

The opportunity and obligation to strengthen national immunization programs

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Summary and recommendations

Vaccine-preventable disease (VPD) control is one of the operationally simplest and financially most cost-effective public health interventions available. Immunization only achieves its greatest potential to avoid illness and save lives, however, when it is extended to all corners of society. New, more expensive vaccines such as pneumococcal conjugate vaccine (PCV) and rotavirus vaccine (RV) are a means to prevent diseases which commonly kill children in impoverished communities. In communities with access to high-quality curative care for pneumonia and diarrhoea, however, mortality from these conditions may already be low. It is essential for these vaccines to reach the hard-to-reach groups. The magnitude of immunization's contribution to the achievement of Millennium Development Goal 4 (MDG4: reduce by two-thirds, between 1990 and 2015, the under-five mortality rate) depends upon our ability to achieve and sustain universal vaccination coverage in all countries and districts and to overcome geographic, political, socio-economic or cultural barriers to effective provision and use of health services.

Despite considerable progress since the inception of the global Expanded Program on Immunization (EPI) in 1974, routine vaccination coverage during the past 5 years (2005-09) fell or remained stagnant at inadequate levels in 21 of the lowest-income countries. Many of the countries, and areas within countries with the highest numbers of unvaccinated or incompletely-vaccinated children, including Chad, Ethiopia, India, Indonesia, Nigeria and Pakistan, also have high under-five mortality rates. In some of these countries, governments do not recognize that coverage is low and thus lack commitment to improving it.

A competently-managed, well-resourced and financially sustainable routine immunization (RI) program provides the platform upon which new vaccines and vaccination technologies can be introduced, elimination/eradication initiatives implemented and other essential interventions delivered successfully. Hence, it is essential for programs to enjoy appropriately skilled and deployed human resources, an uninterrupted flow of vaccines and injection supplies, and a logistics system with appropriately maintained and utilized controlled temperature chain and transport. This infrastructure must be complemented by timely and accurate coverage and adverse events monitoring, VPD surveillance and outbreak response, social mobilization and public and professional Information, Education and Communication (IEC). To achieve and sustain programmatic success, a solid base of political commitment, effective management and reliable financing is required. Countries with this solid foundation have reduced VPD morbidity and mortality to low levels and introduced new vaccines and technologies smoothly to further protect their populations.

At the World Economic Forum in Davos in January 2010, Bill and Melinda Gates announced their unprecedented commitment to realizing the potential of vaccines with a \$10 billion donation for a "Decade of Vaccines". At the same time, they and others continue their commitment to the Global Polio Eradication Initiative (GPEI). As long as Wild Polio Virus (WPV) transmission has not been interrupted worldwide, all polio-free countries and areas remain at risk of re-importation. From 2003 to 2009, the World Health Organization (WHO) recorded 133 WPV importation events in 29 previously polio-free countries, leading to 60 outbreaks and a total burden of 2193 polio cases. The risk of importation with subsequent spread was highest in countries immediately bordering endemic countries, and was also higher in countries with low coverage of routine immunization. There is thus both opportunity and obligation to improve countries' capacity to reduce mortality in communities at greatest need by strengthening their routine immunization programs.

The Bill and Melinda Gates Foundation, recognizing the importance of a strong immunization platform to the achievement of polio eradication and realization of the potential impact of new vaccines, has embarked on a strategic planning process to further define its role in improving routine immunization services. To complement the investments previously made in this area, such as the Africa Routine Immunization System Essentials (ARISE) project being conducted by John Snow, Inc., the Foundation commissioned the authors to undertake a detailed review of vaccination coverage data, review the published and grey-literature evaluations of mechanisms to overcome barriers to raising coverage and improve the quality of routine service delivery, and undertake key informant interviews with experienced national EPI managers and senior staff serving with partner agencies in headquarters, regions and countries.

Our review highlighted that many successful interventions have been documented over the years. Improving program management through a comprehensive, district-based approach such as “Reaching Every District” (RED), conducting door-to-door visits (channeling) to identify and refer eligible children for vaccination at nearby vaccination sites, using flexibility in vaccine delivery through outreach vaccination strategies, use of community health workers, and the deployment of mobile teams into geographic areas with difficult access have all been successful in specific settings, although their costs and cost-effectiveness are less well documented. In recent years, the conduct of media-enhanced Immunization Days or Weeks at national or regional levels (“periodic intensification of routine immunization”) has become common, but the contribution of such efforts to increasing coverage has been poorly documented to date.

There are many tools available to help program managers improve planning and monitoring. These include methodologies for assessing missed opportunities for vaccination, templates for effective micro-planning from districts up to the national level, modules for training health workers, checklists for supportive supervision, tools for assessing vaccine storage and handling, and guidelines for conducting coverage reviews and surveillance assessments, and they have been used with positive impact in many settings. Efforts to increase political commitment, accountability and financial sustainability in developing countries have also been initiated. The risk factors associated with unvaccinated and incompletely-vaccinated children have been documented extensively. With few exceptions, the reasons for chronic under-performance among certain EPI programs are understood and the tools are available to maximize vaccination coverage and the quality of service delivery, but what has been lacking in some countries is **commitment, coordination and management**. When national and district managers lack a solid foundation of management training, the plethora of tools may confuse rather than aid them, and lack of career development opportunities or bureaucratic obstacles to innovation reduce the motivation to use available tools.

We argue that BMGF’s Decade of Vaccines should kick-start investment in management capacity and set the foundation for decades of effective health care. With an adequate project time-frame, a generation of strong managers can be built, with lasting impact on delivery of vaccines and essential public health interventions. Monitoring, learning and evaluation (MLE) of programs to strengthen managerial capacity will help convince countries to take greater domestic responsibility for EPI financing and also to utilize international funding (such as funds for Health Systems Strengthening from the GAVI Alliance) more efficiently. Synergies can be achieved through alignment of our recommended actions with the BMGF-supported Optimize Project and a recent proposal for logistics support and training from WHO to BMGF, and also with the on-going transition of GPEI field staff to monitor and analyze key process indicators on routine immunization service delivery and provide supervision and other support where appropriate. With effective coordination, these projects could make a concerted effort to reverse the chronic under-performance of critical EPI programs.

Our recommendations are divided broadly into two categories: demonstration of best practices in strengthening district health services management, and investing in future generations by improving

education as an incentive to improve health care and a means to raise the standard of human resources for health. The table shows suggested timeframes, critical indicators and approximate budgets for these, and more detail of the activities under each category is proposed below.

Table: Recommended activities and outputs to support routine immunization

Activity & timeframe	Outputs/critical indicators	Approximate Budget estimates
Senior management advisors for MLE in 4 strategic locations for 5 years	In each site, national transport and vaccine supply chain assessments conducted, action plan developed, improved utilization and efficiency documented within 3 yrs and government posts for logistics and transport officers created and filled by year 5 In each site, management tool used at district level and improved coverage of hard-to-reach communities documented Mentoring of trainees and graduates from health management training program done (≥ 10 per site over years 2-5) At least 2 operational research studies done in each site demonstrating cost-effective interventions to increase coverage Where posts are at country level, DTP3 and measles coverage in each country reaches 90% by year 3 and is sustained to year 5 and beyond Immunization is line item in national budget and amount increases over time National personnel develop successful grant proposals to international agencies for continued funding of immunization strengthening	\$5 million (\$1.25 million per site)
Health management training program (5 years)	Program developed (yr 1-2) Students attracted and trained (>30 in year 2, increasing to >100 /yr by year 5) Funding attracted to continue the program	\$15 million (\$3 million start-up; \$1.5 million per year running costs to host institutions and \$1.5 million per year tuition fees years 2-5)
Development and use of practical tools to improve management	Tool developed and piloted (yr 1) Senior managers demonstrate improved effectiveness of service delivery after using tool (yr 2) Tool made available on internet and included in short-term and long-term training courses (yr 3)	\$600,000
Operational research studies (4 years)	Studies completed and results are used to improve program planning and monitoring, and to shape grant proposals for continued funding of cost-effective interventions and strategies	\$10 million
Include management in pre-service nurse and doctor training (3 years)	Training modules developed or adapted and translated into multiple languages (years 1-2) Management training incorporated in basic training in sites where senior personnel located (year 2) Nursing and medical associations recommend inclusion of management training in all countries (year 3)	\$1 million
Investing in education (20	Improved teacher training techniques developed Improved learning techniques for young children developed and	\$100 million

years)	implemented Improved learning techniques for high school children developed and implemented Child-to-child IEC programs implemented Literacy rates increased Demonstration of sustained reductions in neonatal, infant and child mortality by improving educational status of women and communities.	
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• **A. Demonstration of best practices in strengthening district health services management.**

1. *Funding of senior management advisors in 4 key strategic locations for Monitoring Learning and Evaluation of efforts to improve planning, management and monitoring of vaccination at country and regional levels (and eventually of other health interventions). They will participate in activities 2-5 below.*

There are different potential mechanisms to fund staff (e.g. via an international agency such as WHO or UNICEF, or via a non-governmental organization (NGO)), each having potential advantages and disadvantages. In EMR and SEAR, secondment of staff to WHO regional offices with a mandate to focus on specific countries is likely to be effective and appropriate. In AFR, secondment of staff to country level (Ministry of Health, WHO or UNICEF country offices) may be more appropriate to ensure maximum field-based work and MLE. An experienced NGO could be contracted to arrange these secondments and to participate in the other activities below.

Potential locations where we would suggest funding for staff for MLE include:

- A country in eastern or southern Africa which has coverage of 70-80% but has the potential to do more, and where improved management and increased advocacy could make a big difference. Examples include Ethiopia, Kenya, Mozambique, Uganda and Zambia.
- A country in western or central Africa which has had chronically low national coverage (but may have some better-performing districts). Examples include CAR (which is included in the CASE project), Guinea, Liberia, Niger.
- SEAR regional office to focus particularly on India (including disseminating lessons to be learned in the Bihar project), Indonesia and Nepal.
- EMR regional office to cover the 5 larger GAVI-eligible countries which have some of the greatest challenges of geography and security, and ongoing polio transmission or threat of importation, with particular focus on Pakistan.

These personnel will be critical to the implementation of the other components below, and to analyzing, documenting and disseminating lessons learned. They will improve the monitoring of inputs, outputs and impact of programs in under-performing countries. They will demonstrate how to improve the functioning of inter-agency coordinating committees. They will advocate within-country and at regional level for increasing domestic financing for immunization, learning from lessons from the BMGF-supported project conducted by the Sabin Foundation. They will also liaise with WHO, Optimize and Transaid/Riders for Health to advocate for countries to budget for posts in logistics and transport management and to develop and recognize vocational training in these disciplines.

2. *Development of a distance-based program of health management training that combines distance-based theoretical learning with hands-on experience in the field and is tailor-made for low income countries, leading to a diploma (for candidates with no prior university qualifications) or degree (for doctors or other graduates).*

Such a program will develop core skills in planning, budgeting and financial management and accounting, human resource management, logistics and transport management, monitoring and evaluation, communications, grant application and advocacy. It should be predominantly field-based, but with adequate theoretical background through a mixture of distance-based learning and short face-to-face courses. It should be modular, with modules being available as stand-alone training modules for a wider audience (e.g. recent nursing and medical school graduates) that may not yet be ready for the complete masters-level training. It should have optional tracks for practical experience in different areas (e.g. based on running vaccination programs; malaria, TB or HIV control programs, Maternal, neonatal and child health programs etc) so that a wide variety of candidates and of funding sources (e.g. GAVI or Global Fund HSS; British Council; bilateral agencies) will be attracted. It should learn from the experience and approaches used by other long-term field-based training programs such as the EPIVAC management training program for Francophone countries, and the Field Epidemiology and Laboratory Training Program (FELTP) approach to capacity-building. It should also benefit from lessons learned by Sabin Institute in advocacy with developing-country parliamentarians to achieve sustainable domestic financing and accountability for public health interventions including EPI. It should be linked to ongoing mentoring and interchange of experience between graduates, e.g. by linking with Technet, Afenet and other networks. The staff placed in key countries/inter-country posts should act as mentors for the program together with other in-country persons. The development of this program can be done through partnership of schools of public health with organizations working in low income countries and with WHO/UNICEF. Competitive bidding for finance from the Foundation to develop and start-up (say, 5 years initial support including scholarships for students) the program should be sought, and applicants should demonstrate a strategy for attracting other funding to continue the program after this period.

3. Harmonizing existing tools to develop field-friendly, practical tools for conducting situation analyses (“district mapping”), diagnosing the problems, planning and monitoring of essential health interventions at national and district levels.

For this, BMGF could begin by hosting a convening of existing and recent grant-holders and key agencies. The primary aim of the convening is to develop a comprehensive situation assessment and planning tool, and to determine if further harmonization of monitoring tools is indicated and if so, how this should be done. A core group of experts would plan (including development of a draft comprehensive tool) and co-ordinate the convening. Participants could include the following:

- Optimize (logistics and vaccine management tools and monitoring systems)
- Transaid and Riders for Health: transport assessment and management tools
- WHO IVB: comprehensive EPI program review tools, post-new vaccine introduction-evaluation tools, and missed opportunity surveys; experience in developing accreditation programs e.g. laboratories and National Regulatory Authorities (NRAs)
- GPEI: community mapping; developing micro-plans; community involvement; tracking children; monitoring and surveillance
- Centers for Disease Control, John Snow Inc. and WHO AFRO: tools for monitoring and evaluating RED implementation and using this to improve guidelines and strategies; ARISE project lessons learnt to date on drivers of strong RI programs in the African region
- Emory University: Evaluating the knowledge, attitudes and practices of immunization providers in India
- Vaccine Delivery Innovations Initiative – ethnographic methods to understand community perspective on barriers to immunization
- PATH: approach to assessing the performance of organizational systems (current grant) and lessons learned from successful and cost-effective interventions to raise RI coverage and quality (past grants from the Childrens Vaccine Program).

- Agence de Medecine Preventive: implementation of the EPIVAC training program in vaccine management, use of a training network to develop advocacy; experience to date in forming National Immunization Technical Advisory Groups and their role in improving RI
- WHO and UNICEF Regional Advisors: lessons regarding utilization of tools at national and district level and how to ensure that the harmonized tool will be practicable to use.

Once developed, the tool(s) will be piloted in countries where the key senior management personnel (recommendation 1) are located, then further adapted and disseminated. They will also be used as part of the work experience of trainees in the program under (2). In addition, the convening will encourage translation of lessons learned into WHO policies and procedures, for example discussion with WHO IVB of the potential to develop an IVB accreditation program for transport management in a similar way to its accreditation of vaccine stores, NRAs, and laboratories. It will also offer an opportunity to forge relationships between the different agencies and potentially develop a consortium that can implement all five activities under category A.

4. Conduct operational research studies in countries where the senior management personnel are located, and where possible, involving trainees of the management training program and existing FELTP programs, to evaluate the costs and effects of using available tools and approaches to increasing vaccine coverage, including:

- Improved transport and vaccine supply chain management
- Improved situation analysis and micro-planning to reach hard-to-reach populations
- Improved monitoring of vaccine coverage at district level, including the assessment of new approaches such as serological surveys
- Door-to-door canvassing to identify and refer children eligible for vaccination and for other essential health interventions
- Methods to increase community demand for vaccination and improve accountability of health services to communities
- Different combinations of outreach, mobile teams or supplementary immunization activities, according to geographic and other characteristics.
- Evaluation of the impact of PIRIs on coverage

Such studies should be co-ordinated with WHO IVB and regional offices to ensure maximum awareness and use of results for action.

5. Ensure that newly trained nurses and doctors have skills in management of immunization and other programs. Develop or adapt existing modules on modern theory and practice of EPI, including management of the vaccine supply chain and transport, for pre-service training of Medical Officers and Nurses (this component can be linked with activity (2)). Liaise with professional associations such as the proposed African Medical and Nursing School association, to ensure that this training becomes a standard part of medical and nursing schools' basic curricula.

Possibility of an overall package of interventions run by a consortium of NGO-academia-WHO, identified by a request for proposals (RFP).

Since all of the recommendations under (a) are best implemented by groups that combine the field experience of NGOs (local and international), the technical expertise of academia, and the public health leadership of WHO, to ensure maximum synergies between the recommendations they could all be part of an RFP for the formation of a consortium for strengthening national immunization programs. This could be the most efficient process for BMGF, instead of running multiple small projects.

B. Investing in future generations – improvement of education as an incentive for strong preventive health programs and a means to transform their effectiveness

Low educational status of communities and especially of women is a major stumbling block for effective health care. Firstly, studies have consistently shown lower uptake of proven effective interventions including vaccination among families where the mother (and to a lesser but still significant extent, the father) is illiterate. Second, school-based, or “child-to-child” programs offer the potential for delivering a range of interventions to school-children and their siblings. Even in remote areas, there is often a school available in areas where there is no health facility and schools offer contact points for delivering health promotion. Third, new vaccines such as HPV and in future, HIV vaccine will need to be delivered to school-age children and improving the quality of schooling will encourage higher school attendance and facilitate school-based health delivery. Fourth, districts where educational achievement is low have few candidates for professional or vocational training schemes and do not attract good quality health care workers, as trained professionals prefer to live in areas where their own children will have access to education. They are thus stuck in a vicious cycle and do not benefit from advances in other parts of the country. Fifth, the quality of education is poor in many low income countries so that, while having a school-leavers certificate offers access to further training, it does not equate with having the ability to be innovative, self-learning, or problem-solving.

Efforts to assist countries to attain MDG 2 (universal primary school education) mostly focus on increasing access to school. The quality of education, however, also needs great improvement. Modern technology and communications options are expanding rapidly, offering an opportunity to transform the learning experience even in difficult environments. BMGF has invested over \$4 billion in schools and scholarships in the USA, from early learning (preschool) to college preparation, and shown that effective teaching is the most important school-based factor in student achievement. The experience from the USA should be translated into improving learning in poor countries.

We propose that BMGF conduct a demonstration project in at least one country, with simultaneous investment in preventive health care (driven by investment in strengthening RI and bringing along other preventive interventions) and in school education (initially primary school then extending to secondary education), with a predicted lifespan of at least one generation. This length of investment may seem long but to put it in perspective, it is the length of time that Rotary and others have been supporting polio eradication. A program to develop innovative teaching techniques for rural areas should be supported, with training of current teachers and use of distance-based techniques, and adapted over time as technology advances. Health promotion messages would be an important part of the curriculum. Tools, techniques and lessons learned from the project would be disseminated over its course.

Beginning investment today to transform the learning experience of school-entry children means that within ten years, a generation of literate school-children would enter their reproductive years able to access and understand information, and by then strengthening secondary education, some of these children will become the next generation of teachers. Within 20 years, the impact of high literacy and education on sustaining immunization coverage in the next generation can be measured. Additional aspects could be addressed and evaluated, such as giving incentives to mothers when their children complete the immunization series, for example paying the costs of school attendance through primary school. Since the project would mainly be investing in improving methods and quality, it should be self-sustaining as other sources of funds would be used for the “bricks and mortar” component and staff would be paid by government (but incentivised by access to improved tools and technology and mentoring by project staff).

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Background information

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1. Introduction

Immunization is one of the most cost-effective interventions available to improve health. In GAVI-eligible countries, traditional vaccines against tuberculosis, diphtheria, tetanus, pertussis, polio and measles have the potential to save 4.5 million lives worldwide each year (WHO, 2010a) at an average cost of US\$24 per fully vaccinated child (Wolfson et al 2008). This astounding potential will only be realized, however, if vaccines reach the communities at greatest risk of dying from vaccine-preventable infections.

Infant and child mortality rates are highest in sub-Saharan Africa, where only two countries (Eritrea and Malawi) are on-track for Millennium Development Goal (MDG)4,¹ and 11 countries have made no progress in reducing child mortality since 1990 (Bhutta et al 2010). They are also high in impoverished communities of Asia and the Middle-East, where despite impressive overall progress, child mortality remains unacceptably high among residents of hard-to-reach and under-served communities. Studies have shown that certain groups are missed by all health interventions, so that while the majority of a population may benefit from powerful health technologies, those in greatest need receive none (Victora et al 2005). Although global immunization coverage is high (82% in 2009 according to WHO-UNICEF estimates of national immunization coverage (WUENIC) – Fig 1), coverage has stagnated at $\leq 80\%$ levels or fallen in 21 GAVI-eligible countries between 2005-9, often in the very areas with highest child mortality rates. Assumptions about the benefit of the introduction of new and underutilized vaccines (e.g. Sinha et al 2007) are over-optimistic unless national immunization programs are empowered to reach high-mortality communities.

At the World Economic Forum in Davos in January 2010, Bill and Melinda Gates announced their unprecedented commitment to realizing the potential of vaccines with a \$10 billion donation for a “Decade of Vaccines”. At the same time, they and others continue their commitment to the achievement of polio eradication. The investment, and the skills being developed through the Global Polio Eradication Initiative (GPEI), offer renewed opportunities to improve countries’ capacity to reduce mortality in communities at greatest need. To date, these potential opportunities have not been seized.

New, more expensive vaccines such as pneumococcal conjugate vaccine (PCV) and rotavirus vaccine (RV) are a means to prevent diseases which commonly kill children in impoverished communities (Cutts et al 2005, Parashar et al 2009). In communities with access to high-quality curative care for pneumonia and diarrhoea, however, mortality from these conditions may already be low (Klugman et al 2003). It is essential for these vaccines to reach the hard-to-reach groups. GAVI Alliance supports low income countries to introduce more expensive vaccines under the expectation that countries will take responsibility for purchasing these vaccines when GAVI support ends in 2015. There is thus an obligation to ensure that countries accelerate efforts to reach the most under-served communities in a systematic and sustainable fashion.

The GPEI has recognized the importance of strong routine immunization programs. In settings where the national OPV3 coverage rate is $>80\%$, indigenous polioviruses are more rapidly interrupted, there is a statistically lower risk of having a polio outbreak following a wild poliovirus importation, and there appears to be a lower risk of both the emergence and spread of circulating vaccine-derived

¹ On track defined as mortality rate in children younger than 5 years of less than 40 deaths per 1000 live births, or less than 39 deaths per 1000 live births plus average annual rate of reduction (AARR) higher than 3.9%; insufficient defined as under-5 mortality rate greater than 29 deaths per 1000 live births plus AARR between 0.9% and 4.0%; no progress defined as under-5 mortality rate greater than 29 deaths per 1000 live births plus AARR lower than 1.0%. Ethiopia, Mozambique, Niger come close to an AARR of 3.9% but still have high mortality (104, 130, 167 per 1000 live births, respectively)

polioviruses (cVDPVs) (WHO 2010b). In addition, it is anticipated that during the final stages of global eradication, some countries will switch to using inactivated polio vaccine (IPV) alone or in combination with OPV, to obviate some of the problems associated with OPV including low vaccine effectiveness in certain settings and the risk of vaccine-associated polio. IPV will likely be delivered through RI services, possibly as a combined hexavalent or heptavalent vaccine. Since IPV alone does not provide indirect protection to contacts, very high coverage is needed to sustain population immunity to polio. For that, strong national immunization programs must be built and sustained.

A national immunization program needs to develop appropriate policies, select appropriate strategies to implement those policies, monitor and evaluate implementation, and modify policies and strategies according to the findings. At global and regional levels, inter-agency coordination committees (ICCs) and national immunization technical advisory groups (NITAGs) assist governments to formulate policies, in part with support from BMGF. Having appropriate policy is a good first step but action is also needed to ensure that those policies are disseminated, accepted, and followed.

Recognizing the importance of a strong immunization platform, the BMGF has embarked on a strategic planning process to further define the role of the foundation in improving routine immunization services. To assist in this effort, BMGF asked the authors to help analyze options for foundation investment in this area. This work will complement the investments previously made in this area, such as the Africa Routine Immunization System Essentials (ARISE) project which is examining factors contributing to strong immunization programs in the African region and is being conducted by John Snow, Inc. We reviewed data on trends in immunization coverage since 2000 among GAVI-eligible countries as reported by governments to the World Health Organization (WHO) and the WUENIC estimates of coverage. We gathered information on current strategies and approaches to organising routine immunization and risk factors for low vaccine coverage from the published and grey literature, regional and country plans of action and progress reports, and presentations by national EPI managers and regional and country staff of WHO, UNICEF, PATH and the U.S. Centers for Disease Control (CDC) to international and regional WHO immunization meetings. Interviews were conducted with immunization staff at WHO headquarters, with WHO regional staff and country EPI managers in SEAR and EMR, and with CDC. Structured questionnaires were used in these interviews, to determine past experience and current policies and strategies being used to strengthen routine immunization in low income countries. This was complemented by discussions on specific topics, e.g. transport for health, vaccine supply chain management, with experts in these areas. To avoid duplication of effort with the ARISE project, only two EPI managers in the African region were interviewed (Ghana and Kenya), and results of stakeholder interviews conducted by the ARISE project were reviewed rather than re-interviewing the same experts.

2. Coverage among GAVI-eligible countries in 2009 and recent coverage trends

Table 1 shows trends for DTP3 coverage among GAVI-eligible countries since 2000, according to WUENIC estimates for 2009 (data downloaded 5 August 2010). DTP3 coverage (often taken as an indicator of utilization of vaccination services) is compared to DTP1 coverage (an indicator of access to health services) and the dropout between the two vaccines, expressed as a percentage of DTP1 coverage, is shown. Countries are arbitrarily classified into four groups: those with high (>80%) and relatively stable coverage since 2005; those with medium coverage (60-80%) in 2005 and/or 2009; those with a marked increase in coverage between 2005 and 2009 (some of which began the increase prior to 2005); and those with ongoing low coverage.

Less than one-third of GAVI-eligible countries have had stable coverage levels for at least 4 years that are close to or above the GIVS target of 90% for DTP3 and MCV1 (MCV1 data not tabulated). In AMR, EUR and WPR, most countries have high coverage, exceptions being Haiti (low) in AMR;

Azerbaijan (medium) in EUR, and Lao PDR and Papua New Guinea (low) and the small islands of Kiribati and the Solomons (medium) in WPR. The birth cohorts in countries in AMR, EUR and WPR that have not yet sustained high coverage are very small. There are several countries in AFR and EMR with low or medium coverage, however, and of these Nigeria in AFR and Sudan in EMR have the highest birth cohorts; Chad and Somalia while having much smaller total populations also have large numbers (>200,000 each) of unvaccinated children. In SEAR, while most countries have high coverage and only Timor-Leste has low coverage, among those with medium coverage are India and Indonesia with very large birth cohorts, and therefore the highest numbers of unvaccinated and under-vaccinated children are in SEAR.

Countries with higher DTP3 coverage tend to spend more on health, as shown by total health expenditure (THE) per capita, though with some exceptions. For example in AFR, Burundi has very low THE but high coverage, whereas Equatorial Guinea has very high THE but low coverage. THE in other regions is generally much higher than in AFR although it is surprisingly low in Myanmar in SEAR and in Pakistan (EMR) which have high coverage.

Several countries (Afghanistan, Angola, Congo, Democratic Republic of Congo (DRC), Ethiopia, Madagascar, Myanmar, Nepal, Niger and the Sudan) have greatly increased coverage in the last 4-8 years despite low overall THE, including countries classified by GAVI as fragile and containing substantial populations that are internally displaced due to conflict (Table 2). Some, but not all of these countries have received substantial official development assistance for child health, including GAVI Immunization Services Support (ISS) funds. Most of the 9 countries with low coverage for DTP3 and low or medium coverage for DTP1 over the last 4 years or more are classified by GAVI as “fragile” or “poorest” states. The exceptions are Papua New Guinea and Nigeria which are lower middle income countries.

In most countries with medium (60-80%) DTP3 coverage in 2005 and/or 2009, DTP1 coverage is high and the main problem is high dropout between these vaccines. This is also the case in some countries with low or increasing coverage. This suggests that health service delivery factors may play a large role in the failure of children to complete the vaccination series. Other major health service delivery factors recognized as important include vaccine stock-outs (see section 6), to which for example a decline in coverage in Kenya in 2008 was attributed (http://www.who.int/immunization_monitoring/data/ken.pdf, accessed 6 August 2010).

Some countries continue to have large differences between government reports of coverage and WUENIC estimates, and as shown in the table, this appears particularly so in countries with low or medium coverage (e.g., 22-52 percentage points difference in the two sources in the 5 African countries with low coverage). This is potentially a major problem because if governments are unwilling to recognize that coverage is low, they are unlikely to design or fund interventions to increase coverage. Data for India are not shown because the government official coverage data for 2009 are not yet available but in 2008, India reported DTP3 coverage 18 percentage points higher than the WUENIC estimates.

Most of the countries which have markedly increased coverage in recent years show good concordance between government reports and WUENIC best estimates (Table 1), though with important caveats. The WUENIC process can only lead to improved estimates if alternative sources of data to administrative reports are available for comparison, and/or if there have been audits of the quality of the administrative data. In countries affected by conflict, often no national population-based surveys are conducted and hence the WUENIC process has little way to verify data. For example, in Afghanistan, the detailed country report (http://www.who.int/immunization_monitoring/data/afg.pdf, accessed 6 Aug 2010) shows that no survey data have been used since 1999, as the one survey conducted in 2006 excluded children without vaccination cards and hence data were not considered valid. Therefore, the WUENIC

estimates are based on the coverage reported by the government. Similarly, among those shown in the table as increasing coverage, WUENIC have recommended that nationally representative, high-quality surveys be conducted in Angola and Sudan due to uncertainties about the reported data and lack of recent surveys in those countries.

3. Current approaches to the delivery of vaccination

Vaccination may be delivered at a variety of sites, using strategies that range from fixed sites to outreach, to mobile teams, to campaigns (Box 1).

Box 1: contact points and delivery strategies for vaccination

Fixed sites: health facilities (HF), e.g. hospitals, health centers, health posts: usually vaccinate at least one day a week; frequency depends on catchment population size

Outreach sites: visited regularly (weekly, monthly, or less) by health staff, usually from the nearest fixed site who return the same day. Vaccination may be done at a health post, school, community building, or community representatives' house.

Mobile teams: teams travel and stay at least one night in remote locations. May administer vaccines at outreach-type sites and/or do door-to-door vaccination.

Campaigns: mass immunization activities e.g. polio national immunization days (NIDs); supplementary immunization activities (SIAs) for measles, tetanus toxoid, yellow fever, etc. Vaccination done during a short period of time via multiple teams that vaccinate at community and/or household levels. Often with expanded age ranges for eligibility.

To strengthen routine immunization services, WHO recommends that countries use the Reaching Every District (RED) approach², a bottom-up approach to district-based planning of immunization and other health services based on data, which was launched in the African region in 2002 (http://www.who.int/immunization_delivery/systems_policy/red/en/index.htm).

Box 2: The RED approach to organizing vaccination and other health services

Initially developed for use in districts with low immunization coverage and subsequently promoted for nationwide use.

Intended as a broad-based approach to planning and delivering routine immunization, with 5 main components:

- Re-establishment of outreach services (now “reaching target populations” in AFRO)
- Supportive supervision
- Enhancing community links with service delivery
- Monitoring and use of data for action
- Improved planning and management of resources, with community involvement

² Microplanning for immunization service delivery using the Reaching Every District (RED) strategy. WHO/IVB/09.11 World Health Organization, Geneva 2009

In 2007, WHO, UNICEF, CDC and IMMbasics reviewed progress toward improving immunization services and coverage in 9 countries (Benin, Cameroon, Democratic Republic of the Congo (DRC), Ethiopia, Ghana, Madagascar, Sierra Leone, Togo and Uganda) which had implemented RED for at least 24 months (Box 3). The evaluation showed substantial progress in implementing RED, but an uneven emphasis on its different components and in general, an over-emphasis on the extension of outreach services without sufficient attention to strengthening the planning, management and monitoring of services. In most of the 9 countries, coverage had increased, but cause and effect could not be attributed (Figs 2a-2i). RED had been scaled up using multiple funding sources, including GAVI discretionary funding in 8/9 countries evaluated, and there were concerns about sustainability if Immunization Services Support (ISS) is discontinued. Following the evaluation, the revised AFRO guide (WHO 2007) incorporates “best practices” and “lessons learned”, and gives more emphasis to planning, management and the use of monitoring data, and to reaching all target populations using a mix of sites, not just outreach. In Sudan, RED implementation is considered a success story, with capacity building for improved microplanning, monitoring and evaluation, and investment in the cold chain and transport. Within northern Sudan, the degree of coverage increased correlated with the score for the level of implementation of RED (Ryman et al in press).

Box 3: Main findings from RED evaluation (WHO 2007)

Outreach: had increased in most countries and was most strongly identified component (health workers often get allowances), usually integrated with other health services. Problems:

- communities not involved in scheduling in 67% instances
- vaccination data often not disaggregated by outreach vs fixed sites
- transport difficulties caused cancellation in ~25%

Planning: microplans common, but lacked details on:

- catchment area - maps missing, don't identify outreach sites & hard-to-reach populations
- plans lacked strategies for reaching the hard-to-reach

Vaccine management: Stockouts of DTP frequent at district and Health Facility (HF) levels

Stockouts meant parents turned away (50% HF) or session cancelled (25%)

Few staff had recent training and high staff turnover

Linking services with communities: had improved;

66% HFs reported regular meetings and 74% had trained community volunteers
Volunteers could be used more to identify/register/track pregnant women and newborns

Supportive supervision: in 65% district workplans (usually integrated), but many problems:

- many planned visits cancelled
- integrated checklists lacked details on immunization
- time for supervision insufficient with little observation of practices
- little documented feedback
- inadequate follow-up on recommendations

Monitoring for action: most districts displayed monitoring charts and had data review meetings, but:

- inadequate understanding of the meaning of the charts at HF level
- inaccurate denominator data in half HFs
- creation of new districts increased difficulties for catchment populations
- desk review found data quality problems
- defaulter tracing methods inadequate

Increasingly, countries are also conducting Periodic Intensification of Routine Immunization (PIRI) activities for advocacy and/or for vaccination. These often include other child health interventions such as vitamin A distribution to children under age 5 years. Multiple terms have been used including “child health days/weeks”, but increasingly the term “immunization days/weeks” (or “vaccination weeks”) is used. PIRIs have been grouped into two broad types (WHO 2009):

- Service Delivery Together with Information, Education, Communication (IEC) and Social Marketing. Done where routine coverage low. Instigated jointly by e.g. nutrition (Child Health Days for vitamin A), immunization, malaria programs to provide a few selected services or commodities to an expanded population.
- IEC/Social Mobilization with only selective service delivery to reach pockets of underserved populations. E.g. Vaccination Week in the Americas and European Immunization Week – generate and sustain high-level and community support, +/- provide specific vaccines such as rubella and yellow fever SIAs.

UNICEF (2006) and WHO (2009) have conducted desk reviews of experience with PIRIs (Box 4).

Box 4: Main findings from reviews of PIRIs

UNICEF (2006) reviewed experience of Child Health Days in 6 African countries in 2006:

- CHDs raised vitamin A coverage by between 15-90 percentage points
- Deworming was popular among mothers
- Effect on measles vaccine coverage varied and CHD effect lower in infants <1 yr
- CHDs may miss same children as do RI services (e.g. rural, poorly educated)
- Bednet coverage was lower
- Very little IEC was done and community support varied widely
- Duplication of effort – co-ordination between programs needs improving
- Monitoring and quality improvement systems are needed

WHO and partners review of PIRIs (WHO 2009)

- Need to be planned with ≥ 6 months lead time
- Budget underestimated especially for reaching hard-to-reach and stakeholder engagement
- Immunization targets not defined in terms of contribution to coverage
- Recording of doses administered major problem
- Supplies and logistics management difficult especially when multiple commodities
- Cascade training didn't work well – better methods needed, including easy-to-use job aids
- Supervision needs improving
- High visibility and support for PIRIs could be used more to encourage use of RI services
- Could use PIRIs better to identify characteristics of underserved populations and design service delivery strategies both for PIRIs and RI

From interviews we conducted with EPI managers in EMR, we found that RED and PIRIs are the main strategies being promoted to increase coverage in the countries with the greatest numbers of under-vaccinated children. Many areas within GAVI-eligible countries in EMR are reliant on outreach, mobile teams and SIAs or PIRIs because access and security problems make it difficult to establish fixed sites. GAVI ISS funds have been used extensively to fund outreach in EMR. In Afghanistan, non-governmental organizations (NGOs) have been used extensively to deliver and fund vaccination services. Yemen plans to use ISS funds to equip more health facilities. There are

concerns that coverage is starting to decline as ISS funds end, leading to a heated debate regarding sustainability.

Informants interviewed in EMR feel that PIRIs are especially valuable in countries with poor infrastructure. Two rounds of maternal-child-health weeks and one immunization day have been conducted in Pakistan and Sudan since January 2009; Afghanistan and Yemen will conduct their first National Immunization Week in 2010. Reported disadvantages are their cost, disruption of other services (e.g. cancellation of outreach in Pakistan during PIRIs) and suboptimal monitoring and evaluation. An evaluation of the cost-effectiveness of PIRIs is planned in Somalia.

Vaccination weeks are considered successful in the Americas and the recent combined PAHO-EUR-EMR vaccination week was very popular among regional WHO staff and the country EPI managers interviewed (though there are no data on their effect on overall coverage). In low-resource settings, however, the problems experienced with the campaigns conducted during the drive for Universal Childhood Immunization in the 1980s (UNICEF 1996) are being faced. In crowded sites, it is often difficult to screen individual children to provide the correct antigen and dose, and there may not be access to the clinic registers since so many different outreach sites are vaccinating simultaneously. Thus, the registers may not be updated appropriately making future tracking of vaccinations difficult.

The specific use of PIRI or RED strategies has been less evident in SEAR. Only Nepal holds an annual Immunization Month, during which vaccination is offered daily at fixed sites rather than the normal weekly sessions, and intensive community mobilization is conducted by teachers and female community health workers. District-level microplanning using some or all of the RED approaches has been used widely.

SEAR has 6 GAVI-eligible countries – Bangladesh, India, Indonesia, Myanmar, Nepal and Timor-Leste; of these all but India and Indonesia have made significant progress in the past 15 years. According to our interviews, high-coverage countries and states/provinces within countries have a culture of obligation to and accountability for providing adequate health service delivery to fellow-citizens, strong management with close monitoring and feedback, and good governance practices. Career development is merit-based and initiative is rewarded. As a result, health workers are committed and have increasingly adopted the culture of using coverage and surveillance data for decision-making, undertaking frequent and high-quality monitoring and supervision, and implementing the recommendations of evaluations. In Bangladesh, ISS funds have been used to improve district management and provide incentives to community volunteers in low-coverage areas for community mobilization and defaulter tracing, in addition to strengthening the cold chain. Community or 'immunization volunteers' are 'posted' as time-limited strategies to fill vacant government posts until the vacancy is filled. In 2009, they numbered roughly 1,500-2,000 in total and their total annual cost was US\$300,000-400,000. In urban areas, a variety of methods have been used to reach the hard-to-reach in SEAR. Bangladesh has been particularly innovative in this respect, working closely with local NGOs (Uddin et al 2009). UNICEF has piloted different approaches in India. In both countries, community volunteers are used to track children and encourage mothers to attend vaccination at NGO or public clinics.

Overall, we conclude that PIRIs and mobile teams may be most appropriate in areas of difficult geographic access or those with low security. If conducted well, PIRIs can be used to increase advocacy for immunization, as in the Americas. The effect of PIRIs on coverage, especially among children who do not attend ongoing clinic-based vaccination, has not been adequately demonstrated, however. These concerns, and some of the findings from the RED evaluation in AFR, suggest that some countries have over-emphasized outreach and campaign-style activities, and not given enough attention to improving management and increasing the effectiveness and efficiency of existing services (see sections 5 and 6 below).

4. Who are the under-served and hard-to-reach?

There are substantial published data and three recent reviews³ on characteristics of children who do not receive DTP1 (“unvaccinated”) and those who begin vaccination but do not complete the series (“under-vaccinated” children). There are a series of barriers at health service, family and community levels to initiating (Box 5) and completing (Box 6) the vaccination series. One of the most consistent findings is the association of low coverage of vaccination and other health interventions with education, particularly female education. This increases the difficulty in attaining high coverage in some GAVI-eligible countries. In EMR, for example, female adult literacy is only 12.6% in Afghanistan (second lowest in the world after Niger); 39.6% in Pakistan (16th lowest) and 40.5% (17th lowest) in Yemen. Geographic barriers (mountains, floods), migrant populations, and security constraints are also common barriers in the GAVI-eligible countries of EMR and to a lesser but still important extent in SEAR and many African countries.

Box 5: Characteristics of families whose children are unvaccinated

- Have the poorest or poor socio-economic status (e.g. urban slums, rural areas)
- Are poorly educated (especially the mother)
- Do not use maternal-child health services (e.g. child born at home, mother no TT)
- Live in conflict-affected areas or have recently migrated from these
- Live in rural areas (not all countries), with increased distance from health facilities
- Belong to an ethnic or religious minority (some countries)
- Lack maternal decision-making power (some countries)
- Lack time (e.g. mothers work outside the home in urban or rural areas)
- Lack funds (e.g. formal or informal user fees discourage attendance)
- Have large families (in some countries)
- Belong to, or live among, communities which are anti-vaccination
- Do not understand the importance of vaccination

Failure to complete the primary vaccination series is associated with many of the above factors plus health systems barriers such as those in box 6.

Box 6: health service barriers to completing the immunization series

- Missed opportunities to vaccinate children who attend contact points, due to:
 - stockouts
 - concern about vaccine wastage/number of injections
 - perceived (false) contra-indications
- Cancellation or delays of planned vaccination sessions including irregular outreach e.g. due to transport failure; cold-chain failure; stockouts; absence of staff; strikes etc
- Negative rumors or publicity against vaccination (in general or specific vaccines)
- Poor understanding by parents of the need to return or when to return
- Bad experience at a previous health center or outreach attendance, e.g. informal or formal user fees; discourteous treatment by health workers; fear of reprimand if child’s vaccination record lost or damaged; previous adverse reaction eg BCG adenitis or post-vaccination abscesses; and long waiting times.

³ The Centers for Disease Control and Prevention reviewed the published literature from 1999-2009, including 209 articles in the final review, and IMMUNIZATIONbasics reviewed the grey literature and summarized 130 documents written after 1980 in a report to WHO in 2009. The Swiss Tropical Institute (STI) in 2009 analyzed the association between family characteristics and one of two outcomes: “access” (receipt of at least one vaccine versus no doses), and “utilization” (fully immunized child versus received at least one dose but not fully immunized), from a total of 242 Demographic Health Surveys (DHS) or Multiple Indicator Cluster surveys in 97 countries.

The potential negative effect on vaccination coverage of real and suspected adverse events following immunization (AEFIs) may be increasing, especially in the European and south-east Asian regions. As immunization coverage increases and VPD incidence and mortality declines, perceived adverse events grow in importance relative to the burden of disease. This may be exacerbated by negative publicity from the media, proponents of alternative medicine and opportunistic politicians. Urban elites in middle income countries from South Africa to Saudi Arabia are accessing anti-vaccination websites and losing confidence in routine immunization. Rare cases of AEFIs are publicized before full investigation, and the deterrent effect is difficult to overcome even when investigation reveals no causal association with vaccination. Suspect AEFIs have led to suspension of vaccination in 3 separate recent incidents in India, one of which was accompanied by jailing of vaccination staff, and in Bhutan, Myanmar and Sri Lanka, in the last 5 years (Unpublished data from SEAR WHO regional office). In Bihar and Uttar Pradesh states in India, 20% and 17%, respectively, of mothers surveyed whose infants had not received DTP3 reported fear of AEFIs (SEAR WHO unpublished data).

WHO has initiated efforts to analyze the capacity of Ministries of Health (MoH), in countries that have not already done so, to respond effectively to this challenge. All reported AEFIs should be investigated promptly, causality should be established by an independent team of experts, and rumors spread by the media and others neutralized quickly to reinforce public confidence in immunization. This initiative is essential and where possible should be accelerated. BMGF has recently funded a project to raise public confidence in immunization programs by better understanding public perceptions of vaccines. A vaccine rumor surveillance system will be established and a diagnostic tool developed to determine the characteristics, scale and timing of vaccine rumors— i.e. the threshold – when intervention is needed to protect public trust in vaccines and prevent possible vaccine refusals.

In addition to these specific causes of un- and under-vaccination, from interviews conducted for this work we conclude that over-arching requirements for high coverage are strong political will, good governance, strong leadership and management, and close monitoring of inputs, outputs and impact of the program with feedback of results and action according to findings. For example, we were informed that the health sector in low-coverage states/provinces of SEAR is characterized by weak leadership, poor accountability and low staff motivation. Bureaucracy is allowed to obstruct progress and in some cases senior staff is unwilling or unable to resolve obstacles to improve performance. Career development is limited and not necessarily merit-based. There is no shortage of qualified staff, but huge numbers of health worker posts remain vacant and turnover in filled posts is high. Encouragingly, one interviewee informed us that this situation is improving in at least one of the northern Indian states. In Indonesia, firm commitment to resolving the stagnation in RI coverage has been announced by the Minister of Health (presentation to the SEAR EPI managers meeting 2010), with a renewed emphasis on improved outreach services, increasing community involvement, reducing dropouts especially in densely populated areas, improving monitoring, data analysis and feedback, conducting advocacy via a “road show” in low coverage and highly populated provinces, giving incentives (bednets) to mothers whose children are fully vaccinated, and giving rewards for the best performance among health providers, with the goal of achieving universal coverage by 2014. This was coupled with a Presidential decree requiring inter-sectoral collaboration and provincial accountability for performance.

5. Summary of literature reviews on the effectiveness of interventions to raise coverage

Missed opportunities should be reduced.

In the 1980s, a standard EPI protocol was used widely and studies found that missed opportunities to immunize were universal. A review of 69 studies in 1993 found that if opportunities to immunize had been taken in the specific populations and health services studied, immunization coverage would have increased by a median of 32 percentage points (Hutchins et al 1993). Population-based studies suggested an increase by a median of 22% (range, 3-77%), while health-service-based studies indicated an increase by a median of 44% (range, 0-80%) among clinic attendees. Missed opportunities to vaccinate women with tetanus toxoid were even more common. Nine intervention studies evaluated the effectiveness of interventions to reduce missed opportunities, and all showed a decline in missed opportunities, although in most studies multiple interventions were implemented at the same time. There has been less focus on reducing missed opportunities in the last decade, as more attention has been placed on reducing wastage rates of newer, more expensive vaccines. It is possible that missed opportunities are more common now that most countries allocate only one or two days a week for vaccination at fixed centers. Mothers of children who attend on other days and are asked to return on the vaccination day may not bring those children back. Evaluation of the cost-effectiveness of interventions to use all opportunities to vaccinate is needed.

Use of community health workers and channeling are cost-effective

In the last decade, four systematic reviews of studies to evaluate the effectiveness of interventions have been published; two of these also included an assessment of costs (Batt et al 2005, Pegurri et al 2005; Ryman et al 2008; Shea et al 2009). Published studies in the 1980s and early 1990s (Batt et al 2005, Pegurri et al 2005), when mean baseline coverage among fully-vaccinated children (FVC) was 34% (range, 3-65%), showed that the interventions with the highest impact were use of community health workers and channeling (also called door-to-door canvassing by community volunteers and/or health workers, to identify and refer unvaccinated and under-vaccinated women and children to the nearest fixed or outreach site). The strategies with the lowest average incremental cost per FVC were peer training and channeling. Cost-effectiveness was higher when community health workers were used than when more highly trained health workers were used for channeling. The use of community health workers has more recently been highlighted in a review by Haines et al (2007) showing their role in a range of preventive and curative interventions and the potential to integrate vaccination with other interventions.

Costs and effectiveness of outreach, mobile teams and campaigns vary but outreach may be most expensive

Importantly, given the current emphasis on RED, Pegurri et al (2005) found that the average incremental costs of outreach teams were higher than those of campaigns and both were higher than those of fixed centers. Average costs per dose of vaccine delivered and per FVC were higher for campaigns than for routine services in three countries, but campaign costs varied 30-fold between countries.

Use of mass media, community-based Information, Education and Communication, giving incentives, and training health workers to improve communications may be effective

Shea et al (2009) extended literature reviews to 2008, with a focus on interventions assessing demand for vaccination. A total of 8 papers met their criteria for inclusion, of which two were published after the previous systematic reviews. A study in Bangladesh (Hutchinson 2006) evaluated the effects of a communication program that included national television drama series, TV and radio spots, newspaper

and local publicity. Children were more likely to receive DTP3 if their mothers recalled seeing promotional material (64% versus 48%), although it was difficult to adjust for confounding. In Pakistan, Andersson et al (2009) showed increases in DTP3 coverage in one village after instituting community discussions about immunization.

Not included in Shea's review are other recent papers on increasing demand in Karachi city, Pakistan. Home-based education about the importance of vaccination and of retaining the immunization card and giving "logistical" ("where and when" of vaccination) information by Village Health Workers increased coverage in Karachi (72% on-time DTP3 in the intervention and 52% in the control group) (Owais et al, submitted); and in another study, giving food/medicine coupons as incentives doubled DTP3 coverage by age 18 weeks, though completion was still very low (47%) (Chandir et al 2010⁴). A health-center based study found that redesign of vaccination card (to highlight the return date) and center-based education about completing the schedule both led to increased DTP3 coverage, with the combined intervention leading to 74% on-time vaccination compared to 55% in the standard care group (Usman et al 2009). The degree to which results from those studies has fed into national decision-making on immunization strategies is unclear.

There are few recent high quality data that compare the effectiveness and cost of four approaches: outreach, increasing demand, changing practices at health centers, or using innovative management.

Ryman et al (2008) searched the published and grey literature from 1975 through 2004. Only 25 papers met their criteria for inclusion in the review; all were published. Only 9 papers provided data on the increase in FVC following the intervention (in 6 of which, working with communities was included) and all 9 showed marked increases. Costs were not reported. Difficulties in drawing or generalizing conclusions about relative strengths of different interventions were highlighted. The paucity of recent data on costs and effectiveness is disappointing given that much work was done on costing EPI in the 1980s, including studies by the REACH program of John Snow Inc. and other groups, and the guidelines that WHO has developed and disseminated for costing immunization programs.

Better data are needed to make conclusions on the most cost-effective strategies in different settings

All authors of the above reviews commented that the quality of studies was not optimal and that several factors such as setting (urban/peri-urban/rural), populations targeted, infrastructure and incentives are all important to consider. Improved measurement of costs and effects of interventions and of vaccination approaches such as PIRIs, is required.

6. Logistics and management

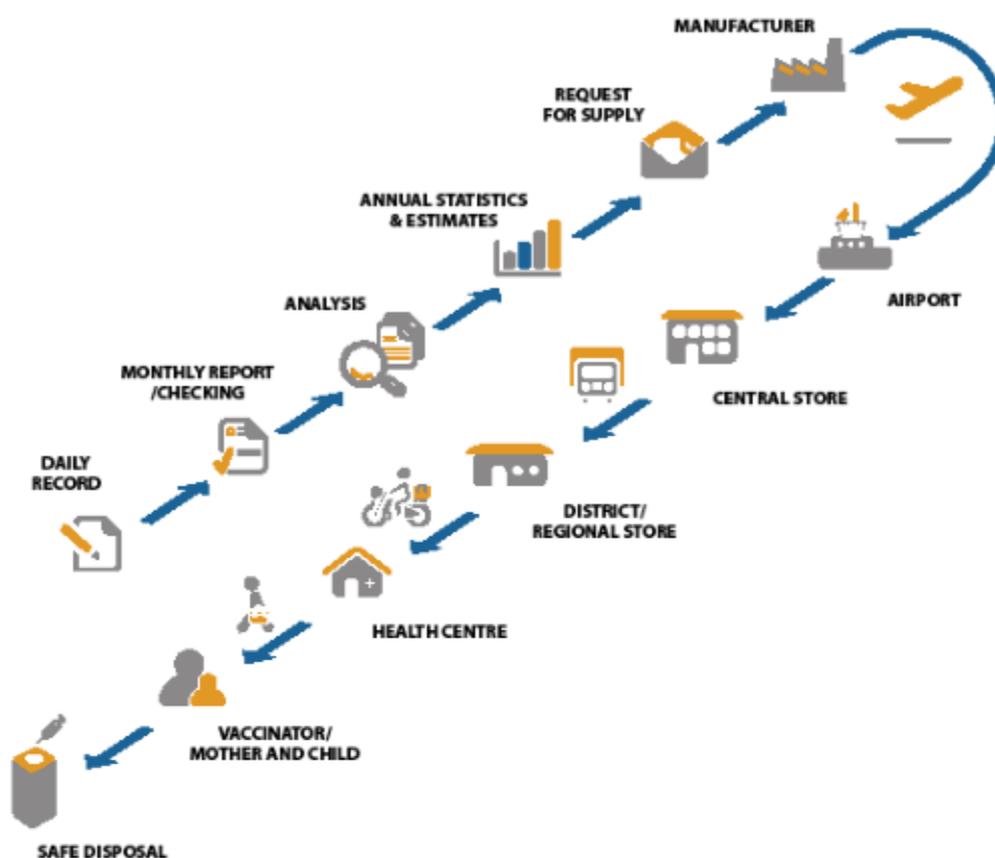
The current vaccine "controlled temperature chain" (widely known as the "cold chain", but encompassing vaccines that have good heat-stability and are susceptible to freezing), used in most low and middle income countries, is based on an uninterrupted series of storage and distribution activities, which allow the vaccine to retain specific temperatures throughout (Fig 1).

In the early years of the Expanded Programme on Immunization (EPI), huge efforts were put into establishing national cold chains for vaccine storage, training and supporting cold chain technicians to maintain equipment, and training health workers at all levels regarding proper storage and handling of vaccines and diluents. By 1990, when Universal Childhood Immunization was declared to have been

⁴ Food-medicine coupon worth \$2 given at each DTP visit. Coupon could be exchanged at one of 6 stores. Not a randomized controlled trial – intervention cohort was first then the control cohort was enrolled after a 6-week gap. Follow-up ended early due to lack of funding.

achieved, there was a belief that the basic infrastructure for the EPI was in place and immunization program priorities shifted to polio eradication and measles and neonatal tetanus elimination, with great investment in epidemiological surveillance.

Fig 1. **Schematic of the vaccine supply chain** (source: Optimize strategy document)



The hands-on approach to capacity-building in logistics changed to a global-level networking approach to interchange of experience and technological updates, through the Technical Network for Logistics in Health, or TechNet, (the name was changed in 2001 to TechNet21), the Safe Injection Global Network (SIGN), the Technical Logistics Advisory Committee to WHO established in 2008 and superseded in 2010 by the Immunization Practices Advisory Committee (IPAC), with expanded terms of reference encompassing innovation and strategy, field operations, and tools and technologies. Recommendations from IPAC meetings which imply changes in WHO policy are presented to WHO's Strategic Advisory Group of Experts (SAGE) that advises WHO on immunizations norms and policies. This global networking has been helpful but does not overcome logistical and management constraints at country-level (Box 7).

Since the establishment of GAVI and relatively rapid scale-up of new vaccines with much larger volume requirements per fully-vaccinated child, evaluations of supply chain have shown major weaknesses with logistics infrastructure, management and planned preventive maintenance (PPM) for cold chain and transport in many countries. For example, in 2008, landscape analyses^{5,6} reviewed data from assessments of vaccine storage and management at country level using the EVSM tool⁷, which

⁵ Optimize. Supply Chain and Logistics for Immunization. Main findings from the Landscape Analyses. Draft 24 June 2008. Also see Optimize. Analysis of EVSM Indicators, February 2008 and Analysis of VMAT Indicators. PATH, Ferney-Voltaire, October 2008.

⁶ Optimize. Supply Chain and Logistics for Health. Main findings from the Landscape Analyses. Draft, 25 June 2008.

reviews the national level storage and management, and the Vaccine Management Assessment (VMA)⁸ tool, which reviews all levels from national to health facility. EVSM assessments were mainly conducted from 2003-5, in AFR, EMR and SEAR, while VMAs were mainly done in AFR, with 60% of these being done after 2005. These assessments found lowest scores on management-related issues including:

- vaccine store management and storage capacity at national and sub-national levels
- vaccine distribution
- stock control (stock-outs were frequent), despite widespread introduction of computerized systems
- equipment maintenance including Planned Preventive Maintenance (PPM)
- avoidance of freezing freeze-sensitive vaccines
- VMAs showed an overall poor standard of performance, which was worse at sub-national than national level, e.g. at the service-point level only 7 out of 31 (23%) applicable indicators were satisfactorily met.

To address some of these problems, in November 2007, the Bill & Melinda Gates Foundation funded a five-year PATH -WHO joint effort to shape the future of immunization and health delivery systems which led to the creation of "*Optimize - Immunization Systems and Technologies for Tomorrow.*" Optimize aims to create a vaccine supply chain that is flexible and robust enough to handle an increasingly large and costly portfolio of vaccines and ultimately, create synergies with the delivery of other health commodities. Optimize focuses on three strategic objectives and areas of work:

- innovation (supporting and guiding ongoing research and development activities, and creating an environment conducive to further innovation);
- demonstration (empirical research to show effectiveness of new technologies and systems);
- facilitation of a coalition of partners to ensure long-term, sustained efforts to extend improved logistics systems globally.

While Optimize looks for innovative solutions for the future, the current reality is that combined with transport deficiencies, vaccine stock-outs are one of the main constraints to increasing routine vaccination coverage in low-income countries.

Lack of transport, or inefficient use of existing transport, for distribution of vaccines bundled with injection supplies (syringes, disposal boxes, etc.), conduct of outreach, supervision or cold chain repair, is a major constraint on health service delivery. Transport is often unavailable due to poor maintenance or lack of fuel, and when it is functional there are competing demands on its use. Outsourcing transport management and maintenance can be more efficient than using government workshops, but still requires strong co-ordination by MoH. Projects to create efficient and sustainable transport planning, utilization, maintenance and replacement by NGOs such as Riders for Health, Transaid and Village Reach have demonstrated short-term success in specific settings, but cover a minority of countries and districts.

In the last 10-20 years, decentralization of health services has meant that in many countries, the MoH immunization unit has reduced in size and received less attention, and many developing countries have none or only one MoH logistician linked to the NIP, often at a low-grade and under-valued clerical level. In the same way that governments have neglected to create and fill posts for logisticians, they lack posts for transport managers, and lack training and career structures.

⁷ WHO-UNICEF Effective Vaccine Store Management initiative: modules 1-4. WHO/IVB/04.16-20. Available at http://whqlibdoc.who.int/hq/2005/WHO_IVB_04.16-20.pdf

⁸ World Health Organization (WHO) Access to Technologies Team. *Vaccine Management Assessment*. WHO/IVB/05.02. Geneva: WHO; 2005. Available at: http://whqlibdoc.who.int/hq/2005/WHO_IVB_05.02_eng.pdf.

For transport, demonstration projects have shown the potential savings to be made by conducting a situation analysis and having appropriate policies as to the most efficient mix of transport for different activities, conducting PPM, and monitoring closely the use of the transport fleet. For example, studies in 2001 showed that 4-wheel drive vehicles were only used for service delivery from 5% to 31% (median 19%) of the time in 3 African countries, compared to 33-58% (median 51%) for motorcycles, yet donors continue to provide 4-wheel drive vehicles without adequate accountability or monitoring of their use. Remarkably little is invested by donors or governments in PPM, despite its demonstrated efficiency and ability to prolong the fleet's useful working life and the finding that transport is often the third highest expenditure (after salaries and drugs) within the health budget (Transaid personal communication). Similarly, there has been inadequate investment in capacity-building for operational management of transport, despite evaluations showing that good operational management improved utilization, reduced costs, and increased the proportion of kilometers traveled for service delivery (Nancollas 2001).

Box 7: Planning vaccination services and managing resources needs improving

- Emphasizing low vaccine wastage (e.g. only vaccinating one day a week; not opening a multi-dose vial for few children) may mean more missed opportunities
- Poor stock control and lack of transport for vaccine distribution mean stock-outs are common
- Mothers turned away because of stock-outs, attendance on days not designated for vaccination, outreach team not arriving on time, health workers' concern about vaccine wastage or false contra-indications, may be discouraged from returning
- Children who are vaccinated are not always protected, as inadvertent freezing of freeze-sensitive vaccines is now more common than damage by excessive heat; transport of vaccine to outreach needs to maintain appropriate temperatures for heat-sensitive and freezing-sensitive vaccines
- Lack of planned preventive maintenance greatly reduces the working life of transport and cold chain equipment
- Projects have demonstrated increased utilization rates of transport by improving transport policies (e.g. using most cost-effective means of transport) and maintenance
- Effective Vaccine Store management (EVSM) evaluations since 2000 constantly identify the need for more, higher-grade and better-trained logisticians to plan and implement efficient vaccine supply chain management, especially now that expensive new vaccines are being introduced.
- Refresher training must be updated and repeated due to frequent staff turnover.
- Governments need to create posts for logistics and transport managers
- The best mix of strategies (e.g. daily vaccination at fixed sites; reducing missed opportunities; using most cost-effective transport and human resources) needs to be evaluated in different settings

7. Monitoring and operational research: what gets measured, gets done

The ultimate indicators of program success are reduced disease incidence and mortality. Disease surveillance has a well-demonstrated key role in disease elimination/eradication programs and detection and response to outbreaks. Surveillance is also one potential method to generate data on burden of diseases and monitor impact of vaccination against those diseases, especially when it is combined with epidemiological (e.g. case-control studies; modelling) and laboratory (e.g. molecular epidemiology studies) investigations. Investment in surveillance is therefore a critical component of vaccination programs.

In addition to timely surveillance, it is also vital to monitoring indicators of program performance (Table 3), to detect potential service delivery problems and identify timely solutions. Coverage is monitored through a mix of methods (Table 4). Indicators of program quality, safety and efficiency are monitored through supervision, and through data provided annually through the WHO/UNICEF Joint Reporting Form (JRF) (http://www.who.int/immunization_monitoring/routine/joint_reporting/en/index.html). Provision of regular feedback on these indicators, and teaching staff how to use data at the local level, are powerful ways to motivate health workers to improve.

Because of the ubiquity and relative simplicity of routine reports on vaccinations administered, WHO-UNICEF and GAVI have invested substantial effort into improving the quality of coverage estimated on the basis of these reports, through two main processes summarized below.

i. WHO-UNICEF estimates of national immunization coverage (WUENIC)

Since June 2000, WHO and UNICEF have done annual reviews of routine immunization coverage worldwide.⁹ Reports of routine administrative coverage by national authorities to WHO and UNICEF (since 1998, collected using the JRF) and any available national coverage survey data are reviewed and survey data ranked in terms of perceived quality. Draft estimates are determined and sent to national authorities, modified in light of comments received and published as the “WHO-UNICEF estimates” of immunization coverage, in August of the year following the end of the reporting period (Burton et al 2009). Country-specific estimates are updated annually. If a new survey becomes available that contains information for previous years, retrospective adjustment of coverage estimates is made for relevant years. This process has helped improve the quality of administrative reports from many countries. However, there are several constraints, including:

- Not all surveys are of good quality or give precise estimates. Sampling frames such as censuses are often outdated. The proportion of children for whom vaccination records are available varies widely and for children without cards, verbal histories of vaccination are less reliable. Even when quality of survey conduct is high, small sample sizes may mean that the confidence intervals around the coverage estimate are wide.
- Delays (often of several years) before obtaining results from surveys such as the DHS so that major retrospective changes in WUENIC estimates take place. For example, estimates in Uganda on the WHO website in 2007 for the years 2002-6 were approximately 20 percentage points higher than the estimates in 2008 which had been adjusted for newly available results of a DHS. Thus for several years, Ugandan authorities would have been complacent in believing that DTP3 coverage was around 90% rather than the 60-68% WUENIC estimates after adjusting for survey results.
- When survey data are not available, as in many countries affected by conflict, the only source of data is administrative reports. Thus, for example, WUENIC estimates are equal to

⁹ <http://www.who.int/vaccines-documents/globalsummary/globalsummary.pdf>

government reports for 2008 in Afghanistan, Somalia, and Timor Leste, but no national coverage survey has been conducted for several years in these countries.

ii. Data quality audits

Audits of administrative coverage data have frequently found problems (Onta 1998; Weeks 2000). To receive renewal of GAVI ISS funding, an adequate score on a standard data quality assessment (DQA) must have been obtained, involving a repeat DQA after action to improve reporting should have been taken (Ronveaux 2005; Woodard 2007, Bosch-Capblanch 2009). The DQA compares data collected from health unit (HU) records with reports at district and national levels and the verification factor (VF) expresses the proportion of immunizations reported at national level that can be tracked down to the HU. The DQA also assigns a quality score (QS) between 1 and 5 for the quality of the information system at national, district and HU levels. Data from DQAs conducted between 2002-5, in 41 countries (30 African, 10 Asian and one Caribbean) showed that 46% of countries obtained a VF below 80% (needed for continued GAVI support), and only 9 of the 41 countries had consistently high VF and QS scores (Bosch-Capblanch 2009). The highest scoring countries were Tanzania, Burkina Faso, Guinea (second DQA) and Kenya (second DQA). In Nigeria it was not possible to estimate the VF due to lack of data. Computers were used to manage data in all national immunization program offices and in 41% of district offices. The most frequent weaknesses were:

- Inconsistent denominators between different levels of the system
- Poor availability of guidelines (eg for late reporting)
- Incorrect estimations of vaccine wastage
- Lack of feedback on vaccine performance
- Lack of calculation of DTP3 dropout rates

Reviews of data quality can be useful training tools and countries are increasingly encouraged to monitor quality themselves, as ongoing efforts and not only audits conducted for GAVI. They can also show the potential to increase coverage by reducing missed opportunities (Weeks et al 2000).

Although the WHO-UNICEF process and DQAs have gone some way towards improving routine data, much remains to be done (Lu et al 2006), and continued focus on data quality and use of data is essential.

Periodic reviews, and operational research studies to assess program performance

National Programme Reviews

These aim to assess all components of a National Immunization Program (NIP). On-site observation and interviews are performed at national, regional, district, health center and community levels in selected areas, using a series of checklists produced by WHO (<http://www.who.int/vaccines-documents/DoxGen/H5-CAT.htm>). Following data analysis, program redesign needs are discussed and a list of major issues prepared. For each issue, achievements and problems are listed and an action plan formulated. In the 1980s, WHO HQ organized international program reviews, using a combined international and national team, regularly in all countries. These reviews helped shape the development of NIPs. Regional offices are now responsible for their organization and follow-up and comprehensive program reviews appear to be less common. Separate reviews focusing on one or two components of the immunization program have been done (e.g. EVSM and VMA – see section 6). Introduction of new vaccines offers other opportunities to review the vaccination program through post-vaccine-introduction evaluations, which may be used as mini-NIP reviews.

Operational research studies to investigate causes of low vaccine coverage

As discussed in section 4, barriers to vaccination are common causes of low vaccine coverage. They can readily be identified by operational research conducted locally.

Health facility-based surveys (health–facility assessments) include a mixture of observation of practices, interviews with providers, and exit interviews with mothers. They are useful to evaluate timeliness of vaccination, dropout rates, and missed opportunities and to assess provider knowledge and practices, and information and education activities (Cutts et al 1990, Gindler et al 1993). These inexpensive studies can easily be coupled with home visits to adjacent neighborhoods to investigate reasons for under-vaccination in households with good access to health services (Gindler et al 1993, Malison et al 1987). Together with rapid feedback of results, monitoring these indicators usually leads to increases in coverage.

Operational research studies done at the local level can be inexpensive and provide useful information for program managers. They are part of training programs such as the two-year Field Epidemiology Training Program (FETP) (<http://www.cdc.gov/cogh/descd/fetp.htm>) and the one-year EPIVAC training program in Francophone west Africa (<http://www.epivac.org>). For example, FETP trainees undertook formative research followed by demonstration projects of interventions ranging from improving relationships between health staff and communities in Kenya, lobbying district authorities to provide regular fuel for outreach in Zimbabwe, and implementing a tickler (reminder/recall system) with a health education component in Uganda (AFENET unpublished report 2007). EPIVAC operational research projects are part of the requirement for a Masters degree. Examples of recent studies are financing mechanisms for immunization, vaccine storage conditions, waste management, vaccine wastage, and causes of dropout (A. Aplogan, EPIVAC unpublished reports).

The importance of monitoring and feedback of information to improved performance

The smallpox eradication program identified three factors critical to success: establishment of measurable objectives, quality control of program performance, and research to solve operational problems (Henderson et al 1987). Marked increases in coverage have been demonstrated in developing and industrialized countries after implementation of systems to monitor performance and provide regular feedback to providers (Cutts et al 1990a,b; Lebaron et al 1997, 1999, Weeks et al 2000). Monitoring of district, or clinic-level performance, can also provide data used for performance-based funding. In England, after the coverage monitoring system was running well, general practices were rewarded for achieving coverage targets and coverage increased further (Noah 1987). In Cambodia, success in coverage improvement is attributed to (1) development of a needs-based micro-plan, (2) application of performance-based contracting between levels of management, (3) investment in social mobilization, (4) securing finance for health outreach programs and (5) strengthened monitoring systems (Soeung et al 2006). Since performance-based funding (Canavan et al 2008) is currently being promoted by the organizations including Norad and the World Bank (http://siteresources.worldbank.org/INTISPM/Resourses/383704-1184250322738/Cluster_P4PinHealth.pdf), (<http://www.norad.no/en/About+Norad/News+archive/Four+countries+suggested+in+the+first+round+of+the+Results-Based+Financing+Initiative.129750.cms>), it is important that the data used to assess district and health facility performance is accurate and timely.

Programmatically, the planned renewed focus of the GPEI's work in support of immunization services strengthening includes assistance in program monitoring. In countries where GPEI has polio surveillance officers (mainly polio-endemic countries and those considered at risk of re-importations), GPEI staff will assist with the collection, collation and analysis of basic data on essential elements of immunization services, including the human resources available for RI (e.g. the percentage of vaccinator positions filled), the completeness of vaccination sessions (e.g. the percentage of planned sessions conducted), the status of vaccine stocks and cold chain capacity for RI, and the vaccination coverage achieved. This increased capacity for data collection on inputs and activities needs, however, to be matched by improved capacity to use data for effective action at all levels.

8. Conclusions

Vaccines have the potential to contribute greatly to the attainment of MDG4. This potential will only be realized, however, if health systems have the capacity to reach all populations, including the hard-to-reach, if governments are committed to child health and there is strong community support. Investment in policy-setting and in provision of technology should be accompanied by investment in the effective and coordinated management of resources and programs.

To reach all populations, there must be sufficient contact points (via fixed sites, outreach or mobile teams) between well-trained, motivated health workers and families. Families must be informed and motivated to attend immunization services and complete the immunization series, with minimum economic, social, bureaucratic or political obstacles. Transport must be available for health workers and, in certain settings, for families to reach these contact points. The transport, storage and supply of vaccines and related equipment must be safe and reliable. The means and methods for effective communications between different levels of the health system and between healthcare providers and families need to be in place and used. Systems to monitor inputs (resources), outputs (numbers of vaccinations), safety (adverse events surveillance) and impact (disease surveillance) must be in place and used effectively. To improve efficiency, the selection of contact point, mode of transport, and number and skills of personnel, should be based on accurate determination of the characteristics and location of the population and of infrastructure.

Health-service interventions to increase coverage include improving management (of the vaccine supply chain, transport, human and financial resources); training and motivating health workers to follow best practices including using all opportunities to vaccinate children who attend health services, to communicate better about the importance of vaccination, the “where” and “when” of vaccination visits, and strengthening systems to remind mothers to return and to follow-up those who don’t attend. Once known health service problems are corrected, potential barriers at family or community levels should be addressed, with emphasis on communities where coverage is lowest. Health workers and community volunteers should be trained to search for unvaccinated women and children, offer them vaccination and actively follow-up their families to ensure timely vaccination of their children. Factors such as maternal tetanus toxoid vaccination status, low educational level, recent migration, and large family size can be used to identify families needing extra support.

Characteristics of successful health services have been identified by Rohde et al (2008), who compared progress in reduction of child mortality since 1978 with gross domestic product (GDP) and other characteristics. Countries that had under-performed included those affected by conflict; those with governance challenges and marked social inequity, and those with very high HIV-AIDS prevalence. Thirty countries were identified with the highest average yearly reduction of child mortality in the previous 30 years, of which only two (Eritrea and Malawi) were in sub-Saharan Africa. Of these 30 countries, 14 also had high coverage of skilled attendance at birth, taken as an indicator of comprehensive primary health care. Almost all of these 14 countries had good governance and progress in non-health sectors. The remaining 16, however, included those that are making progress despite very low income per person (e.g. Nepal and Bangladesh), political instability, and/or high HIV/AIDS prevalence (e.g. Malawi). Lessons learned from all these countries include the need for a nationally agreed package of prioritized and phased primary health care that all stakeholders are committed to implementing, attention to district health management systems, and consistent investment in primary health-care extension workers linked to the health system. Boxes 8 and 9 summarize characteristics of the successful immunization program in Bangladesh, and the improving program of Sudan.

Box 8: Overall success in a large, poor country – lessons from Bangladesh (Fig 3)

3.4 million live births (2009)

Infant mortality rate (2008): 43/1000 live births – fell from ~150/1000 in 1980 (source: <http://www.childmortality.org>)

Child (<5) mortality rate (2008): 54/1000 live births (source: <http://www.childmortality.org>)

72% population rural (2010)

GDP/capita (2010): US\$1580 (PPP adjusted); GNI/capita (2010): US\$ 590 (source: World Bank)

Human Development Indicator ranks higher than GDP/capita

Adult literacy (2006) 48% women; 58% men

Govt expenditure on health=7.4% total expenditure (2006)

Steady increase in coverage from 1987. Coverage >80% since 2000; WUENIC estimates higher than reported coverage; ≥80% districts have >80% DTP3 coverage in 2009

- Political commitment
 - Government funded >60% of vaccine costs before pentavalent introduced in 2009; funds 40% of total routine immunization costs 2009
- Strong management at central and district level.
 - Cold chain strengthened with GAVI ISS funds
 - Cold chain and logistics are regularly reviewed for uninterrupted EPI sessions
 - ISS funds used to strengthen district management, including cash support at District, City Corporation, Upazila and Municipality level in the name of "Envelop budget" which includes fund for supervision, support for volunteer in vacant positions, reward for field workers at different levels and additional vaccine transportation cost for hard-to-reach areas
 - Extra support given to poor-performing districts
 - Extensive use of motorcycles and bicycles for vaccine transport & supervision
- Partnership with local NGOs and other health service providers
 - NGO support especially in difficult areas (e.g. in Bangladesh: boat people, hill tribes, urban slums)
- Use of user-friendly supervision check-list
- Planning process (based on RED microplanning guidelines):
 - All levels of field workers & stakeholders involved
 - Ward or district level analysis
 - Prioritize interventions based on local problems
- Innovative use of human resources:
 - Use of GAVI ISS to fund 32 district immunization medical officers
 - Provision of volunteers against vacant posts
 - Extra porters for vaccine transportation for hard to reach areas
- High community demand for vaccination
 - History of strong community-based projects in hard-to-reach urban and rural areas
- Close monitoring and feedback and supervision.
 - Monthly analysis of data and quarterly review of micro-plan
 - Improving Data Quality and Management
- Collaboration with other programs – Nutrition, Vitamin A, Birth Registration etc.
- Low dropout rates:
 - Community-based birth registry with high coverage
 - Tracking of every child – using new tally sheet with name and details
 - Involve community volunteers for tracking
 - Now assessing use of computerized data of vaccination and follow-up for every child

Box 9: Encouraging progress in a midsize, poor country – lessons from Sudan (Fig 4)

1.3 million live births (2009); 55% population rural (2010)

Infant mortality rate (2008): 70/1,000 live births (~85/1000 in 1980 and ~105/1000 in 1970)

Child (<5) mortality rate (2008): 109/1,000 live births (<http://www.childmortality.org>)

GDP/capita (2010): US\$2,000 (PPP adjusted); GNI/capita (2010): US\$1,230 (source: World Bank)

Human Development Indicator rank lower than GDP/capita rank

Adult literacy (2006): 52% women; 71% men

Government expenditure on health: 6.9% total expenditure (2006)

North Sudan: DTP3 coverage >80% since 2007; WUENIC estimates lower than reported coverage; ≥80% districts have >80% DTP3 coverage in 2009.

South Sudan: reported DTP3 coverage 50% in 2009; 11% districts had >80% DTP3 coverage in 2009.

- Political commitment
 - Government funded 30% of total routine immunization costs in 2008; funded <10% of traditional vaccine costs in 2009.
- GAVI support:
 - US\$24 million for ISS, INS and HSS up to 2008,
 - INS support 2002-04 only,
 - HepB vaccine introduced in 2005,
 - Pentavalent vaccine introduced in 2008.
- Strong management at central and district level:
 - Strong national level team which recognizes the importance of monitoring and evaluation
 - Supportive supervision funded with GAVI funds.
 - Extensive deployment of outreach and mobile teams, with staff incentives and fuel funded with GAVI funds; an estimated 40% and 20% of all routine vaccination delivered by outreach teams and mobile teams, respectively.
- Widespread implementation of RED strategy with strong emphasis on identifying poorly performing districts, conducting microplanning, building local capacity, and implementing monitoring and evaluation,
 - 2007 evaluation concluded that RED was successful
- Extensive use of PIRI strategy in 2009:
 - Two Child Health Days were implemented, delivering all antigens,
 - One Immunization Week was held simultaneously with all EMR countries, mainly for advocacy and strengthening partnerships,
 - During house-to-house polio NIDs, vitamin A and iodine supplements and anti-helminthics were included.
- Investment in logistics and cold chain:
 - Cold chain strengthened with GAVI funds,
 - Virtually no vaccine stock-outs reported,
 - Score of 94% achieved in independent Effective Vaccine Store Management review conducted in 2008.
- Investment in human resources:
 - Mid-level management training conducted annually due to frequent staff turnover.

However: high DTP1-DTP3 dropout rates: around 10% annually during 2005-09, despite:

- Fixed vaccination sites maintain registers and track defaulters,
- Community volunteers involved in raising awareness of vaccination – Immunization Societies and Women's Unions.

Over the last 3 decades, there have been substantial global efforts to prioritize health interventions and promote the most cost-effective (e.g., selective primary health care in the 1980s (Walsh and Warren, 1979), and the World Bank's disease control priorities in developing countries exercises in 1993 and 2006 (World Bank 1993, Jamison et al, 2006)). Global initiatives such as GAVI Alliance and the Global Fund for AIDS, TB and Malaria have provided financial assistance to low income countries to introduce new technologies for the control of priority diseases. This effort to encourage countries to adopt a package of priority interventions has not, however, been matched by consistent investment in strengthening national and district management to deliver the interventions.

The move toward decentralization of health services, with the transition of the health ministry's role from service delivery to policy-making and monitoring, has made the need for support to district management ever more critical (Hutchinson and Lafond 2004). Yet frequently, district managers have no background in management and receive little in-service training for their role. They are expected to plan, budget, coordinate, organize, supervise and monitor health services in their district, using a plethora of tools provided by individual programs. They need to manage their limited resources despite substantial bureaucratic obstacles and little reward. They may be invited to workshops on micro-components of individual programs (e.g. EPI mid-level managers training, or effective vaccine management (EVM)), but there are few high-quality, comprehensive, long-term district management training programs available and accessible to them. They are often away from their workplace, lacking the skills and motivation to meet the competing demands on them.

While Optimize evaluates potential innovations to improve future vaccine supply chains, urgent action is needed now in all countries to improve management. Solutions will require the creation of adequately-remunerated civil service posts, though some activities may be contracted out to the private sector. There will remain a need for monitoring and co-ordination of the vaccine (and other commodities) supply chain(s) by Ministries of Health. Some of these areas are included in a new proposal from WHO IVB to BMGF for support to logistics, which has as priority themes:

- make immediate technical assistance available to countries for the vaccine supply chain
- develop and equip regional training institutions for health logistics
- develop an interactive web-based tool to conduct self-assessment and analysis
- explore solutions and mechanisms for financing equipment, technical assistance and training in the field of logistics for health.

The proposal addresses important elements and, if funded, should begin to fill some of the gaps, although it focuses on the vaccine supply chain and in its current form does not include transport management. The funds are relatively small, however, and additional work will still be required.

We argue that the Decade of Vaccines should kick-start investment in management capacity and set the foundation for effective health care. Compared to the long time spanned by the global polio eradication initiative (already ongoing for over 20 years), a generation of strong managers can be supported, with lasting impact on delivery of vaccines and other essential interventions. Monitoring, learning and evaluation of programs to strengthen managerial capacity will help improve applications for available funds (such as GAVI-HSS) and use them more effectively and efficiently. For example, in the field of transport management, direct comparison between weaker and stronger systems in a study in 2001 demonstrated that the better-managed systems were 50 percent more cost-effective and efficient in supporting health service delivery (Nancollas 2001). Investing in programs to improve management through a mixture of wide-ranging educational programs and in-depth technical assistance in key locations, will complement the proposal from WHO for support for a program to train logisticians. Simultaneously, operational research should be conducted to provide further information on the most cost-effective strategies for vaccination and other essential health interventions in different settings. Improved use of monitoring for action at local and national levels will help to provide long-term and sustainable changes in immunization systems.

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10. List of persons interviewed

International Agencies

Dr Okwo Bele, Director, Immunization, Vaccines and Biologicals (IVB), WHO HQ, Geneva

Dr Thomas Cherian, IVB, WHO HQ, Geneva

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Dr. Stephen Sosler, Deputy Project Manager, Universal Immunization Program, WHO, New Delhi, India

Dr. Satish Kumar Gupta, Immunization Officer, UNICEF, New Delhi, India

Dr. Mercy Ahun, Director, Field Services, GAVI Alliance, Geneva

Dr Vance Dietz, Global Immunization Division, Centers for Disease Control and Prevention

Dr Padma Chandrasekaran, Bill and Melinda Gates Foundation, India office

Non-governmental organizations

Dr. Mike McQuestion, Sabin Institute

Dr Alfred da Silva, Agence de Médecine Préventive, France

Mr Barry Coleman, Riders for Health

Mr Gary Forster, Transaid

Ms Carolyn Miller, Merlin

LSHTM

Ulla Griffiths

Joanna Armstrong-Schellenberg

EPI Managers

AFR:

Dr. K. O. Antwi-Agyei, National EPI Manager, Ghana

Dr. Tatu Kamau, National EPI Manager, Kenya

EMR:

Dr. Agha Gul Dost, National EPI Manager, Afghanistan

Dr. Altaf Bosan, National EPI Manager, Pakistan

Dr. Amani Abdelmonain, National EPI Manager, Sudan

Dr. Eisa Mohammed Eisa, National EPI Manager, Yemen

SEAR:

Dr. Mohamed Abdul Jalil Mondal, National EPI Manager, Bangladesh

Dr. Prima Yosefina Berliana, National EPI Manager, Indonesia

Dr. Khaymar Mya, Assistant Director, Health Services, Myanmar

Dr. Ram Bichha, Director, Health Services, Nepal

WPR:

Dr. Liang Xiaofeng, National EPI Manager, China

In addition, the ARISE group kindly shared their notes from interviews with personnel at the CDC, GAVI, Johns Hopkins Bloomberg School of Public Health, LSHTM, PATH, USAID, US Office of Global Health Affairs, World Bank, and WHO.

11. Tables

Table 1. Recent coverage trends (WUENIC estimates) in GAVI-eligible countries (excluding EUR) and health resources

1a. High (>80%) coverage >4 yrs

Country	DTP 3 (%)			DTP1 2009	Drop- out 2009	Govt diff 2009	Birth cohort 2009 *1000	# un- vacc 2009	# under- vacc 2009	Nurses/ 10k pop	THE/cap 2006 PPP int\$	W Bank Class 2009	ODA CH \$/child
	2000	2005	2009										
AFR													
Burundi	80	87	92	98	6	7	283	5660	22640	2	15	LI	9.6
Eritrea	90	96	99	99	0	-14	185	1850	1850	6	28	LI	5.1
Gambia	89	89	98	98	0	-4	62	1240	1240	13	56	LI	10.7
Ghana	88	84	94	96	2	0	766	30640	45960	9	100	LI	11.8
Lesotho	83	87	83	93	11	-11	59	4130	10030	6	143	LMI	5.1
Malawi	75	93	93	97	4	0	608	18240	42560	6	70	LI	14.5
Rwanda	90	95	97	98	1	n/a	413	8260	12390	4	210	LI	20.7
Sao Tome & Pr	82	97	98	98	0	0	5	100	100	19	141	LMI	n/a
Senegal	52	84	86	94	9	0	476	28560	66640	3	72	LI	11.4
U R Tanzania	79	90	85	90	6	2	1812	181200	271800	4	45	LI	8
Togo	64	82	89	93	4	0	215	15050	23650	4	70	LI	3.1
AMR													
Bolivia	77	85	85	87	2	0	262	34060	39300	21	204	LMI	7.9
Cuba	95	89	96	98	2	0	116	2320	4640	74	363	UMI	n/a
Guyana	88	93	98	98	0	0	13	260	260	23	264	LMI	n/a
Honduras	94	98	98	99	1	0	202	2020	4040	13	241	LMI	n/a
Nicaragua	83	88	98	98	0	0	140	2800	2800	11	251	LMI	n/a
EMR													
Pakistan	62	80	85	90	6	0	5,403	540300	810450	5	51	LMI	3.5
SEAR													
Bangladesh	81	93	94	99	5	-7	3,401	34010	204060	3	69	LI	3.3
Bhutan	92	95	96	98	2	0	15	300	600	3	107	LMI	n/a
D P R Korea (F	54	79	93	94	1	0	327	19620	22890	41	49	LI	n/a
Sri Lanka	99	99	97	98	1	0	364	7280	10920	17	213	LMI	n/a
WPR													
Cambodia	59	82	94	99	5	0	367	3670	22020	9	167	LI	4
China	85	87	97	98	1	0	18294	365880	548820	10	342	LMI	0.3
Mongolia	95	99	95	95	0	0	50	2500	2500	35	149	LMI	n/a
Viet Nam	96	95	96	97	1	0	1,485	44550	59400	8	264	LI	n/a

1b. Medium (60-80%) coverage in 2005 and/or 2009													
	DTP 3 (%)			DTP1	Drop-	Govt	# un-	# under-	Nurses/	THE/	GAVI	World	
Country	2000	2005	2009	2009	out	diff	vacc	vacc	10k	cap	Grouping	Bank	
							2009	2009	pop	2006	(GNI	Class	
										PPP int\$	2005)	2009	
												CH	
												\$/child	
Benin	78	70	83	99	16	15	3490	59330	8	46	Poorest	LI	19.6
Burkina Faso	57	82	82	89	8	17	81180	132840	5	87	Poorest	LI	7.7
Cameroon	62	80	80	88	9	0	85320	142200	16	80	Least poor	LI	5.1
Côte d'Ivoire	67	76	81	95	15	0	36450	138510	6	66	Fragile	LMI	2.4
Guinea-Bissau	49	68	68	85	20	14	9900	21120	7	40	Poorest	LI	4.2
Kenya*	82	76	75	80	6	0	306000	382500	12	105	Intermed	LI	12.9
Mali	43	77	74	85	13	15	82650	143260	6	65	Poorest	LI	7.6
Mauritania	53	71	64	79	19	3	22890	39240	6	45	Poorest	LI	7.3
Mozambique	70	76	76	88	14	0	105240	210480	3	56	Poorest	LI	10.8
Sierra Leone	44	65	75	87	14	16	29510	56750	5	41	Fragile	LI	9.3
Uganda	52	64	64	90	29	19	150200	540720	7	143	Poorest	LI	9.4
Zambia	85	82	81	92	10	17	43920	104310	20	62	Poorest	LI	23.5
Zimbabwe	79	65	73	87	16	0	49270	102330	7	147	Intermed	LI	6.6
EMR													
Yemen	61	65	66	77	14	20	198030	292740	7	82	Poorest	LI	3
EUR													
Azerbaijan	75	72	73	79	8	21	35490	45630	84	218	Least Poor	LMI	10
SEAR													
India	60	67	66	83	20	n/a	5E+06	9107580	13	109	Intermed	LMI	2.7
Indonesia	71	72	82	89	8	0	459140	751320	8	87	Least Poor	LMI	2
WPR													
Kiribati	90	79	86	92	7	0	n/a	n/a	30	290	Least Poor	LMI	n/a
Solomons	82	78	81	83	2	0	2720	3040	14	107	Poorest	LMI	n/a

1c. Increasing coverage													
					Drop-	Govt	# un-	# under	Nurses/	THE/	GAVI	W	ODA
	DTP 3 (%)			DTP1	out	diff	vacc	vacc	10k	cap	Grouping	Bank	CH
Country	2000	2005	2009	2009	2009	2009	2009	2009	pop	2006	(GNI 2005)	2009	\$/child
AFR											PPP int\$		
Angola*	31	47	73	93	22	0	54880	211680	14	71	Fragile	LMI	5.4
Comoros (the)	70	68	83	94	12	0	1320	3740	7	35	Poorest	LI	n/a
Congo (the)	33	65	91	92	1	0	10080	11340	10	31	Fragile	LI	1.3
DRC	40	60	77	91	15	15	263700	673900	5	18	Fragile	LI	3.6
Ethiopia	56	69	79	86	8	0	438480	657720	2	22	Poorest	LI	9.3
Liberia	46	60	64	75	15	28	37250	53640	3	39	Fragile	LI	15.3
Madagascar	57	82	78	80	3	11	139000	152900	3	34	Poorest	LI	5.7
Niger (the)	34	45	70	82	15	23	146700	244500	2	27	Poorest	LI	9.1
EMR													
Afghanistan*	31	76	83	94	12	0	78120	221340	5	29	Fragile	LI	10.3
Djibouti	46	71	89	90	1	0	2400	2640	4	100	Least Poor	LMI	12.8
Sudan (the)*	62	78	84	92	9	7	104000	208000	9	61	Fragile	LMI	11.1
SEAR													
Myanmar	82	73	90	93	3	0	71120	101600	10	43	Poorest	LI	2.5
Nepal	80	75	82	84	2	7	116800	131400	5	78	Poorest	LI	2
Timor-Leste	..	55	72	76	5	0	11040	12880	22	169	Fragile	LMI	n/a
1d. Low (<60%) coverage													
					Drop-	Govt	# un-	# under	Nurses/	THE/	GAVI	W	ODA
	DTP 3 (%)			DTP1	out	diff	vacc	vacc	10k	cap	Grouping	Bank	CH
Country	2000	2005	2009	2009	2009	2009	2009	2009	pop	2006	(GNI 2005)	2009	\$/child
AFR											PPP int\$		
CAR	37	54	54	64	16	22	55440	70840	4	55	Fragile	LI	5.7
Chad	26	23	23	45	49	52	279400	391160	3	40	Poorest	LI	2.1
Eq Guinea	33	33	33	65	49	41	9100	17420	5	280	Poorest	HI	37.8
Guinea	47	59	57	75	24	28	99250	170710	5	116	Poorest	LI	4.2
Nigeria	29	36	42	52	19	29	3E+06	4E+06	17	50	Intermed	LMI	6.9
AMR													
Haiti	49	59	59	83	29	n/a	46580	112340	1	96	Fragile	LI	11.1
EMR													
Somalia	33	35	31	40	23	20	241200	277380	2	...	Fragile	LI	5.8
WPR													
Lao PDR**	51	49	57	76	25	10	41280	73960	10	85	Poorest	LI	4.7
PNG	59	61	52	70	26	12	62400	99840	5	134	Intermed	LMI	12.2

* WHO-UNICEF estimates since 2000 based entirely or almost entirely on administrative reports and WHO-UNICEF recommend a national high-quality survey be conducted

** WHO-UNICEF note uncertainty in the size of the birth cohort. No recent nationally representative survey conducted

Dropout = difference in DTP1 and DTP3 coverage expressed as a percentage of DTP1 coverage = ((DTP1 - DTP3) * 100) / DTP1

Govt DTP3 diff = absolute difference between reported DTP3 coverage and WHO-UNICEF best estimates

THE: total health expenditure

ODA CH: official development assistance for child health services - from Greco et al Lancet 2008 - only estimated for the 68 Countdown priority countries

Table 2. Main countries with internally displaced populations and/or people in refugee-like situations due to conflict, 2007-8

Source: Human Development Report 2009

Country	Internally displaced Populations 2008	People in refugee-like situations in other countries, 2007
Afghanistan	200000	1147800
Angola	20000	
Azerbaijan	573000	
Bangladesh	500000	
Bosnia and Herzegovina	125000	
Burundi	100000	
Central African Republic	108000	
Chad	186000	
Colombia	0	481600
Cote d'Ivoire	621000	
D.R. Congo	1400000	
Eritrea	32000	
Ethiopia	200000	
India	500000	
Iraq	2842000	30000
Kenya	400000	
Myanmar	503000	
Peru	150000	
Philippines	314000	
Serbia	248000	
Somalia	1100000	
Sri Lanka	500000	
Sudan	6000000	
Syrian Arab Republic	433000	
Timor-Leste	30000	
Uganda	869000	

Table 3: **Indicators to monitor immunization program performance** (adapted from Hadler et al 2008)

Program component	Indicators
Program outputs	% Fully vaccinated children (if routine reports are used, DTP3 taken as proxy) % districts with $\geq 80\%$ DTP3 coverage in infants* % districts with U90% measles vaccine coverage in infants*
Service delivery**	% of planned outreach sessions that were conducted on schedule % of planned fixed site sessions that were conducted on schedule
Access to services	% of children up-to-date (BCG and DTP1/OPV1) by age 2 months
Tracking activities	“Dropout” - difference in percentage receiving DTP1/OPV1 and either DTP3/OPV3 or measles vaccine
Use of all opportunities	Percentage of children receiving all vaccines for which they are eligible at each visit
Safety	Proportion of districts that have been supplied with adequate (equal or more) number of AD syringes for all routine immunizations during the year*
Logistics and cold chain	Proportion of districts that had no interruption in vaccine supply* Percentage of facilities storing vaccine at recommended temperatures Vaccine effectiveness in expected range for each vaccine evaluated
Transport***	Kilometers/vehicle or motorbike/month (high km = high utilization) Percent use for service delivery and service delivery support (higher=more effective) Policy of planned preventive maintenance (PPM) & % PPM activities conducted Full cost per km (low cost = more efficient use of vehicles/motorbikes)
Surveillance/monitoring	% expected district disease surveillance reports received at national level * % expected district coverage reports received at national level*
Management and supervision	Country has 5-year immunization plan % districts having microplans that include immunization activities* % districts that did ≥ 1 supervisory visit to all Health facilities in last year*
Provider knowledge***	Proportion of providers who know and follow recommended guidelines, including those on simultaneous administration, contraindications, and safe injection procedures

* on the WHO-UNICEF Joint Reporting Form on Immunization (JRF)

** proposal in GPEI strategic plan that polio officers will assist in monitoring these indicators

*** no indicators routinely monitored by EPI to date

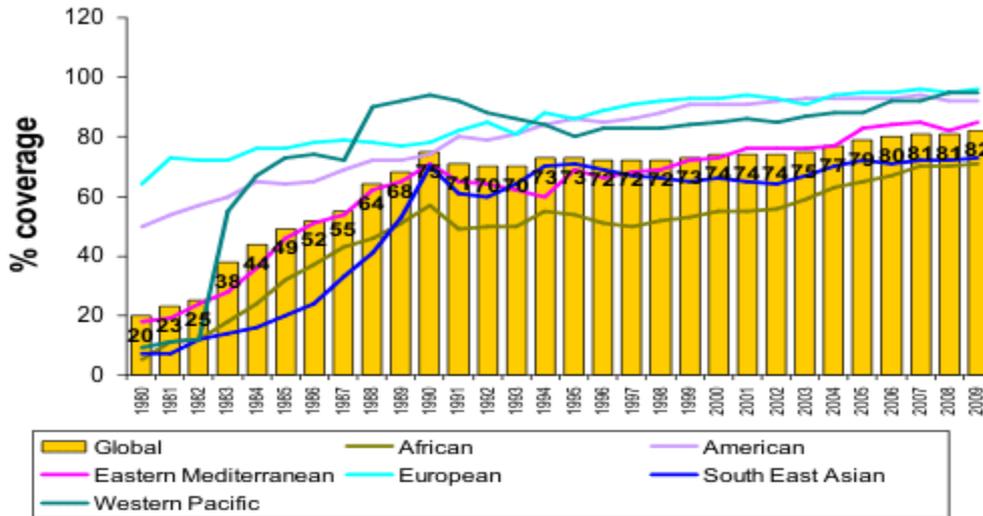
Table 4. Advantages and disadvantages of methods to measure vaccination coverage

Method	Advantages	Disadvantages
Register-based (electronic)	<p>Can give complete and accurate information on cumulative vaccination status of individuals and populations</p> <p>Can be used to set appointments, issue reminders and recalls</p> <p>Use of electronic systems could reduce time spent on paper registers that are widespread in low income countries and often not used</p>	<p>Need good computer access</p> <p>Need complete birth registry for true denominator</p> <p>Need unique ID number that is kept throughout life</p> <p>If held locally, difficult to track vaccination of migrants</p> <p>If held nationally, feedback/use at local level may be slow</p> <p>Requires adequate funding and human resources</p>
Routine reports of vaccinations delivered	<p>Simple in conception</p> <p>Continuous information allows monitoring of cumulative coverage through the year and by district/health facility</p> <p>Can be used at local level to track coverage and dropout rates</p>	<p>Population denominators often inaccurate</p> <p>Private sector often does not report</p> <p>Exaggeration of doses administered common (e.g. double-counting of same child if home-based record mislaid; inclusion of children outside target age group, or purposeful exaggeration)</p> <p>Transcription errors at each health system level when paper-based systems used</p>
Surveys	<p>If well-conducted, can provide accurate information</p> <p>Other indicators (e.g. missed opportunities, caretaker knowledge) can be assessed</p> <p>Involvement of health workers can be training opportunity</p> <p>Large-scale surveys for multiple programs can reduce costs</p> <p>Lot quality sample surveys can be used to identify poor-performing districts/health facilities</p>	<p>Quality of data depends on training, supervision and quality control</p> <p>Sampling frame often based on outdated census information</p> <p>Home-based records may be missing or incomplete</p> <p>Participation rate will determine reliability of results.</p> <p>Often long delays until results are known.</p> <p>Small sample sizes give imprecise results; large sample sizes are expensive and more time-consuming</p>

12. Figures

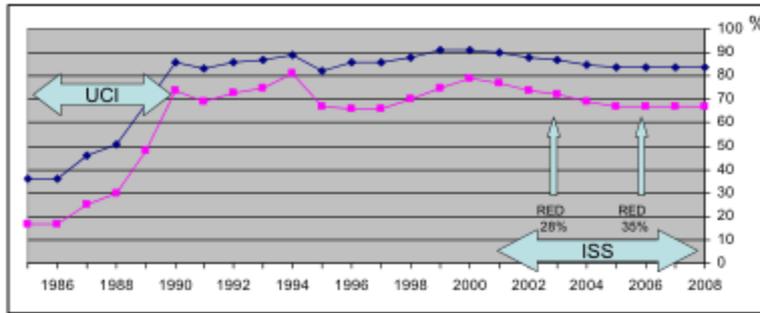
Figure 1.

**Global Immunization 1980-2009, DTP3 coverage
global coverage at 82% in 2009**



Source: WHO/UNICEF coverage estimates 1980-2009, July 2010. Date of slide: 13 July 2010

2a. DTP1 and DTP3 coverage (%), Benin 1985-2008

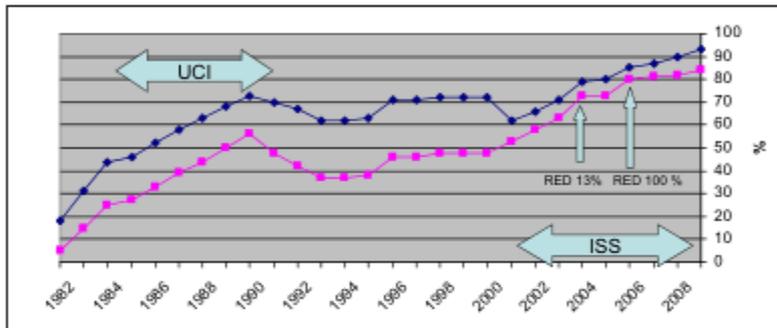


DTP3 — DTP1 — WHO-UNICEF estimates, downloaded 6 May 2010

RED = Reaching Every District approach introduced in 29% of districts in 2003 and 35% since 2004

UCI = Universal Childhood Immunization; ISS = GAVI Immunization Services Support

2b. DTP1 and DTP3 coverage (%), Cameroon 1982-2008

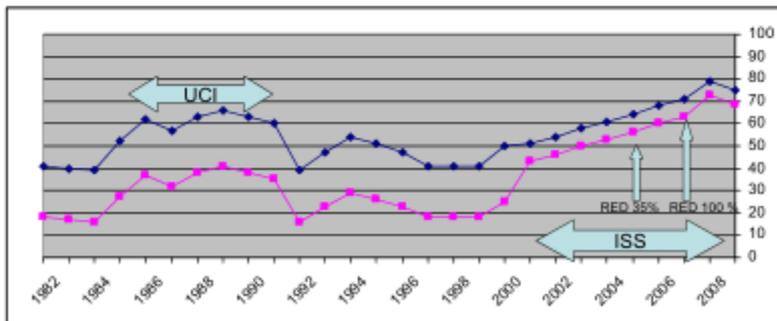


DTP3 — DTP1 — WHO-UNICEF estimates, downloaded 6 May 2010

Reaching Every District approach introduced in 15% of districts in 2003-4 and 100% since 2005

UCI = Universal Childhood Immunization; ISS = GAVI Immunization Services Support

2c. DTP1 and DTP3 coverage (%), DR Congo 1982-2008



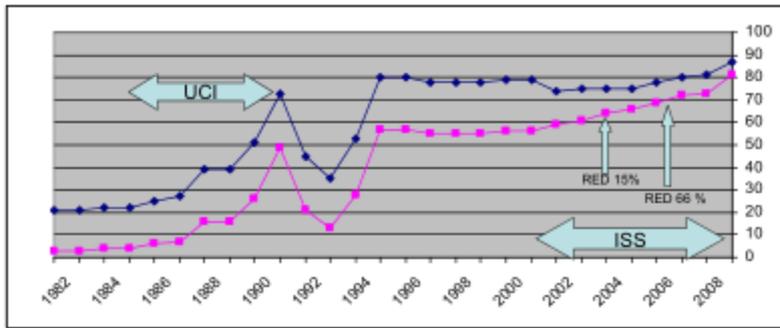
DTP3 — DTP1 — WHO-UNICEF estimates, downloaded 6 May 2010

Reaching Every District approach introduced in 35% of districts in 2004 and 100% since 2006

UCI = Universal Childhood Immunization; ISS = GAVI Immunization Services Support



2d. DTP1 and DTP3 coverage (%), Ethiopia 1982-2008

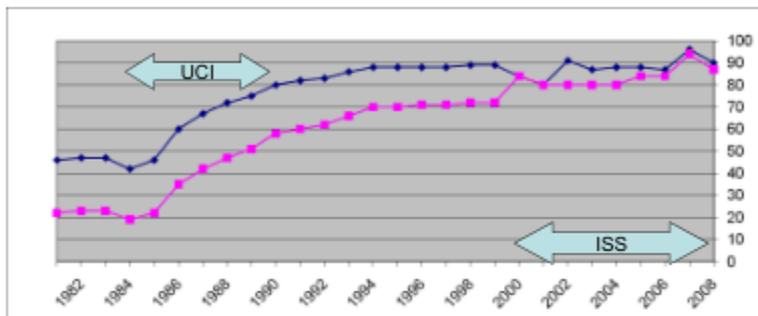


DTP3 — DTP1 — WHO-UNICEF estimates, downloaded 6 May 2010

Reaching Every District approach introduced in 15% of districts in 2003 and 66% in 2005-6

UCI = Universal Childhood Immunization; ISS = GAVI Immunization Services Support

2e. DTP1 and DTP3 coverage (%), Ghana 1982-2008

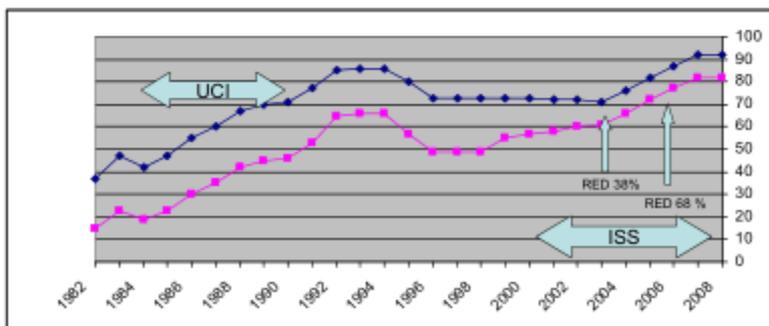


DTP3 — DTP1 — WHO-UNICEF estimates, downloaded 6 May 2010

Reaching Every District approach not formally introduced

UCI = Universal Childhood Immunization; ISS = GAVI Immunization Services Support

2f. DTP1 and DTP3 coverage (%), Madagascar 1982-2008

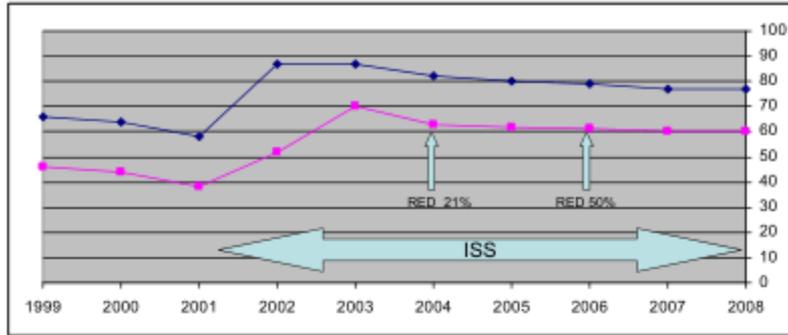


DTP3 — DTP1 — WHO-UNICEF estimates, downloaded 6 May 2010

Reaching Every District approach introduced in 32% of districts in 2003 and 68% in 2005-6

UCI = Universal Childhood Immunization; ISS = GAVI Immunization Services Support

2g. DTP1 and DTP3 coverage (%), Sierra Leone 1999-2008

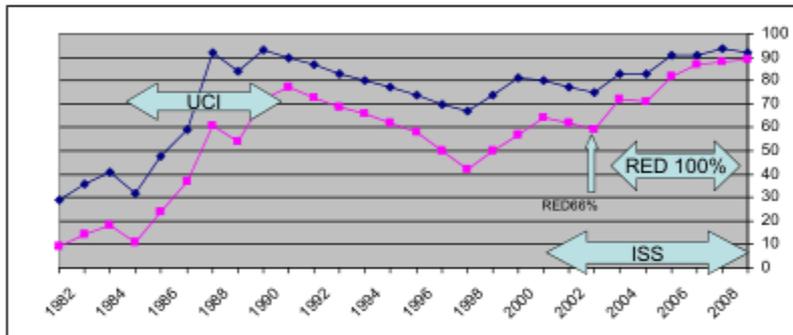


DTP3 --- DTP1 --- WHO-UNICEF estimates, downloaded 6 May 2010

Reaching Every District approach introduced in 21% of districts in 2004 and 50% by 2006

UCI = Universal Childhood Immunization; ISS = GAVI Immunization Services Support

2h. DTP1 and DTP3 coverage (%), Togo 1982-2008

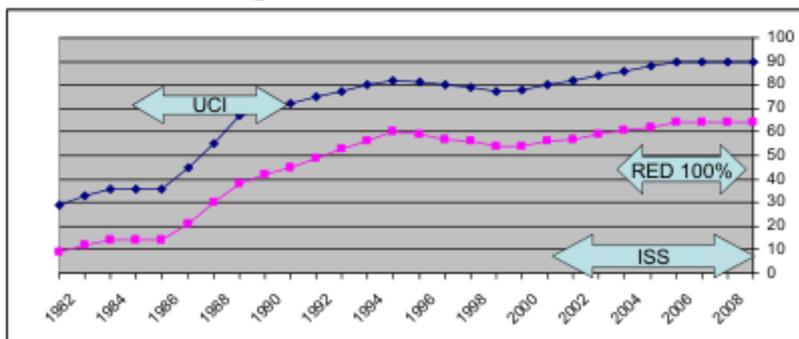


DTP3 --- DTP1 --- WHO-UNICEF estimates, downloaded 6 May 2010

Reaching Every District approach introduced in 66% of districts in 2002 and 100% since 2003

UCI = Universal Childhood Immunization; ISS = GAVI Immunization Services Support

2i. DTP1 and DTP3 coverage (%), Uganda 1982-2008

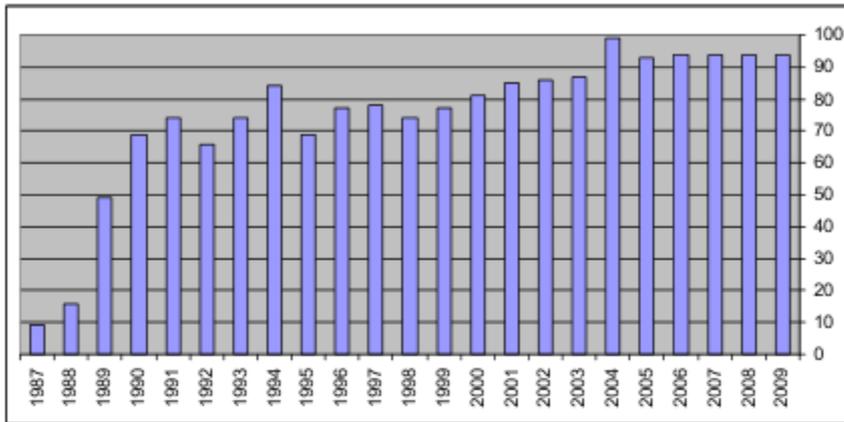


DTP3 --- DTP1 --- WHO-UNICEF estimates, downloaded 6 May 2010

Reaching Every District approach introduced in 100% of districts in 2003

UCI = Universal Childhood Immunization; ISS = GAVI Immunization Services Support

3. DTP3 coverage 1987-2009 in Bangladesh, WUENIC estimates



4. DTP3 coverage 1985-2009 in Sudan, WUENIC estimates

