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Review

Financing vaccinations – The South African experience

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ABSTRACT

South Africa provides a useful country case study for financing vaccinations. It has been an early adopter of new vaccinations and has financed these almost exclusively from domestic resources, largely through general taxation. National vaccination policy is determined by the Department of Health, based on advice from a national advisory group on immunisation. Standard health economic criteria of effectiveness, cost-effectiveness, affordability and burden of disease are used to assess whether new vaccinations should be introduced. Global guidelines and the advice of local and international experts are also helpful in making the determination to introduce new vaccines. In terms of recent decisions to introduce new vaccines against pneumococcal disease and rotavirus diarrhoea in children, the evidence has proved unequivocal. Universal rollout has been implemented even though this has led to a fivefold increase in national spending on vaccines. The total cost to government remains below 1–1.5% of public expenditures for health, which is viewed by the South African authorities as affordable and necessary given the number of lives saved and morbidity averted. To manage the rapid increase in domestic spending, efforts have been made to scale up coverage over several years, give greater attention to negotiating price reductions and, in some cases, obtain initial donations or frontloaded deliveries to facilitate earlier universal rollout. There has been strong support from a wide range of stakeholders for the early introduction of new generation vaccines.

1. Introduction

Vaccination provides a powerful technological tool to improve the health of the world's population. However because of the nature of infectious disease transmission, no country can be entirely secure as long as reservoirs of infectious cases exist in any country; with increasing levels of travel and migration in many parts of the world including Southern Africa, continuous spread of vaccine preventable and other infectious diseases is likely. A significant number of low income countries do not have the health resources to fully finance their vaccination programmes and thus rely on various forms of international financial support.

This article provides a practical country case study of financing vaccinations. South Africa is a middle income country with relatively high child mortality (under 5 mortality rate in 2010 was 57/1000) [1], substantially driven by the HIV epidemic. South Africa's public health care system is funded through general taxes and health services are provided free at the point of use at the primary health care level. Funding new interventions requires, through economic evaluation of cost-effectiveness, the Department of Health to demonstrate the case that additional resources should be allocated during annual budget negotiations. The context for the introduction of new vaccinations in South Africa has been assisted by the overall fiscal stability of government, the presence of fiscal space (i.e. budgetary room that allows a government to provide resources for a desired purpose without any prejudice to the sustainability of government's financial position) [2] and the political priority given to improving maternal and child health, noting the large burden of disease and relatively poor child survival indicators in South Africa. Pneumonia and diarrhoea accounted for 17% of deaths of children under five years of age [3].

There is a high degree of acceptance of vaccination as a basic public good in South Africa and as an essential element of primary health care delivery. In addition to the usual childhood vaccines, South Africa has introduced four new generation vaccines:

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Hepatitis B (1996), Haemophilus influenzae type b (1998) and Pneumococcal and Rotavirus vaccines (2008). In 2002 the Minister of Finance co-chaired a global conference of Ministers of Health and Finance on vaccination in Cape Town and was a patron of Global Alliance for Vaccines and Immunisation (GAVI). South Africa also contributes to the International Finance Facility for Immunisation and is an important global site for vaccine research on tuberculosis (TB) and HIV, illustrating the political will given to vaccines.

1.1. Financing vaccinations

Financing vaccines needs to be seen within the broader architecture of financing health care within specific countries. Health financing is often considered within a conceptual framework of raising revenue (sources of funds, financing mechanism, collecting agency), pooling (risk pools, resource allocation) and purchasing (benefit package, payment mechanisms). GAVI considers a good financing mechanism should be equitable, efficient (administratively not too expensive), effective (generates adequate, timely and reliable resources) and should promote accountability and self-sustainability [4].

Vaccines are generally considered a global public good. Given the nature of infectious diseases it is essential to ensure high enough levels of immunization coverage in order to achieve herd immunity, and reduce and possibly eliminate transmission. For this reason out of pocket payments that may prevent in particular the poor from seeking immunization services are generally a poor method of financing vaccines [5]. Where countries have multiple funding pools, a national regulatory framework for at least a set of minimum benefits (including access to immunization) is needed. There are many useful international publications on the pros and cons of different financing methods [4,6,7]. Besides the more usual methods of financing health services by governments and donors, various innovative methods have been put in place to assist in financing vaccinations on a global level especially to support low income countries or coordinate purchasing across regions. These include advance market commitments (AMC), volume guarantees, long-term purchase contracts, pooled procurement such as Pan American Health Organisation's (PAHO) Revolving Fund, the International Finance Facility for Immunisation (IFFIm) and sector wide donor support (SWAp) [4,8].

2. Methodology

South African government budget documentation from 2008 to 2011 pertaining to new generation vaccines was reviewed, with a particular focus on criteria used to assess new generation vaccines for funding. Funding of vaccinations is presented in the context of recent health financing indicators from South Africa. Prices were determined initially in South African Rand and are presented in $US for purposes of international comparison based on an average exchange rate of R8.25 in 2008:$1. Trends in health expenditure were analysed from publications and databases of the National Treasury (Department of Finance) in South Africa, such as the annual Budget Review [9] and the two yearly Intergovernmental Fiscal review series [10]. Comparisons of global spending by government on health services were derived from the World Health Organisation [11]. Fiscal space was assessed through national indicators including trends in domestic revenue, government expenditure, fiscal deficit, and debt as proportion of gross domestic product (GDP), and interest expenditure as a proportion of total expenditure.

3. Results

3.1. Financing vaccination in South Africa

South Africa is a middle income country and so does not qualify for GAVI support. Despite relatively slow economic growth, its fiscal position has generally been stable with low levels of public debt (33.8% of GDP in 2011/12) and relatively small budget deficits (although these have increased during the recent global recession). Its total level of government revenue, mainly from taxation, amounted to 28.4% of GDP in 2011/12 (as compared for example to 40% in a developed country such as the UK) [9]. These factors have contributed to some fiscal space to increase spending on vaccination, in the context of a high burden of disease, increasing prioritization of health by government and a relatively average level of health financing compared to other middle income countries [11].

In South Africa, approximately 83% of the population of 50.5 million is uninsured and relies primarily on public services; 17% of the population is insured by mainly private health insurance called medical schemes [12]. South Africa is in the process of developing a National Health Insurance (NHI) system, however this is still in the process of policy and legislative development [13]. Total expenditure on health services amounts to 8.5% of GDP in 2011/12, of which 4.2% is from public sources, 4.1% from private sources and 0.2% from donors [10]. Public sector health services (and thus vaccines) in South Africa are financed predominantly in the public sector through general tax revenue. The sources of funds for general tax revenue are mainly personal income tax (36.7%), corporate income tax (19.8%) and value added tax (24.8%). Spending on public sector health services has increased from 3.4% of GDP in 1995/96 to 4.2% in 2011/12 or from 3% to 3.9% using a narrower definition (Department of Health only, excluding other government departments and entities, spending on healthcare).

The vaccination programme is financed virtually entirely through domestic resources. All vaccines provided through the public sector are free at the point of use (i.e. no user charges). The budget for vaccines (medicines component only) is approximately $131 million (R1.08 billion) in 2011/12. Costs of personnel and other components of visit costs are estimated at approximately $57 million per annum (R469m). The introduction of new generation vaccines led to a fivefold increase in expenditure on vaccines (fourfold in real terms) (Table 1). Despite constituting approximately 13% of public sector medicine expenditure, total spending on vaccines amounts to just under 1% of expenditure on public health services in South Africa. This, makes even new generation vaccines

Table 1
Budget for vaccines and as a proportion of total spending on public sector health services (nominal Rand million).

	2004/05	2005/06	2006/07	2007/08	2008/09	2009/10	2010/11	2011/12
Health spending	43,040	49,808	56,719	65,930	79,015	93,020	102,890	115,099
Spending on								
Medicines, total	3,129	3,705	4,538	4,905	5,494	6,403	8,042	8,267
Vaccines	188	197	208	219	320	646	862	1,080
Vaccines spending as a % of								
Medicine spending, total	6.0%	5.3%	4.6%	4.5%	5.8%	10.1%	10.7%	13.1%
Health spending, total	0.4%	0.4%	0.4%	0.3%	0.4%	0.7%	0.8%	0.9%

Sources: National Treasury databases and publications [9] Department of Health unpublished data.

Table 2
Health spending in context of overall fiscus.[a]

Rand billion	2004/05	2005/06	2006/07	2007/08	2008/09	2009/10	2010/11	2011/12
GDP	1,431	1,580	1,807	2,082	2,320	2,443	2,667	2,915
Revenue: GDP ratio	24.3%	26.1%	26.6%	26.9%	26.2%	23.9%	24.8%	25.0%
Total government revenue	348	412	481	560	609	585	660	730
Total government expenditure	369	417	470	541	636	743	810	885
Health spending as a proportion of total government expenditure in main budget	11.7%	12.0%	12.1%	12.2%	12.4%	12.5%	12.7%	13.0%
Health spending in public sector (narrow[b])	43	50	57	66	79	93	103	115
Health spending in public sector (narrow) as % of GDP	3.0%	3.2%	3.1%	3.2%	3.4%	3.8%	3.9%	3.9%

Source: National Treasury databases and publication series [9,10].
[a] Numbers are expressed in nominal terms (i.e. not adjusted for inflation) in SA Rand.
[b] Narrow refers to national and provincial Departments of Health only and excludes health related spending by other departments and entities.

relatively affordable. Latin American countries that have been rapid adopters of new vaccines generally spend around 1% of their health budgets for vaccine purchases. A recent analysis of the 15 countries expected to graduate from GAVI support by 2015 and become financially self-sufficient thereafter also suggests that most of them will be able to pay for all vaccines using less than 1% of estimated future public spending for health [14].

In the private sector, although medical schemes have regulatory imposed prescribed minimum benefits, these are not always perfectly aligned with the public sector vaccination programme. This means that users in the private sector sometimes pay out-of-pocket for vaccines administered by private providers, even though they have the option of receiving them free of charge at public facilities.

Table 2 shows health spending in the context of total government expenditure on the main budget in nominal terms (i.e. not adjusted for inflation). Each year as the GDP grows this leads to revenue increases and additional funds become available for allocation. These amounts increase further if tax policy makes provision for revenue as a proportion of GDP to rise, as it did from 2004/05 to 2008/09. As it happened the rollout of some of the new generation vaccines in the 2009/10 year was followed shortly by the onset of the global economic recession (see reduced revenue: GDP ratio in 2009/10), but government maintained spending levels on social services through the recession by temporarily increasing the deficit (see difference between expenditure and revenue). Health expenditure has increased by on average R10 billion ($1.2 billion) per annum in nominal or current terms (R5 billion or $606 million in real terms) over the period from 2004/05 to 2011/12 and in this context the introduction of new generation vaccines has been relatively affordable.

Comparing the level of government spending for health services across middle income countries (Table 3), South Africa's level of spending (despite the WHO numbers varying slightly from what was presented above) is fairly comparable with that of other middle income countries with similar levels of economic development as measured by percentage of GDP (3.9% for South Africa in Table 2 vs. 3.5% upper middle income average in Table 3). However South Africa's health outcome indicators are considerably poorer, mainly driven by HIV. It has been estimated that the cost of HIV for public health services alone is approximately 0.7% of GDP in 2011/12 and this cost continues to rise [15,16]. Given the higher burden of disease in South Africa it has been suggested that spending should be above the average for middle income countries.

3.2. Economic evaluation of new vaccines

As the financial implications of introducing new vaccinations are fairly substantial they usually require additional resources. In the South African context, given that the vaccination schedule is set through national policy and thus raises similar financial implications for all levels of government, the introduction of new vaccines is typically addressed in the annual round of budget negotiations.

The tabling and consideration of new budget bids by government in South Africa requires inclusion of a range of sufficient evidence to enable the evaluation of the bid. Criteria that have proved useful repeatedly in the South African context include:

- Burden of disease: data reported by the National Department of Health.
- Effectiveness of the vaccine: published studies in reputable international journals, if possible meta-analysis or Cochrane reviews.
- Cost-effectiveness of the vaccine: while international studies provide useful information, local studies are usually required, given very different cost structures across countries.
- Total cost and affordability: depends on fiscal space, prioritization, success in price negotiations and contracting.
- Feasibility of implementation and availability of a credible implementation plan. If there are doubts about feasibility, pilot studies may be useful.
- International guidelines and advice of the South African National Advisory Group on Immunisation (NAGI) and other local and international experts.
- Political process: Besides the technical aspects, the budget process also involves communication between the Ministers of Health and Finance and approval by a wider committee of Ministers, the national Cabinet and Parliament.

3.3. Protecting funding at a sub-national level

South Africa consists of nine provinces which are responsible for operational aspects of health service delivery. Provinces have substantial powers over financial allocations [17,18] and although they have historically had relatively limited discretion in introducing new vaccines there is risk that each province may fund national programmes in a different manner. To address, this several mechanisms were put in place to ensure greater consistency in the approach to adoption and uptake of new vaccines. Changes to the vaccination schedule were thoroughly discussed at a number of inter-governmental forums which coordinate activities across the various levels of government. New vaccination schedules were released as national policy with appropriate guidelines and extensive training was initiated. The new policy was identified as a budget priority and provinces were required to report back to the national level on their proposed budgets for priority areas prior to finalization of the budget process. Conditional grants are a potential mechanism to earmark and protect funding allocated at the

Table 3
Comparing government spending on health across selected middle income countries.

Country	Gov health expenditure as % of GDP		GDP per capita (current US$)	Per capita gov health expenditure (PPP[a] int $)		Total health expenditure as a % of GDP		Gov health expenditure as % of total health expenditure		Life expectancy
	2000	2007	2007	2000	2007	2000	2007	2000	2007	2008
Chile	3.4	3.6	9877	320	507	6.6	6.2	52.1	58.7	79
Mexico	2.4	2.7	9741	236	372	5.1	5.9	46.6	45.4	75
Russia	3.2	3.5	9146	247	512	5.4	5.4	59.9	64.2	68
Turkey	3.1	3.5	8865	272	467	4.9	5	62.9	69	72
Venezuela	2.4	2.7	8252	199	324	5.7	5.8	41.5	46.5	74
Uruguay	6.1	5.9	7206	500	678	11.2	8	54.6	74	76
Brazil	2.9	3.5	7185	202	348	7.2	8.4	40	41.6	72
Malaysia	1.7	2.0	7028	159	268	3.2	4.4	52.4	44.4	74
Argentina	5.0	5.1	6604	452	671	9	10	55.5	50.8	75
Botswana	2.7	4.3	6545	218	568	4.4	5.7	61	74.6	54
South Africa	3.4	3.6	5933	223	340	8.5	8.6	40.5	41.4	51
Costa Rica	5.0	5.9	5891	360	656	6.5	8.1	76.8	72.9	79
Namibia	4.2	3.2	4216	174	196	6.1	7.6	68.9	42.1	61
Peru	2.8	2.5	3771	134	191	4.7	4.3	58.7	58.4	73
Thailand	1.9	2.7	3689	89	209	3.4	3.7	56.1	73.2	69
China	1.8	1.9	2651	42	104	4.6	4.3	38.7	44.7	73
Morocco	2.0	2.3	2373	32	68	4.2	5	46.6	45.4	71
India	1.1	1.1	1096	16	29	4.4	4.1	24.5	26.2	64
Vietnam	1.6	2.8	804	23	72	5.4	7.1	30.1	39.3	74
Low income	1.8	2.2		14	28	4.7	5.3	37.6	41.9	
Lower middle income	1.6	1.8		35	76	4.4	4.3	37	42.2	
Upper middle income	3.2	3.5		243	419	6.2	6.4	52	55.2	
High income	6.1	6.9		1631	2492	10.2	11.2	59.4	61.3	

Source: World Health Statistics [11].
[a] PPP: Purchasing Power Parity.

national level in South Africa for implementation by provinces, but have not to date been used for the examples cited in this article.

3.4. Case study: pneumococcal vaccine

Pneumococcal conjugate vaccine (PCV) was first licensed for use and introduced in the private sector in South Africa in 2005 with the public sector introducing it from the latter half of 2008. Some of the key criteria used in the evaluation were:

Burden of disease: Unlike diphtheria, whooping cough and tetanus which have been virtually eliminated in South Africa, pneumonia is amongst the top four causes of mortality of South African children under five years of age, pneumococcus being the most common cause. Local data provided by the National Advisory Group on Immunisation estimated there are 100,000 cases of pneumococcal pneumonia annually with high fatality rates among the severe cases, which number 14,500–16,000 per annum. South Africa has a high rate of child mortality (57/1000) which motivated strongly for intervention.

Effectiveness: Strong evidence was available on effectiveness of pneumococcal conjugate vaccine. South Africa has a Cochrane centre. The Cochrane review [19] meta-analysis and the results of several trials were considered. As it happened one of the early landmark trials was done in South Africa, showing the vaccine's effectiveness to be 65% in HIV-infected children and 83% in HIV-uninfected children [20].

Cost-effectiveness: According to WHO-CHOICE guidelines for low and middle income countries, interventions which cost less than GDP per capita can be regarded as highly cost-effective and between one to three times GDP per capita as cost-effective [21]. Local estimates of cost effectiveness calculated by the National Treasury and National Advisory Group on Immunisation ranged from R4,312 to R11,109 per DALY averted ($523–$1,347). This is less than national GDP per capita (R51,500) and was considered highly cost-effective.

Total cost and affordability: In South Africa approximately 1.066 million children are born annually [22]. For the purpose of assessing feasibility and affordability prior to procurement, the unit price was estimated at R600 per course ($73, or $24.30 per dose) based on early discussions with suppliers. The total cost estimated at 85% coverage was R542 million per annum ($65.7 million). This was considered too large to be addressed within a single budget, but sufficient fiscal space existed for it to be reached by year two or three, if the intervention could be progressively rolled out. With the benefit of hindsight, these initial unit costs can be considered relatively high, and subsequently turned out to be more expensive than PAHO and GAVI prices [23,24]. However early adoption of the vaccine was deemed imperative, and it was thought likely that cheaper prices would be obtained over time as global and domestic volumes increased, generic and innovator competition entered the market, and improved intelligence on global pricing patterns was obtained. Costs were partially offset by a frontloaded in-kind donation of additional doses and support for cold chain capacity, training of health workers, disease monitoring and social mobilisation and communication, which improved the short-term affordability. While bundling was not a necessity, it was the outcome of negotiations with the single supplier, who made offers of additional support which enabled the early rollout of the vaccine. Various complexities regarding pricing and affordability are considered further in the discussion section below.

Feasibility: Pneumococcal vaccine could easily be incorporated into the routine child immunization schedule, and could be given simultaneously with a new pentavalent combined vaccine. A seven-valent pneumococcal strain was introduced as a short-term decision, as it was the only product licensed and registered at the time (South Africa has since introduced the 13-valent vaccine in 2011). The National Health Laboratory Service has a pneumococcal surveillance programme that monitors incidence and mortality rates. Additional provision will be made for cold chain requirements and extensive training will be implemented on the revised

schedules. Countries such as the UK and Australia had recently introduced the vaccine successfully.

International guidelines: In 2007 the World Health Organisation vaccination recommendations were widened to include pneumococcus, recommending prioritisation in countries with a high level of infant mortality, a high number of annual deaths or in countries with a high prevalence of HIV. In 2008 their use and funding support for low income countries was recommended by GAVI.

Expert advice: The South African National Advisory Group on Immunisation (NAGI) strongly recommended introduction. This view was backed by several leading paediatricians, infectious disease specialists and the South African Medical Research Council.

Political process: Budget bids are tabled by the Minister of Health to the Minister of Finance. The bid for vaccine introduction followed extensive technical advice from NAGI and detailed discussions with provinces. Budget recommendations were approved by national Cabinet and Parliament noting the priority of maternal and child health given poor child survival indicators.

Conclusion: The overall assessment process was systematic and the findings were extremely positive. The only borderline concern was affordability, however the earliest possible adoption of the vaccine was deemed imperative, and prices were expected to fall reasonably quickly. On the basis of this positive evaluation, $131 million (R1.08 billion) was allocated over three years for new vaccines in Budget 2009, with annual allocations rising over three years in line with affordability. The vaccine was introduced mid-year in 2008 in a number of pilot sites and national rollout commenced in 2009. Full national rollout could only be afforded by the third year. Negotiated arrangements with pharmaceutical companies to front-load higher volumes allowed for earlier rollout. In 2011, based on greater competition and transparency about international prices, South Africa has been able to re-negotiate substantially lower prices (see Section 4).

3.5. Case study: rotavirus vaccine

Burden of disease: South Africa has a high child mortality rate (57/1000). Diarrhoea is the third major cause of mortality in infants (10,786 deaths in 2000) and is especially high among poor children. Rotavirus causes 25–50% of child diarrhoea, 3,591–5,383 child deaths and 25–58% (30,000) of hospitalisations due to diarrhoea (personal communication National Health Laboratory Service and NAGI). The majority of rotavirus infections occur in children under one [25,26].

Effectiveness: At the time the decision was taken, substantial evidence was available that rotavirus vaccines are effective in preventing rotavirus infections, particularly serious infections with a 2004 Cochrane review of 64 trials reported effectiveness in preventing 43–90% of severe cases [27,28]. Rotavirus vaccine immunogenicity and safety trials had demonstrated effectiveness and safety in the countries where these trials were conducted, including in Europe, and in North and South America [29,30]. Interim results of a landmark South African and Malawian study [31] became available in 2008 and once published [32] helped to pave the way for revisions in global guidelines for rotavirus [33].

Cost-effectiveness and cost–benefit: Several published studies were available showing cost effectiveness in Asia, Vietnam, Mexico and the USA [34–37]. A local cost–benefit analysis provided by the National Advisory Group on Immunisations suggested benefits of reduced hospitalization alone would cover much of the costs of introducing the new vaccine. Unit costs were expected to decrease over time noting international comparisons [24,38].

Total cost and affordability: Total cost for 1.06 million children was estimated at $22 million per annum (85% coverage, $24 per course). This was considered affordable in the South African context (0.17% of total health expenditure).

Feasibility: SA has a well-established, high coverage vaccination programme and the new vaccine could be added with limited difficulty to the routine child immunisation schedule. Rotavirus is an oral vaccine, and the need for training of health care workers, upgrading of cold chain capacity and other administration issues were considered feasible in the South African context, despite short term health systems weaknesses. Countries in Latin America had recently introduced the vaccine successfully.

International guidelines: In 2008, GAVI endorsed the use of the rotavirus vaccine and was on the point of subsidising its use in low income countries. WHO had prequalified products in 2007 and UNICEF approved its use. From 2007 WHO recommended use of the vaccine in countries where infrastructure and financing was available and where efficacy data showed a significant public health impact [39] and from 2009 for all countries [33].

Expert advice: NAGI and local paediatric and infectious disease experts supported its introduction.

Political aspects: Support was provided from the National Department of Health following a large outbreak of diarrhoea deaths in the Ukuhlamba district of Eastern Cape in a context of high child mortality rates in South Africa.

Conclusion: The decision to introduce the vaccination was driven by the high burden of rotavirus disease, evidence that the vaccine could substantially reduce incidence of severe cases and support from local experts (NAGI) and global organisations (GAVI, WHO). Immunisation for rotavirus appeared to have a positive cost-benefit ratio given high incidence of childhood diarrhoea and related morbidity and mortality in South Africa. The vaccine was funded for implementation from late 2008. South Africa was – the first country in Africa to introduce rotavirus vaccine. Since its adoption, the WHO Strategic Advisory Group of Experts have reviewed the data from efficacy studies conducted in Africa and has recommended the universal inclusion of rotavirus vaccines in national immunization programs.

4. Discussion

4.1. Decision making in South Africa

South Africa provides a useful country case study for financing vaccinations because it has been a fairly early adopter of new vaccines financed virtually exclusively from domestic resources. The analysis shows that despite the higher costs of new generation vaccines, they have been considered affordable given that they constitute a relatively small portion of the health budget (0.9%) while contributing to important outcomes of decreasing child morbidity and mortality. Standard health economic criteria of burden of disease, effectiveness, cost-effectiveness and affordability provided a fairly straight forward and robust way for the country to evaluate the new interventions. On this basis, considerable additional allocations were made leading to a fivefold increase in the vaccines budget.

The technical assessments required for effectiveness, cost-effectiveness and affordability are not unduly complex and these processes have been facilitated by the presence of a strong national vaccine advisory committee and some strong domestic institutions such as the National Institute of Communicable Diseases in the National Health Laboratory Service and the Medical Research Council. These decisions were enabled by the presence of fiscal space, sound macro-economic policy, debt and fiscal management and in the context of a well functioning national revenue service. The decisions were supported by good data from international trials including a meta-analysis (including support from the local Cochrane collaborating centre), clear global recommendations from WHO and GAVI along with expert local advice. The decision was also supported by political prioritization of health and the

need to address relatively poor child survival rates. When all of the evidence and other factors were combined, the government came to the conclusion that the new vaccines represented good value for money and their adoption should be an important component of the national strategies for improving child health.

Where affordability was borderline the intervention was rolled-out over a period of two to three years, to take advantage of progressively increasing availability of public funds and the fact that it can take several years to scale up a new vaccine intervention (even when the new technology can be relatively easily integrated within existing health services).

4.2. Pricing and affordability

Pricing is integrally linked to questions of affordability and universal roll-out of new generation vaccines. In South Africa, purchasing of vaccines is undertaken through a central transversal tender, conducted by a public private partnership, specifically established for the supply and local manufacturing of vaccines. With the benefit of hindsight, lower prices could possibly have been achieved in the initial tender. However given the urgency of introduction of the new vaccines it was considered imperative to embark rapidly on the rollout. Various complexities need to be considered in relation to pricing. It is now generally accepted that vaccine prices should be tiered by country income group, acknowledging the need for innovation and appropriate incentive arrangements to encourage new vaccine development such as for malaria, TB and HIV [40]. Costs for pneumococcal vaccine appear to vary from $7 per dose in GAVI eligible countries (half of which is subsidised [41]) $10–15 a dose for lower-middle income countries, and around $20, (with an upper limit of $30 used in the sensitivity analysis) in upper middle income countries [42]. PAHO appears to have secured a price of $15 per dose [38].

When South Africa entered into initial purchasing arrangements in mid-2008 this preceded the PAHO and GAVI pooled procurement processes. At the time, there was a single innovator supplier. Prior to the tender, the prevailing price in the private sector in the country was more than twice as expensive (personal communication National Health Laboratory Service and NAGI). The country had experienced with the introduction of new antiretroviral medication a pattern of initially high prices as a result of a single innovator company and low volumes, followed by a series of rapid price decreases as greater competition and higher volumes entered the market. At the time of writing it appears likely that pricing reductions of the order of 30–40% will be obtained in the second tender for pneumococcal vaccine to be awarded in the 2011/12 financial year.

Although South Africa has been able to afford the new generation vaccines, it initially paid more than other similar income countries, for example in Latin America [24] and substantially more than low income countries [23]. While the need for tiered pricing for vaccination is understood [4] (some of this may relate to a willingness to pay a premium for innovation to encourage new vaccine development) part of this relates to limited availability of information on global pricing patterns and benchmarks. Efforts to improve intelligence on global price benchmarks and prices being offered to other countries could also help to speed up the pace of price decline and enhance affordability. Substantial use of international price benchmarking and vastly improved availability of information on medications for HIV and AIDS from Médecins sans Frontières (MSF) and the Clinton Health Access Initiative (CHAI) amongst others [43] played an important role in achieving lower prices in a recent South African national tender for AIDS medicines. Similar global benchmarking information on vaccine pricing might allow more middle income countries to negotiate affordable prices and thus speed up universal rollout of new generation vaccines. The global community may be able to assist countries by facilitating the creation of more open and transparent systems for tracking vaccine prices and for refining the basis for fair price tiering [40].

Other strategies include pooled procurement, technology transfer arrangements, and improving the regulatory environment. Regional or global purchasing arrangements such as through PAHO or GAVI [40] have helped bring down prices and improve access, and might be useful for a wider set of countries. Consideration should be given to introducing such arrangements for the Southern African Development Community (SADC) region or to building stronger cooperative agreements with GAVI, UNICEF and PAHO. Even if South Africa does not formally purchase using these mechanisms it might benefit through closer relationships to receive greater intelligence on pricing with these structures. The government did not explore technology transfer arrangements, as those designed in Brazil BioMangiunos, an area that is currently being explored in the new tenders. A recent practice note by the South African Treasury makes publication of tender awards mandatory [44]. More rapid and efficient regulatory registration processes (e.g. for WHO pre-qualified products) to bring products to market earlier and introduce competition are also likely to assist in price reduction.

4.3. Programmatic issues and impact of the rollout

A 2011 WHO/UNICEF/NDOH study [45] evaluated the introduction of the new vaccines, noting that the training for the new vaccines was properly organized, and well cascaded to facility level in all provinces. However it cited some serious challenges including poor data collection, vaccination stock shortages, and shortage of cold chain capacity. There has also been poor collaboration between the public sector support for new generation vaccines and the regulatory aspects of prescribed minimum benefits for private medical schemes, with no accompanying revision of the latter. This led to an inconsistency in the public and private financing environments suggesting a need to coordinate basic benefits across different financing streams and for the regulatory approach to be aligned with policy changes.

These logistical and operational weaknesses suggest greater attention should have been given to planning and to various additional costs of complementary inputs required for rollout. Some form of earmarking of the funds allocated, such as through a new conditional grant, might have made for smoother rollout.

Despite these challenges, the implementation and rollout of the two vaccines was achieved rapidly and has seen some success. In just one financial year from 2009/10 to 2010/11, coverage increased from 22.8% to 72.8% for pneumococcal vaccine, and 34.6% to 72.8% for rotavirus vaccine [46,47]. Initial information on child health outcomes is also promising. Early indications from the National Health Laboratory Service shows the reduction of invasive pneumococcal disease in children under two by 61% [48] and a local case control study on the effectiveness of PCV7 in South Africa, suggests a reduction of between 27.3% and 58.9% of all presumed bacterial pneumonia (PBP) [49]. Mortality data from Statistics South Africa suggest that that total deaths for children under five reduced by 17.3% between 2008 and 2009 (StatsSA, mortality and causes of death: findings from death notification 2011), while data from the South African Medical Research Council suggests a 16% reduction of child deaths from 2008 to 2010 (personal communication Medical Research Council). However these improvements in outcomes are not necessarily attributable to the new vaccines and coincide also with improvements in HIV prevention of mother-to-child transmission and treatment programmes.

4.4. Financing vaccines

The country case studies suggest that it is relatively easy to assess the potential of countries to domestically fund their own vaccination programmes, using a simple set of indicators such as national GDP, a minimum level of public funding for health as a proportion of GDP (e.g. 2%), and affordability based on the share of vaccine costs in total government health expenditures (e.g. 1–1.5%). There is a set of low income countries that (even if they were to increase health spending as a proportion of GDP) do not have a sufficient GDP base to generate sufficient revenue for public health services. These countries are likely to remain partially dependent on global financing support. Approximately 72 countries were candidates for GAVI support at a per capita income of <US$1 000. Given the increase of global GDP/capita amongst low income countries, the eligibility cut off increased to $US1 500 per capita in January 2011 and 16 countries are anticipated to graduate from GAVI assistance by 2015 [14]. The need for such bilateral, multilateral and donor support has been reported by a number of global studies which usefully cost basic packages of health services and highlight the importance of health in economic development [50]. In contrast a middle income country such as South Africa should be able to fully fund its vaccination programmes, although donors may play a transitional role in introducing new initiatives since domestic budget cycles and scaling up of funding levels can take time.

The introduction of Human Papilloma Virus (HPV) vaccine may be the next vaccine candidate to be evaluated for introduction in South Africa. Preliminary analysis suggests that although the vaccine is relatively expensive, this has not been the primary barrier to its implementation, but rather the relatively poor state of school health services and difficulty of reaching pre-adolescents most at risk. Attention is being given to strengthening these services, while cost and cost-effectiveness are further analyzed.

5. Conclusion

South Africa provides a useful case study of a middle income country that has been an early adopter of new generation vaccines. In a context of relatively high child mortality, vaccines are considered a priority intervention and a public good. Introduction of new vaccines is predominantly tax funded from the central level (although some difficulties may arise in maintaining prioritization of funds at provincial level). Evaluation of new vaccines for funding follows fairly standardized economic evaluation techniques of effectiveness, cost-effectiveness and affordability. Although new generation vaccines have led to a fivefold increase in spending on vaccine products, spending is still less than 1% of the public health budget and the introduction of new generation vaccines has been considered cost-effective.

The successful introduction of new vaccines in middle income countries is likely to be facilitated by:

- Improved understanding of effectiveness, cost-effectiveness and cost–benefit ratios for new generation vaccines.
- Better access to information on global pricing and benchmarks.
- Further development of global and regional partnerships such as for purchasing and information sharing.
- Improved regulatory processes to bring new products and competition earlier to the market.
- Appropriate incentive design to reward new vaccine development and innovation.

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Conflict of interest statement

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