Commentary

*Quo vadis, expanded programme on immunization?*

“We have found the enemy, it’s us” (Thoreau)

All mothers wish good health for their children. Health workers desire all children immunized against vaccine-preventable diseases. The Government wants them protected from progressive primary tuberculosis, diphtheria, pertussis, tetanus, poliomyelitis and measles through the Expanded Programme on Immunization (EPI, or Universal Immunization Programme, UIP). The total quantity of required vaccines and injection equipment are purchased and distributed, but many vaccine doses do not reach a majority of infants and children in most districts in India. Why is there such a wide gap and who should bridge it and how?

Datar et al ask if more rural health care facilities or staff might improve vaccine coverage. They summarize vaccine coverage data in the two National Family Health Surveys (NFHS) of 1993 and 1998. The age-appropriate coverage in rural communities was 39 and 48 per cent respectively for poliovaccine and 27 and 35 per cent for other vaccines. The urban result was somewhat better with 59 and 63 per cent coverage for polio and 46 and 58 per cent for all others, in the 1993 and 1998 surveys. They analysed coverage levels according to the presence or nearness of subcentre, primary health centre or community health centre and according to the presence of community health worker in villages. Surprisingly, or rather disappointingly, none of these infrastructure elements made much difference. At best, the availability of a health centre within 5 km improved coverage of age-appropriate vaccine doses by just 4-5 per cent. This is a crucial finding: merely increasing the physical structures (health centres) or staff by themselves will not improve vaccine coverage. That is an indictment on the low quality of services provided by them.

There is another check on quality of immunization services. The primary health care (PHC) system reports their achievement of vaccination coverage through the district and State immunization officers to the Government of India (GoI). Such reports are cumulated and converted to national data sets. The information collected on vaccine coverage in the NFHS-91 and 92 and the GoI reports for the corresponding periods show an unacceptable degree of variance. The coverage data from these two sources are shown in the Table.

We must presume that the NFHS data are nearer the truth and the information submitted by the PHC system to the Government is inflated and untrue. According to the GoI reports, EPI has achieved very high coverage; but according to NFHS-3, nearly half of all infants missed DPT-3 and measles vaccine, a quarter missed BCG and one-third missed OPV-3.

But why are we relying on vaccine coverage data to measure the success of UIP? A systems analysis of the UIP must examine the inputs, processes, output and evaluation, the essential four elements in any system. Theoretically, all necessary inputs - buildings, infrastructure, staff, training, vaccines and
injection equipment have been put in place. The processes have been streamlined and are supervised by senior officers at district and State levels. Unfortunately, the output has not been defined. Evaluation is confined to vaccine coverage, which is a measure of the efficiency of the inputs and processes, but not of the output.

The output of UIP consists of two elements: the reduction of disease burden (with consequent cost-saving), and the creation of public demand. A disease surveillance system is essential to measure the magnitude of disease reduction, but it is not included in the design of UIP. This flaw has caused many problems in the system. For example, if we do not know what proportion of children developed the target disease in spite of vaccination, we cannot distinguish between false reporting and low vaccine quality or efficacy. The inflated vaccine coverage reports are not challenged even when the target disease is rampant, since its epidemiology and risk factors remain uninvestigated. The staff knows this deficiency and continues to report inflated coverage rates. As coverage is falsely inflated, large amounts of vaccine are siphoned off, but this potential scam has not been detected by audit process. Are these sold in black market or simply discarded?

The urban communities seek out immunization service indicating that vaccine demand has been created in towns but not in villages. The NFHS-2 and 3 have shown low coverage in rural population as well as in families with illiterate parents. Do towns and the flourishing private sector provide a clandestine market for EPI vaccines? It should be possible to document the volume of vaccine sales to the private market from the companies themselves and to tally the total coverage through the private sector - and thus explore any discrepancy explainable by black marketing of UIP vaccines. This requires ‘application of the mind’ by the national and state officers of UIP.

Had the design of EPI included even rudimentary disease surveillance for vaccine-preventable diseases, it would have grown and evolved over the 28 yr since inception. During the inaugural function of the new building of the ICMR School of Public Health in Chennai, on October 30, 2006, the Minister of Health of the GoI was reported to have stated that “the national disease surveillance system is outdated and should have been replaced 30 years ago”. He also promised a new system to be functional in two years, giving us much hope for tomorrow, even though belated in time. However, today we cannot measure the benefits of the huge inputs in quantitative terms of the number of cases averted and the financial savings thus accrued. If economic profit is not measured or even understood as output, all inputs may be mistaken as expenditure without returns and not understood as investment for returns. Unless the GoI measures the economic burden of unprevented morbidity and mortality (caused by vaccine-preventable diseases), the benefits of vaccination

<table>
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<tr>
<th>Source of information</th>
<th>Coverage (%) for vaccine</th>
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<tbody>
<tr>
<td></td>
<td>BCG</td>
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<tr>
<td>NFHS 1993²</td>
<td>62</td>
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<tr>
<td>GoI website, for 1991-92³</td>
<td>93</td>
</tr>
<tr>
<td>GoI website, for 1992-93³</td>
<td>97</td>
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<tr>
<td>NFHS 1998³</td>
<td>72</td>
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<tr>
<td>GoI website, for 1996-97⁴</td>
<td>98</td>
</tr>
<tr>
<td>GoI website, for 1997-98⁴</td>
<td>100</td>
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*Third dose of DPT or OPV; Superscripts denote reference numbers.
cannot be counted in economic terms. If UIP is not profitable, there may not be economic justification on the part of the Finance Ministry for increasing investment for inputs, disease surveillance and audit of processes. The lack of health economics expertise is a glaring deficiency in the Ministry of Health and Family Welfare. Anyone would restrict expenditure if it does not bring tangible benefits - so too would any nation. The under-recognition of the true value of immunization (in terms of human suffering and loss as well as economic profit) is one of the root causes of the general neglect of UIP in the country. The poor becomes poorer due to disease - as for families, so for nations. Have we not repeatedly heard the aphorism that immunization is the most cost-effective health intervention? Is that true for India?

The PHC system also reports the numbers of cases of vaccine-preventable diseases. Experts know that the numbers are neither representative of reality nor comprehensive in extent. The reliability of diagnosis is also highly questionable. Many sick children attend private sector health care and the PHC system cannot capture the information. The South East Asia Regional Office of the WHO publishes weekly summary results of vaccine-preventable disease surveillance in the member countries. In 2006, reports of weeks 33, 38 and 42 give the tabulated numbers of all vaccine-preventable diseases relevant to EPI. The statistics of every other country is given, but for India the space is blank in the Table. India is given zero marks for completeness and timeliness of reporting.

I had inspected one teaching hospital in Hyderabad early last year, on behalf of the Medical Council of India. The annual numbers of cases of diphtheria admitted to that hospital were 708 in 2005 (19 died), 825 in 2004 (19 died) and 625 in 2003 (13 died). When I toured Uttar Pradesh to study the polio situation three years ago, in many places the lament was heard repeatedly: “Our children die of diphtheria and measles and you do not give us vaccines. Instead you want our children to take polio drops.” One of the main reasons why polio eradication has not succeeded in UP and Bihar is the very low levels of routine vaccination coverage - a deficiency known for many years, through the NFHS data. Yet, EPI was not strengthened at least for the sake of polio eradication.

In spite of the low national average of vaccine coverage, it is remarkably high in 5 States - Tamil Nadu, Himachal Pradesh, Goa, Kerala and Maharashtra, in that order. If these States are excluded, the national average vaccine coverage would be dismally low. There is high correlation between literacy rates among parents and vaccine coverage - thus the high values in Kerala and Goa may be attributed to high literacy. Since the health system cannot address literacy, this model is non-replicable in poor-performing States. In Tamil Nadu and Maharashtra the literacy rate is <55 per cent and the success of UIP appears to be due to better management and that model is replicable in other States. The GoI must identify the success factors in this model and the failure factors in the poor-performing States and ensure equity across all States.

The world has progressed much since 1978 when India adopted EPI and several newer vaccines have become available. Our UIP continues to use only the original list of 6 vaccines (BCG, DPT, OPV, Measles) but has not included any of the newer vaccines for several reasons, including the lack of (i) measurement of disease prevalence (surveillance); (ii) political will to enhance EPI budget; (iii) understanding of health economics; (iv) proven success (coverage and disease reduction) with the old vaccines; (v) technical leadership (in epidemiology, vaccine efficacy and effectiveness); and (vi) public and professional demand (and mechanism to counter anti-vaccine lobbying).

If we are not able to reach a majority of children in India through the existing EPI services, adding newer vaccines to the EPI list is not likely to achieve much benefit. Until 1990, EPI was ‘centrally
sponsored’ and the estimated national coverage had reached 80 per cent enabling India’s participation in the Summit for Children in New York in 1990. Soon thereafter the central support was restricted to vaccines, injection equipment, and cold chain. The salary of PHC staff responsible for immunization was shifted to State budget. States that accepted the fiscal responsibility sustained EPI, whereas others States that did not, resulting in weakened EPI delivery system. In 2007, we look forward to the re-invigoration of EPI through the National Rural Health Mission, a centrally sponsored scheme to improve the PHC service delivery.

In summary, India’s UIP has too many deficiencies. India must re-examine the structure, functions, performance and funding of UIP. The very low priority given to UIP is reflected in the National Health Policy-2002 which abstained from enunciating a policy on childhood immunization. Thus, a clear policy framework must be enunciated. The relationship and interactions between GoI and State governments need to be re-engineered for efficiency and accountability. Vaccine utilization and vaccination coverage must be monitored and tallied at local levels and cumulated at district level. District level disease surveillance must be established and the vaccine coverage and disease prevalence should be matched for epidemiological evaluation of vaccine efficacy/effectiveness and quality. Every child must have a family-retained health card and every dose of vaccine given - including those given in mass campaigns - must be documented on it. Every institution giving immunization service must also maintain suitable records that could be verified and audited. Information from private sector health care institutions must be captured in district level statistics. Auditing should be performed on UIP inputs and output. As India is developing economically, we urgently need a refurbished 21st century model of EPI/UIP.

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References