16 NEW MODELS FOR PUBLIC-PRIVATE PARTNERSHIPS IN HEALTH PROMOTION

Jacob Puliyel

The last two decades have been the era of public-private partnerships (PPPs). The Saskatchewan Institute of Public Policy defines PPPs as co-operative ventures between public and private sectors, built on the expertise of each partner which meets clearly defined public needs through appropriate allocation of resources, risks and rewards (Allan 2001).

A particularly important element is the emphasis upon risk-sharing, joint investment of resources, and sharing of authority. These factors differentiate a PPP from contracting-out and also privatisation. In all the three models, the public sector ceases to be a direct provider of services to the public, but instead becomes a procurer of services and a regulator. With contracting-out, the private-sector party provides the service in return for payments, but it is not involved in the decision-making nor is there transfer of responsibility. In privatisation, the public sector hands over the responsibility for the project to the private party, and subsequently the government's role is minimal. The partnership aspect is what is crucial to the PPP.

The concept of PPP evolved in the context of ballooning public debt in the 1970s and 1980s. The first systematic programme in the United Kingdom (UK) aimed at encouraging PPPs was the private finance initiative (PFI) introduced in 1992 by the Conservative Government. It was structured in a manner so that a public sector body seeking to make capital investments did not incur any borrowing. The borrowing was incurred by the 'private sector vehicle' implementing the project and therefore, from the public sector's perspective, a PPP was an 'off-balance sheet' method of financing the delivery of new or refurbished public sector assets (Tan 2012). It was argued that the expertise and efficiencies of the private sector could be harnessed by this contract for services traditionally procured and delivered by the public sector (Allan 2001). A large number of hospitals were refurbished under this scheme.

PFI: The Failed Experiment

The PFI for hospitals failed miserably. Allyson et al. (2002) show that using the PFI to build the UK National Health Service (NHS) hospitals is an expensive way of building new capacity that constrains services and limits future options. PFI have also had a negative impact on levels of service. Crucially it has been shown that hospitals financed through PFIs had reduced their bed capacity by 30 per cent and hospital staffing by 20 per cent (Gaffney et al. 1999, Pollock et al. 1999). It was shown that one PFI hospital replaced two or three hospitals. The new hospitals were built in out-of-town sites using proceeds from the sale of land of the original hospitals in prime locations (Pollock et al. 2002), and so adds to the inconvenience faced by the public.

Allyson et al. (2002) demonstrated that PFI brings no new capital investment into public services and it

creates a debt which has to be serviced by the future generations. The PFI costs are almost double the estimated costs of a similar scheme funded by public finance. In spite of all the tall-talk of sharing risks in a PPP, where a trust wishes to terminate a contract either because of poor performance or due to insolvency of the private consortium, it still has to pay the consortium's financing costs, even though the latter is in default. It would otherwise have to take-over the consortium's debts and liabilities, given that the lending institutions make their loans to the consortiums conditional on NHS guarantees. In such cases, 'the attempt to shift financial responsibility from the public to the private sector fails' (ibid.).

The UK Treasury Select Committee has now added its criticism. It examined PFIs funding for new infrastructure, such as schools and hospitals, and concluded that it does not provide taxpayers with good value for money, and stricter criteria should be introduced to govern its use (Commons Select Committee 2011). The Chairman of the Treasury Select Committee, Andrew Tyrie, Member of Parliament, observed that the average cost of capital for a low-risk PFI project is over 8 per cent—double that of government gilts.

The Committee observed that the higher borrowing costs resulting from the credit crisis meant that PFIs are now an 'extremely inefficient' method of financing projects. The Committee has not seen any convincing evidence that savings and efficiencies during the lifetime of PFI projects offset the significantly higher cost of finance. Indeed, the report raises concerns that the current 'value for money' appraisal system is biased to favour PFIs. It identified a number of problems with the way costs and benefits for such projects are calculated.

The Treasury Sub-Committee Report of 2011 is telling and begs to be quoted verbatim, '… PFI means getting something now and paying later. Any Whitehall department could be excused for becoming addicted to that. We can't carry on as we are, expecting the next generation of taxpayers to pick up the tab. PFI should only be used where we can show clear benefits for the taxpayer. PFI should be brought on balance sheet. The Treasury should remove any perverse incentives unrelated to value for money by ensuring that PFI is not used to circumvent departmental budget limits'.

Replication across Sectors and across Countries

Interestingly, the spectacular failure of the original programme did not hinder replication of this grand scheme. The concept of PPP has spread both in the developed and in the developing countries. Initially they were used for infrastructure development, e.g. ports, rail, power, roads and hospitals. Over the past two decades, more than 1,400 PPP deals were signed in the European Union (EU), representing a capital value of approximately €260 billion (Kappeler and Nemoz 2010). In Pakistan, economic advisors advised the public sector to 'mend its ways' and promote PPPs as the only way forward for the development of the infrastructure and power sectors (Ahmad 2013). Today, Monsanto with no infrastructure development in the traditional sense of the term advertises its involvement in a PPP[1] with state governments in India reaching farmers with their seeds that are modified, patented and genetically locked (Shiva 2013), leading to farmers being forced to buy more every season.

Tinkering with the Model

It is now widely recognised that the problem with most PPP is that the private investor makes all the profit (with returns higher than the government bond rate) and nearly all the income risk is borne by the public partner. It is suggested that PPP can survive if the focus of evaluation is changed from reduction in debt of the public sector partner, to looking at 'value for money' after appropriate allocation of risk. The New Zealand Treasury released a report in 2006 by Katz (2006) suggesting that '… there is little empirical evidence about costs and benefits of PPP' and that any '… advantages of PPP must be weighed against the contractual complexities and rigidities they entail'. It suggested that the decision whether to proceed with a PPP rather than with a conventional procurement process should be hinged on the following three questions:

1. Is the public agency able to specify outcomes in service-level terms, thereby leaving scope for the PPP consortium to innovate and optimise?
2. Is it easy for the public agency to specify outcomes in a way that performance can be measured objectively and rewards and sanctions applied?

[1] See http://www.monsantoindia.com/public-private-partnership.html, accessed on 1 November 2013.

3. Are the public agency's desired outcomes likely to be durable, given the length of the contract?

If the answer to any of these three questions is 'no', then conventional procurement is likely to be preferable to a PPP (ibid.).

Product Development Partnerships

An offshoot of the traditional PPP for infrastructure development is Product Development Partnerships (PDPs). This is a form of PPP that develops drugs especially for neglected diseases like tuberculosis (TB) and tropical diseases of the developing countries. Not-for-profit organisations provide industry cash incentives needed to develop these interventions and market them. An example of this is 'The Global Fund to fight AIDS, Tuberculosis and Malaria', which was established to finance interventions against these three diseases. Similarly, the 'Roll Back Malaria Partnership' mobilises resources to fight malaria in endemic countries. The Global Alliance for Vaccines and Immunisation (GAVI) is a product development partnership for vaccines.

PDPs and Vaccines

The vaccine marketing enterprise is now a PPP. Most modern vaccines are produced by private manufacturers, and profits from sales of these vaccines accrue to them. However, publicly-funded international organisations and tax-free charities—the World Health Organisation (WHO)/United States Agency for International Development (USAID)/GAVI invest in research to develop new vaccines and for field trials to promote its use. The target vaccine market is usually publicly funded. This chapter examines PPPs broadly in the context of health and looks more specifically at PPP in vaccines. The chapter argues that this scheme puts international organisations in an unenviable position of selling vaccines—some of doubtful utility—and this erodes the very credibility of the organisations.

Public Funding of Vaccine Research

Research and Development (R&D) on vaccines is considered a public good (Kremer 2002). Efforts to encourage research on vaccines can adopt one of the three strategies. The first two have their advantages and disadvantages while there are no takers for the third.

a) Research grants and tax credits can be given to research organisations to promote research. Such research is done mostly in academic and research organisations which are not directly involved in manufacture or marketing of the products. This

BOX 16.1 Case Studies

H.influenza B (Hib) is a bacterial pathogen that can cause pneumonia and meningitis in children. A vaccine against Hib is now available. However, studies done by the World Health Organisation (WHO) in Indonesia (Gessner et al. 2005) and Bangladesh (Baqui et al. 2007) looking at Hib disease prevented by Hib vaccine found that there was no statistically significant difference among those full vaccinated compared to those not immunised. The press release about the study jointly issued by the WHO, Johns Hopkins Bloomberg School of Public Health, The GAVI Alliance, The Hib Initiative, USAID, Government of Bangladesh (JHSPH 2007), however, misleadingly states that the study shows Hib vaccine protects children from a significant burden of life-threatening pneumonia and meningitis (Puliyel et al. 2010, Puliyel 2010).

Hepatitis B virus causes inflammation of the liver and in some; it causes a chronic hepatitis that may progress to liver cancer and death. A vaccine against Hepatitis B is available. Mark Miller (of the Children's Vaccine Initiative of the WHO and the National Institute of Health, Bethesda) claimed that 250,000 persons die in India each year due to Hepatitis B-related liver disease (Miller 2000). Initially, Dr Miller wrote that a model 'stratified by income group and geographic region' was used to arrive at this estimate of deaths. However, data from well-maintained cancer registries suggests that the number of deaths from Hepatitis B-related cancers was about 5,000 per year (Dhir et al. 1998). When challenged to publish his model, Dr Miller claimed his model was lost (Puliyel 2004). The paper was not retracted.

Soon after the Pentavalent Vaccine was introduced in Sri Lanka there was a series of five deaths. A WHO group of experts investigated the deaths. They could find no alternate explanation for three deaths. Using the Brighton Protocol they were bound to have classified these deaths as 'probably related to the Pentavalent vaccine' (WHO 2008). The experts modified the Brighton Protocol and removed the categories 'probably related' and 'possibly related' from the classification. Their report states that although they could find no alternate explanation for the events, the deaths were classified as unlikely to be related to the vaccine using their modified Brighton classification (ibid.).

is called the 'push' strategy—paying for research in the hope that the industry will find it useful. Quite often the projects supported by taxpayer funds do not result in new vaccines or other tangible results. The 'push' method has been criticised as being wasteful and inefficient.

b) 'Pull' mechanisms on the other hand, incentivises the development of actual vaccines. The research is usually done by the pharmaceutical industry. Industry does its own research and develops useful and marketable vaccines and this is rewarded. Here, the public pay nothing unless a viable vaccine is developed. This encourages researchers to self-select projects that yield viable products. If an acceptable vaccine is developed, the 'pull' programme is committed to purchase the vaccine for use the world over. An annual market of $ 330 to $ 660 million is considered necessary to stimulate research. This market is guaranteed by a purchase commitment—the Advance Market Commitment (AMC) which is integral to the 'pull' mechanism (ibid.). However, the pull mechanism is criticised because the commitment to purchase vaccines at a fixed price violates the laissez-faire principle allowing the market forces to determine prices. This removes the basic incentive to innovate and bring good quality vaccines to the market. These days, the pull mechanism is preferred by the international funding agencies.

   For this purpose, the Global Fund for Vaccines was launched by GAVI, a public-private venture formally launched at the World Economic Forum (WEF) in Davos in January 2000. GAVI's founding partners include WHO, United Nations Children's Fund (UNICEF), World Bank, Bill & Melinda Gates Children's Vaccine Programme, Rockefeller Foundation, International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), and a few other national governments. It was created starting with a $ 750 million donation by the Bill & Melinda Gates Foundation. Since this initial donation, the Fund has received commitments from the governments of the US ($ 50 million), Norway ($ 125 million), the United Kingdom ($ 5 million) and The Netherlands ($ 100 million) (Hardon 2001).

c) There is a third strategy which is to allow the market forces to control both supply and demand for vaccines. Paradoxically, votaries of the free market are strangely silent where vaccine markets are concerned.

This chapter will dwell mostly on the 'pull strategy' of the PPPs.

GAVI and Advance Market Commitments

As explained above, GAVI utilises AMC to incentivise vaccine development. AMC was launched in 2005 (Center for Global Development 2005). Poor countries cannot afford to buy expensive vaccines and the vaccines meant for them have to have their prices marked down. To encourage multinational companies to make these vaccines for the poor, the AMC underwrites the losses they incur in this way. Donors (donor countries and philanthropic organisations) put up the monitory equivalent of sales proceeds that a multinational pharmaceutical company would make from developing and testing a new drug for the western market, for making a drug for a neglected disease in poor countries (Kremer and Glennerster 2004). The normal profit for a new drug in the West is considered to be $400 million. The donors make a binding commitment to buy a few hundred million doses of a new vaccine for a neglected disease at a buy-out price that will yield about $400 million in profits for the manufacturer. In return, the manufacturer would commit to making the vaccine available to low-income countries thereafter, at a low 'tail price' on a no-profit basis (Light 2011).

The manufacturer who accomplishes the task of making an acceptable vaccine first, takes the prize of the AMC. Light (2011) has suggested that this is a vaccine developer's nightmare as they have to bear all the risks and costs of discovering and testing the drug without financial support if they are pipped at the finish line. All their efforts would be a total loss to the company. The AMC scheme would in fact also work as a disincentive for competitors wanting to develop a more efficacious or less expensive products as there would be no buyers for the product in the face of the highly subsidised AMC funded product. Light notes that despite the proposed buy-out worth billions of dollars, the AMC design included no arrangement for acquiring intellectual property rights or for technology transfer (ibid.).

AMC and Pneumococcal Vaccine

One of the first vaccines awarded the AMC was the pneumococcal conjugate vaccine (PCV). When the AMC for the vaccine was agreed in 2008, it was clear that the subsidy would initially be exclusively granted to Pfizer and GlaxoSmithKline (GSK) for a vaccine

that was already in the market. In 2008, Pfizer reported $ 2.72 billion in revenue for the first generation pneumococcal vaccine, Prevnar. According to Berman and Malpani (2011), presenting the pneumococcal AMC as a cost-effective mechanism was 'disingenuous'. They argue that at the agreed price of $ 3.50 per dose of pneumococcal vaccine, Pfizer and GSK will be given a 'subsidy' of $ 225 million.

Berman and Malpani (2011) suggest that GAVI needs to eliminate the conflicts of interest that have led to advantageous arrangements for multinational pharmaceutical companies.

Four points need to be highlighted with regard to the PCV AMC (Birn and Lexchin 2011):

(1) The vaccine is of questionable benefit, since it assumes that the prevalence of disease strains (serotypes) is the same worldwide, an assumption that is not necessarily valid (also see Puliyel et al. 2011);
(2) The AMC was extended to an existing vaccine developed for a high-income market rather than for its stated purpose of developing new vaccines for low-income settings;
(3) The PCV AMC is financing exorbitant pharmaceutical company profits;
(4) The efficacy and cost-effectiveness of PCVs, as opposed to other vaccines and child health interventions—or integrated socio-political primary healthcare approaches—are dubious.

Conflicts of Interest at GAVI

Birn and Lexchin (2011) note that GAVI has been accused of practising 'scientific imperialism'. According to them, the interests of almost three-fourths of GAVI members are aligned with profit-making rather than people's health. Of the 20 members, two represent pharmaceutical companies themselves; five of the donor countries are heavily influenced by corporate lobbying; two are involved in PPPs with pharmaceuticals (WHO and UNICEF); two consider profit-making as compatible with addressing global inequality (Bill & Melinda Gates Foundation and World Bank); and four are 'private citizens' who are connected to finance, banking and insurance industries.

Hardon (2001) records that at the first GAVI-partners meeting, the Head of SmithKline Biologicals outlined the conditions for industry participation; '… a guarantee for reasonable prices, support for a credible and sustainable market, respect for intellectual property rights, a tiered pricing system including safeguards against re-export of products back from developing countries to high-priced markets, and a prohibition on compulsory licensing.' Industry representatives opposed technology transfer arrangements, ' … claiming that vaccines were too complex for public research institutes and local production' Birn and Lexchin (2011). Hardon (2001) notes that GAVI partners appeared unconcerned about possible conflict of interest between the large research-based companies' interest in markets for new products and the public health objective of preventing childhood mortality in the developing countries.

Light (2007) agrees that the so-called G8 'AMC pilot' for pneumococcal vaccine was really a large long-term procurement and it was not an AMC. In 2007, several affluent countries—the UK, Italy, Canada, Russia and Norway—and the Bill & Melinda Gates Foundation announced donations totalling $1·5 billion to buy new vaccines to ease the burdens of disease that will help eradicate pneumococcal diseases in the world's poorest children and foster economic growth. According to Light (2007), only a quarter of the money was spent on covering the costs of vaccines—three-quarters went towards extra profits for vaccines that are already profitable. Light (2007) argues that '… by commercializing vaccines for poor people, the AMC approach is making the culture of the GAVI Alliance more commercially oriented than it previously was, and it is shifting the Alliance towards becoming the vehicle for making vaccines for poor individuals into the next main market for the drug industry'. In a review of five immunisation initiatives, Hardon and Blume (2005) concluded that the GAVI Alliance is more corporate-led, less transparent, not really accountable outside of itself, and more oriented to paying profitable prices than were previous initiatives.

Underestimating Costs

Light (2007) points out that the criticism of GAVI AMC for pneumococcal vaccine is covered up by the Alliance's claim that the AMC will prevent 5·4 million child deaths—89 per cent of which are projected to take place after the donors' money has been spent This claim is itself dubious. According to WHO, the vaccine saves only 3.6 lives for every 1,000 children vaccinated (Madhi et al. 2008). The cost per life saved is often underestimated. Farlow (2011) points out that the cost per death averted from the initial $ 5.6 billion investment on pneumococcal vaccine is about $ 2,000. Light's (2011) figure, based on non-GAVI studies,

is $ 4,722 per death averted. The projection of Light (2011) had a decimal place error and the actual cost per life saved is $ 47,220 (Puliyel 2011)! Looking at opportunities foregone because of the programme, in comparison, the cost per death averted from the use of Expanded Programme of Immunization (EPI) vaccines (diptheria, pertussis, tetanus [DPT] vaccine, oral polio vaccine measles vaccine and Bacillus Calmette-Guerin [BCG] vaccine) is $ 205 in South Asia and Sub-Saharan Africa. GAVI faces a stark choice between promoting the use of new and more expensive vaccines, and improving access to inexpensive vaccines for polio, measles, yellow fever and hepatitis, to millions not yet reached (Farlow 2011, Light 2011).

Safety Concerns

Safety concerns have got short shrift in the push for introducing new vaccines. Telling examples are the deaths surrounding the use of Pentavalent vaccine (which combines Hepatitis B and H influenza B vaccines with the older DPT Triple Antigen. The vaccine is promoted mostly in the developing countries by GAVI and WHO. It is not used in the West because the combination vaccine is less effective than the components used separately (Bar-On et al. 2009). In these circumstances the safety of the combination vaccine has not yet been tested in the developed countries, known for their strong surveillance systems.

The Pentavalent vaccine has been associated with deaths soon afterwards in many countries where it has been administered. The deaths have been sporadic and as in deaths following allergic reactions to drugs, others vaccinated from the same multi-dose vial remain unscathed.

When deaths occur soon after the administration of a vaccine, the investigating team looks for other plausible explanations for the reaction. The vaccine is considered as probably the cause of the adverse event only when there is no alternate explanation (according to WHO's Brighton classification) (WHO 2005).

As described in the case studies above (Box 16.1), in Sri Lanka the WHO experts found no alternate explanation for the deaths following use of the pentavalent vaccine so they deleted the categories 'possibly related and probably related' from the Brighton Classification and certified that the adverse event following immunisation (AEFI) was unlikely to be related to immunisation (WHO 2008)

The vaccine was introduced in Kerala in December 2011. Within 6 months there were 5 deaths. It was apparent that 1 child in 10,000 vaccinated children, died as the result of an AEFI (Puliyel 2013).

In the context of all these deaths, the Council for International Organizations of Medical Sciences (CIOMS)/WHO Working Group on Vaccine Pharmacovigilance got together to alter the way AEFI are reported and investigated (CIOMS/WHO 2012). The presumption that any AEFI must be considered as 'probably' related to vaccine if there is no alternate explanation for the adverse event has been done away with. The new algorithm suggests that only reactions that meet 'AEFI-specific case definitions' will be classified as AEFI and investigated. If the vaccine is new, like the pentavalent vaccine, deaths following vaccination may be classified as '[Not an AEFI]' (ibid., see p. 170 notes for guidelines). Using this new method of evaluating causality, all the deaths that have occurred have been classified as 'Not an AEFI'.

This last step of designating an AEFI as 'not an AEFI' is patently unscientific, illogical and nearly Orwellian. King (2012) has pointed out that the agenda of the Global Advisory Committee on Vaccine Safety (GACVS) is to develop a system that will minimise the reporting of AEFI, especially those considered severe, to minimise the risk that the reporting of AEFI will be 'programmatically disruptive'. Of the 40 members on the CIOMS/WHO committee, 19 were private partner representatives of vaccine manufacturers.

In Vietnam, 61 children have died so far following use of the pentavalent vaccine (Tuoitrenews 2013). In March 2013, the WHO-AEFI group was called to investigate a spate of 12 deaths following pentavalent vaccine use in Vietnam. Armed with the new COIMS/WHO tool, its Vietnam report stated,'… no fatal AEFI *has ever* been associated with this vaccine' (WHO 2013). This suggests that even deaths recorded previously by experts in Sri Lanka as 'AEFI—unlikely to be related to vaccine' has been changed to 'Not an AEFI'. The new scheme is discussed extensively on the PubMed Commons (Tozzi 2013).

Increasing Health Inequities

Interestingly, Hardon (2001) has pointed out that by spending such a large amount of its resources on new vaccines, GAVI and the Global Fund run the risk of compounding health inequities in the poorest countries which they have prioritised for support. In nine of the countries selected for support in the first round, immunisation coverage remains below 75 per cent. 'In the programmes approved by GAVI, developing

country governments will join hands with multilateral and bilateral agencies to increase the number of children reached by the services who receive new, expensive and under-used vaccines. Those children not reached by current immunization programmes will probably lose out again. As inequity in access to vaccines persists, they will remain the losers' (ibid.).

AMC as Incentive for Vaccine Research

In the face of the mounting criticism of AMCs and the AMC for pneumococcal vaccine, Kane (2011) has defended the need for an AMC incentive to promote vaccine research. He feels that the vaccine industry needs a signal that GAVI is capable of raising billions of dollars to buy vaccines like PCV and Rotavirus vaccines. He writes, 'Every health worker in the developing world understands the importance of pneumonia (the number one cause of death in children) and diarrhoea (the number two cause of death in children in many countries). GAVI, to remain relevant, has no choice but to try to raise the resources to make these vaccines available to children in the poorest countries, and to continue its efforts to solve the financial problems of getting new and underutilized vaccines to the poor' (ibid.).

Paradoxically Kane's (2011) defence exposes the flaw in GAVI's logic for disease amelioration. Pneumonia and diarrhoea are caused by numerous pathogens. Just because there is a vaccine available for a limited number of strains of one of the many pathogens causing pneumonia and in the same way for diarrhoea, it cannot be the justification for spending billions of dollars on vaccines as if that would tackle the problem of diarrhoea and pneumonia entirely. The unrealistic expectation propagated by such propaganda will ultimately erode the very credibility of the organisation and vaccination programmes in general.

The Way Forward: Absolute Risk Reduction

The relevance of vaccines depend on local factors, especially the prevalence and magnitude of the problem in a locality. Data on usefulness has to be generated locally and market commitment must depend on this. An AMC on the other hand by implication assumes that the prevalence of serotypes is the same worldwide and the same vaccine will be considered as the priority intervention in all countries. To assume that GAVI or any other organisation can make one decision for the whole world is presumptuous. Having committed to an AMC, international organisations are placed in the unenviable position of selling this around the world. This puts them in the embarrassing situation described at the start of this article.

Fiona Godlee, the editor of the *British Medical Journal*, started a campaign suggesting that researchers must report data in terms of absolute risk reduction (ARR) rather than relative risk. She points out that '… impressive sounding reductions in relative risk can mask much smaller reductions in absolute risk' (Godlee 2008). Data on ARR must be used to decide about vaccine selection for different regions.

ARR describes the difference between two treatments. It tells actual numbers (or rates) of people who experience harms or benefits as compared with another treatment. In the case of pneumococcal vaccine, suppose a vaccine prevents 50 per cent of the strain-related disease, the relative risk (or proportional difference) of 50 per cent can sound impressive. However, if the strain itself is rare, say 2 per cent of the population has the disease due to the strain, a 50 per cent risk reduction will work out to be a 1 per cent ARR—meaning that there will be 1 person saved from pneumonia in 100 people taking the drug. Once this data is available, it is easy to calculate the numbers needed to treat (NNT) to prevent one case of disease or death. The numbers needed to vaccinate (NNV) to prevent one case of pneumonia is 100 in the illustration above. The cost per disease avoided or death averted, can then be calculated easily. In the case of the pneumococcal vaccine, Madhi et al. (2008) have reported that 3.6 children avoid pneumonia per 1,000 children vaccinated in the areas where it was studied. This will differ by region and so a blanket prescription of AMC drugs is inappropriate. A detailed discussion on how to estimate the affordability of the intervention against the gross national product (GNP) of the country is available elsewhere (Dhanasiri and Puliyel 2007, Tyagi et al. 2003). Dhanasiri and Puliyel (2007) also discuss how to compare cost-utility of the programme against utility of other programmes which may compete for scarce heathcare budgets.

Conclusion

GAVI must be credited with increasing international interest in vaccines. A new model of PPP is emerging called public-private community partnership (PPCP) where the government and the private players work together for social welfare eliminating the prime focus

BOX 16.2 Selecting Vaccines for Universal Programme of Immunisation in India

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 immunisation 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 immunisation programmes. However, of late, the WHO has been making recommendations for universal inclusion of vaccines like the rotavirus vaccine without regard to local cost effectiveness. Organisations like the GAVI have been persuading the 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 realised once funding is withdrawn, after the vaccine has been included in the universal immunisation 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).

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.

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 immunisation 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 programme—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 crore and saves 1 QALY per Rs 10,000 spent, rotavirus control costs Rs 200 crore and saves one QALY per Rs 20,000 spent, and tuberculosis control costs Rs 700 crore and saves one QALY per Rs 5,000 spent. Assume also a budgetary constraint of Rs 1,000 crores. The first programme to be accepted should be TB control as it provides the best utility (1 QALY/Rs 5,000). Once this is accepted, there is only Rs 300 crore remaining in the budget. The next programme to be accepted must be polio control. Rotavirus control costs only Rs 200 crore, which is less than the cost of polio control (Rs 350 crore), but polio control takes precedence as it provides more utility.

Source: Puliyel (2014).

of private players for profit (CARD, undated, Cohesion Foundation Trust, undated). Health and vaccines are suitable candidates for PPCP. Given the persuasive abilities of GAVI in raising funds for immunisation, it must work to shed its conflicts of interests and endeavour in a PPCP to promote child health.

References

Ahmad, Mansoor. 2013. 'Public Sector Urged to Promote Public-Private Partnership'. *The News*, 29 October 2013, http://www.thenews.com.pk/Todays-News-3-210793-Public-sector-urged-to-promote-public-private-partnership, accessed on 28 October 2013.

Allan, John R. 2001. 'Public-Private Partnerships: A Review of Literature and Practice'. Saskatchewan Institute of Public Policy, Paper no. 4, http://www.uregina.ca/sipp/documents/pdf/cicreport.pdf, accessed on 28 October 2013.

Bar-On, E. S., E. Goldberg, A. Fraser, L. Vidal, S. Hellmann, and L. Leibovici. 2009. 'Combined DTP-HBV-HIB Vaccine versus Separately Administered DTP-HBV and HIB Vaccines for Primary Prevention of Diphtheria, Tetanus, Pertussis, Hepatitis B and Haemophilus Influenzae B (Hib)'. *Cochrane Database Syst Rev.* 3: CD005530.

Baqui, A. H., S. El Arifeen, S. K. Saha, L. Persson, K. Zaman, et al. 2007. 'Effectiveness of Haemophilus Influenzae Type B Conjugate Vaccine on Prevention

of Pneumonia and Meningitis in Bangladeshi Children: A Case-control Study'. *Pediatr Infect Dis J*. 26 (7): 565–71.

Berman, D., and R. Malpani. 2011. 'High Time for GAVI to Push for Lower Prices'. *Human Vaccines* 7: 3: 290, March.

Birn, Anne-Emanuelle, and J. Lexchin. 2011. 'Beyond Patents: The GAVI Alliance, AMCs and Improving Immunization Coverage through Public Sector Vaccine Production in the Global South'. *Human Vaccines* 7: 291–92.

CARD (Center for Advanced Research and Development). Undated. 'Public Private and Community Partnership Programme at Mandla'. http://www.cardindia.net/pub7.asp, accessed on 1 November 2013.

Center for Global Development. 2005. 'Making Markets for Vaccines: Ideas into Action'. Washington, *DC Center for Global Development*, http://www.cgdev.org/publication/making-markets-vaccines-ideas-action, accessed on 20 June 2014.

CIOMS/WHO. *Report of Working Group on Vaccine Pharmacovigilance: Definition and Application of Terms for Vaccine Pharmacovigilance*, http://whqlibdoe.who.int/publications/2012/9789290360834_eng.pdf, accessed on 1 November 2013.

Cohesion Foundation Trust. Undated. 'UNDP Supported Project on Public–Private–Community Partnership (PPCP)', http://ppcp.in/dungarpur-rajastan/cohesion-foundation-trust.pdf, accessed on 1 November 2013.

Commons Select Committee. 2011. 'Committee Publishes Report on Private Finance Initiative Funding'. 19 August, http://www.parliament.uk/business/committees/committees-a-z/commons-select/treasury-committee/news/pfi-report/, accessed on 20 June 2014.

Dhanasiri, S. K., and J. M. Puliyel. 2007. 'Regulating Vaccines: Can Health-economics Tools be Used Profitably?' *Indian Pediatrics* 44: 11–14.

Dhir, V., and K. M. Mohandas. 1998. 'Epidemiology of Digestive Tract Cancers in India. III. Liver'. Jul–Sep, 17 (3): 100–03.

Farlow, A. 2011. 'Fixing GAVI's Cash Crunch'. *Hum Vaccin* 7: 295–96.

Gaffney D., A. M. Pollock, D. Price, and J. Shaoul. 1999. 'PFI in the NHS: Is There an Economic Case?' *BMJ* 319: 116–19.

Gessner, B. D., A. Sutanto, M. Linehan, I. G. Djelantik, T. Fletcher, et al. 2005. 'Incidences of Vaccine-preventable Haemophilus Influenzae Type B Pneumonia and Meningitis in Indonesian Children: Hamlet-randomised Vaccine-probe Trial'. *Lancet* 365: 43–52.

Godlee, F. 2008. 'Absolute Risk Please'. *BMJ* 336: 0.1.

Hardon, A. 2001. 'Immunisation for All? A Critical Look at the first GAVI Partners Meeting'. *HAI Europe* 6: 2, http://www.haiweb.org/pubs/hailights/mar2001/HAILightsMar2001_1.pdf, accessed on 18 June 2014.

Hardon, A. and S. Blume. 2005. 'Shifts in Global Immunization Goals (1984–2004): Unfinished Agenda and Mixed Results'. *Soc Sci Med* 60: 345–56.

JHSPH (Johns Hopkins Bloomberg School of Public Health). 2007. 'Hib Vaccine: A Critical Ally in Asia's Effort to Reduce Child Deaths' (press release), http://www.jhsph.edn/news/news-release/2007/baqui-h.b.html, accessed on 1 November 2013.

Kane, M. 2011. 'New Vaccines for the Least Developed Countries'. *Human Vaccines* 7: 298–99.

Kappeler, Andreas, and Nemoz Mathieu. 2010. 'Public-Private Partnerships in Europe before and during the Recent Financial Crisis'. *Economic and Financial Report 2010/04*. July. European Investment Bank, http://www.bei.europa.eu/attachments/efs/efr_2010_v04_en.pdf, accessed on October 2013.

Katz, Dieter. 2006. 'Financing Infrastructure Projects; 'Public-Private Partnerships (PPPs)'. New Zealand Treasury Policy Perspectives Paper 06/02, http://www.treasury.govt.nz/publications/research-policy/ppp/2006/06-02/08.htm, accessed on 15 November 2013.

King, Paul G. 2012. *Draft Review of: A Report by WHO's Global Advisory Committee on Vaccine Safety*. June, [Eng], http://dr-king.com/docs/20120928_FAMESYstems_ReviewOfGACVSJune2012ReportOnSafety_Thimerosal_AluminumAdjuvants_OtherVaccineIssues_fnl_r2b.pdf, accessed on 1 November 2013.

Kremer, M. 2002. 'A Purchase Commitment for Vaccine', in Inge Kaul, Katell Le Goulven and Mirjum Schnupf (eds), *Global Public Goods Financing: New Tools for New Challenges, A Policy Dialogue*, pp. 37–42. New York: United Nations Development Programme (UNDP).

Kremer, M., and R. Glennerster. 2004. *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases*. Princeton: Princeton University Press.

Light, D. W. 2011. 'Saving the Pneumococcal AMC and GAVI'. *Human Vaccines* 7: 138–41.

———. 2007. 'Is G8 Putting Profits before the World's Poorest Children?' *The Lancet* 370: 297–98.

Madhi, Shabir A., Orin S. Levine, and Thomas Cherian. 2008. 'Reply to Incidence of Pneumonia is not Reduced by Pneumococcal Conjugate Vaccine: Pneumococcal Conjugate Vaccine is Efficacious and Effective in Reducing the Burden of Pneumonia'. *Bull World Health Organ 86 (10)*. October.

Miller, M. A., and L. McCann. 2000. 'Policy Analysis of the Use of Hepatitis B, Hemophilus Influenzae Type B, Strepto-coccus Pneumoniae-conjugate and Rotavirus vaccines in the National Immunization Schedules'. *Health Econ* 9: 19–35.

Pollock, A. M., M. Dunnigan, D. Gaffney, D. Price, and J. Shaoul. 1999. 'Planning the New NHS: Downsizing for the 21st Century'. *BMJ* 319: 179–84.

Pollock, A. M., J. Shaoul, and N. Vickers. 2002. 'Private

Finance and Value for Money in NHS Hospitals: A Policy in Search of a Rationale?' *BMJ* 324: 1205–09.

Pollock, Allyson M., Jean Shaoul, and Neil Vickers. 2002. 'Private Finance and "Value for Money" in NHS Hospitals: A Policy in Search of a Rationale? *BMJ* 324(7347): 1205–1209, 18 May, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1123165/#B2, accessed on 14 June 2014.

Puliyel, J. 2014. 'Immunisation: Challenges of Ensuring Public Health: Assessing the Past, Charting the Future', *Yojana*, Februray, http://yojana.gov.in. http://jacob.puliyel.com/download.php?id=309, accessed on 20 July 2014.

———. 2013. 'AEFI and the Pentavalent Vaccine: Looking for a Composite Picture'. *Indian Journal of Medical Ethics* 10 (3) July–September. http://ijme.in/pdfs/213ed142.pdf, accessed on 20 June 2014.

———. 2011. 'Cost of Pneumococcal Vaccine Underestimated Ten-fold'. *Human Vaccines* 7: 1.

Puliyel, J., J. Mathew, N. Vashisht, and V. Sreenivas. 2011. 'Effectiveness Versus Efficacy of Conjugated Pneumococcal Vaccine: A Systematic Review of Randomised, Controlled Trials with Meta-analysis Examining Absolute Risk Reduction and Relative Risk'. *Clinical Microbiology and Infection*: 17, Issue Supplement s4, p. 299 (p. 1442), http://onlinelibrary.wiley.com/doi/10.1111/j.1469-0691.2011.03558.x/pdf, accessed on 20 June 2014.

Puliyel, J. M. 2010. 'GAVI (Global Alliance for Vaccines and Immunisation) and WHO: Demanding Accountability'. *BMJ* Aug 4: 341:c 4081. WHO Expert Panel 2008. Report of a WHO Ad Hoc Expert Panel to Review Reports of Serious AEFI following administration of pentavalent vaccine and other vaccines—Sri Lanka 2008, http://jacob.puliyel.com/download.php?id=213, accessed on 20 June 2014.

Puliyel, J. M., J. L. Mathew, and R. Priya. 2010. 'Incomplete Reporting of Research': Et tu, WHO? *Indian J Med Res* 131: 588–89.

Puliyel, J. M. 2010. 'GAVI (Global Alliance for Vaccines and Immunisation) and WHO: Demanding Accountability'. *BMJ* Aug 4: 341:c 4081. WHO Expert Panel 2008. Report of a WHO Ad Hoc Expert Panel to Review Reports of Serious AEFI following administration of pentavalent vaccine and other vaccines—Sri Lanka 2008, http://jacob.puliyel.com/download.php?id=213, accessed on 20 June 2014.

Puliyel, J. 2004. 'Policy Analysis of the Use of Hepatitis B, Hemophilius Influenzae Type B, Steptococcus pneuomniae-conjugate and Rotavirus Vaccines in the National Immunization Schedules. *Health Econ*, November 13 (11): 1147–48.

Shiva, Vandana. 2013. 'How Economic Growth Has Become Anti-life'. *The Guardian*, 1 November. http://www.theguardian.com/commentisfree/2013/nov/01/how-economic-growth-has-become-anti-life, accessed on 1 November 2013.

Tan, Virginia. 2012. 'Public-Private Partnership (PPP)', http://a4id.org/sites/default/files/files/%5BA4ID%5D%20Public-Private%20Partnership.pdf, accessed on 20 June 2014.

Tozzi, A. E., E. J. Asturias, M. R. Balakrishnan, N. A. Halsey, B. Law, and P. L. Zuber. 2013. 'Assessment of Causality of Individual Adverse Events Following Immunization (AEFI): A WHO Tool for Global Use'. *Vaccine*. 17 31 (44): 5041–46, October. doi: 10.1016/j.vaccine.2013.08.087. Comments on PubMed Commons available at http://www.ncbi.nlm.nih.gov/pubmed/24021304, accessed on 18 June 2014.

'Tuoitrenews 15 Infants Die after Quinvaxem Vaccination This Year', http://tuoitrenews.vn/society/15499/15-infants-die-after-quinvaxem-vaccination-this-year, accessed on 1 January 2014.

Tyagi, V., S. K. Singh, A. Sawhney, V. Taneja, and J. M. Puliyel. 2003. 'Using Gross National Product to Calculate Acceptable Immunization Costs. Deploying Cost-effectiveness Calculations in Reverse'. *Pharmacoeconomics* 21: 497–99.

WHO (World Health Organisation). 2013. 'Safety of Quinvaxem (DTwP-HepB-Hib) Pentavalent Vaccine', 10 May, http://www.who.int/immunization_standards/vaccine_quality/quinvaxem_pqnote_may2013/en/index.html, accessed on November 2013.

———. 2008. Report of a WHO Ad Hoc Expert Panel to Review Reports of Serious AEFI Following Administration of Pentavalent Vaccine and Other Vaccines—Sri Lanka 2008, http://jacob.puliyel.com/download.php?id=213, accessed on 20 June 2014.

———. 2005. 'Adverse Events Following Immunization (AEFI): Causality Assessment', http://www.rho.org/files/rb3/AEFI_Causality_Assessment_WHO_2005.pdf, accessed on 1 November 2013.

———. 2005. Brighton Classification, http://www.rho.org/files/rb3/AEFI_Causality_Assessment_WHO_2005.pdf.