



CONSULTATION ON ECONOMIC EVALUATION OF VACCINES

Report of the consultation

Centre for Technology and Policy IITM | IC&SR Building – Hall 1 | April 29, 2016

1 ACKNOWLEDGEMENTS

We would like to thank all those who participated and actively took part in the discussions. Without their active participation the consultation would not have produced the rich sharing and learning that it did.

We would especially like to thank Dr. Jayaprakash Muliyl, Dr. Madhavi and Dr. Girija Vaidyanathan with whom we had conversations before the meeting and helped us conceptualize and refine the plan.

We would also like to thank all those who came from out of station for taking the time.

For those who were not able to attend, but contributed over email we thank you and trust that you will continue your support in the long term.

We believe that this is just the beginning of a long journey of learning and discovery and we at the Centre for Technology and Policy (CTaP) IIT M are happy to have you all as part of the process.

2 PROGRAM

Time	Agenda
9.30am – 11.00am	Introductory session Welcome / Introduction / Why this meeting? (VR Muraleedharan) Overview of dimensions of evaluating vaccines (Rakhal Gaitonde) Issues with Hepatitis B vaccine introduction (15 mins) (Madhavi Y) decision making on Rotavirus vaccine - A qualitative study (15 mins) (Sunil Mathew George) Discussion
11.00 am – 11.30 am	Tea
11.30 am – 1.15 pm	Towards developing a Methodology for evaluation of vaccines Chairperson - T Sundararaman Trigger Presentation 1 – J P Muliyl (15 mins) Trigger Presentation 2 – Denny John (15 mins) Trigger Presentation 3 – Girija Vaidyanathan (15 mins) Open discussion Way forward
1.30 onwards	Lunch



3 INTRODUCTION

Welcome address – Prof. Muraleedharan

The meeting began with a welcome address by Prof. Muraleedharan where he briefly set out the broad objectives of the meeting. While pointing out the complexity of the issue of decision making around vaccine introduction, he said that there is need to make the overall decision making process more informed and at the same time more transparent. He pointed out that this meeting had been called after a process of reading and meeting with people who are involved in the area, and he believed that all who had been invited were convinced that this is an important issue to engage with. He referred to the paper of Rakesh Agarwal that sought to measure the effectiveness of the Hepatitis B vaccination program 10 years after its introduction, as a good example of the type of studies that could be done. This could produce data useful in assessing the actual impact of vaccination

program as well as validating or questioning some of the assumptions made at the time of introduction. The idea of this meeting was to start a process of discussion around this key area and come up with ideas on what could be done in terms of specific work over the next year that will help bring some clarity and transparency on the issue.

This was followed by a round of self-introduction by the participants.

Presentation of the background note – Dr. Rakhal Gaitonde

Rakhal presented the various dimensions of vaccine decision making from the brief study of various policies, guidelines, and studies with reference to inclusion of new vaccines into a national program. He summarized what was also circulated as a background note. He summed up the presentation again highlighting the three questions that were the key objectives of the meeting:

1. What would be the dimensions for evaluating a new vaccine for introduction into the Universal Immunization Programme (UIP)?
2. How do we operationalize the various dimensions – especially in the face of time pressure as well as lack of a robust data / information system?
3. What would be the various pieces of work that need to be done to achieve this over the next 5 years and in the long run?

Rakhal ended by showing a mind-map on vaccine decision making that had been prepared based on the literature discussed in the background note.

Discussion during the introductory session

It was highlighted by Prof. Muraleedharan that while only a few aspects of this have actually been tackled so far; the challenge is how many of these can be addressed to bring about some degree of clarity to the issue.

To a question regarding the particular motivating factor for the meeting today, Prof. Muraleedharan said it was both a question of assessing vaccines that had already been introduced, as well as pro-actively looking at vaccines that were planned to be introduced; he pointed out the study on Hepatitis B (circulated) which showed how many of the assumptions based on which decision making was done may not necessarily hold good in

actual practice. It was also pointed out that this discussion is especially crucial given the number of vaccines that were to be introduced in the future.

Dr. Sundararaman pointed out the processes of Health Technology Assessment especially as practiced by NICE in UK. He said that it was a very important process / mechanism to engage with because it takes many of the issues highlighted into account, while at the same time being extremely transparent about it and being highly respected and trusted.



4 PRESENTATION OF EMPIRIC STUDIES ON VACCINATION IN INDIA

Hepatitis B introduction in India – Dr. Madhavi

The next presentation was by Dr. Madhavi – she presented a critique of the decision making process and the assumptions surrounding the introduction of the Hepatitis B vaccine in India. She pointed out that the indicator taken as a marker for the prevalence is crucial and has to be chosen based on an understanding of the natural history of the disease and the representativeness of the population groups on which the studies had been done. She pointed out how many of the assumptions made during decision making around the introduction of Hepatitis B was questionable. She also discussed the findings of the Agarwal study and pointed out how the main emphasis on the vaccine program in

India is on coverage – while studies like that done by Agarwal pointed to the fact that many of these assumptions did not hold good in actual practice, like when it failed to show a reduction in the carrier rate of Hepatitis B between those vaccinated and not vaccinated. This underlined the importance of scientific and epidemiologic evidence before the introduction of any new vaccine.

She then discussed the WHO guidelines that she had reviewed. She welcomed its insistence on a systematic decision making process. However, she was concerned about the recommendation that perceptions of the public and medical profession have to be taken into account. She wondered how perceptions can be taken on par with scientific evidence. Similarly, she pointed out how it maintained that countries could also base their decisions on recommendations by WHO. While this may be practical for those countries that cannot afford to do these types of studies or did not have the resources, it was certainly not appropriate for countries like India that had all the expertise required. She also pointed out to the way in which equity had been interpreted which was as though the poor were being deprived of vaccines that the rich were accessing. She pointed out that this was a very twisted meaning of equity, which took the necessity of the vaccine for granted. She further emphasized that rather than focus on whether the vaccine fits in with global or regional priorities, it is more appropriate for a country to see if the vaccine works under local conditions. She concluded by saying that vaccine cost-effectiveness should be conditional on vaccine protection, epidemiological necessity and risk assessment.

Discussion

Prof. Muliyl in his comments stressed on how the pressure to act or to be seen to doing something was a crucial aspect to be considered while understanding the motivations of the health department in decision making. Similarly, powerful interests may actually work against the release of relevant data for decision-making.

Study of the decision to give of Rotavirus in private sector – Sunil Mathew George

Sunil Mathew George made the next presentation that was based on a qualitative study done on the introduction of rotavirus vaccine in the private sector. He pointed out the

presence of two lists in the mind of an average practicing pediatrician. One is the government list of the Universal Immunization Program (UIP) that is compulsory for all children and the list approved by the Indian Association of Pediatricians (IAP), which is based on the ability to pay. It was pointed out that this was accompanied by a subtle or sometimes not so subtle insistence on the parents to give all vaccines on the IAP list. Parents on the other hand largely went by whatever their pediatrician said – especially if they had a good relationship with the doctor.

While talking to decision makers the study revealed that while evidence was claimed to be helpful in the long run, but in actual cases various windows of opportunity opened up enabling the pushing through of a decision. Sunil ended with a story that again highlighted the importance of chance events and such windows of opportunity in the actual policy making process.

Discussion

Dr. Sundararaman pointed to the need of some caution while approaching the study of policy making using ethnographic approaches. In stories like these he pointed out that the underlying and background role that good evidence played may be missed, alternatively he pointed out that the actual power struggle and the way it plays out may be missed by the focus on the more cultural aspects.

Denny John pointed out that we need to keep in mind the strengths and weakness of each of the methodological approaches especially in the present context we are working in.

There was then a discussion on the struggle between waiting for “full knowledge and the urgency to make a decision”. While at one level it may not be feasible or even desirable to wait for complete information, the lack of such information can be turned into an excuse for not doing anything. Prof. Muraleedharan also pointed out that while on the one hand in immunization the clinicians were following the government UIP guidelines, this was not the case when it came to DOTS, where the private clinicians continue to use daily regimen saying that was what they were taught, while DOTS was being reserved for the poor.



5 RIGGER PRESENTATIONS

Prof. Jayaprakash Muliyil

Prof. Jayaprakash Muliyil then presented the story of how Leprosy was “eliminated” in India. He pointed out that there are political circumstances under which serious research and data are given short shrift. Through a number of vignettes on various vaccines he showed in many cases the political and administrative pressures trumped the systematic use of data. Similarly he pointed out that there was a lot of systematic evidence available

on many of the issues, but many a times the issues are sensationalised and then the discussion goes into a completely different path, missing the main issues.

Denny John

In the next presentation Denny John presented his study where a decision analytic model of cost-effectiveness for glaucoma screening was constructed. He walked the audience through each step in the process pointing out the various assumptions that were made and the basis for these assumptions, thus giving a comprehensive overview of the process. He underlined the importance of the fact that the model one uses is only as good as the data this is fed into the model and the assumptions that accompany it. He ended with briefly introducing the group to two other approaches – the budget impact approach that gives short-term projections of resource use from the system perspective and the Multi Criteria Decision Analysis framework that is presently being adopted by a number of technology assessment bodies including NICE. This approach is unique in going beyond cost-effectiveness as the sole criteria in decision-making and in the involvement of a wide range of persons with different backgrounds in the actual process.

Discussion

During the discussion while concern was raised about the sensitivity of these models to 'tweaking' and thus making them extremely dependent on the assumptions, it was also pointed out that modeling helps in making the basis of decision making transparent and is able to project also into the future.

Dr. Girija Vaidyanathan

In her presentation Dr. Girija Vaidyanathan first pointed out the complete lack of involvement of the state governments in decisions around the introduction of vaccines. The only issue discussed is mostly logistical and preparedness of the system to deliver the vaccines and occasionally the management of adverse events. Again adverse events are not approached systematically, but more in terms of managing any potential media sensationalism. She pointed to the fact that bureaucrats rarely have access to all points of view and many times are left with only media driven points of view. She shared the example of the use of data collected along with a number of NGOs, presented and used

strategically to bring about policy change, and underlined the way in which good data that addressed the concerns of the bureaucrat implementer and the politician could be used effectively to bring about change. However, there were some doubts regarding the amount of transparency we could achieve given the particular structure of politics and administration in the country.

Dr. Sundararaman then highlighted the importance of being able to craft and run institutions that can not only handle complexity, but also the incompleteness of data and all the competing pressures. In his mind the crafting and the constituents of these institutions should be accorded top priority.



6 WAY FORWARD

In the final session, the following suggestions were made for future action:

- We could do one or two retrospective studies on vaccine effectiveness, but we need to get the state government on board for this.
- While studying the impact of vaccines we need to carefully choose the clinical outcome of interest.
- There was a suggestion for developing case studies of a few vaccines from the laboratory bench to the field – in order to follow the whole process and see the various decisions made, the basis of each and the type of information required etc.
- It was also pointed out that the ICMR was evolving its 5 year vision and that this was a good time to approach the present director to discuss the setting up of stronger institutional mechanisms for vaccine decision making.
- Performing a few modelling studies on vaccines like dengue which is going to be introduced in the near future.
- Choose a recently introduced vaccine like pentavalent vaccine to discuss how its effectiveness can be assessed; and vaccines going to be introduced like rota and rubella and plan baseline data / studies on them that can be followed up.

7 PARTICIPANTS

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