much. And secondly, you have treatment for the disease, so that even if a person develops the infection, that person is treated and sort of started what is called Controlled Human Infection rather than uncontrolled and random haphazard infection that was done in the earlier times. So the control human infection stage of the CHIM arrived in 1970 and a large number of clinical trials are carried out in the high income country. Another reason why they wanted to do those kinds of clinical trials in the high income countries was that when they travel to the low income country, they did not have good protection, prophylaxis and also they wanted to ensure that they are able to do studies there and are able to have some prophylaxis for treatment. Another reason is very simple. It is saving money. They'd like to do it in a low income country and do the clinical trials there. So, this CHIM gradually took shape. So, now, what they do is that the CHIM is done in two stages. First stage you infect the person and study the pathophysiology of the infection. And once you are very good at understanding the model of the infection, and then you go to the another step where new volunteers are, you know, infected for either to discover new treatment or to discover a new vaccine. So, the argument in COVID is that when we since you have large number of, of you know, candidate vaccine more than 100 ,100 or 150 now, which are in the laboratory state, and gradually they want to bring them into the human trials then best thing is to first, you know test them out in the CHIM studies and then to decide whether there is a need to do large studies in the communities or in the field. That way they would like to decrease the time taken for developing new vaccines or weighted loss will also be very cheaper to develop as compared to doing large scale clinical trials. As soon as you know the COVID, the pandemic was declared, there were a lot of efforts being made and under what conditions CHIM can be carried out. In April, the World Health Organization also came out with a document saying that the criteria for undertaking the CHIM kind of studies and those criterias are quite stiff. As of now they are there the conditions are not met and so no CHIM study has been carried out but there is definitely a lot of talk going on about doing them in order to reduce the time and select the right kind of candidates for doing a larger study.

Sandhya Srinivasan: *You have explained when and why a human challenge trial is conducted. Has the use of CHIM led to any substantial advances in vaccine research? For example, how many vaccines have been developed and reached the stage of the market using CHIM?*

Dr Amar Jesani: Well, I don't know exactly how many but there have been efforts made that have been CHIM carried out for the vaccine for malaria, which after I think they have gone to CHIM And all the large scale community level trials are on of the malaria vaccine. We also had CHIM recently. I think two years back on typhoid, from Oxford, you know, in the UK, Now, there are certain things which you need to keep in mind that CHIM, if it does a vaccine testing, that testing is done in a very controlled condition in the laboratory. Even after you develop an effective vaccine in the laboratory, there may be a need to find out whether the vaccine works in the industry, in the field or not in the natural environment. So, there are some vaccines which were developed in the CHIM in the past, but that did not work as well in the natural environment.

Sandhya Srinivasan: *So would a covid CHIM be of use?*

Dr Amar Jesani: So, in COVID also the same thing will remain that you may be able to select in a speedy way out of said 10,20 or 30 candidate vaccines, one or two to bring them into the field, but you may not completely be able to scrap the field testing because the generalizability from from laboratory to the natural environment needs to be established.

Sandhya Srinivasan: *Would a vaccine for COVID-19 meet the criteria for conducting a human challenge study?*

Dr Amar Jesani: If you look at the, what is the ideal condition in which the CHIM is carried out? The first ideal condition that is to be satisfied is a scientific one, which is about what kind of infectious pathogen that could be used for the CHIM. First it should be an infection of public health significance COVID-19 is a coronavirus and is a pandemic and it has caused lock downs and big, big harm to the economy. The animal models are unlikely to be useful, that is another criteria. Now, in this case COVID that is not so, because there are transgenic animals available, which have a lot of H2 receptors on which the animal studies could be carried out. So, there are other pathogens where the animal models are not easily available or useful there the CHIM becomes a very, very useful way of conducting research. But COVID still they are not, I haven't heard that anyone models are not useful. On the contrary, you will find even Indian Vaccine, the Bharat Biotech and ICMR vaccine, you go through the regulators and it shows that there is data being generated from the animal model. So, animal models are already there, you can carry out CHIM on the animals and then carry out CHIMs on the humans. If it is working, then the COVID CHIM may not be immediately necessary. The other is, is that when you have infection you are deliberately causing the infection then you must have treatment. Because you are doing it on a healthy human being with a promise that nothing will happen to that person or it will be minimum that will happen to the person. That means you either you have to have a good treatment available or you have a disease, which is self limiting, and it does not leave any sequel that means post infection that does no big damage to the person. Now, this is another area where

COVID does not qualify for the CHIM. The reason is very simple: we don't have treatment available. There are a lot of emergency treatment sanctions or approved by the drug controllers all over the world, you know, in the US, in Europe, in India, but none of them is an ideal and fully proven drug at the moment. All of them are experimental and they are being allowed as an emergency use. Another thing is that this virus may be self limiting in large number of people, large number of people don't require, 80-90% of the people don't require much treatment, it is self limiting, but those who really develop it at the moderate and in the acute phase, even if they survive there is a possibility of an injury to various organs of those bodies in their body. So, we still do not know what kind of pathophysiology of COVID is, you know, it is being studied in an emergency phase. There is a lot of news, you know, some autopsies are being conducted, clinical data are being assembled, and there is a better understanding emerging, but none of them is very, very optimistic. We still do not know how to take care of each kind of problem it is causing. It's not only a problem in the lung but it also causes problems in all the organs which are, to you know, receptors. It may be kidney liver heart, it also affects the blood. So one doesn't know you know if infection goes out of control what will happen to the volunteers who are participating in the CHIM, it's a very, very difficult time when very are not able to have a good idea about the about the pathogens, so that doesn't make at the moment coronavirus, a very ideal organism for undertaking CHIM but that is what is required if you if you are doing you know, a CHIM. The other thing that is required is this kind of CHIM has to be done, this organism has to be, you know, manufactured in the laboratory. You know, it is a biological thing that they are manufacturing and it should be, it should be having a done through good the plenty good manufacturing practice that means, it should be very, very stable, it should not be mutating all the time and it should have a consistent quality of the organism that you are getting, so, that they can be used as a for the CHIM that is still not very, very clear whether it is available or not. I think there is a lot of work, but if they are getting closer to that part, you have to have good decontamination measures which are what we know now, how to decontaminate places. Another thing is that you should be able to isolate the experimental area is very important otherwise, if the organism releases in the environment, and other people get infected, and animals and all then it may cause havoc to the environment and to the community. And the last thing is that those who are doing the CHIM should have proper bio protections otherwise there is a possibility of the researchers getting infected and suffering from it. So, you know CHIM in COVID is very challenging at the moment it seems that is not enough information about the pathogen, nor treatment. And as a consequence, this CHIM possibilities appears to be deemed although I must say that the line number of volunteers ready to undergo CHIM, I don't know why either they're misinformed or they're, they are so altruistic that they want to sacrifice themselves. But I don't know whether a scientist or a doctor. I would not like to, you know, take advantage of people coming forward and saying that, well, I don't want to sacrifice myself, but I do mind as a scientist and a doctor to sacrifice people, when I know that I am not able to carry out very safe research.

Sandhya Srinivasan: *Vaccine trials require large numbers of participants to get infected with the disease naturally. This is done to compare the number of infections among those given the vaccine compared to those who were not given the vaccine. This can take many months, even years. CHIM studies speed this process up by directly infecting the participants. In the case of COVID-19, thousands of people are getting infected every day. Researchers can easily test vaccines in the field.*

Dr Amar Jesani: When infection is even prevalent in the developed country, why should they try to CHIM? They can easily do it so that maybe it may cost slightly more, but the findings will be very generalizable. And you don't have to again carry out a field trial if you have done, you know, the classical vaccine development rather than using the CHIM. There's one more point I forgot earlier, is that where the COVID is a problem is that in COVID, we still do not know what kind of antibodies are developing. You know, there are countries which have flattened the curve and there is a big debate going on whether the flattening of the curve took place because of the lockdown. And there is a strong evidence to show that lockdown can slow the infection but it cannot really flat everything, flatten everything. There is a theory that well, we are looking for herd immunity and the vaccine can help in increasing the herd immunity. But the issue is there is no known enough information about it. We don't know what amount of antibodies are required in order to stop infection and how long these antibodies once they are developed in the body, they will last. So this is another major challenge. Challenges in Phase 1 and Phase 2 clinical trials where you have to decide what is the upper limit of the viral dose that you have to use in CHIM in order to get the right kind of antibody. And if you use a very high dose, there is a possibility that they were the volunteers who are in the CHIM may develop acute disease for which we have absolutely no answer how to tackle them and treat them. So this is a theoretically very attractive idea that you use CHIM and reduce the time. But in practice, we still don't have a very plausible case that the CHIM when done will really protect participants.

Sandhya Srinivasan: *So what you're saying is that CHIM cannot be done safely for COVID-19. The disease is new and we're learning more about it every day. And there are still many unknowns about it. Likewise, we are not sure of how to measure a covid19 vaccine's efficacy. Finally, CHIM may not be the best way to get the information we need. Are there other ways of getting this information?*

Dr Amar Jesani: In a pandemic like this, which is causing a lot of harm to humanity, there will be consideration of all kinds of design in doing research. So it is not only, you know, randomized control trial with a placebo there, but you can have many adaptive designs also, there's a lot of well monitored designs, observational study can also provide good information. So there's a wide range of designs that are going to be considered CHIM is one of them. And each design the contexts and the development of science and knowledge will determine whether it is safe to do this kind of study. So, the context is also very, very

important. I remember in Ebola in, you know, epidemic in 2014 and 15, they were not able to do randomized control trials with placebo control why? a large number of people were dying; the mortality rate was from 40% to more than 80%. Nobody would like to get randomized to get a placebo. Everybody would like to go on any experimental drug of any kind. Because they believe that well, any experimental drug will be less harmful than the death that was being caused by the virus. COVID is not that kind of virus which is causing a large number of deaths, it is infecting a large number of people and as a consequence even the people who are needing hospital care is a very small fraction of them, it is overwhelming the health system. So, it is causing harm to the health system and it is causing harm to the economy. So, in that context, you will have to keep it in mind the whole anxiety to develop a cure as well as develop the prevention of it. At the moment non pharmaceutical prevention is the best. What has worked the best is physical distancing, mask that you have, testing that you carry out, isolating and quarantining people who are exposed to the infection or were caught the infection, they have worked beautifully. And those countries who did the best they have really controlled the infection there.

Sandhya Srinivasan: Is it possible to ensure that participants in human challenge studies for a covid19 vaccine give their voluntary informed consent?

Dr Amar Jesani: Because of this whole emergency and people being panicked about what is happening, there are a large number of people who have come forward. There is a website called onedaysooner.org, you go there and you will find that there are a large number of people more than 30,000 people have volunteered to be on this CHIM and they come from hundred and forty countries. People are ready to, you know, take risks in order to develop Vaccine. Now When there is a desperation, there is undermining of some amount of, you know, of volunteerism in the informed consent run when when said that, well, I don't care how harmful it is, but I want to do it for the people. Now, if they want to just sacrifice themselves for the people, would you be allowing it, that is a part that comes there. The other is in a normal circumstance. Suppose you are doing it in India and you are recruiting people. What kind of people do you recruit? There are scientists then the educated people who are saying the CHIM should be done, CHIM should be done. But are those educated people going to participate? I remember a long back about 12 years back when HIV AIDS vaccine trials were done in India and the Phase 1 clinical trial. There are very clear cut guidelines that was they allowed saying that well you cannot take people who are uneducated, who are not able to understand you know, what kind of risk they are taking, that means go for people with higher education, you see that people whom you are, you know, inviting to participate in CHIM are not under any kind of pressure. For instance, if you go to the employer to get their employees to participate, or you go to the commander of the army to get the soldiers to participate, then you may be putting a lot of pressure, we also have to see that the people who are participating are not under social pressure, saying that, well, certain kind of people should be sacrificing themselves in order to protect other people. So, informed consent and where the voluntariness part and really understanding

what kind of risk they are taking is very very important. The other thing is that when you have this kind of CHIMs carried out, you will have people without any kind of comorbidities, you will have fully healthy people and that way, you may argue young people, are you saying that, well, the the possibility of harm or death in them is low, but then you are going to develop a vaccine, or testing a vaccine, which is for those people who actually may not require and even if they don't get it, they're going to survive, you require a vaccine where there are a lot of other people that means you will have to even after doing CHIM go to the field and test it out on these larger cross section of the people. So, it's a it's an issue of, of this kind are important and the last thing, historically, if you look at CHIM being done in the high income countries, I have been going through one after another studies and I find that in all of them invariably and including I think even in the developing countries low and medium income country like Kenya and Zimbabwe, other place, all of them, all the participants were paid handsomely good money. In the high income countries, most of the participants came from those strata, which had, which needed liquid cash immediately. Large number of students participate. Why? Because they are under debt to get higher education. And this gives them good enough cash money to offset some of the loans that are taken or the immediate requirement of the fees or the education expenses. Now, in COVID kind of situation, I think that type of undue inducement which may cloud people's judgement about risk that they're taking in developing countries would be a problematic thing, because then it will immediately go into a big controversy, saying that you are buying the volunteers. Actually, people are coming forward in order to, you know, or in order to volunteer for out of altruism. There are more than 30,000 volunteers listed out, I don't know how many of them have some idea of getting paid, because traditionally, volunteers in the CHIM have been paid. And in India, there is a lot of sensitivity. I think hypersensitivity rather than the undue inducement of the participant. They believe that if you pay too much, people can do anything. People have been selling their organs and taking risks there and we had to bring a law to stop it. So, this is the environment in which you are going to do a CHIM. All those things are quite related to what you were asking me about informed consent and voluntariness information, understanding, all those things are there. So, we have a better I don't think there is 100% voluntariness is 100% understanding, So to have a higher level of voluntariness and higher level of understanding, there will be a lot of efforts to be made. And it's very, it's going to be very difficult to get the right kind of volunteers for it.

Sandhya Srinivasan: *Despite these concerns, human challenge trials for a covid-19 vaccine may happen sooner rather than later. A group of scientists in Oxford has announced plans to conduct a human challenge study to test its covid19 vaccine. The CHIM study will be conducted either parallel to its phase 3 trial, or after it is completed. The specific objectives of this study are not known. Among the concerns you identified when doing a CHIM are the need to do it scientifically and safely. Second is whether there are other ways of getting the information needed. And for example, in the case of COVID-19, you mentioned that vaccine trials in the community will collect sufficient information because of the high incidence of infection. And third is the question of informed consent and the risk of inducement and this*

has been seen in countries both wealthy and not so wealthy. So these are three major concerns that I understand you have identified in the use of human challenge studies. CHIM has been discussed in India, though not for the COVID-19 vaccine. What is the state of preparedness in India to undertake human challenge trials of any kind?

Dr Amar Jesani: I don't know how prepared the scientists are. But there has been some background work being carried out. For the last three years, there have been scientists who were making preparations. I think in 2018, January, there was also a conference organized at Tata Institute of Social Sciences on this where number of people from a different stakeholders were invited to discuss this part, but there is a there is a interest among in the scientific establishment that doing CHIM may be useful and we may be able to you know, speed up some of the candidate vaccines to decide which one should go to the for trial and which should not go for the trial that is the minimum there. So, this part is there, there is another thing that has also been done is I think some kind of social science study anthropological qualitative research to find out what is what would be the people's perception when this kind of studies are carried out. I think some scientists are making efforts to have collaboration with the international institution where our scientists can go and collaborate and learn how to do CHIM. I don't know whether they have already done it, but there were plans for that. CHIMis not being carried out even by the high income countries for COVID 19. So, India has not talked about it explicitly. No scientists as I remember have come out saying that let us do CHIM let us do CHIM. But yes, I'm sure that there is some preparation being made. If not for COVID or some other vaccines but the CHIM may be there for discussion in future, definitely.

Sandhya Srinivasan: *Do you have any concerns about the state of preparedness of India to do such human challenge trials?*

Dr Amar Jesani: Well, this is the same concern that, you know, you have to decide if they are going to do it. We are to know what kind of organism when they're doing that. This is that looking at what kind of you know, safety that it will provide? What kind of institutions where it will be carried out? There is also a larger, what I would call, macro level concern, which is that India has a regulatory system that is not as strict and strong as the high income countries regulatory system. Will this lead to a lot of private players starting CHIM at the drop of the hat not only for a disease of public health importance, but for any disease, right?, because people are available. India has been doing bioavailability and bioequivalence trials on very poor people who needed money to test out the generic drugs which were to be exported. So, India has a checkered history of using poor people for this kind of work. If CHIM is not regulated in the manner as it is required, then there is a possibility that there may be misuse of it. So, in order to do a more complex and risky kind of research you require a more complex system to both regulate it as well as to create a standard of care which is commensurate to the risks that people will be taking without having that kind of system in place. I remember a friend of ours, you know, who made a suggestion saying that,

and I think that was also one of the findings of the qualitative research that was conducted on to find out people's opinion on CHIM, whether they said that well, those researchers who want to do CHIM they should also be the participant in the clinical trial, they should also volunteer, which I don't know theoretically believe is a good idea. The ideal solution is, is having an excellent regulatory system and a good state of the art healthcare system which minimizes the risk to the participant those are more important than you know the individualized solution, but yes, this kind of situation will come up which may which may keep out you know, fly by the night you know kind of kind of laboratories and research but but not provide you a systematic you know, security for the participant.

Sandhya Srinivasan: *Dr Jesani, thank you for your insights into the ethical concerns regarding this research technique i.e the human research study particularly regarding its use in COVID-19.*

Thank you for listening to this episode of The Suno India Show. You can listen to this episode on sunoindia.in or any podcast app of your choice. In the next episode, you will hear from Veena Johari, a lawyer and patients rights advocate on access to vaccines to drugs. She will answer pertinent questions regarding this.

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