

UNIVERSITY OF THE WESTERN CAPE
Faculty of Community and Health Sciences
MINI-THESIS REPORT

Title: A Cost Analysis of Medicine Donation Programs to Tanzania's Neglected Tropical Diseases Control Program

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ABSTRACT

Background and Rationale

Overreliance on donor supported health programs has crippled many African countries and there is inadequate long-term planning on the future sustainability of health systems. In the age of uncertainty in global politics and global economy, the future of these donor funded programs is also uncertain. It is imperative for African nations to begin to take responsibility for their health programs.

In as much as the name “donation” suggests that something is given free of charge, in actual sense this may not be the case due to hidden costs attached. In medicine access, the hidden costs are the supply chain costs including cost for clearance, storage and distribution of such medicines which are charged as a percentage of claimed commodity costs on donors’ or suppliers’ invoices.

Since the medicines donated are in originators’ brands, the invoiced prices are high thus supply chain costs are high as well. In some cases, it is thought that the hidden costs are higher than the cost of medicines had they been sourced locally as generics.

The aim of this research was to assess and determine the hidden supply chain costs associated with the four medicine donation programs supporting the Tanzania Neglected Tropical Diseases Program and inform policy decision on optimal financing options for the program

Methodology

The cost analysis of the two options was undertaken from a payers’ perspective which in this case is the Government of Tanzania (Ministry of Health). Data was collected on both product and supply chain cost drivers incurred in the medicine donation programs from July 2014 to June 2017. Costs of the current mechanism were obtained from the program’s quantification reports and transaction data for the study period. Transactional data was obtained from shipment documents including sales invoices, packing list, proof of delivery and goods receiving notes were evaluated for actual quantities shipped, commodity prices and other supply chain cost. To verify the actual supply chain cost charged by the program, both the official bills from Medical Stores Department (MSD) to the program and the electronic bills available at MSD electronic database covering the study period were studied.

The cost of an alternative mechanism (use of generics funded by Government of Tanzania) considered the same cost drivers (quantities for commodity cost and related supply chain costs calculated as percentage of total commodity cost). To get data on prices of generic medicines in Tanzania, the pricing survey using the WHO/HAI tools was done involving 39 pharmacies both wholesale and retail outlets. To facilitate comparisons of the two mechanisms, the international prices taken from the 2015 Management Sciences for Health (MSH) International Drug Price Indicator Guide (IDPG) were used as benchmark. Where

the medicine was not found in the local market, the IDPG prices were used as the sole reference price for that item.

Results

The invoice value of donations was USD 111,633,983.33 for three years under study period; 67% of such cost was contributed by the cost of ivermectin. The invoiced price of ivermectin supplied under Mectizan Donation Program hiked 3000 times from USD 0.0005 to USD 1.5 per tablet given the same brand. The unusual price hike for ivermectin may have overstated the actual value of commodities; while the mean value of commodities per year was USD 37,211,327.94, the median value was only USD 11,705,446.75

The overall price of donated medicines as per supplier's invoices was 5 times higher than IDPG prices of generic equivalents. Out of five (5) medicines in active donation programs, four (4) were available in the local market (excluding ivermectin). The overall price of donated medicines was found to be twice the price of generic equivalents locally available. On comparing with IDPG prices, the generic equivalents found in the Tanzania market costs 27% higher than the equivalent IDPG prices; therefore, Tanzania is likely to pay 27% more on sourcing locally than importing generics equivalents.

Despite the product cost of \$ 111,633,983.33 in three years, the supply chain cost incurred by the government of Tanzania over the same period is USD 855,591.88 which is only 0.8% commodity value, way below the optimal service fee of 11.6% commodity value as set by MSD. Moreover, 98% of donations were exempted on, customs destination inspection fee (0.6% on invoice value), development levy (1.5% invoice value), VAT and import duty (exempted as per 2014 VAT act) and importation permit fee by TFDA (2% on invoice value). The exemptions are exclusively beneficial to the NTD program while they have health system wide implications thereby affecting financial viability of government agents to undertake their legal mandate.

The three years' supply chain cost for donation programs using MSD optimal service fee of 11.6% commodity value amounts to USD 12,949,542.12 which is equivalent to 50% of total cost (product plus supply chain cost) needed to source generic equivalents using government of Tanzania's own resources for the same period (USD 26,129,083.87).

Conclusion.

The optimal cost of handling medicine donation programs to NTD currently is half the cost of buying equivalent generics using Government of Tanzania own funds. The roadmap towards self-financing option that gives Tanzania greater autonomy in meeting her present and future needs is needed to sustain gains achieved in the NTD program. The Total Market Approach and integration of NTD medicines into MSD managed pooled procurement are seen as immediate actions. The two actions will ensure mobilization of financial resources, reduce procurement prices and operational costs of managing a separate vertical supply chain.

DECLARATION

I declare that *A Cost Analysis of Medicine Donation Programs to Tanzania's Neglected Tropical Diseases Control Program* is my own work that has not been submitted for any degree or examination at any other university, and that all sources I have used or quoted have been indicated and acknowledged by complete references.

Adam Omary Rassa

April 2019



Signed.



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Thanks be to God for his grace that helped me undertake this fulfilling work at the University of the Western Cape.

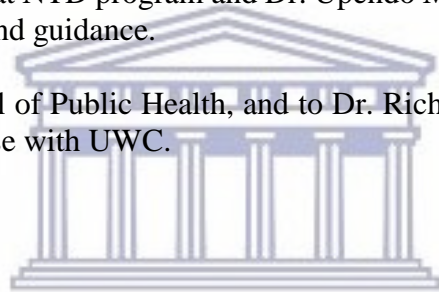
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To God be all the glory.



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ABBREVIATIONS

ERP	Enterprise Resource Planning
GoT	Government of Tanzania
HAI	Health Action International
IDPG	International Drug Prices Indicator Guide
IRP	International Reference Price
MSD	Medical Stores Department
MSH	Management Sciences for Health
MPR	Median Price Ratio
NPAP	National Pharmaceutical Action Plan
NTD	Neglected Tropical Diseases
PSM	Procurement and Supply Management
UHC	Universal Health Coverage
USAID	United States Agency for International Development
TFDA	Tanzania Food and Drugs Authority
TMA	Total Market Approach.
WHO	World Health Organization

Contents

ABSTRACT.....	2
Chapter 1: Introduction.....	8
Problem Statement.....	9
Purpose of the research.....	10
Chapter 2: Literature Review.....	11
Aim and Objectives.....	19
Chapter 3: Methodology.....	20
3.1 Study design.....	20
3.2 Ethics.....	21
3.3. Population and Sampling.....	21
3.4 Data collection.....	22
3.5 Validity and reliability.....	24
3.6 Data analysis.....	24
Chapter 4: Results.....	25
4.1 List of Donated Medicines to the Neglected Tropical Diseases Program.....	25
4.2 Quantity and value of medicines donated and received by NTD July 2014 to June 2017.....	26
4.3 Medicine price comparison – donations versus MSH IDPG Median prices.....	28
4.4 Cost incurred by the government of Tanzania for the handling of the donated medicines from July 2014 to June 2017.....	29
4.5 Comparing the actual cost charged by MSD and the ideal cost as per optimal service fee cost structure.....	31
4.6 Supply Chain Cost of NTD Consignments using the MSH IDPG prices.....	33
4.7 Medicine pricing survey – determining generic prices in Tanzania market.....	33
4.7.1 Supplier and Retail median prices of surveyed medicines.....	34
4.7.2 Price comparison between the generic medicine median prices and MSH IDPG median prices.....	34
4.8 Comparing costs of current donation programs and the use of generic medicines.....	35
Chapter 5: Discussion.....	37
Chapter 6: Conclusion.....	40
References.....	41
Appendices.....	48

Chapter 1: Introduction

Access to quality, safe, efficacious and cost-effective medicines is one of key building blocks of a well-functioning health system (WHO, 2007). Medicines along with other health commodities are central to a health program's performance and its outcomes (Perez-Casas et al., 2001). In resource limited settings, medicines donations form a major part of medicine supply for public access and use (Hanson et al., 2012). While good donations relieve countries to have savings in their development budgets enabling the resources to be used for other purposes; there are many cases of medicine donations that have caused problems instead of bringing relief as expected (WHO, 2011; Berckmans P. et al., 1997). The donations, though given "free of charge" to countries have significant hidden supply chain costs attached to them which range from 10% to 50% in value of commodities donated. Value is determined from the invoiced cost of medicines in shipping documents (Sanderson, 2014). Since donations for Neglected Diseases Programs come from the Big Pharma, Pfizer, GlaxoSmithKline and Merck; they are given in originators' brands whose price can go as far as 300% higher than the generic equivalents in low- and middle- income countries (Cameron et al, 2009). The resulting supply chain cost which is calculated as a percentage of commodity prices is high as a result.

In Tanzania, the pharmaceutical companies, through WHO office Tanzania provide medicines donations to Neglected Tropical Diseases Program for mass chemotherapy to prevent transmission (Mwakisu et al., 2011). The central medical store namely Medical Stores Department (MSD) is responsible for clearing, storage and distribution of donated medicines and in turn charges the service fees to cover supply chain costs incurred which stands at 11.6% to 20.4% of product prices (Printz N. et al., 2013; Rosen J. et al., 2015; Deloitte, 2015). Ultimately, the government of Tanzania is responsible for such costs which are very high for two reasons; firstly, the price is quoted in the originators' brand prices and secondly, the price is in a foreign currency, US dollar (USD) and hence on a weaker shilling, the charge becomes unbearable. This has contributed to MSD's capital erosion since it had to use its capital to pay for service fees as government was not able to reimburse the same to MSD on time (Deloitte, 2015). The Tanzania NTD medicines' donation programs process flow is summarized in figure 1.

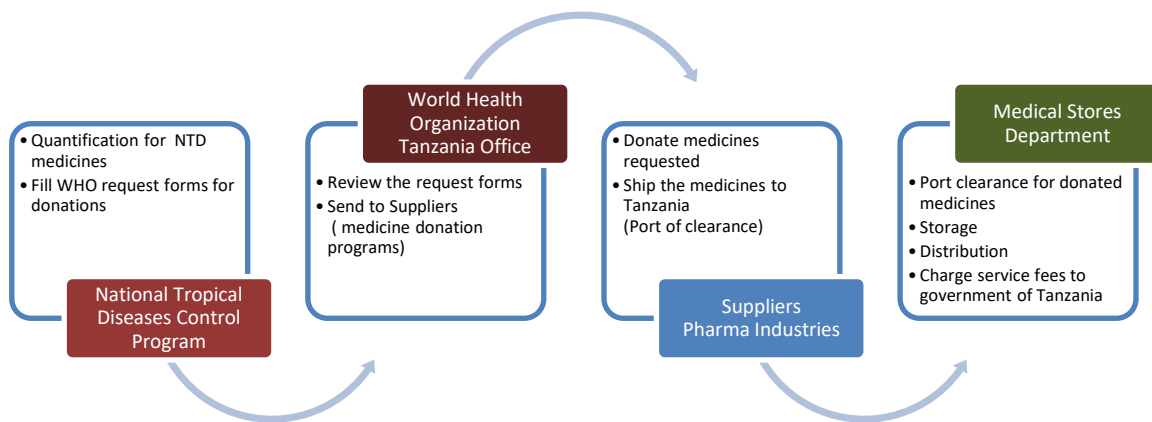


Figure 1: Tanzania NTD medicines' donation programs process flow

The MSD is also a clearing agent for such donations; it is estimated that MSD incurs demurrage fees of approximately 3 billion Tanzanian Shillings annually due to inefficiencies in clearance of commodities from the points of entry (Deloitte, 2015). All this is eventually funded by Tanzania taxpayers' money. Also, donations which are unplanned were blamed for increasing expiry of commodities at the MSD Warehouses (The Global Fund, 2016). Meanwhile, most of donated medicines are also produced by local pharmaceutical industries in Tanzania and are also available in local markets as generics from India, Cyprus and Egypt to mention a few (Israel C. et al., 2014). It is perceived that the cost incurred to pay the service fees due to originators' brand prices are higher than the cost of buying actual medicines in generic form (including any associated costs). However, there is not enough evidence to what extent the differences in costs are; thus, the aim of this study is thus to assess and determine the hidden supply chain costs associated with the four medicine donation programs supporting the Tanzania Neglected Tropical Diseases Program and inform policy decision on optimal financing options for the program.

Problem Statement

African nations including Tanzania celebrate donations from multilateral donor agencies such as USAID, Global Fund to fight Aids, Tuberculosis and Malaria (GFTAM), Bill & Melinda Gates Foundation, GAVI alliance and pharmaceutical companies. Most of the donations from USAID, GFTAM, GAVI and Gates Foundation are highly monitored by

civil societies, pressure groups, academics and have their performance results openly published and accessed.

However, for Neglected Tropical Diseases medicine donations involving pharmaceutical industries; less than 30% of the programs were evaluated on their impact on health and there was no standard and consistent metrics used to evaluate such (Jenny et al., 2016). While those evaluations were carried by donor companies, little is known about recipient country's own evaluation of such programs. This denies recipient countries the opportunity to determine if they engage in rational donation programs or not.

In Tanzania, the actual cost incurred by the government due to medicine donations is not well documented; as a result, there is no evidence that the cost of generic equivalents if bought in Tanzania using local funding would be necessarily cheaper or more expensive compared to current costs due to handling of donations in originators' branded medicines. The following questions remain unanswered to date; what is the actual cost of handling donations is incurred by the government? What if the government uses its own sources to fund medicines, would such an approach decrease the cost? What are the lessons learnt in the processes of donation programs? What are the bottlenecks and successes that could inform any sustainability of medicine procurement and access?

Purpose of the research



This study examined the four donation programs supporting the National Program for Neglected Diseases Control in Tanzania mainland. The donation programs are:

- i. Mectizan Donation Program (MDP): involves donation Mectizan (ivermectin 3mg, tab) by Merck to tackle onchocerciasis (river blindness) and lymphatic filariasis
- ii. Albendazole Donation Program: involves donation of albendazole by GlaxoSmithKline (GSK) to tackle lymphatic filariasis and soil-transmitted helminthiases.
- iii. International Trachoma Initiative Donation Program: Pfizer donates Azithromycin to control and eliminate blinding trachoma.
- iv. Merck Praziquantel Donation Program (MPDP): Merck donates Praziquantel to fight schistosomiasis.

The study has therefore determined the actual cost incurred by the government of Tanzania due to donation programs and compared the costs with local generic purchase prices to provide evidence for decision making. The findings of this study inform the financing framework for neglected tropical disease medicines, form a baseline for health financing sustainability planning, guide efficient resource allocation and provide insights to the government of Tanzania on similar donation programs.

The study findings provide lessons to the WHO, Global health donors and other African countries through Tanzania's experience and assist in negotiations of better terms that are more beneficial to countries in need. This study thus sets ground for analyzing policy options such as promoting generic medicines and alternative financing mechanisms to sustain coverage, accessibility and reduce overall cost to health programs (Cameron et al.,2009).

Chapter 2: Literature Review

Neglected tropical diseases (NTDs) are a diverse group of 17 infectious diseases prevailing in tropical and subtropical regions. Out of these, seven diseases comprise the bulk of the NTD burden i.e. lymphatic filariasis, onchocerciasis, schistosomiasis, three soil transmitted helminthiasis infections (hookworm, ascariasis and trichuriasis) and trachoma affecting 1.4 billion people worldwide (Hotez et al.,2009). The groups affected are the vulnerable, disadvantaged people living in poverty. On average one person in seven suffers from one or more NTDs (IFPMA, 2017).

NTDs not only cause blindness (Frick KD, et al., 2001), disfiguring due to lymphatic obstruction, pains, disability and death but also have economic and social impacts. For example, in India an average of USD 1 billion was lost to lymphatic filariasis annually due to healthcare costs and loss of productivity (Chu BK.et al., 2010). In addition, there is evidence that worm infestations in children reduce the probability of school enrolment by 20% and a subsequent 40% reduction in income as adults (Hoyt Bleakley, 2007).

Neglected tropical diseases and United Nations' Sustainable Development Goals.

Neglected tropical diseases are formally recognized in the Sustainable Development Goals through the goal number 3 - good health and wellbeing (UN, 2015). The target number 3.3 as set by inter-agency and expert group on sustainable development goals (IAEG-SDGs) is to end the epidemics of HIV, tuberculosis, malaria and neglected tropical diseases by 2030 (UN,2017).

The success of target 3.3 on NTDs also contributes to success of other SDG such as SDG 1 which targets the ending of poverty in all its forms and SDG 2 (zero hunger). While

health care costs and loss of productivity are one of key effects of NTDs (Chu BK.et al., 2010); their control play important role in reducing financial burden of healthcare and increase productivity. Also, NTDs have been known to reduce school attendance (Hoyt Bleakley, 2007)., therefore SDG 4 (quality education) can be effectively met when target 3.3 on NTDs is achieved. Other SDGs are aligned to control and elimination of NTDs as they have direct positive impact on NTD programs. Such goals are SDG 6 (clean water and sanitation), SDG 11 (sustainable cities and communities) and SDG 17 (partnerships for the goals).

Tanzania profile of Neglected Diseases

The United Republic of Tanzania has the second highest prevalence of schistosomiasis (19 million cases) and third highest prevalence of two NTDs namely lymphatic filariasis (31 Million at Risk) and trachoma (2.1 million cases) in sub-Saharan Africa (Hotez PJ, Kamath A., 2009; Steinmann P, et al., 2006). The active trachoma (TF) had a prevalence of 10% and above in 43 districts while the overall prevalence in 2006 was 25.4 % (95% CI 24.6 – 26.3) in Tanzania mainland (Masesa, et al., 2007).

NTDs published data in Tanzania mainland suggest that all regions have schistosomiasis infection with a prevalence ranging from 13% to 88% around Lake Victoria (Malenganisho et al., 2008). There is high prevalence of soil-transmitted helminthiasis (STH), with prevalence rates up to 100% in certain ecological settings such as Kagera, Mwanza, and Tabora (MoHSW, 2009). The 2004 results indicated that Lymphatic Filariasis (LF) is endemic in all districts of the country. Rapid Epidemiological Mapping of Onchocerciasis (REMO), conducted in (1999) and refined in 2004, indicated that approximately 4 million people in Tanzania mainland are at risk. The prevalence of onchocerciasis was as high as 63.6% in certain focal endemic areas, including Mbeya, Iringa, and Morogoro (Mwakisu, et al., 2011).

Control of NTDs using Mass Chemotherapy

The NTD control and elimination is feasible through mass drug administration coupled with addressing the environmental conditions that are responsible for their spread, such as clean water, improved sanitation initiatives and vector control. A total of 28 countries were found to have eliminated one or more NTDs according to Hudson Institute review (Norris, J. et al., 2012). In Tanzania, mass distribution of ivermectin is done in communities with a prevalence of 20% and above for onchocerciasis control, while for lymphatic filariasis a combination of ivermectin and albendazole is administered to all populations at risk where prevalence is 1% and above. Meanwhile, azithromycin is distributed for trachoma prevention in districts with prevalence of 10% and above; whereas for schistosomiasis and soil-transmitted helminthiasis, a combination of albendazole and praziquantel is administered in areas with prevalence of 30% and above (Mwakisu et al., 2011). All

medicines used in mass chemotherapy are supplied through medicine donations programs to Tanzania NTD control program via WHO coordination.

Medicine donation programs for neglected tropical diseases

Medicine donations have been the pillar to success of preventing and treating the neglected tropical diseases. Mass drug administration (MDA) to populations at risk reduce the pool of human infection and levels of transmission; MDA is made possible by drugs supported by pharmaceutical industry donations (WHO, 2007). Each of those donation programs have independent application process; hence coordination and streamlining of donation applications is done by WHO through her department of neglected tropical diseases control. The WHO country offices manage the donation applications by country specific Neglected Tropical Disease programs (Mwakisu et al., 2011). The following medicine donation programs are currently supporting the Tanzania Neglected Tropical Diseases Control program (NTDC);

Mectizan Donation Program (MDP): It was established in 1987 to oversee Merck's donation of Mectizan (ivermectin 3mg, tab) for control of onchocerciasis (river blindness) worldwide (Merck &Co. Inc, 1987; Colatrella B, 2003). In 1998 the MDP joined the Global Alliance to Eliminate Lymphatic Filariasis (GAELF) and its scope was widened to include donation of ivermectin to 28 African Countries and Yemen where onchocerciasis and lymphatic filariasis co-exist (Colatrella B, 2008). Ivermectin is co-administered with albendazole once a year for at least 5 years to break transmission cycle of lymphatic filariasis (WHO, 2000; Ottesen et al., 1997).

Albendazole Donation Program: GlaxoSmithKline (GSK) donates albendazole 400mg, tab since 1997 for elimination of lymphatic filariasis and control of soil-transmitted helminthiasis. Up to 600 million tablets are donated annually for preventive chemotherapy of lymphatic filariasis and 400 million tablets are donated annually for preventive chemotherapy of soil-transmitted helminthiasis in school-age children (WHO, 2016). GSK's albendazole donation program was the pioneer in forming the global alliance to eliminate lymphatic filariasis (GAELF) together with Merck and donations are available until global elimination for lymphatic filariasis is achieved (Colatrella B, 2008).

International Trachoma Initiative (ITI) Donation Program: Founded in 1998 by Edna McConnell Clark Foundation and Pfizer Inc, it is an international agency solely dedicated to elimination of blinding trachoma (Dawson C, Schachter J, 1999). ITI manages the donation of Zithromax (azithromycin) by Pfizer, Inc. an antibiotic used for trachoma control. Azithromycin is administered in mass chemotherapy for elimination of trachoma in in WHO priority countries including Tanzania (Sharp D, 1998).

Merck Praziquantel Donation Program (MPDP): Started in 2007, MPDP is a partnership of WHO and Merck in the fight against schistosomiasis in Africa. Merck donates praziquantel 600mg tablets to 35 African countries to date through MPDP for use in mass chemotherapy for school-age children against schistosomiasis (WHO, 2016). WHO coordinates the donations of over 200 million tablets annually to country programs.

Cost of Treating NTDs

Various studies have been done on cost of treating neglected tropical diseases. One year of treating the seven NTDs (lymphatic filariasis, onchocerciasis, schistosomiasis, three soil transmitted helminthiasis infections (hookworm, ascariasis and trichuriasis) and trachoma would cost \$200 million (Vogel G, 2006). This means that, seven of the most common NTDs can be treated for as low as \$0.50 per person per year compared to an estimated \$6.64 to treat one case of malaria and \$700 to treat one case of HIV per year (Norris J. et al., 2012). However, the cost per treatment in mass drug administration for lymphatic filariasis elimination, has ranged between \$0.06 to \$2.23 varying across countries (Goldman et al., 2007). For onchocerciasis, the annual cost per person was found to be \$0.78 in Uganda under the APOC (African Programme for Onchocerciasis Control) program (Haddad D, et al., 2008). In Burkina Faso the MDA of Albendazole and Praziquantel to children through schools and communities had a cost of \$0.32 per child (Gabrielli AF. et al., 2006). To control STH in Vietnam, a wide scale de-worming program for 2.7 million children had a cost of \$0.03 per child (Montresor A. et al., 2007); while in Tanzania a school based program had a cost of \$1 per child (Guyatt HL. et al., 2001).

In all studies discussed here, since medicines used were donated by global pharmaceutical companies the cost of such donations were not included. Also, the associated supply chain costs of such medicine donations were not documented. Ensuring that adequate resources are available to fund the health commodity needs is becoming a challenge to many developing countries with limited financial resources (Yadav, 2015). Meanwhile it has been noted for the world's poorest nations, even free medications may be unaffordable due to delivery costs (Guyatt H, 2003). It is therefore pertinent that we quantify such hidden costs related to medicines donation.

In Ghana, the supply chain costing study in public health sector involved logistic systems for essential drugs, non-drug commodities and contraceptives supplies throughout the public sector. Storage was the largest cost driver contributing to 71% of total supply chain cost (Huff-Rousselle et al., 2002). In Zambia, the costing study involving the antiretroviral (ARV) supply chain was conducted using the Supply Chain Costing Tool developed by USAID|DELIVER Project. The primary finding was that the cost of delivering ARVs to the last mile ranged between 7.6% to 16.1% of the value of the commodities (Baruwa et

al., 2010). Similar studies were conducted in Mozambique and Nigeria where the focus was on vaccine supply chains and contraceptives supply chains respectively. In both countries, costing was critical input for supply chain system designs, promoted adequate funding and led to more rational use of resources (Hasselback et al., 2012).

The USAID|DELIVER project’s recommended supply chain costing methodology estimates the cost of performing each supply chain function at each level (tier) of the supply chain. The cost is then aggregated to determine the total cost of the supply chain (McCord et al., 2013). Figure 2 summarizes the framework.

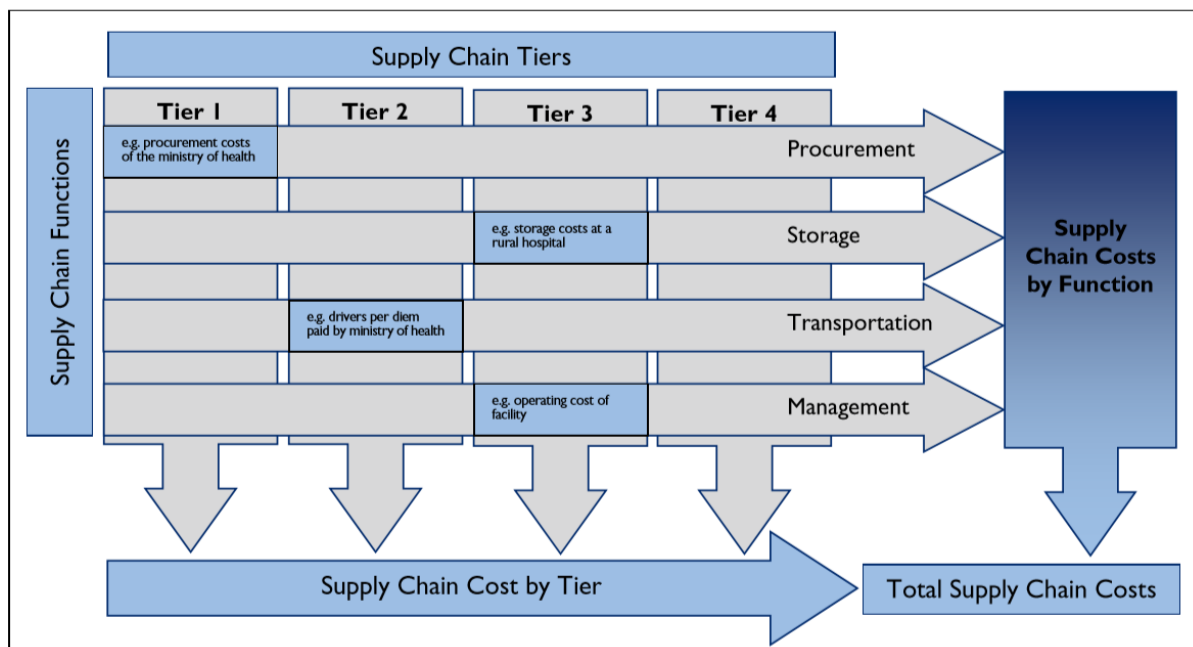


Figure 2: *Supply Chain Costing Framework*

Source: McCord, Joseph, Marie Tien, and David Sarley. 2013. *Guide to Public Health Supply Chain Costing: A Basic Methodology*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4.

In the Tanzania’s NTD program, it is worth noting that the tier 1 cost which is a procurement cost is handled by global pharmaceutical companies as donation programs, while tier 2 activities which include cost of clearing, forwarding, pharmaceutical quality control, warehousing (storage) and distribution to targeted sites for mass chemotherapy are handled by MSD. The government of Tanzania pays a service fee of 11.6% of value of commodities to MSD to cover for costs incurred for Tier 2 activities (Printz N. et al., 2013; Rosen J. et al., 2015; Deloitte, 2015).

Figure 3 details tier 2 activities undertaken by MSD in handling the donated medicines.

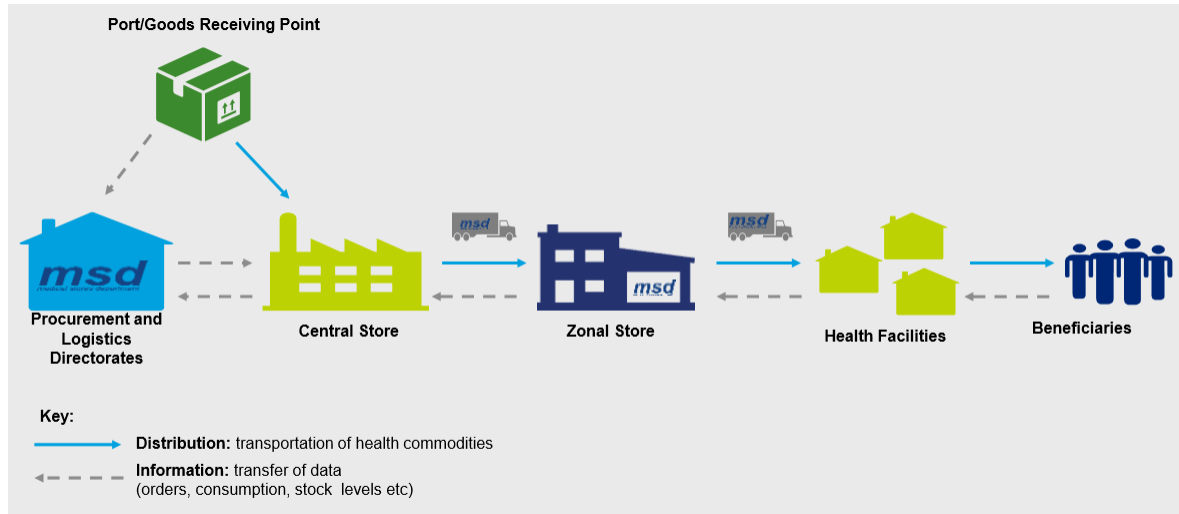


Figure 3: *MSD commodity and information flow for donated medicines.*

Adapted from: Deloitte (2015). *The Strategic Review of Medical Stores Department of Tanzania: The Journey to Efficiency*. Dar es Salaam, Tanzania. Deloitte.

Financing the public health commodities supply chain costs.

Globally, health commodities are the health system's second largest health expenditure item after personnel costs (Lu et al., 2011; MSH, 2012). The expenditure on supply chain has been estimated to consume above a quarter of the health system expenditures (Lu et al., 2011; Wirtz et al., 2017). Even though financing for operational costs of the supply chain is a distinct aspect of financing, too often it is a neglected aspect. Programs, donors and MOH leaders prioritize purchase of medicines and medical supplies (Sanderson et al., 2014). Figure 4 below details typical health commodities supply chain costs.

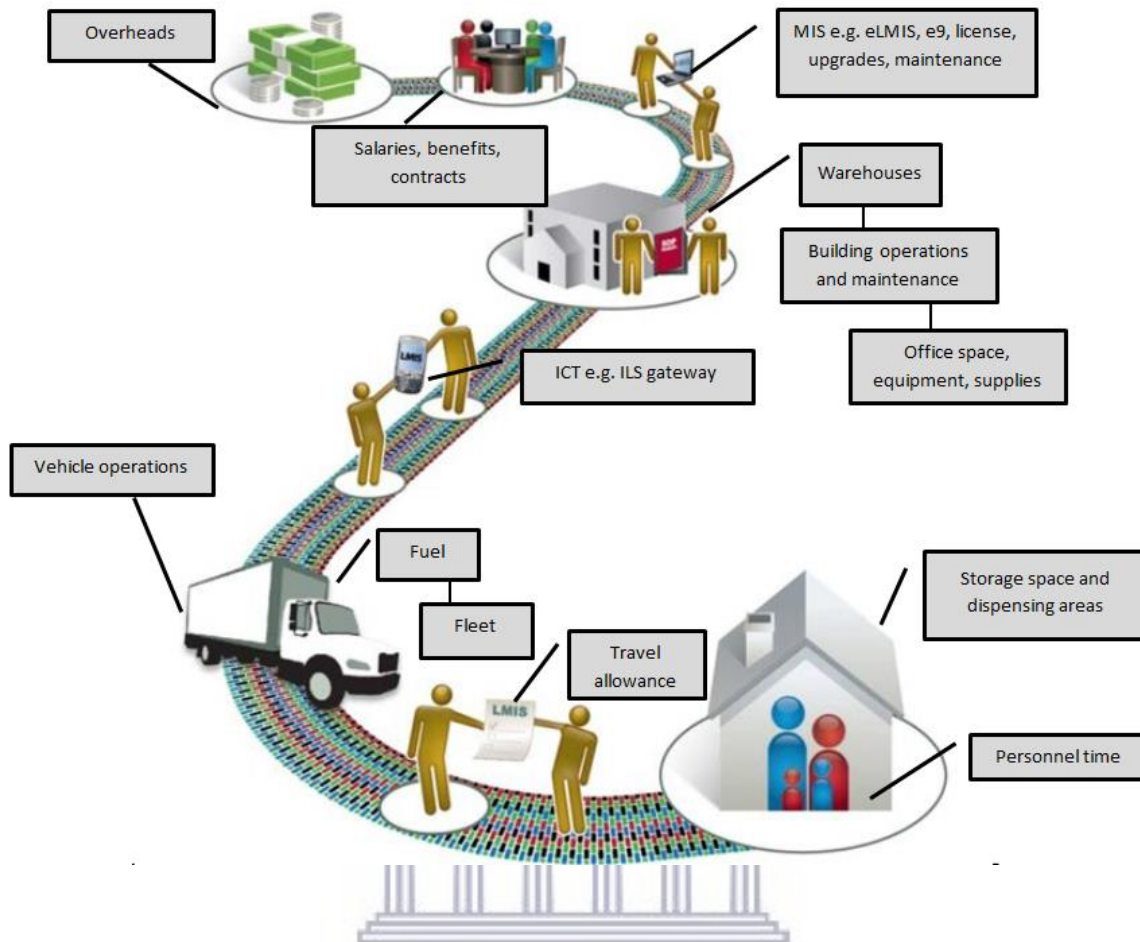


Figure 4: Supply Chain Costs

Source: Sanderson, Jeffrey, Chris Wright, and James Rosen. 2014. *Financing the Health Commodity Supply Chain: The Role of Service Fees*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4.

According to Sanderson et al., 2014, the commonly used financing options for public health commodity supply chains include:

Government revenues from the national budget, government allocated assets such as buildings, donor in-kind assets and mark up on sales where by the purchase price of commodity include all or some supply chain costs. The other financing option is service fees charged for specific supply chain services e.g., storage and distribution which is paid either by the user of such services or an agent on behalf of the user.

In Tanzania, the medical stores department (MSD) charges service fees to the programs for supply chain services offered. Figure 5 summarizes the MSD service fees structure.

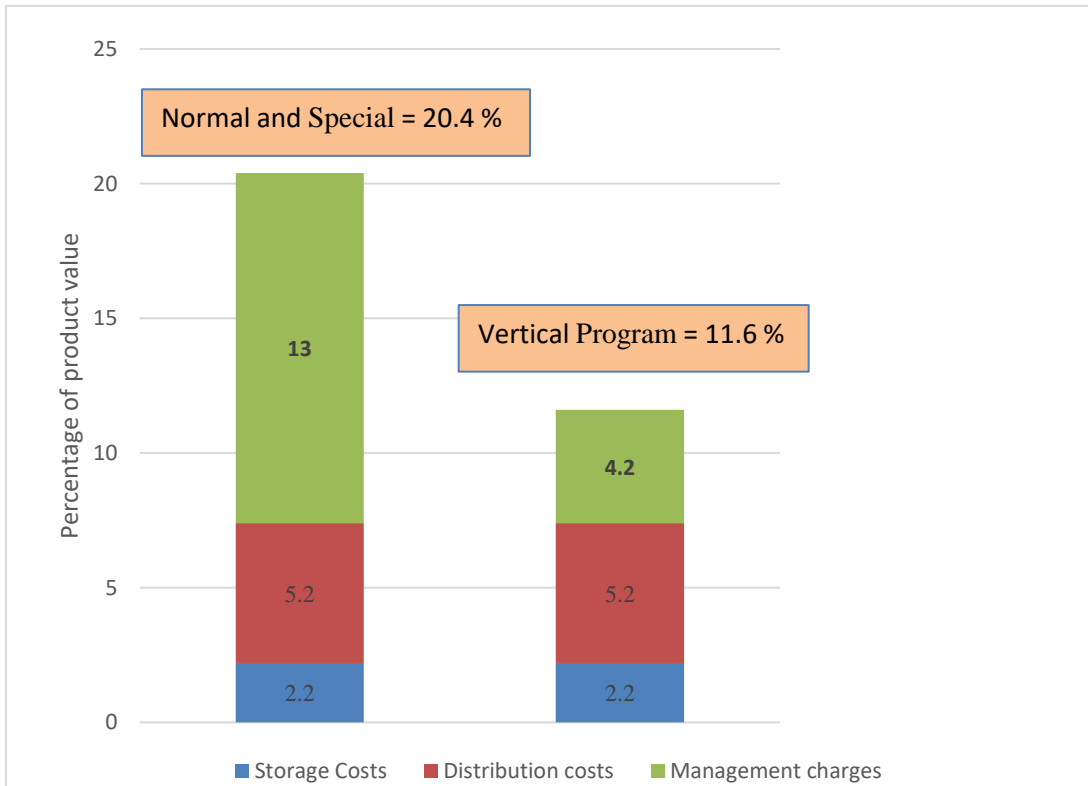


Figure 5: *MSD service fees structure*

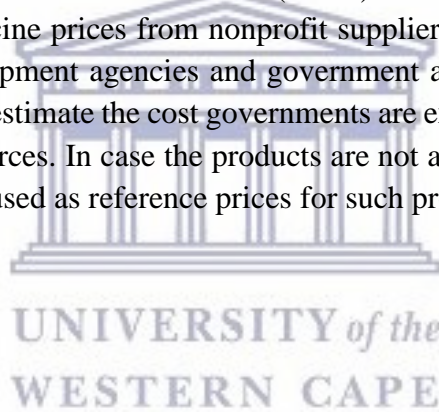
Financing of health commodity supply chain in Tanzania is mainly through general budget support from central government and development partners (MOHSW, 2012). The medical stores department charges service fees for providing supply chain services to ministry of health programs including the NTD program. The service fees set by MSD depends are based on value of commodities and they range from 11.6% to 20.4% of commodity value (Printz N. et al., 2013; Rosen J. et al., 2015; Deloitte, 2015).

Since the donated medicines for NTD program are given in originators' brands whose price can go as far as 300% higher than generic equivalents (Cameron et al., 2009); the resulting supply chain costs are high as well. In Tanzania, government was not able to pay for service fees to MSD for services rendered to vertical programs which resulted in erosion of MSD working capital and failure to meet its operational obligations (Deloitte., 2015). Moreover, the pharmaceutical companies enjoy some incentives which translates to after-gains to a donor company (Guenther G, 1999; USG, 1986; Cristina P, 2008; Berckmans P. et al, 1997; Guillox & Moon, 2001), this may lead to overstating invoice value of donated medicines hence further increasing the financial burden to recipient country. This forms the basis for investigating the actual supply chain cost for NTD donation programs and compare such

with the cost for alternative mechanism of using locally sourced generic medicines for NTD program.

Alternative cost of using generic medicines

Analyzing policy options such as promoting generic medicines and alternative financing medicines can potentially sustain coverage, accessibility and reduce overall cost to health programs (Cameron et al., 2009). The medicine pricing methodology and tool developed by WHO and Health Action International (HAI) is useful to study generic medicine prices and availability in a given market (WHO/HAI., 2008). The methodology and tools can be adapted to suit the context to answer the study question (Ewen M. et al., 2017). The prices are expressed as median price ratios (MPR) which is the ratio of the price in local currency divided by an international reference price (IRP) converted to local currency using the exchange rate on the first day of data collection (WHO/HAI., 2008). The standard international price reference guide commonly used is Management Sciences for Health (MSH) International Drug Prices Indicator Guide (IDPG). Published since 1986, the IDPG provides spectrum of medicine prices from nonprofit suppliers, commercial procurement agents, international development agencies and government agencies (MSH, 2015). The MSH IDPG prices helps to estimate the cost governments are expected to pay on procuring medicines from various sources. In case the products are not available in the local market ,the MSH IDPG prices are used as reference prices for such products.



Aim and Objectives

The aim of this study was to assess and determine the hidden supply chain costs associated with the four medicine donation programs supporting the Tanzania Neglected Tropical Diseases Program and inform policy decision on optimal financing options for the program. Specifically, the objectives are:

1. To measure the actual supply chain costs incurred by government of Tanzania in the four donation programs for the financial years 2014/15 to 2016/17
2. To determine prices of the equivalent locally available generic medicines used by the Program
3. To determine the projected cost of medicines and related supply chain cost based on prices of locally available generics

Chapter 3: Methodology

3.1 Study design

To conduct a cost analysis, a retrospective cross-sectional study using a structured quantitative survey was conducted. A cross sectional study design provides information for a specified period of time and can describe time trends hence useful for planning and allocation of health care resources (Hennekens C.H & Buring J. E., 1987). The retrospective study covered a time period from July 2014 to June 2017. The study focused on analyzing costs of two financing options for Neglected Tropical Diseases Program medicines used in mass chemotherapy. The first option is the current mechanism whereby the program uses donated medicines and government incurs supply chain costs; and the second option (alternative mechanism) is the use of generic equivalents where both product cost and supply chain costs are fully funded by the government of Tanzania. The cost analysis of the two options was undertaken from a payers' perspective which in this case is the government of Tanzania (Ministry of Health). Data was collected on both product and supply chain costs incurred in the medicine donation programs from July 2014 to June 2017.

The cost of the current mechanism was obtained from the program's quantification reports and transaction data entailing both product and supply chain costs incurred under the study period. Transaction data provided details on actual quantities shipped, commodity prices and related supply chain costs. The documents used included shipments' sales invoices, packing lists, proof of delivery and goods receiving notes. In addition, to verify the actual supply chain cost charged by the program, the official bills from MSD (service fees) regarding the program commodities were studied.

The cost of an alternative mechanism (use of generics funded by government of Tanzania) considered the same cost items as the first option (quantities for commodity cost and related supply chain cost calculated as percentage of total commodity cost) to allow for comparisons. To get data on prices of generic medicines in Tanzania, a pricing survey involving a minimum of 34 facilities as per WHO/HAI protocol (WHO/HAI, 2008) was done. For commodities currently not available locally in the market, the International Drug Price Indicator Guide (IDPG) was used as reference for median prices (MSH, 2015).

The output measure in both options was the total cost of medicines per year (product cost + supply chain cost). A limitation is that, the past reality might be quite different from the present. Therefore, findings of this cost analysis cover the most recent implementation period (3 years from July 2014 to June 2017) to catch up with the most recent reality and thus provide "real time" evidence.

3.2 Ethics

The study got the ethical clearance from the University of the Western Cape Biomedical Research Ethics Committee. Also, permission letter from the Government Chief Pharmacist was obtained and was later used to get permissions from heads of Institutions namely Medical Stores Department and Neglected Diseases Control Program to access needed documents for the study. Since the study was purely a retrospective analysis of NTD program transactional data, no potential risk was posed to study participants

3.3. Population and Sampling

The study involved all key documents guiding the four donation programs to Tanzania, transaction data sources such as commercial invoice, delivery notes and MSD bills (Invoices) to National Tropical Diseases Control Program from July 2014 to June 2017.

Inclusion criteria:

1. For review documents: Papers and policies within the sub- Saharan Africa setting
2. Donation programs related to medicines only
3. Donation Programs functional in 2014 to 2017 only
4. Supply chain assessment documents done in Tanzania

Exclusion criteria

1. Donation programs of other commodities than medicines

Sample and Sampling

Sample Size: To study the current mechanism, all transactions related to NTD medicines in Tanzania from June 2014 to July 2017 were studied. Since the program receives at least 5 types of medicines a year, thus over three years at least 15 consignments were included in the sample.

3.4 Data collection

Data on the current mechanism was obtained from the medical stores department and Neglected Tropical diseases Program. The following documents were shared by MSD
The following documents were shared by MSD.

A total of 55 Commercial Invoices and Goods Receiving Notes for NTD medicines, 53 of which represented a period from July 2014 to June 2017. Commercial invoices are shipping documents from the manufacturer or supplier of medicines to the intended client, which is MSD and NTD program in our case. Commercial invoices contain information on product descriptions such as name of commodity, strength and dosage form. Moreover, they have information on batch numbers, date of manufacturing, expiry date, quantity and cost of the medicines. This was the primary source of studying quantities donated and their financial value. Goods receiving notes (GRN) is the document which validates the quantities shipped by the supplier have been received and it is generated by the recipient. MSD GRNs' have details on product name, batch number, expiry date, shelf life on arrival and quantities. Hence GRN were used to match and validate with quantities on donations' commercial invoices from suppliers.

The MSD Statement of Account for NTD detailing service fees charged to the program for storage and distribution of program commodities from July 2014 to June 2017. MSD statement of account is a system generated report (by the MSD ERP) which has details for all program-based stock movements and related cost. It is the primary document which generates the service fees to be paid by the program for storage and distribution of program commodities by MSD.

MSD port clearance bills to the Ministry of Health detailing the actual clearing cost incurred by MSD for each NTD medicine consignment received and cleared by MSD from July 2014 to June 2017. These are paper based bills which are generated by MSD clearing department and are used to request reimbursement from the program / Ministry of Health for clearing costs incurred on program commodities.

MSD Price Catalogue for financial year 2017/18. The price catalogue contains information of health products available for MSD customers, pack sizes and unit prices. Catalogue is updated yearly and is shared both in hard and soft copies to public health facilities and other stakeholders to communicate available stock and prices for each.

The NTD program shared the following documents

Tanzania WHO Joint Request for Selected Preventive Chemotherapy Medicines and Joint Reporting Forms for 2014 to 2017. These are MS excel files which are used by the program to quantify and request donations via WHO Tanzania office. Instead of filling different forms for each donation request, these forms have integrated all medicine donations requests and they are filled every year prior to receiving the donations.

List of items (laboratory and medicines) received by NTD program from July 2014 to June 2017. This is program-based database of all commodities received by the program from various sources, the product name and financial value was documented in this database. The format of the database was in MS excel sheet and is managed/updated by the program pharmacist. It was used to match and validate with information shared by MSD.

MSD port clearance bills to the Ministry of Health for all items received from July 2014 to June 2017. This was a replica of the data shared by MSD as the copies are also sent to the program for reimbursement of clearing charges incurred by MSD for program commodities.

To get data on prices of generic medicines in Tanzania, a pricing survey using a Medicine Price Data Collection form (Appendix A) in 39 facilities as per WHO/HAI protocol was done. Prior to the survey, the Tanzania Foods and Drugs Authority (TFDA) registry was used to determine the registered medicines in Tanzania Market. A probability sampling (cluster sampling) method was used to randomly select the facilities for data collection; one cluster involved facilities which serve the end users (retail outlets) and another cluster involved facilities which supply to retail outlets (wholesalers). The pricing survey involved pharmaceutical outlets located in Dar es Salaam, the main business capital of Tanzania and the headquarters of the Medical Stores Department. The type of premises studied were 22 Wholesale pharmacies and 17 retail pharmacies. Prices were collected in Tanzania Shillings which were later converted to US Dollars at exchange rate of 1USD = 2282

The MSH International Drug Price Indicator Guide (MSH, 2015) was used as a benchmark to determine median prices of generic medicines supplied to MSD by the donation programs. Such prices were used to compare with prices obtained from the pricing survey and those obtained from commercial invoices of donated medicines. To analyze the prices above, the prices were expressed as median price ratios (MPR). MPR is an expression of how much greater or less the price in the country is than the international reference price (IRP), which is our case is IDPG. MPR of 1 means the country price was equivalent to the IRP, whereas an MPR of 2 means the country price was twice that of the IRP. The MPR of less than 1 means the price was cheaper than that of IRP.

The key measures:

1. Quantities of donated medicines received from July 2014 to July 2017
2. The invoice value of donated medicines in USD

3. Related supply chain cost for all donated medicines in USD
4. Median prices of generic medicines in Tanzania market in USD
5. Median prices as per International Drug Price Indicator Guide in USD

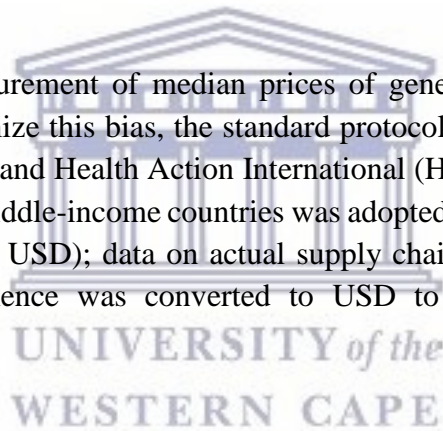
3.5 Validity and reliability

Dealing with selection bias:

The sampling to assess the current mechanism, the quantitative data on medicine donations was not be sampled; instead all data covering the study period was used to generate results for three years. For pricing survey to determine cost of generic equivalents, the stratified random sampling for pharmaceutical importers, pharmaceutical wholesalers and retail pharmacies in the main business capital Dar es Salaam was used to select sample.

Measurement bias:

The major bias is in measurement of median prices of generic medicines available in Tanzania market. To minimize this bias, the standard protocol and tool developed by the World Health Organization and Health Action International (HAI) on surveying medicine prices in low-income and middle-income countries was adopted. The second bias is foreign exchange rate bias (TZS to USD); data on actual supply chain cost and data on generic prices was in TZS and hence was converted to USD to enable measurement and comparison.



3.6 Data analysis

The medicine unit prices collected from the facility (pharmacies) survey and those from donations suppliers' invoices were entered into the computerized MS Excel-based WHO/HAI Medicine Prices Workbook, leveraging on the built-in automated analysis feature of the workbook, the workbook is found at

<http://www.haiweb.org/medicineprices/manual/documents.html>

The international reference prices used in this survey were taken from the 2015 Management Sciences for Health (MSH) International Drug Price Indicator Guide. For each medicine, the Price ratio was calculated as:

$$\text{Price ratio} = \frac{\text{Median unit price in USD as per supplier invoice (donation) OR survey}}{\text{MSH median unit international reference price in USD}}$$

Data collected from MSD and NTD program on supply chain costs (clearance, storage and distribution) were entered and analyzed using MS Excel.

Chapter 4: Results

Product cost is the major driver for supply chain cost charged by MSD as service fees to vertical programs. The study was systematically able to determine the actual product cost of all consignment to NTD and actual service fees that the NTD program was charged by MSD.

4.1 List of Donated Medicines to the Neglected Tropical Diseases Program.

The shipping documents obtained from the NTD program and MSD indicated the active donation programs which donated the following medicines to the NTD from July 2014-June 2017.

Table 1: Medicine donation programs active between July 2014 and June 2017

Product Description	Brand Name	Supplier
Albendazole 400MG	Albendazole 400(Zentel)	GlaxoSmithKline
Praziquantel 600MG TABS	Praziquantel	Microlabs, Medochem, Mission Pharma*
Azithromycin coated 250mg Tabs	Zithromax	Pfizer
Azithromycin OS 1200MG 200mg/5ml	Zithromax	Pfizer
Ivermectin 3MG TAB	MECTIZAN	Merck Sharp & Dohme Corp

*Supplied under Merck Praziquantel Donation Program (MPDP)

The study found all four donation programs were active during the study period.

- i. Mectizan Donation Program (MDP): donated ivermectin to tackle onchocerciasis (river blindness) and filariasis.
- ii. Albendazole Donation Program: donated albendazole tabs to tackle lymphatic filariasis and soil-transmitted helminthiasis.
- iii. International Trachoma Initiative Donation Program: donated Azithromycin tabs and azithromycin oral suspension to control and eliminate trachoma
- iv. Merck Praziquantel Donation Program (MPDP): donated Praziquantel to fight schistosomiasis.

4.2 Quantity and value of medicines donated and received by NTD July 2014 to June 2017

The quantity of received commodities were obtained from the paper based commercial invoices and Goods Receiving Notes (GRN) at MSD and they were double checked with the amounts recorded in the MSD's ERP (Epicor 9 software). Below are the quantities and corresponding value of medicines.

Table 2: Quantities and Invoice Value of received medicines (July 2014 – June 2017)

Product	UOM	July 2014- June 2015		July 2015- June 2016		July 2016- June 2017		TOTALS	
		Quantity	Total Cost	Quantity	Total Cost	Quantity	Total Cost	Quantity	Cost
ZITHROMAX OS 1200MG 200MG/5ML	3omls	243,408	\$ 1,379,274	101,328	\$ 577,570	128,016	\$ 729,691	472,752	\$ 2,686,535
ZITHROMAX COATED 250 MG TABLETS	p/500	17,611	\$ 8,805,500	22,292	\$ 11,120,779	17,496	\$ 8,748,000	57,399	\$ 28,674,279
ALBENDAZOLE 400MG TABLETS	p/200	124,130	\$ 496,520	149,775	\$ 599,100	118,729	\$ 474,916	392,634	\$ 1,570,536
IVERMECTIN 3MG TABLETS	p/500	101,238	\$ 25,310	100,130	\$ 75,097,500	109,001	\$ 27,250	310,369	\$ 75,150,060
PRAZIQUANTEL 600 MG TABLETS	p/500	23,259	\$ 998,843	33,504	\$ 1,137,187	41,734	\$ 1,416,544	98,497	\$ 3,552,574
			\$11,705,447		\$ 88,532,136		\$11,396,401		\$111,633,984

*UOM – is unit of measure, which connotes the pack size as supplied by the manufacturer or supplier.

The above quantities and corresponding costs were extracted from donations 'commercial invoices and validates with other sources at MSD. However, to understand the cost drivers on total commodity value of USD 111,633,984; figure 6 shows how much has each medicine contributed to total cost of donations over three years.

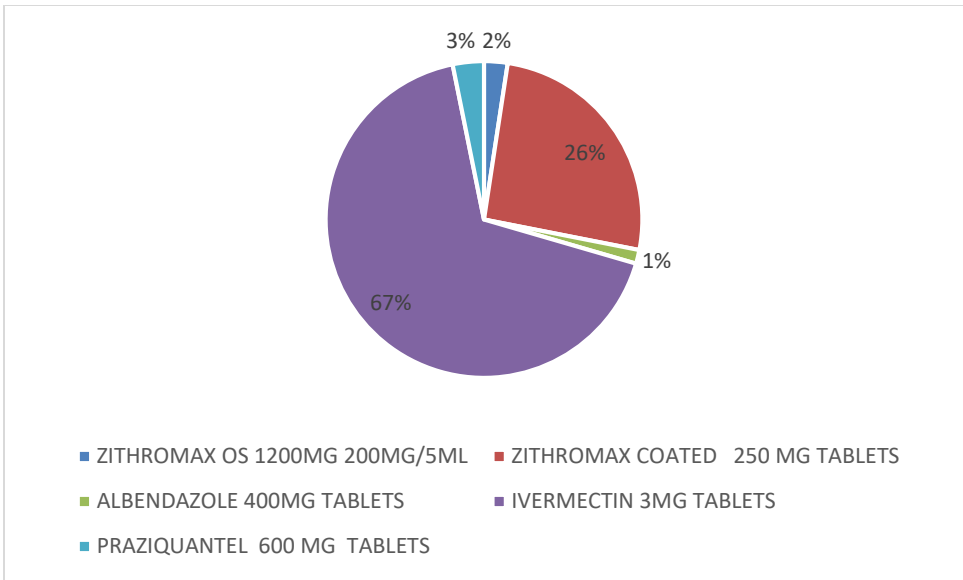


Figure 6: Percentage distribution of total cost of medicines received (product cost only)

From figure 6, two-third (2/3) cost of medicine donations for three years was attributed to a single medicine – ivermectin.

The drug ivermectin which was supplied by Mectizan Donation Program had unusual price hiking from USD 0.0005 to USD 1.5 per tablet given the same brand, supplier and pack size. Figure 7 shows ivermectin unusual price over three years.

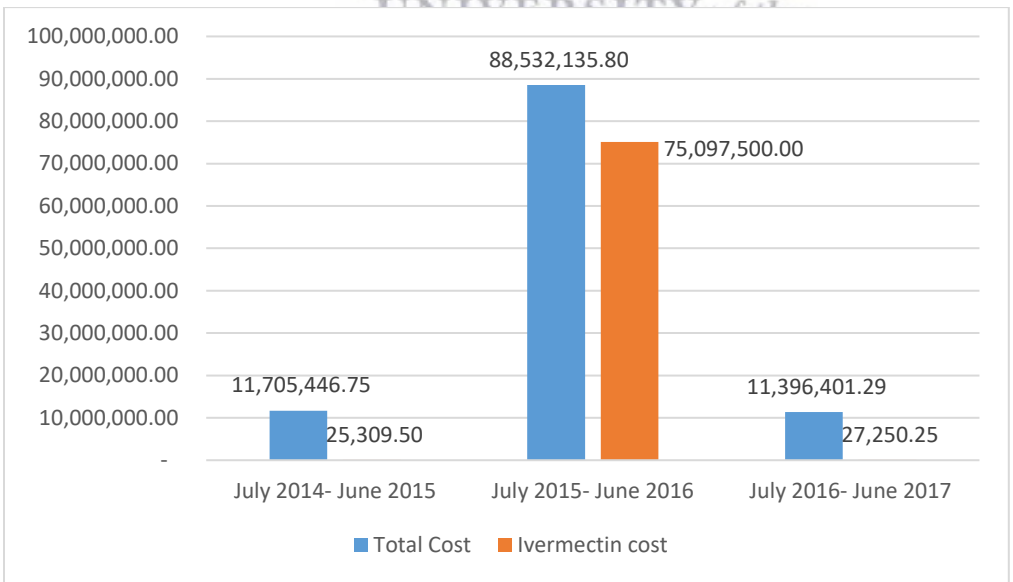


Figure 7: Total cost of all donated medicines v/s price of ivermectin alone.

The unusual price hike for ivermectin may have overstated the actual value of commodities as evidenced by figure 8 which compares the MEAN value of commodities and MEDIAN value of commodities per year.

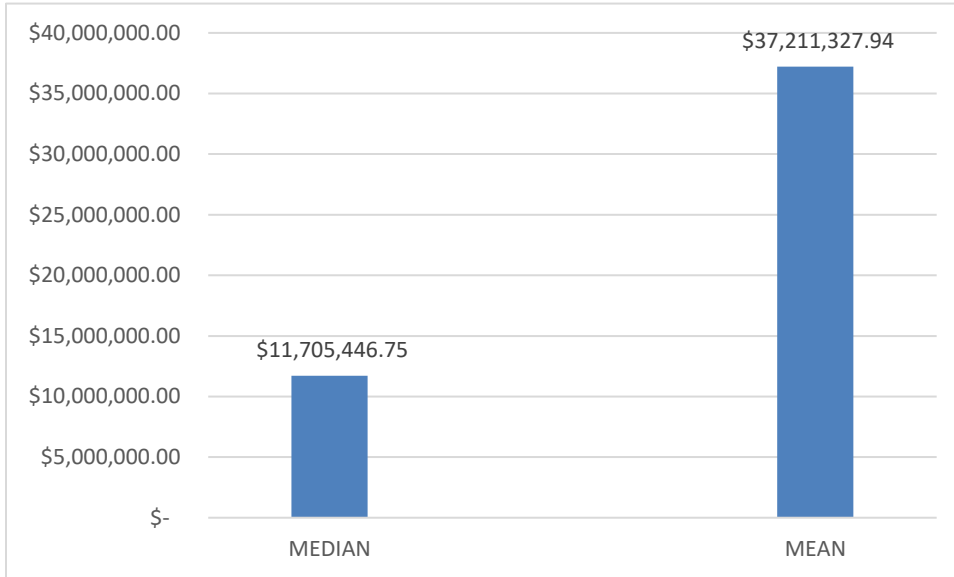


Figure 8: Mean and Median cost of donated medicines per year.

4.3 Medicine price comparison – donations versus MSH IDPG Median prices

The supplier invoices were used to find median prices of the five (5) medicines donated to NTD and such prices were compared with IDPG median prices to find the Median Price Ratios (MPR). The results are presented in table 3 below.

Table 3: Median Price Ratios - Donations/IDPG

Commodity	Comparison Unit	IDPG Prices		NTD Donations	Supplier Median Price Ratio (MSD/IDPG)
		Buyer Median	Supplier Median	Supplier Median	
Albendazole 400MG	TAB-CAP	0.28	0.08	0.02	0.25
Azithromycin OS 1200MG 200mg/5ml	Per ML	0.03	0.06	0.19	3.17
Azithromycin coated 250mg Tabs	TAB-CAP	0.20	0.12	1.00	8.55
Ivermectin 3MG TAB*	TAB-CAP	0.05	N/A	0.00	
Ivermectin 3MG TAB*	TAB-CAP	0.05	N/A	1.50	
Praziquantel 600MG TABS	TAB-CAP	3.14	0.11	0.06	0.57

**Ivermectin 3MG tabs though supplied by the same supplier and same brand, it had unusual price sparks from 0.25 USD per pack of 500 tabs in July 2014 – June 2015 period to 750 USD per pack in July 2015- June 2016 period; and in the June 2016- July 2017 period, the cost went back to 0.25 USD per pack of 500 tabs.*

Donated albendazole 400mg was 4 times cheaper than IDPG price (MPR of 0.25); whereas donated azithromycin oral suspension was 3.3 more expensive than the IDPG price (MPR of 3.2). Donated azithromycin was 8.6 times more expensive than the IDPG price (MPR of 8.6) while donated praziquantel was cheaper than the IDPG prices (MPR of 0.57). For ivermectin 3mg tab, there was no supplier median price in MSD IDPG which could be used to compare with donated ivermectin price (supplier median). However, using buyer median prices, the donated ivermectin price was 30 times that of IDPG.

4.4 Cost incurred by the government of Tanzania for the handling of the donated medicines from July 2014 to June 2017.

The supply chain cost includes the cost of port clearance, storage and distribution by the MSD. The table below summarized the actual cost charged by MSD for handling the donations for the 5 medicines as extracted from MSD financial records. (MSD's Epicor 9 Statement of account for NTD and clearing bills for NTD consignments). Table 4 below summarizes the findings.

Table 4: Supply Chain Cost for medicines received from July 2014 to June 2017

Period	Storage and Distribution	Clearance Cost	Total PSM Cost
July 2014-June 2015	\$ 164,915.83	\$ 49,240.68	\$ 214,156.50
July 2015-June 2016	\$ 108,884.27	\$ 372,423.41	\$ 481,307.67
July 2016-June 2017	\$ 112,187.07	\$ 47,940.63	\$ 160,127.70
			\$ 855,591.88

The data on actual cost incurred by the government in handling the NTD donations over three years is also presented graphically in figure 09 below to understand the cost drivers. It is evident that the cost of ivermectin tab had impact on the total PSM cost recorded over three years. The price hiking for ivermectin tabs happened in July 2015 – June 2016 period hence contributing to 56% overall supply chain cost, see figure 9.

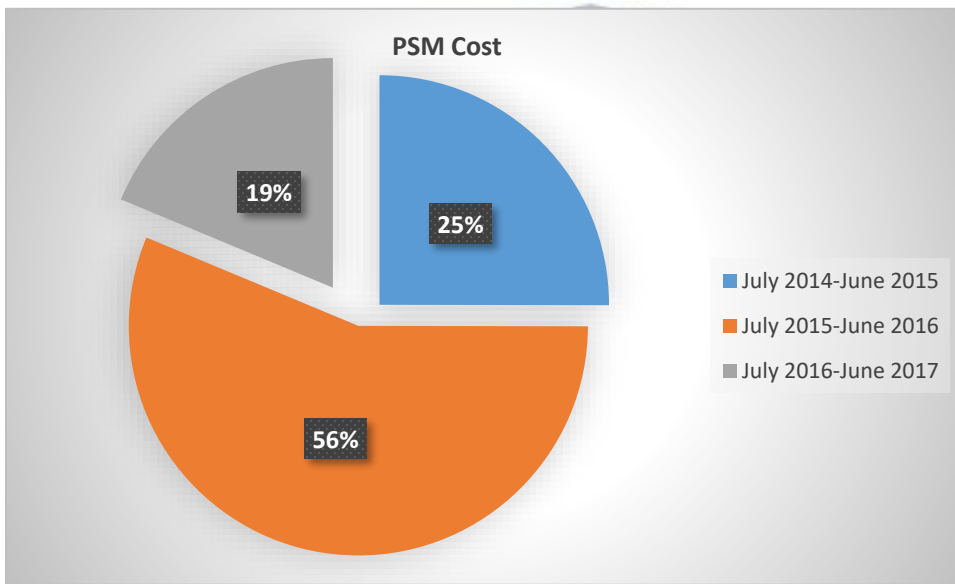


Figure 9: Medicine donations' Supply Chain cost (PSM cost) variations for three years

The PSM cost was only 1.8% of the product cost in FY 2014, it dropped further to 0.5% product cost in FY 2015 and it was 1.4% product cost in FY 2016. In all the three years, the PSM cost was far lower than the set rate of 11.6% product cost. See figure 10.

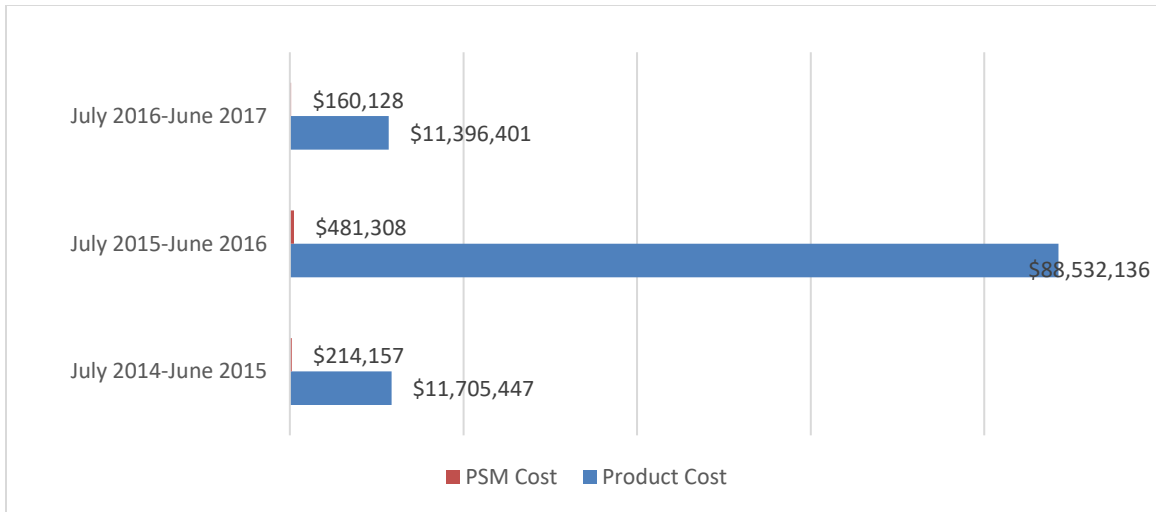


Figure 10: Comparing Product Cost versus Supply Chain Cost over three years.

4.5 Comparing the actual cost charged by MSD and the ideal cost as per optimal service fee cost structure.

The Service fees, “charges made by a supply chain organization (public or private) for providing supply chain services,” (Sanderson et al. 2014) are an important way for central medical stores like MSD to cover their operational costs. MSD service fee is value based (Deloitte 2015) and is divided into:

- Low volume, high value items – 11.6% commodity cost.
- High volume, low value items – 20.4% commodity cost

The NTD commodities falls in the first category whose PSM cost is 11.6% commodity cost. The MSD service fee structure is summarized in figure 11.

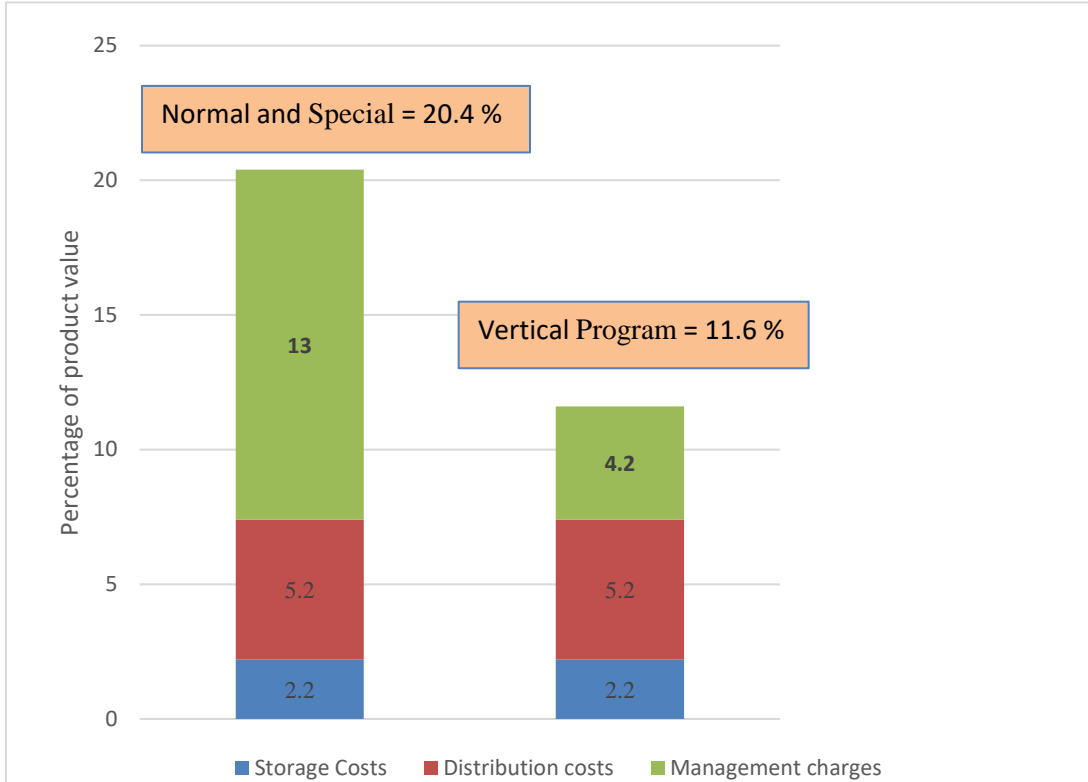


Figure 11: The MSD service fee structure

Therefore, the ideal PSM cost for goods received is 11.6% of USD 111,633,984, which is USD 12,949,542.12; MSD however charged only 0.8% commodity value as PSM cost for NTD medicines over three years.

The actual supply chain cost charged as service fee was only 0.8% commodity value instead of an optimum fee of 11.6% commodity value.

Further analysis of MSD clearing bills indicated that over 98% of NTD consignments were exempted the below statutory fees:

- Customs Destination Inspection fee (0.6% on invoice value)
- Railway development levy (1.5% invoice value)
- VAT and Import duty (exempted as per 2014 VAT Law)
- Importation permit fee by TFDA (2% on invoice value)

4.6 Supply Chain Cost of NTD Consignments using the MSH IDPG prices.

Table 5: Commodity costs using International Drug Price Indicator Guide

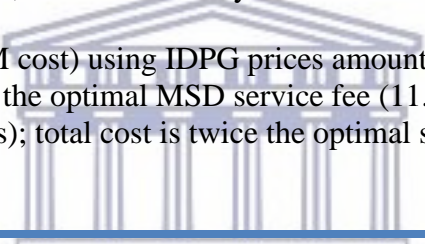
Commodity Costs July 2014 - June 2017

Commodity	IDPG	Donated
Albendazole 400MG	\$ 6,187,911.84	\$ 1,570,536.00
Praziquantel 600MG TABS	\$ 5,412,410.15	\$ 3,552,573.99
Zithromax coated 250mg Tabs	\$ 3,357,841.50	\$ 28,674,279.12
Zithromax OS 1200MG 200mg/5ml	\$ 850,953.60	\$ 2,686,534.98
Ivermectin 3MG TAB*	\$ 7,604,040.50	\$ 75,150,059.75
Total	\$ 23,413,157.59	\$ 111,633,983.83

The overall product cost using donations' prices is 5 times the cost using IDPG prices.

If the IDPG prices were to be used to calculate PSM cost (the 11.6% commodity value), then the cost would be \$2,715,926.28 for three years.

Total cost (commodity +PSM cost) using IDPG prices amounts to USD 26,129,083.87 for three years. Compared to the optimal MSD service fee (11.6% commodity value) for current mechanism(donations); total cost is twice the optimal supply chain cost for the donations.



The cost of procuring NTD medicines using Government of Tanzania's own resources is twice the current optimal cost for handling the donations.

4.7 Medicine pricing survey – determining generic prices in Tanzania market.

Table 6 below depicts the type and number of NTD medicine brands registered for use in Tanzania by the TFDA.

Table 6: The NTD medicines registered by the TFDA and have Tanzania market authorization.

Generic Name	Formulation	Strength	No of registered brands
Albendazole	Tabs	400mg/200mg	17
Albendazole	solution/suspension	400mg/200mg/100mg	9
Azithromycin	Tabs, Caps	500mg/250mg	27
Azithromycin	Oral Suspension	300mg/200mg	7
Praziquantel	Tabs	600mg	6
Ivermectin*	Tabs	3mg	N/A

*19 brands of ivermectin for veterinary use were found but none for human use.

4.7.1 Supplier and Retail median prices of surveyed medicines

Supplier median prices are median prices of medicines as collected from wholesale pharmacies and retail median prices are median prices of medicines as collected from retail pharmacies. The prices are presented in table 7 below.

Table 7: Supplier and median prices of surveyed medicines.

Generic Name	UOM	UOM	Supplier Median Price	Retail Median Price
Albendazole tab, 400mg	Each	TAB-CAP	0.12	0.44
Azithromycin OS 1200MG 200mg/5ml - 15mls	Bottle of 15mls	Per ML	0.06	0.13
Azithromycin tab, 250mg	P/6	TAB-CAP	0.14	0.37
Praziquantel tab,600mg	P/100	TAB-CAP	0.11	0.23

The comparison of above results with International Reference Prices is shown in table 8 below.

4.7.2 Price comparison between the generic medicine median prices and MSH IDPG median prices

The median price ratios between the generic prices and corresponding MSH IDPG prices were used to compare the two prices.

Table 8: Median Price Ratios between survey medicine prices and MSH IDPG median prices.

Commodity	Comparison Unit	IDPG Prices		Pricing Survey Prices		Supplier Median Price Ratio (Survey/IDPG)	Buyer Median Price Ratio (Survey/IDPG)
		Buyer Median	Supplier Median	Buyer Median	Supplier Median		
Albendazole 400MG	TAB-CAP	0.28	0.08	0.44	0.12	1.56	1.55
Azithromycin OS 1200MG 200mg/5ml	Per ML	0.03	0.06	0.13	0.06	1.02	4.19
Azithromycin coated 250mg Tabs	TAB-CAP	0.20	0.12	0.37	0.14	1.19	1.84
Praziquantel 600MG TABS	TAB-CAP	3.14	0.11	0.23	0.11	1.04	0.07

From table 8, the following are observed;

Albendazole 400mg – the lowest priced generics (both supplier and retail) were found to be 1.5 times the IDPG prices. Azithromycin Oral suspension – the lowest priced supplier’s generics were found to be 1.02 (nearly equal to) the IDPG prices and the lowest priced retail generics were 4.2 times the IDPG prices. The lowest priced supplier’s generics for Azithromycin coated 250mg tabs was 1.19 the IDPG prices and the lowest priced retail generics was 1.84 times the IDPG prices. For Praziquantel 600mg tabs - the lowest priced supplier’s generics were found to be 1.04 the IDPG prices and the lowest priced retail generics were 0.07 times the IDPG prices.

4.8 Comparing costs of current donation programs and the use of generic medicines.

Comparisons were made under the following key assumptions (considerations)

1. The IDPG prices are product costs only (EXWORK prices) and hence don’t include related PSM costs such as freight, insurance, port clearance, storage and distribution.
2. The medicine prices determined by the pricing survey in the local market include the PSM cost of freight, insurance, port clearance, storage and distribution
3. Ivermectin is excluded from the comparison because there is no comparable supplier and buyer median price in Tanzania market as it is not TFDA registered.
4. Analysis assumes the supplier median prices obtained from the pricing survey remained the same for the past three years.
5. Comparison assumes the same quantities acquired by NTD using different price types and financing mechanism.

Table 9: Cost Comparison – Generics medicine prices, IDPG prices and donations.
Commodity Costs July 2014 - June 2017

Commodity	IDPG cost (USD)	MSD Suppliers - donated cost (USD)	Pricing Survey (Generics) cost (USD)
Albendazole 400MG	6,187,912	1,570,536	9,635,190
Praziquantel 600MG TABS	5,412,410	3,552,574	5,611,135
Zithromax coated 250mg Tabs	3,357,842	28,674,279	3,982,548
Zithromax OS 1200MG 200mg/5ml	850,954	2,686,535	870,096
Total	15,809,117	36,483,924	20,098,969
Add: Supply Chain Cost (11.6% product cost)	1,833,858	4,232,135	
Grand Total (Product Cost + PSM)	17,642,975	40,716,059	20,098,969

From the table above:

1. The cost of medicines as per donations suppliers' invoices is nearly twice the cost of generic equivalents found in the local market
2. The locally available generic equivalents cost 27% higher than the equivalent IDPG prices. The individual exception is on Praziquantel (only source found was locally produced) in which the generic equivalent was 4% cheaper than IDPG prices.

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Tanzania is likely to pay 27% more on sourcing locally than importing generic equivalents

Chapter 5: Discussion

There were four active donation programs during the study period, the DEC donation program by Eisai which donates diethylcarbamazine citrate (DEC) was not active in Tanzania. DEC is primarily used to treat lymphatic filariasis; its efficacy was first reported in 1947 (Hewitt et al., 1947) and its standard use in treatment of lymphatic filariasis was endorsed by the WHO expert committee in 1974 (WHO, 1974). However, in treating and interrupting transmission of lymphatic filariasis in most sub-Saharan Africa including Tanzania, a combination of ivermectin and albendazole is currently used instead of DEC (Simonsen PE, et al., 2010). Therefore, the findings of this study are consistent with the Tanzania's lymphatic filariasis treatment and control guidelines in place.

The price cost of ivermectin contributed 67% of the total value of donations for the period under study. The price hike for ivermectin was unusually high and kept fluctuating downwards and upwards yearly from USD 0.0005 to USD 1.5 per tablet given the same supplier, brand and pack size. Stating very high medicine prices in donations given (in this case 30 times the IDPG buyer's median price), may be influenced by tax incentives (tax deductions, tax breaks) enjoyed by pharmaceutical companies at the countries of origin which translates to after-tax gains to a donor company meanwhile it is additional cost to public sector of a donor country due to lost tax revenues (Guenther G, 1999; USG, 1986; Cristina P, 2008; Berckmans P. et al, 1997; Guillox & Moon, 2001). The effect of inflating the value of donated medicines to a recipient country such as Tanzania is high supply chain costs such as import taxes and overheads for storage and distribution which is covered by deducting the government's pharmaceutical budget (MSH, 2012).

The cost of donated azithromycin 250mg coated tab was consistently very high over a three years' period. Medicine price is considered as high by WHO when it's median price ratio (MPR) reaches 4 (WHO, 2008); the azithromycin 250mg coated tab had an MPR of 8.6. The high price reflects the unfair pricing of branded products by the global pharma companies, an area which has attracted governments' regulations both in Africa and across the globe (MOHSW,2015; Calcagno et.al.,2019). The IDPG prices were lower compared to the price of cheapest available generics in Tanzania market; only Praziquantel was exceptional in this regard. The IDPG prices are ex-works, prices don't include the loading, insurance and freight cost (MSH, 2015); therefore, it is not uncommon that they are cheaper than locally available generics with exception of Praziquantel which is locally manufactured in Tanzania.

The undercharging of supply chain cost for donations handled by the MSD poses operational risk to MSD which may affect the entire health system as MSD is the sole government supply chain agency responsible for procurement storage and distribution of health commodities in in Tanzania. (URT, 1993). The optimal service fee charged by MSD to cover for its services of clearing, storage and distribution to vertical programs including the NTD is 11.6% (Deloitte, 2015). As with all government run supply chains which operate with social welfare in mind, the service fees charged by MSD are for cost recovery (MIT- Zaragoza.et al., 2011). The Ministry of Health in a bid to address MSD financial sustainability, working capital erosion and debt accumulation; spearheaded the signing of

Memorandum of Understanding between MSD and vertical programs which included the charging rate of 11.6% commodity value (MOHSW, 2015). However, the undercharging of donated medicines by MSD exposes MSD to working capital erosion as the funds which were to procure medicines and medical supplies would be used to cover the unbilled cost of clearance, storage and distribution. The report by Global Fund's Office of Inspector General pointed out the delays in distribution of key health commodities (taking 65 days) was due to MSD's inadequate working capital (The Global Fund, 2016), further analysis by Deloitte indicated MSD working capital erosion was contributed mainly by failure of vertical programs to pay MSD the required service fees for its services (Deloitte, 2015). While it is not clear as to why the NTD donations were undercharged by MSD, it is however very clear that such undercharging undermines the self-sustainability and financial viability of the MSD which will eventually affect the entire Tanzania health system.

What Next? - suggestions for the future

Despite the above facts, the donation programs pose harmful competitions with generic manufacturing industry in developing countries as the producers cannot compete with free products (Guillox & Moon, 2001). Also, their sustainability is questionable as some big Pharma involved have started to think of "adequate return on investment to fund future research" instead of donations in long term (Gilmartin R., 1998).

A roadmap to independence can include the following actions:

Deploy Total Market Approach (TMA) to neglected tropical diseases medicines. A Total Market Approach (TMA) is referred to as a process which brings together the public and private health sectors for the purpose of coordinating policies and programs for greater health impact and sustainability.

Richard Pollard defined TMA as one in which all sectors (public, private and NGO or donor-financed social marketing) are integrated within one "market" that is segmented by willingness to pay (Pollard, R., 2007). In case of neglected tropical disease program; the key sectors would include public sector (government of Tanzania), donor companies (current in donation programs) and the private sector.

- For medicines which we have local production capacity such as Praziquantel, Azithromycin and albendazole – government resources can procure and distribute in integrated supply chain.
- For items such ivermectin which there is no local production capacity currently– The donor companies can keep donating for agreed period to allow smooth transition to government to source from generic competitors at affordable prices.
- Private sector can play crucial role in service provision for segment of Tanzanians who have access to National Health Insurance and those who can afford out of pocket payment.

TMA is key for transition plan away from donor dependency in health programs. TMA made possible the inclusion of family planning (FP) commodities in insurance schemes and closer private sector involvement in FP services in Europe and Eurasia regions (Berdzuli et.al, 2008), facilitated insecticide treated nets uptake in commercial sector across sub-Saharan Africa including Tanzania (AED, 2005). With well-defined roles for different sectors under a TMA and right policy climate, TMA can promote sustainability and guarantee continuity of service to all population segments both the rich and poor (Armand F. & Mitchell S., 2014).

Integrating donated medicines into Tanzania’s drug procurement system by MSD.

This option offers economies of scale for MSD especially for those items which have uses apart from the “program specific uses”. Azithromycin and albendazole have broader use than program specific, while Praziquantel is readily needed throughout the year and not during program specific Mass Drug Administrations (MDA) only. The latter is evidenced by wider availability of Praziquantel during the pricing survey in this study. The economies of scale due to integration is helpful in pooled procurement which MSD can help negotiate better prices due to economies of scale. The Global Fund’s Pooled Procurement Mechanism helped to reduce the prices of ARVs worldwide by at least 16% (Sung WK & Jolene SW, 2017).

Accelerate the Universal Health Coverage (UHC) Policy with mandatory Health Insurance coverage for all citizens. The Tanzania National Health Accounts (NHA) survey of 2010 revealed that Out of Pocket Payment for healthcare contributed to 32 % of the total health expenditure while Government contributed by 26% and only 2% was contributed by the National Health Insurance Fund (MOHSW, 2011). These results are reflective of low coverage of health insurance which is fairly low at 14% contributing below 5% of the total national health expenditure (MOHSW, 2011, 2012). The UHC policy will set pace for better Total Market Approach and increased funding for health commodities including medicines for the NTD Program.

Invest in local generic manufacturing of NTD medicines: The NTD medicines do not represent a viable commercial market for global pharmaceutical companies, therefore developing nations have to invest in local generic manufacturing as a sustainability measure (Holt F. et al, 2012). To achieve this goal; clear pharmaceutical policies, good business environment and taking advantage of collaborations which make transfer of technology and capital easy are needed as in case of CIPLA investing in Uganda (United Nations, 2011). In Tanzania, the National Pharmaceutical Action Plan 2015-2020 which is a guiding document outlining the core business of pharmaceutical sector stakeholders, does not have local pharmaceutical manufacturing as one of its core objectives (MOHSW, 2015). Local manufacturing in Tanzania has potential to increase access to low price generics; published reports indicated that Tanzania Government paid less for locally produced medicines than imported medicines (Ewen M.et al., 2017).

Generalizability.

The findings of this study might be generalizable to low and middle-income Sub-Saharan African countries especially those under the Southern African Development Community (SADC) and East African Community (EAC) regional block since SADC countries have similar trade and tax policies to Tanzania. The landlocked SADC and EAC countries have higher supply chain costs than Tanzania. The cost drivers in these countries are attributed to the high cost of freight services and unpredictability in transportation time due to bottlenecks in neighboring countries' ports, poor road quality and delays at border crossings (Arvis et al., 2007).

Chapter 6: Conclusion

The optimal cost of handling medicine donation programs to NTD currently is half the cost of buying equivalent generics using the government of Tanzania's own funds. The roadmap towards self-financing option that gives Tanzania greater autonomy in meeting her present and future needs is needed to sustain gains achieved in the NTD program. The Total Market Approach and integration of NTD medicines into MSD managed pooled procurement are seen as immediate actions. The two actions will ensure mobilization of financial resources, reduce procurement prices and operational costs of managing a separate vertical supply chain.



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Appendices

Appendix A: Medicine Price Data Collection Form

A	B	C	D	E	F	G	H	I	J
Generic Name, dosage form, strength	Medicine Type	Brand or Product Name	Manufacturer	Available : 'yes' or 'no'	Pack Size recommended	Pack size found	Price of pack found	Unit Price(4 digits)	Comments
Albendazole tab, 400mg	Originator Brand	ZENTEL	GSK					/tab	
	Lowest- Priced Generic							/tab	
Ivermectin tab, 3mg	Originator Brand	MECTIZAN	MERCK					/tab	
	Lowest- Priced Generic							/tab	
Azithromycin tab, 250mg	Originator Brand	ZITHROMAX	PFIZER					/tab	
	Lowest- Priced Generic							/tab	
Azithromycin tab, 500mg	Originator Brand	ZITHROMAX	PFIZER					/tab	
	Lowest- Priced Generic							/tab	
Praziquantel tab,600mg	Originator Brand	Cesol	MERCK					/tab	

	Lowest- Priced Generic							/tab	
Diethylcarbamazine citrate (DEC) tab, 100mg	Originator Brand	DEC	EISAI					/tab	
	Lowest- Priced Generic							/tab	



Appendix B: Ethical Clearance from University of Western Cape



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16 March 2018

Mr AO Rassa
School of Public Health
Faculty of Community and Health Sciences

Ethics Reference Number: BM18/1/6

Project Title: A cost analysis of medicine donation programs to Tanzania's neglected tropical diseases control program.

Approval Period: 15 March 2018 – 15 March 2019

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.

A handwritten signature in black ink, appearing to read 'Josias'.

*Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape*

PROVISIONAL REC NUMBER -130416-050

Appendix C: Permission letter to collect data from Ministry of Health, Tanzania

**JAMHURI YA MUUNGANO WA TANZANIA
WIZARA YA AFYA, MAENDELEO YA JAMII, JINSIA, WAZEE NA WATOTO**

Anwani ya Simu: "AFYA", DODOMA
Simu ya Mdomo: +255 26 2323267
Fax No.

(Barua zote ziandikwe kwa Katibu Mkuu)



Chuo Kikuu Dodoma,
Kitivo cha Sanaa na Sayansi ya
Maendeleo ya Jamii,
Jengo Na. 11
S.L.P. 743,
40478 DODOMA.

Kumb. Na. HD 209/309/04/50

11 Aprili, 2018

Director General,
Medical Stores Department,
P.O Box 9081,
DAR ES SALAAM.

Program Manager,
Neglected Tropical Diseases Control Program,
P.O Box 9083,
DAR ES SALAAM.

**RE: SUPPLY CHAIN COSTING ANALYSIS STUDY ON NEGLECTED TROPICAL
DISEASES CONTROL PROGRAM.**

Please refer to the above heading.

This is to introduce Mr. Adam Omary Rassa, a Pharmacist who will undertake the supply chain costing analysis study between March and May 2018. The purpose of study is to understand the supply chain costs associated with medicine donation programs supporting the NTD control program and inform policy decision on optimal financing options for the program.

To undertake this task, the following documents will be accessed from your office; the quantification reports, the WHO Joint Request Form for medicine donations, the shipment receiving documents such as commercial invoices, goods receiving notes and related documentation.

With this letter, I request your good office to avail the necessary support and cooperation for successful completion of the activity. Thank you for your usual cooperation

A handwritten signature in blue ink, appearing to read 'Daudi Msasi'.

Daudi Msasi

FOR PERMANENT SECRETARY - HEALTH