Challenges of Ensuring Public Health: Assessing the Past, Charting the Future

Jacob Puliyel

To start the process, the government must publish the vaccine under consideration. Stake holders – (patient groups, health professionals, academic institutions, industry producing the vaccine, trade unions and international organizations like the WHO and GAVI) can then register their interest. Public participation is of essence here

THE PRACTICE of medicine traditionally, used to be a paternalistic affair – with the doctor telling the patient what to do and the patient being expected to follow orders. The wishes, feelings, beliefs and values of the patient did not merit much consideration. The arrogant assumption was that the doctor knows best. Doctors felt that yielding autonomy to patients was likely to result in decisions that were not in best interest of the patients themselves. Seen in the context of information asymmetry, patients were particularly disadvantaged because of the disparity between them and their doctors in terms of education, information about their condition and the treatment options for it. They were especially vulnerable in the background of more serious and life threatening or life shortening illnesses.

Fortunately, this has begun to change recently as we move into an age of patient empowerment and 'patient-centered medicine'. Underlying this change is more widespread acceptance of the principle of patient autonomy. Doctor-patient interactions are now more informative, interpretive and deliberative, creating space for 'shared decision making' and 'negotiation' between doctor and patient. The interpretive model portrays the doctor as a counselor who will inform the patient and interpret relevant values, and implement the treatments chosen in accordance with the patient's value system.

Unfortunately, these changes in how clinical medicine is practiced have had little impact on how public health decisions are taken. This paper will review how the process has, in fact, changed for the worse, with regard to vaccine decision-making. It will explore the possibility of having a more explicit, evidence based, logical and transparent method which can inspire public confidence and enhance uptake of this essential child protection tool.

Public Health and Individual Autonomy

There is strong and persuasive literature for moving away from paternalistic public health models. According to Buchanan, public health should seek to expand individual autonomy to improve population health on both ethical and empirical grounds. Seeking to shore up support for paternalistic interventions may only undermine trust of public health authorities. Paternalism in public health erodes the basic ethical principle of 'autonomy' of the individual just as it does in clinical medicine. He points out that the critical point is being in a position of deciding and accepting. This concept of autonomy has health benefits and needs to be promoted but it

The author is Head of Department of Pediatrics, St Stephens Hospital, Delhi. He is a member of the National Technical Advisory Group on Immunization (NTAGI) of the Government of India. He has contributed in internationally indexed journals including British Medical Journal, Lancet, American Journal of Perinatology, Pharmacoeconomics, Paediatrics, and Expert Review of Pharmacoeconomics Outcomes Research.

puts an onus on public health authorities to secure agreement from the public. To avoid soliciting agreement from the public, on the specious grounds that public health issues are too complex for the populace to comprehend, is unacceptable, can be counterproductive and erode confidence in public health schemes that are clearly beneficial to the community. It is for the authorities to see how best to explain matters to the public and secure their agreement.

NTAGI in the Past

The Government of India set up the National Technical Advisory Group on Immunization (NTAGI) in 2001 to advise it on technical matters related to immunization. The world over, such groups have been set up to promote advocacy for vaccines, especially for the introduction of new vaccines in the national immunization programmes. The push to form such advisory committees came from the World Bank and other international agencies.

Vaccines are introduced into the national programme of countries based on the burden and seriousness of disease to be prevented, the safety and efficacy of the vaccine and its economic affordability in the context of the national economy. Feasibility for inclusion in the routine immunization schedule and acceptance of the people at large also needs to be considered.

Vaccines are introduced into the national programme of countries based on the burden and seriousness of disease to be prevented, the safety and efficacy of the vaccine and its economic affordability in the context of the national economy. Feasibility for inclusion in the routine immunization schedule and acceptance of the people at large also needs to be considered.

Resolution 45.17 of the World Health Assembly mandates that member countries integrate cost-effective 'newer vaccines' into the national immunization programs. However, of late, the WHO has been making recommendations for universal inclusion of vaccines like the rotavirus vaccine without regard to local cost effectiveness. Organizations like Global Alliance for Vaccines and Immunization (GAVI) have been persuading developing countries to use new vaccines by providing donor-grants (effectively driving costs to nearly zero in the initial stages). The full cost implications are only realized once funding is withdrawn, after the vaccine has been included in the universal immunization programme (UIP) of the country. This form of pressure on governments to introduce new vaccines into their UIP without evaluating the local burden of disease or cost-benefits, in effect perverts the intention of the World Health Assembly: Resolution 45.17. This essay is based on the premise that national governments have to evaluate cost-effectiveness of newer-vaccines.

Until recently, when a vaccine was proposed to be introduced, a subcommittee of the NTAGI would review the available literature and consult prominent experts to make an informed decision about introduction of the vaccine into the UIP. To promote transparency and to facilitate access to everyone, the minutes and recommendations (http://mohfw.nic.in/dofw per cent20website/june.pdf) were published on the MoHFW website (http://mohfw.nic.in/dofw per cent20website/dofw.htm).

However, as a consequence of this openness, NTAGI decisions were subjected to scrutiny and it made it vulnerable to criticism for using evidence selectively.[11], [12] For example Minz *et al* performed meticulous surveillance of Hib meningitis in a population of 6.5 lac persons, over a two year period (1997 to 1999).[13] They found the incidence of Hib meningitis of 7 per 100,000 children under 5. In real terms, if the year's birth cohort in India (25 million babies) are vaccinated against Hib, nation-wide it will prevent only 1750 cases of Hib meningitis. Yet, the NTAGI recorded that there are 52,000 new cases of Hib meningitis in the country each year based on a small survey of cases of 'presumed meningitis' in one district in Kerala.

NTAGI Reconstituted

In this background in June 2013, the NTAGI was reconstituted and an Immunization Technical Support Unit (ITSU) was set up to help the NTAGI. The ITSU is funded by Bill & Melinda Gates Foundation specifically to provide technical and managerial support to accelerate coverage and to ensure system preparedness for new vaccines. A new confidentiality clause has been inserted, ostensibly to protect the 'proprietary' interests of commercial, academic and other research institutions. However, the confidentiality clause extends beyond proprietary matters and no member is allowed to disclose the discussions, opinions or decisions of the NTAGI on a public or private forum for 10 years after leaving the committee.

In real terms, if the year's birth cohort in India (25 million babies) are vaccinated against Hib, nation-wide it will prevent only 1750 cases of Hib meningitis. Yet, the NTAGI recorded that there are 52,000 new cases of Hib meningitis in the country each year based on a small survey of cases of 'presumed meningitis' in one district in Kerala.

The committee is selected by the Government and it is neither representative of the population nor of all the experts in the field; and voting numbers at such meetings are meaningless. Decisions will have to be taken on the strength of the evidence on the table, not on the number of votes. With the new confidentiality clause, the public will have less access to the rationale for decisions. This is why, it is crucial that the minutes of the NTAGI must faithfully record the data that was presented and the basis on which decisions are made. The minutes of the first meeting is yet

to be publicized and the public must await this with anticipation in the context of the confidentiality rules. If the records are not sufficiently detailed and explicit, the public will view with suspicion what was transacted behind such a heavy veil of secrecy and this could affect public trust and compliance.

Choosing from the Best Models Overseas

Fortunately, there are different models of 'vaccine advisory committees' in various countries and

...the general guideline is that interventions that cost less than the per capita gross national product (GNP), per quality adjusted life years (QALY) saved, are considered cost effective. According to the WHO Commission on Macro-economics and Health, interventions that costs less than three times GDP per capita for saving a 'healthy life-year equivalent' is worthwhile and good value for money.

the Government can pick the best for India. Allowing the Ministry of Health free rein in selecting the committee, can skew the vote. In the USA, the committee called the U.S. Advisory Committee on Immunization Practices (ACIP) is selected from applicants through an advertisement and they hold their position for a limited duration of time. When openings for membership occur, nominations are solicited on the ACIP website and in the '*Federal Register'*. Suggestions for members are also sought annually from a variety of sources, including professional societies, current and former ACIP members, and the general public. Application for membership has purposely been made open, transparent and uncomplicated. Meetings of the ACIP are open to the public. Specifically, the meetings are conducted in accordance with the Federal Advisory Committee Act of 1972 (FACA), which stipulates that meetings be announced in the *Federal Register* at least 15 days before the meeting date (http://www.gpoaccess.gov/fr/), that members of the public be permitted to attend meetings and to speak or file written statements and that meeting minutes be maintained and made available to the public in a timely fashion. The emphasis is on openness, not confidentiality.

Algorithm for Decision Making

The essential step to moving away from paternalistic decision making in public health, is to be able to explain the logic and rationale for introducing public health measures. Once it is explained, the public will enthusiastically support the programmes, as it is in their self interest to do so. The process used by the NTAGI for decision making needs to be transparent. For vaccine selection, the process can be logical and mathematical and so it is particularly easy to present the data to the public to garner their support. This has been described elsewhere. Briefly, the general guideline is that interventions that cost less than the per capita gross national product (GNP), per quality adjusted life years (QALY) saved, are considered cost effective. According to the WHO Commission on Macro-economics and Health, interventions that costs less than three times GDP per capita for saving a 'healthy life-year equivalent' is worthwhile and good value for money.

Allocative Efficiency

Data on absolute risk reduction by the intervention in the country must be sought and from this, the numbers needed to treat (NNT) (number of individuals who must be vaccinated) to avoid 1 case of disease can be derived. The cost of immunization to avoid 1 case of disease can then be calculated easily. Evaluations up to this point are mathematical. Interventions that have poor risk-benefit ratio, those that are not cost-effective or affordable cannot be recommended. If, however the intervention is both cost-effective and affordable, there is also the need to evaluate efficiency of the program – whether it is capable of providing better returns than other uses of this resource.

If a cost-utility assessment has been done, the 'optimum decision rule' involves ranking the incremental cost-utility ratios of different interventions and selecting those with the lowest ratio ("best value") until the budget is depleted.

A hypothetical example may be used to clarify this. Assume polio control costs Rs.350 crores and saves 1 QALY per Rs 10,000 spent, rotavirus control costs Rs 200 crores and saves one QALY per Rs. 20,000 spent, and tuberculosis control costs Rs 700 crores and saves one QALY per Rs. 5000 spent. Assume also a budgetary constraint of Rs. 1000 crores. The first program to be accepted should be TB control as it provides the best utility (one QALY / Rs. 5000). Once this is accepted, there is only Rs. 300 crores remaining in the budget. The next program to be accepted must be polio control. Rota virus control costs only Rs. 200 crores, which is less than the cost of polio control (Rs. 350 crores) but polio control takes precedence as it provides more utility.

The cost of immunization to avoid 1 case of disease can then be calculated easily. Evaluations up to this point are mathematical. Interventions that have poor risk-benefit ratio, those that are not cost-effective or affordable cannot be recommended. If, however the intervention is both cost-effective and affordable, there is also the need to evaluate efficiency of the program – whether it is capable of providing better returns than other uses of this resource.

Public Participation in the Process

The process utilized by the National Institute for Care and Health Excellence (NICE) UK has been adapted below for this purpose. To start the process, the government must publish the vaccine under consideration. Stake holders – (patient groups, health professionals, academic

institutions, industry producing the vaccine, trade unions and international organizations like the WHO and GAVI) can then register their interest. Public participation is of essence here.

In the next stage, the NTAGI sub committee may assess the clinical evidence and the economic data on benefits. Based on the evidence, draft guidelines can be drawn up for assessment by the registered stakeholders. NTAGI must revise the guidelines if more evidence is provided by the stake holders. An 'independent-review-panel' then reviews the guidelines to decide if all valid stake holder comments are taken into account. The final guidelines can then be published by the NTAGI and government can get clear and unbiased advice on which to base decisions. Such explicitly formulated recommendations are easy to explain to the public and will inspire public confidence and better compliance.

Funding Needs

This process need not entail unaffordable costs as most of the experts volunteer time and the resources of their parent organization for working on the NTAGI. It is crucial not to take funding from international organizations so that they may not be seen as subtly influencing decisions. Like with the move from paternalistic clinical medicine, the barrier is never a lack of resources but the difficulty in shifting the mindset of the professionals involved.

Endnotes

1 Alastair Campbell, Grant Gillett, and Gareth Jones (2005). Medical Ethics. Oxford: Oxford University Press.

2 *Rachel Warren.* Paternalism in Medical Ethics: A Critique. Journal of The University of York Philosophy Society. http://dialecticonline.wordpress.com/issue-06-summer-10/paternalism-in-medical-ethics-a-critique/

3 Hope. T, Savulescu. J and Hendrick. J, 2008, Medical Ethics and Law: The Core Curriculum (Second Edition) Edinburgh: Churchill Livingstone Elsevier.

4 Buchanan DR. Autonomy, paternalism and justice: Ethical priorities in public health. Am J Public Health. 2008 Jan;98(1):15-21)

5 T Jacob John. National Technical Advisory Group on Immunization: a major step forward for child health. Indian Pediatr. 2002 Apr;39(4):327-30.

6 T Jacob John. National Technical Advisory Group on Immunization: a major step forward for child health. Indian Pediatr. 2002 Apr;39(4):327-30.

7 John TJ. India's National Technical Advisory Group on Immunisation. Vaccine. 2010 Apr 19;28 Suppl 1:A88-90. doi: 10.1016/j.vaccine.2010.02.041.

8 WHO. Rotavirus vaccines. WHO position paper – January 2013. Wkly Epidemiol Rec. 2013 Feb 1;88(5):49-64

9 Subcommittee on Introduction of Hib Vaccine in Universal Immunization Program, National Technical Advisory Group on Immunization, India. Indian Pediatr. NTAGI subcommittee recommendations on Haemophilus influenzae type B (Hib) vaccine introduction in India. Indian Pediatr 2009 Nov;46(11):945-54.

10 John TJ. India's National Technical Advisory Group on Immunisation. Vaccine. 2010 Apr 19;28 Suppl 1:A88-90. doi: 10.1016/j.vaccine.2010.02.041.

11 Lone Z, Puliyel J. Introducing pentavalent vaccine in the EPI in India: A counsel for caution Indian J Med Res 132, July 2010, pp 1-3.

12 Puliyel J. Making a case for universal Hib immunization in India: over interpreting the data. Indian J Med Res. 2013 April; 137(4): 639–641.

13 Minz S, Balraj V, Lalitha MK, Murali N, Cherian T, Manoharan G, et al. Incidence of *Haemophilus influenzae* type b meningitis in India. Indian J Med Res. 2008;128:57–64.

14 Pharmabiz Bureau, New Delhi. Bill Gates commits more support to national programmes, priority areas in India. Pharmabiz 1 June 2012. http://pharmabiz.com/NewsDetails.aspx?aid=69338&sid=2

15 Smith JC. The structure, role, and procedures of the U.S. Advisory Committee on Immunization Practices (ACIP). Vaccine. 2010 Apr 19;28 Suppl 1:A68-75.

16 Dhanasiri SK, Puliyel JM. Regulating vaccines: Can health-economics tools be used profitably? Indian Pediatrics 2007;44:11-14

17 World Health Organization (WHO). The World Health Report 2002. Reducing risks, promoting healthy life. Geneva: WHO, 2002.

18 Palmer S, Byford S, Raftery J. Economics Notes: Types of economic evaluation. BMJ 1999;318:1349.

19 Martin B. Implications of the appraisal function of the National Institute of Clinical Excellence. Value Health 2001;4:212-216 ❑

(E-mail :puliyel@gmail.com)