Outsourcing the vaccine supply chain and logistics system to the private sector

The Western Cape experience in South Africa

October 2011

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Abbreviations

BCG	Bacilles Calmette-Guérin
CMD	Central Medical Depot
DOH	(South Africa National) Department of Health
DTP	Diphtheria-tetanus-pertussis
EPI	Expanded Programme on Immunization
EVM	effective vaccine management
EVSM	effective vaccine stores management
FIC	fully immunized child
Hep B	Hepatitis B
Hib	*Haemophilus influenzae* type b
IPV	inactivated polio vaccine
KPI	key performance indicators
MOH	ministry of health
OPV	oral polio vaccine
PCV	pneumococcal conjugate vaccine
PPP	public-private partnership
R	Rand
RV	Rotavirus
SA	South Africa
SOP	standard operating procedures
Td	Tetanus-diphtheria (reduced dose)
TT	tetanus toxoid
VVM	vaccine vial monitor
WCDH	Western Cape Department of Health
WHO	World Health Organization

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Executive summary

In recent years, vaccine supply chain management has become a priority for many countries working to scale up vaccine delivery. The introduction of new vaccines is an increasingly complex as well as costly activity, however, bringing with it a number of challenges. In addition, the resources necessary for expanding the supply chain capacity and better enabling health care workers to effectively manage, store, and distribute vaccines are often unavailable. Without external resources, many ministries of health are hesitant to make large capital investments in the kind of vaccine supply chain system that scale-up would require.

As a result, more and more countries are engaging the private sector in supply chain and logistic functions. When such expertise is available in country, as it is in South Africa, governments are frequently outsourcing the physical storage and handling of commodities to specialized private-sector logistic operators.[1]

Outsourcing is a growing trend in high- and middle-income country settings, yet remains an emerging trend in low-income country settings. Although the theoretical benefits of outsourcing are clear, the true costs and benefits remain unclear. Information regarding the challenges of outsourcing public health supply systems is lacking as is information regarding the conditions necessary to make outsourcing successful. This review attempts to address these information gaps with evidence-based information around the cost and benefits of outsourcing the supply chain and logistic functions of the system. As part of the review, a case study was conducted in the Western Cape of South Africa whereby the Biovac Institute (a third-party private-sector company) took over roles of vaccine procurement, warehouse management, inventory management, and vaccine distribution directly to health centers.

The outsourced supply chain led to a streamlined three-step supply chain for vaccines—from the national to the provincial level (up to 1,400 km one-way) and from the provincial level to the health centers (with distances ranging between 5 km and 300 km one-way). This review provided some evidence on the potential benefits of both a streamlined and outsourced system to address the growing pipeline of future vaccine. Moreover, the review was undertaken in a context where three new vaccines were being introduced into the national immunization schedule—Pentaxim (diphtheria-tetanus-pertussis, inactivated polio vaccine, *Haemophilus influenza* type B), Rotarix (rotavirus), and Prevnar (pneumococcal) vaccines. In 2010, three new vaccines were introduced in the Western Cape, and these vaccines are not only more costly, but voluminous. In South Africa, the vaccine cost per fully immunized child increased from US$25 in 2008 to US$175 in 2010 following the decision to introduce the new vaccines.

The methodology for the review utilized two approaches to analyze the outsourcing experience. The first approach was to interview key stakeholders at each level to understand the historical context and rationale that led to the decision to outsource, the perceived strengths and weaknesses of the system from an operational and management perspective, and the perception of the clients (i.e., health centers) in terms of their satisfaction with the services provided. The second approach relied on three factors: (1) a

diagnosis of the strengths and weaknesses of the outsourced supply chain based on an effective vaccine management assessment; (2) a temperature monitoring analysis along all storage points and transport routes as the quality control measure to ensure that vaccines handled by the outsourced company are kept at the recommended temperature ranges and vaccines are not at risk of freezing or damaging heat exposure; and (3) a detailed economic and financial analysis to review the costs of the outsourcing model and understand to what extent outsourcing is good value for money.

The review concludes that the outsourcing of the vaccine supply chain to Biovac has been a good solution for the Western Cape Department of Health (WCDH) and is a viable option for future consideration by other provinces. In fact, the outsourcing agreement proved a key factor in the Western Cape's ability to handle a 2010 measles outbreak and the introduction of the three new vaccines. In addition to storing and transporting vaccines in good condition and meeting the orders received from the district on behalf of the clinics in a timely fashion, the 6% overhead fee is highlighted as a cost-effective investment—adding to the value proposition for outsourcing. Had the Central Medical Depot (CMD) of the Western Cape carried out these services, they would have levied a 5% overhead charge. In addition, far more training and support would have been required as CMD has no routine vaccine cold chain expertise. In other words, CMD could have taken responsibility for these services (for less), but did not have the necessary cold chain capacity nor expertise. Biovac's overhead charges are also competitive compared to other private-sector providers in South Africa that have less cold chain and vaccine management expertise.

By comparison, outsourcing is not a good value proposition for health centers in the Western Cape Province that receive their vaccines via resupply points, which results from some districts not wanting Biovac to bypass their level (district level) in the system. It is also not a good value proposition for district stores that want to have more control over the vaccine stockpiles of health centers for which they are responsible. In the end, the costs of the systems are higher for those health centers that the Biovac distribution contract did not cover. This is something that other provinces should consider before adopting a similar outsourcing model.

The weaknesses of the outsourced system are mainly attributable to the WCDH's lack of management oversight of the contract, problems in the contract itself (i.e., the terms of the service-level agreements) and the lack of key performance indicators, and the decoupled ordering information systems between the WCDH and Biovac. These weaknesses can serve as lessons learned for other countries that are considering outsourcing their supply chain and logistics system to a third party. Addressing these weaknesses early on in the decision-making process can help other countries to avoid making similar errors.

The lessons learned from this review highlight many considerations that other provinces in South Africa and other countries in the African continent should weigh before deciding to outsource. Outsourcing can help to increase the supply chain performance of the existing system but it is by no means a panacea. Venturing down the path of outsourcing will require new sets of skills and will result in a host of new challenges.[1] It is important

that the right framework and approach be established in order for an outsourcing public-private partnership to be successful.

Introduction

Vaccine supply chain management has received increasing attention in recent years—as both a priority and a challenge for many countries—as ministries of health find themselves struggling to scale up health interventions because of the increasing number of health commodities to manage in their programs.

With an expanding number of health commodities to manage, many ministries of health are struggling to scale up health interventions—particularly those involving the vaccine supply chain. Challenges are all the more acute in the immunization world, due to the introduction and availability of many new vaccines within the past decade and the promise of an even newer pipeline of vaccines in the next.

Immunization programs face vast and numerous challenges associated with scale-up and meeting global goals and targets, such as Millennium Development Goal 4, the Global Immunization Vision and Strategy, and the Decade of Vaccines—all three of which involve a progressively large, complex, and costly throughput of vaccines. In addition, there are limited resources available to expand and adequately scale up the supply system as such.

On the other hand, more and more countries are recognizing the benefits of engaging the private sector in supply chain and logistics functions and are, when such expertise is available in country, outsourcing the physical storage and handling of commodities to specialized logistic operators in the private sector.[2] During the American/African Private Health Sector conference in Washington, DC (October 4–6, 2010), Dr. Luis Sambo, World Health Organization (WHO) Regional Director for Africa, called for greater private-sector involvement, stating "that the health systems challenges in the African Region are too complex for the public sector to address alone." Referring to health commodity supply chain systems, Dr. Sambo highlighted the clear role that the private sector can have in complementing governments' efforts to improve health logistics in specific areas including procurement, storage, and the distribution of drugs and vaccines.[3]

However, despite Dr. Sambo's high-level endorsement of the need to build better partnerships and synergies with the private sector in order to address supply chain challenges, there are few documented reviews of such practices in developing countries.

Rationale for outsourcing

Throughout Africa, vaccine supply chains developed some thirty years ago are reaching their limit. Supply chain and logistic assessments conducted in the region have shown that many are ill-equipped to manage the challenges associated with introducing new, more voluminous, and costly vaccines now and into the future (authors' unpublished data, 2011).

In addition, as the cost of vaccines continues to rise, the systems need to increase efficiencies to avoid stockouts, minimize wastage, and ensure safety in vaccine management. In 2010, a quarter of a million doses of DTP-hep B-Hib (diphtheria-tetanus-

pertussis, hepatitis B, *Haemophilus influenza* type B) vaccine that were newly introduced into the national immunization schedule of one country became expired in the national vaccine warehouse because the system charged with delivering the vaccines was not ready. At US$3.60 per dose, close to a million dollars' worth of vaccines were lost due to inefficiencies in the government-run distribution system. Another country was forced to delay its plans to introduce a new vaccine because the vaccine volume required for the introduction necessitated a nine-fold expansion in the national vaccine warehouse. The investments required to expand the cold chain storage capacity tied up budgets, causing a delay in the building of extra storage space in the government-owned vaccine store, which resulted in cohorts of children not being vaccinated on time.

The stories mentioned above represent two of many anecdotal stories from the field and highlight the changing context of vaccine supply chain systems—most especially as they struggle to accommodate new, more bulky, and more expensive vaccines. Moreover, ministries of health can no longer afford to have inefficient and ineffective vaccine supply chains when vaccines are now priced in dollars and tens of dollars rather than cents per dose.[i]

Supply chain outsourcing is one solution with enormous potential for the future. In the commercial sector, outsourcing is a growing trend and has been for several years.[3] In public health programs, however, experience with supply chain outsourcing is rather limited although there are signs that governments are beginning to catch up with private-sector practices.[4]

There are two broadly defined outsourcing models in the health sector. In the first model, the outsourcing partner (the provider) manages part of the system including the equipment, staff, and information systems as a service to the ministry of health (MOH). For the immunization program, the provider is typically responsible for one or more of the following:

- Vaccine arrival and transfer (customs clearance at port of entry and transfer to the national warehouse).
- Vaccine warehousing at all levels of the chain (storage).
- Vaccine distribution and deliveries (transport).

In the second model, the provider leases materials or equipment to the MOH or provides regular ongoing support service. In this model, the provider is typically responsible for one or more of the following:

- Cold chain equipment preventive maintenance contract.
- Vehicle leasing and maintenance contracts.

In practice, neither of these models is mutually exclusive—one or several supply chain functions for vaccines can be outsourced.

[i] A dose of measles vaccine is less than US$0.15.

The aforementioned models underscore specific advantages in outsourcing, based on the rationale that in an outsourced model, long-term and expensive capital investments and their maintenance are absorbed by the provider, and the MOH will gain allocative and productive efficiencies in health commodity management.

Private-sector providers traditionally have great incentives compared to public systems in the following areas:

- Using efficient processes that minimize wastage of resources.
- Making the best use of available resources and technologies.
- Exploiting economies of scale where possible.
- Relying on high-quality managerial efficiency.

Thus, outsourcing is theoretically more cost-effective for the MOH despite that it has greater recurrent costs. However, the costs and benefits of outsourcing are often not clear, and supply chain managers and logisticians have limited information to guide them in the evaluation of outsourcing as a viable option for their context.

Purpose of the review

As part of its work in identifying innovative solutions for the future, project Optimize reviewed the vaccine supply chain outsourcing experience in the Western Cape Province of South Africa in order to:

- Generate an evidence base that vaccine supply chain outsourcing to a private-sector third-party logistics (3PL) provider is a viable and cost-effective option for the future, particularly in the context of a growing pipeline of new vaccines.
- Provide the Western Cape Province MOH and the provincial immunization program an evidence base for the outsourcing model.
- Gain a better understanding of the challenges associated with outsourcing and the necessary conditions for its success.

On November 24, 2009, the outsourcing review was formally endorsed and launched by all key stakeholders at a one-day workshop in Cape Town (authors' unpublished data, 2009). Stakeholders at the workshop reached consensus as to the research design, the key areas of investigation, and the methods/metrics to be used for the assessment. Following the workshop a specific project proposal was drafted (authors' unpublished data, 2009) in which the broad areas of collaboration between project Optimize, the Collaborative Centre for Cold Chain Management, the Western Cape Department of Health (WCDH), and the Biovac Institute were identified and articulated.

The goal of the collaboration with South Africa was to demonstrate the benefits of outsourcing as a supply chain solution to address anticipated challenges in the vaccine supply chain in South Africa and other countries in the region. The main areas of inquiry were organized around management and operational themes in order to answer questions about:

- The historical context that led to considering outsourcing as a solution.

- The decision-making process and key drivers leading to WCDH to decide to outsource.
- The contracting process, implementation, and monitoring of the outsourcing agreement.
- The client's perceived satisfaction with the outsourced services.
- The operational performance of the service provider in terms of storage, transport, and managing and responding to vaccine orders.
- The economics of outsourcing.

This review came against the backdrop of the WCDH wishing to evaluate the outsourcing model in view of renewing their contract with the service provider. As such, it was hoped that the findings from this review would:

- Help the WCDH strengthen any revised outsourcing contract with Biovac.
- Provide guidance to other provinces in South Africa that wish to outsource their vaccine supply chain system to the private sector, and can use the Western Cape model as a possible blueprint.
- Be an outsourcing model for other countries that may choose to outsource their vaccine supply chain and logistics systems to a 3PL provider.

South African context

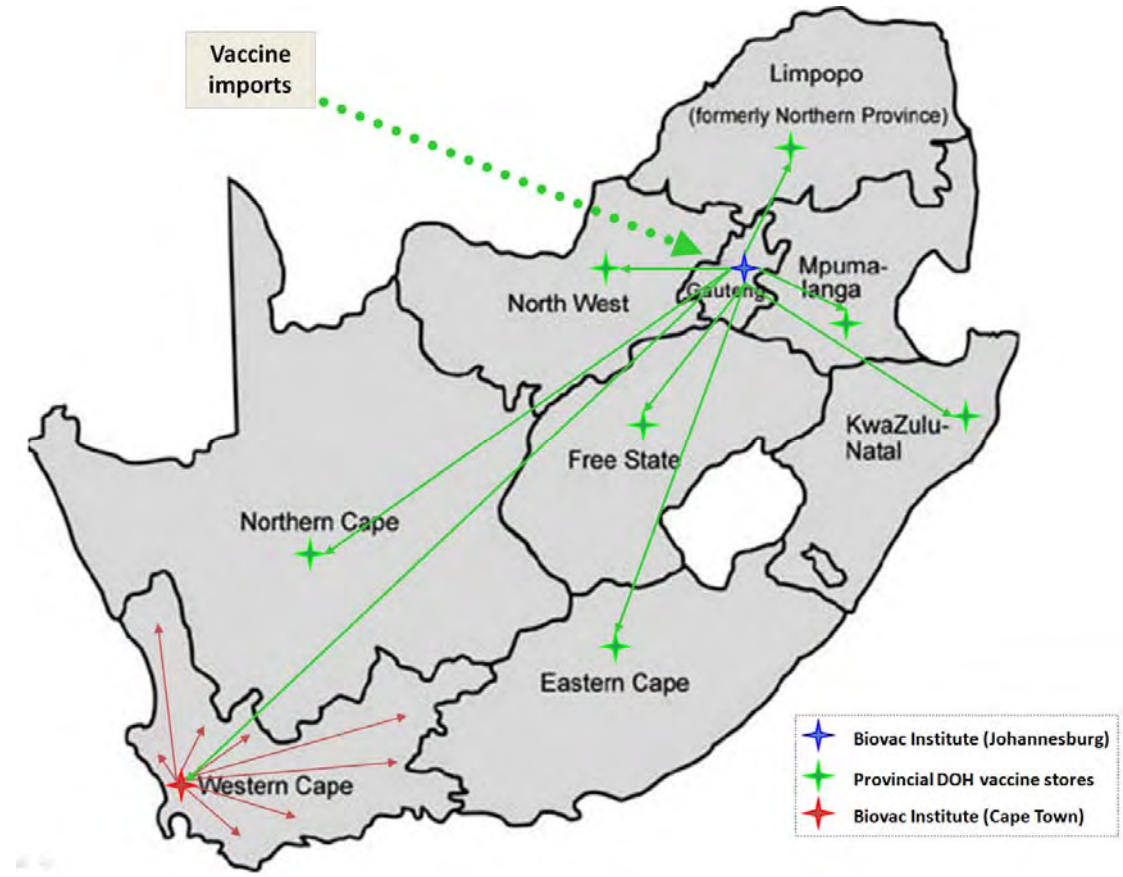
The Supply Agreement

In 2003, the South Africa National Department of Health (DOH) entered into a public-private partnership (PPP), known as the Supply Agreement, with a third-party private-sector company named the Biovac Institute. The initial contract enabled Biovac to import and supply all pediatric vaccines for South Africa until December 31, 2010. Following a review of the PPP in 2010, the DOH renewed the Supply Agreement with Biovac effective from January 1, 2011, to December 31, 2016.[4]

The Supply Agreement details the South African DOH outsourcing of procurement, central level storage, and distribution of vaccines to nine provincial vaccine storage depots. In essence, the vaccine supply chain above the provincial DOH stores is managed by Biovac according to the terms of the contract (authors' unpublished data, 2011). That said, the DOH continues in its role of forecasting the annual vaccine requirements for the country and corresponding provinces. It also provides the forecasts to Biovac. In essence the national immunization program for South Africa became a de facto virtual warehouse.[ii]

[ii] This means that the physical storage and handling of the commodities is not done by the DOH, but control is maintained on the information systems and the quantification of needs.

Figure 1. Supply Agreement between Biovac and the DOH



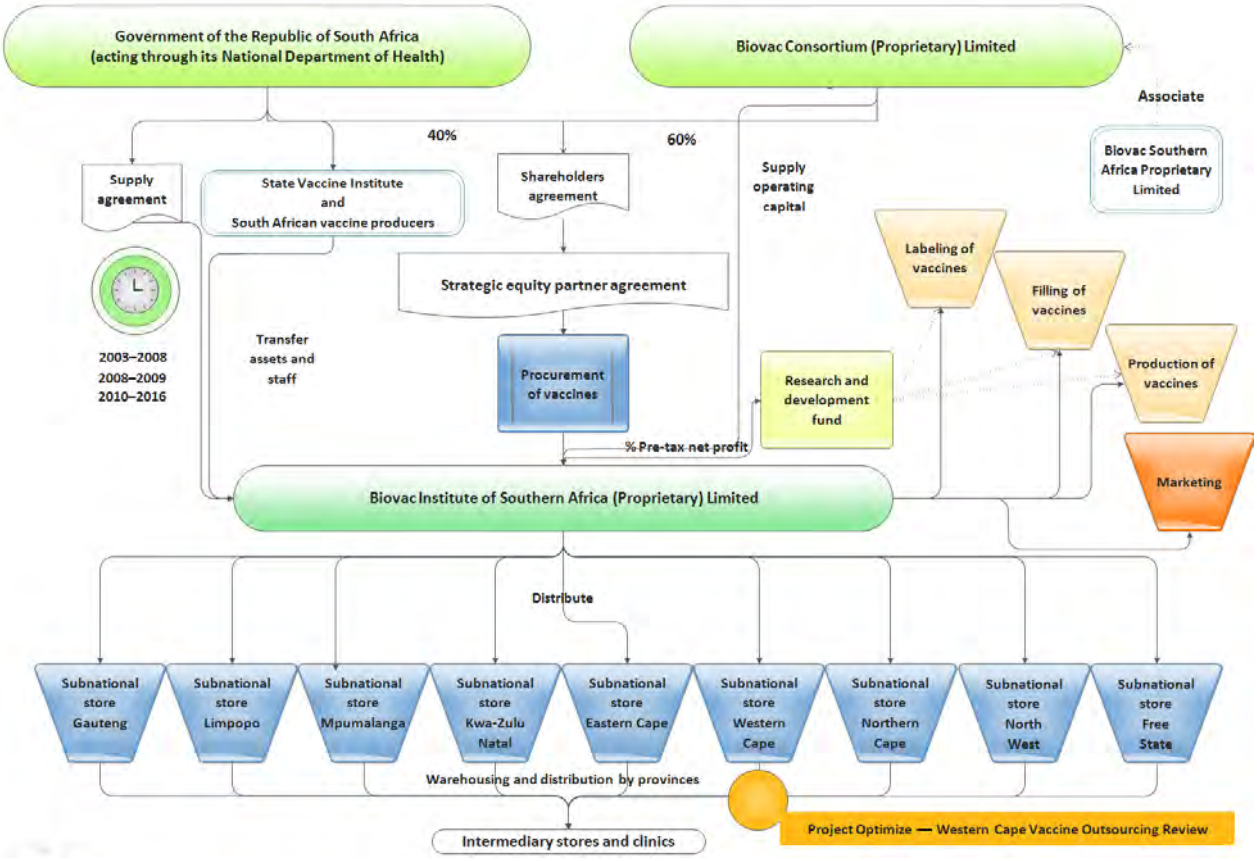
The provincial departments of health for the Eastern Cape, Northern Cape, Western Cape, KwaZulu-Natal, Free State, Gauteng, Mpumalanga, Limpopo, and North West Provinces manage the provincial depots and the vaccine supply chain down to health facilities. In the Western Cape Province the Supply Agreement is different and is described in more details in a separate section.

In effect, the Supply Agreement is an outsourced contract whereby a 3PL company manages the supply chain function of national-level procurement, storage, and distribution of vaccines to each of the nine provinces. Biovac charges either 15% or 22% of the value of the vaccines to cover their overhead in providing the services. Biovac charges 15% if the imported vaccine is a finished product and 22% if the imported vaccine comes in bulk and requires Biovac to do the filling, packaging, and labeling of the vaccine. Although these rates are relatively high, it should be noted that in addition to the Supply Agreement there is a Strategic Equity Partner Agreement between the DOH and Biovac. This agreement governs the strategic nature of the partnership in terms of vaccine production, packaging, marketing, and profit sharing.[iii] In other words, the profits

[iii] Although the Supply Agreement has been renewed as part of the PPP, at the time of this report the Strategic Equity Partner Agreement was still under discussion.

Biovac generates from the Supply Agreement serve to fund the development of Biovac's vaccine production capabilities.

Figure 2. Biovac and Department of Health PPP arrangement and schematic



New vaccines introduced

In 2009, South Africa decided to expand its national immunization schedule by introducing three new pediatric vaccines to prevent against certain respiratory infections (Hib and pneumococcal) and diarrheal diseases (rotavirus). Table 1 shows the current vaccination schedule.

Table 1. South African national immunization schedule for 2010

Vaccine (doses per FIC)	Birth	6 wks.	10 wks.	14 wks.	9 mo.	18 mo.	6 yrs.	12 yrs.
BCG (1)	X							
OPV (2)	X	X						
DTP-IPV-Hib (4)		X	X	X		X		
Measles (2)					X	X		

Vaccine (doses per FIC)	Birth	6 wks.	10 wks.	14 wks.	9 mo.	18 mo.	6 yrs.	12 yrs.
Hep B (3)		X	X	X				
Rotavirus (3)		X						
Pneumococcal (3)		X		X	X			
Td (2)							X	X

BCG = Bacilles Calmette-Guérin; DTP-IPV-Hib = diphtheria-tetanus-pertussis, inactivated polio vaccine, *Haemophilus influenzae* type b; FIC = fully immunized child; hep B = hepatitis B; OPV = oral polio vaccine; Td = tetanus-diphtheria (reduced dose).

By the age of 18 months, a fully immunized child will have received 16 inoculations. This means that there are a lot of vaccines in the supply chain.

Decentralization

South Africa is a heavily decentralized country. Financial functions and accountability are the core responsibilities of provincial and local governments, who by law must have an adequate budget—either raised locally or transferred from the central government—as well as the authority to make decisions about expenditures.

For vaccines that are entirely funded by the government, the budget allocation is voted on annually, and each of the nine provinces receives its share based on a per capita allocation. At the provincial level, the vaccine budget and financing is further decentralized to district offices[iv] within the province, which act as decentralized budget centers. They are allocated their proportion of the provincial vaccine budget on a per capita basis. Health centers then place their vaccine orders, which must be subsequently approved by the district budget center.

Western Cape context

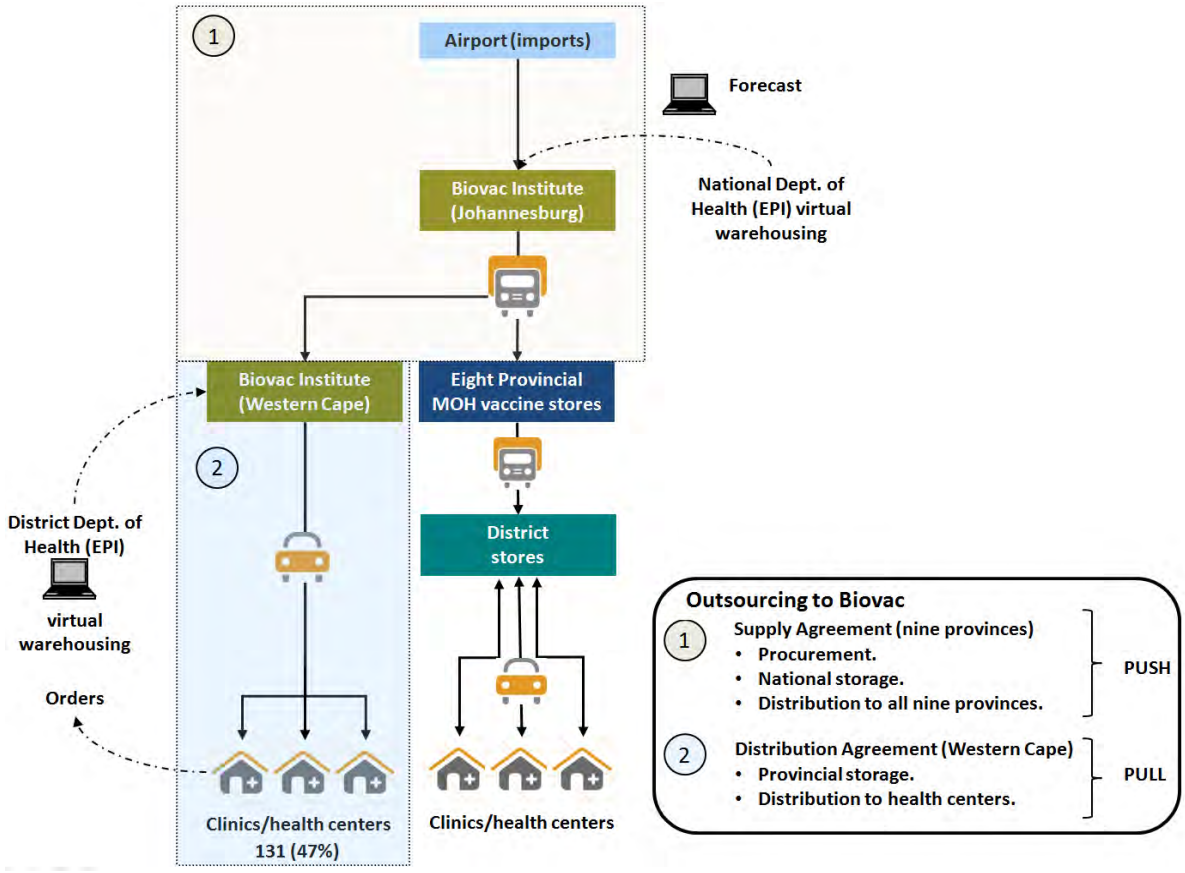
The Distribution Agreement

In South Africa, the Western Cape Province has a unique agreement in place to manage its in-province supply system for vaccines. Since 2005, the province benefits from both the broader PPP with Biovac (described as the Supply Agreement) but also from an extended partnership with Biovac known as the Distribution Agreement. In this agreement, Biovac is responsible for the provincial storage of vaccines and their distribution to health centers[v] across the province. In the eight other provinces of South Africa, the provincial departments of health manage the warehousing and transport of vaccines to health centers. In other words, the WCDH outsourced its provincial vaccine supply chain system to a private-sector third-party cold chain logistics company.

[iv] The term “district office” refers to a sub-provincial administrative level. The Western Cape is divided into six areas: City of Cape Town, West Coast, Overberg, Cape Winelands, Central Karoo, and Eden Districts. Each of these six areas contains a district office of the WCDH.

[v] The term “health center” is used loosely to refer to any facility where vaccinations occur. These can be clinics, district hospitals, regional hospitals, or other facilities.

Figure 3. Distribution Agreement between Biovac and the WCDH



EPI = Expanded Programme on Immunization; MOH = Ministry of Health.

Streamlined supply chain

The Western Cape system has several advantages. In addition to the benefits derived from outsourcing described earlier in the review, the Western Cape's supply chain is streamlined.

Any system that supplies vaccines directly or in the most direct manner possible from the national level to the health center level is considered streamlined. A streamlined supply chain decreases the number of touch points for vaccines before reaching their final destination. There are a number of perceived benefits to a streamlined vaccine supply chain. Reducing the number of storage points and transport legs in the chain can:

- **Decrease the amount of time between the initial vaccine request and their receipt at the point of delivery** since the vaccines have fewer touch points (storage points/transport legs). A streamlined system has the advantage of being more responsive and closer to the supply chain goal of just-in-time delivery.
- **Minimize the risks to vaccines.** Fewer touch points in the supply chain results in fewer opportunities for error. This lowers the risk of mishandling vaccines and the risk of temperature excursions (breaks in the cold chain). Fewer touch points also minimize the risks of vaccine wastage, leakage, and breakage.

- **Raise efficiency by reducing the need to hold buffer stock.** Having buffer stock can cause vaccine inventory to be idle at different points in the supply chain, and reducing buffer stock reduces the costs of having idle vaccine leading to efficiency.

The vaccine supply chain in the Western Cape Province with the Distribution Agreement is comprised of a lower number of touch points (national level, provincial level, and health centers) for a very large country.[vi] In contrast to other provinces, the Western Cape model bypasses the district-storage level. By comparison to most models in other countries in the region, the Western Cape supply chain model has at least two fewer storage points.

Outsourcing contract with Biovac

In 2004, the WCDH and Biovac signed the Distribution Agreement which serves as a contract that describes the terms and conditions of the public-private partnership (authors' unpublished data, 2004). The Distribution Agreement is an extension of the Supply Agreement and is intricately linked to it in terms of duration. The former would continue to be in effect for the duration of the Supply Agreement contract. Since 2004, the Distribution Agreement has not been changed, formally reviewed, evaluated, amended, or modified. The main features of the outsourcing contract that were in effect during the time of this review are summarized below.

Orders

Vaccine orders originate from health centers and are sent to the district office. For this to happen, a vaccine order is entered at the health center level into the government's procurement system named Logis.[vii] Once entered in the networked system, the responsible district officer reviews and approves the purchase order. Note that the responsible district financial officer is merely approving a purchase order for vaccines on the basis of available funding.

Once an order is accepted, it is passed from the district office to Biovac stipulating the full details of the vaccines required as per the health centers' request including the quantities and the place of delivery. Once the order arrives at Biovac, it is picked, packed, and delivered by Biovac drivers to the specified place of delivery. Upon receipt at the health center level, the Biovac driver and assigned health worker check the order. If satisfied, the health facility signs the invoice. A copy of the invoice is returned to the district office to initiate payment to Biovac for that specific order.

Storage and transport

All vaccines in the Western Cape Province are stored at the Biovac Pinelands facility which has a state-of-the-art cold room and freezer room (see Annex 2). The Distribution Agreement requires Biovac to maintain a three-month minimum supply of vaccines for

[vi] South Africa is ranked 25 in size out of 220 countries and territories.
[vii] Note that the City of Cape Town uses a different procurement system called Systems Applications and Products or SAP.

the entire province at all times (subject to the availability from vaccine manufacturers[viii]). For each health facility order received, the vaccines are packed in insulated vaccine carriers labeled with their contents and the delivery address. Each individual parcel contains sufficient chilled ice packs (or dry ice) to maintain recommended temperature levels for the duration of the transport. They are also organized in the parcel to ensure that freeze-sensitive vaccines are not exposed to sub-zero temperatures. A disposable temperature monitor to note heat exposure and a Freeze Watch™ freeze indicator[ix] to note possible freeze damage are placed in every parcel and are checked by the health center upon arrival. Once an order is picked and packed, the parcel is placed inside the Biovac cold room until it is ready to be transported.

The maximum lead-time for deliveries as specified in the contract is 14 business days from Biovac's receipt of the order. In most instances, picking and packing is done within two to three days, and deliveries are done within five days of receiving the order.

Two modes of transport are used for deliveries of vaccines to the health center. In the majority of cases the dedicated Biovac delivery vehicles are used. The Biovac delivery vehicles are converted pick-up trucks equipped with insulated but non-refrigerated cabins. If the orders are small and the distances are great, Biovac resorts to using a third-party courier service to transport the vaccines rather than use its own vehicle.

Delivery points

One of the annexes of the Distribution Agreement details the distribution points served under the contract and can be revised at any point with consent from both parties. In theory, all health centers in the Western Cape Province can benefit from the services of Biovac. In practice, however, some districts have exercised their right to not have Biovac transport vaccines directly to their health centers, even if this service is covered by the outsourcing contract. Instead, these districts requested that the outsourcing contract dictate that the distribution point be the district hospital. These district points then act as a re-supply point to health centers and are equipped with their own cold chain storage capacity. In other words, the vaccine supply chain is less streamlined for those health centers that receive their vaccines from the district hospital.

Out of the 277 health centers in the Western Cape (excluding satellite and mobile-service sites), Biovac distributes vaccines directly to 131 (or 47%) health centers. For the remaining 146 health centers (or 53%), Biovac distributes vaccines to the corresponding district hospital. In these instances, the transport of vaccines from the district to health centers is covered by the district hospital at their own expense—either by using a district vehicle and drivers or by using a courier service.

It is not entirely clear why such districts prefer that Biovac not deliver vaccines directly to health centers. Anecdotal evidence suggests that these districts prefer to keep control of the vaccine stock and will not place their trust in a system of decentralized vaccine ordering to health centers that operates without any determined minimum/maximum

[viii] The Supply Agreement contains specific clauses and penalties regarding vaccine availability and supply.
[ix] Freeze Watch is a trademark of 3M.

stock levels. For these districts, the perception is that without such control, the risks of stockouts are too great. Stockouts are more difficult to handle if health center orders go directly to Biovac, who will simply respond to an order without knowledge of the appropriate order size per facility. Without a system of checks and balances, it is easy for some health centers to order more than they need—depleting their district's annual vaccine budget and increasing the risk of stockouts elsewhere once the budget is used up. As such, these districts prefer to have oversight and the ability to reallocate vaccines from their level to ensure that no stockouts occur in any of their health centers.

Fees and payments

Per the Distribution Agreement, Biovac charges for the cost of the vaccines according to its quarterly published price list. In addition, a 6% charge (excluding value-added tax) is levied on the value of the vaccine orders to cover the overhead incurred by Biovac for the services rendered: the provincial storage of vaccines, the picking and packing of individual orders, and the transport of the orders directly to health facilities (or other specified addresses). Biovac imposes a minimum order size of R1,000 (about US$120) excluding deliveries to very small clinics, which are covered by district resupply points.

Although the contract stipulates that Biovac is entitled to annual price adjustments on the 6% overhead in accordance with published consumer price index figures from the national statistics office, no adjustment has ever been made in practice. Since 2004, the 6% flat rate has been levied for the services.

On the WCDH side, district offices have 30 days lead-time to pay Biovac, which is one month after the vaccines have been received at the specified delivery point. In practice, the 30-day grace period was rarely met, causing arrears to accumulate.

Reporting

According to the outsourcing contract, Biovac is expected to regularly communicate information regarding their vaccine stock levels and any other issues that may impact stock levels in South Africa more generally (from the Supply Agreement).

In the 2004 contract, it was stipulated that this information would be provided through a website reporting system that would enable the WCDH and each of the district offices to retrieve information and statistics on stock levels, monthly sales, expenditures, vaccine prices, and orders of the vaccines to their facilities. To date, this website has not been developed. The reporting is done by circulating monthly information to the provincial immunization program (usually monthly reports sent by email).

Methodology

The overall approach to the review consisted of several interrelated activities. The first involved interviewing different sets of key stakeholders to get qualitative information on (a) the historical context, background, and evidence that led to the decision by the WCDH to outsource the vaccine supply chain system to Biovac; (b) the operational and

management side of the Distribution Agreement and lessons learned; and (c) the perceived quality of the services at the health center level.

Various sets of questionnaires were developed and tailored to address the needs of various stakeholders.[x] The questionnaires provided a way of generating the qualitative information on the rationale for outsourcing the vaccine supply chain, the areas of strength and weakness of the Distribution Agreement from an operational and management perspective, and the perceived quality of services by the health facilities. In total, 32 people were interviewed and represented different stakeholders and perspectives.

Table 2. Composition of the sample of stakeholders interviewed

Location	Type of interview	Interviewees	Number of interviews
Cape Town	Historical	City of Cape Town	3
		WCDH	3
	Management and operational	City of Cape Town	2
		Biovac	3
		WCDH	5
Johannesburg	Historical	Litha Healthcare	4
	Management and operational	Litha Healthcare	4
Western Cape	Operational and perception	WCDH (regions/districts)	8
Total			**32**

WCDH = Western Cape Department of Health.

Three additional quantitative activities were advanced that measured the performance of Biovac in carrying out the Distribution Agreement in the Western Cape Province: an effective vaccine management assessment, a temperature monitoring study, and an economic evaluation.

Effective vaccine management assessment

In order to determine whether vaccine management practices were up to standards, this review carried out an effective vaccine management (EVM) assessment at the Biovac facility in Pinelands and in a sample of eight health facilities in the Western Cape Province.

This review used the WHO EVM Tool for the assessment. The tool has a standardized methodology endorsed by WHO and the United Nations Children's Fund to diagnose vaccine supply chain systems according to nine key criteria for effective vaccine

[x] Naomi Wasserman is the lead author of these questionnaires and interview guides.

management.[xi] See the findings and results section for an in-depth description of the criteria.

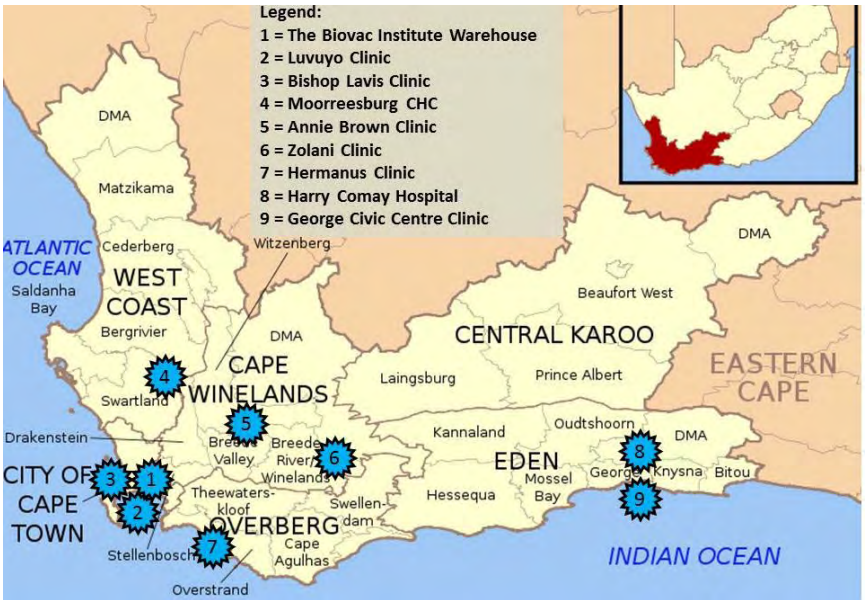
Table 3. Characteristics of the EVM sampled sites

EVM sampled site	No. of infants by site	Area	No. of infants by area	EVM level
Biovac		Cape Town		Subnational store
Bishop Lavis Clinic	584	Cape Town	70,337	Service point
Luvuyo Clinic	195			
Zolani Clinic	173	Cape Winelands	13,212	Service point
George Clinic	213	Eden	9,552	Service point
Harry Comay Hospital	9,160			Lowest distribution level
Hermanus Clinic	83	Overberg	4,442	Service point
Moorreesburg Clinic	312	West Coast	5,413	Service point

EVM = effective vaccine management; WCDH = Western Cape Department of Health.

For the assessment, eight delivery sites were selected: the Biovac provincial store in Cape Town, six health facilities representing approximately 10% of the overall birth cohort of the Western Cape, and one district hospital acting as a resupply point for vaccines.

Figure 4. EVM sampled sites



Source: WHO. *Western Cape EVM assessment, 22-26 November 2010: Findings and Recommendations of the Assessment Team*. Geneva: WHO; 2010.

[xi] For more information see: http://www.who.int/immunization_delivery/systems_policy/logistics/en/index6.html.

Temperature monitoring

While the EVM tool is an excellent way to measure the quality of vaccine management practices, temperature monitoring proved an important quality control measure for ensuring that vaccines handled by Biovac were kept at the recommended temperature ranges during both storage and transport. This ensured that vaccines were not at risk of becoming frozen or damaged by heat exposure.

The WHO study protocol for temperature monitoring served as the basis of the methodology[xii] and was adapted by the Collaborating Centre for Cold Chain Management to fit the Western Cape context (T. Raubenheimer, unpublished data, 2011). The temperature of the cold chain at the Biovac warehouse was analyzed and temperature monitoring on 12 distribution routes was conducted during an eight-month period. The distribution routes were selected in a way that represents all possible ambient temperature limits across the Western Cape, and logistics/accessibility challenges (see Annex 4). The temperature study focused on the furthest points of delivery for each route.

A total of 24 LogTag® device[xiii] (LogTag is a registered trademark of LogTag Recorder Limited) temperature recorders (TRIX-8) were used. The review logged temperatures and compared them against the start benchmarks for an excursion event:

- Less than -0.5ºC for 60 minutes indicated a freeze alarm.
- Greater than 8.0ºC for 10 hours indicated a heat alarm.

Figure 5. Transport routes where temperature monitoring was conducted

Source: WHO. *Western Cape EVM assessment, 22-26 November 2010: Findings and Recommendations of the Assessment Team*. Geneva: WHO; 2010.

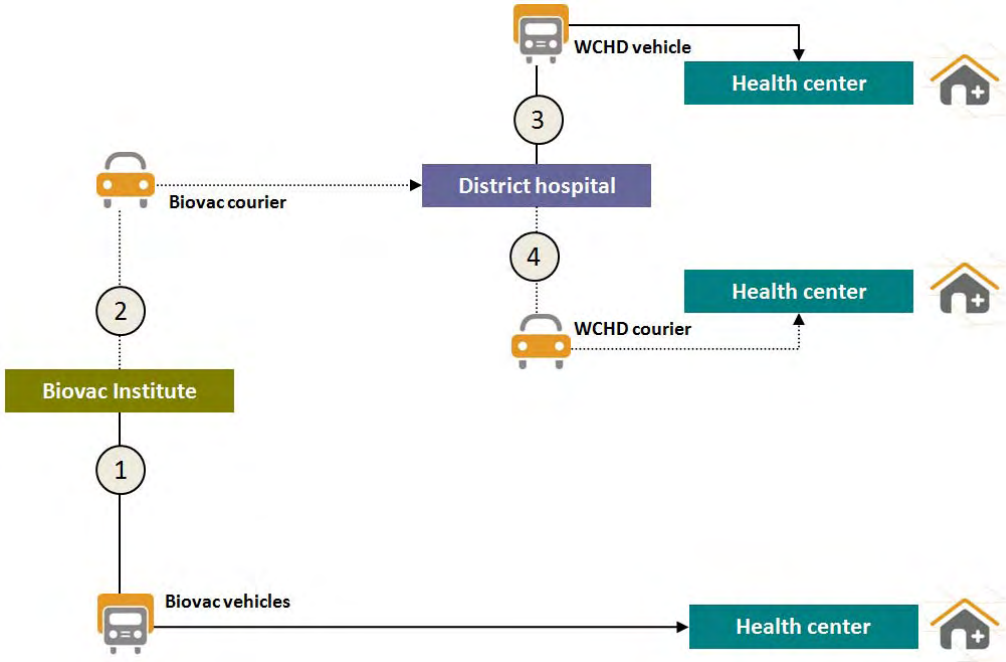
[xii] For more information see: http://www.who.int/immunization/documents/WHO_IVB_05.01/en/index.html.

[xiii] For more information see: http://www.who.int/immunization_standards/vaccine_quality/who_pqs_e06_06_logtag.pdf.

The study grouped distribution routes into four types and each was analyzed separately (Figure 6):

- Type 1: Biovac deliveries made directly to health centers using their own vehicles and along primary routes.
- Type 2: Biovac deliveries made using a courier service.
- Type 3: District resupply point deliveries made using district hospital vehicles.
- Type 4: District resupply point deliveries made using a courier service.

Figure 6. Type of transport routes where temperature monitoring was conducted



Note: Numbers correspond to distribution group types.

WCDH = Western Cape Department of Health.

LogTag recorders monitored temperatures along the four types of transportation modes for the one- and two-legged journeys.

Although the main aim was to review Biovac's performance on keeping vaccines in the recommended temperature ranges during storage and transport, the study was extended to include temperature performance at the final point of delivery—health centers (even if this is not under the responsibility of Biovac but is the responsibility of the WCDH). The extended temperature monitoring review was done in 12 health facilities, 4 of which received their vaccines through district resupply points (see Annex 3). In addition, 16 health center workers were given a short questionnaire regarding their knowledge of vaccine temperatures (in relation to heat-/freeze-sensitive vaccines) and temperature monitoring practices (temperature charts, vaccine vial monitors [VVMs], etc.). Altogether, this provided a clearer picture and a broader context of how vaccines in the Western Cape were being kept from end to end in the cold chain.

Economic evaluation

Finally, it was not only important to understand the performance of the Distribution Agreement in terms of vaccine management and temperature performance measures (the benefits), but to also understand the entire economics of the outsourcing model (the costs). Biovac charges a 6% overhead charge for their service. This begs the question: if Biovac performs up to standards, is the 6% overhead charge for the services a good investment for the WCDH? To answer this question, the study conducted a detailed economic analysis to assess the costs and the benefits of the system. Analyses were performed using standard economic evaluation methods.

Results and findings

The results and findings from the review are presented according to the themes and the identified research areas as summarized in Table 4 below.

Table 4. Summary of the approach and methodology

Themes	Areas identified	Method
1. Management	Historical context	Stakeholder questionnaires
	Decision-making process	
	Process and implementation	
	Reports and monitoring	
	Client perspectives	
2. Operations	Storage	EVM assessment
	Deliveries	Temperature study
	Orders and payments	Descriptive analysis
	Biovac charges and overhead (6%)	Economic analysis

EVM = effective vaccine management.

Management

Historical context

In 1994, the new South African constitution made the government subject to new laws and regulations. While it took a while for these to trickle down and become binding at the provincial level, the repercussions were that the Western Cape vaccine store (at Karl Bremer Hospital) was no longer compliant with quality standards set by the new pharmacy act. By June 2005, any stores that had not been upgraded to meet the new quality standards were considered illegal.

Although some attempts were made to improve the provincial vaccine store to meet the new standards, the results of an Effective Vaccine Stores Management (EVSM)[xiv]

[xiv] In 2001, WHO-UNICEF jointly developed the EVSM Tool to assess vaccine stores according to best-practice criteria in vaccine management. In 2009, the revised EVM Tool was developed.

assessment conducted in 2004 revealed numerous shortcomings and highlighted the need to make significant upgrades to the entire cold chain system, particularly if new vaccines were going to be introduced. Upgrading the Western Cape vaccine store would have required large capital investments for which no budget was available, and there was general reticence about improving a store that was a refurbished nurse's home kitchen (see Annex 3).

Decision-making process

In July 2005, the provincial vaccine store was formally closed down. Before the closure alternative solutions for the provincial storage of vaccines were researched and evaluated. The immediate thinking was to explore whether the entire vaccine store could be transferred to the Central Medical Depot (CMD), an autonomous supply agency[xv] for pharmaceuticals, wholesaling, and distribution for the Western Cape Province. Biovac was also considered an option since they owned a warehouse in Cape Town, and discussions with the DOH on the Supply Agreement were occurring around the same time. Lastly, options that included both the CMD and Biovac were considered.

The advantage of the CMD was that they were equipped with the information systems to handle the Direct Delivery Vouchers—a system that allows health centers to make orders and receive supplies directly from the supplier. A second advantage of the CMD was that they had competitive overhead charges of 5% of the value of the products being handled for storing, distributing, and order management. The disadvantages of the CMD option were their lack of technical know-how in cold chain management and their lack of experience in handling vaccines. Likewise, while they had sufficient storage space in their warehouse, they did not have the cold chain capacity required. Further investment would be required to expand the cold chain capacity.

After visiting the Biovac warehouse and state-of-the-art cold rooms, the WCDH was convinced Biovac was the right company to take on the Western Cape vaccine supply chain. Biovac was approached and they were keen to support the provincial immunization program since it was a natural fit with their business model and a natural extension of the Supply Agreement. Implementation would be easy for Biovac as they could provide the service without much additional investment and had the technical expertise in vaccines and cold chain logistics.

The packaging and labeling branch of Biovac, located in Pinelands, Cape Town, became the de facto provincial store for the WCDH. In addition, Biovac agreed to distribute the vaccines across the province. The Distribution Agreement between Biovac and the WCDH had the desired advantages described earlier in the review. Long-term and expensive capital investments and their maintenance were avoided since Biovac would absorb them. Also, WCDH would gain efficiencies in the vaccine supply chain through streamlining—the Distribution Agreement with Biovac shortened the supply chain from the source to the user and eliminated intermediary storage at the district level (at least for half of the province).

[xv] An autonomous supply agency is a nonprofit, independent procurement service for the ministry of health that operates under commercial business practices.

Since the WCDH would continue to be responsible for needs forecasting, and the physical storage and transport of vaccines to nominated delivery points would be the responsibility of Biovac, the concept of virtual warehousing was made explicit in the Distribution Agreement.

Key drivers for outsourcing

The historical context above provided insights on the drivers to outsource the vaccine supply chain. However, to gain a deeper understanding into the specific and non-historical drivers that led to the decision to outsource, the project conducted interviews and advanced a survey with the stakeholders that were part of the decision-making process. Eight key stakeholders were asked to score different outsourcing drivers according to three value attributes: financial, strategic, and operational (1 = not important and 5 = very important). Table 5 summarizes the results of the survey.

Table 5. Stakeholder perception of the key outsourcing drivers

Value attribute	Relevance[a]	Importance[a]
Financial	**4.67**	**4.25**
Need to reduce and control logistics costs in immunization	4.67	4.25
Strategic	**4.07**	**3.89**
Focus more on core competencies of the national immunization programs (service delivery, monitoring, and surveillance)	5	5
Gain visibility in the supply chain systems for health	5	5
Reduce complexity in the system and gain efficiencies	5	4.75
Risk-sharing with a partner company	3.67	3.25
Ability to access new technologies, innovative systems, or gain superior managerial efficiency as compared to government systems	3.25	3
Outsource to deal with an internal management problem	2.50	2.33
Operational	**4.02**	**4.13**
Increase customer satisfaction (health centers/clinics)	4.67	4.75
Improve quality of services by lowering wastage, stockouts, and risks to vaccines	4.67	4.5
Increase delivery speed and improve vaccine traceability	4	4.33
Lack of logistics management experience	4	4.25
Desire to extend the PPP	4	4
Policy pressures (adherence to regulations and standards)	3.33	3.75
Programmatic pressures (for example, new vaccine introduction)	3.50	3.33

a = The perception in value attribute's relevance and importance is measured by a rank between 1 and 5 where 1 is not important and 5 is very important.

PPP = public-private partnership.

Outsourcing drivers that attained the highest scores came from the desire to:

- Reduce and control logistics costs in immunization.
- Enable the Expanded Programme on Immunization (EPI) to focus more on service delivery, monitoring, and surveillance (rather than storing and transporting vaccines).
- Reduce complexity in the supply chain system and gain efficiencies.
- Increase customer satisfaction at the health centers/clinics.
- Lower wastage, stockouts, and risks to vaccines.

Drivers such as risk-sharing with a partner company did not rank as highly as expected. Stakeholders in general did not view outsourcing as a way of dealing with internal management challenges for storing and transporting vaccines. Anecdotally, some stakeholders mentioned that an outsourcing agreement with a third party would mitigate the risks of private immunization practitioners misusing the public vaccine supply chain system and using loopholes to get free vaccines.

Process and implementation

Vendor selection

There was not a formal process to select a service provider for outsourcing the vaccine supply chain in the Western Cape (e.g., requests for proposals, bidding, creating a selection committee to shortlist the vendor). Some landscaping of providers was done and some of the largest pharmaceutical distributors were visited (e.g., CMD). However, aside from Biovac, no competitors in the market at the time had core competencies in vaccine and cold chain management.

Although no formal economic analysis was done, the WCDH entered into negotiations with the provider armed with knowledge of the type of fees to expect. For instance, the Western Cape Supply Chain Department had information on courier services used for transporting vaccines, and they knew what the storage and delivery charges were from the CMD. In the end, CMD used the 5% fee as the benchmark figure to calculate the overhead costs of warehousing and distribution services.

On the provider side, Biovac derived their 6% overhead charge from their cost calculations for warehousing, transport, and deliveries. Given the turnover of vaccines, their break-even point was 6%. Since Biovac viewed the Distribution Agreement as a strategic alliance with the DOH rather than as a way of generating profit, the 6% calculation was their break-even rate.

In the end, the WCDH agreed to the 6% overhead fee. Although this was effectively a 1% markup from the CMD benchmark (5%), the WCDH preferred to outsource to Biovac for a couple of reasons. The CMD was in the central business district of Cape Town , limiting access for health facilities. Unlike the CMD, the Biovac warehouse was located in the Pinelands. This had the advantage of keeping vaccines within easy access to all health facilities. Secondly, the 1% markup was justified since vaccines required specific cold chain storage and Biovac had more expertise in this regard. More importantly, the understanding by both parties was that Biovac would be making a profit from the broader

Supply Agreement for the procurement of vaccines on the national contract. As such, there was no reason for them to be making a profit on the Distribution Agreement for the Western Cape.

Transition

The transition from the WCDH-managed vaccine supply chain system to the Biovac system was relatively straightforward and seamless. Despite the absence of a specific project plan to ensure the transition and the lack of a formal pilot project to test the system, the implementation was still smooth. The implementation was phased over a couple of months and scaled up from an initial list of delivery points identified by both parties—mainly those in the city of Cape Town.

Because Biovac already had the existing storage and transport infrastructure in place and because the DOH had already signed the Supply Agreement PPP, the transition was greatly simplified. Moreover, Biovac was already proficient in vaccine and cold chain management, so there was no need to train staff or to develop new standard operating procedures (SOPs) for storage. That said, new procedures were needed for receiving vaccine orders, picking up and packaging individual vaccine orders, and transporting vaccines to health centers. These new procedures were articulated into SOPs to manage the Distribution Agreement.

For the health centers, the WCDH organized information sessions with all districts before and after the transition, and the process to order vaccines was unchanged. The only difference was that health centers would now receive their orders from Biovac. Although no specific training was provided to health facilities, some would have found it helpful to standardize the procedures for receiving vaccines and setting maximum and minimum stock levels for each center.

Contract and service-level agreement

The development of the contract was fairly straightforward since it became an expansion of the Supply Agreement for the Western Cape. In hindsight, the contracting process was rushed and perhaps some of the specifics could have benefited from a more in-depth discussion.

Biovac felt that the closure of the WCDH vaccine depot hastened the decision to outsource. Biovac was worried about assuming the responsibility for the vaccine management of an entire provincial system that had not been properly tested when the legal responsibilities had not been clearly defined. Therefore, the initial list of health facilities that Biovac had to distribute vaccines to was inaccurate. This was a clear weakness in the contractual arrangements.

There was no service-level agreement in place for the outsourcing arrangement. The Distribution Agreement contract was the service-level agreement combined with the broader Supply Agreement contract. Since there was never a review of the Supply Agreement, there was also no revision of the Distribution Agreement. The contract was still in effect during the review period. It had been unchanged since 2004.

Contract management

The partnership between the WCDH and Biovac was based on trust and the collaboration between these two groups was good. This may be why the WCDH did not assign a dedicated person to oversee the Distribution Agreement and outsourcing contract. Soon after the outsourcing arrangement began in 2005, the acting provincial cold chain manager left and the position remained vacant until late 2009. This resulted in a long period where there was no cold chain manager and no oversight of the contract. Biovac had no counterpart in the WCDH which was problematic. If Biovac faced any issues, they had no way of voicing them. Likewise, the health centers had no way of voicing the challenges they were experiencing at the health center level. Luckily, no major hiccups occurred between 2005 and 2009. In 2009, a new provincial cold chain manager was hired. Since then, communication between the two groups has markedly improved, and regular meetings between WCDH and Biovac are held to discuss operational challenges and forecasting.

Reporting and monitoring

The outsourcing contract requires Biovac to report regularly to the WCDH on vaccine stocks, orders, deliveries, vaccine prices, and service charges. The initial plan was for Biovac to develop an online reporting system and website that would enable all levels (provincial, district, and health center) to retrieve information and statistics on stock levels, monthly sales, expenditures, vaccine prices, and vaccine orders to their facilities. To date, Biovac has not developed a website, but they disseminate this information in monthly reports. Biovac is invited to attend the quarterly EPI managers meeting where a review of vaccine requirements is conducted.

The contract did not stipulate that Biovac should report on the performance of the system, which would have required them to do monitoring. This is a clear weakness in the contract. During the contracting phase key performance indicators (KPIs) were not stipulated or requested by the WCDH, and no performance standards were set other than keeping the vaccines at recommended temperatures and allowing a 14-business-day turnaround on vaccine deliveries (from initial order to delivery). Some additional stipulations were articulated in the stockout clause covered by the broader Supply Agreement.

As a result, reporting on the performance of the system only occurs when there is a problem. A better plan would have been to set up a monitoring system that allowed Biovac and WCDH to anticipate problems or find ways to mitigate their impact.

Client perspectives

In order to get a sense of whether health centers (the clients) were satisfied with the services provided by Biovac, the project conducted a small survey during the EVM assessments and made health center visits to discuss and collect facility-level information about the perceived quality of their services. See Table 6 for a summary of the findings from the perception survey.

Table 6. Perception of the quality of services at the health center level

Statement	Ranking[a]	Score[b]
Vaccine is available when it is needed.	2.7	54%
Vaccine order fulfillment time is optimal	2.9	57%
Vaccine delivery is on time.	3.0	60%
The vaccine supply chain can respond quickly to supply shortages.	1.7	34%
Biovac can expedite orders effectively when needed.	2.6	51%
Overall	**2.6**	**51%**

a = The perception in quality is measured by a rank between 1 and 5 where 1 is the perception of very bad-quality services and 5 is the perception of very high-quality services.

b = The score in percent is the conversion of the rank into percent. In other words, a rank of 2 would correspond to 2/5 expressed in %.

The general perception was that Biovac provided mediocre-quality services. Out of a maximum ranking of 5, the average is 2.6 (or a score of 51%). Although generally the scores from all the statements asked in health centers were low, relatively speaking, two came out stronger (orders are correct and delivered on time). There were not any reported cases of the wrong order being received by a health facility or of the delivery being made beyond the 14-business-day requirement. Vaccines arrived undamaged, and the temperature monitoring devices showed that vaccines had not been exposed to temperatures outside of the recommended range. On the other hand, health centers were extremely unhappy with the inability of the supply chain to respond quickly to supply shortages.

Although these findings are not flattering to Biovac, the perceptions were tainted by the recent stockouts of some new vaccines at the time when the survey was conducted. Likewise, there are several misdirected criticisms toward Biovac that are worth highlighting. The results from the health-center perception survey need to be seen within this light.

Recent stockouts of Pentaxim

At the time of the review in 2010, a series of stockouts of DTP-inactivated polio vaccine (IPV)-Hib occurred throughout the province, and health facilities were unhappy about running out of vaccines. The majority of all the sites visited for the EVM assessment had experienced stockouts.

Slow ordering system

The government ordering system (Logis) is very cumbersome, slow, and not linked to Biovac. It can take weeks before a health-center order is cleared by the district office and before it gets passed on to Biovac. Although the mean time between receipt of an order and its delivery is less than a week on the Biovac side, the start to finish process for health centers takes more than one month. For health centers, this is much too long and indicative of poor service. Unfortunately health centers often blame Biovac when in fact the bottleneck is on the WCDH side.

Fees

Another factor that causes frustration at the health center level and can explain the poor results on the perception of service quality is the 6% overhead charge. As explained earlier in this review, some health centers get their vaccines from district redistribution points rather than directly from Biovac. This is by choice, as some districts prefer to keep control of the vaccine stocks at their level. That said, when Biovac receives an order from a health center belonging to a district that acts as a resupply point, the 6% overhead is still levied on that health center order even if Biovac delivers it to the district resupply point—the specified address for those health centers. These health centers can see that Biovac is charging them the 6% overhead and do not fully understand this charge. For Biovac, the 6% charge covers the storage at the provincial level and deliveries to the distribution point addresses listed in the outsourcing contract. It does not matter whether this distribution point is a health center or a district resupply point. The fact that some districts in the Western Cape do not want Biovac to distribute directly to the health facility but would prefer they send the vaccines to a district or sub-provincial store is immaterial; the 6% charge still applies. This charge is passed on to the health facilities that do not benefit from the full service but are still charged 6%. Hence, they feel short-changed by the Biovac service and rank its quality as poor.

Zero brand refrigerators

In 2009, vaccine manufacturers got together to fund new cold chain equipment for South Africa which was donated as part of the new vaccine introductions. The DOH selected a specific model of refrigerator and Biovac procured it on behalf of the DOH. Approximately 2,000 models were provided, and after a year most health centers in the Western Cape reported problems with the equipment and that the “Zero” brand refrigerator was the main reason for cold chain failures. Health centers knew that Biovac procured the equipment, and therefore, health centers pointed the finger at Biovac even though Biovac had not been involved in the choice of the equipment. They simply facilitated the process of buying the equipment for the DOH.

Operational aspects

Storage and deliveries

Effective vaccine management

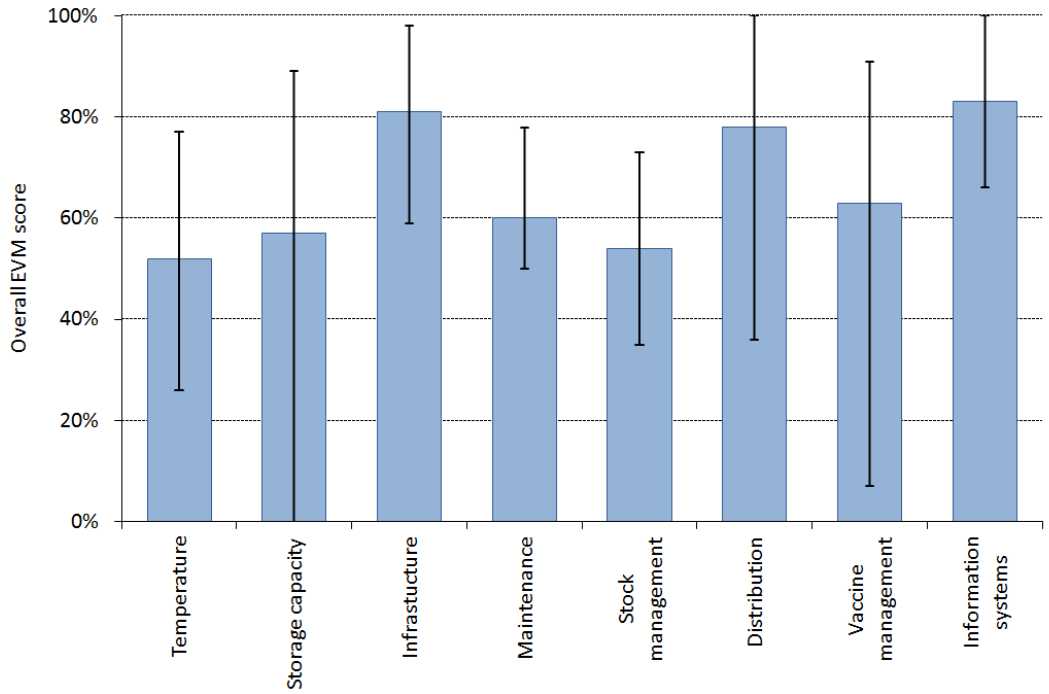
In order to determine whether vaccine management practices are up to standards, the project carried out an EVM assessment at the Biovac warehouse using a sample of eight health facilities in the Western Cape Province.

The EVM assessment is a WHO-developed tool that provides a complete diagnostic of the vaccine supply chain system from a management perspective according to nine criteria that are given a score between 0% and 100%. In order for a criterion to be considered effective, a score of 80% or higher is required. The nine criteria cover vaccine arrival procedures, temperature, storage capacity, infrastructure (building, equipment, and transport), maintenance, stock management, distribution, and vaccine management and information systems (including supportive functions). Since the vaccine arrival criteria measured effective performance on the international segment of the supply chain (from

manufacturer to the country), the study excluded the criterion from the EVM assessment in the Western Cape.

The overall EVM performance across the province irrespective of the level of the supply chain (provincial, district, or clinic level) and the responsible party (Biovac, WCDH, City of Cape Town) show that of the eight relevant criteria, only two reached the 80% benchmark score (see Figure 7).

Figure 7. Overall EVM results for the Western Cape Province, 2010



Overall, infrastructure was the strongest performing criterion—the state of the buildings where vaccines are kept (the health facility), the equipment they are stored in (the state of the cold chain equipment), and the condition of the vehicles used to transport vaccines. This criterion comes out on top with a score of 81%, with a narrow range that implies that the state of infrastructure is more or less good everywhere. This is not all that surprising since most of the buildings in the Western Cape, whether they are district hospitals or clinics, are in good condition (see Annex 3).

The distribution criterion has an overall score of 78%. That said, there is variability in the range of scores on this criterion, as shown in Figure 6. In some sites the score reaches as high as 100% and as low as 36%. The third highest scored criterion is vaccine management. Vaccine management looks at whether the policies and procedures that ensure the integrity of the vaccines in the supply chain are in place. The overall score for this criterion was 63%, but shows variability around the average value. One site scored as low as 8% on vaccine management practices while a few sites exceeded the 80% benchmark. Clearly the level of understanding of good vaccine management practices is quite inconsistent.

The lowest overall scores were stock management, storage capacity, and temperature (the criteria for all three of which examined whether vaccines are kept in the recommended temperature ranges). These management areas will require strengthening, particularly with the introduction of new and expensive vaccines.

The aggregate scores paint a general picture of the situation, pinpointing the areas of the strengths and weaknesses in the management of the vaccine supply chain. It is equally useful to look at how the scores vary by level. Figure 8 shows how the scores vary by level of the supply chain system (provincial, district, or clinic level) and by the responsible party (Biovac, WCDH, City of Cape Town).

Figure 8. Overall EVM score by criteria and by levels of the supply chain, 2010

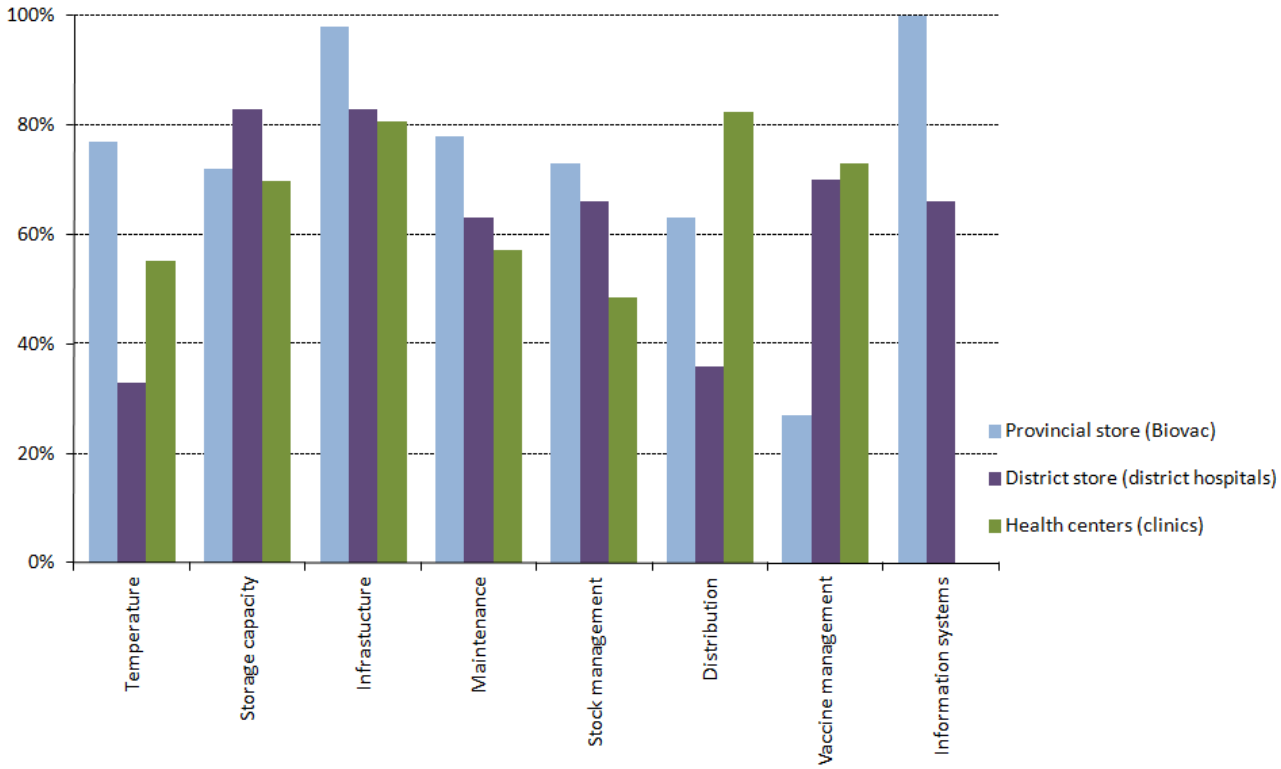


Figure 8 shows that scores are generally higher at the provincial level and lower at the health center level. The overall score across all criteria for Biovac averages 74%. The results show that as vaccines move down the supply chain, their management tends to weaken—63% at the district level and 58% at the health center level (average across all relevant criteria). This trend is quite clear when looking at the infrastructure, maintenance, and stock management criteria. Two criteria contradict this finding. Distribution and vaccine management have higher scores at the health center level than at the provincial level. The lack of VVMs on vaccines and the lack of vaccine wastage monitoring penalize the provincial level scores on vaccine management. That said, while these scores affect Biovac, they are the management responsibility of the WCDH.

For the temperature and distribution criteria, the district level scored lower than both the provincial and health center levels. This suggests that district resupply points are creating a bottleneck in the supply chain and are a point of risk for vaccines.

The full EVM report elaborates on the scoring and provides key recommendations by criteria, level of the system, and responsible party (authors' unpublished data, 2011). The main recommendations from the EVM on the weakest performing criteria are summarized in Table 7.

Table 7. Main recommendations from the EVM on the weakest performing criteria

Temperature	• Regularly review and analyze temperature monitoring charts. • Utilize digital temperature monitoring devices at the clinic level.
Storage capacity	• Expand Biovac's vehicle capacity for new vaccines. • Reassess the clinic refrigerator capacity, especially since the allocation of refrigerators is not optimal across the province.
Maintenance	• Develop preventive maintenance plans, rather than reactive solutions.
Stock management	• Establish maximum and minimum reorder levels between Biovac and the WCDH to better fit with the "push" supply system at the national level. • Improve vaccine-stock management records at all levels of the supply chain. Stock records were incomplete and did not record all the critical information. That is, diluent records did not match vaccine records, and wastage records were non-existent below the provincial level at the Biovac warehouse. Likewise, six monthly reviews were missing. • Improve management of available stock at the clinic level to prevent "avoidable" stockouts and overstocking.
Vaccine management	• Develop mechanisms that provide clinics advance notice of deliveries by Biovac. • Record VVM status on all distribution records (e.g., dispatch notes, receipt notes, etc.). • Require contingency plans for storage and distribution. • Monitor wastage and calculate wastage rates at all levels of the supply chain. • Use conditioned ice packs at the service level.

EVM = effective vaccine management; WCDH = Western Cape Department of Health; VVM = vaccine vial monitor.

Temperature

Temperature monitoring was conducted as part of the operational review of the outsourcing model in an effort to ensure that vaccines handled by Biovac were being kept

at recommended temperature ranges, that is, they were not at risk of freezing or damage from heat exposure during storage and transport.

Temperature during storage

Findings from the temperature monitoring study show that vaccines are kept in excellent temperature condition at the Biovac warehouse and that the cold chain is preserving them in the recommended temperature ranges at all times. The average storage temperature at the Biovac warehouse is 4.9ºC with a range of 4.4ºC to 5.6ºC. At the district level, vaccines are also kept within the recommended temperature ranges in the cold chain. The average storage temperature at this level was found to be 5.3ºC and with a range of 4.2ºC to 7.8ºC. That said there is one instance where the vaccines breached the 8.0ºC threshold for a period of eight hours; however, the length of time was below what would have triggered a heat alarm.

The cold chain is much less robust at the health center level. While the average temperature is 3.1ºC, the temperatures breach both ends of the recommended 2.0ºC to 8.0ºC range. Findings show that cold chain temperatures at the health center level range from an average low of 0.9ºC to an average high of 9.2ºC. Table 8 shows results by level.

Table 8. Temperature monitoring results during vaccine storage

Service point	**Biovac warehousing**			**Health center storage**			**Time >8ºC**	**Time <2ºC**	**Time <0ºC**
Name	**Avg.**	**High**	**Low**	**Avg.**	**High**	**Low**	**Hrs.**	**Hrs.**	**Hrs.**
Bloekombos	5.2	6.2	4.5	2.6	7.2	0.8		120	
Ocean View	5.5	6.4	4.7	4.2	7.3	2.1			
Luvuyo	5.1	5.8	4.3	-1.2	9.8	-4.7	1.5	278	254
Velddrift	5.2	6.0	4.7	4.0	7.6	0.5		20	
Porterville	5.2	6.2	4.5	0.7	9.6	-1.9		336	123
Montagu	4.5	5.0	4.2	4.0	6.5	2.1			
Lamberts Bay	4.4	4.8	4.2	3.4	17.3	2.3			
Service point	**Biovac warehousing**			**District hospital storage**			**Time >8ºC**	**Time <2ºC**	**Time <0ºC**
Bitterfontein	4.7	5.2	4.3	4.6	5.2	3.9			
Beaufort West	4.7	5.1	4.2	4.4	10.4	3.1	8		
Harry Comay	4.5	5.0	4.3	7.1	7.9	5.7			
Service point	**N/A**			**District hospital storage**			**Time >8ºC**	**Time <2ºC**	**Time <0ºC**
Rietpoort				6.0	7.6	4.5			
Laingsburg				1.1	12.2	-2.1	9	226	146
Oudtshoorn				6.1	6.7	5.1			

Note: All average, high, and low temperatures are in ºC.

The study summarizes the detailed temperature data as follows:

- In 30% of health centers, vaccines were exposed to temperatures below 0ºC beyond the WHO set level for a freeze alarm to go off (< -0.5ºC for 60 minutes). As such, in these clinics the freeze-sensitive vaccines were exposed to temperatures that could have resulted in a loss of potency.
- In 50% of health centers, vaccines were exposed to temperatures below the 2.0ºC minimum threshold for an average duration of 196 hours, and durations ranged from 20 hours to 336 hours.
- In 20% of health centers (2 out of 10), vaccines were exposed to temperatures above the 8.0ºC maximum threshold. In one clinic this occurred for 1.5 hours and in the other the breach lasted 9 hours. That said, the duration of the breach was not long enough to have triggered a heat alarm since WHO requirements state that the alarm be triggered when the temperature is greater than 8.0ºC for 10 hours continuously.

For vaccine storage, the temperature study shows that vaccines are kept in a robust cold chain until they reach the service delivery point. The weakest link in the cold chain is at the health center level. The greatest risk for vaccine is exposure to freezing temperatures. No serious heat excursions beyond WHO requirements were recorded.

These poor results are due to substandard cold chain equipment and health care workers' poor understanding of vaccine management practices. In a very limited survey of knowledge conducted in 16 health centers, the following results were obtained: although 75% of health workers knew that frozen vaccines needed to be discarded, only 12.5% of them knew how to determine whether a vaccine had been frozen or not. When questioned about the causes of freezing and the temperature levels that put vaccines at risk of freezing, 44% of health workers could not venture a guess (7 out of 16). Of the remaining health workers that did answer, 24% of them got the answer wrong (2 out of 16). Only 12% (2 out of 16) knew that managing the temperature monitoring logs could prevent freezing in clinic refrigerators.

Temperature during transport

The overall findings from the temperature monitoring study show that in 85% of cases Biovac transported vaccines within the controlled temperature range. On transport routes to health facilities, the average time of delivery was 5 hours and 18 minutes. On the routes where Biovac outsourced transportation to a third-party courier service, the average time of delivery was 21 hours.

When Biovac was in charge of the transport, no instances of freezing were reported. On the other hand, on two deliveries, vaccines were exposed to temperatures above 8.0ºC. For one of the deliveries the duration was 30 minutes, and for the other the temperature breach lasted 11 hours. This would have caused a heat alarm according to the WHO-set standards for alarms. Further investigation of the 11-hour breach revealed that Biovac had outsourced to a courier service.

Vaccines that are transported to health centers via district resupply points are at higher risk of heat exposure. In 67% of cases the vaccines were exposed to temperatures above 8.0ºC for at least one hour.

Table 9. Temperature monitoring results during vaccine transportation

Service point	**Transport (one leg)**			**Time > 8ºC**
Name	**Avg.**	**High**	**Low**	**Hrs.**
Bloekombos[a]	5.0	5.8	3.7	
Ocean view [a]	5.4	9.4	4.1	0.5
Luvuyo[a]	6.2	7.6	6.0	
Velddrift[a]	4.3	5.7	3.7	
Porterville[a]	4.3	6.2	3.2	
Montagu[a]	4.3	6.5	3.0	
Lamberts Bay[a]	7.9	9.2	5.5	11
Service point	**Transport (one leg)**			**Time > 8ºC**
Bitterfontein Hospital[a]	5.0	6.0	4.5	
Beaufort West Hospital[b]	2.6	3.0	2.5	
Harry Comay Hospital[b]	5.1	5.9	4.7	
Service point	**Transport (two legs)**			**Time > 8ºC**
Rietpoort[c]	8.8	9.7	7.8	1
Laingsburg[c]	2.3	3.6	1.7	
Oudtshoorn[c]	8.2	8.3	8.0	1

Note: All average, high, and low temperatures are in ºC.

a = Direct deliveries to health centers made by Biovac using their own vehicle; b = Deliveries to district resupply points made by Biovac couriers; c = Deliveries from resupply points to health centers made by WCDH vehicles.

These findings indicate that Biovac almost scores full marks on maintaining the vaccine cold chain during transport, except in cases where they use a courier service. The transport of vaccines by WCDH is the second best option. The transport of vaccines from a district resupply-point to a health center using a courier service is the lowest performing option.

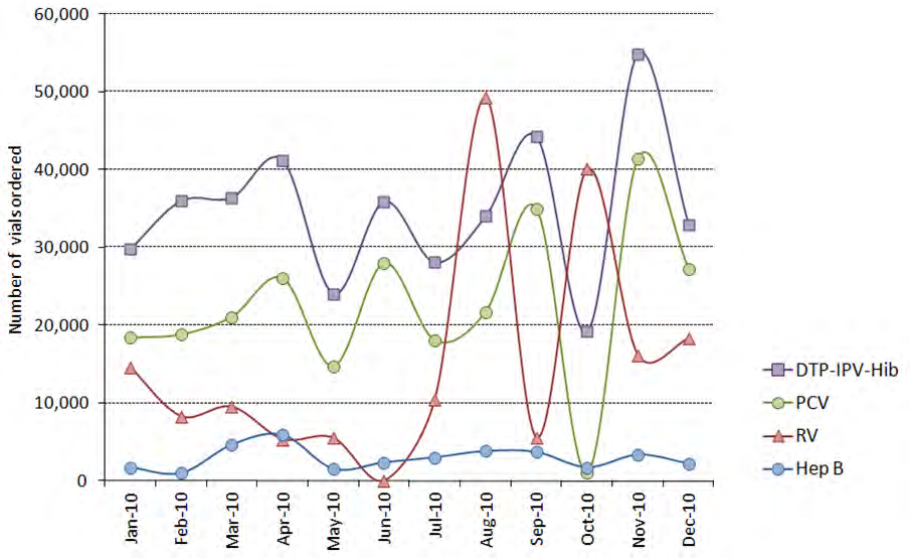
Orders and payments

One of the KPI listed in the outsourcing contract with Biovac requires the maintenance of three months' worth of reserve stock to effectively address the challenges associated with vaccine orders coming from the national level.

Figure 9 presents a 12-month trend in monthly orders from the national level to the Biovac warehouse in Cape Town. This figure highlights the challenge of maintaining three months' worth of stock at the Biovac warehouse, especially for the new vaccines. Figure 9 clearly shows, from January 2010 to June 2010, fewer and fewer doses of rotavirus ordered until rotavirus stocked out in June 2010. Similar challenges were faced in the second half of 2010 with pneumococcal and the pentavalent vaccine. The consequences of this were that during 2010, significant stockouts occurred at the Biovac warehouse, and these stockouts then rippled down the supply chain to the clinic level as orders could not be fully met.

Stockouts occur for two reasons. The first reason they occur relates to the Supply Agreement between the national DOH and Biovac, operationalized as a push system based on demand predictions. The demand for vaccines is determined at the national level based on official population statistics. Each province is then allocated their share based on the projected per-capita demand of vaccines, which is calculated using official demographic figures. Unfortunately, these figures do not reflect the demographic situation at the provincial level. In the Western Cape, the community survey data contradicted official population statistics. The official figures were lower than the survey data. The official demographic figures, therefore, under-calculate the real needs and consumption rates further down in the system (i.e., at the health center level).

Figure 9. Monthly stocks in Biovac for selected vaccines, 2010



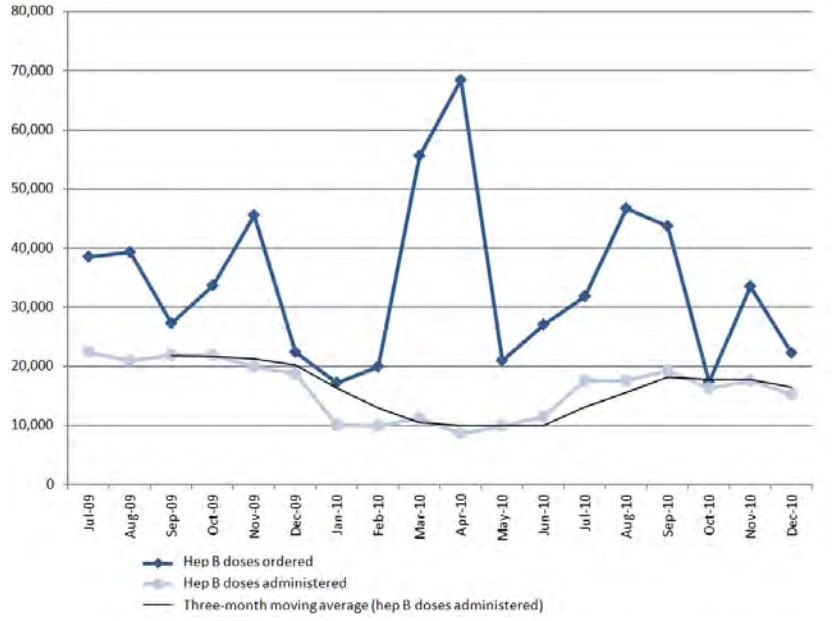
DTP-IPV-Hib = diphtheria-tetanus-pertussis, inactivated polio vaccine, *Haemophilus influenzae* type b; Hep B = hepatitis B; PCV= pneumococcal conjugate vaccine; RV = rotavirus vaccine.

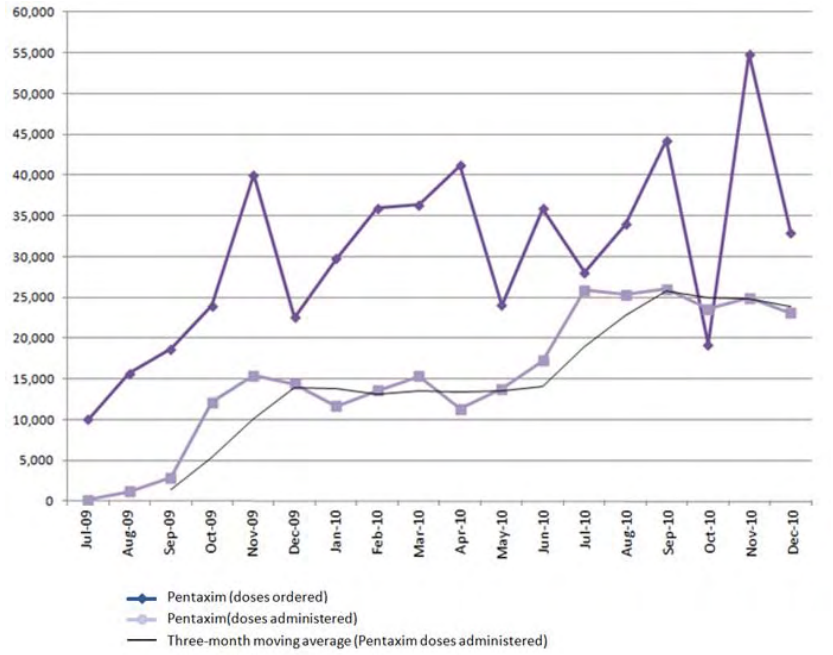
Forecasting errors can disrupt and increase the inefficiencies within a push-pull ordering system, wherein decision-makers at the national level push down vaccine orders to the clinics that pull in supplies. The Biovac warehouse in the Western Cape is at the boundary of a push-pull ordering system, an especially challenging position if orders are pulled by health centers that are not closely monitored. Any variation between the forecasted need and actual demand can intensify difficulties experienced within the supply chain.

The second reason stockouts occur relates to the ordering behavior at the clinic level. Risk-averse clinics have a tendency to overstock vaccines if they feel that vaccines might be in short supply higher up in the chain or if their confidence is lost in the system's ability to weather fluctuations (e.g., because they lack a three-month buffer stock at the provincial level). Risk-neutral clinics that are not keeping an eye on the situation will be caught off guard and discover too late that an order of vaccine cannot be met. They will run out of stock.

Figure 10 shows the consequences of these different scenarios and shows how they could explain the vaccine stockouts that occurred in 2010. Using hep B and Pentaxim as examples, Figure 10 compares hep B orders and their receipt at the Biovac warehouse with the hep B doses administered in the province during the same period of time. This highlights the challenge that Biovac faced with maintaining three months' worth of stock of hep B, particularly in January and October (points where the order curve and the three-month moving average curve intersect). On the other hand, the Pentaxim graph shows that for the most part the Biovac warehouse kept enough stock of vaccine to meet the demand, at least from July 2009 to September 2010. It appears that Biovac did keep a three-month buffer stock.

Figure 10. Challenge of maintaining stock at provincial level—hep B and Pentaxim example



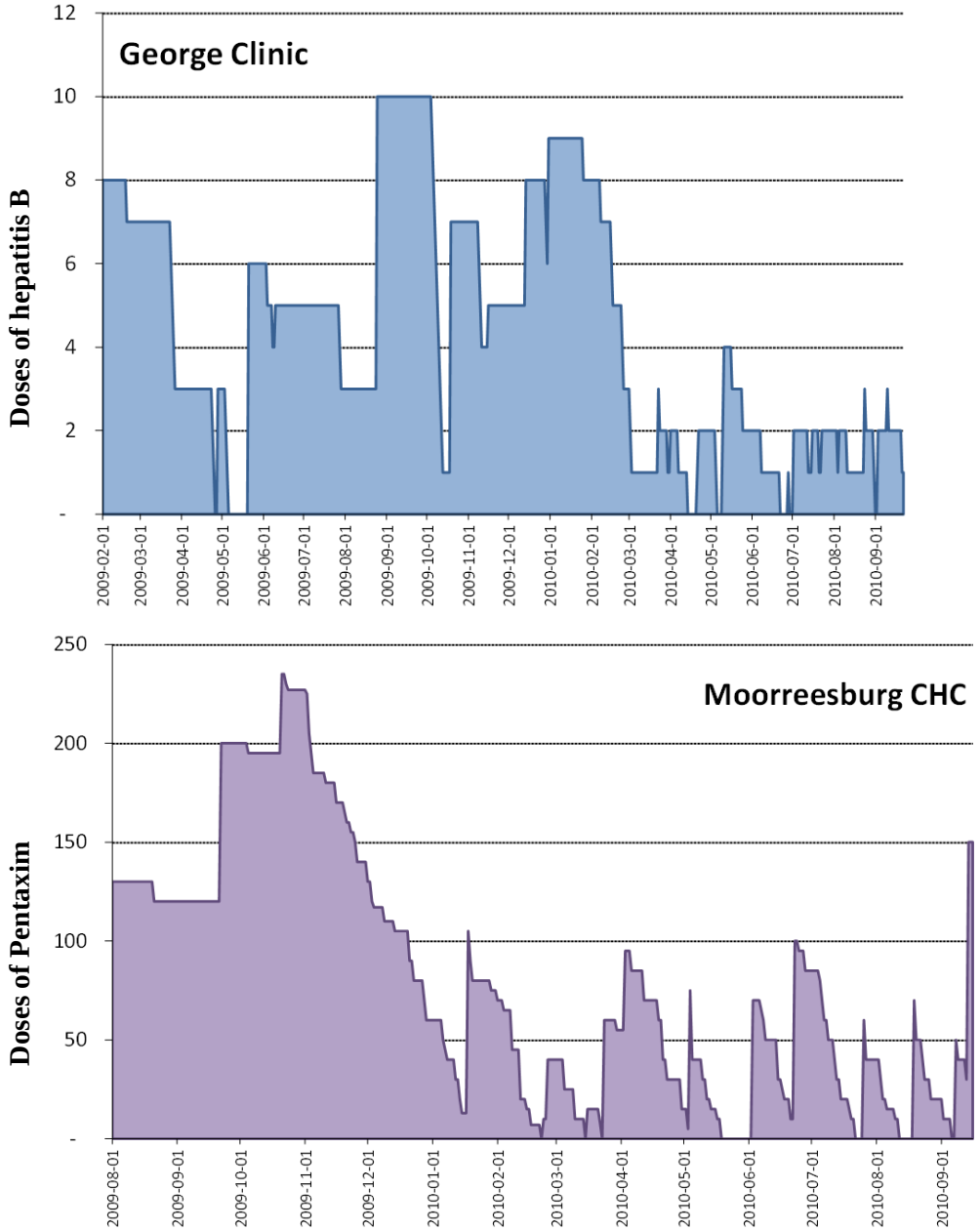


Based on the above analysis, one would conclude that all health centers would have experienced stockouts of hep B in 2010 but no stockouts of Pentaxim. Yet, when looking at the situation in health centers, the analysis shows that some would not be running out of stock of hep B vaccine while stockouts would be experienced with Pentaxim.

Figure 11 illustrates the clinics' ordering behaviors and how these behaviors can compound the stockout problems whether they are risk-averse or risk-neutral health centers. For hep B, we see how George clinic would be frequently running out of stock while the Hermanus clinic would be overstocking on hep B vaccines. For Pentaxim we see a similar example of stockouts occurring in Moorreesburg clinic and overstocking in Zolani clinic.

According to estimates made during the EVM assessment, stockouts at the health center level could be responsible for missed opportunities to vaccinate 14% of the target population per facility. This could potentially lead to a loss of immunization coverage, though the data cannot support this direct causality. Moreover, the overstocking would be responsible for an average amount of idle vaccine in each clinic of about US$10,000. This investment in vaccine could potentially be lost due to expiry or damage during storage given that health centers are extremely weak on vaccine management and maintaining temperatures in the recommended ranges. If this is extrapolated for the whole province, this could represent US$2.7 million or approximately 15% of the value of vaccines.

Figure 11. Challenge of maintaining stocks in health centers—hep B and Pentaxim example



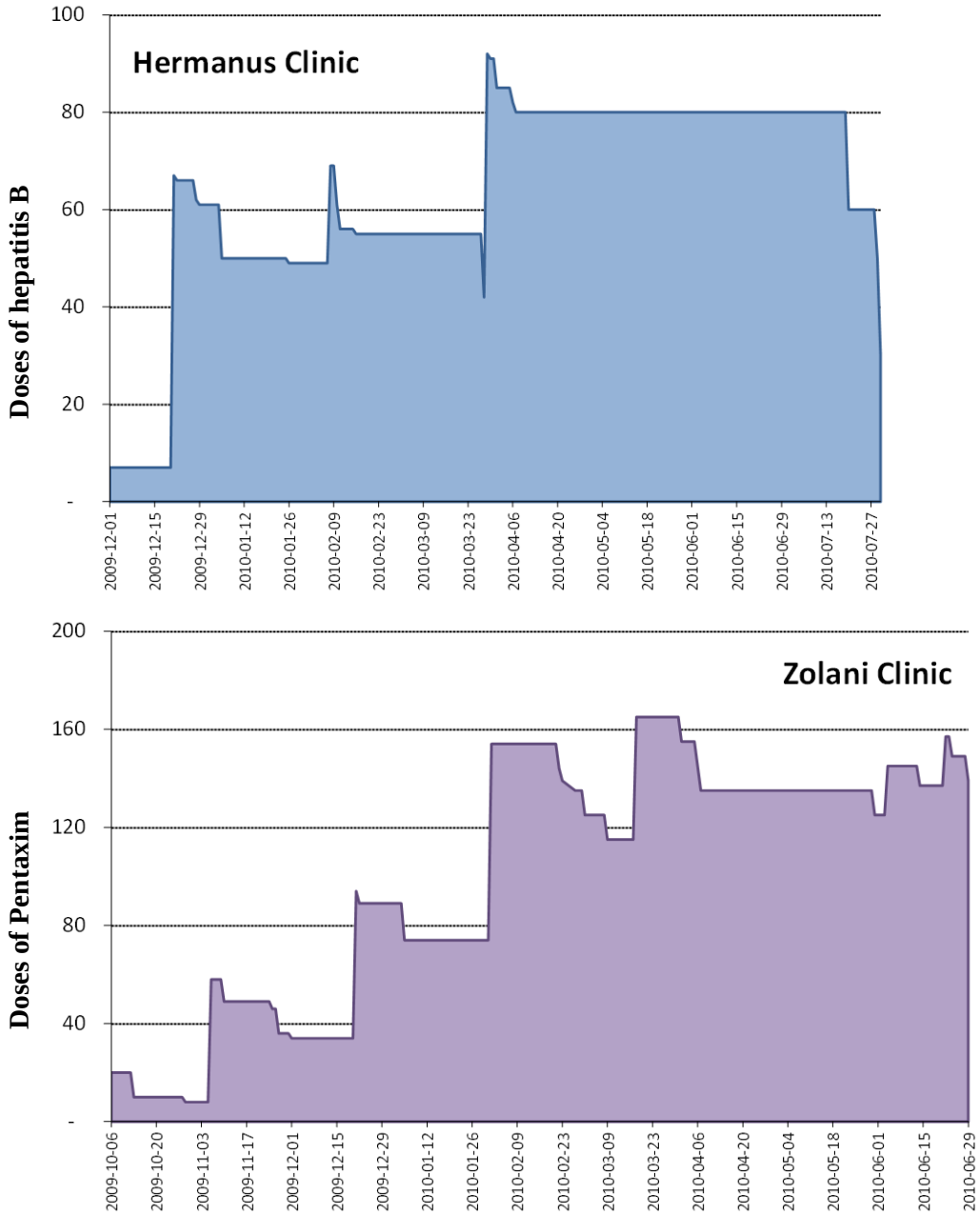


Table 10. Vaccine stock indicators at the health center level

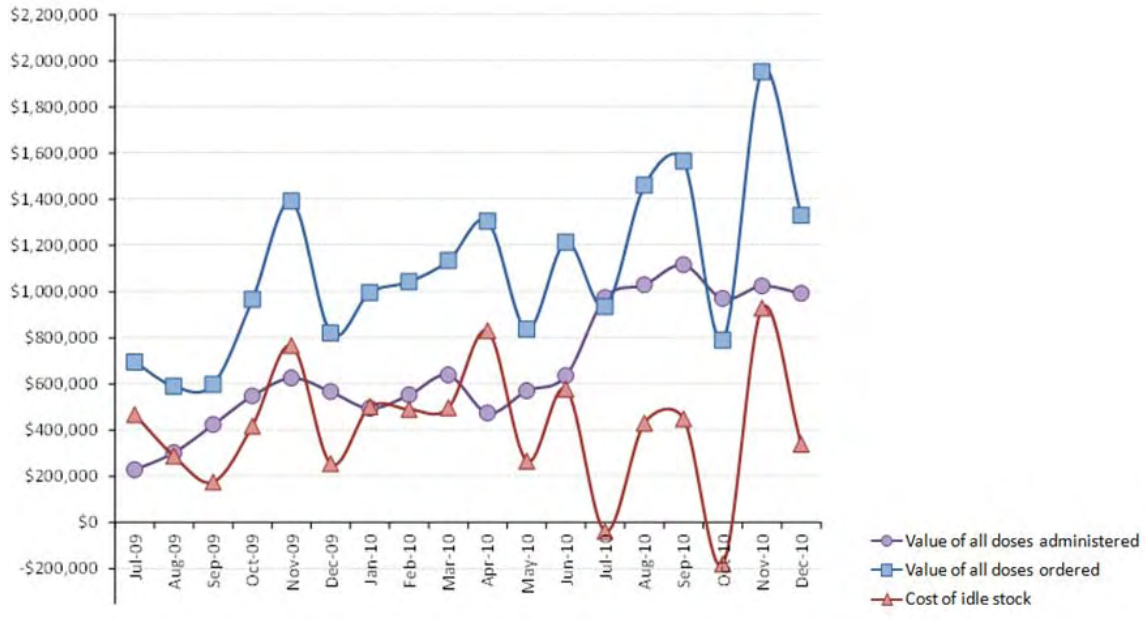
	George	Hermanus	Moorrees-burg	Zolani	Harry Comay	Avg.	
	Hep B		Pentaxim			(a)	(b)
Turnover per year	9	2	4	2	8	7	2

	George	Hermanus	Moorrees-burg	Zolani	Harry Comay	Avg.	
	Hep B		Pentaxim			(a)	(b)
Avg. days in stock	42	162	98	164	49	63	163
Stockout (no. days)	39	0	31	0	23	31	0

Note: a = health centers with stockouts; b = health centers without stockouts.

Figure 12 gives insight into the level of wastage in the system by showing the difference between the value of all vaccines ordered against the value of vaccines administered. This difference shows the unavoidable open vial wastage, closed vial wastage due to breakage, loss and expiry, and idle stock. It amounts to R2.8 million for the entire Province (about $US370,000). It is most likely the case that a portion of this amount corresponds to idle stock in the system and this amount could potentially be lost due to expiry (see Annex 3—A3.8). Another way to look at these amounts is to consider them the cost of inefficiencies.

Figure 12. Value of all doses ordered versus doses administered and difference[xvi], July 2009 to 2010



It is not clear to what extent this wastage might be due to cash-flow difficulties at Biovac. Delays between invoicing and payment occur and the WCDH accrues arrears toward Biovac for the services rendered. In other words, the 30-day payment clause stipulated in the outsourcing contract is seldom met. Coupled with the need to provide a greater

[xvi] The value of all doses ordered refers to the sum product of all doses ordered multiplied by their corresponding vaccine price. The value of all doses administered is the sum product of all doses administered multiplied by the corresponding vaccine price.

amount of funding up front due to the three new vaccines being introduced into the system, it is possible that Biovac experienced important cash-flow problems that could explain not being able to maintain three months' worth of stock in their warehouse. However this study cannot substantiate this hypothesis.

2.3 Economics and financing

Cost analysis

One of the aims of the review is to understand the economics of the outsourcing contract in order to get a sense of whether the 6% overhead fee levied on the value of the vaccines is good value for money for the WCDH and for the services provided. The following analysis is presented according to the areas of procurement, warehousing, and transport costs. Note that the term "procurement" in this section refers to the cost of the commodities (vaccines) that arrive from the national store in Johannesburg to the provincial Biovac store in the Western Cape as part of the broader Supply Agreement.

Procurement

For the 12-month period in 2010, the total turnover of pediatric vaccines for routine immunization was 2.8 million doses for the Western Cape Province. This turnover represented a volume of 53 cubic meters and a value of US$14.5 million. This contrasts with the 2004 value of vaccines for the province which hovered around US$2 million—nine times less.

If all childhood vaccines including those for supplemental immunization activities are combined, the total annual turnover of vaccines for 2010 was short by five million doses. This represents a total volume of 55 m^3 and a value of US$15.3 million.

The most expensive vaccine is Prevenar for pneumococcal. It is priced at about US$30 per dose, which represents more than half of the total value of all vaccine for routine childhood immunization. The Pentaxim vaccine is the second most expensive vaccine at about US$10 per dose. Pentaxim, a combination vaccine, also represents an important share of the total value of all routine vaccines (28.5%), but more interestingly, it accounts for more than 80% of the total volume of all routine vaccines.

Table 11. Annual turnover of vaccines at Biovac for the Western Cape, 2010

Vaccine (doses per FIC)	Vial size	Price per dose (US$)	Turnover (doses)	Overall vol. (m^3)	Share of vol. (%)	Overall value (US$)	Share of value (%)
BCG (1)	20	$0.13	520,000	3.89	7.4%	$67,600	0.5%
DTP-IPV-Hib (4)	1	$9.88	416,520	42.84	81.2%	$4,115,218	28.5%
Hep B (3)	10	$0.62	349,430	0.70	1.3%	$216,647	1.5%
Measles (2)	10	$0.43	414,500	1.49	2.8%	$178,235	1.2%
OPV (2)	10	$0.28	438,200	0.63	1.2%	$122,696	0.8%
PCV (3)	1	$29.80	271,620	1.46	2.8%	$8,094,276	56.0%

Vaccine (doses per FIC)	Vial size	Price per dose (US$)	Turnover (doses)	Overall vol. (m^3)	Share of vol. (%)	Overall value (US$)	Share of value (%)
RV (3)	1	$8.72	183,162	0.76	1.4%	$1,597,173	11.1%
TT (2)	10	$0.33	165,500	0.98	1.9%	$54,615	0.4%
Campaigns			**2,228,300**	**2.13**	**3.9%**	**$863,774**	
Measles		$0.43	1,599,000	1.53		$687,570	
Polio		$0.28	629,300	0.60		$176,204	
Routine			**2,758,932**	**52.7**	**96.1%**	**$14,446,459**	
Total			**4,987,232**	**54.86**		**$15,310,233**	

BCG = Bacilles Calmette-Guérin; DTP-IPV-Hib = diphtheria-tetanus-pertussis, inactivated polio vaccine, *Haemophilus influenzae* type b; FIC = fully immunized child; Hep B = hepatitis B; PCV= pneumococcal conjugate vaccine; RV = rotavirus vaccine; TT = tetanus toxoid.

Warehousing and transport

The introduction of three new vaccines caused a surge in the value of vaccines, the volume stored, and the volume transported. The total volume jumped by a factor of 125 from 46.2 cm^3 to 5780.2 cm^3 per fully immunized child.

Pentaxim in its single-dose presentation, prefilled device and in its four-dose schedule is by far the bulkiest vaccine. It represents 97% of the overall volume of vaccines at the Biovac warehouse (see Annex 2—A2.12 and Annex 3—A3.4 and A3.7) despite representing only 14% of the overall turnover.

Table 12. Evolution of the vaccine volume per fully immunized child, 2008 to 2010

Vaccine	Volume per dose	Schedule (2008)	Schedule (2010)	Total volume per FIC (2008)	Total volume per FIC (2008)
BCG	3.3	1	1	3.3 cm^3	3.3 cm^3
DTP-Hib	2.5	4		10.0 cm^3	
DTP-IPV-Hib	1361.6		4		5446.4 cm^3
Hep B	3.3	3	3	9.9 cm^3	9.9 cm^3
Measles	6.5	2	2	13.0 cm^3	13.0 cm^3
OPV	2.0	2	2	6.0 cm^3	6.0 cm^3
PCV	55.9		3		167.7 cm^3
RV	43.3		3		129.9 cm^3
TT	3.0	2	2	6.0 cm^3	6.0 cm^3
Total volume per FIC				46.2 cm^3	5780.2 cm^3

BCG = Bacilles Calmette-Guérin; DTP-Hib = diphtheria-tetanus-pertussis, *Haemophilus influenzae* type b; DTP-IPV-Hib = diphtheria-tetanus-pertussis, inactivated polio vaccine, *Haemophilus influenzae* type b; FIC = fully immunized child; Hep B = hepatitis B; OPV = oral polio vaccine; PCV= pneumococcal conjugate vaccine; RV = rotavirus vaccine.

Figure 13. Breakdown of Biovac's costs by main cost category, 2010

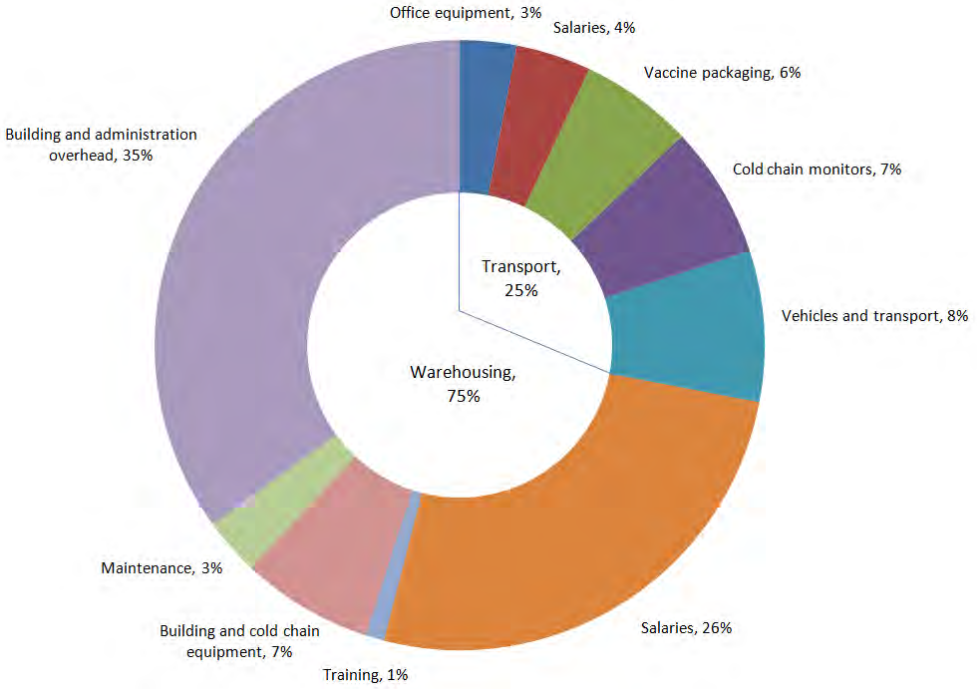
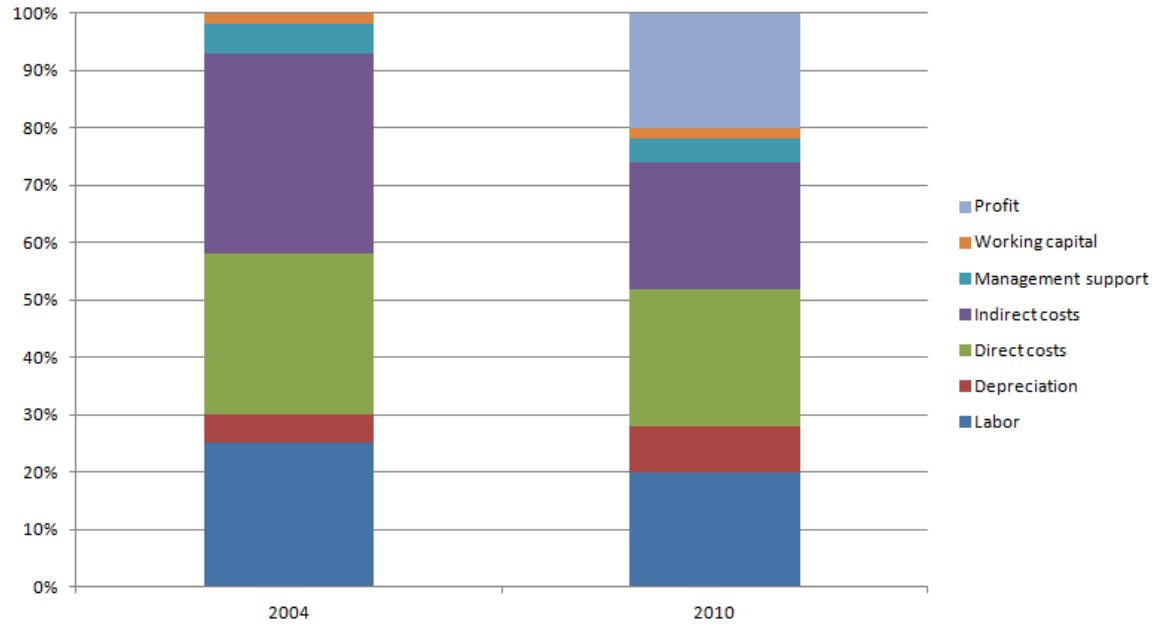


Table 13. Biovac's cost of providing the outsourcing services in 2004 and 2010

Cost type	Cost category	Details	2004 (US$)	2010 (US$)	2004 ZAR	2010 ZAR
Recurrent	Vaccine	Turnover (routine vaccines only)	$2,066,946	$14,446,459	13,327,899	105,831,051
	Salaries	Management staff	$0	$35,767	0	68,719
		Logistics staff	$30,054	$137,048	193,793	1,003,981
		Drivers	-	$23,970	-	175,598
		Other (compensations, etc.)	$737	$1,473	4,749	10,788
	Training	Training	$0	$4,254	0	31,164
	Packaging	Insulated packing boxes	$647	$27,301	4,169	200,000
		Ice packs, chilled water packs	$259	$10,920	1,668	80,000
		Bubble wrap, poly chips, tape, labels	$113	$4,778	730	35,000
	Cold chain monitors	Temperature monitors	$11,706	$43,682	75,480	320,000
	Cold chain supplies	Protective clothing	$542	$1,465	3,497	10,732
	Transport	License and registration	-	$2,531	-	18,541
		Fuel, oil, repairs	$11,892	$10,500	76,684	76,922
		Trackers	-	$1,139	-	8,347
		Vehicle rentals	-	$2,047	-	14,996
		Third-party courier services	-	$31,182	-	228,430
		Logistic fees	-	$2,355	-	17,254

Cost type	Cost category	Details	2004 (US$)	2010 (US$)	2004 ZAR	2010 ZAR
Recurrent	Maintenance	Building	-	$329	-	2,408
		Cold Chain	$2,761	$3,413	17,805	25,000
		Vehicles	-	$3,413	0	25,000
		Other Equipment	$1,614	$17,996	10,407	131,836
	Overhead	Management	$32,720	$169,118	210,982	1,238,916
		Communications (phone, fax, etc.)	$2,474	$6,442	15,951	47,194
		Electricity and water	$805	$16,769	5,191	122,842
		Insurance	$1,356	$7,435	8,745	54,465
		Rent	$700	$3,583	4,511	26,250
		Security system	$1,319	$6,729	8,504	49,297
		Printing and stationary	$5,139	$17,175	33,134	125,822
		Cleaning	$1,675	$5,377	10,800	39,391
Capital	Building	Warehouse	$2,114	$26,046	13,633	190,807
	Cold chain equipment	Cold room (positive and negative)	$7,901	$7,901	57,880	57,880
	Vehicles	Vehicles	$1,241	$2,328	8,000	17,051
	Other equipment	Machinery (forklifts, etc.)	$1,356	$10,751	8,742	78,760
	Office equipment	Office equipment (phone, fax, etc.)	$292	$461	1,880	3,380
		Office furniture	$234	$3,050	1,512	22,344
		Computer equipment	$877	$4,463	5,656	32,696
		Computer software	$223	$12,287	1,440	90,011
Recurrent	Profit	Profit	-	156,952	-	1,149,790
Total cost			$2,187,696	$15,268,888	14,113,440	111,662,660
Total cost (excluding vaccines)			$120,750	$822,429	785,541	5,831,609
Total cost (excluding vaccines) % cost of vaccines			5.8%	5.7%	5.9%	5.5%

Figure 14. Evolution of Biovac's costs by category in 2004 and 2010



Biovac's costs of storing and transporting these vaccines amounted to US$120,750 in 2004. This translated into a logistics cost of 5.8% of the value of routine vaccines (5.9% if calculated on the Rand values). The 5.8% is a close match to the 6.0% overhead fee that Biovac charges for the service. This is a clear indication that Biovac is providing a service that is not generating profit and that they are breaking even once costs are considered.

By 2010, the cost to Biovac rose to US$822,429 to cover the storage and transport of vaccines as part of the Distribution Agreement with the Western Cape, including any scaling up to accommodate new vaccines. The 2010 cost to Biovac represented 5.7% of the overall value of vaccines to a point where a profit was beginning to be generated (US$157,000 for 2010). That said, the profits generated were marginal and linked more to the high value of the three introduced vaccines. If the price of the new vaccines were to drop by 50%, the cost to Biovac would rise to 9% of the value of the vaccine (8.8%).

Table 14. Evolution of key-cost indicators in 2004 and 2010

Logistics cost	2004 (US$)	2010 (US$)	Percentage change
Per child under one year of age	$1.3	$7.9	500%
Per dose administered	$0.061	$0.706	1053%
Per US$1,000 of routine vaccines	$58.4	$56.9	-3%
Percentage value of routine vaccines	5.8%	5.7%	-3%

Biovac's cost of logistics as a share of the value of vaccine remained largely unchanged between the start of the outsourcing contract in 2004 and the year of this review in 2010. The same cannot be said for other indicators. The logistics cost per child rose from US$1.3 in 2004 to US$7.9 in 2010, a five-fold increase. Likewise, the logistics cost per dose administered rose by a factor of 10 from US$0.06 in 2004 to US$0.71 in 2010.

The main cost driver is centered on warehousing which represents 75% of the overall costs. The cost of transporting vaccines accounts for the remaining 25%. Table 12 and Figure 13 give more details as to the breakdown of the warehousing and storage costs. The main costs are labor and the building overheads, which represent 65% of the costs.

Table 15. Changes in Biovac in 2004 and 2010

	2004 (US$)	**2010 (US$)**	**Percentage increase**
Capital value of the Biovac site (excluding the warehouse)	$1,700,718	$8,090,101	475%
Size of the Biovac site (m^2 excluding the warehouse)	5,270	5,363	2%
Total number of staff at the Biovac site	38	143	276%
Capital value of the warehouse	$712,436	$705,048	-1%
Size of the warehouse and stores (m^2)	849	1500	77%
Number of staff at the warehouse	3	16	433%
Percentage of the facility used for the Western Cape outsourcing	35%	35%	0%
Percentage value of electricity used by the warehouse	16%	28%	74%

Between 2004 and 2010 the information provided by Biovac shows that investments were made to increase the size of the warehouse (77% increase in surface area) and the number of staff (from 3 to 16). The data also show that the cost of some types of overhead increased substantially (electricity).

Cost indicators

Various cost indicators were computed to get a sense of the cost of the outsourcing contract by infant in the birth cohort, dose procured, dose administered, and by vaccine volume. Although useful, their value is limited by this review's inability to compare these cost indicators against benchmarks or against values from other provinces where the supply chain is managed by the DOH and not outsourced.

Table 16. Supply chain cost indicators in 2010

Cost indicators (averages)	Total[a]	Warehousing	Transport
Percent of overall costs	100%	75%	25%
Per child under one year of age	$7.9	$4.8	$1.6
Per dose procured	$0.338	$0.205	$0.069
Per dose administered	$0.706	$0.428	$0.144
Per cm^3 of vaccine	$0.013	$0.008	$0.003
Per $1,000 worth of vaccines	$56.9	$34.5	$11.6
Percentage value of vaccines	5.7%	3.4%	1.2%
Per km traveled	$13.1	$7.9	$2.7
Per health center order	$298.96	$181	$61

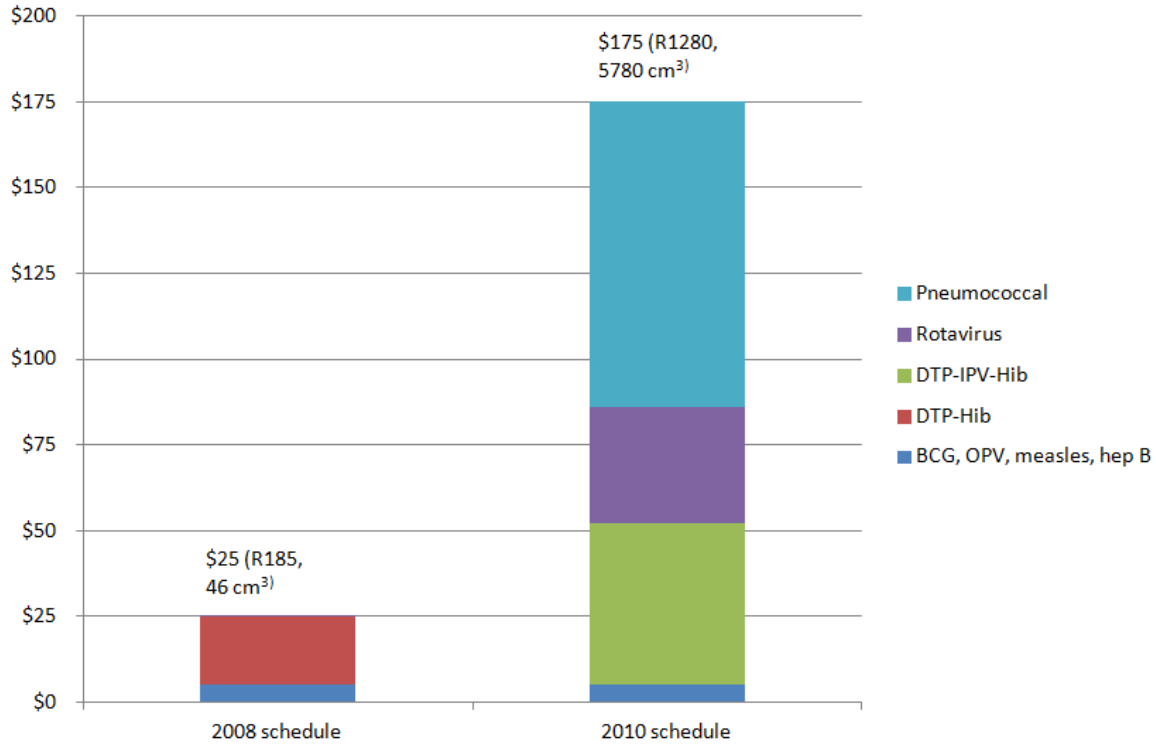
a = Total includes the profits made in 2010.

Financial analysis

Until the introduction of the three new vaccines, the South African government was funding the entire vaccine bill. At the central level, the vaccine budget allocation is voted on annually. Each of the nine provinces receives their share of the overall vaccine budget, based on a per capita allocation. Once these amounts enter the provincial health budget, they are no longer ring-fenced. At the provincial level, the financing of vaccines is decentralized to district offices within the province. Districts are also allocated their proportion of the provincial vaccine budget on a per capita basis. Health centers belonging to a district can place vaccine orders up to the limit of the district budget allocation. Each order for vaccines from a health center is cleared by the district DOH.

For the planned introduction of Pentaxim, Rotarix, and Prevenar, the South African Government did not have the cash flow to cover the additional US$120 million needed for the first year of introduction. In 2009, the Minister of Health convened a donor meeting to raise external funds. The majority of the financing for the first year of introduction was covered under a ring-fenced budget of donor resources created as a special Presidential Initiative. The pharmaceutical companies producing the new vaccines donated the remainder. In addition, the pharmaceutical companies provided financial support for the cold chain expansion needed to accommodate the increased volume of vaccines. Approximately 2,000 refrigerators were provided to the National Immunization Program.

Figure 15. Vaccine cost per fully immunized child of the South African vaccination schedule



BCG = Bacilles Calmette-Guérin; DTP-Hib = diphtheria-tetanus-pertussis, *Haemophilus influenzae* type b; DTP-IPV-Hib = diphtheria-tetanus-pertussis, inactivated polio vaccine, *Haemophilus influenzae* type b; hep B = hepatitis B; OPV = oral polio vaccine; R = rand.

Note: no vaccine wastage was included.

Beyond 2010, it is not clear how the national government will fund the newly introduced vaccines. If external partners are not providing support, national budgetary reallocations within the health budget will be required. This is likely to be at the expense of other health programs. One simply needs to look at the change in the vaccine cost to fully immunize a child following the decision to expand the national immunization schedule to include the Pentaxim (DTP-IPV-Hib), Prevenar, and Rotarix vaccines. Following this decision, the cost per fully immunized child increased from US$25 in 2008 to US$175 in 2010.

What is also unclear is how Biovac is managing this surge in vaccine value. The cash flow and outlays needed up front to procure vaccines on behalf of the national DOH as part of the Supply Agreement PPP must have risen seven-fold. It is unknown how this was financed or whether cash flow problems for procurement were experienced.

Discussion and conclusion

In recent years, vaccine supply chain management has become a priority for many countries working to scale up vaccine delivery. The introduction of new vaccines is an increasingly complex as well as costly activity, however, bringing with it a number of

challenges. In addition, the resources necessary for expanding the supply chain capacity and better enabling health care workers to effectively manage, store, and distribute vaccines are often unavailable. Without external resources, many ministries of health are hesitant to make large capital investments in the kind of vaccine supply chain system that scale-up would require.

As a result, more and more countries are engaging the private sector in supply chain and logistic functions. When such expertise is available in country, as it is in South Africa, governments are frequently outsourcing the physical storage and handling of commodities to specialized private-sector logistic operators.[1]

Outsourcing is a growing trend in high- and middle-income country settings, yet remains an emerging trend in low-income country settings. Although the theoretical benefits of outsourcing are clear, the true costs and benefits remain unclear. Information regarding the challenges of outsourcing public health supply systems is lacking as is information regarding the conditions necessary to make outsourcing successful. This review attempts to address these information gaps with evidence-based information around the cost and benefits of outsourcing the supply chain and logistic functions of the system. As part of the review, Biovac took over roles of vaccine procurement, warehouse management, inventory management, and vaccine distribution directly to health centers.

The outsourced supply chain led to a streamlined three-step supply chain for vaccines—from the national to provincial level (up to 1,400 km one-way) and from the provincial level to the health centers (with distances ranging between 5 km and 300 km one-way). This review provided some evidence on the potential benefits of both a streamlined and outsourced system to address the growing pipeline of future vaccine. Moreover, the review was undertaken in a context where three new vaccines were being introduced into the national immunization schedule—Pentaxim (diphtheria-tetanus-pertussis, inactivated polio vaccine, *Haemophilus influenza* type B), Rotarix (rotavirus), and Prevnar (Pneumo) vaccines. In 2010, three new vaccines were introduced in the Western Cape, and these vaccines are not only more costly, but voluminous. In South Africa, the vaccine cost per fully immunized child increased from US$25 in 2008 to US$175 in 2010 following the decision to introduce the new vaccines.

The methodology for the review utilized two approaches to analyze the outsourcing experience. The first approach was to interview key stakeholders at each level to understand the historical context and rationale that led to the decision to outsource, the perceived strengths and weaknesses of the system from an operational and management perspective, and the perception of the clients (i.e., health centers) in terms of their satisfaction with the services provided. The second approach relied on three factors: (1) a diagnosis of the strengths and weaknesses of the outsourced supply chain based on an effective vaccine management assessment; (2) a temperature monitoring analysis along all storage points and transport routes as the quality control measure to ensure that vaccines handled by the outsourced company are kept at the recommended temperature ranges and vaccines are not at risk of freezing or damaging heat exposure; and (3) a detailed economic and financial analysis to review the costs of the outsourcing model and understand to what extent outsourcing is good value for money.

The review concludes that the outsourcing of the vaccine supply chain to Biovac has been a good solution for the WCDH and is a viable option for future consideration by other provinces. In fact, the outsourcing agreement proved a key factor in the Western Cape's ability to handle a 2010 measles outbreak and the introduction of the three new vaccines. In addition to storing and transporting vaccines in good condition and meeting the orders received from the district on behalf of the clinics in a timely fashion, the 6% overhead fee is highlighted as a cost-effective investment—adding to the value proposition for outsourcing. Had the CMD of the Western Cape carried out these services, they would have levied a 5% overhead charge. In addition, far more training and support would have been required as the CMD has no routine vaccine cold chain expertise. In other words, CMD could have taken responsibility for these services (for less), but did not have the necessary cold chain capacity nor expertise. Biovac's overhead charges are also competitive compared to other private-sector providers in South Africa that have less cold chain and vaccine management expertise.

By comparison, outsourcing is not a good value proposition for health centers in the Western Cape Province that receive their vaccines via resupply points, which results from some districts not wanting Biovac to bypass their level (district level) in the system. It is also not a good value proposition for district stores that want to have more control over the vaccine stockpiles of health centers for which they are responsible. In the end, the costs of the systems are higher for those health centers that the Biovac distribution contract did not cover. This is something that other provinces should consider before adopting a similar outsourcing model.

The weaknesses of the outsourced system are mainly attributable to the WCDH's lack of management oversight of the contract, problems in the contract itself (i.e., the terms of the service-level agreements) and the lack of key performance indicators, and the decoupled ordering information systems between the WCDH and Biovac. These weaknesses can serve as lessons learned for other countries that are considering outsourcing their supply chain and logistics system to a third party. Addressing these weaknesses early on in the decision-making process can help other countries to avoid making similar errors.

The lessons learned from this review highlight many considerations that other provinces in South Africa and other countries in the African continent should weigh before deciding to outsource. Outsourcing can help to increase the supply chain performance of the existing system but it is by no means a panacea. Venturing down the path of outsourcing will require new sets of skills and will result in a host of new challenges.[1] It is important that the right framework and approach be established in order for an outsourcing public-private partnership to be successful.

Recommendations

Based on the review, the major strengths and weaknesses of the outsourcing system from both the Biovac Institute side and the WCDH side can be listed. Both parties should work to maintain the strengths of the system and find ways to address the weaknesses so that the vaccine supply chain outsourcing model continues to be a viable option for the future.

Table 16. Strengths and weaknesses of Biovac as the outsourcing provider

Biovac strengths	Biovac weaknesses
Streamlined supply chain that responds to specific vaccine orders from health centers and the delivery of these orders are direct to health centers (no intermediate storage points).	At the boundary of a push-pull system. Vaccines are being pushed from the national level to the Western Cape, but Biovac responds to orders from clinics (pull).
State-of-the-art warehousing facility with ample capacity and skilled/trained staff.	Inability to maintain the right level of stock, especially since orders are responded to in a mechanical way without reviewing trends and consumption patterns (easy for health centers to order more than they need).
Strong understanding of vaccines and cold chain.	There is no contingency planning in the case of sole vaccine suppliers and lack of supply.
Effective storage of vaccines (high EVM scores).	New vaccines have put pressure on the system leading to stockouts on the orders. That said, it was more of an issue of inadequate planning, insufficient funds to manage the large cost of vaccines, or problems of supply with the manufacturers.
Effective transport of vaccines to health centers (temperature study showed good results).	Not informing health centers as to when the order will be delivered and when the Biovac driver will show up.
Effective packing of vaccines for transport.	Not keeping up with the latest temperature monitoring device technologies for transport nor managing stocks with VVMs.
Good logistics management and information systems and temperature monitoring systems.	There are lags on the latest WHO policies regarding vaccine and cold chain management.
Responsive system—orders are fulfilled within five days of receipt.	Reporting and information-sharing website was never developed.
Client service—the driver checks orders with the health center upon delivery.	
The 6% overhead is a competitive rate.	

EVM = effective vaccine management; VVM = vaccine vial monitor; WHO = World Health Organization.

Table 17. Strengths and weaknesses of WCDH as the outsourcing client

WCDH strengths	WCDH weaknesses
Sustains very high immunization coverage.	Antiquated government ordering system (Logis) leads to a very slow ordering process.
Excellent infrastructure throughout the province especially at the health center level.	Weak contract • No service -level agreement defined. • Limited KPIs. • Decoupled information system for orders, forecasts, etc.
	• Not all health centers covered in the contract (only 47%). • Limited reporting requested. • No stockout penalty clause as in the Supply Agreement. • No annual review of the contract performance. • No review of the system prior to renewing the contract.
Extremely motivated and dedicated health workers at district and health center levels.	Absence of a cold chain and logistics manager at provincial level for many years.
Cold chain manager appointed in 2009 to handle all logistics issues in the province.	Key SOPs lacking. The outsourcing contract should include the development of a joint WCDH and Biovac SOP that clearly articulates all procedures of the system and roles, responsibilities, and accountabilities.
	Cold chain equipment at health center level is unstable.
	Vaccine management knowledge at health center level is weak.

KPI = key performance indicator; SOP = standard operating procedures; WCDH = Western Cape Department of Health.

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3. WHO Regional Director for Africa Dr Luis Sambo calls for greater private sector involvement in health [press release]. Geneva: World Health Organization; October 6, 2010. Available at: http://tinyurl.com/3v72dv4.

4. Biovac extends supply agreement with DOH [serial online]. *Business Live*. Available at: http://www.businesslive.co.za/Feeds/inet/2011/02/15/biovac-extends-supply-agreement-with-doh. Accessed: September 1, 2011.

Annex 1. Resource documents

Below are some resources that may be of interest to the reader. For more information please contact lydonp@who.int.

1. **Background documents:**
    a. Optimize analysis of EVSM and VMA—Immunization Landscape Analysis.
    b. Optimize outsourcing Rapid Assessment of Value Exercise.
    c. Optimize project proposal for the South Africa outsourcing review.
    d. Notes of the first stakeholder workshop meeting.
    e. Notes of the final stakeholder workshop meeting.

2. **Methods and tools:**
    a. Questionnaires—historical and management (developed by Naomi Wasserman).
    b. Effective Vaccine Management Tool.
    c. Temperature monitoring study protocol (developed by Ticky Raubenheimer).
    d. Stock-Analysis Tool (developed by Jan Grevendonk).

3. **Related resources:**
    a. Supply Agreement.
    b. Distribution Agreement.
    c. Department of Health and Biovac Supply and Distribution agreement (outsourcing contract).
    d. WHO Regional Director for Africa Dr Luis Sambo calls for greater private sector involvement in health [press release]. Geneva: World Health Organization; October 6, 2010. Available at: http://tinyurl.com/3v72dv4.
    e. Biovac extends supply agreement with DOH [serial online]. *Business Live*. Available at: http://www.businesslive.co.za/Feeds/inet/2011/02/15/biovac-extends-supply-agreement-with-doh. Accessed: September 1, 2011.
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4. **Data sets:**
    a. Quarterly vaccine price list.
    b. Biovac vaccine monthly orders by month and by vaccine (2009 to 2010).
    c. Western Cape Department of Health doses administered by month and by vaccine (2009 to 2010).
    d. Biovac vaccine orders to EVM sampled sites (2010).

5. **Final reports:**
    a. EVM report for the Western Cape Province.
    b. Temperature monitoring report.
    c. Vaccine expenditure report.
    d. Compiled historical and management questionnaires.
    e. Compiled health center satisfaction questionnaire.
    f. Biovac costing analysis.

Annex 2. Biovac facilities for the Western Cape Province

A2.1: Vaccine warehouse[xvii]

A2.2: Picking and packing area

A2.3: Positive cold room

A2.4: Negative cold room

A2.5: Health center order

A2.6: Individual packed order

[xvii] All images in Annex 2 are credited to World Health Organization/Patrick Lydon.

A2.7: Insulated vaccine carrier

A2.8: Chilled water packs

A2.9: Remote temperature monitoring

A2.10: Visible standard operating procedures

A2.11: Biovac vehicle

A2.12: Volume of Pentaxim

Annex 3. Facilities in the Western Cape Province

A3.1: Original vaccine store (Karl Bremer Hospital) [xviii]

A3.2: Luvuyo Clinic

A3.3: Hermanus Clinic

A3.4: Harry Comay Vaccine Store
(Right side = Pentaxim, rotavirus, and pneumococcal vaccine)

A3.5: Harry Comay Vaccine Store
(Left side = BCG, DTP, OPV, measles, HepB, TT)

A3.6: Zero brand refrigerators

[xviii] All images in Annex 3 are credited to World Health Organization/Patrick Lydon.

A3.7: Inside Zero refrigerator (1)

A3.8: Inside Zero refrigerator (2)

A3.9: Suspected high wastage

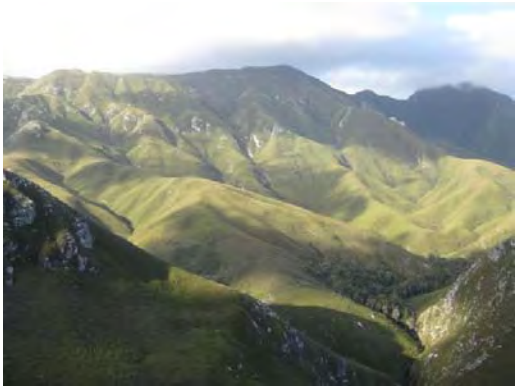
Annex 4. Topography and geography in the Western Cape Province

A4.1: Central Karoo[xix]

A4.2: Cape Winelands

A4.3: Western Coast

[xix] All images in Annex 4 are credited to World Health Organization/Patrick Lydon.



A4.4: Eden and Overberg