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Correspondence

Vaccination policy for benefit and profit, public & private

"When introducing change for development, ask how the poorest of the poor will benefit from it"

*(*Adapted from Mahatma Gandhi)

Sir,

This is with reference to the Editorial "Vaccines: Policy for public good or private profit?" [1]. Public good need not be incompatible with private profit. Public good must be qualified with equity, while private profit should be ethical.

It may seem strange that paediatricians promote disease-prevention. Their income derives from diseases, preventing which may seem against self-interest. The reality is that most paediatricians have a personality trait of loving children and deriving emotional satisfaction by caring for them when they are sick and keeping them well when they are not. Preventive care including vaccinations is integral to professional paediatrics. Individually and collectively paediatricians try to get as many relevant vaccines as are reasonably possible into the National Immunization Programme (NIP) so that under-privileged children will also benefit from important vaccines that are often beyond their economic reach. That, of course, is 'public good' with equity.

Exceptions do exist. Some want newer and life-saving vaccines exclusively in the private market, as unabashedly argued in the Editorial[1]. There are two potential benefits to them. Low vaccine coverage and more illnesses in children will fetch more business and income. Private market vaccines will fetch additional income for the paediatrician – after all, if the family could afford an 'expensive' vaccine, they may very well pay the doctor a commensurate consultation fee for counselling, prescribing and inoculating it. These, of course, spell the dubious ethics of the paediatrician's 'private profit', which is at stake when the equity-in-public-good principle is applied.

Such competing interests are submerged in arguments against equity in disease-prevention. Since no substantive evidence is available to support such a stand, unverifiable allegations of the exploitative intentions of all those who promote equitable distribution of vaccines are projected as if they were factual[1]. Even emotive patriotic stance may be faked by favouring indigenously made vaccines against imported ones, public-sector-manufactured against private-manufactured vaccines and old vaccines against new ones, even if that means injustice to children who are the major beneficiaries of vaccinations. Self-righteous finger-pointing at legitimate profit for those who invested in sophisticated biotechnology research, clinical trials and quality-assured manufacture of newer vaccines camouflage selfish interest. Those who publicly denounce new vaccines often privately provide them to rich family children.

The distinction between vaccines in the Expanded Programme on Immunization (EPI) and all others, as presented in the Editorial[1], is not fixed for all time. One of the main jobs of National Advisory Committees is to review the lists periodically. Certain principles had guided the World Health Organization (WHO) in the choice of vaccines in EPI, launched in 1974. India adopted EPI in 1978, but did not include measles vaccine for reasons similar to those raised now against newer vaccines. Hospital-based paediatricians in the capital reported to the Ministry of Health (MoH) officials that measles was an uncommon and insignificant problem. Measles vaccine was also more costly than other vaccines developed earlier. In 1984, the Planning Commission was persuaded to introduce measles vaccine as it had been found to be a life-saver in the community by those who had experience in community paediatrics[2,3]. WHO was right and MoH was wrong.

When quality products of hepatitis B vaccine (HBV) and *Haemophilus influenzae* b (Hib) vaccine became

available, WHO has recommended their inclusion in EPI one by one, but history has repeated. A few city paediatricians assumed the role of experts in public health and health economics and opposed their inclusion in NIP. Overcoming such anti-progress propaganda, the MoH has already accepted HBV in the NIP. HB virus transmission takes many routes – mother-to-infant, sexual, iatrogenic, cultural practices of skin-piercing; it is also very weakly contagious. Vaccination is a simple and inexpensive way to prevent infection in order to protect against the serious, life-threatening consequences which occur mostly outside the paediatric age range. One has to be callous to argue against preventing them simply because paediatricians do not see them. Early prevention of infection also leads to a reduction in further transmission, a multiplier benefit to the community at large.

One set of infectious diseases (IDs) are caused by contagious infections – diphtheria, pertussis, polio, measles, rubella, mumps, varicella, Hib and pneumococci (all highly contagious) and tuberculosis (weakly contagious). All highly contagious IDs are ubiquitous and universal and all children of all countries are at risk. The only practical prevention against them is vaccination. Their incidence (of first infection) is proportional to (in many cases equal to) the local birth rate. But the incidence of disease varies according to age spectrum of infection, disease-to-infection ratio of the pathogen and immunity parameters related to disease after first and subsequent infections. Highly contagious infections tend to saturate the population, although varied disease incidence may not make it apparent. Every child is at equal risk of infection and of disease as others in the community. Contrary to the statement that "[there are] places where the [Hib] disease is non existent"[1], there is no such place. It is inevitable that Hib vaccine will also have to be included in EPI in due course - since it fits in with the basic principles of EPI.

The severity and consequences of disease may also vary according to the age at first infection, nutritional status and available medical care. All of the above listed highly contagious IDs are now vaccine-preventable. If the target disease is usually mild and non-life-threatening (such as rubella, mumps and varicella), the inclusion of vaccines against them in EPI may be deferred for justifiable and practical reasons. However, such choice may be ethically unjustified since serious sequelae may occur in a small proportion of subjects and it is society's responsibility to be equitable in preventing them.

The purpose of prophylaxis is to prevent pathology - caricaturing it as mere pushing of products solely for private profit is disinformation. However, all those who profit from vaccinations - researchers who discover immunogens, companies that make or market vaccines, paediatricians who prescribe or inoculate them – must be professional, conscientious, ethical and fair to the society that enables them to receive fair profit for their efforts. With such vaccines everybody wins – companies, doctors, Governments, families and children themselves. Public good and private profit are not necessarily mutually exclusive; they can be mutually complementary and mutually stimulating.

Prevention of as many diseases as reasonably possible is all the more important in India since medical care in the public sector is not characterized by quality, equity and access. It is unfair to the underprivileged in society that vaccines against diseases resulting in disability or death are denied to the poor who need them most, but are made available to the rich for out-of-pocket purchase. In 1974 or 1978 paediatric vaccines were not available against Hib and pneumococci, but they are today. India's economy has grown several-fold since then and there is hardly any vaccine that Indian Government cannot afford for our children. Not to include affordable and life-saving vaccines is not ethically correct and works counter to poverty alleviation. Indeed one could argue that the Government need not give free vaccines to the rich, but there is no justification to withhold them from the poor.

Non contagious IDs are not ubiquitous or universal; individual risk is non random. Vaccines against such IDs for which alternate public health interventions were available [such as typhoid fever, Japanese encephalitis (JE)] were excluded by WHO from EPI as they are not needed universally and in order to keep the list short and cost low. In EPI tetanus vaccination was specifically targeted to pregnant women since neonatal tetanus was a very common 'killer disease' in many low income countries, although it is non contagious. Tetanus was not a problem in the paediatric age group (barring neonates) and its inclusion in childhood vaccinations was simply because of the convenience of already available DTP combination vaccine. In agrarian communities tetanus is an adult disease. Thus the principles of paediatric vaccination against adult disease and of acceptability of combination vaccines were inherent in EPI. The safety and immunogenicity

of newer combination vaccines are scrutinized by the National Regulatory Agency (NRA) and only if found to be satisfactory will they be approved. Adding newer vaccines to the platform of DTP is for the purpose of reducing the number of injections - for the comfort of children and convenience of parents and care-givers. But combination vaccines may cut into the paediatricians' private profit, as the number of injections is curtailed.

In summary, the purpose of disease prevention by vaccinations under the NIP is to ensure equity in child survival with health and quality of life. The view that every vaccine under consideration for inclusion in NIP should have proven status as a profit-making financial investment[1] exposes a misconception. The economic benefits of vaccinations or the loss due to non vaccination cannot be measured accurately in India. India did not invest in disease surveillance or quality microbiology in health care and for these reasons the incidence of most IDs are unknown. While many vaccine-preventable IDs are clinically diagnosable, aetiological diagnosis of pneumonia due to Hib or pneumococci is difficult in the best of circumstances. Without quality microbiology laboratory support even childhood bacterial meningitis remains undifferentiated for aetiology in many hospitals in India[4-6]. When properly investigated, Hib is found to be the commonest and pneumococci the second commonest causes of childhood bacterial meningitis in India[4-6]. Under these circumstances what should the NIP do - leave such vaccines in private market for the benefit of only rich children, or include them in NIP for equitable use by the poor also? Since public health is to ensure equity in sharing benefits of health-promoting interventions, the ethical answer is that vaccines against serious IDs due to highly contagious infections should be made available to the poor, once they are found to be suitable for registration in the country by the NRA. The question is not which vaccines should be included in EPI but which may be excluded.

When disease is known to be prevalent but the burden of disease is not measured, and when all children with disease are not diagnosed and treated, cost-benefit cannot be calculated. Since alternate control measures or assured diagnosis and treatment are not applied, it cannot also be determined whether a vaccine will be cost-saving to the health system or to society. Thus, to demand *a priori* proof of economic profit from each vaccine is to deter the inclusion of that vaccine in NIP. However, the burden of disease and the cost per healthy life-year saved can be estimated through the use of the best available data and appropriate mathematical models. A critical review of the assumptions and models by national Advisory Committees, rather than uninformed arguments for or against the use of a vaccine would be the appropriate approach that needs to be promoted in countries like India.

In the absence of reliable health economics information, an essential principle that has to be applied in resource-limited settings is that of 'affordability'. Can or cannot India afford life-saving vaccines for her children? Are there not ways and means of reducing the cost of vaccines? Instead of approaching the issues constructively using the best available scientific evidence, to suggest that it is cheaper to let children die or develop disability than to prevent them by vaccinations is a stand worthy of condemnation. The estimated health economics should be balanced with the obvious humanitarian, rights-to-health and public health ethics aspects of the choice of vaccines in NIP.

Human capital is a special asset of India. Education and health are the basic investments in improving human capital. Health has already been declared as human right. Therefore, it is unethical to license a vaccine against a highly contagious ID but not include it in NIP. On the other hand, the Government may be justified in discriminating between the rich and the poor, with free-of-cost vaccines provided only for the poor, not for the rich, as pointed out earlier. This choice deserves careful consideration by the MoH.

A word must be said about vaccines against non-contagious but communicable (typhoid fever, JE, hepatitis A, human papilloma virus) diseases. For these IDs the risk is not random or universal and prevention is possible without vaccination. Vaccines are one option, but other interventions (water and food safety, education and information, informed and responsible behaviour, screening, *etc*.) are available and should be applied first. However, vaccination may be a simple and practical intervention that must also be assessed by the Advisory Committees for selective use where the need exists.

Progress is inevitable, equity is essential and ethics inalienable. India's investments and achievements in curative medicine for quality and equity, in public health for functional effectiveness and in research to inform

both arms of the health system, are the causes worthy of promotion by the Journal.

I declare no competing interest.

Opinions expressed here are personal and not necessarily in conformity with those of organizations in which I am active member or office-bearer.

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