## Framework on New Vaccine Introduction Impact on the Immunization and Health System

<table>
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<th>Building Block</th>
<th>Sub-Area</th>
<th>Potential Effect on Immunization System</th>
<th>Potential Effect on Health System</th>
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<tbody>
<tr>
<td>ACCESS &amp; COVERAGE</td>
<td>Physical and geographic access</td>
<td>Addition of Hepatitis B vaccine (HBV) improved overall coverage of routine EPI vaccines in &lt;1 year olds, Peru (Cabezas 1995); Inclusion of HBV to those endemic remote areas improves the total EPI coverage and it is safe and effective (Cabezas 1995); Inclusion of HBV shows increases in coverage after integration into routine immunization programme (Cui 2009); Introduction of HBV did not impact coverage of other routine antigens, Thailand (Chunsuttiwat 1997); Vaccine coverage before and after new vaccine introduction remains high, Kenya - pentavalent - did not affect coverage of routine antigens (Ndiritu 2006); Despite increased resources and planning, district vaccination coverage remained low in Pakistan (Loevinsohn 2006); Pneumococcal conjugate vaccine (PCV) introduction to influenza programme resulted in high vaccination rates of both vaccines in Netherlands (Opstelten 2001); New vaccine introduction draws attention to the potential weakening of local health systems (Garrett 2007); Generic systemic problems such as lack of access to funding, a range of behavioral problems, and locally specific organizational barriers inhibit outreach to remote areas (Clements 2006); The success and growth of the school-based adolescent program demonstrate that school-based HBV vaccination programs can be highly efficient and effective (Cassidy 1998); National/sub-national polio immunization days increased coverage rates for other vaccines (BCG, DTP3 and measles) in the Western Pacific Region (Aylward 1997); In China, concentrated efforts to detect susceptible children</td>
<td>Adolescents would require 2-3 additional primary care visits to receive HPV in a medical home in the US (Rand 2007); A 3-country study of the impact of polio eradication on health systems found no major impact on service delivery (Mogedal and Stenson 2000); A study in Nepal indicated that family planning activities were ‘somewhat’ hampered by national immunization days as they coincided with the most suitable times for sterilization camps. However routine MCH services data had not changed relative to the pre-polio eradication era (Loevinsohn 2002); A study in Lao PDR, Nepal and Tanzania found that the effect that polio eradication national immunization days had on the delivery of other health services depended very much on staff productivity (Loevinsohn 2002); A study in India found half the stakeholders believed polio eradication had improved PHC services, although there were concerns that villagers may expect all services to be delivered at their door (Loevinsohn 2002); A study in Kenya found that distribution of free insecticide-treated bednets to pregnant women through antenatal clinics increased the use of regular antenatal services (WHO MPSC Group, 2009); In Rwanda a significant correlation was noted between HIV interventions and improved antenatal services and family planning – HIV-specific resources were used to build health facilities and improve labs and training. In Haiti an integrated prevention and care of HIV/AIDS</td>
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<td>Service Delivery</td>
<td>who had missed previous immunization activities brought them to the attention of health workers and increased their access (Aylward 1997); A national polio eradication campaign did not lead to any improvements in complete immunization against non-polio EPI diseases in rural North India (Bonu 2003); A study of 15 S. Asian and African countries found that national polio immunization days were associated with increased EPI coverage in some countries, whilst coverage decreased in others or stayed the same (Bonu 2004); A study in Benin showed no relationship between polio eradication activities and routine immunization coverage. In Niger it found that the poor performance of routine services did not improve (Loevinsohn 2002)</td>
<td>program had a positive association with several primary care goals e.g. vaccination, family planning – it was designed to generate simultaneous improvements in a range of health outcomes beyond HIV (WHO MPSC Group, 2009)</td>
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<td>Social and demographic access</td>
<td>Adolescents living in high-risk settings (detention, group homes) may require targeted programs to achieve high coverage (Tedeschi 2007; Sneller 2008); Outreach in shelters for homeless youth can increase HBV coverage (Schwarz 2008); Targeting Vietnamese-American children/adolescents for HBV vaccination in Texas had a cost-benefit ratio of 5.26:1 (Zhou 2003); Differential uptake of HBV vaccine in household contacts compared with adolescents can be due to different patient characteristics and outreach efforts (Scognamiglio 2009); Campaigns or special policies needed to assure HBV vaccination of prisoners (Sutton 2008); An accelerated delivery schedule for homeless drug users in New England had 7-times the completion rate than traditional services (Wright 2002); Higher coverage achieved among intravenous drug users when linking vaccination to syringe exchange programs, US (Altice 2005); HBV offered in specialist drug services in Glasgow (Morrison 2002); HBV vaccination was acceptable to IV drug users when</td>
<td>A study in Lao PDR found polio eradication helped promote a new district strategy that stressed health care delivery closer to the community (Loevinsohn 2002)</td>
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<td>Service Delivery</td>
<td>Affordability</td>
<td>Reductions in caregiver lost income by 25% from rotavirus vaccination, NZ (Milne and Grimwood 2009); Pentavalent vaccine fulfils value proposition for managed Health Care plan in US (Mullany 2003);</td>
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<td>Provided free and at drug treatment outreach sites in New Zealand (Rogers and Lubman 2005); Aggressive and large-scale funding often fail because much of goes to support specific groups of recipients, but who rarely reach the broader populations that could be served by simpler alternatives (Christensen 2006); A study of 15 S. Asian and African countries found that national polio immunization days were associated with reduced social inequalities in EPI coverage in some countries, though not in the majority (Bonu 2004);</td>
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<td>Inadequate public funding for HBV vaccine results in decreased access in high risk prison inmates, US (Charuvastra 2001); The cost of the vaccine is the most important deterrent for adopting a universal HBV immunization strategy in Nova Scotia (Poulin 1992); Reduced doses of Hib from 3 to 2 reduce cost and make vaccines more affordable in developing countries (Peltola 1999); Increased pneumococcal and influenza vaccine coverage among elderly as a result of implementation of publicly funded vaccine program, Australia (Andrews 2005; Andrews 2005); Availability of free PPV-23 vaccine for elderly quickly increased coverage in initial 2 years then stabilized, Spain (Vila-Corcoles 2006); Public vaccine financing programs for PCV7 essential to achieve high coverage in eligible population, US (Stokley 2006); An initial lack of insurance reimbursement for the cost of the vaccine caused physicians in NY to delay introducing PCV (Schaffer 2002); Children living in households with higher socioeconomic status were more likely to receive newly introduced rotavirus vaccine, US (Smith 2003); Physicians identified cost as a barrier to HPV vaccination, US (Tariq 2009); Providing reimbursed or free HPV vaccine to specific age groups of girls affects vaccine coverage (Simoens</td>
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<td>Service Delivery</td>
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<td>2009); A physician survey in Malaysia found that high cost of HPV limited its use (Wong 2009); The compensation for immunization was insufficient to meet costs, (Fontanesi 2004) Rotavirus vaccine (RV) argued to be more cost effective among poor in Mexico (due to higher underlying mortality and morbidity) (Valencia-Mendoza 2008)</td>
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<td>Social &amp; cultural acceptability</td>
<td>HPV vaccine accepted among college students if perceived as a normative behavior, US (Allen 2009); HPV leads to media messages that may adversely impact HPV uptake in Australia (Watson 2009); Malay Muslim physicians agreed that cultural sensitivity was an issue when recommending HPV vaccines; acceptance is better if vaccines are recommended to prevent cervical Ca rather than STDs; majority of patients preferred to defer immunization. Physicians reported cultural disparities in HPV uptake (Wong 2009); Compliance with new OPV-IPV schedule is high in Georgia state USA despite addition of injections (Kolasa 2000);</td>
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<td>QUALITY OF CARE:</td>
<td>Improving program managements, adoption of safe injection practices, and immunization systems improves equitable access India (Cooley 2004); French courts have awarded compensation to sufferers of multiple sclerosis (MS) which occurred following HBV vaccination because the 'cause' is viewed as inexpert practice (Rouge-Maillart 2007); HBV does not increase risk of MS in childhood in France(Mikaeloff 2007); DTP-Hib not associated with increased hypotonic-hyporesponsiveness episodes above rates in published literature in Brazil (Martins 2007)</td>
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<td>Immunization safety</td>
<td>Use of combination vaccines improved timeliness and coverage in both routine and new vaccine, US, Scotland, Thailand (Aiken 2002; Chunsuttiwat 2002;</td>
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<td>Timeliness</td>
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<td>Service Delivery</td>
<td>Breen 2003; Happe 2007; Happe 2009); Only 51% of infants at risk for HBV infection were immunized correctly (within 24 hours, and active prophylaxis at 0,1,6 months in Switzerland (Rhiner 2007); Proportion of children who received HBV birthdose was lower than receipt of BCG and OPV and significantly lower in rural area than urban area and (Kuruvilla and Bridgitte 2009); Approximately 20% of physicians in NY who gave PCV delayed administering other vaccinations (varicella, HBV, or polio) because of concern about administering 4 or more vaccines simultaneously (Schaffer 2002). An accelerated delivery schedule for homeless drug users in New England had 7-times the completion rate than traditional services (Wright 2002); Use of standing orders in health care institutions increases coverage (HBV, PPV) US, Australia (Connors 1998; CDC 2003; Goldstein 2005; Sokos 2005); RV timeliness affected by minimum and maximum age for delivery (de Oliveira 2008)</td>
<td>DELIVERY MODALITIES:</td>
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| Alternative delivery strategies | Societal costs of HBV Immunization lower in school-based program than community-based program, Canada (Guay 2003); Use of existing school-based clinics for HBV delivered vaccine with minimal increase in cost, personnel and resources, US (Cassidy 1998); School-based campaign delivery of typhoid vaccine well accepted, safe, logistically feasible, requirement of individual informed consent lowered attainable coverage (Thiem 2006); Teacher involvement important for success of school-based vaccination esp enrollment and informed consent (Tung and Middleman 2005); Large scale school-based implementation of school-based delivery of typhoid vaccine logistically feasible, safe and minimally disruptive, Indonesia, China (Yang 2005; Agtini 2006); Outpatient vaccine delivery perceived more convenient than hospital delivery of HBV to low-risk neonates decreasing birth dose delivery, US (Aiken 2002); Birth-dose administration of HBV highly dependent on community based pregnancy tracking practices and relationship with private maternity practices in Viet Nam (Murakami 2008); Timely administration of HBV birth dose improved by out-of-cold chain storage and administration at the village level, esp in children born at home, China (Wang 2007); A multifaceted strategy is needed to have successful HBV coverage of adolescents (Seid 2001); Unvaccinated, at-risk HCWs need to be targeted for HBV immunization (Simard 2007); Literature review of delivery strategies found 25 out of 11,000 to be sufficiently rigorous & highlight needs for new research (Ryman 2008). Combination vaccines decrease discomfort of vaccines recipients and reduce delivery costs (Di Fabio and de 2001); Combination vaccine provides better value than monovalent vaccines (Jacobson 2003); Universal

| Notwithstanding the extensive work in this area, there nevertheless exists little agreement on a standard set of indicators and assessment methods for health system performance service delivery outputs that can be used for a cross-country comparison (Alliance for Health Policy and Systems Research 2009); Following the success of national polio immunization days in the Philippines, a similar approach was adopted for several other priorities e.g. a national micronutrient day (Tangermann 1997) |
| Alternative delivery strategies | HBV vaccination of Australian infants using a combination Hib-HBV vaccine is regarded as a worthwhile investment of public funds (Hay and Daum 1987); In Philippines, HBV vaccination coverage was low (44%) due to erratic vaccine supply, lack of policies for birth dose delivery. New funding, policy and technical delivery developments now make progress possible (Ruff 2009). Uptake of influenza vaccine was considerably reduced when offered in combination with 3 other vaccines (PPV, Hepatitis A Vaccine (HAV), and HBV) in an inner-city vaccination blitz in Vancouver (Watt 2003); Inpatient administration of PPV in age 65+ significantly increased vaccination rate (0-15%) (Eckrode 2007); A Meningococcal Conjugate type C (MCC) vaccine mass campaign was carried out in Spain- incidence decreased in all regions though the decrease was greater for regions that had not previously vaccinated (Salleras 2003); In Kansas, a program to work with pharmacists improved PPV for CAP and at-risk patients and helped the hospital meet regulatory targets (Robke and Woods); Two studies agreed that polio eradication provided models that were used during other disease epidemics (Loevinsohn 2002) |
| Degree of integration and other intervention add-ons (GAPP, cancer, CAH, IMCI, across programme) | Integrated reproductive health services provides new opportunities for ensuring access to HPV vaccines (Pollack 2007); Integrating school immunization with general practice provides continuity with preschool immunizations and provides a convenient location for parents to bring children who have missed out on immunizations in Australia (Reeve 2008). The incremental costs of adding new services or interventions with current EPI is low and can increase involvement of local community, Bangladesh (Khan 2004); Major cause of difficulties in implementation NUV was the poor implementation of the HF/District micro-plans. WHO underscores importance of and integrated approach to integrated services delivery – especially at the peripheral levels, sustainability accountability and ensuring value for money developed (Duclos 2009) coverage for HBV vaccine increased among intravenous drug users increased when combined with syringe exchange programs, US (Altice 2005); Vaccination of injecting drug users with HCV and HBV at drug agencies was found to be unacceptably low in England and Wales (Winstock 2000); HBV vaccination of blood donors could be an alternative to HBV Nucleic Acid Technology testing particularly for donors with a high vaccination rate and donation frequency in US (Ringwald 2005); Attaching HBV to an anonymous HIV testing program in the US is one way to expand coverage (Savage 2000) | Impacts of integration with other services yet to be proven and will depend on intervention compatibility and strengths of EPI (Wallace 2009) Public health system performance (measured as expected immunization period) determined the use of public health systems for vaccination in Italy (Faustini 2001); A hotline was found to be useful in reassuring the public and providing consistent advice for a school-based, mass meningococcal vaccination campaign, and reduced burden of calls to hospitals and public health units (Ward 2001). Cost-efficiencies of HIV/AIDS interventions with scale reflect different ways of delivering services, including lower quality outputs (Kumaranayake 2008); A study of 6 Sub-Saharan African countries found child health days (which included immunization and other interventions) were associated with quality of care problems, due mainly to the use of lay health workers at outreach posts. Key informants were concerned the days may negatively affect coverage and quality of PHC services. Also concerns that incentives may act as a disincentive during regular health service provision (Doherty) |
### DEMAND & ACCEPTANCE:

| Social mobilization, advocacy and communication | Requirements for vaccination, opposition from socially conservative groups, and ethical considerations can affect social acceptability of new vaccines (Schwartz 2007); Physicians identify lack of information, parental delay, lack of public awareness, as reasons for delayed PCV introduction in UK (Shankar 2009); Pediatricians and general practitioners believed that immunizing older children in office feasible but difficult, Switzerland (Vaudaux and Steinemann 1998); Health care workers with concerns about cost and scientific merit of HBV immunization will not comply with HBV vaccine recommendations, USA (Siegel 1994); Television ad campaign increased awareness among hospital and general practice staff, and parents of eligible children for PCV7 and in elderly for PPV-23 introduction in an urban setting, New Zealand, Australia (Thomas 2004); Telephone follow-up is an effective method to promote improvements in Medicare PPV immunization in NY (Quinley and Shih 2004); Telephone messaging was successful at increasing PCV vaccination rates in the US (Winston 2007); Text-message reminders were an acceptable and effective method of follow-up resulting in high HBV vaccination rates among MSM who did not routinely access health services (Warwick 2007); Catalytic interventions (e.g. NUVI) focus on social change through scaling and replication (Christensen 2006); A one-to-one education program for HBV vaccination among high risk Pacific Islander population in Philadelphia improved coverage, but less than what has been shown for other programs (Watson 1998). Community mobilization for HBV vaccination among Vietnamese-American children/adolescents in Texas had a cost-benefit | Child health days may change care-seeking behavior, promote district autonomy; increase community organization (Fiedler and Chuko 2008) |
ratio of 4.47:1 (Zhou 2003); Factors influencing HBV vaccination coverage levels amount Asian and Pacific Island fourth graders were speaking English at home, living in the US less than 5 years, and not having discussed HBV with a care provider (Pulido 2001); Inherent tension between public health publicity needs and print media needs, New Zealand (Turner 2009); Negative media messages provided a strong platform for individuals who opposed HPV vaccination, Australia (Watson 2009); Accurate messages about the safety of vaccines, especially dispelling rumors important for improving coverage, such as association between HBV and MS, France (Balinska 2009); A Canadian study reveals information access barriers, such as lack of access to physician’s recommendations, knowledge of the efficacy and security of vaccines, and admissibility of clients to the PQIIP. Organizational barriers included restricted choices of time and location and poor coordination mechanisms (Rousseau 2007); There was variation in HPV vaccine availability, recommendations, cost, policies and educational materials that could affect distribution in one US state (Katz 2009); National/sub-national Polio immunization days raised awareness of the importance of routine services in the Western Pacific Region. The social mobilization efforts increased demand for immunization services in provinces without immunization days (Aylward 1997); Polio eradication activities increased the overall visibility and awareness of DoH preventive programs in the Philippines (Tangermann 1997)

| Incentives (clients) | Monetary incentives increase HBV coverage among IDUs (Seal 2003) |
| Community and parental acceptance | The messages and methods by which HPV vaccination was marketed present important challenges to physician practice and medical professionalism (Rothman and Rothman 2009); Medical practices' concerns on HPV vaccine (Keating 2008); HPV marketing against common sense (McGee and Johnson 2007); Misconceptions or lack of information decrease demand for vaccine, US (Goldstein 2001); Healthcare provider recommendation for vaccine improves acceptance, US, Canada (Goldstein 2001; Bigham 2006); High parental acceptance of school-based delivery of typhoid vaccine, Indonesia (Agtini 2006); Insufficient knowledge of disease burden among public decrease public acceptability of hepatitis B vaccine, Hong Kong China (Chan 2009); Equity of access to information that relatively rare but severe disease may be prevented by vaccines should be shared with all parents (Siegrist 2006); Educating students did not increase HBV demand (Skinner 2000); Physicians believed that vaccinating infants at the cost of 3 injections would not be accepted, Switzerland (Vaudaux and Steinemann 1998); Physicians perceived HPV vaccination barrier as low compliance with dosing schedule, US (Tariq 2009); Reasons for delaying HBV vaccination in Taiwan are explored (Wong and Tsang 1994) Providers in US respond to parents preferences for fewer vaccines in shifting to multivalent vaccines (Freed 2006); Consumers in US find RV safety profile favorable (Patel 2007); Coverage of HBV during a campaign (supported by personalized information given to adolescent in the classroom) was influenced by use of other vaccines, origin and classroom type of the patient–five times greater effect than other interventions. The AIIMS study in India concluded that the polio eradication initiative had increased confidence in and perceptions of the health care system (Loevinsohn 2002) |
| factors (Woringer 2000) |  |  |  |
| Health workforce | No. and distribution of staff | Donor aid continues to be “disproportionately channeled to NGOs, but the NGOs has provoked a brain drain from the public sector (Pfeiffer 2008); A study of 6 Sub-Saharan African countries found child health days (which included immunization and other interventions) diverted clinic staff from routine services and that health institutions function at reduced capacity during the days (Doherty ); A study in Mali found that a campaign to treat neglected tropical diseases disrupted basic health services due to staff absences (WHO MPSC Group, 2009) |
| Health workforce | Workload | Use of existing school-based clinics for HBV delivered vaccine with minimal increase in cost, personnel and resources, US (Cassidy 1998); Time constraints seen as significant impediment to emergency department pneumococcal vaccine program in US despite favorable attitudes (Dexheimer 2006); HBV programme for HCW increases workload in UK (Jachuck 1990); In Mozambique a large share of the EPI management time was used to plan national immunization days, so diverting staff time away from routine programs (Melgaard 1998) |
| | | A study of 6 Sub-Saharan African countries found child health days (which included immunization and other interventions) found workloads were increased during these days (Doherty ); A study in Lao PDR, Nepal and Tanzania found that the effect that polio eradication national immunization days had on the delivery of other health services depended very much on staff productivity (Loevinsohn 2002); In Cambodia, planning and implementation of the first national immunization days in the early 1990s demonstrated the MoH’s capacity to conduct nationwide health initiatives whilst strengthening management systems (Melgaard 1998); A study in Mali found that a campaign to treat neglected tropical diseases led to staff being overburdened in 14 of 16 health facilities (WHO MPSC Group, 2009) |

| TRAINING AND CAPACITY OF STAFF: | Pre-service training | Simplified messages on new or interim recommendations may result in increased |
| | In-service training | A 3-country study of the impact of polio eradication on health systems noted delays and |
| Health workforce | compliance by providers, US (Groom 2008); Low levels of staff training impeded implementation of EPI in Kenya particularly with pentavalent vaccines (Ayaya 2007); On-the-job peer training improves vaccine coverage and quality of practice Indonesia (Robinson 2001); In-service courses increase knowledge scores of HCWs (Kumar 2009); Improved knowledge, greater compliance with vaccine mgmt practices and improved vaccine coverage after in-service training in Mali (Milstien 2007); Timely administration of birth dose HBV improved by communication and training activities, China (Wang 2007); Successful universal HBV vaccination often require educational training activities that target the nursing staff’s attitudes and knowledge, and misinformation among health professionals (Connors 1998); During a YF campaign, training to raise awareness of AEFI at all levels conducted, and mechanisms for systematic and timely collection and processing of biological samples and data at the national level, Burkina Faso (Yameogo 2009); A UNICEF study in Niger and Benin noted ‘missed opportunities’ to coordinate training sessions between routine immunization and polio eradication services (Loevinsohn 2002) | disruption to training schedules in Tanzania, although there was no impact on schedules in Nepal and training and training capacity had increased in Nepal and Lao PDR (Mogedal and Stenson 2000) |
| Technical capacity | Twenty-nine countries of the Americas indicate continuing technical need for technical support and for assistance with strengthening capacity and infrastructures (Burns 2009) | |

**REMUNERATION & SATISFACTION:**

<p>| Incentives | A study of 6 Sub-Saharan African countries found child health days (which included immunization and other interventions) found key informants were concerned that incentives may reduce QoC during regular health service provision outside of the health days (Doherty) |</p>
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<th>Wages and career</th>
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<tr>
<td>PERFORMANCE AND SUPERVISION:</td>
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<tr>
<td>Supportive Supervision</td>
<td>Improvements in vaccine supervision improving all service utilization in country of Georgia (Djibuti 2009); A 3-country study of the impact of polio eradication on health systems found that supervision had been disrupted in Tanzania, although no effect was reported in Nepal (Mogedal and Stenson 2000)</td>
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<td>ROUTINE DATA COLLECTION &amp; REPORTING:</td>
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<td>Data quality</td>
<td>Tracking systems assisted for catch-up vaccines among missed doses, US (Groom 2008)</td>
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<td>Data collection process</td>
<td>Insufficient attention to collecting and analyzing output-level measures (JSI Research and Training Institute 2009)</td>
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<td>Integration w/ HMIS</td>
<td>Immunization information system reduces administrative burden and leads to cost-savings in Utah (Bartlett 2007); EPI disease surveillance has benefitted from the polio AFP surveillance (Tangermann 1997) Minnesota Department of Health increased efforts to provide education to birth registrars on the importance of HBV vaccination data on birth certificates and to promote regular transmission of hospital vaccination data to the ISS (White 2009); A study of 6 Sub-Saharan African countries found child health days (which included immunization and other interventions) found data collection, compilation and reporting were parallel and separate for the days and the routine national health data systems (Doherty)</td>
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<td>SURVEILLANCE:</td>
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<td>Surveillance sites and platform</td>
<td>Assistance with surveillance and severity data are critical to accelerate wider adoption of Hib (Wenger 1999) External funds encourage the establishment of multiple and even stand-alone structures and facilities with separate systems for data control and storage. This encourages health system fragmentation (Center for Global Dectection 2008); Polio eradication programs make substantial human and financial investments in</td>
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strengthening disease surveillance, including diagnostic laboratory capacity. However studies only found improvements in surveillance in the Americas, not elsewhere (Loevinsohn 2002); In Cambodia the surveillance system for polio eradication was gradually expanded to include other diseases (Melgaard 1998); In Mali, a campaign-specific HIMS established for a neglected tropical diseases campaign had adverse effects on the existing system as a result of additional reporting requirements. Anecdotal reports suggest global health initiatives may lead to innovations in the generation and use of information (WHO MPSC Group, 2009)

| Impact monitoring | Practical methods of measuring impact of vaccination programs and targeted vaccination efforts for high risk communities is needed for HBV (Shepard 2006); Serotype changes after PCV7 introduction in Scotland (McChlery 2005); Indirect protection (herd effect) of PCV7 (Isaacman 2008); Increase in non-serotype b strains after Hib introduction in Alaska (Perdue 2000); Continued surveillance is needed to characterize the effect of routine childhood RV on rotavirus disease in U.S. children (CDC 2009); Causal pathways between intervention, outcome and impact continue to be insufficiently understood (Alliance for Health Policy and Systems Research 2007) | Elimination of racial disparities in incidence of Invasive pneumococcal disease after introduction of PCV7 (Talbot 2004); Reduction in occult bacteremia due to S. pneumonia vaccine serotypes, US (Stoll and Rubin 2004) |

| Adverse Events Following Immunization (AEFI)/post-marketing evaluation (PME) | Meningococcal (A+C) mass campaigns need effective surveillance system in West-Africa (Parent du Chatelet 2001); Intensive AEFI surveillance implemented for YF campaign in Burkina Faso required planning well in advance with increased funding (Yameogo 2009) |  |

| USE OF DATA FOR DECISION MAKING: |
| Data management | In a review of 21 developed countries, 6 countries | A study of 6 Sub-Saharan African countries found |
| **Medical products, vaccines & technologies** | has published economic evaluations for meningococcal vaccine cost-effectiveness; in four of these countries, evaluation was done before a decision to introduce the new vaccine; and in three countries, decisions were made to introduce Mening C on the basis of economic evaluations. On the other hand, 6 countries introduced the vaccine without economic evaluation (Welte 2004; Welte 2005); A CEA of PCV7 formed the basis of introducing the vaccine in Norway (Wisloff 2006) | child health days (which included immunization and other interventions) found that CHD reports were not being used for routine health service planning or assessment (Doherty) |
| **FORECASTING:** | Demand and supply forecasting | A study of 6 Sub-Saharan African countries found child health days (which included immunization and other interventions) found district managers frequently reported receiving no feedback of data (Doherty) |
| **PROCUREMENT:** | Stock management | Inability to procure constant vaccine supply a challenge to universal sustaining universal Hepatitis B vaccination program (Van Damme 2006); There was variation in HPV vaccine availability, recommendations, cost, policies and educational materials that could affect distribution in one US state (Katz 2009) |
| | Pooled procurement | |
| **COLD CHAIN & LOGISTICS:** | Cold chain management | Changing vaccine formulation (pentavalent) lead to increases in storage capacity and increased capital and training costs for cold storage in Ethiopia, Switch from DTwP to single dose pentavalent (Hib introduction) increased refrigeration storage volume per fully vaccinated child by 106% at national and regional levels and by 71% at three lower levels of vaccine distribution, Ethiopia (Griffiths 2009); Vaccine storage site main determinant for birth-dose of HBV in Vietnam (Murakami 2008); | A study of 6 Sub-Saharan African countries found child health days (which included immunization and other interventions) found drug and supply systems for the days were not integrated well with the routine PHC systems (Doherty); A review found that in some countries, global health initiatives have strengthened national procurement and distribution networks, however in others, they have duplicated and displaced country supply chains and poor |
Evaluation of cold chain capacity provides information on burden that new vaccines will place on EPI, Bangladesh (Trama 2005); RV delivery in outreach session affected by presentation of vaccine (de Oliveira 2008); Influenza vaccination needs critical infrastructure for vaccine deployment (Hessel 2009); Timely administration of birth dose HBV improved by out-of-cold chain storage and administration at the village level, esp in children born at home, China (Wang 2007); A UNICEF study in Niger and Benin noted ‘missed opportunities’ to coordinate cold chain vaccine management between routine immunization and polio eradication services (Loevinsohn 2002); A 3-country study of the impact of polio eradication on health systems found improvements in the cold chain in all three countries (Mogedal and Stenson 2000)

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<th>Effective Vaccine Management (EVM) Tools</th>
<th>Use of AD syringes improved immunization coverage significantly in Madagascar (Drain 2003)</th>
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<tr>
<td>Efficiency and wastage</td>
<td>Potential of PCV vial sizes on overall wastage &amp; need for expanded wastage management plans (Parmar)</td>
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<td>Waste disposal</td>
<td>Appropriate vaccine products like Uniject reduce waste and are economically worthwhile, promote injection safety, and improve resource utilization (Levin 2005)</td>
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<td>Sustained financing</td>
<td>Major economic constraints identified for Hepatitis B sustainability of universal vaccination program (Van Damme and Vorsters 2002); There is considerable variation in the costs of providing vaccines across geographical regions and different types of facilities, Peru (Walker 2004)</td>
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<tr>
<td>Vaccine unit prices</td>
<td>Instant scale up with Japanese encephalitis vaccine</td>
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### Financing & Sustainability

| Healthy markets, fostering developing country manufacturers | (JEV), cost effectiveness in Indonesia (Liu 2008); One-dollar/dose Korean manufactured HBV cost-effective, Thailand (Kalayanarooj 1996); Including boys in HPV vaccination not cost effective (Kim and Goldie 2009); RV is cost-neutral at 40-92 USD/dose in Hong Kong (Ho 2008); increased from $4.2 per FIC to $31.3 per FIC at a price of $1 per dose due to other system costs (Hutton and Tediosi 2006); Rotavirus vaccine can reduce the short term morbidity burden due to rotavirus but unlikely to be cost effectively unless competitively proceed (Jit and Edmunds 2007); Prevnar costs creates treatment disparity (Levenson 2003). |

| Fiscal space | A financial sustainability planning process is necessary to advocate for increased domestic and international sources of funding. Cambodia (Soeung 2006); Introducing Typhoid vaccine (Lauria 2009); HBV increases immunization costs by 11% (Fendrick 1999); Introduction of HBV has increased the annual budget for immunization services by approx 56%, Mozambique (Griffiths 2005); Implementation of hepatitis B vaccine in China between 1995-2005 yielded total benefits 272,825 Yuan and net benefits 267,477 Yuan (Zhang 2008); A study in Nepal showed that National immunization days represented the first time funds were released directly to regions and districts (Loevinsohn 2002). |

| Fund handling | Government support for JE vaccine reduced disease incidence by 90% and eliminated the inter-provincial variations (Liu 2006); Incremental capital costs of cold storage equipment, training and communication amounted to US$ 4.8 million, or US$1.53 per child in the 2007 birth cohort, Ethiopia (Griffiths 2009); A three-country study found that government funding of routine immunization had increased since initiation of polio eradication (Loevinsohn 2002); Following successful national polio immunization days, the government of the Philippines approved a much larger budget for vaccine purchases (Tangermann 1997). |

### External Financing:

- A study in Lao PDR, Nepal and Tanzania found no evidence that polio eradication reduced the financial resources available for other health services (Loevinsohn 2002).
<p>| Budget support | A financial sustainability planning process is necessary to advocate for increased domestic and international sources of funding, Cambodia (Soeung 2006); It is necessary to anticipate the substantial financial resources needed to purchase and introduce the vaccines (Peny 2005); New vaccine introduction is not limited by delivery structure or vaccine availability, but rather it is limited due to inability of governments to finance vaccine in a sustainable fashion (Batson 1998) |
| Innovations in Financing &amp; Sustainability | A public-private partnership set the long-term, maximum public-sector pricing increase access of a Japanese encephalitis vaccine for the developing world (Yaich 2009) |
| Innovative mechanisms | In low-income settings continuing weaknesses in health systems impede performance and absorption capacity, and prevent sustained gains in coverage and health outcomes. ISS funds are most promising where they provide the financial means to implement locally-appropriate technical strategies to strengthen routine immunization (Alliance for Health Policy and Systems Research 2007) |
| Donor pooling (SWAp) | A study of 6 Sub-Saharan African countries found child health days (which included immunization and other interventions) were perceived to foster improved coordination at district and sub-district level between health workers, development partners and community groups (Doherty) |
| Donor pooling | A study of 6 Sub-Saharan African countries found child health days (which included immunization and other interventions) were perceived to foster improved coordination at district and sub-district level between health workers, development partners and community groups (Doherty) |
| DISBURSEMENT &amp; RESIDENCE ALLOCATION | Incremental cost of adding new services, vaccines, or interventions is not much higher than the cost of the new vaccines or drugs to be added. Bangladesh (Khan 2004); Need to assess costs of introducing HBV into a national program. Ethiopia (Edmunds 2000). PCV does not meet conventional standards of cost effectiveness (Jacobs and Meyerhoff 2001); The |
| Competing priorities, opportunity costs | Conflicting data on administration of PCV in HIV patients leads to call for improvement of ARV therapy instead (Pierce and Hoy 2001); Positive economic benefit to Philippines Government and society by introducing Hib vaccination programme by factor 1:7 (Limcangco 2001); Aggressive and large-scale funding often fail |
| Financing &amp; Sustainability | Treatment and hospitalization costs | main challenges identified are: financial sustainability, national health budget ceilings, displacement within the Health Sector, high opportunity costs for introducing new vaccines in countries with large population, competing regional and global priorities (polio, measles campaign)(Lee 2007) | because much of goes to support specific groups of recipients, but who rarely reach the broader populations that could be served by simpler alternatives (Christensen 2006) |
| Treatment and hospitalization costs | HPV vaccination is cost-efficient for the Medicaid system in Kentucky when considering total expenditures associated with illness (Prasad and Hill 2008); HBV vaccination in Tunisia was found to cost less without previous serology (Saadallah 2001). In Scandinavia, there is a cost reduction exceeding 50% for a HBV booster compared to the regular regimen (Sangfelt 2008); Cost of Pneumococcal vaccine and its administration is 566 times lower compared to average cost of treatment for one IPM case in Czech (Madar 2008); Cost effectiveness of RV vaccine in Vietnam - 67% reduction in visits, hospitalizations and deaths (Kim 2009); The Taiwanese mass vaccination program has protected most children younger than 10 years from becoming carriers, reducing both perinatal and horizontal HBV transmission (Chang 1998) | In Taiwan, universal hepatitis B vaccination programme resulted in 86% reduction in hepatocellular carcinoma cases and deaths. The average life years gained was 3.9 (Hung and Chen 2009); PCV vaccinated group experienced a 2% reduction in clinic related costs and 14% reduction in OP hospitalization costs in California (Ray 2002); HPV vaccine has the potential to reduce Cervical cancer by half of its current incidence (Jeurissen and Makar 2009); Fulminant hepatitis B in Taiwan significantly reduced in infants after introduction of universal vaccination (Kao 2001); Use of PCV7 resulted in 39% reduction in hospital admissions among children &lt;2 years, medical visits for acute otitis media and pneumonia, reduced antibiotic use, US (Bricks and Berezin 2006; 2008); Introduction of PCV7 associated with reduction in medical visits for AOM, Canada (Wals 2009); PCV costs in Italy too high to be cost-effective (Giorgi-Rossi 2009); Reduction in pneumonia related hospitalization 0.6 to 0.3 per 1000 children, and rates of ambulatory visits declined from 1.7 to 0.9 per 1000 children after PCV introduction; estimated expenditures for all-cause hospitalizations and ambulatory visits in young |</p>
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<th>Financing &amp; Sustainability</th>
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children reduced approximately $310 million between 1997/1999-2004, US (Zhou 2007); Evaluation and management of the febrile children has changed in the conjugated vaccine era, US (Akintemi and Roberts 2006); After PCV7 introduction, decrease in medical visits for influenza-like illness in young children and elderly, US (Shafinoori 2005); Use of Hib vaccine resulted in a reduction of mean annual cost of care calculated at 62 million pesetas, Spain (Asensi 1995); Hib vaccine in children <5 years resulted in decreased hospitalizations in the age group for meningitis, US (Bent and Beck 1994); Hib vaccine reduces Hib-related orthopedic disease (Shoaib 2007); Hib immunization reduced medical visits for epiglotitis in preschoolers (Wurtele 1995); Nonmedical costs associated with hospitalization due to rotavirus are significant, US (Lee 2005); Meningococcal vaccine is not cost-saving among college students in the US (Scott 2002; Shepard 2005); Universal RV vaccination in France would avoid 249,400 RVGE cases resulting in 25,700 hospitalizations, 6000 noscomial infections, 81,200 emergency visits, 39,900 consultations, 11 deaths and 206,700 work days lost (Huet 2007); No signif. changes in length of stay or antibiotic use following RV In Panama (Nieto 2008); Reduced hospitalization and use of other services countries vaccines (rotavirus, (Brazil, Egypt, Kenya, Oman, Kyrgyzstan, China, India, New Zealand, Mexico, (Al Awaidy 2009; Constenla 2009; Flem 2009; Gurgel 2009; Milne and Grimwood 2009; Ortega 2009; Tate 2009; Wang 2009); Vaccination reduces rotavirus hospitalization costs – Uzbekistan (Isakbaeva...
RV prevents 90% of RV incidence, mortality, hospitalization, etc. through direct immunity and herd immunity (Shim and Galvani 2009); RV significantly reduces hospitalizations and costs in <2 yo and unimmunized older children in NY (Chang); RV reduces hospitalization costs in Australia (Paulke-Korinek 2009); RV decreases AGE episodes and treatment costs in Nicaragua (Orozco 2009); RV reduces hospitalization costs in Uzbekistan (Flem 2009); Global RV is cost-effective (Widdowson 2009); RV in US leads to shorter RV seasons (CDC 2009); RV cost-effective in one/five European countries (Jit 2009); RV unlikely to be cost-saving in Taiwan at present price (Goossens 2009); RV not cost-effective in NL (Zomer 2008); RV provides net cost savings of $6-40 USD in US (Griffiths 1995); A school-based HBV vaccination program in the US was shown to reduce the cost of administering the vaccine by $1.46 with a potential savings of $24 million in health care costs by the program (Wilson 2000)

<p>| HEALTH &amp; REGULATORY POLICIES: |<br />
|---|---|
| Establishment of NRAs &amp; Regulatory policies | Barriers among universities developing new vaccine products and biologicals include access to patents, materials and knowledge. Increasing access to these will allow more products to be evaluated efficiently, global (Cragar 2009); Call for compulsory licenses possible for HPV to ensure availability of vaccines to all around the world (Maybarduk and Rimmington 2009); New type of license that uses market forces to lower prices through competition in LMICS (Outterson and Kesselheim 2008) |
| National Immunization Technical Advisory | NITAGs in PAHO to be improved with ProVac assistance to accommodate NUVI (Burns 2009) |</p>
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<tr>
<th>Groups (NITAGs)</th>
<th>Norms and standards</th>
<th>Legislation</th>
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<td>After new implementation of a 7th grade HBV requirement, the number of HBV immunizations did increase at health departments where alternative strategies (e.g., school-based programs) were used, increase not as dramatic for sites where no such strategies were employed, US (Wilson and Luther 2002); HBV state policies improve HBV and Varicella vaccine coverage in US (Olshen 2007); School requirement law for HPV seen as resulting in more children vaccinated than with no law in US (Dekker 2008); Making Hib vaccination free and obligatory for all children less than 5 years of age has had a significant impact on coverage rates and on morbidity and mortality in Uruguay (Ruocco 1999)</td>
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**POLITICAL COMMITMENT:**

| Coalition building | Adopting a time-bound regional HBV control goal led to greater political commitment with reduced inequalities in vaccination between countries (Rani 2009) The Society for Adolescent Medicine urges compliance with ACIP recommendation for adolescent vaccination in US (Middleman 2006); | Two studies agreed that polio eradication helped to improve political support given to health systems (Loevinsohn 2002) |

**ORGANIZATION, STRUCTURE & REFORM:**

<p>| Governance &amp; accountability | Basic structures and mechanisms indicate that a country’s “readiness to implement” is not in place when disbursements begin (JSI Research and Training Institute 2009); A UNICEF study in Niger and Benin noted ‘missed opportunities’ to coordinate planning activities between routine immunization and polio eradication services (Loevinsohn 2002) | The AIIMS study in India concluded that the polio eradication initiative had strengthened management capacity (Loevinsohn 2002); A 3-country study of the impact of polio eradication on health systems found mostly positive improvements in organizational capacity in Nepal and Lao PDR, but negative examples from Tanzania (Mogedal and Stenson 2000); A review found that global health initiatives distracted government leaders and planners from their general responsibilities, through their focused |</p>
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<th>Programme planning and management</th>
<th>Sustained impact in planning, implementation and financing – especially at the peripheral level will require improvements in staffing, financing and guidelines (Milstien 2007)</th>
<th>intensive planning processes with tight application deadlines and heavy implementation conditionalities (WHO MPSC Group, 2009)</th>
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<td>NEGOTIATION, STEWARDSHIP:</td>
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<td>Inter Agency Coordinating Committees (ICCs)</td>
<td>The National Task Force on HBV immunization was an effective coalition for achieving 90% vaccination rate among Asians and Pacific Islanders (Reilley 2001); Two studies noted that ICCs were not always used to strengthen the immunization program as a whole (Loevinsohn 2002)</td>
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REFERENCES


