

## Situation analysis: new vaccine introduction in an under-performing programme — a dilemma for Pakistan

Fida Shah,<sup>1</sup> Muhammad Bashir-ul-Haq,<sup>2</sup> Kumari Vinodhani Navaratne,<sup>3</sup> Tayyeb Masud,<sup>4</sup> Inaam-ul-Haq,<sup>5</sup> Kees Kostermans,<sup>6</sup> Garry Presthus,<sup>7</sup> Christopher John Clements<sup>8</sup>

### Abstract

**Objectives:** To review the national immunisation programme as a means to providing the government of Pakistan with strategic options for improving the service; to evaluate the impact of the Eighteenth Amendment to the Constitution on immunisation services; and to assess the situation regarding the introduction of new vaccines.

**Methods:** The situation analysis of Expanded Programme on immunisation was conducted from January to May 2011 through a review of available data and literature. The official database and various financial documents of federal and provincial governments were analysed to estimate the programme costs. Interviews were held with key informants, including staff of government immunisation services in all provinces and areas, as well as with United Nations agencies, academics and development partners. Workshops in three provinces were attended by immunisation staff from government and non-government organisations. Views of all participants were recorded and used in to the overall review.

**Results:** The proportion of children who are fully immunised is around 43-62% (depending on the survey and year). But the proportion of children fully immunised within the national schedule by 12 months of age is more realistically as low as 40%. This implies that around 60% of Pakistan's infants are not getting immunised, or are getting immunised late. The cost of introducing any new vaccines will place a huge burden on the resources of Pakistan.

**Conclusions:** There is an opportunity to save thousands of lives by introducing pneumococcal and rotavirus vaccines, but it would be unwise to introduce new vaccines into a system that is not working properly. It makes more sense to invest in correcting the deficiencies in the routine immunisation service before adding the new vaccines.

**Keywords:** National immunisation programme, New vaccines, Pakistan. (JPMA 63: 997; 2013)

### Introduction

Pakistan has faced multiple challenges over the last decade, including natural and man-made disasters, as well as an unstable macroeconomic situation. With a large and still growing population, it is not surprising that the health system has struggled to keep up with this extraordinary demand, and that the Expanded Programme on Immunisation (EPI) has faltered, with persistently low levels of immunisation coverage and failure to achieve polio eradication.

The Eighteenth Amendment to the Constitution of Pakistan was passed by the National Assembly on April 8, 2010, devolving authority and functions from the federal to the provincial governments in 40 areas, including health. The devolution has posed institutional and capacity challenges, and has called into question the

ability of provincial governments to assume effective authority regarding key preventive programme and primary health services, including immunisation.

Despite these concerns, the Amendment is a stimulus, and provides opportunities to re-look at how the immunisation programme can better be managed and what innovations might revitalise immunisation.

But in an era of political uncertainties, insufficient resources and competition for those that are available, introducing anything additional or new to public services must be carefully evaluated for cost and impact before introduction. Part of this wider debate is whether Pakistan's under-performing immunisation programme should introduce expensive new vaccines that would undoubtedly save lives. Plans are in hand to introduce pneumococcal (PCV) and rotavirus (RV) vaccines in the near future.

Pakistan has the eighth highest newborn death rate in the world.<sup>1</sup> In addition, approximately 10 per cent of children born in Pakistan die before they reach their fifth birthday. The infant and child mortality rates in Pakistan were 78 per 1000 live births and 94 per 1000 in 2007<sup>2</sup> respectively, with death rates being particularly high in rural areas where

.....  
<sup>1,2</sup>SoSec Islamabad, Pakistan, <sup>3</sup>SASHN, World Bank, Colombo, Sri Lanka, <sup>4,5</sup>SASHN, World Bank, Islamabad, Pakistan, <sup>6</sup>SASHN, World Bank, Washington DC, USA, <sup>7</sup>Independent Immunisation Consultant, USA, <sup>8</sup>University of Melbourne, Melbourne, Australia.

**Correspondence:** Inaam-ul-Haq. Email: ihaq@worldbank.org

Table-1: Causes of death for children in Pakistan, 2005 (percentages by age).

Cause	Age of child at death			
	<1 month	1-11 months	1-4 years	Total <5 years
Pneumonia	6.3%	25.7%	16.9%	13.3%
Meningitis	0.8%	9.1%	6.6%	4.0%
Diarrhoea	1.0%	26.9%	17.7%	10.8%
Subtotal	8.1%	61.7%	41.2%	28.1%
Other/unknown cause	91.9%	38.3%	58.5%	71.9%
Total	100%	100%	100%	100%
Number of deaths	1,651	788	503	2,043

access to medical care may be limited, and among the poor.

There is no comprehensive system of death registration in Pakistan, leaving an uncertainty about the exact numbers of attributable deaths. According to verbal autopsy reports, about half of all the deaths in post-neonatal children were caused by pneumonia, meningitis or diarrhoea (Table-1).<sup>2</sup> In a recent study, of the 464,886 deaths of children younger than 5 years reported in Pakistan, 84,210 were estimated to be caused by pneumonia.<sup>3</sup> In Pakistan, access to timely and effective treatment for these three conditions may be difficult for households, particularly in rural areas. However, new vaccines offer the potential for averting death and disease for thousands of infants and children each year throughout the country. Two of these vaccines protect against *Haemophilus influenzae* type b (Hib) and pneumococcal infections, both of which cause pneumonia and meningitis; and one vaccine protects against rotavirus, a cause of diarrhoea.

While the need for new vaccines is evident, it is also clear from our review that the EPI would have difficulty supporting their introduction. EPI in Pakistan has been in existence for nearly 30 years, but its performance and coverage have improved only slowly during the last two decades. In addition, its supplementary immunisation programme to eradicate polio has struggled to stop transmission of the virus. EPI provides vaccines against eight diseases (Table-2) to children and one disease to women of child-bearing age through routine immunisation (RI) and against three diseases using supplemental immunisation activities (SIAs). The target groups are children less than 1 year of age for routine immunisation, up to five years of age for polio eradication, nine months to 13 years of age for measles elimination, and women of child-bearing age for tetanus.

The challenge for Pakistan is to strengthen the health system and improve the performance of routine EPI coverage from the current stagnant low rates, while

Table-2: National Immunisation Schedule, Pakistan.

Age	Vaccines	
At birth	BCG and OPV 0	
6 weeks	OPV 1	Pentavalent 1
10 weeks	OPV 2	Pentavalent 2
14 weeks	OPV 3	Pentavalent 3
9 months	Measles	
Second year of life	Measles	

*The national EPI schedule aims to immunize all children between 0 and 11 months against eight vaccine preventable diseases that include: infant tuberculosis, poliomyelitis, diphtheria, pertussis, neonatal tetanus, hepatitis B, Haemophilus influenzae type B (Hib) and measles. Hepatitis B vaccine (HepB) was successfully included in the EPI schedule in 2002 while the combination vaccine (DPT/HepB) was introduced in 2006 and the pentavalent (DPT/HepB/Hib) vaccine in 2008.*

BCG: Bacillus Calmette-Guerin. OPV: Oral polio vaccine.

maintaining high rates of coverage in campaigns. Cognizant of the challenge, the Government of Pakistan (GOP) requested the World Bank to conduct a review of EPI to provide them with policy and strategic options that need to be in place to improve the programme's performance. The objective of this study was to provide the GOP with a review of the salient parts of the national immunisation programme, with an analysis of the current situation and a summary of the barriers to progress.

## Methods

A situation analysis of EPI was conducted from January to May 2011 by two local independent consultants through a review of the secondary literature, with additional input through primary data collection to fill any gaps. The review of secondary literature was based on the analysis of available literature, published and unpublished, federal and provincial governments programme documents, various nationally representative surveys conducted in the last 10 years, studies published by various researchers, and an on-line search of material available from United Nations agencies such as the World Health Organisation (WHO), United Nations Children's Fund (UNICEF). The official databases of the EPI, as well as various financial documents of federal and provincial governments were analysed to estimate the programme costs, human resource deployed and consumer education. The visits to the stakeholders also assisted in capturing their views and perceptions about the strengths and weaknesses of the programme. An overall checklist was prepared for data collection. Questionnaires were used to obtain in-depth information on functioning of the programme and to highlight possible deficiencies in the availability of data/information at federal and provincial levels.

Two international consultants joined the team in Pakistan during May. The team conducted workshops in Islamabad,

Lahore and Karachi when key individuals in the national and provincial EPI were invited, along with representatives of partners. Here the participants were invited to discuss the issues raised by the consultants during their review. During these workshops, the participants themselves offered strategic options for solving the problems faced by them. On June 26, 27, the World Bank hosted a two-day workshop to discuss the findings. Senior officers of the Federal Ministry of Health, provincial and district authorities as well as partners were invited to participate.

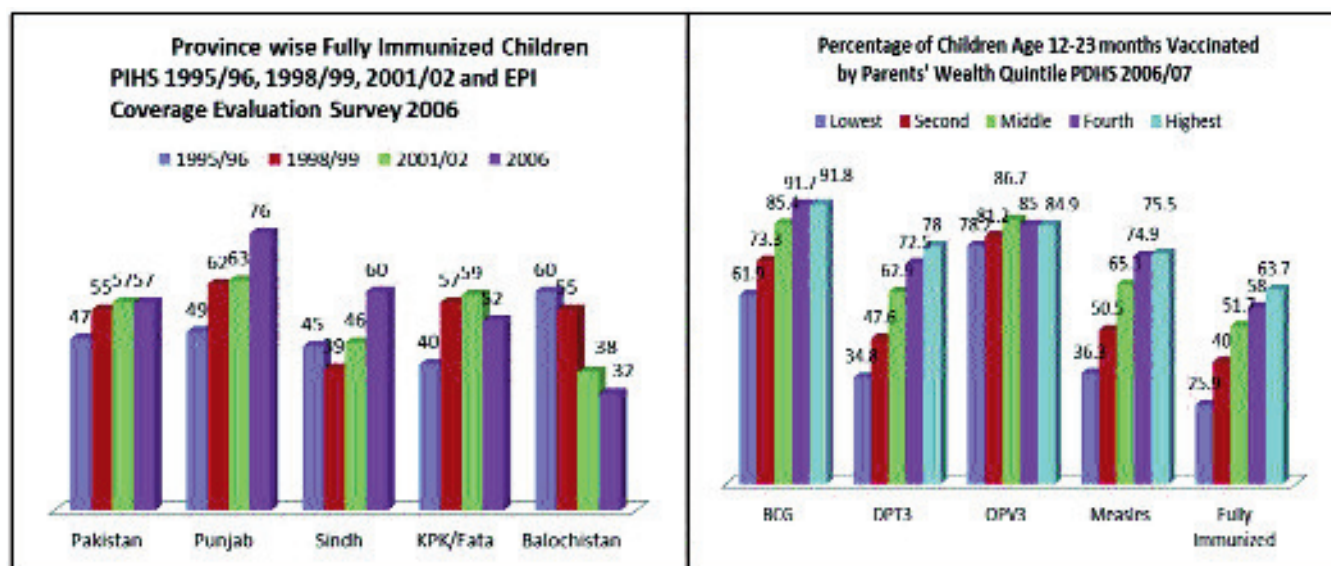
**Results**

UNICEF/WHO best estimates for 2010 indicate coverage of 88% for the third dose of pentavalent vaccine.<sup>4</sup> But this figure conceals troubling details. Immunisation coverage in Pakistan has stagnated, and those in most need are being served least well. A recent household survey (PDHS 2006/7)<sup>2</sup> indicated that the programme had been performing inadequately, with only 47% of children (12-23 months) fully immunised, with large inter-provincial and inter-district variations in coverage, ranging from 14-93%. As well as stagnant growth in the proportion of children immunised, the reported coverage indicates a decrease in the absolute number of children immunised during the last two years another sign that the system is not keeping pace. The proportion of children who are fully immunised is actually around 43-62% (depending on the survey and year). But the proportion of children fully immunised within the national schedule by 12 months of age is more realistically as low as 40% (Figure). This implies

that around 60% of Pakistan's infants are not getting immunised, or are getting immunised late. Vaccines delivered late mean children are being exposed to potential disease for longer than necessary.

The key reasons behind EPI's failure in achieving the coverage targets, as revealed through a literature review and through the interviews conducted by the team, included inadequate number of fixed facilities. Though the national policy<sup>7</sup> recognises that all Union Councils (UCs) should have fixed centres, about one-sixth of them do not actually provide such centres. With insufficient fixed centres to reach the entire target population, outreach and mobile teams are needed to reach the remainder. The outreach strategy faces significant challenges due to lack of detail in micro-plans, weak monitoring, inadequate supervision, and inadequate human and operational resources. Remote and rural communities are mostly served by outreach and mobile teams, thus further disadvantaging those in most need. In a study conducted in Sindh province,<sup>8</sup> the inability of vaccination teams to access remote areas led to many pockets of undetected (and therefore unvaccinated) populations.

Besides, inadequate service delivery, resulting in irregular access and poor service utilization, was found to be the key reason for poor performance.<sup>9-11</sup> Access was limited due to long distances to EPI centers, unaffordable cost to reach the centres, and non-availability of vaccinators. Distance to the health centre was also highlighted in a study conducted in 2009<sup>12</sup> with 30% of mothers reporting



KPK: Khyber Pakhtunkhwa. BCG: Bacillus Calmette-Guerin. DPT: Diphtheria, tetanus, pertussis. OPV: Oral polio vaccine

**Figure-1:** Routine immunisation coverage (fully immunised by 12 months of age) as measured in the Integrated Household Survey (PIHS) 1995/96 and PDHS 2006/07.

difficulty in reaching the nearest health facility from their place of residence. In addition, service delivery is also compromised for internally displaced persons (IDP), nomads, and those in insecure areas.

Another reason was mal-distribution of staff. It is essential to have the required number of vaccinators at the UC level to manage fixed and outreach services, but currently there is a significant mal-distribution of vaccinators. A majority of the vaccinators work more in urban areas than in rural areas with significant provincial variations.

Also, immunisation staffs in post are experiencing increased demands on their time due to an expanding population and an additional workload due to special disease control campaigns such as polio, measles and maternal and neonatal tetanus. There is an inadequate level of demand creation for the use of immunisation services throughout the country, but especially among vulnerable groups. The Coverage Evaluation Survey, Punjab 2003<sup>13</sup> and EPI Coverage Evaluation Survey 2006<sup>14</sup> highlighted that parental lack of awareness about the need for immunisation was the most important reason for low levels of coverage

Cold chain storage capacity and its repair and maintenance, especially at the district level are also issues affecting performance. The new vaccines being offered in single-dose packaging will substantially affect cold storage requirements. With the new vaccines being costly, the need for a proper cold chain and effective supply line is even more important. A credible system does not exist for the repair and maintenance of the cold chain at district level and below. As power failures are likely to be a reality for the foreseeable future in Pakistan, the situation could jeopardise the correct temperature control in refrigerators that store the vaccines in the periphery. The loss of consignments of expensive vaccines to heat damage would be disastrous.

While it is clear that there are some technical problems that need to be addressed in the Pakistan EPI if stagnation in vaccine coverage is to be overcome. Perhaps the most important aspects in need of changing are governance, leadership and accountability. The lack of appropriate leadership throughout the system is having a major detrimental effect on the EPI service.

With the implementation of the Eighteenth Amendment, responsibility for EPI was devolved from federal level to the provinces. As an interim measure, in discussion with all provinces, the procurement of vaccines will be managed at the federal level until 2014 during which period the federal government will continue to provide

resources for vaccines. From 2014 onwards, the allocations will be part of the provincial budget, placing the onus on provinces to procure—a task they have little or no experience of.

The cost of introducing any new vaccines will place a huge burden on the resources of Pakistan. A federal-level decision with technical partners (WHO and UNICEF) has been made to introduce two of the vaccines (PCV and RV) shortly. In a press release from the Pakistan Paediatric Association on December 19, 2011, it was announced that "hopefully by March 2012, pneumococcal vaccine will be available to children free of cost... and 100 million doses will be available".<sup>15</sup> The cost of PCV is high (approximately \$21 per child (\$7.19 a dose) and for RV approximately \$15 per child (\$5.27 a dose) at current costs, compared with three doses of diphtheria, tetanus, pertussis (DTP)/HepB vaccine of around \$2 per child. To give it a perspective, the cost of one dose of is in excess of the government's total commitment of Rs 350 (around \$4) for all health-care for one individual for a year. There are also hidden costs to be considered such as increased cold storage requirements (most new expensive vaccines are likely to be mono-dose vials and bulky).

With the implementation of the Eighteenth Amendment, total financing for EPI is expected to flow from the provincial allocations from 2014 onwards. This becomes a crucial issue if responsibility for vaccine procurement is passed to the provinces. Purchasing will have to be carried out within the provincial allocation, competing with all other financial commitments of provinces.

A recent World Bank study<sup>16</sup> compared the cost-effectiveness and financial implications of introducing PCV, RV, and Hib vaccines in the country. Overall, the study suggested that all three vaccines would be cost-effective in Pakistan with Hib vaccine being the most cost-effective. PCV would have the greatest impact at about 10,300 deaths avoided per year, followed closely by Hib vaccine at about 9,500, and RV with 5,700 deaths prevented. Of these vaccines, Hib vaccine is already included in the pentavalent vaccine that was introduced recently. However, the study also found that the cost implications would be very large for the three new vaccines, amounting to 40% of the national immunisation expenditure, and 15 per cent of government health expenditure. The study suggests that the country should consider the long-term financing implications after support ends from the Global Alliance for Vaccines and Immunisation (GAVI).

Is there enough money in the coffers to pay for new expensive vaccines? With support from WHO, the



Government of Pakistan (GOP) prepared a long-term financial sustainability plan for 2003/12<sup>17</sup> to forecast funding needs for the EPI. But in light of the post-Amendment situation, this forecast may need updating. The total cost of strengthening and upgrading EPI, including the addition of pentavalent vaccine, was estimated at \$1,106 million. The share of the federal and provincial governments was estimated at 22% and 14% of this requirement respectively - 6.4% is already committed by GAVI, while another 46% (\$509 million) is likely to be supported by GAVI for the period 2008/12. The remaining 11% (\$119 million) was planned as support from the other EPI partners, who have collectively supported much larger amounts in the past.

## Discussion

The performance of EPI needs to be improved. Millions of doses of vaccine are delivered successfully by GOP services every year to target populations. But there are tremendous challenges to be overcome in delivering these services; not least the sheer numbers involved, and many children remain unimmunised or under-immunised. As many as 4 in 10 are not fully immunised by one year of age. Those children not receiving current vaccines will likely be the ones who would not receive new vaccines. This raises the question of whether new vaccines would make a difference to the health of those most in need, or would simply help those who are better off. Stagnating immunisation coverage jeopardises the chance of the proper distribution of new vaccines. Continuing routine immunisation as before will not achieve immunisation goals. Nor will it reach those currently unreached by services. New strategies and attitudes are needed across the board. Management of the immunisation programme is often weak and ineffective. New vaccines must be given as early as permissible for maximum impact on disease prevention. The coverage rates are known to be much lower among poorer and rural households across the country - precisely the target groups that would benefit most from the new vaccines. The impact of a new vaccine is reduced if coverage is low and the vaccine only reaches a proportion of the target group. Data collected during this review raise the question of whether it would be appropriate for the programme to add more vaccines before the service is in better shape.

There are political realities that are having an impact on immunisation and the introduction of new vaccines. Pakistan has built up its routine immunisation service over many years, but now is in the process of adapting in the face of major political and administrative changes generated by the Eighteenth Amendment to the

Constitution. There are currently uncertainties surrounding the implementation of this Amendment, particularly in the area of funding. Until now, it has been the responsibility of the federal-level Ministry of Health to procure vaccines. But who will be left paying the bill for procuring both existing and newly introduced vaccines in five years' time - the federal government, the provinces or the donors? Also, the expertise for vaccine purchase is not likely to exist in every province; potentially leading to costly mistakes. The procurement responsibility during the transition period at the federal level is still not fully defined for the total period, but a temporary arrangement to manage it through the Ministry of Inter-Provincial Coordination (MOIPC) has been agreed in 2012. There are clear advantages in maintaining vaccine procurement as a central government responsibility after 2014. This would maintain the financial advantage of bulk purchasing at the federal level and also ensure quality of vaccines and a smooth supply of them to the provinces. In the event that procurement for vaccines is devolved to provinces, before agreeing to introduce any new vaccine, GOP would do well to confirm that all provincial Finance and Planning and Development Departments are prepared to take on funding responsibilities in the years to come when partners may phase out support for procurement of each proposed new vaccine.

There is hope. Even though polio is not yet eradicated from Pakistan, the immunisation community has become extremely skilful at conducting polio campaigns. This expertise has not yet been transferred to routine immunisation services to the same extent. Polio eradication must be expedited so that focus can return to routine services, not just as an end in itself, but to build the correct platform on which to mount all other immunisation activities, including the introduction of new vaccines. One option might be for one or both vaccines to be introduced in selected areas with the highest mortality, gradually phasing in the new vaccine to other geographical areas.

New vaccines offer tremendous possibilities in disease control. But the cost of them will place a huge burden on the resources of Pakistan. We, therefore, urge caution from a fiscal point of view before GOP and provinces introduce any new vaccines. They should recognise the long-term fiscal and programmatic implications of such an introduction, and more importantly, must avoid budget commitments that will be impossible to fulfil in 2-5 years' time.

It is important that discussions on the above issues take place now, as other new vaccines are likely to become available in the coming decade. These may include Human Papilloma Virus vaccine (HPV), human

immunodeficiency virus (HIV), malaria and tuberculosis (TB) vaccines. All are likely to be at least as expensive as RV vaccine. It would, therefore, be unwise for GOP to assume that provinces will automatically agree to purchase the extremely expensive PCV and RV vaccines (or any other new vaccines) down the track, even in the face of any international agreement between GOP and partners or manufacturers.

### Conclusions

Children in Pakistan have the same right to access new vaccines as children anywhere else in the world. Assuming the new vaccines reach children successfully, the PCV and RV each have the potential to save thousands of lives. It is difficult to avoid the conclusion that the vaccines must therefore be introduced, whatever the cost. But it would be unwise to introduce them into a system that is not working properly. It makes more sense to invest in correcting the several deficiencies in the routine immunisation service before adding the new vaccines. The GOP should not embark on introducing any new vaccines until the current political and fiscal uncertainties are sorted out and measures are operationalised to have raised routine immunisation coverage, especially in low-performing communities.

### Acknowledgements

The GOP requested the World Bank to conduct a review of EPI to provide them with policy and strategic options that need to be in place to improve the programme's performance. A report was generated as a response to this request and was conducted as an independent analysis to provide policy and strategic options that could be implemented to increase the program's performance in Pakistan. This article draws on the World Bank Report (The Expanded Program on Immunisation in Pakistan: Strategic options for improving performance. December 2011. World Bank, Islamabad, Pakistan). The authors wish to sincerely thank all those who assisted in providing the information that went into this report and taking time for consultation. Individuals who contributed included staff from the Ministry of Health at Federal level, Federal EPI Manager and his staff, Directors of EPI from Provincial Departments of Health and staff at District levels from the Government of Pakistan, representatives from UNICEF, WHO, JICA, AusAID, DfID and USAID. The authors particularly wish to thank the staff of World Bank in Islamabad for facilitating the work. Thanks also to SoSec

Consulting Services, Pakistan for ably conducting the situation analysis as well as organizing three regional workshops. The World Bank received grant resources from the Global Alliance for Vaccines Initiative (GAVI) to conduct an independent assessment of the EPI Programme in Pakistan.

### References

1. United Nations Children's Fund. State of the World's Children. New York, NY: UNICEF; 2009.
2. National Institute of Population Studies, Islamabad, Macro International, USA. Pakistan Demographic Health Survey, 2006-2007 (PDHS). (Online) June 2008. (Cited 2011 December 24). Available from URL: <http://www.measuredhs.com/pubs/pdf/FR200/FR200.pdf>.
3. Black RE, Cousens S, Johnson HL, Lawn JE, Rudan I, Bassani DG, et al. Global, regional, and national causes of child mortality in 2008: a systematic analysis. *Lancet* 2010; 375: 1969-87.
4. WHO/UNICEF estimate of national immunisation coverage 1980-2008, Pakistan. Geneva: WHO Press 2009. (Online) (Cited 2011 December 24). Available from URL: [http://www.who.int/immunisation\\_monitoring/en/globalsummary/timeseries/tswuc/coveragebycountry.cfm?country=PAK](http://www.who.int/immunisation_monitoring/en/globalsummary/timeseries/tswuc/coveragebycountry.cfm?country=PAK).
5. Federal Bureau of Statistics, Statistics Division. Pakistan social and living standards measurement survey. Islamabad; 2004/05.
6. Federal Bureau of Statistics, Statistics Division. Pakistan integrated household survey. Islamabad; 2001/02.
7. Ministry of Health, Government of Pakistan. Pakistan Millennium Development Goal Report, 2010, Government of Pakistan. Draft National Health Policy, 2010, Islamabad.
8. Mangrio NK, Alam MM, Shaikh BT. Is expanded program on immunisation doing enough? Viewpoint of health workers and managers in Sindh, Pakistan. *J Pak Med Assoc* 2008; 58: 64-7.
9. Faisal A. Understanding barriers to immunisation in Pakistan. Islamabad, Ministry of Health, Expanded Program on Immunisation, 2009.
10. Coverage evaluation survey 2006. Islamabad, Ministry of Health, Expanded Programme on Immunisation, 2007.
11. Hasan Q, Bosan AH, Bile KM. A review of EPI progress in Pakistan towards achieving coverage targets: present situation and the way forward. *East Mediterr Health J* 2010; (16 Suppl): S31-8.
12. Coverage evaluation survey - Punjab 2003. Lahore, Director General Health Services of Punjab, 2003.
13. Expanded Program on Immunisation, Ministry of Health. Coverage Evaluation Survey - Punjab 2003. Lahore; 2003.
14. Expanded Program on Immunisation, Ministry of Health. Coverage Evaluation Survey 2006. Islamabad; 2007.
15. Bhatti MW. Pneumococcal vaccine will be available in country for free by March 2012. *International The News*. 19 December 2011. (Online) (Cited 2011 December 24). Available from URL: <http://www.thenews.com.pk/TodaysPrintDetail.aspx?ID=82032&Cat=4>.
16. Brenzel L, Sanderson C, Galayda V, Masud T, Haq I. Cost-effectiveness and financial consequences of new vaccine introduction in Pakistan. Washington DC, USA: World Bank Publications; 2011.
17. Expanded Program on Immunisation Financial Sustainability Plan 2003-2013 Islamabad, Ministry of Health, Government of Pakistan, 30 November 2003.