THE ROLE OF POLICY ANALYSIS TO SUPPORT DATA VISIBILITY ACROSS PUBLIC PHARMACEUTICAL DELIVERY SYSTEMS: THE CASE OF VAN

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ABSTRACT

The World Health Organisation defines health as a "state of complete physical, mental and social well-being". Unfortunately, for the majority of South Africans, this definition of health does not conform to their current situation. Rising drug prices, stock-outs, and the lack of supply chain competence at facilities all contribute towards the cause of concern. The National Strategy: Visibility and Analytics Network (VAN) aims to improve the public sector's medicine availability by transforming the current uninformed pull system to an informed push system. This is achieved by placing a cadre of supply chain experts at the provincial level that have end-to-end visibility along the supply chain, and are responsible for most of the supply chain administration—moving the highly sophisticated supply chain management work away from the facilities. The VAN is the combination of people, processes, technology and policies organised coherently to ensure medicine availability. Currently, the VAN strategy has fully developed roles and responsibilities with data driven processes that use analytical methods to continually plan, proactively respond to, and recommend improvements. However, the VAN strategy lacks understanding of the effect policies may have on new operational practices and approaches that form part of the VAN implementation. This is especially true in the case of the use of data driven systems that can provide end-to-end-visibility and the effect of policies on the feasibility of implementing such systems. To provide the necessary context and background, this study commences with a description of the VAN initiative, focussing on the overarching philosophy of the strategy as well as its four elements. Following this, a pharmaceutical logistics framework is explored to illustrate the importance of policies on the design of a pharmaceutical information system. Furthermore, the VAN operations are analysed within the context of the pharmaceutical logistics framework to gather the necessary requirements (i.e. standard operating procedures and data requirement that need to be supported) for the VAN information system. Finally, the legislative environment is investigated to provide insight to VAN stakeholders and government authorities on how laws, regulations and policies may influence the operational, tactical and strategic levels of an initiative such as the VAN. It is found that South Africa's legislation supports the establishment of an information system within the healthcare sector, with funds to implement such a system, however, there is lack of sufficiently detailed regulations to clearly define and govern the operation of such a system to ensure end-to-end visibility across the supply chain network. Specific guidelines that should be incorporated into legislation to address this shortcoming are proposed, based on the identified requirements of an information system to support the VAN.

Key words: pharmaceutical supply chain; primary healthcare; medicine availability; policy analysis; data visibility system; technology.

INTRODUCTION

Background

South Africa's healthcare delivery system is characterised by a private and a public healthcare system that differ significantly. The over-stretched public healthcare institutions cover the majority (approximately 84%) of the South African population (Gray & Vawda, 2017). In the past few decades the public sector's healthcare delivery system (referring to primary healthcare) failed to provide the adequate quantities of essential medicines to satisfy the demand, and ultimately foster the desired level of population health (National Department of Health, 1994). Essential medicines are drugs[i] that satisfy the majority of the population's healthcare needs, and should be available at all times and in the right amounts (World Health Organization, 1998). In 1996, a National Drug Policy was adopted, with the aim of ensuring the accessibility and availability of safe, efficient, affordable, and high-quality medicines to the public (National Department of Health, 1994). Rising drug prices, irrational use of drugs, and ineffective procurement and logistics have contributed to an inability to deliver on the aim of the National Drug Policy (Pharasi & Miot, 2012). In the past decade, multiple stock-out problems were detected across multiple facilities in South Africa, and the stock-outs became more prevalent over the following years (Kleynhans, et al., 2017).

Stock-outs or the lack of available medicines at primary healthcare facilities depend heavily on the facility's supply chain management capabilities (Raja & Mohammad, 2004). A supply chain is the interrelationships among organisations, people, processes and resources with the aim of successfully delivering a product or service (Raja & Mohammad, 2004). Public healthcare procurement systems, also defined as public pharmaceutical supply chains, differ from commercial supply chains in the private sector due to the extended global pipelines, the uncertainty and fluctuation in demand, and the high product level requirements (Kleynhans, de Kock, & Bam, 2017; Raja & Mohammad, 2004). A procurement system is based on obtaining the right commodities and services, in the right quantities, at the right place, at the right time, and at an affordable price (USAID Deliver Project, 2011). Therefore it is highly recommended that all the links that form part of a supply chain should be taken into consideration in order to have an effective impact on a healthcare delivery system (Raja & Mohammad, 2004). There are various activities and (demand and supply management) tools available to support the healthcare system in the distribution of drugs from the suppliers to the facilities. In order to distribute the right amount of drugs, forecasting is crucial. Therefore, accurate and high-quality data should be available to forecast the estimated demand. The right amount of drugs can only be delivered to the right facility at the right time if a transportation logistics system is well-managed. Supply chain tools are available that could enable effective procurement of essential medicines, however, these tools need to be utilised by individuals who have been formally trained in drug logistics and supply management systems and who have access to adequate resources (Raja & Mohammad, 2004; Roy et al., 2009).

In low and middle income countries, weak supply chains are a major contributor to underperforming health systems. Although great strides have been made to improve medicine availability upstream at lower prices, issues with in-country supply chains are resulting in high stock outs and wastages at facilities. This in turn reduces the availability of medicines at the point and time of need (Goel & Llewellyn, 2015). To help address these challenges, the Bill and Melinda Gates Foundation has

[i] In this paper, medicines, drugs, commodities and products are considered similar terms.

identified the concept of supply chain Visibility and Analytics Networks (VANs) as a focus area. Leading supply chain organizations in the private sector have implemented VANs, also referred to as 'Control Towers', to improve the cost effectiveness and agility of their supply chains (Goel & Llewellyn, 2015). The goal of the VAN Project is to leverage private sector design approaches and leading practices to improve end to end visibility of the most relevant public health supply chain information, and enable this information to be used in a way that improves beneficiary outcomes by using integrated and closed loop supply chain management practices (Goel & Llewellyn, 2015). A Blueprint Reference Model (BPRM) has been developed to aid any country in designing a VAN strategy specific to their current circumstances. However, the BPRM is not intended to be 'a single answer' for a country's challenges, but a proposed guideline to how a VAN could work.

South Africa's National Department of Health (NDoH), with inputs from multiple funders, health organisations, and African governments have developed a VAN strategy specifically for South Africa, with the aim of resolving the issues of medicine availability from a supply chain perspective. The VAN model is a combination of different key design elements, namely: people, processes, technology and policies. These elements must be organized and aligned from a national level all the way to a facility level in order to achieve the vision (Llewellyn, 2016). In the context of South Africa, the VAN model aims to transform the current pharmaceutical supply chain from a 'uninformed pull' system, to an 'informed push' system (Llewellyn, 2016). The transition from a pull-based to a push-based system is achieved through placing highly qualified supply chain experts, who are responsible for analysing and subsequently optimising the supply chain, at the complex links in the supply chain (Llewellyn, 2016). These supply chain experts will make use of analytical processes and information technology to perform the majority of the supply chain management work.

Currently, the VAN strategy describes the people that need to be involved, the processes required for implementation, and the need for an integrated information technology system to provide end-to-end visibility across the supply chain. However, at an aggregate level there is a lack of understanding in terms of the enabling and limiting effects of country-specific policies on the VAN strategy. The VAN can only be effective at delivering supply chain services across health programmes when it is subject to a clearly defined single governance structure with reporting lines and active communication channels (World Health Organization, 1946), and needs to be supported by agreed governing policies, role descriptions and accountabilities. Therefore this article will focus on the role of policy analysis on a pharmaceutical operational model such as VAN, specifically placing the emphasis on the technology element of the VAN.

Research Objectives and Methodology

In order to satisfy the VAN objective of end-to-end visibility across the pharmaceutical supply chain, an information technology system is required. Technology is one of the four key elements of the VAN strategy, and it, like the people and process elements, is governed by the policy element of the VAN strategy.

Therefore, the research objectives (RO) for this article are to: (i) examine the different key elements of the VAN strategy to understand the contribution each element has towards the end-to-end visibility goal; (ii) investigate the influence of policies on information systems within a public sector pharmaceutical environment; (iii) analyse the flow of information and data within the key VAN elements to extract the requirements for a VAN information system; (iv) explore whether South

Africa's current legislative instruments enables the information requirements of the VAN; (v) and provide recommendations on specific elements that should be incorporated into policies in order to clearly define and govern the operation of an information system to provide the end-to-end visibility required by the VAN.

The research study follows a systematic approach, whereby the study is executed amongst three mutually exclusive sections. The research objectives (RO) are aligned to continuously build onto one another throughout the three separate sections. Figure 1 illustrates the research approach that is followed to achieve each objective.

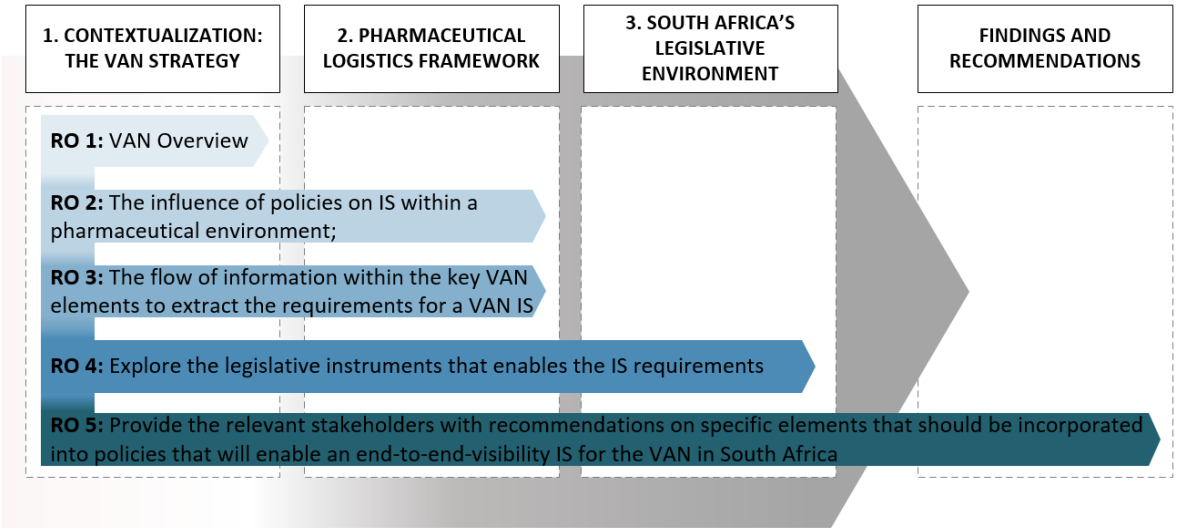

Figure 1: Research approach.

CONTEXTUALISATION: THE VAN STRATEGY

This section contains a succinct overview of the VAN model to provide background and context to the research study. This section starts off with an introduction to the VAN model, followed by an in-depth description of each element that the VAN model is comprised off. The discussion of the policy element provides insight on the motivation for this research.

Introduction to the VAN model

A Visibility & Analytics Network (VAN) is a group of supply chain experts empowered by processes, technology and policies with the objective of making a public sector pharmaceutical supply chain more collaborative, aligned, and agile (Goel & Llewellyn, 2015). The design goal is to ensure the right commodities are delivered at the right time and place, and in the right quantities (Llewellyn, 2016). The VAN may be designed to sit at any level of the supply chain, however it should: provide end-to-end visibility across the entire supply chain network; consist of a highly skilled team of people to deliver well-defined supply chain services; incorporate complex analytics to enable the right decisions to ensure medicine availability; and ensure continuous improvement on functional processes (Goel & Llewellyn, 2015).

As previously mentioned, the VAN for South Africa is designed to move the current pharmaceutical supply chain from an uninformed pull system, to an informed push system. The four stages of transitioning between these two modes of supply chain operation are illustrated in Figure 2. In a

pull-based supply chain, the ordering and distribution of goods are demand driven. This is dependent on the customers' true demand; however, a push-based supply chain is dependent on the estimated demand calculated by means of forecasting (Harrison, et al., 2006). The transition between the two systems (stage 2 to stage 3) does not only require supply chain experts, it also requires the technology that will enable the end-to-end visibility across the supply chain.

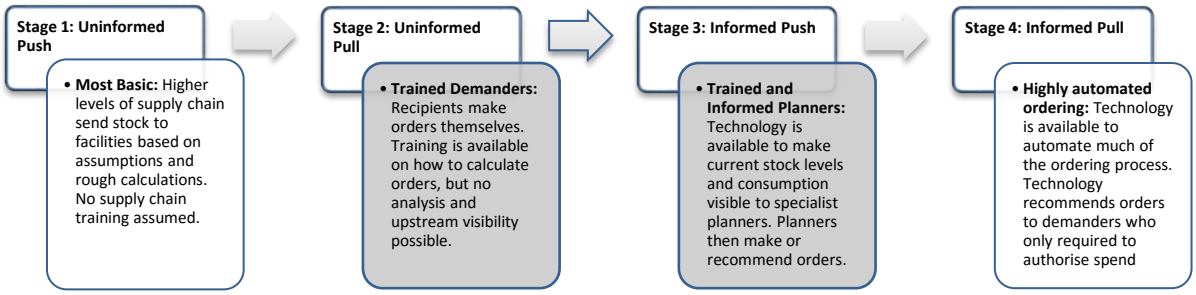

Figure 2: A description of the various pull and push system, based on supply chain visibility (informed or uninformed). Excerpted from: (Llewellyn, 2016)

Implementing the VAN in a complex context and transitioning the current system to an informed push model implies significant change, and will require certain enablers to be in place. These enablers are situated amongst the four elements of the VAN: people, processes, technology, and policies. The people element defines the responsibilities of the current and new VAN roles; the process element sets the new standard operating procedures of the informed data driven system; the technology element argues for an integrated data system that will provide visibility and insight along the supply chain; and the policy element is the element that governs the other elements by means of a cross-cutting governance framework.

People element

The roll-out of the VAN model will be executed among three tiers of South Africa's governance structure: national level, provincial level, and the district/facility level. Each level has a set of actors and organisations that have specific roles and responsibilities within the VAN model. The VAN model builds on the existing split of responsibilities between the national and provincial levels. The VAN operates as a tactical centralised unit within each province, which is referred to as a Provincial Medicine Procurement Unit (PMPU) as shown in Figure 3. The PMPUs are responsible for managing the majority of the supply chain activities and administration for the district facilities in their respective provinces (Llewellyn, 2016), using modern delivery methods (Department of Health, 2017). The highly skilled supply chain analysts in each PMPU are encouraged to make or suggest ordering recommendations for facilities, rather than facilities being responsible for their own ordering. The Affordable Medicines Directorate (AMD), which is a subset of the National Department of Health (NDoH), is responsible for governing the processes of each PMPU at an aggregated (national) level (Llewellyn, 2016). In order for data to flow from each PMPU in the country to the national level, an integrated platform should be available to enable the aggregation of the various data.

The VAN provides an approach to supply chain management within each PMPU, which in the South African context aims to improve and sustain the availability of, and equitable access to, health

products and medicines (Llewellyn, 2016). The BPRM identifies the supply chain categories for a VAN as demand planning, supply planning, and distribution planning (Goel & Llewellyn, 2015).

The BPRM refers to supply chain management as "many overlapping things" (Goel & Llewellyn, 2015), therefore, important to note that the three supply chain categories are interlinked and the output from one category forms the input of another category (Goel & Llewellyn, 2015).

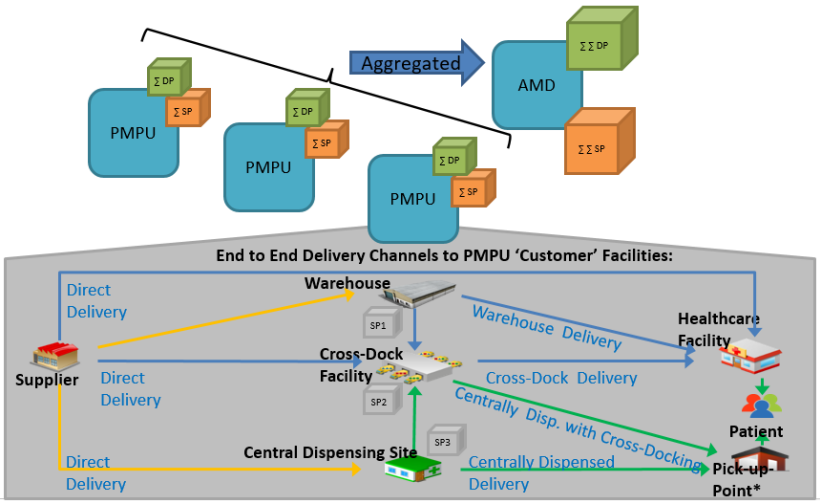

Figure 3: Overview of the split responsibility between the national and provincial level. Source: (Llewellyn, 2016)

Process element

The three supply chain planning categories are illustrated by means of process maps, showing the various activities that relate to each of these categories. The process maps not only illustrate the sequential activities, it also indicates responsible actors, as well provide insight to how data should be shared amongst the different organisational levels. The first category to be discussed is the demand planning category, illustrated in Figure 4. Demand planning activities apply trend analysis to historical data gathered from the various districts and facilities, and use statistical modelling to determine the demand plan consensus across all facilities in the respective provinces (Kleynhans et al., 2017; Llewellyn, 2016) .

Long term forecasting processes (governed by the AMD Demand Manager) take place annually with inputs from national statistical data which is aggregated from the PMPUs (Llewellyn, 2016). The annual estimated demand plan determines the tenders of possible suppliers and annual budget allocations. It is the responsibility of the National Treasury and the NDoH's Chief Financial Officer (CFO) to inform the annual budget allocation to each province for the procurement of pharmaceuticals (Kleynhans et al., 2017; Llewellyn, 2016). Every six months, the selection and update of the Master Procurement Catalogue (MPC) is reviewed by an AMD manager to ensure the best treatments and medicines are selected to improve a patient's outcome. The selection of medicine is primarily programme-specific, i.e. the Essential Drugs Programme (EDP). PMPUs are responsible for updating the monthly demand plans in order to track and reflect the actual consumption data received from respective district facilities. The PMPUs also need to conduct quarterly reviews to ensure that the actual consumption aligns with the budget that was agreed to from the national level, and re-adjust the budget where applicable (Llewellyn, 2016). The consumption data and changes in budget allocation are subsequently aggregated and used at the

national level to provide a baseline for annual or tender[ii] plans (Kleynhans et al., 2017; Llewellyn, 2016). A change in the updated demand forecasts from the consumption data will have a direct effect on the budget, therefore a designated budget holder is responsible for executing quarterly updates and amending the budget allocation for supply plan according to the forecasted data (Llewellyn, 2016). These updates are used to inform monthly supply planning processes, which in turn are used to calculate supplier orders and replenishments (Llewellyn, 2016).

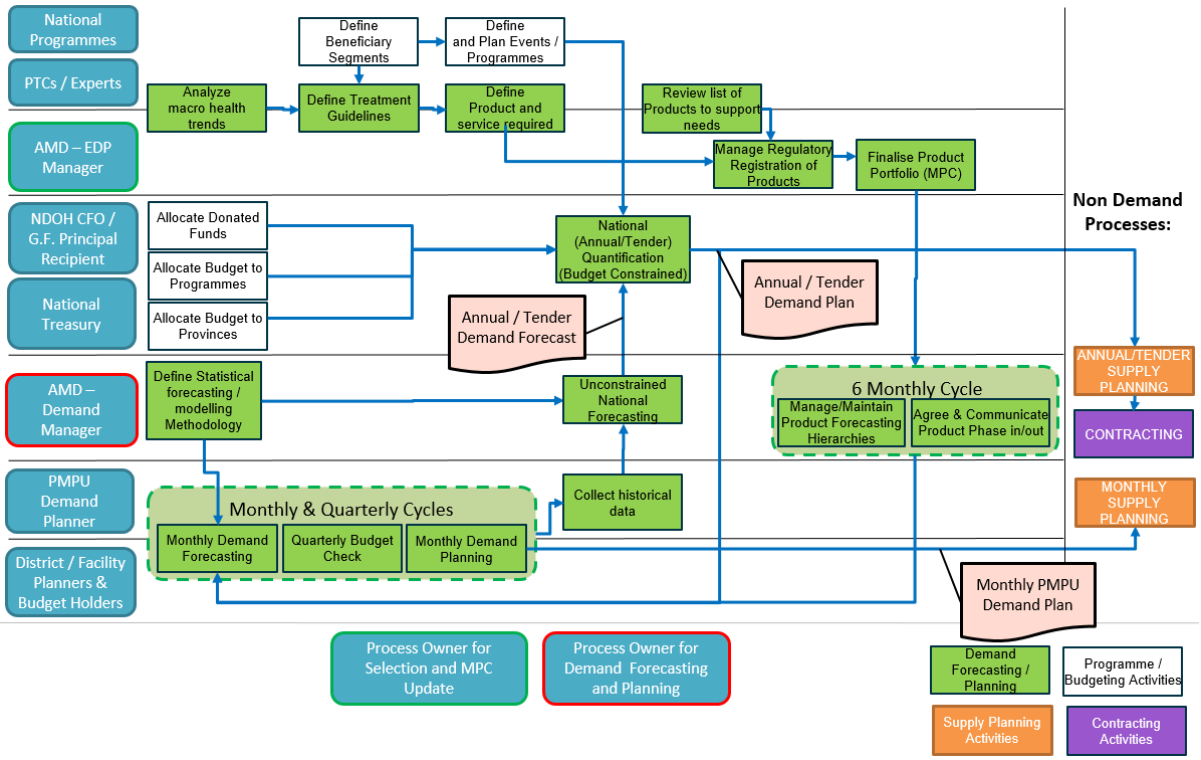

Figure 4: Demand Planning Category. Excerpted from: (Llewellyn, 2016)

Supply planning activities (Figure 5) aim to optimally coordinate inventory levels, number of orders, and shipment plans, in order to ensure sufficient stock, and to fulfil the demand plan, which is the input for the supply planning activities. The forecast data from the demand plan, along with multiple planning variables, are used to determine the following inputs for the supply plan: replenishment frequencies, demand variability, order cycles, lead time, stock on hand, sample rate, etc. Once the annual demand planning and forecasting activities have taken place, an AMD Supply Manager is responsible for analysing the ordering quantities required to ensure stock availability, and works in collaboration with a contracting team, governed by an AMD Contracting Manager, which is responsible for managing the tenders (Kleynhans et al., 2017; Llewellyn, 2016).

Six monthly and quarterly updates are performed by the demand planning actors that informs the supply planning actors about the timing of implementation of the Standard Treatment Guidelines (STG) and new product selection. The AMD Supply Manager and Essential Drug Program (EDP) Manager collaborate in order to create contracts and orders, based on the EML and STG, to achieve the required new product availability (Llewellyn, 2016).

[ii] "The documentation and initiation of a process for soliciting bids; the specifications for the product / service desired and opening the contract to the bidding process" (USAID Deliver Project, 2011).

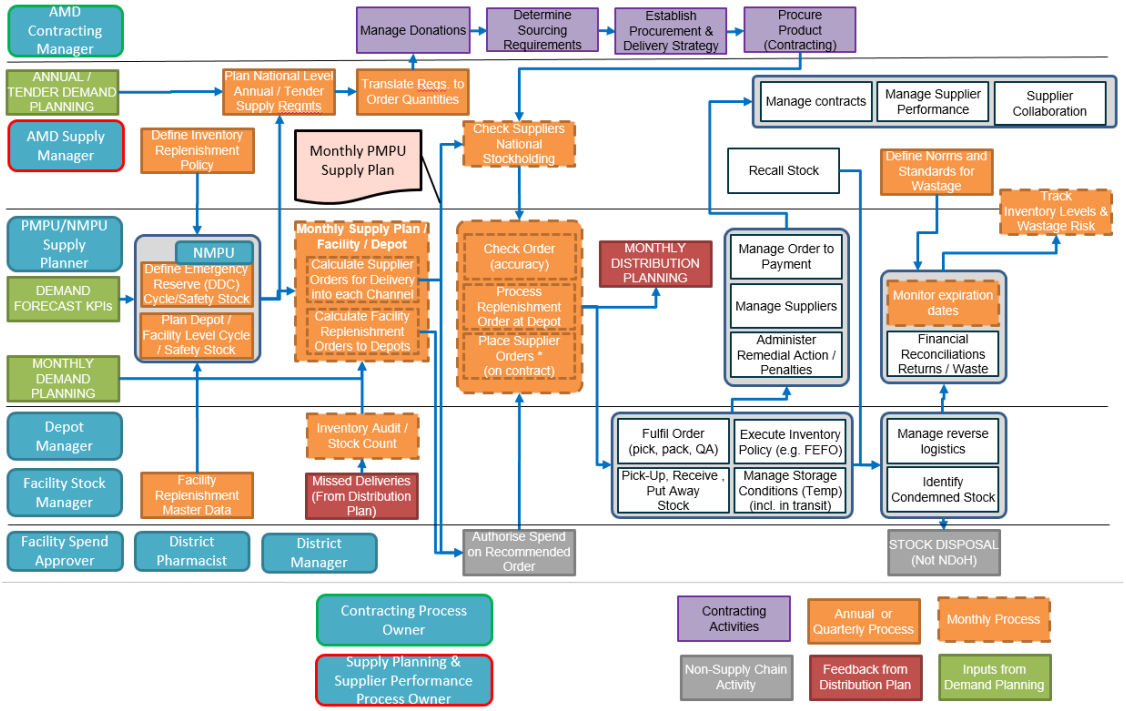

Figure 5: Supply Planning Category. Excerpted from: (Llewellyn, 2016)

As mentioned, the demand planning division is also responsible for the quarterly review on budget availability (Llewellyn, 2016). Evidently, this budget has an impact on the supply plan when the monthly process creates order recommendations that need to be authorised by the spend approvers at facility or district level. The PMPUs are responsible for the monthly supply plan of orders required from the suppliers, as well as the replenishment plan for the movement of stock throughout the depots (Llewellyn, 2016). These monthly plans will be aggregated to the national level to confirm whether the suppliers have sufficient stock to meet the current (and future) demand (Kleynhans et al., 2017; Llewellyn, 2016). After the orders are placed at the suppliers, the demand / supply data is then used for the distribution planning activities.

Distribution planning activities (Figure 6) are concerned with the scheduling of shipments and the distribution of products between the different warehouses and facilities (as illustrated in Figure 3), in response to the output from the monthly supply planning consensus (Llewellyn, 2016). Operations that are involved in both the supply and distribution planning stages include: the execution of the physical delivery of material flow, the operations from the picking and packing, supplier management, stock logistics and storage management. The distribution plan determines the shipment and loads that are required by the respective depots and facilities in order to meet the replenishment plan. The distribution plan aims to use storage and available capacity as efficiently as possible, and feeds back information to the supply and replenishment plans respectively in the event that unwanted issues arise.

Long term (1-3 year cycles) distribution trend analysis is done to calculate the capacity plans and to ensure network optimisations (Kleynhans, et al., 2017). This process generates data on order deliveries, shipment reliability, and costs of shipments. Short term (weekly/ daily cycle) consists of creating a distribution plan to schedule replenishment between the various government depots and facilities (Llewellyn, 2016). The short term updates are done by the depot managers and third party

logistics companies. In the VAN operationalisation, the updates are done at a weekly or daily frequency and will provide input on the available capacity, window for dispatch, and information on the delivery and receipt of stocks.

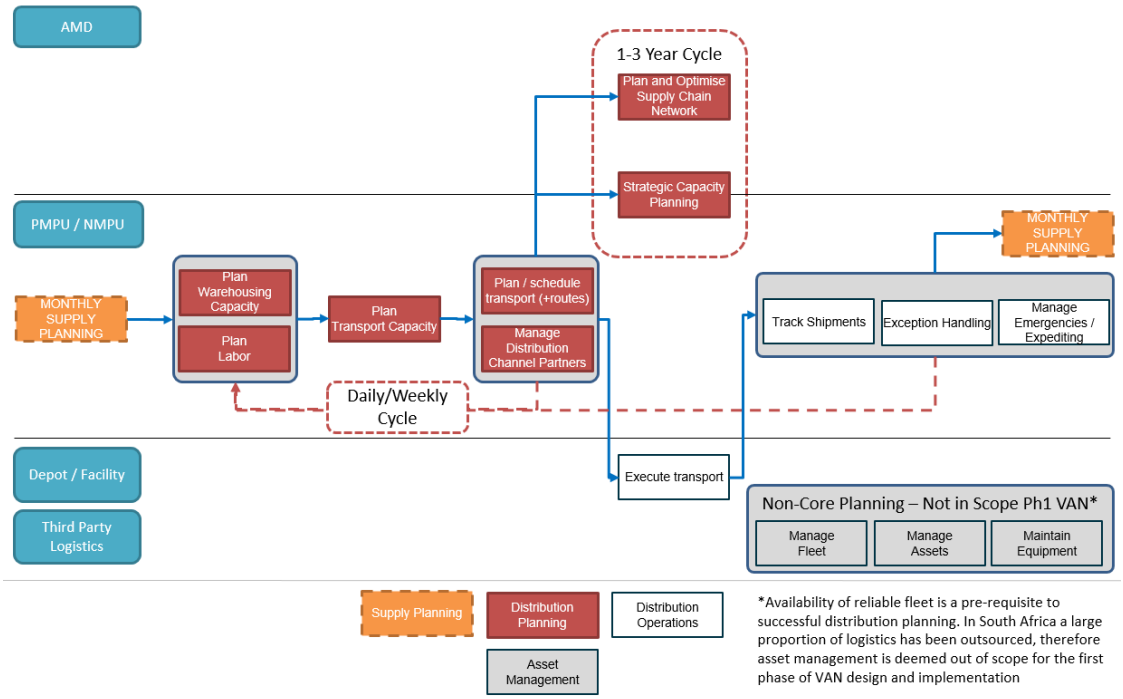

Figure 6: Distribution Planning Category. Excerpted from: (Llewellyn, 2016)

It is evident from these process maps that the VAN is a complex model with intricate processes that are interlinked at various levels of the pharmaceutical supply chain. It also indicates that there are many processes that demand data sharing among different levels of the organisational structure, as well as across the various supply chain categories.

Technology element

The technology element of the VAN strategy aims for an integrated network of multiple data systems to generate alerts and provide accountable insight across the value chain with automation wherever possible (Llewellyn, 2016). For this approach to work, it is critical that the supply chain planners have access to the following (Llewellyn, 2016):

i. Timely and accurate stock on hand data—accurate stock on hand data enables supply planning by ensuring accurate historical consumption for demand forecasting.

ii. Up to date 'slow changing' data—accurate formularies per facility for the informed push of the correct medicines to the facility.

iii. Consistent product and location master data—product nomenclature visibility for all planners, product and packaging specification for distribution planning, and accurate location and replenishment data to enable supply planning and inventory management optimisation.

There are currently multiple software systems in use across the pharmaceutical supply chain (e.g. MEDSAS, RFx, and Sourcelink) and these software systems are used inconsistently to perform the same function in different parts of the system, e.g. the tender and contract management system

used in one province is different from the system used in another province (Department of Health, 2010). Of the multiple software systems being used, the two primary information systems used in South Africa's public healthcare pharmaceutical supply chain are the Stock Visibility Solution (SVS) and the RxSolution. The SVS is a smartphone application, available for PHC dispensing facilities, to capture daily stock levels (Mezzanine, 2017). The application is capable of capturing information for all contracted essential medicines, and this data is automatically uploaded to a central, online repository or cloud (Mezzanine, 2017), which is available to district and provincial authorities in real-time. The RxSolution is an integrated pharmaceutical management software package that supports best practices for procurement, storage, distribution and dispensing of pharmaceuticals.

South Africa's public sector pharmaceutical supply chain operates on a fragmented and incomplete information system (Llewellyn, 2016). The use of different software technologies at different levels of the healthcare system makes visibility within a supply chain difficult and cumbersome (Department of Health, 2010). This is primarily because the use of different information systems makes data aggregation difficult or infeasible. Data aggregation is an important function for a VAN information system in order to provide visibility across the supply chain. Currently, the SVS and RxSolution systems are used in conjunction with one another and integration plans are in development to incorporate these two systems into a comprehensive pharmaceutical information system. The future integration plan will allow the upstream system to automatically place replenishment orders for clinics in line with an informed push replenishment approach (stage 4 from Figure 1), a further modernisation of supply chain practices (Department of Health: Aaron Motsoaledi, 2016). The orders placed automatically will be based on monthly stock consumption determinations based on regularly reported medicine availability information uploaded into the SVS.

The integration plan aims to either assess available software technology or to propose a system that meets the requirements of the VAN, which will in the near future operate under the influence of a National Health Insurance (NHI)[iii] policy (Department of Health, 2017). However, planning the implementation of a system that provides a great deal of data visibility—especially in primary healthcare that is managed by government authorities—does raise the question of ensuring both data integrity and data confidentiality.

Policy element

The BPRM and the VAN strategy for South Africa provides little information regarding the policy element of the VAN. The BPRM states that the policy element aims to provide a "cross-cutting governance framework with clear responsibilities and accountability and empowered decision makers with defined 'spans of control' across the supply chain" (Goel & Llewellyn, 2015). The VAN strategy for South Africa has well-planned roles and processes, however, the policy element is the least-developed element, therefore, special focus needs to be placed on the interaction between policy and the other VAN elements. While this study only focuses on the interaction between policies and technology, some level of interaction does of course also exist between the technology element and the people and process elements. For example, the people element identifies the

[iii] "National Health Insurance is a health financing system that is designed to pool funds and actively purchases services with these funds to provide universal access to quality, affordable personal health services for all South Africans based on their health needs, irrespective of their socio-economic status" (Department of Health, 2017).

actors managing and handling the information system, and the process element describes what type of data is needed and at what level.

In order for the VAN designers and authorities to develop the desired cross-cutting governance framework, the link between the different elements and policies should be understood, especially within the complex environment the VAN operates, namely the public healthcare sector.

THE LINK BETWEEN POLICIES AND A PUBLIC HEALTHCARE INFORMATION SYSTEM

To implement a system that can provide the necessary end-to-end visibility across the supply chain, it is important to understand how the country's current legislative environment is structured, and whether policies are able to support such a system. There are a few questions that come to mind about the possible links between policies and an information system: does a confidentiality clause exist to protect sensitive data such as patient information? Are regulations in place to promote transparency and equal competition between the suppliers with regards to the tender management process, in order to prevent unfair preference?; Are there different levels of detail at which data elements are shared, e.g. is visibility on the product type quantity enough, or should district/facility details also be available to, for example, the forecasting analysts?; Are there regulations/guidelines that provide ownership for different data, and does monitoring policies provide incentives to the responsible entity for providing high quality data?; Does the human resource management system ensure that there are trained and qualified staff members at facilities to capture stock data?; and Does the country have the appropriate infrastructure (i.e. hardware and internet connection) to support an integrated information system?

These questions illustrate the need to investigate the link between policies and an integrated information system within the public healthcare sector's pharmaceutical supply chain. Identifying the interconnectedness of supply chain activities within the healthcare sector and how policies link with the different components, will provide insight on how to analyse policies that may possibly affect the VAN strategy. In the first part of this section, the functions and components of a pharmaceutical logistics framework (PLF) are studied to understand the importance of policy within the pharmaceutical landscape. Each of the components within this framework are described in light of data and information systems.

Pharmaceutical Logistics Framework

The term supply chain and supply chain management has come to prominence over the past decades (Cooper, et al., 1997). Supply chain management is defined as a network of organisations (manufacturers, suppliers, warehouses, distributors, and customers), working in collaboration with one another that is directly involved in the upstream and downstream flows of processes and activities, logistics services, technology, material, information, and finances in order to achieve customer satisfaction (Cooper, Lambert, & Pagh, 1997; Croom, Romano, & Giannakis, 2000). In most cases the terms supply chain management and logistics management are used interchangeably, and they refer to the functions that need to be carried out by the supply chain partners (Raja & Mohammad, 2004). In the pharmaceutical landscape of a public health sector, the framework in Figure 7 depicts the various functions that constitute a pharmaceutical supply chain (USAID Deliver Project, 2011).

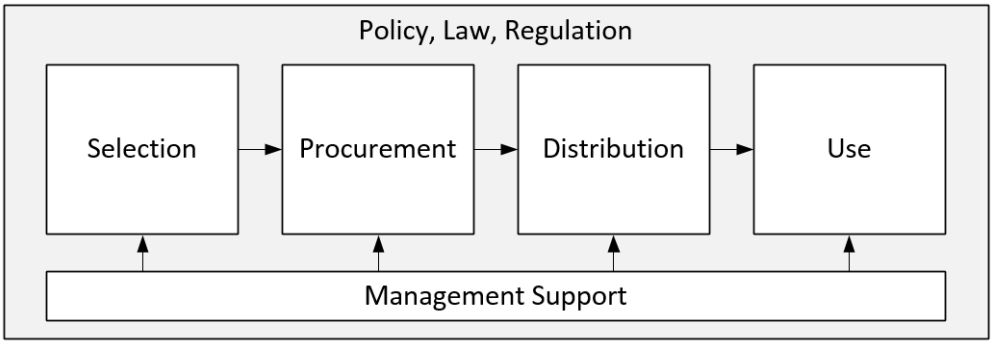

Figure 7: Pharmaceutical Logistics Framework. Source: (Management Sciences for Health, 2012)

The framework consists of four main functions that are considered the main operational activities. At the core of the four main functions are various supporting systems that impact the functions. All of the operational components and supporting bodies are governed by policies, laws and regulations. This framework is considered the same for any level of the healthcare system, however, the process within each function might vary between countries in accordance with local policies, laws and regulations (USAID Deliver Project, 2011).

Operational Functions

A short description is provided on each of the operational functions, for the sake of brevity, the focus is restricted to activities that are affected by end-to-end visibility of high-quality information:

i. **Selection**–product selection identifies the product that needs to be procured.

ii. **Procurement**–the procurement function is the most intricate function that involves efforts to quantify medicine requirements, select appropriate procurement methods, and prequalify suppliers and products. It also involves the management of tenders, establishing contract terms, assuring medicines quality, obtaining the best prices, and ensuring adherence to contract terms. After the selection process, forecasting is required to determine the estimated quantities of products needed, and financial analysis is required to determine and coordinate the available funds accordingly (Ripin, et al., 2014). The future estimates determined by forecasting is used to build a demand consensus plan to conduct a supply plan for the procurement of the products. The budget is a plan by the government that outlines how the income generated by the national government, along with donor funds, will be distributed amongst the national, provincial, and district governments (Hassim & Heywood, 2007).

iii. **Distribution**—the distribution function focuses on the necessary activities to ensure products are delivered and stored according to the right procedures. There are a view different strategies of supply systems used through different combinations of public and private roles (Management Sciences for Health, 2012): central medical stores; direct; prime vendors; and fully private. The logistics that informs the responsible party when to order, how much to order, based on the stock levels are known as inventory management (Raja & Mohammad, 2004). Inventory management ensures that depots and warehouses maintain a high enough stock level in order to provide sufficient amount of products to the facilities when necessary, but still low enough not for stock to become obsolete or expire. Storage involves keeping medicines in good condition throughout the entire supply cycle. Every

inbound and outbound process in the distribution of the medicines must be monitored for appropriate physical conditions and the storage procedures (World Health Organisation, 2014).

iv. **Use**—the aim of a pharmaceutical supply system is to deliver the correct product to the patients who need the medicine, and to ensure the rational use of the delivered medicines (Management Sciences for Health, 2012).

Management Support

The supporting functions are organised into various categories to support the four operational functions of the logistic system and are those that the system cannot function without. These supporting functions include: organisation and human resource management; finance management; monitoring and evaluation; and donor coordination (USAID Deliver Project, 2011). Information systems is also one of the supporting functions. The information system is considered the engine that drives the PLF—an integrated technology system that manages various data requirements to enable visibility across the supply chain to support the supply chain activities within the operating functions (USAID Deliver Project, 2011). The PLF illustrates that information systems are a supporting function to the operational functions, therefore the VAN's technology element should be designed to support the VAN.

Policy, Law and Regulation

In many countries, the government has created policies on: the selection of medical products; how these items need to be procured; when items need to be distributed; how and where the items are stored; and the quantities customers receive (USAID Deliver Project, 2011). The World Health Organisation advises that every country should have a National Drug Policy (NDP) which is concerned with ensuring that effective, safe, and good quality medicines are available through various supply chain functions (World Health Organisation, 2003). A NDP is supported by legislative frameworks that enforce the implementation and governance of the various components within the NDP. Laws and Acts are passed by legislative bodies, and are formulated in general terms to meet the current and future needs of the NDP (World Health Organisation, 2003). Regulations enable government authorities to set out in more detail how the Acts should be interpreted, and how they will be implemented and enforced (World Health Organisation, 2003).

Countries should review their health legislation and promulgate new legislation and regulations as needed to ensure that their policy intent is supported and that legislative gaps are filled, creating an environment for effective delivery of affordable, appropriate, equitable, and accessible quality care for an entire population (African Union, 2007). For this study the legislative gaps with regards to the technology component of the VAN are analysed to determine whether additional or updated policies are required to enable and enforce the required information system.

The PLF provides an illustration of how the different functions within a pharmaceutical supply chain connect. When applying the logistics framework to the VAN, the process element (demand, supply and distribution planning) will fit within the four main operational functions of the framework. The people element is situated within the management support function of the framework in the form of human resource management, and the technology element refers to the information system. In terms of the role of the policy element, the VAN and the PLF are aligned in viewing policy as the

element that governs all of the other elements of the supply chain, providing the framework within which the supply chain operates. The PLF indicates a direct link between the information system and the operational functions, and indicates that this link is both governed and enabled by laws, regulations, and policies. Therefore the link between the VAN's technology and process elements should be identified to determine how the technology element supports the process element, before the relationship amongst those two elements can be analysed in terms of country legislations.

Analyses on the data requirements for the VAN model

To develop an integrated system, one must understand what the necessary data requirements are. In this section, the VAN process is analysed to determine what type of data elements will support the visibility objective, and to determine for example, what data the various actors need to have access to, and who is responsible for generating this data. Table 1 describes the data elements that are required for the various operational activities of the VAN, indicating the responsible actor (level of organisation) to generate/capture the data, what actors need to have access to the data, the frequencies at which the data are updated, and at which planning category the data is used.

Table 1: Data requirements to support the VAN's end-to-end-visibility objective, identifying the responsible actors involved across the supply chain planning categories.

Label	Data Description	Generated by	Available to	Frequency updates	Planning Category
1	Product Master Data	AMD	PMPU	6 monthly	DP & SP & DP
2	STGs and MPC	Programmes	AMD Facilities	6 monthly	DP
3	Facility Replenishment Master data: consumption rate, health trends.	Facility	AMD PMPU	Daily	DP
4	Statistical Forecasting Methodology	AMD	PMPU	Annually	DP
5	Forecast demand estimates	PMPU	AMD PMPU NDoH CFO	Monthly Monthly Annually	DP SP DP
6	Budget Allocation	NDoH CFO / NT	AMD PMPU Budget Holder	Annually Monthly Quarterly	DP & SP DP & SP DP
7	Tendering	AMD	Suppliers	Annually	SP
8	Contracting	AMD and Suppliers	PMPU	Annually	SP
9	Supplier orders	PMPU	AMD Spend Approvers	Annually Monthly	SP
10	Supplier stock availability	Suppliers	AMD	Monthly	SP
11	Storage Capacity at depots and facilities	Facilities / Depots	PMPU	Monthly	SP & DP
12	Inventory /SOH at depots	Depots	PMPU	Monthly	SP
13	Lead time, order cycle, replenishment frequencies,	PMPU	AMD PMPU	Annually Monthly	SP DP

	facility location				
14	Third Party Logistics transport Capacity	3PL	PMPU	Monthly	SP & DP
15	Transport status	3PL	PMPU	Daily/Weekly	SP & DP
16	Missed deliveries	PMPU	Depot Manager	Daily/Weekly	DP
17	Recall of condemned / damaged stock	Facility	AMD PMPU	On delivery	SP

The data from Table 1 was analysed based on the operational activities within the different planning categories of the VAN model (Figures 4, 5, and 6), as well as the operational functions from the PLF. The data descriptions provide a high-level perspective of the data required, however, within those elements are sub-data requirements, e.g. supplier orders (label 9)—this data element may appear simple, however, supplier orders actually contain a large amount of information i.e. the product type, the package size, the quantities needed, and the location at which the product needs to be delivered. The data required for calculating the orders are: the demanded quantities (label 5); the frequencies at which the stock at facilities and depots need to be replenished (label 3); the time it takes an order to reach the destination from the time of ordering (label 13); and the current stock available at the facilities and depots (label 10 and 12). This clearly indicates that the data elements are dependent on one another, and that the information will only be able to successfully support the functioning of the VAN if data ownership that enforces the capturing/gathering of high-quality data is enforced.

The information in Table 1 is used to illustrate the flow of information amongst the different levels of the organisation (Figure 8). The various directions of the arrows indicate that there is not only vertical integration required between the national, provincial and district level, but also horizontal integration amongst the different planning categories as well. It can also be interpreted that the flow of information happens amongst the people element as well as the process element. This confirms the supporting role of the information system in the pharmaceutical supply chain.

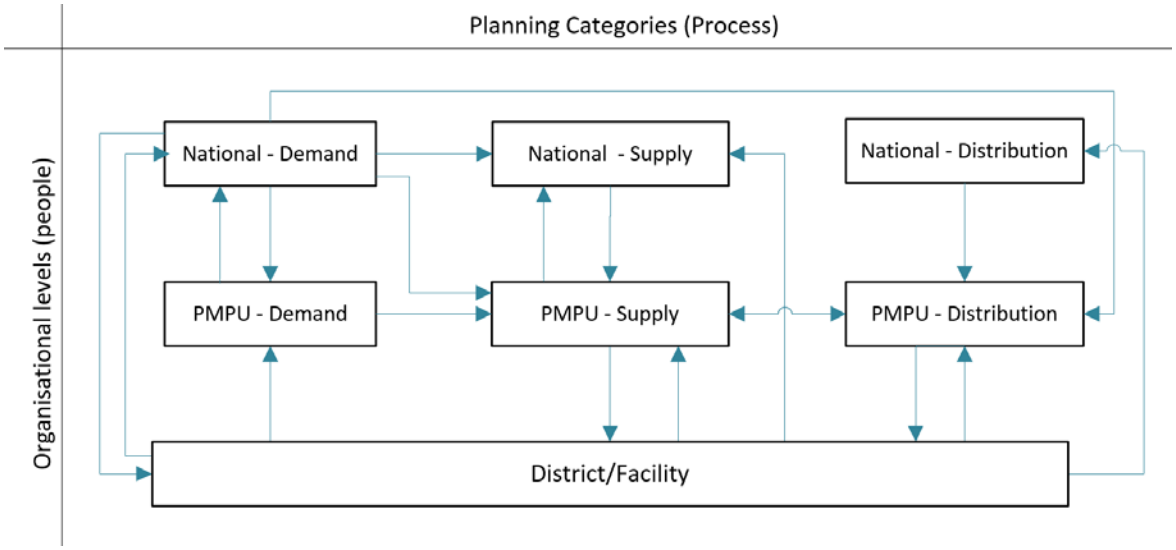

Figure 8: Illustrating the various directions of information flow amongst the organisational levels and process levels

Not only are there multiple information channels, but the frequency at which the data should be generated varies. Because there are different frequencies at which data needs to be available, policies play an important role in formalising the frequency requirements and ensuring that the responsible actor complies with these.

This argument can be applied to all the data requirements in Table 1, because the operating processes, such as demand forecasting, rely on consumption data from the facilities, but if the facility does not fulfil the responsibility of providing accurate and quality data, then the demand planning PMPU will not be able to provide the correct demand estimate to the supply planning PMPU, which will result in inaccurate order quantities at the suppliers, and probably lead to over/under-stocking at the facilities. Therefore, policies that stipulate and enforce the responsibilities of various actors in terms of data capturing are essential to ensure that the information system contains high-quality, comprehensive data to enable the effective functioning of the supply chain.

ANALYSES AND RECOMMENDATIONS: THE ROLE OF POLICY AND LEGISLATION INSTRUMENTS IN GOVERNING AND ENABLING INFORMATION SYSTEMS

Up to this point the VAN strategy has been analysed in terms of the technology element. From the PLF, it is clear that policy is an important function that determines whether certain processes and systems are allowed in terms of the law. Therefore, the legislative environment of a country should be investigated, before the integration of an information system can be implemented. In this section, South Africa's current policies and legislations are analysed—policy analysis for this study entails the investigation of guidelines and regulations (in terms of national Acts) that are in line with the information system requirements discussed in the previous section.

In 1996, South Africa adopted a National Drug Policy (NDP) with the objective to guide governments on how medicine should be procured. Acts and regulations were written to enable the aims and objectives of the NDP. The NDP briefly identifies the various areas for which information systems should be developed: a data base for transparency in the pricing structure of suppliers; a computer system to record drug purchases by provincial authorities for forecasting purposes; and a computerised inventory control system, interlinked between the facilities and depots (National Department of Health, 1994). The NDP seems to be outdated with regards to a system used for procurement and information sharing. The policy promotes the use of a system, COMED, but there is currently no connection found between the use of such a system and public medicine delivery.

Following the NDP, other legislative instruments have been published that touch on the key sections of data sharing and health information systems. Section 217 of the Constitution requires that entities entrusted with supply chain management functions (in this case the PMPUs), must perform such functions in a transparent manner (Department of Justice, 1996)—this term supports the objective of end-to-end visibility. Section 74 within the National Health Act states that the NDoH must facilitate and co-ordinate the establishment of a health information system (National Department of Health, 2003). And section 37 from the Norms and Standards Regulations of the National Health Act states that "all health establishments must establish systems to produce accurate and timely information to inform managerial and clinical decision-making" (National Department of Health, 2017). These legislations support the establishment of health information systems that are transparent, however, other legislative instruments come into play when

regulations are set to determine how information systems need to be managed to ensure the transparency.

The implementation of the National Health Insurance (NHI) policy aims to establish, amongst a variety of other objectives, an integrated repository and data system, in support of the following functions (Department of Health, 2017): monitoring health coverage; tracking the population's health status; financial management functions; decision-making around contracting, purchasing and communication; and quality assurance. These functions are in line with the data requirement from the VAN model. Even though the NHI policy includes detail on the change this policy will bring to the healthcare environment, the policy does not provide a sufficient level of detail to govern the information flow within the system.

Beyond legislation from the NDoH, legislation instrument on information systems exist within different departments of the government, e.g. the Protection of Personal Information Act (PPIA) and the Promotion of Access to Information Act (PAIA) fall under the Department of Justice. The PPIA ensures that patient data is protected, however, the Act allows for "special personal information" to be processed on subjects such as health, under the authorisation of an information regulator (Department of Justice, 2003). These Acts only provide a broad overview of the right to data protection and access to information, and does not provide the necessary detail to how the sharing of data amongst the different levels of the VAN should be enabled or not.

The pharmaceutical environment, especially in the public sector, is governed by legislation across multiple departments, which makes the regulatory framework intricate. While there are many regulations and legislations that refer to establishing or implementing an information system, none of these legislative instruments provide detailed guidance on the management of information systems, especially within a complex environment such as public healthcare. .

RECOMMENDATIONS

South Africa's current legislations are sophisticated and comparable to those in other countries, however, there is a lack of clear and comprehensive legislative instruments to provide a framework to govern the sharing of information across the entire public healthcare sector.

As previously mentioned, South Africa's public health information systems operate on different software at different levels of the organisation (Department of Health, 2010). These software silos across the country's healthcare system will make it difficult to consolidate the information and data that is currently captured due to a lack of data management standards. Therefore, it is recommended that VAN officials and government authorities should investigate the development of policies that can enable the end-to-end visibility that is crucial to the successful operation of the VAN.

In 2010, a full review that was done on the public healthcare delivery system concluded that there is a lack of central pharmaceutical data management standards, which restricts the implementation of a consolidated information system (Department of Health, 2010)—seven years since this finding was made public, there is still no significant improvement on data management standards. The following statement stands out in the report: "Ease of information sharing and exchange is one of the pre-requisites for transparent visibility across the supply chain. Improved integration of software will facilitate the ease of information sharing and exchange and the resultant improvement in managing

pharmaceutical availability" (Department of Health, 2010). Taking into account the data requirements determined in a previous section, it is recommended that the following elements should be incorporated into policies to enable and govern the information system:

i. There needs to be a governing authority in terms of section 47 of the National Health Act (National Department of Health, 2003).

ii. Each level of the health system, vertically (national, provincial, and district) and horizontally (demand, supply, and distribution planning) as illustrated in Figure 8, should be held responsible for the data that needs to be captured and generated within the section of the supply chain that falls under their. A sense of ownership can further be encouraged through incentive policies that give recognition to those generating high-quality data that is accurate.

iii. Achievement of the previous recommendation can be strengthened through quality assurance, as well as monitoring and evaluation policies. Quality assurance should touch on the following subjects: data integrity; accessibility of data; reliability; data security; timeliness of data collection and submission; and data analysis

iv. In order to determine national statistics for forecast functionality—for health research, where patient data is required—protocols should be in place to guard the records and ensure data confidentiality.

v. To enable high-quality data, policies should identify crucial data elements (as determined in Table 1) that need to be gathered via formalised platforms, rather than via free-form mechanisms, e.g. telephone calls or emails.

vi. Human resource development policies should ensure that there are competent staff and resources along the pharmaceutical supply chain that are able to use the system—this can be achieved through training. These policies should also take into consideration the new supply chain analysts being employed at provincial levels and how the employment of these analyst could affect the current functions at the provincial level.

In summary, it is recommended that government authorities and VAN officials should aim to implement a single national policy with structured guidelines that are aligned to the requirements for the integrated information system, specifically in the context of a public medicine delivery system.

CONCLUSION

In this article, background on the existing healthcare conditions in South Africa is provided, specifically referring to the essential medicine stock-outs at primary healthcare provision-level. The national strategy that aims to ensure medicine availability by means of an end-to-end visibility (information) system across the supply chain, based on the principle of informed push, the Visibility and Analytics Network (VAN), was subsequently introduced. From the four key elements of the VAN (people, process, technology, and policy), the technology element is the least-developed, but is nonetheless considered the most important element in order to achieve the required visibility. Due to the fact that the policy element governs all of the other elements of the VAN, it is important to understand the role of policies in enabling the required technology to achieve end-to-end visibility. This statement is substantiated by the pharmaceutical logistics framework, which indicates that

information systems are the driving force behind operational activities, and that the interaction amongst these two functions should be understood before the effect of policies on such a system can be analysed.

This article followed a systems engineering approach towards policy analysis concerned with information systems used in public healthcare supply chains, which is comprised of multiple stakeholder and government inputs. Even though there are existing systems such as SVS and RxSolution (although they are not integrated), this article does not assess the ability of existing technologies to provide end-to-end visibility, instead, the focus is on identifying what the necessary data requirements are for an information system to support the VAN strategy and subsequently investigates South Africa's current legislations against this set of requirements. This approach enables the formulation of a set of recommendations on the role of policy analysis to ensure that the appropriate governance legislation are in place to enable the implementation of an information system that is required by the VAN initiative.

However, there are a number of factors that limit the analysis of policy within the South African context. Whilst a number of sophisticated legislative- and regulatory instruments exist in the healthcare sector, these do not comprehensively address the needs for an integrated health information system. The data requirement used in this study are obtained and analysed from the South African VAN project, which has not been published yet, therefore there are no additional information available with regards to the VAN project.

In conclusion, this research has revealed specific aspects that should be incorporated into policies and detailed guidelines are recommended with a view to enabling the integrated information system that is required to effectively support a complex, interconnected model such as the VAN. The technology aspect of this study is but one of the four VAN elements. Further research will encompass policy analysis on all of the remaining three elements, taking into account the interconnectedness between the four mentioned elements. Subsequent to the analysis, the next step is to provide the NDoH, along with all the VAN stakeholders, with a typology that contains recommendations on how policies might enable or limit the VAN model—based on all levels of the health system—to guide the NDoH on effective policy development to support the VAN innitiative.

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