

**HEALTH SYSTEM GOVERNANCE IN
TANZANIA: Impact on service delivery in
the public sector**

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Dekan

*Dedicated to Poppie:
"No one will ever be able to take this away from you".*

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Summary

Governance in the health system has perhaps been the least explored building block of the health system, receiving less attention due to its vague definition and complex nature. When discussed at the country level it often focuses on single elements such as corruption or accountability and doesn't consider wider interactions of relevance to how policies are formed. How well governed a health system is can often mean the difference between the efficient use of resources and inefficient waste, which is even more important in a resource constrained environment.

The United Republic of Tanzania has been a major recipient of donor aid over the past few decades. Tanzania's health sector in particular has been the subject of much donor interest, especially regarding medicines. One of the first donors to support medicines was Danida who funded the essential medicines kit, and since then numerous donors have been involved in either funding medicines, designing policies around medicines selection, procurement and distribution, or direct medicines donations. Although Tanzania has largely benefited from this increase in donor support, not all of it has been designed and implemented adequately to suit the situation and needs of Tanzania. In other words, health systems governance may sometimes have been weakened by donor-interest, resulting in reduced quality of health care.

The aim of this research was to contribute to a better understanding of health system governance and apply this knowledge to the Tanzanian health system. The insights gained should aid policy makers and other stakeholders to design

interventions that are appropriate for the local context to ensure a stronger health system which is able to attain its goals of improving the level and distribution of health, while responding to the population's needs and protecting them from large, often catastrophic financial expenditures.

The research was carried out as part of the Governance of Health Systems project, a collaborative endeavour between the Swiss Tropical and Public Health Institute and the Basel Institute of Governance. Quantitative and qualitative methods were applied to data collected in two areas of the local Health and Demographic Surveillance System (HDSS), Ulanga District and Rufiji District. We used both primary data collection and secondary data, covering the period from 1999 – 2011.

The overall findings are that despite the interest over the past decade to develop frameworks to assess governance in the health system, few have been empirically applied. The first part of this thesis focuses on developing a framework to assess governance in the health system; the second part applies this framework to a selected governance issue in Tanzania, namely the delivery of essential medicines to public health centres in Tanzania. At the national level, this investigation found that the medicines ordering system was based on a complex paper-based system which had not been designed with local capacity in mind, nor did it improve the accountability of medicines. Lack of accountability was also found at the health facility level, where over half of respondents interviewed who sought care in the public sector for fever, subsequently experienced the consequences of one form or another of non-compliant health-worker behaviour (overcharging for treatment and medicines, stocking out of the first line antimalarial, dispensing an inappropriate monotherapy). This resulted in an additional cost to the patient, on average, of USD1.62 per treatment episode, representing 125% of the national per capita daily income, or 164% of the rural per capita daily income.

Stockouts of essential medicines are an immediate indicator of governance failure and in the case of fully funded donor medicines, stockouts represent a health system failure. This research identified that in a 15 month period from October 2011 until the end of 2012, an estimated 29% of health facilities were stocked out of the first line antimalarial at any one time. These stockouts were due to failures at the national and international level where excessive bureaucratic procedures resulted in fragmented and dysfunctional procedures for procurement of the first line antimalarial.

The findings in this thesis suggest that Tanzania should redesign the medicines ordering system, with greater participation from health workers, in order to better understand the challenges they face. We recommend various interventions across the health system to strengthen it and improve the availability of medicines. The most important recommendation would be to increase accountability and transparency of the medicines delivery system and force reconciliation between data sources thereby creating information on medicines consumed.

The findings of this thesis contribute to a more comprehensive understanding of governance in health systems and how overlooking governance can cause major catastrophic stockouts of essential medicines, in addition to a reduced level of service delivery and greater economic hardship for households.

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List of abbreviations

ACT	Artemisinin-Based Combination Therapy
ADDO	Accredited Drug Dispensing Outlet
AIDS	Acquired immune deficiency syndrome
ALu	Artemether-Lumefantrine (trade name: Coartem)
AMFm	Affordable Medicines Facility – malaria
CHF	Community Health Fund
CI	Confidence Interval
CPIA	Country Policy and Institutional Assessment
DMO	District Medical Officer
EDP	Essential Drug Program
HDSS	Health and Demographic Surveillance Site
GAVI	Global Alliance for Vaccines and Immunization
GDP	Gross Domestic Product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GIS	Geographic Information System
HIS	Health Information Systems
HIV	Human Immunodeficiency Virus
ILS	Integrated Logistics System
INDEPTH	International Network for the Demographic Evaluation of Populations and Their Health

INESS	INDEPTH Effectiveness and Safety Studies
MoFEA	Ministry of Finance and Economic Affairs
MoHSW	Ministry of Health and Social Welfare
MSD	Medical Stores Department
NGO	Non-Governmental Organization
NMCP	National Malaria Control Programme
ORS	Oral Rehydration Salts
PCA	Principle components analysis
PMI	U.S. President's Malaria Initiative
PSS	Pharmaceutical Services Section
mRDT	Rapid Diagnostic Tests
R&R	Request and Report
SES	Socio-Economic Status
SP	Sulphadoxine -Pyrimethamine
Swiss TPH	Swiss Tropical and Public Health Institute
THMIS	Tanzania HIV/AIDS and Malaria Indicator Survey
TEHIP	Tanzania Essential Health Interventions Project
TFDA	Tanzania Food and Drugs Authority
TZS	Tanzanian Shilling
USD	US Dollar
VA	Verbal Autopsy
WHO	World Health Organization

PART 1

BACKGROUND

*“Health systems approaches to aid may be intellectually correct,
but they are politically problematic”*

– R. Horton “Offline: One day in Brussels”, February 18, 2012



1. Introduction

Section 1.01 *Understanding Health Systems*

The establishment of the United Nations Millennium Development Goals in 2000 coincided with an era when global health policy was becoming increasingly more complex with new challenges, new priorities, new players from private philanthropy and new global health initiatives and disease specific programs. As country health officials and donors increased their spending on health, concerns arose about the ability of health systems to effectively absorb this enormous increase in resources and deliver results. Partly in response to these developments, the World Health Organization (WHO) focused its *2000 World Health Report* on '*Health Systems: Improving Performance*' which is widely considered as a landmark report across the health system literature, in part because it showcased the importance of focusing on health systems (WHO 2000a). In this report, the health system was defined as "*all activities whose primary purpose is to promote, restore or maintain health*", and was presented as having four functions: stewardship; resource generation; financing; and service provision. The report also explicitly defined the goals of the health system as: 1) improving the health of the population they serve; 2) responding to people's expectations; and 3) providing financial protection against the cost of ill health (WHO 2000a). Moreover, the framework allows for an empirical assessment of health system performance which has been applied to compare the efficiency of national health systems across 191 countries (Evans et al. 2001). In addition, an in-depth analysis of the specific components of the *2000 World Health Report* incorporating different perspectives was also carried out by Murray and Evans (2003) (Murray and Evans 2003).

Since the *2000 World Health Report*, health systems have been defined and conceptualised in various ways (see Table 1.1). Roberts et al. (2004) conceptualized the health system as a set of relationships between the major

components of the health system 'control knobs' and health system outcomes (Roberts et al. 2004). These control knobs include: financing; macro-organization of provision; payments; regulation; and persuasion. The 'control knobs' framework focused more on the financial aspects of a health system and less on building capacity in health workers; it also included consumer satisfaction as a goal. Mills et al. (2006) define a health system as having four functions: stewardship and regulation; organizational structures and their financing; general management functions, namely human resources; and quality assurance (Mills et al. 2006). This framework focuses on the relationship between the health system and its patients and their communities. It also provides special recommendations for low capacity environments including the provision of basic preventive and curative services and ensuring that disease specific programs have an element of health system strengthening.

The WHO 2000 health system framework was later updated in 2007 with the release of the WHO report *'Everybody's Business: Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action'* (WHO 2007) where the health system architecture was further elaborated as having six building blocks: leadership and governance; health workforce; information; medical products, vaccines and technologies; financing; and service delivery (WHO 2007). This, however, was a shift away from the *2000 World Health Report* as neither populations nor the importance of how the elements of a health system interact were highlighted. A year later, the WHO further developed their conceptual framework for primary health care by placing people in the centre of the health system (WHO 2008a). A further refinement of the WHO 2007 framework was proposed by de Savigny and Adam (2009) who highlighted the importance of incorporating a systems thinking view of the synergies and complex interactions among and across all building blocks in the health system (see Figure 1.1) (de Savigny and Adam 2009) This framework highlights the importance understanding

not only what was going on in each building block, but what happens in between them. It also emphasizes the importance of moving away from linear thinking towards understanding the importance of feedback loops.



Figure 1.1: Rearranging the health system building blocks into a ‘systems thinking’ approach

Source: de Savigny and Adam (2009)

In their framework, de Savigny and Adam (2009) highlight that any intervention in one building block of the health system is likely to have system-wide effects which may need to be mitigated or prevented. They also propose a ‘Ten Steps to System Thinking’ as a guide for the empirical application of systems thinking.

Another framework rooted in systems thinking and highlighting the central role of people was developed by van Olmen et al. (2012) who expanded the building blocks to include four new elements: populations, context, goals and values (van Olmen et al. 2012). This framework emphasised that not all health system elements are equal, as well as the importance of considering complexity in strategy development and analysis.

Differentiating between long term and intermediate goals, Atun and Menabde (2008) define the health system as being made up of elements that interact to achieve health system goals around financial risk protection and consumer satisfaction, but there are also intermediate goals identified including: equity; efficiency; effectiveness and choice (Atun and Menabde 2008). This framework differs from the others in that it positions the health system within a wider context, emphasising the broader nature of the health system through its interactions, and dependency, on a wide variety of factors, including the demographic, economic, political, legal and regulatory, epidemiological, socio-demographic and technological contexts.

The health system definitions and characteristics underlying the various initiatives identified in Table 1.1 have all served to focus attention on health systems, and on their various components and interactions.

Table 1.1: Major health system definitions, frameworks and concepts since 2000

Conceptualisation	Reference
Health System Performance	(WHO 2000b)
Essential Public Health Functions	(Pan American Health Organization 2002)
Control Knobs	(Roberts et al 2004)
Strengthening Health Systems	(Mills et al 2006)
Health System Building Blocks	(WHO 2007)
Health Systems Dynamics	(Atun and Menabde 2008)
Maximizing positive synergies	(WHO 2008a)
Systems thinking for Health Systems Strengthening	(de Savigny and Adam 2009)
Monitoring Building Blocks of the Health System	(WHO 2010a)
Health Systems Dynamics	(van Olmen et al 2012)

The health system frameworks listed in Table 1.1 are useful guides to inform broad conceptual discussions; however, they are limited, in that they do not provide a

clear guide for health system practitioners within countries as to how to incorporate the health system in decision making and how to practically assess health system performance, or specific components of it.

In parallel with this increased focus on conceptualising health systems in the literature, there has also been a growth in interest among the policy community around health systems. For example, the Alliance for Health Policy and Systems Research launched in 1999, the global symposia on health systems research (first held in Montreux in 2011) and the 'International Health Partnership Plus' aimed to align the efforts of international organisations, bilateral agencies and developing countries to develop sustainable health systems and improve aid effectiveness. More recently, the Health Systems Funding Platform by the World Bank, the GAVI Alliance and the Global Fund to fight AIDS, Tuberculosis and Malaria (henceforward referred to as the 'Global Fund'), with facilitation from WHO, have attempted to streamline health system strengthening support according to country budgetary and programmatic cycles. However this funding platform never attained its goals due to different funding mechanisms between the three agencies and the financing crisis that the Global Fund experienced in 2011, cancelling Round 11 funding applications (Hill et al. 2011).

As expressed in 2012 by Richard Horton, the editor of the Lancet when he said "*Health systems approaches to aid may be intellectually correct, but are politically problematic*" (Horton 2012) the rate of application of health system frameworks has been considerably slower than their development. Moreover, questions have been raised as to whether global health initiatives, with narrow foci on disease or interventions, including the control of HIV/AIDS and malaria, and the promotion of vaccines, undermine health system development (Biesma et al. 2009; Hanefeld and Musheke 2009; Reich and Takemi 2009). Often, evaluations of these and similar vertical programmes have tended to focus on single or specific elements like

human resource strengthening or financing, and have neglected other components such as health information strengthening (Car et al. 2012).

One of the more established health system toolkits for describing health systems and facilitating comparative health system research was developed by the European Observatory on Health Systems and Policies, which published a template for *Health Systems in Transition (HiT) country profiles* to conceptualise health systems at the country level. These were initially focused on European countries, but were recently expanded to a selection of countries in the Asia-Pacific region including Fiji, the Philippines, Mongolia (Roberts et al. 2011; Romualdez et al. 2011; Tsilaajav et al. 2013) and Malaysia, under the newly-established Asia Pacific Health Systems Observatory.

In 2010 the WHO produced a health system assessment toolkit with an indicative list of indicators to be collected at the country level. However, many of these indicators are very difficult to report on accurately (such as, the proportion of counterfeit drugs or under-the-table payments) (WHO 2010a). Furthermore, the indicators in the WHO (2010) report are limited to disease-specific or vertical programmes such as HIV/AIDS, reproductive health, malaria and tuberculosis, thus leaving out other key areas such as mental health. To my knowledge, this toolkit has not yet been applied. Perhaps to accelerate application, a rapid assessment tool covering the six dimensions of the health system as defined by WHO (2007) was developed by Islam (2007), and was designed to gather information on key indicators during both desk reviews and interviews with key stakeholders (Islam 2007) with the objective to inform USAID staff and Ministries of Health on the relative strengths and weakness of the health system, priority issues and potential reforms. The framework has so far been applied in Vietnam (Tran Thi Mai Oanh et al. 2010), Kenya (Luoma et al. 2010), Angola (Connor et al. 2010), South Sudan (Boulenger et al. 2007) and Ukraine (Tarantino et al. 2011). Both of these

frameworks provide a reasonable assessment toolkit for each of the health system building blocks, but their contribution towards assessing the complexity and dynamic nature of the health system is limited. Further work is needed to stimulate and guide the discussion on how health systems are functioning in countries, and on the key impediments to their development.

Section 1.02 ***Governance in Health Systems***

Probably one of the least well understood and most complex functions of a health system, but one which is common to most health system frameworks, is the concept of governance. Each one of the health system frameworks listed in Table 1.1 includes some mention of governance, either in terms of stewardship, regulation, organization arrangements, or enforcement or governance itself. In the WHO 2007 framework, governance is defined as “*ensuring that strategic policy frameworks exist and are combined with effective oversight, coalition building, regulation, attention to system-design and accountability*”. In other words, governance is seen as a core function that influences all the other elements of the health system.

Good health system governance has risen in importance as funding for health has increased and donors are demanding more accountability and transparency from recipients, especially following the findings of the Office of the Inspector General of the Global Fund (2011) (The office of the inspector general 2011). Governance in health has been discussed across various dimensions including global governance, corporate governance, governance in development and also how the private sector can be governed in providing public services. However, as for health systems, much of the literature on governance is more conceptual and less concerned with practical ways and priorities for governing a health system. A substantial number of studies have discussed the various effects of selected aspects of governance on

the health sector (Brinkerhoff 2004;Brinkerhoff and Bossert 2008;Chaudhury et al. 2006;Das Gupta et al. 2003;Lagomarsino et al. 2009;Nishtar 2010;Ramiro et al. 2001;The Global Fund to Fight AIDS Tuberculosis and Malaria 2008;Transparency International 2006;Vian 2008;WHO 2009). Indeed, some studies have empirically assessed the magnitude and impact of certain governance elements on health sector performance (Gupta et al. 2000;Lewis 2006;Rajkumar and Swaroop 2008). In general, most of the literature on governance and health has focused on single elements of governance such as degree of government effectiveness, degree of corruption and community participation. Typically these components have been assessed against proxy indicators of health sector outcomes or performance such as immunization rates, percentage of low birth weight babies or levels of child mortality.

Islam (2007) approaches the assessment of governance in the health system by developing a framework that proposes a set of illustrative questions to be answered by key stakeholders such as how information is used, how government coordinates donor inputs and who participates in setting the policy agenda. This framework provides a comprehensive range of issues to explore and even provides suggestions on which stakeholders to interview. Common governance challenges include fragmented roles and responsibilities, lack of participation from local health staff at sub-national level in policy making, and limited transparency and strategic vision (Boulenger et al 2007;Connor et al 2010;Luoma et al 2010;Tarantino et al 2011;Tran Thi Mai Oanh et al 2010). Using a similar approach, the WHO (2010) toolkit to assess health systems included a governance module where they divide the assessment of governance in the health system into either rules-based or outcome-based indicators. Although important, asking about the 'existence' of such policies, says little about their implementation. To my knowledge, there is no example in the literature where the WHO governance monitoring module has been applied.

Lewis and Pettersson (2009) developed a list of governance indicators for health systems grouped into five topics: budget management; human resources; institutional providers; informal payments; and institutions. These indicators, together with questions on the design of incentives, allow the researcher to gain a more in-depth understanding of the governance challenges for that particular topic. The indicators are generic enough to allow for comparisons and are a mix of those which can be obtained easily (such as the Country Policy and Institutional Assessment – CPIA index) and those which are more challenging to collect such as the frequency of under-the-table payments. This framework too has not been applied in full in any country to date.

Yet another health-systems specific governance framework was developed by Siddiqi et al (2009). The authors adapt the UNDP good governance concept (United Nations Development Programme 1997) to suggest a framework which encompasses ten health system governance principles to assess governance of the health system, and outlines a set of questions to be asked at different implementation levels. Their analytical framework has been applied to assess health system governance in Pakistan and identified several areas of weakness such as lack of accountability at the national level and little strategic vision in designing policies.

A sector-specific governance assessment toolkit has been designed for medicines ('Good Governance for Medicines') developed by WHO which focuses entirely on the pharmaceutical sector (WHO 2009). The aim of this toolkit is to evaluate transparency in the sector and is accompanied by a guide on how to assess responses, thus reducing the possibility of subjective judgement. This assessment has been applied in 26 countries including: Bolivia; Cambodia; Jordan; Indonesia; Mongolia; and Papua New Guinea. Most of these frameworks provide 'snapshots'

of the state of governance in health systems by developing both quantitative and qualitative indicators. This is advantageous as they can highlight areas of possible gross weakness; for example, if a country has no recent essential medicines list, or if there are irregularities in the payroll for health workers, or a lack of transparency in resource allocation. However, it is likely that health system stewards would already know where these governance weaknesses are and instead need to better understand why, where, and how to intervene.

Assessing and understanding governance in the health system is crucial as public officials, donors and researchers strive to understand how to improve the performance of health systems. The concept of governance in health systems has evolved from a complex and often neglected issue in health policy debates to one which now features regularly in discussions and has motivated new research. However a practical tool which can be readily and reliably used by policy makers to assess governance across the health system has, until now, not been developed.

Section 1.03 ***Health Systems in Tanzania***

Tanzania is a developing country classed as a low income country by the World Bank with a per capita income of USD473 in 2011 (The World Bank 2012). The health system in Tanzania services an estimated population of approximately 46 million, with an annual growth rate of 3%, with the majority of the population living in rural areas (73%) (The World Bank 2012). Tanzania is experiencing health system challenges that typically arise due to resource constraints, as summarised in Table 1.2.

Table 1.2: Indicators across health system building blocks, Tanzania and neighbouring countries and sub-Saharan Africa (developing countries), 2009 and 2011

Health System BB	Indicator	Tanzania	Kenya	Uganda	Mozambique	sub-Saharan Africa
Human Resources	Physicians/1000 pop	0.008	0.181	0.117	0.026	0.161
Information	Completeness of birth registration (%)	16	60	n/a	31	n/a
Financing	Health Exp as % of GDP	7.3	4.5	9.5	6.6	6.5
Service delivery	Children with fever receiving antimalarial drugs (% of children under 5 with fever)	59.1	23.0	64.5	29.9	36.9

The quality of health care in Tanzania is compromised by an unskilled and extremely scarce health workforce compared to its neighbours. The low number of qualified physicians in Tanzania is due to both an employment freeze in the 1990's and persistent underinvestment in training of health staff (Sikika 2010). The Health Information System (HIS) (MTUHA as it is known in Tanzania) was developed in the early 1990's (Ministry of Health and Social Welfare Tanzania 2010a) and requires health facilities to manually record data in 12 booklets which contain forms and registers. This information is summarised quarterly and submitted to the district where it is computerised and made accessible at the regional level. As the HIS was deemed inadequate for some large programmes, a number of parallel vertical information systems for specific diseases such as HIV/AIDS, Tuberculosis and Leprosy were subsequently developed (Ministry of Health and Social Welfare Tanzania 2007a). Vital registration is low in Tanzania, in part because fees are required to obtain both birth and death certificates. The share of government expenditure for health as a percentage of total government expenditure in 2009/2010 was 6.5%, a reduction from 2005/2006 when it was 6.7% (Ministry of Health and Social Welfare Tanzania 2010b) and still a long way off the Abuja target of 15%. Total health in 2009/2010 was 8.2% of Gross Domestic Product with a per

capita amount of USD41 in the same period (Ministry of Health and Social Welfare Tanzania 2010b). The majority of public health expenditures were financed by the donors (39.6%), followed by private expenditure (34.4%) and with public expenditure making up the remaining 26% (Ministry of Health and Social Welfare Tanzania 2010b). Donor funding is focused mainly on malaria and HIV/AIDS, where donor contributions in 2009/2010 represent 40% and 70%, respectively, of the total health expenditure for each of these diseases (Ministry of Health and Social Welfare Tanzania 2010b).

Despite resource limitations, Tanzania has achieved remarkable success in improving child health, with under-five mortality declining by 65% from 1990 to 2010 (Lozano et al. 2011). However, these gains have not been repeated in adults, with death rates among females aged 25-29 years, for example increasing by 71% over the same period (Institute for Health Metrics and Evaluation 2010b). The burden of disease in the country is still dominated by communicable diseases with HIV/AIDS, malaria and lower respiratory infections being the leading causes of disease burden in Tanzania (Institute for Health Metrics and Evaluation 2010b).

Health services in the public sector are provided by a network of hospitals (101), health centres (404) and dispensaries (3715). In the private sector they are provided by Non - Governmental Organisations (NGO), laboratories and private clinics, as well as a mixture of hospitals, health centres and dispensaries (total of 1767). The health system is decentralised, although certain functions, such as financing for medicines, have remained centralised.

Section 1.04 ***Delivery of medicines***

The accessibility of medicines across the country is an important indicator of the quality of service delivery and a contributing factor to the health system goal of

improving both the level and distribution of health. Medicines stockout is also a common indicator across frameworks to measure governance in the health system, and is especially important for certain essential medicines. In Tanzania. Expenditure on pharmaceuticals is estimated at 18% of public health expenditure in 2009/2010 (Ministry of Health and Social Welfare Tanzania 2011). However, this figure is likely to be an underestimate as it doesn't capture expenditure from donors who do not go through the government (such as the US President's Emergency Plan for AIDS Relief –PEPFAR and the President's Malaria Initiative -PMI) nor over the counter expenditure on pharmaceuticals which is recorded in the National Health Accounts. Using information from these various sources, I estimate that in 2010, pharmaceutical expenditure is more likely to be closer to 30% of total health expenditure in Tanzania (see footnote 1 in Chapter 4). Due to the significant expenditure on medicines and for the various reasons discussed above, this thesis has focused on the topic of medicines and investigates the health system factors that influence their availability. In addition, the delivery of medicines in Tanzania has recently changed from a “push” to a “pull” system, thereby further emphasising the need to study how the new medicines delivery system has been integrated into the health system.

Essential Drug program Kit (“push” system) 1983 - 2008

Since the 1990's Tanzania's health sector like the rest of the country has been going through a process of decentralization (Semali et al. 2007), however, medicines and other supplies have remained centrally provided. Prior to 2008, these were provided as standard, pre-packed Essential Drug Program (EDP) “kits” to all health facilities (excluding hospitals) from the Medical Stores Department (MSD), a semi-autonomous, non-profit department under the Ministry of Health and Social Welfare (MoHSW). Kits were coloured either blue or yellow depending on the level of health facility (dispensary or health centre, respectively) (Amenyah et al. 2005). Kits were designed to last a month and as they were procured pre-

packed from both international and national suppliers (Euro Health Group 2007a), the MSD only had to manage up to four variants (Center for Pharmaceutical Management 2003). The standardized nature of the kits, however meant that in some areas certain medicines were depleted at a faster rate, causing stockouts or accumulated surpluses due to differences in catchment areas and disease burdens (Amenyah et al 2005;Center for Pharmaceutical Management 2003;COWI et al. 2007).

Indent/Integrated Logistics System (“pull” system) 2004 -present

In early 2000 the Pharmaceutical Supply Section (PSS) within the MoHSW designed a new “pull” system (indent) which included 70 essential medicines and allowed health facilities (excluding hospitals) to specifically order individual medicines. Vertical programs such as family planning and specific disease control programs including sexually transmitted infections, malaria and HIV, remained independent and developed their own individual supply chains. Under the indent system, health facilities were required to estimate quarterly consumption (current ‘stock on hand’ subtracted from quarterly monthly consumption) for the 70 items and to place quarterly medicines orders through the district office. The indent system meant that the MSD moved away from supplying four stock items, to individually packing 70 products in the orders for over 3000 health facilities every month (Center for Pharmaceutical Management 2003). As with the kit system, health facilities were almost entirely dependent on the MSD for medicines supplies; a study carried out in 2005/2006 found little difference in medicines availability between the two systems (Euro Health Group 2007a).

In 2005, the MoHSW expanded the indent “pull” system to include all vertical programs under the umbrella of the *Integrated Logistics System* (ILS) and rolled it out nationally in 2009. The Expanded Program of Immunization and the National Tuberculosis and Leprosy Programs were excluded however, as they were

deemed to perform well under their own vertical programs (Amenyah et al 2005). The ILS introduced a new ordering system of 12 forms to be completed by health facilities, the Request and Report (R&R) form. The R&R form is used for quarterly ordering of around 100 pre-determined priority medicines and contains a fixed algorithm which requires data from stock ledgers, together with physical counts of inventory, to estimate *presumed* quarterly consumption which is subsequently used to estimate the quantity needed. Health facilities order for seven months in advance: for the three months in a quarter, plus two months to allow for the MSD and District processing time and the remaining two months as a buffer stock to account for any increases in consumption due to seasonal disease patterns and any delays in ordering (Amenyah et al 2005). The ILS therefore increased both the number of medicines ordered and the complexity of the ordering formula.

The DMO is required to check R&R forms for calculation errors before submitting a copy to MSD. Copies of the R&R form are kept at the health facility, the office of the DMO and the MSD. At the district level, health facilities are divided into three ordering groups submitting R&R forms for the quarter in different months at different periods to ease the packaging and processing load at the MSD.

Funds for the purchase of medicines are a combination of the district block grant (from government) and a “basket fund” (from donors). Allocation of funds for medicines purchase is based on the size of the service population and health facility type. Based on the recommendations of the PSS, funds are released quarterly by the Ministry of Finance and Economic Affairs (MoFEA) to health facility accounts in the MSD via the MoHSW. Funding for medicines is based on a revolving fund, whereby once health facilities place orders with the MSD, the funds are released from the individual accounts and transferred to the MSD working capital which can be used for future procurement. The MSD finances its operating costs by charging a 17.4% mark-up on all medicines and supplies, except for

vertical programs where the overhead is lower, at 14% (Euro Health Group 2007b). Health facilities therefore rely almost entirely on delivery from the MSD which, in turn, is reliant on the timely and complete allocation of funds from the MoHSW, which in turn relies on the release of funds from the MoFEA.

Examining the governance issues around the delivery of medicines is crucial as medicines are not only a life saving commodity but they are also a tangible commodity and can be easily diverted. Governance challenges in the delivery of medicine are a global problem (The Economist 2012), both with regard to where fake or counterfeit medicines are found, but also with regard to the supply chain within which these medicines are produced and how they cross international borders. Several international bodies have been designed to address the issue of counterfeit medicines including the WHO's International Medical Products Anti-Counterfeiting Taskforce, and the Medicrime convention signed in 2011 by 19 European countries. At the national level, various reports have studied the availability and traceability of essential medicines in Tanzania and have illuminated areas of concern (Euro Health Group 2009;GIZ and Tanzanian German Programme to Support Health TGPSH 2011a;Ministry of Health and Social Welfare Tanzania 2009;The Global Fund to Fight AIDS Tuberculosis and Malaria 2009b). The Global Fund Audit report carried out in 2009 in three regions focusing on five Global Fund grants that cover HIV/AIDS, tuberculosis and malaria identified capacity shortcomings and lack of coordination which in the case of malaria, simultaneously resulted in an oversupply of ACT (creating expired stock), stockouts of ACT at the health facility level and a large unaccounted amount of ACT (The Global Fund to Fight AIDS Tuberculosis and Malaria 2009b). The 2009 Euro Health report carried out in two regions identified failures at the national level in terms of flow of funds, with budget disbursement being erratic, delayed and often incomplete. Medicines forecasting and procurement were also identified as areas of weakness (Euro Health Group 2009). The 2011 GIZ report carried out in four

regions found severe shortages of several essential medicines and Rapid Diagnostic Test (RDTs) at the health facility level. They identified the main causes to be poor completion of medicines requests at the MSD and lack of capacity at the health facility level to complete medicines orders (GIZ and Tanzanian German Programme to Support Health TGPSH 2011a).

Section 1.05 ***Malaria policy***

Challenges in access to essential medicines become even more important when the medicines are used for treatment against a major public health consequence such as malaria. Malaria is a leading public health concern in Tanzania, especially for children under the age of five and for pregnant women (Tanzania Commission for AIDS (TACAIDS) et al. 2012). According to the latest Tanzania HIV/AIDS and Malaria Indicator Survey (THMIS) 2011-2012, the prevalence of malaria in children under five was 9% (when tested with RDTs (Tanzania Commission for AIDS (TACAIDS) et al 2012), although this reflects a considerable reduction compared to the 2007 – 2008 THMIS which found that 18% of children under five tested positive for malaria (Tanzania Commission for AIDS (TACAIDS) et al. 2008). Malaria prevalence increased with age in under-fives and large regional variations exist. Expenditure on malaria accounts for 19.4% of total health expenditure and 1.6% of GDP in Tanzania (Ministry of Health and Social Welfare Tanzania 2010b) although the domestic budget for malaria activities has fallen by around 30% since 2005 (The Global Fund to Fight AIDS Tuberculosis and Malaria 2009a). The disease places a large burden on the health sector, accounting for around 40% of out-patient department visits in 2008 (Ministry of Health and Social Welfare Tanzania 2008a). Chloroquine was used as the first line antimalarial in Tanzania since the 1960s, as it was readily available in both the public and private sectors at low cost (Kitua 1999), until 1999 when its high failure rate (42%) forced the government to change its national malaria treatment policy to sulphadoxine –

pyrimethamine (SP), banning chloroquine (Eriksen et al. 2005). Following recommendations by WHO, Tanzania again changed its malaria policy in late 2006, deciding that the first line antimalarial for uncomplicated malaria in Tanzania would be an artemisinin-based combination therapy (ACT) - artemether lumefantrine (Alu) (Ministry of Health and Social Welfare 2005). Given the high cost of ACT, Tanzania was granted USD75 million from the Global Fund during its Round 4 disbursements in 2005 (and currently through Round 9) to purchase ACTs for use in the public sector.

Malaria expenditure by donors has doubled as a proportion of total malaria spending, from 18% in 2005/2006 to 40% in 2009/2010; concurrently, public sector contributions to control malaria have declined from 37% in 2002/2003 to 19% in 2009/2010 (Ministry of Health and Social Welfare Tanzania 2010b). According to the 2010 National Health Accounts, there is no (0.0%) government public spending on pharmaceuticals for malaria (ACT) (Ministry of Health and Social Welfare Tanzania 2010b). Tanzania's National Malaria Control Programme (NMCP) is responsible for forecasting ACT demand and managing Global Fund grants for malaria (President's Malaria Initiative 2012). The MSD handles ACT procurement, storage and distribution together with other medicines (Boex and Msemo 2007). Health facilities order ACT along with other medicines via ILS (Amenyah et al 2005). ACTs are provided at no charge to the health facility and, according to policy, are dispensed free to children under the age of five and to adults over 60 years of age (Mubyazi 2004). Those covered by a health insurance fund (National Health Insurance Fund or the Community Health Fund) (www.nhif.or.tz/) are also exempt from payment at the health facility (Chee et al. 2002;Humba 2011). Others pay a user fee of TZS1,000 (USD0.70) (2007 fee) (Mushi 2007). According to the Integrated Management of Childhood Illnesses Guidelines, ACTs are given as a presumptive treatment in the absence of diagnostic tests when a child presents with fever without other symptoms such as rapid breathing or other respiratory

symptoms which could indicate pneumonia or a common cold (WHO and UNICEF 2005).

In addition to ACT, SP is recommended as an intermittent preventive treatment during pregnancy and quinine is used as a second-line treatment when no ACT is available and is also administered to pregnant women in their first trimester (National Malaria Control Programme 2006). These monotherapies, together with others, are widely found on the private market but are often of poor quality and consequently less effective (AMFm Independent Evaluation Team 2012). To remove these monotherapies from private sale, an innovative financing mechanism, the Affordable Medicines Facility – malaria (AMFm) was trialed in seven countries, one of which was Tanzania (others being Ghana, Kenya, Madagascar, Niger, Nigeria and Uganda). AMFm is hosted and managed by the Global Fund and has four objectives, to increase the availability, affordability, market share and use of quality-assured ACTs. It operates at a national scale in private facilities, both for profit and not-for-profit, and also in the public sector. AMFm negotiates price reductions with ACT manufacturers and provides a co-payment to ACT manufacturers and subsidies to countries together with supporting interventions such as training and community outreach (AMFm Independent Evaluation Team 2012). After the first year of implementation, there is evidence that Tanzania has largely achieved these goals for AMFm.

With the availability of a selection of technologies to prevent (bed nets, indoor residual spraying), diagnose (RDTs) and treat (ACT) malaria, all of which are nearly entirely funded by donors, the fact that Tanzania, along with its neighbours such as Kenya (Kangwana et al. 2009b), Uganda (Zurovac et al. 2008) and Zambia (Zurovac et al. 2007a) have been experiencing public sector ACT stockouts over the past five years (GIZ and Tanzanian German Programme to Support Health TGPSH 2011a; Kangwana et al. 2009a; President's Malaria Initiative 2012; The

Global Fund to Fight AIDS Tuberculosis and Malaria 2009b;The PLoS Medicine Editors 2009), is a clear indication of health system failure to deliver both preventative and curative treatment against the second largest cause of premature mortality in the country (Institute for Health Metrics and Evaluation 2010b).

Section 1.06 ***Rationale***

Health is a basic human right and health systems have a responsibility to their citizens to deliver safe, effective medicines at the right price, time and quantity to those in need. In order to meet these goals, health system stewards are required to design systems that facilitate both access and use of quality medicines through public sector health facilities. A clear indicator of health system failure is when tangible resources such as health staff, medicines or supplies are missing.

Discussions around health systems have dominated the global health agenda for over a decade with a wealth of contributions towards defining and assessing health systems and their governance. This has been accompanied by a major shift in donor thinking around the importance of investing in health systems to achieve population health gains. The importance of understanding health systems dynamics becomes increasingly apparent when countries like Tanzania, who receive substantial aid and attention from the donor community, are still unable to offer a complete level of basic care, thereby hampering efforts towards universal coverage. This thesis will attempt to identify the important underlying factors in the governance of the health system in Tanzania that contribute to reduced access to, and efficiency of, health care services.

The principal findings of the thesis are presented in Chapters 3, 4 5 and 6 , in the form of a series of journal articles which bring together in a coherent fashion the

body of research on health system governance in Tanzania. Chapter 3 begins by reviewing the literature about the role of governance in the health sector, and identifies the principal characteristics of these various frameworks that have been proposed, beginning with the seminal framework put forward by WHO in its 2000 World Health Report. We propose an alternative approach to assessing governance issues, built around the identification of a specific governance issue and tracing its effects via a systems thinking framework. In Chapter 4, we examine the implications of the major changes in medicines delivery systems in Tanzania over the past decade with the previous “push” system being replaced by a “pull” system. We conclude that this change has not resulted in a material gain in the delivery of essential medicines, focusing on selected tracer conditions. In Chapter 5, we assess the causes underlying stockouts of the key first-line antimalarial in Tanzania taken as a specific and important consequence of weak health system governance in the country, particularly in the light of seemingly adequate supply of medicines from major donors such as the Global Fund. Finally, in Chapter 6, we examine in greater detail the consequences of governance, as reflected by lack of accountability at the health facility level, on out of pocket payments for already poor households in Tanzania.

These various findings about the availability of essential medicines in Tanzania raise a number of questions, including why are there stockouts of a fully donor funded essential medicine – ACT? What might be the contribution of national and international factors to this pattern of stockouts? And what might be the impact of such stockouts on the health and economic well being of households in Tanzania? This thesis sets out to answer these questions and to contribute to a better understanding of the role of health system governance in improved health system delivery.

PART 2

AIMS, OBJECTIVES, STUDY AREA AND METHODOLOGY

*“We need more money for health, but we need to deliver more
health for the money”*

Julio Frenk, 21 May 2013, Geneva



2. Aims and Objectives

Section 2.01 *Aims*

Specifically, this study aims to contribute to the literature on health system governance by improving the conceptualisation of governance within the health system based on a systems approach to understanding medicine supply issues. It also expands on the current literature by looking at international influences that affect the delivery of essential medicines in Tanzania and the downstream impact on households of some of these decisions.

The insights learned from this research should help identify areas of weakness and guide the development of health system strengthening interventions in Tanzania, and possibly in other countries facing similar concerns.

Section 2.02 *Objectives*

The overarching goal of the work encompassed in this thesis is to demonstrate the importance of taking a systems perspective when evaluating specific health system challenges. We also propose simple, operational methods that could be applied to reconcile data in order to create useful information for policy makers and stewards of the health system.

This thesis has two broad objectives:

Objective 1: To define a framework for the assessment of governance within a health system

Within this objective, we define a series of more specific objectives; namely to ensure that:

- the framework takes a comprehensive health systems approach
- the framework is practical, and

- the framework can be empirically applied

Objective 2: To empirically apply the framework in Tanzania

In this case, the specific objectives are to:

- select a pertinent governance issue affecting the health system in Tanzania and apply the framework to it
- discuss key governance challenges identified from using the health system framework, and
- provide suggestions for future governance interventions

The first research thrust will therefore be to develop a framework that incorporates the latest health systems thinking, highlighting key areas of governance. This will be followed by the application of this framework to the issue of essential medicines availability in Tanzania. Following this, we focus on the availability of the fully donor-funded first line antimalarial and propose reasons why stockouts occurred and how they could be prevented. This will also include an analysis of the behaviour of households during antimalarial stockout when they are seeking care for fever.

Section 2.03 Study areas

Tanzania was selected as a country case study for this research. Tanzania's mainland is composed of 132 districts and 24 regions. This study focuses on two districts in South East Tanzania, the Rufiji District in the Pwani Region, and the Ulanga District in the Morogoro Region (Figure 2.1). Twelve of the 65 villages in the Ulanga District form part of the Ifakara Health and Demographic Surveillance Site (HDSS) that was set up in 1996 (Armstrong Schellenberg et al. 2002). Data on health facility out-patient numbers, medicines consumption, antimalarial stock

counts, household expenditure during care-seeking for fever, and household assets were collected from 2009 – 2011.

The Ulanga district has an estimated population of 265,203 according to the 2012 census, with a malaria parasite prevalence rate in children under five years as tested by RDT of 13.0% in 2011 (Tanzania Commission for AIDS (TACAIDS) et al 2012). The Rufiji District had an enumerated population of 217,274 with a malaria parasite prevalence rate in 2011 in children under the age of five as tested by RDT of 10.2% (Tanzania Commission for AIDS (TACAIDS) et al 2012).

Within both Districts, health services are provided by a mixture of government and private health centres, together with a plethora of private retailers including Accredited Drug Dispensing Outlets (ADDO) and general shops. As both districts are in close proximity to the capital, they both use the central MSD for packaging and delivery of medicines.



Figure 2.1: Location of the Rufiji and Ulanga Districts in Tanzania

INESS

The International Network for the Demographic Evaluation of Populations and Their Health (INDEPTH) Effectiveness and Safety Studies of Antimalarials in Africa (INESS) were designed with the objective to provide decision makers at the national and international level with independent and objective evidence on the safety and the effectiveness of new antimalarial medicines to enhance malaria treatment policy in Africa (INDEPTH Network 2011). INESS undertakes Phase IV studies of new combination therapies for malaria in at least eight INDEPTH HDSS sites in four African countries to provide longitudinal evidence on antimalarial efficacy in real life settings. In Tanzania the study drug is the first line antimalarial ACT, *Coartem*. The INESS project also tracks costs and health seeking behaviour during a fever episode.

In Ulunga, longitudinal survey data was collected on household costs drawing on the INESS methodology with data collection starting in September 2009 until present (INDEPTH Network 2011). Rolling daily household surveys in the Ifakara HDSS identify fever episodes using a two-week recall whereby a randomly pre-selected group are chosen for an in-depth questionnaire about their health-related behaviour and expenditures. Data on individual treatment-seeking pathways, access to treatment, outcomes, outpatient numbers and household costs are captured, together with other key indicators such as the different treatments and sources of medicines, as well as the total cost. Direct financial costs include direct medical costs including consultation fees, prescription fees, and charges for medicines, together with non-medical costs associated with seeking care for fevers such as transport, accommodation, food, water and mobile phone use, together with any gift payments.

In the Ifakara HDSS, households are visited three times a year and once a year an asset survey is administered. The socio-economic status of the households was

defined using Principle Components Analysis (PCA) (Filmer and Pritchett 2001; Vyas and Kumaranayake 2006) based on 15 dichotomous variables. The index was constructed for 5,676 of the households from the following dichotomous variables: ownership of a bicycle (65% of households); radio (69%); mobile phones (43%); watch (6%) and iron (5%); living in rented accommodation (11%); as well as various characteristics of the dwelling such as: mud floor (83%); cement floor (9%); stone walls (33%); brick walls (6%); grass roof (9%); tin roof (1%); kerosene fuel (20%); electricity (2%) and type of sanitary facilities including presence of a toilet (94%). The first principle component explained 23% of the variability in socio-economic scores. Greatest weight was given to ownership of a cement floor (0.38), the use of kerosene for cooking fuel (0.34) and ownership of a mobile phone (0.30). Households were classified into wealth quintiles based on their PCA scores and assigned their own socio-economic score index. Household and health facility Geographic Information Systems (GIS) coordinates were also collected.

SMS for Life

In 2009 an initiative based on mobile phones was launched to investigate stockouts of the first line antimalarial *Coartem* led by the pharmaceutical company Novartis, and piloted in three districts in rural Tanzania. *SMS for Life* trained and engaged health workers to use their mobile telephones to respond to weekly SMS messages reporting on the *Coartem* stock levels in their storage rooms (Barrington et al. 2010a). It also mapped health facilities so that district managers could be informed about stock distribution of all four dosages of *Coartem*. The system is based on asking local health workers to use their personal phones, and sending them a credit when they reported back within a certain time frame. The *SMS for Life* initiative provided real-time detailed data on *Coartem* stock levels in Tanzania.

Health Facility Information

Data on out-patient department numbers, together with the principle disease for which they were treated, as well as medicines dispensed were collected from health facility books under two programs. One of these falls under the routine HIS which requires health facility workers to report yearly summaries of the number of outpatients treated for various diseases collected and collated in *Book 2*. The other data collection system used in this study is based on the forms from the medicines delivery system which recorded the amount of medicines dispensed and consumed.

Section 2.04 *Data entry and analysis*

All data were doubled entered and cleaned. Univariate logistic regression analysis of ACT stockouts on malaria prevalence (see chapter 5) was carried out using Stata 10 and found a highly significant relationship with the slope = 0.88 and a (CI: 0.13 – 1.44), (p=0.004).

Student's t-Test was used to compare differences in means in household expenditure between seeking treatment for fever in the public and the private sector and yielded a t statistic of 1.26 (p=0.21).

Health facility catchment areas were determined using the ArcGIS software (ArcGIS 2012) to create 1km Euclidian buffers around health facilities.

Confidence intervals (CI) were calculated using the Confidence Interval Analysis tool to quantify the uncertainty of estimates (as seen in chapters 4 and 6). This allows a more informative presentation of results than just using *p* values which can sometimes misinterpret non-significant results in small samples.

Section 2.05 ***Ethics***

All of the research reported in this thesis received ethical clearance from the National Institute for Medical Research of the United Republic of Tanzania (NIMR/HQ/R.8a/Vol.IX/998). I also received clearance from the Tanzania Commission for Science and Technology to carry out research activities in Tanzania.

PART 3

RESULTS

“What we know for sure is that donated products, which are supposed to be given free to clinics, are not reaching patients and are being stolen and diverted”

Bates, R. 31 August 2010, *Wall Street Journal*



**How superb malaria
plan has failed TZ**

3. An approach to addressing governance from a health systems framework perspective

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Section 3.01 ***Abstract***

As countries strive to strengthen their health systems in resource constrained contexts, policy makers need to know how best to improve the performance of their health systems. To aid these decisions, health system stewards should have a good understanding of how health systems operate in order to govern them appropriately. While a number of frameworks for assessing governance in the health sector have been proposed, their application is often hindered by unrealistic indicators or they are overly complex resulting in limited empirical work on governance in health systems. This paper reviews contemporary health sector frameworks which have focused on defining and developing indicators to assess governance in the health sector. Based on these, we propose a simplified approach to look at governance within a common health system framework which encourages stewards to take a systematic perspective when assessing governance. Although systems thinking is not unique to health, examples of its application within health systems have been limited. We also provide an example of how this approach could be applied to illuminate areas of governance weaknesses which are potentially addressable by targeted interventions and policies. This approach is built largely on prior literature, but is original in that it is problem-driven and promotes an outward application taking into consideration the major health system building blocks at various levels in order to ensure a more complete assessment of a governance issue rather than a simple input-output approach. Based on an assessment of contemporary literature we propose a practical approach which we believe will facilitate a more comprehensive assessment of governance in health systems leading to the development of governance interventions to strengthen system performance and improve health as a basic human right.

Section 3.02 ***Governance in the health sector***

Low- and middle-income countries are in an era of unprecedented expansion of financial resources for health, both from development assistance and government spending (Institute for Health Metrics and Evaluation 2010a). However, during the recent financial crisis, many donors and governments cut back funding for health (Feachem et al. 2010a), requiring health system stewards to pay more attention to the traceability of fund allocations. Although funding levels can significantly influence health system performance, a large part of the variation in health system performance across countries cannot be entirely explained by conventional factors such as resource allocation (financial, human, technical). Rather, a deeper exploration of governance mechanisms such as formal rules and informal customs could explain some of these differences. Governance has been studied in various dimensions including global governance (Bradford and Linn 2007; Finkelstein 1995), governance of the private sector in offering public services (Salamon 2002), corporate governance (OECD 2004) and governance for development (de Ferranti et al. 2009; Kaufmann et al. 1999). There has also been an increasing interest in understanding the relationship between governance and health at the global level through discussions on global health governance (GHG) (Fidler 2007; Hein et al.; Lee K 2011; Ng and Ruger 2011), together with the development of theoretical frameworks for defining and measuring general governance (Arndt and Oman 2006; Kaufmann et al 1999; United Nations Development Programme 1997). Corresponding to this, there has been an increased interest in the assessment of governance in the health sector. This is particularly important considering the characteristics of the health sector such as asymmetry of information and influence among the growing number of health system stakeholders (Svedoff 2006) who have specific interests and different positions of power which may affect policy development (Walt and Gilson 1994). This has been particularly dynamic over the past decade with the rapid growth in the number of global health initiatives and

their agents at country level. Therefore much conceptual thinking has gone into governance, especially from a political science perspective. It is not the intention of this paper to further contribute to the discourse in this area as, at least for health, this has been done by others (Brinkerhoff and Bossert 2008; Fattore and Tediosi 2010; Savedoff 2009). Instead we aim to provide examples of how these often theoretical considerations could be applied to health system governance. We build on previous literature to develop a modified approach to assess select governance elements within the health system with a view to guiding health system-level interventions. This approach is aimed towards health sector stewards and practitioners who wish to understand potential governance issues within their health system and require a practical tool to do so.

Section 3.03 ***Governance in health systems***

Furthering the discourse on governance is important as this topic is often neglected in international and national debates due to its complex and sometimes sensitive nature. The complex nature is underlined by the numerous definitions of governance and how it differs from management. We use the WHO (2007) definition of governance, namely “*ensuring strategic policy frameworks exist and are combined with effective oversight, coalition-building, the provision of appropriate regulations and incentives, attention to system-design, and accountability*” (WHO 2007). Therefore, good governance from that perspective is understood to be policy- centric including consideration of all actors who exert an impact on the health system together with the various incentives which influence or regulate the system and stakeholder behaviours, though transparent rules overseen by strong accountability links. Improving the understanding of governance is especially important in less developed countries whose health systems are sometimes congested by numerous externally driven health initiatives, who do not necessarily work together or respect country priorities (Ooms et al.

2010) and who need to manage a plethora of stakeholders who influence policies. Governance also incorporates management which is concerned with implementing policies and decisions (Fattore and Tediosi 2010). The importance of governance in health systems is evident from the fact that most conceptualisations and descriptions of health systems developed over the past decade refer to aspects of governance, either in terms of stewardship, regulation, oversight or governance itself (Table 3.1).

Table 3.1: Chronology of major health system definitions, frameworks and concepts

Conceptualisation	Main governance aspects	Reference
Health System Performance	First emphasis on stewardship as a health system function	(WHO 2000b)
Essential Public Health Functions	Strengthening public health regulation and enforcement capacity as one of the eleven essential public health functions	(Pan American Health Organization 2002)
Control Knobs	Regulation as one of the health system control knobs to improve performance	(Roberts et al 2004)
Strengthening Health Systems	Strengthening health system capacity by focusing on stewardship and regulation	(Mills et al 2006)
Health System Building blocks	Articulation of governance as one of the six major building blocks of the health system, and rephrasing stewardship into governance	(WHO 2007)
Health Systems Dynamics	Identifying stewardship and organizational arrangements as one of the four levers available to policy makers to achieve objectives and goals	(Atun and Menabde 2008)
Maximizing positive synergies	Ensuring that governance along with the other six functions of a health system are driven by people to promote equity	(WHO 2008a)
Systems thinking for Health Systems Strengthening	Links system thinking to health system building blocks, and conceptualizes governance across the building blocks	(de Savigny and Adam 2009)
Monitoring Building Blocks of the Health System	Proposes indicators for monitoring governance and the other building blocks of the health system	(WHO 2010a)

One of the most well known and provocative contributions to the health system discourse is the World Health Organisation's 2000 World Health Report on 'Health Systems: Improving Performance'. In this report, the health system was defined as "*all activities whose primary purpose is to promote, restore or maintain health*" and was presented as having four functions: stewardship; resource generation; financing; and service provision. Governance is included under the concept of stewardship which in turn was defined as "*the careful and responsible management of the well-being of the population*". The objectives of the health system were defined as: 1) improving the health of the population they serve; 2) responding to people's expectations; and 3) providing financial protection against the cost of ill health (WHO 2000a). The WHO 2000 health system framework was later updated in 2007 with the release of the WHO report '*Everybody's Business: Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action*' where the health system architecture was further elaborated as having six building blocks: leadership and governance; health workforce; information; medical products, vaccines and technologies; financing; and service delivery (WHO 2007). Here, governance was proposed as "*ensuring that strategic policy frameworks exist and are combined with effective oversight, coalition building, regulation, attention to system-design and accountability*". A year later, the WHO further developed their conceptual framework for primary health care by placing people in the centre of the health system (WHO 2008a). People are vital to the functioning of a health system, both benefiting from it and contributing to it as tax payers and also co-producers of health by adopting certain lifestyle choices (Frenk 2010). A further refinement of the WHO 2007 framework was proposed by de Savigny and Adam (2009) who highlighted the importance of incorporating a systems thinking view of the synergies and interactions among and across all building blocks in the health system (de Savigny and Adam 2009). They point out that governance operates in its own right in the system as well as in every other building block. This is important as any intervention in one building block of the health system is likely to have

system-wide effects which may need to be mitigated or prevented. A systems thinking viewpoint requires a deeper understanding of the complex interactions among the various stakeholders, who may have different objectives and power levels, and how decisions may affect them. Beyond systems thinking in health, it is also important for stewards to recognise the role and impact of the health system in the broader socio-political environment and that health systems are themselves social determinants which can influence education and employment (WHO Commission On The Social Determinants Of Health 2007).

Thus, as the conceptualisation of health systems has evolved, so has a deepening of the understanding of the critical role of governance. However, approaches and methods to systematically assess governance in health systems remain scarce. In the following section, we review various studies which have focused on governance in health and highlight the substantial contributions which they have made towards our overall understanding of the importance of governance.

Section 3.04 *How has governance in health systems been conceived so far?*

A substantial number of studies have discussed the various effects of select aspects of governance on the health sector (Brinkerhoff 2004;Brinkerhoff and Bossert 2008;Chaudhury et al 2006;Das Gupta et al 2003;Lagomarsino et al 2009;Nishtar 2010;Ramiro et al 2001;The Global Fund to Fight AIDS Tuberculosis and Malaria 2008;Transparency International 2006;Vian 2008;WHO 2009). Furthermore, some studies have empirically assessed the magnitude and impact of certain governance elements on health sector performance (Gupta et al 2000;Lewis 2006;Rajkumar and Swaroop 2008). In general, most of the literature on governance and health has focused on single elements of governance such as degree of government effectiveness, degree of corruption and community

participation. They investigated these components using proxy indicators of health sector outcomes or performance such as immunization rates, percentage of low birth weight babies or child mortality. Although important in that they provide evidence of a relationship, these studies do not account for other potential governance elements which could affect the performance of a health system.

Defining governance within the health sector is still relatively new and the composition of governance varies across reports, suggesting that the conceptualisation of governance is an ongoing process. There are, however, a few common elements in governance as identified in Table 3.2.

The latest body of work on governance in health goes further into developing approaches to assess overall governance within the health system (Islam 2007; Lewis and Pettersson 2009; Siddiqi et al. 2009; WHO 2010a). These examples suggest indicators which can be broadly divided into two groups: 1) determinants of governance; and 2) governance performance indicators (Savedoff 2009). Determinants of governance (or rule-based indicators as they are sometimes referred to (Kaufmann and Kraay 2008)) describe whether a procedure, regulation, policy or law exists, whilst a governance performance indicator assesses to what degree rules or policies have been followed and enforced. In general, it is easier to obtain determinants indicators than performance indicators which usually require surveys such as Public Expenditure Tracking Surveys (PETS), facility surveys, exit interviews and household interviews.

Islam (2007) approaches the assessment of governance in the health system by using two summary components. The first is composed of the World Governance Indicators (WGI) (Kaufmann et al. 2009) developed by the World Bank which rates a country on six governance dimensions: voice and accountability; political stability; governance effectiveness; rule of law; regulatory quality; and control of corruption,

leading to an overall governance score for a country. The second component is health specific and breaks governance into five dimensions: information and assessment capacity; policy formulation and planning; social participation and system responsiveness; accountability; and regulation. It proposes a set of illustrative questions to be answered by key stakeholders such as how information is used, how government coordinates donor inputs and who participates in setting the policy agenda? This framework provides a comprehensive range of issues to explore and even provides suggestions on which stakeholders to interview. It has so far been applied in various countries including: Vietnam (Tran Thi Mai Oanh et al 2010), Kenya (Luoma et al 2010) and Angola (Connor et al 2010). Common areas of 'weak' governance found were lack of participation, transparency and strategic vision.

Using a similar approach, WHO (2010) developed a toolkit to assess health systems which included a governance module where they divide the assessment of governance in the health system into either rules-based or outcome-based indicators. The rules-based indicators cover topics such as the existence of an essential medicines list and the existence of key health sector documents. The outcome-based indicators ask questions about the rate of stock-out or the proportion of informal payments. Both rule-based and outcome-based indicators are important. However a weakness of the WHO (2010) toolkit is that despite it being a 'health system toolkit', it asks questions that are limited to disease-specific or vertical programmes such as HIV/AIDS, reproductive health, malaria and tuberculosis, thus leaving out other key areas such as mental health. Furthermore, asking about the 'existence' of such policies says little about their implementation. At present, we can find no example where the WHO governance monitoring module has been applied.

Lewis and Pettersson (2009) developed a list of governance indicators for health systems grouped into five topics: budget management; human resources; institutional providers; informal payments; and institutions. Within each topic, groups of questions are proposed to investigate the topic in detail. For example, within human resources, questions include both governance determinants such as the existence of a licensing system for health care professionals, and performance based such as the frequency of illegal side-payments influencing hiring decisions, or the fraction of contracted staff not on site during a visit. These indicators together with questions on the design of incentives allow the researcher to gain more in-depth understanding of the governance challenges for that particular topic. The indicators are generic enough to allow for comparisons and are a mix of those which can be obtained easily (such as the Country Policy and Institutional Assessment - CPIA index) and those which are more challenging such as the frequency of under-the-table payments. This framework too has not been applied in full in any country to date.

Table 3.2: Summary of governance elements as addressed in selected contemporary health literature

<i>Governance element</i>	<i>Reference</i>			
	WHO 2007	Islam 2007	Siddiqi et al. 2009	Lewis & Pettersson 2009
Accountability	●	●	●	●
Effectiveness / efficiency			●	
Equity			●	
Ethics			●	
Existence of standards		○		●
Incentives	○			●
Information/ Intelligence	●	●	●	●
Participation /collaboration	●	●	●	
Policy/System Design	●	●		
Regulation	●	●		
Responsiveness		●	●	
Rule of Law			●	
Transparency	○	○	●	○
Vision / Direction	○		●	

Key: ● indicates the governance element is identified as a discrete element
○ indicates the governance element is mentioned in context of other elements

Another health-system specific governance framework was developed by Siddiqi et al (2009). The authors adapt the UNDP good governance concept (United Nations Development Programme 1997) to produce a framework which encompasses ten health system governance principles to assess governance of the health system. For each principle, broad questions are proposed for both the national policy formulation level and at the implementation level. The analytical framework has been used for an assessment of health system governance in Pakistan and

identified several areas of weakness such as lack of accountability at the national level and little strategic vision in designing policies.

Finally, there is also a sector-specific governance assessment toolkit ('Good Governance for Medicines') developed by WHO which focuses entirely on the pharmaceutical sector (WHO 2009). The principle goal of this assessment framework is to evaluate transparency in the sector and is accompanied by a guide on how to assess responses, thus reducing the possibility of subjective judgement. This assessment has been applied in 26 countries including: Bolivia; Cambodia; Jordan; Indonesia; Mongolia; and Papua New Guinea.

Most of these frameworks provide 'snapshots' of the state of governance in health systems by developing both quantitative and qualitative indicators. This is advantageous as they can highlight areas of possible gross weakness, for example, whether or not a country has a recent essential medicines list, or if there are irregularities in the payroll for health workers, or a lack of transparency in resource allocation. Some of these frameworks such as WHO (2010) and Lewis and Pettersson (2009) also permit cross-country comparisons which are useful at the international level. However, despite this information being useful for donors or international organisations, it is questionable whether it is useful for health system stewards who probably already know where such governance weaknesses are in their health systems and instead need to better understand why, where and how to intervene.

Section 3.05 *Towards a new approach to assessing governance in health systems*

For a governance framework to be of use to a health system steward it should: 1) be indicative of where governance issues are; 2) weight the individual elements

composing governance in order to identify major drivers for “strong” or “weak” governance; and 3) provide a systematic way to assess these complexities. Our conceptual framework is based on the WHO (2007) model of the health system, but modified to adopt the systems thinking approach suggested by de Savigny and Adam (2009) where all the areas (or building blocks) intertwine (Figure 3.1).



Figure 3.1: Major interdependent health system building blocks

Reproduced with permission from de Savigny and Adam (2009)

For the purposes of extending a system-wide view of governance in the health system we appreciate that not all six building blocks are conceptually equivalent blocks. We see service delivery as a health system output and a primary interface for perceived quality of the health system. Conversely, the health workforce; information; medicines and technologies; and financing building blocks are health system inputs. As governance includes overseeing the entire health system, it permeates all other building blocks and is driven by people and actors in the system. This re-orientation of the WHO (2007) building blocks informs the basis of our framework.

In our approach (Figure 3.2), we draw the most relevant and common governance elements found in Table 3.2 into a non-linear, systems thinking perspective on the health system. These elements can influence the functionality of the health system and can aid stewards to understand how the health system performs.

A vital element of good health system governance is the drive for long term strategic vision which is led by stewards using transparent information and which needs to be translated into appropriate policies with clear rules and correctly set incentives. A well designed system should increase integration and reduce fragmentation and duplication, and it should encourage participation of all relevant stakeholders, both state and non-state (such as citizen groups, pharmaceutical companies, insurance firms), in designing policies. As participation should include voices of numerous stakeholders which may not always be homogenous, health system stewards should strive to seek consensus. Although participation is encouraged, there are instances when too much participation could delay or even harm the delivery of health care (Savedoff 2009). It is also important for stewards to understand the possible informal influences which various stakeholders could be susceptible to and which could influence their voice. To ensure that the rules of the system are adhered to, a major process element of good health system governance is being accountable. Accountability involves “holding public officials/service providers answerable for processes and outcomes and imposing sanctions if specified outcomes are not delivered” (Lewis and Pettersson 2009). More specifically, accountability requires identifying who has authority over what decisions and what their responsibilities include. It also includes understanding how transparent information on responsibilities, available resources and performance is transmitted and used, and what incentives and sanctions are in place which may distort behaviours (Savedoff 2009). If all these elements are in place they can aid in addressing corruption i.e., “misuse of entrusted power for private gain” (Transparency International 2006).

Although both ‘regulation’ and ‘information’ were common governance elements seen in Table 3.2, we did not include them as elements in their own right in our approach. Creating information, we believe, is addressed in the information building block and since regulation includes addressing incentives, setting rules and enforcing them, we consider that this is covered under accountability and system design.

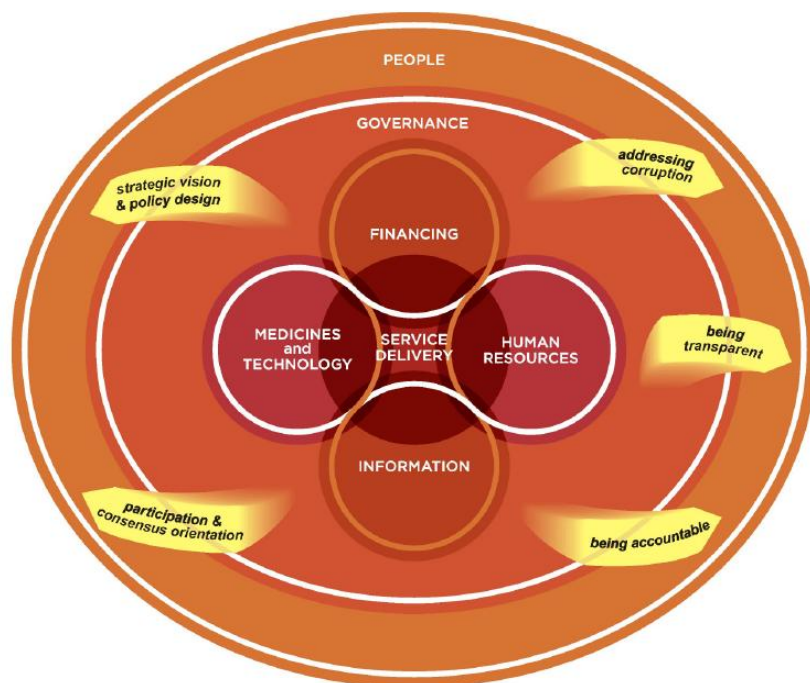


Figure 3.2: Assessing governance across the health system

Note: ‘strategic vision & policy design’ and ‘participation & consensus orientation’ can be viewed more conventionally as governance inputs, whilst ‘addressing corruption’, ‘being transparent’, and ‘being accountable’ are more governance processes

In summary, a well governed health system should have clear goals based on a certain degree of participation of relevant stakeholders especially those from disadvantaged groups or who may have less power to influence policies, and from which transparent policies are designed and adhered to by promoting accountability and reducing the risk of corruption. Although we describe ‘strategic vision & policy design’ and ‘participation & consensus orientation’ as inputs and the

others as processes, these are all interlinked within the governance building block and are dynamic and interchangeable. For example, improving accountability can be considered as an input to strengthening governance. Even an improvement in a single governance element would be an improvement in governance. For example, mitigating ways in which corruption can develop, or improving the transparency of budget allocation would both be considered an improvement in governance. However, these improvements in governance may not be sufficient to increase overall functioning of the health system due to various non-governance factors which can influence overall health system performance (Savedoff 2009). Improved health system performance is a rather general term which could include various outcomes depending on the different interest groups within the health system. It could mean, for example, increased profit maximization for insurance companies, better effective coverage (Lozano et al. 2007) for policy developers, increased responsiveness to the demands and needs of the population for citizen groups, or a general increased level and distribution of health.

Section 3.06 ***Example of an application***

The starting point for the application of our approach would be to select an issue which impedes a health system outcome, for example limiting access and benefit from a public health care service. Various examples have been given above, so for purposes of illustration here we look at governance challenges in the health workforce, more specifically with regards to absenteeism. We recognise that there are other important governance challenges in the health workforce such as the migration of workers from rural to urban areas, or even at a global level which have been addressed by the 2010 WHO Global Code of Practice on International Recruitment of Health Personnel (WHO 2010b). Absenteeism in a health system is an example of an issue which impedes timely access to health care services.

The **first** step the applier would need to do to understand why absenteeism could be occurring and persisting would be to map all the relevant stakeholders involved in human resource decisions and responses and what their roles, authorities, responsibilities and power relationships are (Walt and Gilson 1994). This could be done by using the Policy Maker software which maps out the political dimensions of public policy and provides a guide for thinking about policy reform (Reich and Cooper 1995). It is important to include as many stakeholders as possible as different stakeholders may see the reasons for absenteeism and the possible influence on the health system differently according to multi-finality (de Savigny and Adam 2009).

The **second** step after stakeholder mapping is to work with stakeholders to identify areas where potential problems could be occurring. This can be done as a facilitated brainstorming looking, for example, at possible reasons for absenteeism through considering the design of the system, lines of authority to make decisions, the level of inclusiveness of various groups in the design stage, or transparency of information and how it flows to those with managerial capacity. This can then be represented in a table according to our approach (the **third** step) Table 3.3 illustrates this with an example (health worker absenteeism). As we encourage the assessment of governance throughout the health system, we have included a column for governance as the user also needs to assess the governance of the governing structures (such as health boards). This table guides the user across the approach to ensure that the various elements of governance are considered and how they manifest across the health system. It thus forces the user to take into account areas of the health system which they may not necessarily have considered. For example, the irregular flow of medicines and supplies could discourage health workers from being present. The **fourth** step is a stakeholder assessment to examine this table and rank the most likely combination of tractable issues to be evaluated and identify the balance of incentives and disincentives

which could explain the root cause of the problem (which may vary depending on the context). For example, the evaluators may find that the design of the system has not been adapted to recent health reforms (such as decentralisation) which will affect the balance of power and authority and may result in increased absenteeism in rural areas due to lack of supervision. This process could also aid in identifying the areas of strong governance which could be replicated in other areas of the system.

Table 3.3: Illustration of application of the approach: Considering the determinants for unauthorized health worker absenteeism in public facilities

Governance Element	Building Block				
	Financing Governance	Human Resources Governance	Information Governance	Medicines & Technology Governance	Governance
Participation & Consensus Orientation	Low participation from health workers in defining salary scales	Limited avenues for bringing together community and health workers for discussion	Information on how community can participate in human resource decisions is not clear		Limited channels (such as health boards) for community or health workers to participate and have their voices heard
Strategic Vision & System Design	System does not allow for incentives to be provided for working in less attractive areas; Salary increases not based on performance	Lack of performance appraisals; Distribution of staff not based on service population	The design of the system does not require that data are regularly collected on staff attendance and transmitted to the district	Under-resourced health facilities making working environments less attractive	System not designed to include sanctions that can be placed on health worker by management unit thereby reducing the ability to hold absent staff accountable
Addressing corruption	“Ghost” workers are not identified and continually receive payments	Inability to replace ghost workers	Information on absenteeism is deliberately missing or altered before it is transmitted; no information on sanctions	Absent staff may be taking publicly funded resources with them to sell in the private sector thus increasing incentive to be absent	Lack of supervision to ensure that health workers are present
Being transparent	Transparent information on salary scales and overtime payments is not available to staff	A list of staff on duty is not available to the public	Information on staff attendance is not transferred to the authorities	Knowledge on future stock and flow is not transparent which could reduce the motivation for health staff to be present	Decisions made by health facility boards or management unit on hiring, promotions and firing are not made available to community
Being accountable	Ministry of Finance is not held to account when salary or bonus payments are late	Staff are not held to account when absent	No one is accountable for ensuring that regular, transparent data on staff attendance is collected & turned into information	No one is held accountable if medicines go missing	Lack of enforcement options to hold absent staff accountable at the community or district level when staff are absent

The **fifth** and final step is to design an evaluation of the system-level governance interventions that follows the systems thinking approach (de Savigny and Adam 2009) of combining process, contexts, effects and economic evaluation. For example, if absenteeism was consequent in part due to a lack of supervision because ,following the decentralisation reform, clear policies on supervisory responsibilities and sanctions on health staff absent without leave were not established, then the governance intervention would be to design clear policies on responsibilities and to ensure the authority and resources to implement them. In this example, the direct outcome for the health system of having unnecessary staff absenteeism at public health facilities will be reduced services for patients which may result in longer waiting times and increased dissatisfaction with the health system. If there are limited alternatives in the public sector, patients may lose faith in the public system and turn to the private sector which is usually more expensive and generally even less regulated. This will have equity implications as the poorest segments of the community who may have benefited from free health care now need to purchase their care, or go without care at all. Once these reasons for absenteeism of health staff are identified and understood, the health system can respond by developing and implementing interventions that try to promote incentives which make being absent less attractive. The outcome of this will be to reduce the problem of absenteeism which should have positive consequences for the health system.

Section 3.07 *Differences between approaches to assess governance in health systems*

Assessing and understanding governance in the health system is crucial as public officials, donors and researchers strive to understand how to improve the performance of health systems. The concept of governance in health systems has evolved from a complex and

often neglected issue in health policy debates to one which now features regularly in discussions and has motivated new research. Our approach draws heavily on prior work but differs in that it takes a problem-driven, system-wide approach and suggests a practical way to look at governance concerns through the WHO (2007) building block framework. It is designed to start from a certain governance issue which constrains the health system in performing to its optimum capacity, for example informal payments or unaccounted losses of essential medicines. In this way, our approach follows that of Savedoff (2009) who suggests that for assessment of governance in the health sector, a particular unit of analysis must be identified to focus the attention on relationships and issues which matter (Savedoff 2009). However, it differs in that our starting point is not necessarily an organisation or unit, but a problem which may involve various dimensions across building blocks of the system and therefore requires a broader assessment approach. Our approach guides the evaluator to assess comprehensively the various elements of the governance failure across the system. Like Siddiqi et al (2009) we also recommend that governance is assessed at different levels of the system such as the community, health facility, district, through to the national policy level and beyond (Siddiqi et al 2009), even considering the influence of other organisations such as unions, insurance companies and international partners who may profoundly affect the relationships and rules of the system. Depending on the initial starting point problem, the relevant importance of the different building blocks or governance elements may vary. For example, the relationships which are studied to understand the reasons for variations in medicine prices throughout a country will be different to those which look at whether recruitment is based on skills. If our approach is applied to various issues, it may illuminate common governance issues across various levels of the health system or common entry points for intervention. By promoting an outward driven assessment which includes all building blocks of the health system, our approach avoids reductionist thinking of only

looking at input-output-outcome considerations for any given problem and encourages the applier to see the health system as a set of continuous and synergistic relationships. We recognise however, that there is no panacea to solve governance issues. This is an approach to improve and mitigate governance weaknesses but we do not propose that it would eliminate all governance bottlenecks.

A limitation of our approach is that as it doesn't provide a standard list of indicators. It also does not allow comparisons between different contexts due to its broad nature, but it does take better account of the complexity of governance and is more flexible in that it includes all relevant aspects compared to other approaches based on standardised indicators. Our approach is also limited in that it depends on being able to identify a specific weakness in governance. This could, however, be identified by applying one of the previous frameworks such as Islam 2007, Siddiqi et al. (2009), or Lewis and Petterson (2009). Another limitation is that it only highlights where the barriers are and not how to design appropriate interventions. However by providing this first piece of the puzzle, stewards would be more informed and thus empowered to design interventions.

Section 3.08 ***Concluding remarks***

In summary, based on an assessment of contemporary literature we propose this approach as a practical tool to facilitate the comprehensive assessment of governance in health systems which can be implemented by health system practitioners who are not necessarily specialists in governance analysis. This approach will help to identify the most promising entry points for system-level governance interventions and also has the potential to contribute towards the appropriate design of policies ,taking into consideration the potential impact they have on the entire health system. This approach should also

assist in advancing our understanding of governance in developing and transitional countries where health systems are often underperforming due to lack of investment, poor design and weak management practices, all of which can reduce the level of health care provided which is after all, a basic human right and a fundamental goal of any health system.

Competing Interests

The authors declare that they have no competing interests.

Authors' contributions

IML, KW and DDS contributed equally to the conceptualisation and design of the approach. IML wrote the manuscript and all authors reviewed, contributed to, and approved the final manuscript.

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4. Essential medicines in Tanzania: Does the new delivery system improve supply and accountability?

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Section 4.01 **Abstract**

Objective: Assess whether reform in the Tanzanian medicines delivery system from a central “push” kit system to a decentralised “pull” Integrated Logistics System (ILS) has improved medicines accountability. **Methods:** Rufiji District in Tanzania was used as a case-study. Data on medicines ordered and patients seen were compiled from routine information at six public health facilities in 1999 under the kit system and in 2009 under the ILS. Three medicines were included for comparison: an antimalarial, anthelmintic and oral rehydration salts (ORS). **Results:** The quality of the 2009 data was hampered by incorrect quantification calculations for orders, especially for antimalarials. Between the periods 1999 and 2009 the percent of unaccounted antimalarials fell from 60% to 18%, while the percent of unaccounted anthelmintic medicines went from 82% to 71%. Accounting for ORS, on the other hand, did not improve as the unaccounted amounts increased from 64% to 81% during the same period. **Conclusions:** The ILS has not adequately addressed accountability concerns seen under the kit system due to a combination of governance and system-design challenges. These quantification weaknesses are likely to have contributed to the frequent periods of antimalarial stock-out experienced in Tanzania since 2009. We propose regular reconciliation between the health information system and the medicines delivery system thereby improving visibility and guiding interventions to increase the availability of essential medicines.

Section 4.02 **Introduction**

The effective delivery of medicines requires integration and coordination of the entire health system. Policies are needed that shape the supply systems and its processes, financial systems are needed to purchase medicines, trained human resources are

needed for procurement and delivery, health information systems are needed to identify which diseases are prevalent (and therefore the extent of need) and finally, governance is necessary at all levels to provide oversight and ensure overall availability and accountability of resources in the system. Medicines play an integral role in the performance of the health system (Roberts and Reich 2011;Ruxin et al. 2005); therefore, losses of essential medicines are not only a public health issue, but are an overall indicator of the ability of the health system to deliver adequate and quality health care. Deficits of medicines represent a direct loss of resources, particularly concerning in low income countries like Tanzania where medicines along with medical supplies, constitute the largest discretionary spending in health and account for approximately 10% of total health expenditure (Euro Health Group 2009).

The aim of this study was to investigate how the medicines delivery system has changed in Tanzania over the past decade moving from a “push” to a “pull” system. Our focus was to track the accountability of both systems by following tracer medicines to establish whether the governance of the medicines delivery system has been strengthened as a result of this transition.

Essential Drug Program Kit (“push” system) 1983 - 2008

Despite the various waves of decentralisation experienced in Tanzania during the early 1990’s, medicines and other supplies were still centrally provided (“push”) as standard, pre-packed Essential Drug Program (EDP) “kits” to all health facilities (excluding hospitals) from the Medical Stores Department (MSD). The MSD is the national semi-autonomous, non-profit department under the Ministry of Health and Social Welfare (MoHSW), responsible for the procurement and delivery of medicines to public and Non-

Governmental Organization health facilities. Kits and the MSD were established with help from the Danish International Development Agency, Danida, together with UNICEF and the Government of Tanzania. Kits were coloured either blue or yellow depending on the level of health facility (dispensary or health centre respectively) and delivered six times a year (two kits per delivery) (Amenyah et al 2005). Each kit was designed to last a month and as they were procured pre-packed from both international and national suppliers (Euro Health Group 2007a), the MSD only had to manage up to four variants (Center for Pharmaceutical Management 2003). The kits contained 35 medicines, 17 medical supply items and five stationary items (United Republic of Tanzania 1998). Medicines were selected based on a combination of the National Essential Drug List of Tanzania (NEDLIT) (first created in 1991, and updated in 2006) together with national morbidity data. The MSD delivered kits to the district capital which had two weeks to distribute the kits to health facilities ensuring their arrival on the first day of the month (Euro Health Group 2007a). A study in 1998 found that nearly all (99%) of kits distributed arrived at their destination, suggesting few were being lost during delivery (Price Waterhouse Coopers Tanzania 1999). Nevertheless, the standardized nature of the kits meant that in some areas certain medicines were depleted at a faster rate, causing stock-outs or accumulated surpluses due to differences in catchments areas and disease burdens (Amenyah et al 2005; Center for Pharmaceutical Management 2003; COWI et al 2007). To mitigate stock-outs and expired medicines, the District Medical Officer (DMO) was authorized to re-allocate medicines between facilities; however, due to lack of funds for transport and significant political pressure by communities not to move medicines away from their local facilities, re-distribution of medicines seldom occurred (Gilson et al. 1994).

Indent/Integrated Logistics System (“pull” system) 2004 -present

In early 2000 with support from DANIDA, the Pharmaceutical Supply Section (PSS) within the MoHSW designed a new “pull” system (indent) which included 70 essential medicines and allowed health facilities (excluding hospitals) to specifically order individual medicines. Vertical programs such as family planning and specific disease control programs including sexually transmitted infections, malaria and HIV remained independent and developed their own individual supply chains. Under the indent system, facilities had individual accounts at MSD and received a standard credit roughly equivalent to three monthly kits worth every quarter (Boex and Msemu 2007). Health facilities were required to estimate quarterly consumption (current ‘stock on hand’ subtracted from quarterly monthly consumption) for the 70 items and place quarterly medicines orders through the district office. The DMO was responsible for examining the orders against the available fund credit and then distributing the packages upon receipt from MSD. The indent system meant that MSD moved away from supplying four stock items, to individually packing 70 products in the orders for over 3000 health facilities every month (Center for Pharmaceutical Management 2003). As with the kit system, health facilities were almost entirely dependent on the MSD for medicine supplies; a study carried out in 2005/2006 found little difference in medicines availability between the two systems (Euro Health Group 2007a).

In 2005, the MoHSW in collaboration with John Snow Inc’s DELIVER Project expanded the indent “pull” system to include all vertical programs under the umbrella of the Integrated Logistics management System (ILS) and rolled it out nationally in 2009. The Expanded Program of Immunization and the National Tuberculosis and Leprosy Programs were excluded however, as they were deemed to perform well under their own vertical programs (Amenyah et al 2005). The ILS introduced a new ordering system of 12 forms to be completed by health facilities. The Request and Report (R&R) form (Figure 4.1) is

used for quarterly ordering of around 100 pre-determined priority medicines (all items in the kit were included in this list). The R&R form contains a fixed algorithm which requires data from stock ledgers together with physical counts of inventory to estimate *presumed* quarterly consumption which is subsequently used to estimate the quantity needed.

Beginning Balance	+	Received This Period	±	Lost/ Adjusted	-	Ending Balance	=	Estimated Consumption	Quantity Needed
A		B		C		D		E	$F = (E \div 3) \times 7 - D$

Figure 4.1: Ordering formula used in ILS Request & Report forms, Tanzania

Source: Amenyah, J. et al 2005

From the R&R form, the quantity needed (F) is estimated using the quarterly consumption (E) divided by three to attain the monthly consumption which is multiplied by seven and from which any stock on hand (D) is deducted. Health facilities order for seven months in advance: for the three months in a quarter, two months for the MSD and District processing time and the remaining months as a buffer stock to account for increases in consumption due to seasonal patterns and any delays in ordering (Amenyah et al 2005). The quantity requested is based on quantity needed (F) and the MSD sale catalogue which contains information on pack sizes. The ILS therefore increased both the number of medicines ordered and the complexity of the ordering formula.

Completed R&R forms are submitted to the district for review by both the District Pharmacist and the DMO before being sent to the MSD. Copies of the R&R form are kept at the health facility, the office of the DMO and the MSD. At the district level, health facilities are divided into three ordering groups submitting R&R forms for the quarter in

different months at different periods to ease the packaging and processing load at the MSD.

Funds for the purchase of medicines represent a combination of the district block grant (from government) and a “basket fund” (from donors). The PSS is responsible for providing oversight on medicines policy and assisting health facilities to order medicines using the ILS. Allocation of funds for medicines purchase is based on service population. Based on the recommendations of PSS, funds are released quarterly by the Ministry of Finance and Economic Affairs (MoFEA) to health facility accounts in the MSD via the MoHSW. Funding for medicines is based on a revolving fund, where once health facilities place orders with the MSD, the funds are released from the individual accounts and transferred to the MSD working capital which can be used for future procurement. The MSD finances its operating costs by charging a 17.4% mark-up on all medicines and supplies, except for vertical programs where the overhead is lower at 14% (Euro Health Group 2007b). Health facilities therefore rely almost entirely on delivery from the MSD which, in turn, is reliant on the timely and complete allocation of funds from the MoHSW, which relies on the release of funds from the MoFEA.

MTUHA/Health Management and Information System

At the national level, the forecasts of the demand for selected medicines is based on data collected by the health information system (HIS or MTUHA as known in Tanzania). The current MTUHA developed in the early 1990's (Ministry of Health and Social Welfare Tanzania 2010a) requires health facilities to manually record data in 12 booklets which contain forms and registers. This information is summarised quarterly and submitted to the office of the DMO for review before being computerised and made accessible at the

Regional level. As the MTUHA system was deemed inadequate for some large programmes, a number of parallel, vertical information systems for specific diseases such as HIV/AIDS, Tuberculosis and Leprosy have subsequently been developed (Ministry of Health and Social Welfare Tanzania 2007a) .

Tanzania therefore has two sources of information for monitoring medicines accountability, on the demand side they have the health information system (MTUHA), while data on the supply of medicines come from the ILS at present, and previously from the EDP kits.

We reconcile these two sources of information from both medicines delivery systems to determine whether the accountability of medicines delivery has improved under the ILS.

Section 4.03 **Methods**

“Push” - 1999

Our case-study is based in the Rufiji District in South East Tanzania, one of the 132 districts of Tanzania. The Rufiji District is representative of a rural coastal district in Tanzania and the district selected by the Ministry of Health and Social Welfare for the coastal sentinel demographic surveillance system. In 1999, the Rufiji District, as in the rest of the country, was receiving medicines through the “push” kit system. At the same time, Rufiji was one of two pilot districts (along with Morogoro District), selected for the ‘Tanzania Essential Health Interventions Project’ (TEHIP) (de Savigny et al. 2008) which sought to apply the principles and methods of the *1993 World Development Report* (WDR) on evidence-based planning to guide strategic investments in health based on burden of disease and cost-effectiveness analyses. We went to health facilities to collect individual patient data from ledger books on patient attendances, diagnoses as well as corresponding medicines dispensed at the health facility level. The data collected from facility ledger books were also compared to summary statistics compiled at the facility

under the MTUHA. Data on medicines stock levels were taken from health facilities as the sum of the opening balance inventory carried over to 1999 from the previous year plus the total amount of medicines received in the kits (including any other additional medicines received) minus stock on hand at the end of the year compensating for any expired medicines removed from inventory during the year. From this, the amount of medicines specifically dispensed was compared to identify the fraction of unaccounted medicines (any consumed medicines which could not be accounted for in patient registers). For 1999 this was conducted in six of the 53 public health facilities in Rufiji using a total of 11 “tracer” medicines: mebendazole; metronidazole; ferrous sulphate; penicillin V; magnesium trisilicate; chloroquine; doxycycline; tetracyclin ointment; aminophylline and oral rehydration salts (ORS).

“Pull” - 2009

In 2009 we replicated the analysis for unaccounted medicines in the same six health facilities to determine whether the amount of unaccounted medicines had changed following Rufiji’s move, like the rest of the country, to ILS with training completed in 2009. We used data available at the district level from both the ILS and the MTUHA. As a proxy for medicines dispensed, we used the estimated consumption recorded in the ILS orders. We verified the reported estimated consumption figure by re-doing the arithmetic using the data provided (as part of Figure 4.1). As we were unable to obtain information about medicines dispensed, we restricted the sample medicines to those which were uniquely prescribed for a single disease therefore assuming that the medicines would only be used for treatment of a single disease: artemisinin combination therapies (ACT) as the first line treatment for malaria; albendazole (current anthelmintic) for the treatment of all protozoa infections; and ORS for diarrhoea.

From MTUHA we obtained annual summaries of out-patient data collected at the health facility for malaria, worms and diarrhoea.

Section 4.04 **Results**

Reconciliation of medicines supply under the “Push” system, 1999

The 1999 results illustrate that the summary health information reported under the MTUHA was accurate, with less than 1% difference in total out-patient numbers compared to the information collected from the patient ledgers. Figure 4.2 illustrates that there were important disparities between recorded amounts of medicines dispensed and out-patients recorded for all 11 medicines investigated. We could not account for over 50% of medicines received in 1999 this was most evident in the case of mebendazole where almost the entire stock (83%) was unaccounted for.

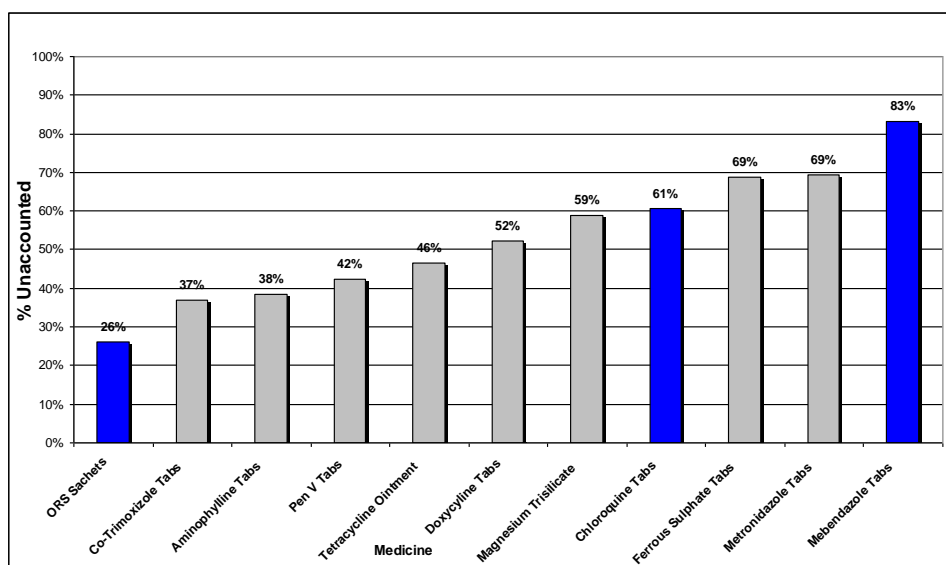


Figure 4.2: Reconciliation of medicines received vs. medicines dispensed, Rufiji, 1999. Sample of two health centres and five dispensaries

* Dark bars represent medicines for tracer disease followed in 2009

Reconciliation of medicines supply under the “Pull” system, 2009

Data gaps existed in the completion of R&R forms where not one of the six health facilities submitted all four forms in 2009. As a consequence of data gaps we combined quarterly estimated consumption from 2009 and 2010 (Table 4.1) to estimate a yearly average. Data gaps resulted in a slight seasonal bias towards dry season orders (Q2 and Q4) – 10, compared to 9 quarters of rainy season (Q1 and Q3) - however the impact would be minimised as dry season orders immediately follow a rainy season.

Table 4.1: Quarterly R&R forms submitted across six health facilities, Rufiji, 2009 and 2010

Health Facility	2009				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1		■	■				■	
2		■	■		■			
3		■		■			■	
4			■		■	■		■
5	■	■		■				
6			■	■		■		

The second challenge was miscalculation by the health worker of ‘estimated consumption’ due to arithmetic errors. These errors in estimated consumption arise from a number of miscalculations including the addition of extra zeros, adding the closing balance instead of subtracting it, or counting medicines that had not been recorded as received (this was especially the case for ACT). Where arithmetic errors were obvious, they were corrected.

Combining the estimated consumption together with information from the health information system, we were able to estimate the amount of unaccounted medicines and then to compare it with the values from 1999 for the same three classes of medicines (Table 4.2).

Table 4.2: Percentage of unaccounted medicines (anthelmintic, antimalarial, ORS) in 1999 and 2009 across six public health facilities in the Rufiji District, Tanzania

Medicine	1999 (95% CI)	2009 (95% CI)
Antimalarial	59.8% (59.7-60.0)	17.8% (17.5 – 18.2)
ORS	63.8% (63.1-64.5)	80.7% (80.1 – 81.3)
Anthelmintic	81.9% (81.6 - 82.1)	71.1% (70.2 -72.0)

Antimalarial: The amount of unaccounted antimalarials was reduced from 60% in 1999 to 18% ten years later. The results are statistically significant at the 95% level.

ORS: The accountability of ORS appears to have deteriorated over the past ten years from 64% unaccounted ORS in 1999 to 81% unaccounted ORS in 2009. The results are statistically significant at the 95% level.

Anthelmintic: The amount of unaccounted anthelmintic was reduced from 82% in 1999 to 71% ten years later. This too, is statistically significant at the 95% level.

Section 4.05 ***Discussion***

As medicines budgets typically constitute a large proportion of discretionary health spending, countries must ensure that the appropriate quantities of medicines arrive at health facilities on time, and once there, are dispensed according to medicines distribution

and treatment policies. The current ILS was introduced to provide *“routine reporting of data coupled with routine ordering of resupplies, which enhances accountability and provides the central level with data for decision making”* (Amenyah et al 2005) and indeed, has the potential to do so. However, from the evidence presented here, not one of the surveyed health facilities studied routinely reported as part of the ILS and there was no uniform improvement in accountability for the three selected “tracer” medicines. Although accountability of anthelmintic and antimalarial medicines appears to have improved, the fact remains that still 71% and 18% are unaccounted respectively, whilst the accountability for ORS appears to have deteriorated. Although reaching a level of 0% of unaccounted medicines would be ideal, counting and arithmetic errors are realistically likely to occur in administrative data. Therefore, for the purpose of this study, we set a level of 85% accounted medicines as acceptable. This level reflects the general uncertainty, inaccuracy and incompleteness of information available from routine reporting systems, it is a generous margin of error, and not intended as a gold standard. The ILS did not reach this level and is therefore in need of a management response.

Considering that the MSD price of a tin of 100 tablets of albendazole is currently TZS 1,600 (US\$ 1.00), TZS 11,000 (US\$ 7.09) for 100 ORS sachets (MSD price catalogue 2011) and the government recommended retail price of a subsidised dose of ACT is TZS 1,000 (US\$0.60) (Yadav et al. 2012), then the yearly value of the unaccounted medicines in 2009 was US\$ 3,630 for the six health facilities. Projected to the Rufiji District level, the annual value of unaccounted medicines would be around US\$ 31,500.

Due to the use of secondary data which in some instances was incomplete, our study is subject to bias. For example, the six health facilities were not randomly selected but

selected on the basis of accessibility to facilitate data collection. The implication of this could be that the health facilities were more likely to have a larger flow of medicines but also more frequented by patients, therefore the bias could move in both directions. We also assume that each of the three “tracer” medicines is used for a single disease, yet this may not always be the case.

A possible limitation of our study design is that our methods rely on different data sources for the amount of consumed medicines; where in 1999 this came directly from medicines dispensed, whilst in 2009 this was derived from estimated consumption. Although demand driven (number of patients) information was collected the same way in both periods (using summary HMIS records), we were only able to verify the accuracy of the 1999 data. The health information data may have deteriorated over the years as health workers become increasingly burdened with the rise in the number of vertical programs and may not see the purpose of accurately reporting data. Therefore, a likely contribution to the unaccountability of “tracer” medicines may be that not all patients seen were recorded.

Poor record keeping and late submission of ordering forms by health facility workers has been found by others (Chimnani et al. 2010;Euro Health Group 2007a;GIZ and Tanzanian German Programme to Support Health TGPSH 2011a). The lack of capacity of health facility staff to correctly order and manage medicines was also reported in a GIZ-funded project assessing 87 health facilities in four Regions in 2011 (GIZ and Tanzanian German Programme to Support Health TGPSH 2011a). In addition, the GIZ report found that in some cases during redistribution of medicines by the District Pharmacists, medicines ledger books were not adjusted. The risk of mistakes in ordering at the health facility level is accentuated in the case of ACT due to the four separate doses (based on patient weight) and because of the seasonality of malaria. Ordering mistakes could have contributed in part to the frequent periods of ACT stock-out which Tanzania has

experienced since 2009 together with other factors such as delayed procurement and distribution by the MSD due to lack of funds or capacity.

On the demand side, another limitation could be the changes in clinical treatment guidelines where for example, in the past albendazole was more readily dispensed, or changes in patient demands may have resulted in patients receiving a dose of ACT, ORS or albendazole even if they came into the health facility for another purpose.

A contributing factor to some of the “tracer” medicines not being fully accounted for could be leakage along the medicines supply chain, perhaps, involving direct pilferage. Incidences of theft of medicines at the health facility level in Tanzania have frequently been reported in the press (Siyame 2012a;The Citizen 2011); for example, the Daily News recently described the arrest of several pharmacists from a pharmacy owned by employees of the regional hospital who were discovered selling medicines intended for the public sector, especially malarial medicines (Siyame 2012b). The Audit Report on Global Fund grants to Tanzania in 2009, reported a comparison between number of malaria cases and estimated ACT consumed which found nearly twice the amount of ACT consumed for the number of malaria patients, suggesting a “leakage” in the ACT medicines delivery (The Global Fund to Fight AIDS Tuberculosis and Malaria 2009b). ACTs also have a much higher re-sale value than previous antimalarials (chloroquine) and the street value of ACT would have increased during periods of national public sector stock-outs which may increase the incentive for pilferage. Such leakages have also been found in other countries; a study by McPake and colleagues (McPake et al. 1999) in Uganda using similar methods to ours together with qualitative evidence, found very high medicines leakages which resulted in weaker health worker performance.

Our results are inconclusive whether the ILS is better or worse, but emphasize the point that both systems clearly reveal an unacceptable accountability gap. Two general obstacles could explain this, the first is complexity in the design of the logistics system, the second being its governance. Design weaknesses in the ILS include an increased work burden on staff by requiring them to make many difficult calculations for over 100 products every three months and submit forms in person to the district capital. Going to the district capital could mean over a day's travel for those working in some remote locations which would leave these health facilities without staff during the travel period. Limitations of health worker capacity were also found during an evaluation of the ILS pilot in Dodoma and Iringa regions in 2005 where health workers were failing to fill in requests for all priority medicines and to submit the R&R forms on time (Amenyah et al 2005). These problems could be mitigated through increased training of staff and if the ordering was done using mobile phones or digital devices and the ordering system was simplified, for example, with calculations of estimated consumption being done only once a year and quarterly deliveries from the MSD being based on these estimates.

The ILS was designed to integrate the vertical programs with the essential medicines program but certain vertical programs such as TB, AIDs and vaccines still operate separately. These items are delivered through their respective vertical programs, with additional reporting systems which have the potential to create further confusion and workload for health workers. Integrating these programmes into the ILS would avoid parallel systems and reduce the burden on health workers to report separately. Design failures of supply chains in low income countries have been identified as one of the most important barriers to access to medicines (Kraiselburd and Yadav 2012).

Regarding governance, the ILS appears to have limited accountability structures. For instance, no individual (health facility worker or district health official) is held accountable if an ILS form is not submitted or if repeated mistakes in calculations are being submitted to the MSD, gaps in the data hamper efforts towards improving accountability. If no order is placed, then no medicines arrive with the ultimate consequence that the community goes without medicines. Lack of district oversight was also found in the 2010 evaluation by Chimnani et al. (Chimnani et al 2010). Our study also found cases where the district re-submitted old forms with new dates. Achieving accountability requires a degree of transparency, although the ILS is designed to increase transparency, if health workers do not complete forms adequately, then the ILS cannot provide information on medicines distribution once at the facility level. Data reconciliation with the health information system (MTUHA) as done in this study, would be a simple way to check the plausibility of medicines ordered.. Introducing systematic data reconciliation between the ILS and the MTUHA would greatly improve information on rational medicines consumption. Without the ability of the ILS to fully account for medicines ordered, delivered, prescribed and used, the system will continue to suffer from inherent inconsistencies combined with increasing vulnerability and negligence. In the case of essential life saving medicines such as ACT, the need for accountability is increased to ensure avoidable mortality is reduced.

At present Tanzania is investing significant resources towards a mHealth strategy which will strengthen some of the limitations of the ILS under the 'ILS Gateway' model, a USAID funded project. The ILS Gateway is a mobile phone-based alert and reporting system for the supply and logistics of 20 essential health commodities and is being piloted across 1,600 public health facilities. The mHealth rollout will also include other disease monitoring initiatives using mobile phones. Together, these initiatives should make reconciliation of data easier and highlight inconsistencies. Another recent change is that

the MSD will deliver directly to health facilities (bypassing the DMO), making the MSD fully accountable for the entire supply chain. This, in combination with the mHealth strategy is encouraging considering the increasing number of new initiatives (medicines donations and low cost access initiatives) together with an expected rise in the number of health facilities (7,000 by mid 2013), both of which may augment the workload and complexity at the MSD increasing the need for a reliable reporting system.

Section 4.06 **Conclusion**

The availability of medicines at health facilities is a critical element of service delivery quality, without which the districts will be seriously limited in their ability to provide adequate health care. To our knowledge, this study is the first to critically examine the availability of medicines under the current logistics supply system compared to the previous kit system. This study suggests that there is an opportunity to reconcile information on the demand for essential medicines with their supply. This approach could be a way of exploring the accountability of resources in a health system, which was not exploited under either medicines delivery system. Of the three medicines we compared, absolute accountability rates were still low in the ILS with around 20% to 80% of medicines not being accounted for, and with one tracer (ORS) experiencing a deterioration in accountability compared to the previous kit system. Such degrees of unaccountability in the distribution of medicines suggest that the ILS is unable to effectively monitor the supply and use of medicines, thus facilitating a health system environment in which obfuscation can occur and in which performance can go unrewarded. Although the ILS was designed to increase accountability and to reduce wastage of resources, its overly complex and “paper-driven” design together with other factors such as limited regular staff

training and supervision has constrained it from fully achieving these targets. As essential medicines constitute a key component of service delivery quality, which in turn is critical for improving effective access, urgent system design and governance interventions need to be developed to fundamentally strengthen this critical aspect of the health system.

Authors' contributions

DDS and IML contributed equally to the conceptualisation and design of the approach. PC, GR, DDS, HK and CM led the work in the field in 1999 and IML and DDS led the field work in 2009. DDS and IML managed and analyzed data. IML, DDS, PC and GR wrote the manuscript and all authors reviewed, contributed to, and approved the final manuscript.

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District Medical Officer who granted us permission to collect facility based information and the staff at the District Hospital and the Rufiji Demographic Surveillance Site (DSS) who helped locate the data. Finally we are most grateful to the reviewers who provided valuable suggestions on the final manuscript.

5. The challenge to avoid anti-malarial medicine stock-outs in an era of funding partners: the case of Tanzania

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Section 5.01 **Abstract**

Background

Between 2007 and 2013 the Tanzanian public sector received 93.1 million doses of first-line anti-malarial artemisinin-based combination therapy (ACT) in the form of artemether-lumefantrine entirely supplied by funding partners. The introduction of a health facility ACT stock monitoring system using SMS technology by the National Malaria Control Programme in mid 2011, revealed a high frequency of stock-outs of ACT in primary care public health facilities. The objective of this study is to determine the pattern of availability of ACT and possible causes for observed stock-outs across public health facilities in Tanzania since mid-2011.

Methods

Data was collected weekly by the mobile phone reporting tool SMS for Life on ACT availability from over 5,000 public health facilities in Tanzania starting from September 2011 to December 2012. Stock data for all four age-dose levels of ACT across health facilities was summarised and supply of ACT at the national level was also documented.

Results

Over the period of 15 months, on average 29% of the total health facilities in Tanzania were completely stocked out of all four-age dose levels of the first-line anti-malarial with a median duration of total stock-out period of six weeks. Patterns of total stock-out by region ranged from a low of 9 to a high of 52%. The ACT stock-outs were most likely caused by: a) insufficient ACT treatments entering Tanzania (e.g. in 2012 Tanzania received 10.9 million ACT doses compared with a forecast demand of 14.4 million doses); and b) irregular pattern of ACT supply (several months received no ACT stock).

Conclusion

The reduced ACT availability and irregular pattern of supply were due to cumbersome bureaucratic processes and delays both within the country and the main donor, the Global Fund to Fight AIDS, Tuberculosis and Malaria. Tanzania should invest in strengthening both the supply system and the health information system using mHealth solutions such as SMS for Life. This will continue to assist in tracking ACT availability across the country where all partners work towards more streamlined, demand driven and accountable procurement and supply chain systems.

Section 5.02 ***Background***

Malaria is of leading public health concern in Tanzania, especially for children under the age of five and pregnant women. According to the latest Tanzania HIV/AIDS and Malaria Indicator Survey in 2011-12, the prevalence of malaria rapid diagnostic test (mRDT) - confirmed malaria in children under five was 9% (National Bureau of Statistics (NBS) et al. 2012). This is an important reduction compared to findings from the previous five years in the 2007-08 Malaria Indicator Survey, when 18% of children under five tested positively for malaria (National Bureau of Statistics (NBS) et al. 2008). Expenditure on malaria interventions (including prevention and curative) accounts for 19.4% of total health expenditure and 1.6% of Gross Domestic Product in Tanzania (Ministry of Health and Social Welfare Tanzania 2010b), although the domestic budget for malaria activities has decreased by around 30% since 2005 (The Global Fund to Fight AIDS Tuberculosis and Malaria 2009a). The disease places a large burden on the country's health sector, accounting for around 40% of outpatient department diagnoses in 2008 (Ministry of Health and Social Welfare Tanzania 2008a).

At the end of 2006, Tanzania changed its policy on first-line anti-malarial treatment for uncomplicated malaria to use of artemisinin-based combination therapy (ACT) - artemether-lumefantrine (ALu) (National Bureau of Statistics (NBS) et al 2008); due to the high cost of ACT, Tanzania received USD 75 million from the Global Fund to Fight AIDS, Tuberculosis and Malaria (henceforth referred to as the Global Fund) during its Round 4 disbursements in 2005 (continuing currently through Round 9) to purchase ACT for use in the public sector. In rural Tanzania, for fever it has been shown that 58% of the population access their health services from public health facilities and the remaining 42% access from the private sector including faith-based organizations (Mikkelsen-Lopez et al. 2013).

Tanzania's Ministry of Health and Social Welfare (MoHSW), through its National Malaria Control Programme (NMCP), is responsible for forecasting ACT demand and managing Global Fund grants and President's Malaria Initiative (PMI) ACT supplies for the malaria programme (President's Malaria Initiative 2012). The Pharmaceutical Services Section (PSS) is tasked with developing policy on pharmaceutical services and technologies. The Medical Stores Department (MSD), a parastatal of the MoHSW, is charged with handling health commodities for the public sector, including ACT procurement, storage and distribution (Boex and Msemo 2007). Public health facilities order ACT quarterly along with other medicines through a "pull" system via the Integrated Logistic System (ILS) (Amenyah et al 2005). ACT are provided to the public from government health facilities and, according to policy, are dispensed free to children under the age of five years and to adults over 60 years (Mubyazi 2004). Others pay a user fee in the public sector of TZS 1000 (USD 0.70) (fee since 2007) (Mushi 2007). As stated in the 2005 Integrated Management of Childhood Illnesses Guidelines, ACT are given as a presumptive treatment in the absence of diagnostic tests, when a child reports with fever without other

symptoms, such as rapid breathing or other respiratory symptoms, which could indicate pneumonia or a common cold (WHO and UNICEF 2005). However recognising that presumptive treatment may result in over prescribing of ACT, mRDTs were rolled out in Tanzania in early 2009 with national coverage by early 2012 for routine use in all levels of care for parasitological confirmation of malaria (Masanja et al. 2012). Apart from ACT, other anti-malarials offered include sulphadoxine–pyrimethamine (SP), which is recommended only as intermittent preventive treatment during pregnancy, and quinine which is a second-line treatment for cases contra-indicated for ACT, administered to pregnant women in their first trimester, or in cases of severe malaria, not responding to first-line treatment (National Malaria Control Programme 2006).

The design of the ACT procurement and delivery system is intended to guarantee routine availability in the public sector. Nonetheless, Tanzania, along with its neighbours, has been experiencing public sector ACT stock-outs over the past five years (GIZ and Tanzanian German Programme to Support Health TGPSH 2011b;Kangwana et al 2009a;President's Malaria Initiative 2012;Sudoj et al. 2012;The Global Fund to Fight AIDS Tuberculosis and Malaria 2009b;The PLoS Medicine Editors 2009;Zurovac et al. 2007b;Zurovac et al 2008) with serious consequences for health care delivery and also to household health expenditure as seen in the Ulanga District in Tanzania (Mikkelsen-Lopez et al 2013). The objective of this study is to describe ACT availability across public health facilities in Tanzania and highlight some of the factors that influence it.

Section 5.03 **Methods**

Data on the availability of ACT were obtained from the *SMS for Life* reporting system (Barrington et al. 2010b), which was originally developed by the partnership of the NMCP,

Roll Back Malaria, Novartis Pharma AG, Vodafone, IBM, Medicines for Malaria Venture, and the Swiss Agency for Development and Cooperation, and which is now fully owned and operated by the MoHSW with support from the Global Fund. The *SMS for Life* system monitors weekly ACT stock levels via a mobile phone Short Message Service (SMS) for all four age-specific dose levels of ACT plus quinine. The ACT doses are divided into individual colour-coded blister packets according to weight of the patient: yellow packs for infants weighing 5 kg to under 15 kg; blue packs for toddlers weighing 15 kg to under 25 kg; red packs for children weighing 25 kg to under 35 kg; and, green packs for children weighing more than 35 kg and adults. Weekly SMS prompts are sent to designated primary care facility health workers in each health facility on their personal phones. Facility health workers are then required to report back within 27 hours on the stock count of full boxes of ACT in the store room for each of the four types. These messages are free of charge and if the health worker reports within 27 hours, they receive a credit on their phone (TZS 1,000, equivalent to USD 0.7) for personal use (pay for performance). Weekly summary and detailed status reports of stock situations in each facility are subsequently provided automatically to the District Medical Officer (DMO) and District Pharmacist. This aids to determine and indicate which health facilities are at risk of stocking out, or actually stocked out of any dose level of ACT. The data are also made available on a password-protected website which displays current and historical stock status by health facility in a user-friendly, dashboard-driven application. Information is provided both graphically in trend format and on weekly-updated, interactive maps for greater interpretability. The website is available to the DMOs, the Regional Medical Officers, the NMCP, the MSD and the MoHSW-PSS and others stakeholders including Population Services International (PSI), Medicines for Malaria Venture (MMV) and the Swiss Agency for Development and Cooperation (SDC). The *SMS for Life* system began as a 21-week pilot in October 2009 covering 129 health facilities in three rural districts: Kigoma Rural (Kigoma Region), Lindi

Rural (Lindi Region) and Ulanga (Morogoro Region). It was rolled out nationally two years later across all 132 districts, eventually covering 5,014 public health facilities by September 2011.

Data was collected from *SMS for Life* for 15 months from October 2011 to December 2012 inclusive for this study. The data, comprising the weekly numbers of boxes in stock, by colour-code, for each facility were downloaded in delimited ASCII format and tabulated using SAS v9.3 statistical software. A small number of facilities reported stocks that were multiples of thirty of plausible numbers of boxes. It was assumed these reports referred to numbers of blister-packs rather than of boxes, and divided accordingly.

Weeks where stock increased (compared with the preceding report) were assumed to correspond to deliveries, and a stock-out was identified when the facility reported that they had no stock for one or more colours of blister packs. The study concentrated on total ACT stock-out when all four colours of blister-packs are simultaneously stocked out, since health workers could otherwise cope with a stock-out of only one or a few dose levels by dividing or combining blister packets of other dose levels. Stock-out data by health facility type (public and voluntary) is shown in Figure 5.1.

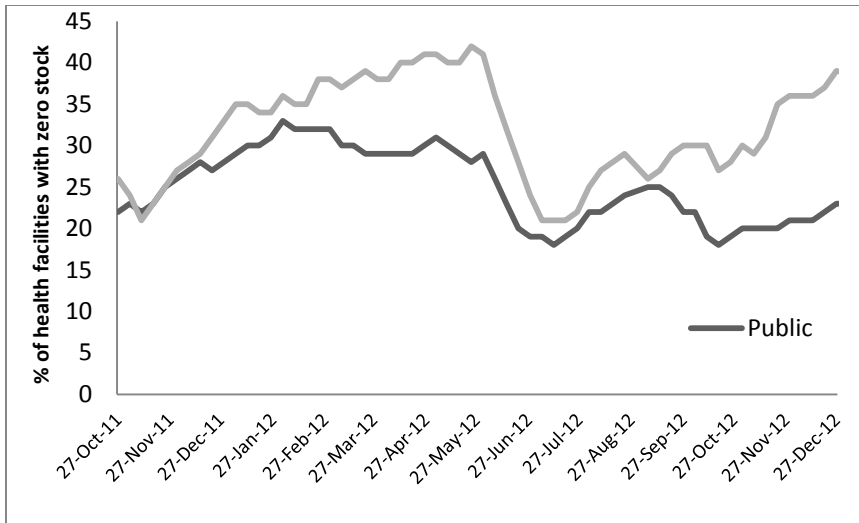


Figure 5.1 Percentage of health facilities reporting total artemisinin combination therapy stock-out, by health facility type (Public and Voluntary), Tanzania, October 2011 to December 2012

The 55,047 weeks when a stock-out was reported fell into 11,423 sequences of continuous reporting of stock-out in the same facility. 5,936 of these periods ended with an ACT delivery and the remaining terminated with a censoring event, (either a week where the report was missing or the end of the study). Kaplan-Meier analysis was used to estimate the distribution of durations of periods of stock-out allowing for these censoring events.

The drug usage rate in facilities that were not stocked-out was estimated as the average rate of decrease in stocks when there was no delivery. This estimated drug usage was added to the reported increase in stocks during weeks when there was a delivery to give an estimate of the total amount of drug delivered. This study also documented the quantities of ACT shipped and delivered to Tanzania by Novartis Pharma Ag, (which at the time of the study was providing all public ACT in Tanzania).

Not all health facilities reported every week in both 2011 and 2012. Table 5.1 illustrates the percentage of health facilities which failed to provide any report by region for both years. For the complete year of 2012, 11% of health facilities failed to report across the country and 8.6% of health facilities failed to report at all during the entire study period. Wide variations in the regional reporting performance were identified from approximately 30% of health facilities in Singida and Dodoma regions failing to report at all, whilst only 0.5% of health facilities in Iringa and Shinyanga regions provided no reporting.

Table 5.1 Percentage of health facilities never reporting under *SMS for Life* by region, 2011 and 2012

Region	2011	2012
	(%)	(%)
Singida	29.6	29.1
Dodoma	29.5	29.8
Morogoro	21.7	21.7
Manyara	14.0	16.0
Arusha	13.2	12.2
Lindi	13.1	10.8
Katavi	11.5	13.5
Mbeya	11.1	12.0
Kigoma	11.0	10.5
Ruvuma	10.1	7.6
Kilimanjaro	9.9	16.0
Dar	9.7	13.7

Tanga	8.9	9.3
Coast	8.1	7.0
Rukwa	8.0	8.0
Mwanza	6.7	8.5
Mtwara	6.5	9.5
Tabora	6.4	8.2
Simiyu	4.4	2.3
Njombe	3.8	4.3
Mara	3.1	4.3
Kagera	2.8	4.0
Geita	1.9	5.5
Iringa	0.6	1.2
Shinyanga	0.5	1.9

Short-term average, non-response rate in 2011 showed that 19.8% of weekly SMS request prompts sent received no response, while in 2012 this had increased to 27.7%. However the duration of non-response in any given facility was short (average 1.8 weeks). In instances when there was a missing report, the information was interpreted from the stock data of the previous week.

Stock-out data by region is derived from the number of weekly SMS received across all health facilities that reported zero stock as a proportion of the total number of SMS received by region across the 15 month study period and is reported in Table 5.2.

Table 5.2 Regional malaria prevalence and average regional artemisinin combination therapy total stock-out rates in health facilities in 2011-2012

Mainland

region	Prevalence	% total stock-out
Tabora	9.2	52.4
Kigoma	26	51.6
Ruvuma	12	42.6
Geita	31.8	42.5
Shinyanga	6.8	42.1
Mtwara	17.4	41.1
Mwanza	18.6	40.3
Rukwa	4.5	37.8
Simiyu	3.4	36.8
Morogoro	13	35.6
Mara	25.4	31.7
Katavi	5.4	29.7
Lindi	26.3	24.7
Tanga	5.6	24.3
Njombe	2.4	22.5
Dar es Salaam	3.6	22.4
Iringa	0.4	21.9
Arusha	0.05	19.7
Kagera	8.3	19.2
Pwani	10.2	18.1

Mbeya	0.05	15.1
Kilimanjaro	0.05	14.8
Manyara	0.9	14.4
Singida	0.2	12.4
Dodoma	2.5	8.7

A simple univariate linear regression analysis was used to study the relationship between malaria prevalence rates and ACT stock-out rates, where regional average ACT stock-outs across the 15 months were regressed against regional malaria prevalence rates for 2011.

Section 5.04 **Results**

During the period of study, there were 3030 logins of which 620 logins were by DMOs in districts, 32 by Ministry system administrators and 150 by the NMCP.

The proportion of health facilities that recorded simultaneous zero ACT stock of all four doses (total stock-out) as a proportion of all health facility weeks, averaged across the month and across all health facilities by region, is illustrated in Figures 5.2 and 5.3.

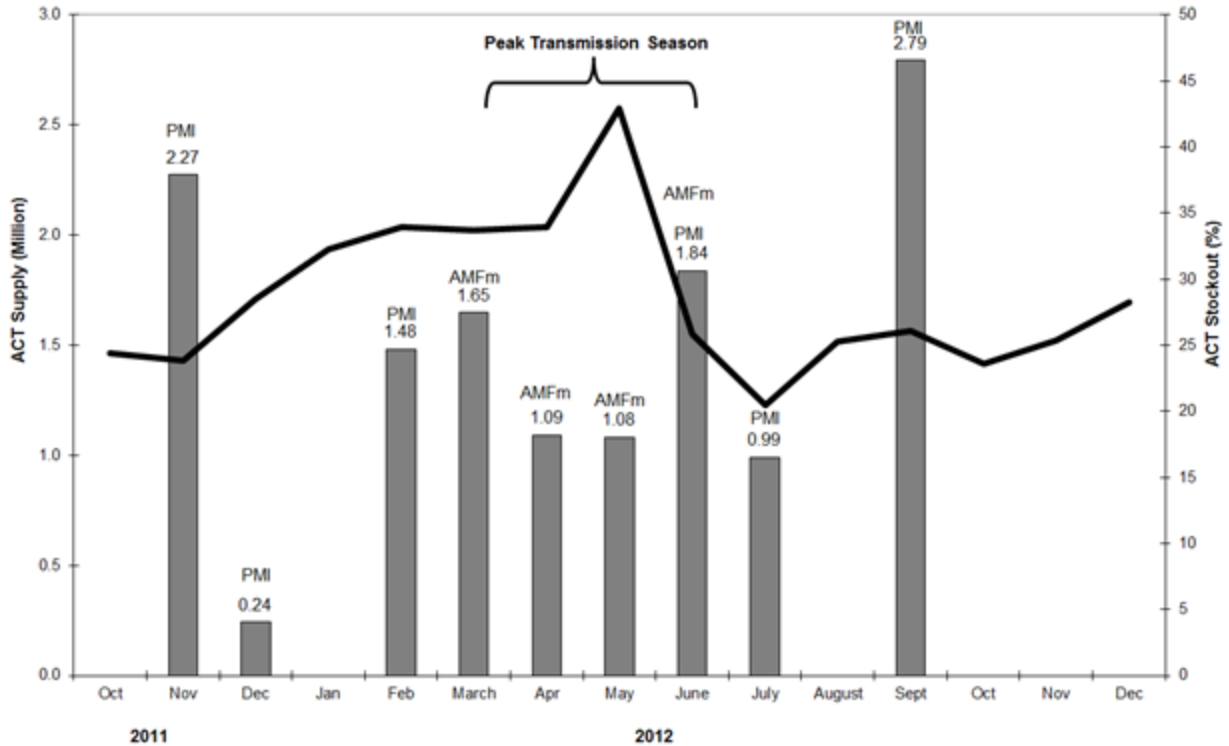
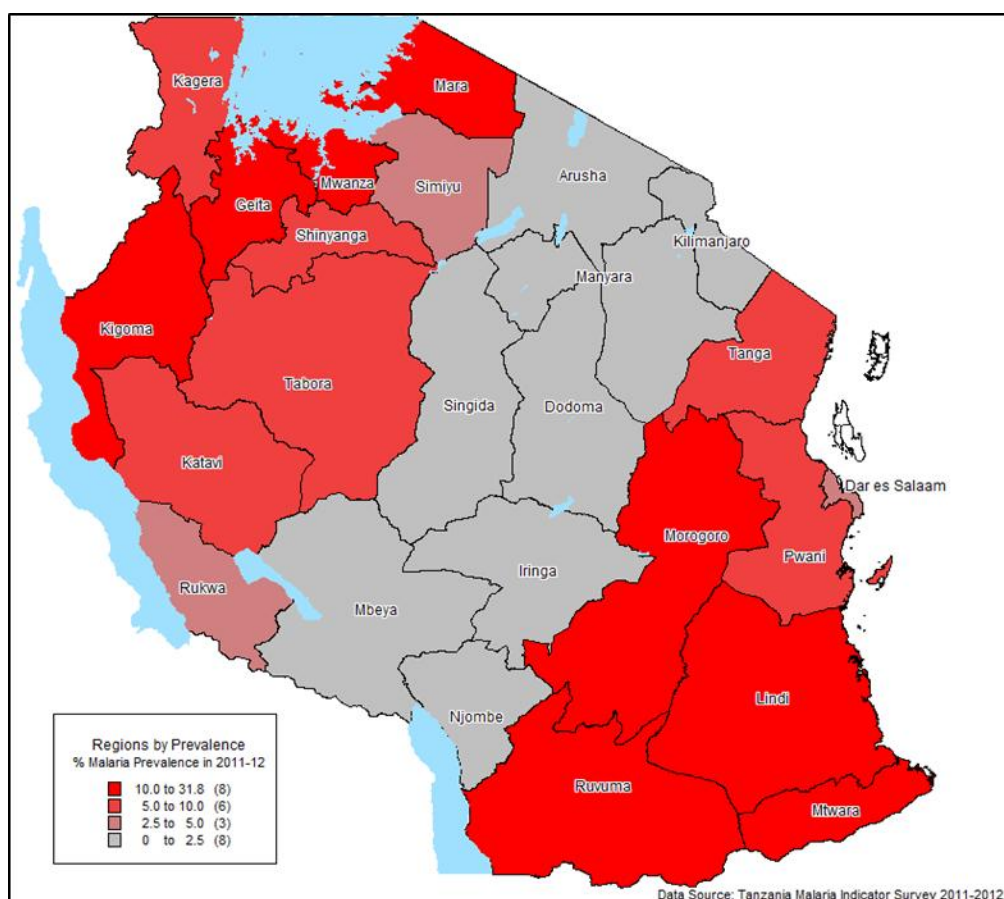


Figure 5.2 Percentage of health facilities with total artemisinin combination therapy stock-out, Tanzania, October 2011 to December 2012

Bars show ACT dose shipments (millions) from the supplier to the public sector (either from PMI or AMFm or both in June 2012)

Figure 5.2 shows the proportion of health facilities with ACT stock-out (line) and the bars indicate the ACT supply quantities (with corresponding source). For example, in May 2012 43% of health facilities reported zero ACT stock. For the whole period from October 2011 to December 2012, on average 29% of SMS health facility responses reported a total ACT stock-out. The peak total ACT stock-out period was in the rainy season of April-May 2012, when total ACT stock-out rates reached 40%, implying that nearly half the country was totally stocked out of ACT in the public sector. The estimated median duration of stock-out was six weeks (inter-quartile range 2-14 weeks), with Dar es Salaam experiencing the shortest ACT stock-out and Shinyanga the highest.

Figure 5.3 compares average stock-out rates from the *SMS for Life* reporting system and malaria prevalence in children under the age of five from 2011-2012 Tanzania National HIV/AIDS and Malaria Indicator Survey across the 25 regions of Tanzania mainland. A simple linear regression analysis suggests that higher malaria prevalence rates correlate positively with higher ACT stock-out rates where for every 0.8% increase in prevalence is associated with 1% higher stock-out rates ($r^2=0.34$, $p=0.002$).



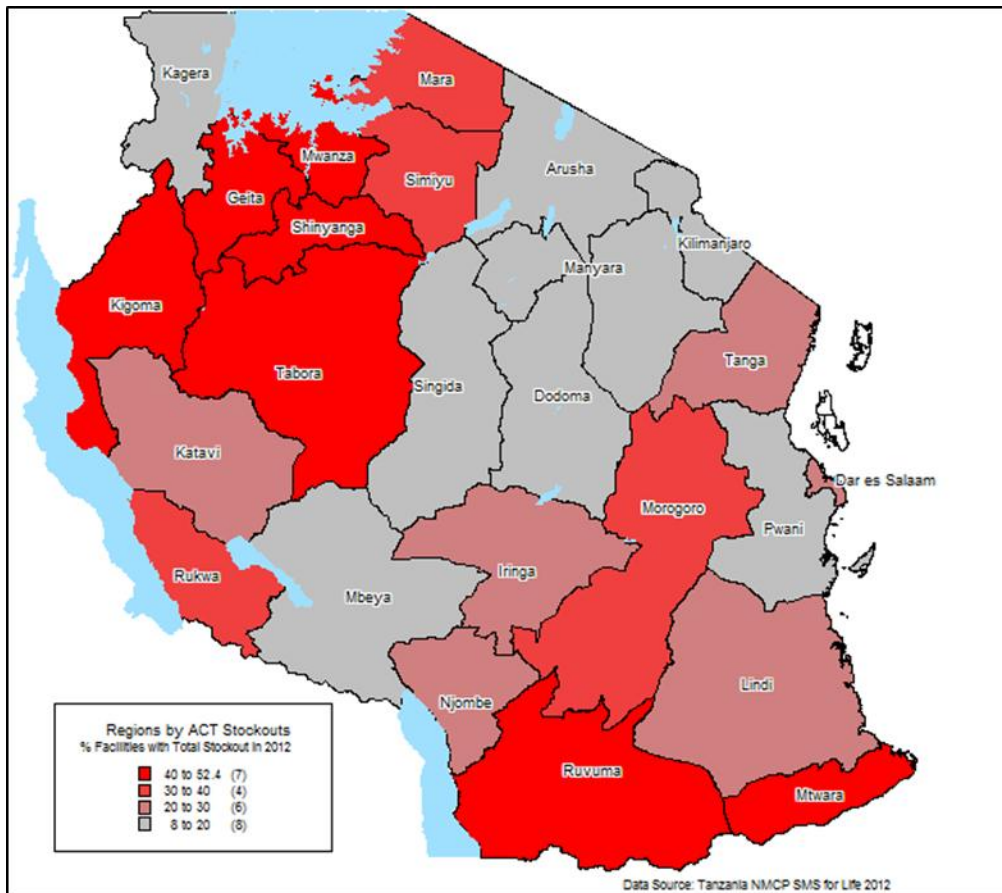


Figure 5.3 Malaria prevalence (top panel) and average annual total stock-out rate of artemisinin combination therapy in health facilities (bottom panel) by region in 2011-2012 in mainland Tanzania

The study found that over 90% of ACT doses that were reported delivered from Novartis in 2012 were documented by *SMS for Life* as passing through the supply chain to the front-line public health facilities, however this is a conservative estimate as it is not adjusted for non-reporting.

Section 5.05 **Discussion**

The ACT stock-outs in Tanzania mainland have not been well documented in the literature. By the mHealth innovation of *SMS for Life* producing real-time weekly stock

reporting, it has been possible for the first time to determine the frequency, magnitude and distribution of stock-outs at the point of delivery in primary care facilities. It was found that across the 15-month study period, average weekly health facility total ACT stock-out rates were 29%, although short-term, non-response among reporting units may mean actual levels are higher. Moreover, of particular concern is that ACT stock-outs averaged around 40% during the rainy season of March-May 2012. These overall results are disappointing considering the pilot programme demonstrated promising results, where stock-outs of three out of the four doses of ACT were greatly reduced or eliminated after the 21-week pilot study period in three districts (Barrington et al 2010b). A similar pilot study undertaken in Kenya in 87 health facilities across 26 weeks from mid-2011-mid-2012 found that 5% ACT stock-out identified at the start of the *SMS for Life* programme was completely eliminated by the end (Githinji et al. 2013). Considering ACT is both lifesaving and available to Tanzania through various donor assistance programmes, these long and persistent stock-outs highlight an unacceptable situation. These are evidence of severe and prolonged health system failures which deserve prompt response at local, national and global level.

Various factors could account for these periods of stock-outs. At national policy level, the current system is designed in such a way that Tanzania forecasts its needs for ACT in discussion with the Global Fund and relies entirely on donor support for its supply (Ministry of Health and Social Welfare Tanzania 2008b) (Figure 5.4).

Year Quarter	Global Fund				Doses (M)	PMI Emergency doses (M)	Comment
	R4	R7	AMFm	R9			
2004 Q1							Global Fund Grant Status
2004 Q2							Submitted
2004 Q3							Signed
2004 Q4							ACT orders
2005 Q1							
2005 Q2							
2005 Q3							
2005 Q4							
2006 Q1					0.53		
2006 Q2					1.08		
2006 Q3					2.54		
2006 Q4					4.86		
2007 Q1					2.56		
2007 Q2					10.95		GF withholds US\$1.2m due to stock management issues
2007 Q3					1.62		
2007 Q4						0.52	
2008 Q1					6.56	0.15	
2008 Q2					5.8		Local Fund Agent warns against stockouts in report
2008 Q3							PMI report predicts stockout: Q3 2009 - Q3 2010
2008 Q4					3.23		
2009 Q1					3.42	0.52	
2009 Q2					3.22		Global Fund Round 7 Reprogrammed to host AMFm
2009 Q3					7.53		AMFm and Round 9 grant proposals both warn about ACT stockout Q4 2010
2009 Q4						3.48	
2010 Q1							PMI report predicts stockout Q3 2011
2010 Q2					4.76	3.65	
2010 Q3						3.57	R7 reprograms USD 5M ACT from private sources for emergency public sector use
2010 Q4							
2011 Q1						1.53	
2011 Q2					2.71		
2011 Q3					2.21	2.52	
2011 Q4						2.52	
2012 Q1					1.65	1.48	
2012 Q2					3.27	0.74	
2012 Q3						3.78	
2012 Q4							
Totals					68.5	24.48	
					93.0		

Figure 5.4 Chronology of important procurement and supply events for artemisinin combination therapy on Tanzania mainland, 2004 to 2012

PMI has intervened numerous times in the public sector and in 2012 provided over half the total amount of ACT (55%), whilst the rest was provided under the Affordable Medicines Facility - malaria (AMFm) initiative through the Global Fund (AMFm Independent Evaluation Team 2012), aimed at increasing universal access to malaria medicines (Adeyi and Atun 2010).

Increased reliance on funding partners raises the risk of creating a moral hazard where records indicate that the Tanzanian government has reduced its malaria budget from USD 5.2 million in 2006-2007 to USD 2.0 million in 2008-2009 (President's Malaria Initiative (PMI) USAID 2013), a trend identified across other countries that have reduced their

domestic funding to health subsequent to increased donor funding (Lu et al. 2010). Relying on donor support puts Tanzania at risk of having to abide by external rules and processes; for example, the delay in Global Fund Round 7 application in 2009 for almost two years was a consequence of changes in grant architecture including consolidating various rounds that included malaria under one grant as 'Single Stream Funding' and having to restructure the grant to host the new AMFm (AMFm Independent Evaluation Team 2012;The Global Fund to Fight AIDS Tuberculosis and Malaria 2011). Since the government could not foresee this delay it had no plans to mitigate the shortage. As a result, during 2009 and 2010 Tanzania had to rely on various PMI emergency ACT procurements (another moral hazard), in addition to using residual funds from Round 4 and reprogramming funds from the initial Round 7 grant for emergency ACT procurement (Figure 5.4).

Only in the second quarter of 2011 did AMFm-funded ACT for the public sector enter the market. The entry of AMFm resulted in a dramatic price reduction of ACT for Tanzania. Despite this price reduction in 2012, Tanzania received from AMFm and PMI a monthly average number of doses of 0.9 million, 25% less than the estimated required 1.2 million doses per month calculated from the yearly ACT consumption, taken from the Round 9 Proposal from Tanzania (The Global Fund to Fight AIDS Tuberculosis and Malaria 2009a). The roll out of AMFm into the public sector followed the introduction of AMFm in the private sector. The private sector was less bureaucratically constrained in accessing the AMFm mechanism and was able to move rapidly to acquire co-paid product. This could also explain why the public sector did not receive sufficient quantities in the early stages of AMFm (AMFm Independent Evaluation Team 2012).

Another policy change which could impact ACT stock was the rollout of mRDTs where other things being equal, one could expect a reduced ACT demand following an mRDT negative confirmation. Unfortunately *SMS for Life* did not record stocks of mRDTs.

At local level, ACT together with other essential medicines are delivered to health facilities through a “pull” system, requiring health facility workers to manually fill in orders for medicines. They further submit these quarterly to the DMO, who forwards the requests to the MSD to pack individual health kits. The delivery of ACT in this study took place during a change in delivery system from a system where previously the MSD was responsible for delivery from the central warehouse via its nine zonal stores to the districts, where the DMO was then responsible for storing and delivering them to health facilities. However in 2011, the MSD changed policy to ‘Direct Delivery’ where the MSD delivers medicine packages directly to the health facilities (USAID Deliver Project 2011). If health facility workers do not place orders, they do not receive medicines or other commodities.

Furthermore, as there is weak reconciliation between the health information system and the medicines ordering system, it is impossible for the health system to assess whether health facility workers are ordering sufficient quantities to cater for the disease profile of the community they serve. The Tanzania procurement and supply logistics system requires that health facility orders be made quarterly, based on the consumption/usage from the previous quarter. The formula for ordering includes a buffer stock of two months, but such ordering systems can be confused by seasonal demand and by stock-outs if they occur. Even with precise and adequate ordering, stock-outs at front-line levels can occur when commodities are not in full supply at regional or national levels. This type of stock-out cannot be managed at the facility level.

Prevalence of malaria and the need for treatment varies geographically across Tanzania. Figure 5.3 suggests that stock-out rates are higher and of greater duration in areas of high prevalence compared to low prevalence, as might be expected when there are limitations in supply. A key implication of such consistently higher stock-out rates in areas of higher prevalence is that populations, especially children in most need of anti-malarial treatments, are unable to obtain them from their local health facility.

Assuming that Tanzania orders sufficient quantities of ACT, contributing factors to stock-outs could be poor distribution or leakage of ACT. A study of the diversion of anti-malarial medicines in Africa found that the largest share of diverted anti-malarials came from Tanzania, particularly ACT, which were found in private pharmacies in Accra and Lagos, Nigeria (Bate et al. 2010). Additionally, there are recent reports that some ACT purchased from a street market in Angola in early 2013 were part of a shipment that was originally donated by either PMI or the Global Fund to Tanzania (Faucon et al. 2013). However, as this study reported, in 2012 90% of ACT doses shipped were documented by *SMS for Life* as arriving to front-line public health facilities. This figure is surprising considering that 11% of health facilities in 2012 did not report. Several explanations could contribute to this, firstly, the assumption that any increase in supply from one week to the next corresponds to a delivery maybe incorrect, where possibly the increase was just due to undercounting in the previous week. Secondly, additional supplies could have entered the system from previous deliveries in 2011. Lastly, the missing data correspond disproportionately to stock-outs, where some facilities never had ACT and didn't see any point in reporting. Whatever the explanation, the 90% figure is conservative and it is clear that there was plenty of ACT in the system.

All of these factors suggest that the reasons behind stock-outs could include a complex mix of challenges with bureaucracy around vertical purchasing and procurement, issues related to distribution strategies in relation to malaria risk, other health system barriers and weaknesses in delivery systems, and illegal diversion. All of these challenges contribute either directly or indirectly to constrain availability of ACT at front-line health facilities.

Transparency of ACT supply is increasingly being demanded as the situation becomes a topic of civil society discussion (HabariLeo 2013; Msikula 2013; The Citizen Reporter 2013). *SMS for Life* reporting is password-protected and directly accessible to only a limited group of people in the NMCP, the MSD and PSS. However, all involved in forecasting, procurement and delivery of ACT are informed of national stock-outs through the NMCP ACT Technical Working Group, and consequently may be unaware of stock-outs at the dispensary level. Therefore a policy option available to Tanzania would be to make *SMS for Life* type data publicly available to enable all stakeholders involved in ACT supply and provision to obtain information on ACT stocks.

To lower the risk of future ACT stock-outs, Tanzania mainland could consider securing subsidized ACT through the AMFm programme and allocate domestic funds to co-finance ACT purchase, thereby creating a national buffer and security stock in addition to buffers built in to the front-line health facility stocks, and thereby reduce dependency on donors. However a buffer or security stock is only of value if health system barriers in supply can be overcome. *SMS for Life* could also be used for setting more accurate minimum stock levels at the health facility. Most importantly, DMOs and District Health Management Teams (DHMTs) must use the data to make decisions on re-ordering, restocking and redistribution among health facilities to minimize short-term stock-outs between ordering cycles. A pattern of demand could be plotted and modelled to be able to determine the

consumption rates trends and seasonal variations, in order to have a more accurate mitigation plan to avoid stock-outs.

This study has some limitations. *SMS for Life* data included short periods of non-reporting by individual health facilities. The high frequency of short-term, non-response in 2012 could have been due to the lack of immediate response to, and follow-up of, non-reporting health facilities by the DMO or the District Malaria Focal Person or possibly also to a lack of managing health facility worker administrative data (e.g., changes in personnel and phone numbers and thus request messages not reaching the right persons). Another possible explanation could be that the regions receiving initial training during the pilot did not benefit from a refresher training and subsequently had higher non-reporting rates; for example, in the initial three pilot regions, Kigoma, Lindi and Morogoro, had relatively high short-term, non-response rates of between 26 and 37%. Finally, given that stock-outs in some facilities were prolonged, the health staff may have thought it not worthwhile to report weekly once a stock-out started.

This study was unable to determine whether stock-out rates were higher among non-reporting units compared to those that did report; if that were the case, then the estimate of 30% total ACT stock-out, on average, might be 10-20% too low. Further, this study was not able to examine the stock of ACT in the private sector because such data from *SMS for Life* are not available (however the Independent Evaluation of the AMFm Phase 1 does include information on ACT availability in the private sector (AMFm Independent Evaluation Team 2012). It is likely that the ACT availability would be better as the private sector is less affected by constraints in procurement faced by the public sector, in addition, the private sector may have better defined incentives or disincentives structures which encourage efficiency, but this would need to be explored further.

Section 5.06 **Conclusions**

This study investigated ACT availability across public health facilities in Tanzania for 15 months from October 2011 until the end of 2012 and found that during this period, 29% of health facility-weeks were completely stocked out of first-line anti-malarial (ACT). An immediate consequence of this was that a significant number of the 14 million cases of malaria that Tanzania experiences each year could not receive first-line treatment at a public health facility. The principle reasons for not receiving the first line treatment at a public health facility and failure of the health system to maintain quality of care was due to the heavy reliance on, and difficulties in, compliance with international funding cycles, and fundamental delivery system design flaws at national level and subnational level. Both of these risks are addressable, and should be done so urgently by Tanzania and its development partners to avoid a catastrophic resurgence of malaria mortality in the country. With potential ACT resistance, it is imperative that Tanzania secures a stable ACT supply with adequate buffer stock, and implements the use of mRDTs to provide the population with rational use of an affordable treatment against one of the country's major public health concerns as part of its strategy of ensuring universal coverage for the treatment of malaria. Both ACT and mRDTs need to be monitored weekly at central and zonal warehousing and at all public front-line health facilities, taking advantage of new mHealth innovations, such as *SMS for Life*. *SMS for Life*-type systems are useful to understand stock availability at point of delivery. More importantly, such real-time information needs to be directly used for managing the supply chain, not merely to understand how much it is failing.

Competing Interests

JB and RZ are employees of Novartis Pharma AG, Switzerland

Authors' contributions

DDS, IML, JB, and RZ contributed equally to the conceptualization and design of the approach. IML, TS and DDS analysed the data. IML, WS and DSS wrote the manuscript and all authors reviewed, contributed to and approved the final manuscript.

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6. Beyond antimalarial stock-outs: Implications of health provider compliance on out-of-pocket expenditure during care-seeking for fever in South East Tanzania

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Section 6.01 **Abstract**

Background: To better understand how stock-outs of the first line antimalarial, Artemisinin-based Combination Therapy (ACT) and other non-compliant health worker behaviour, influence household expenditures during care-seeking for fever in the Ulanga District in Tanzania. **Methods:** We combined weekly ACT stock data for the period 2009-2011 from six health facilities in the Ulanga District in Tanzania, together with household data from 333 respondents on the cost of fever care-seeking in Ulanga during the same time period to establish how health seeking behaviour and expenditure might vary depending on ACT availability in their nearest health facility **Results:** Irrespective of ACT stock-outs, more than half (58%) of respondents sought initial care in the public sector, the remainder seeking care in the private sector where expenditure was higher by 19%. Over half (54%) of respondents who went to the public sector reported incidences of non-compliant behaviour by the attending health worker (e.g. charging those who were eligible for free service or referring patients to the private sector despite ACT stock), which increased household expenditure per fever episode from USD0.14 to USD1.76. ACT stock-outs were considered to be the result of non-compliant behaviour of others in the health system and increased household expenditure by 21%; however we lacked sufficient statistical power to confirm this finding. **Conclusion:** System design and governance challenges in the Tanzanian health system have resulted in numerous ACT stock-outs and frequent non-compliant public sector health worker behaviour, both of which increase out-of-pocket health expenditure. Interventions are urgently needed to ensure a stable supply of ACT in the public sector and increase health worker accountability.

Section 6.02 **Background**

Universal Coverage

The key goals of universal coverage as outlined in the *World Health Report 2011* require knowledge about: the proportion of the population covered by health services, together with widening the range of available services and reducing the proportion of total costs born by individuals (World Health Organization 2010). In order to meet these objectives, some countries have focused their efforts on achieving universal coverage for selected health topics by developing essential medicines lists, which, according to the WHO, identify medicines that “satisfy the priority health care needs of the population” and should be available at prices the public can afford, with assured quality.

Essential Medicines in Tanzania

Tanzania’s current 2007 National Essential Medicines List includes medicines for 26 priority conditions, one of which is malaria (Ministry of Health and Social Welfare Tanzania 2007b). Malaria is a leading public health concern in Tanzania especially for children under five and pregnant women (National Bureau of Statistics (NBS) Tanzania and ICF Macro 2011). Expenditure on malaria programs make up 19.4% of total health expenditure and 1.6% of GDP (Ministry of Health and Social Welfare Tanzania 2010b). The disease places a large burden on the health sector accounting for around 40% of out-patient department visits in 2008 (Ministry of Health and Social Welfare Tanzania 2008a). Since 2006, the first-line antimalarial for uncomplicated malaria in Tanzania is an Artemisin-based Combination Therapy (ACT) - Artemether lumefantrine (Alu). However, given the high costs of ACT, Tanzania was granted USD75 million from the Global Fund to fight AIDS, Tuberculosis and Malaria (henceforth referred to as the ‘Global Fund’) during its Round 4 in 2005 (and currently through Round 9) to purchase ACTs (which come in four

doses based on patient weight). Tanzania's National Malaria Control Programme is responsible for forecasting ACT demand and managing Global Fund grants for malaria (President's Malaria Initiative 2012), while the Pharmaceutical Supply Unit is charged with setting policy on medicines and supplies and budgeting for medicines. It also monitors the use of funds and supervises health facilities. The Medical Stores Department (MSD) handles ACT procurement, storage and distribution together with other medicines (Boex and Msemu 2007). Health facilities order ACT along with other medicines through a 'pull' system via the Integrated Logistic System (ILS) (Amenyah et al 2005). The ACTs are provided at no charge to health facilities and, according to policy, are dispensed free to children under the age of five and to adults over 60 years of age (Mubyazi 2004). Those covered by a health insurance fund (National Health Insurance Fund or the Community Health Fund) (www.nhif.or.tz/) are also exempt from payment at the health facility (Chee et al 2002;Humba 2011). Others pay a user fee of TZS1000 (USD0.70) (2007 fee) (Mushi 2007), although independent confirmation has found this to vary and can be as low as TZS500 per visit. According to the Integrated Management of Childhood Illnesses Guidelines (IMCI), ACTs are given as a presumptive treatment in the absence of diagnostic tests when a child reports with fever without other symptoms such as rapid breathing or runny nose which could indicate pneumonia or a common cold (WHO and UNICEF 2005). Apart from ACT, other antimalarials are Sulphadoxine – Pyrimethamine (SP), which is recommended only as intermittent preventive treatment during pregnancy, and quinine which is a second-line treatment administered to pregnant women in their first trimester (National Malaria Control Programme 2006).

The design of the ACT procurement and delivery system should ensure availability in the public sector. However, Tanzania along with its neighbours, has been experiencing public sector ACT stock-outs over the past five years (GIZ and Tanzanian German Programme to Support Health TGPSH 2011b;Kangwana et al 2009a;President's Malaria Initiative

2012;Sudoj et al 2012;The Global Fund to Fight AIDS Tuberculosis and Malaria 2009b;The PLoS Medicine Editors 2009;Zurovac et al 2007b;Zurovac et al 2008) which cripples the delivery of health care services. Our objective is to investigate the impact of public sector ACT stock-outs together with health worker behaviour on care-seeking during a fever episode and the associated household expenditures.

Section 6.03 ***Methods***

Data for our case-study were obtained from the Ulanga District in South East Tanzania with an estimated population of 265,203 according to the 2012 census and with a malaria parasite prevalence rate in children under five years of age as tested by a Rapid Diagnostic Test of 13.0% in 2011 (Tanzania Commission for AIDS (TACAIDS) et al 2012). Health service infrastructure in Ulanga is composed of two hospitals (one public), three health centres and 30 dispensaries (16 public). The estimated population per facility is 4,571. We combined data from three surveys carried out in Ulanga District between November 2009 and August 2011.

Household behaviour and expenditure

We used longitudinal survey data on household costs drawing on the International Network for the Demographic Evaluation of Populations and Their Health (INDEPTH) Effectiveness and Safety Studies of Anti-malarial Drugs in Africa (INESS) methodology, starting in September 2009 until present (INDEPTH Network 2013). Rolling daily household surveys in the Ifakara Health and Demographic Surveillance Site (HDSS) identify fever episodes using a two week recall where a randomly pre-selected group is

chosen for an in-depth questionnaire on their behaviour and expenditures. There was no clinical verification that a fever episode was a case of malaria. Data on individual treatment seeking pathways, access to treatment, outcomes, services at provider level and household costs are captured, together with other key indicators such as the different treatments and sources of medicines as well as the total cost. Direct financial costs are considered to include direct medical costs such as consultation fees, prescription fees and charges for medicines, together with non-medical costs such as transport, accommodation, food, water and mobile phone use in addition to any gift payments. Respondents are grouped into public or private sector based on their first provider, even if they received medicines from the other.

Household demographics

As part of the Ifakara HDSS, households are visited three times a year and once a year an asset survey is administered. The socio-economic status of households is based on 15 dichotomous variables using principle component analysis (PCA) (Filmer and Pritchett 2001; Vyas and Kumaranayake 2006). The index was constructed for 5,676 of the households from the following dichotomous variables: ownership of a bicycle (65% of households); radio (69%); mobile phones (43%); watch (6%) and iron (5%); living in rented accommodation (11%); as well as various characteristics of the dwelling such as: mud floor (83%); cement floor (9%); stone walls (33%); brick walls (6%); grass roof (9%); tin roof (1%); kerosene fuel (20%); electricity (2%) and type of sanitary facilities including presence of toilet (94%). The first principle component explained 23% of the variability in socio-economic scores. Greatest weight was given to having a cement floor (0.38), the use of kerosene for cooking fuel (0.34) and ownership of a mobile phone (0.30). Households were classified into wealth quintiles based on their PCA scores and assigned their own socio-economic scores index. Household and health facility Geographic

Information Systems (GIS) coordinates were also collected in the HDSS. Health facility catchment areas were determined using the ArcGIS software (Esri 2012) to create 1km Euclidian buffers around health facilities.

SMS for life

We used information provided by the *SMS for Life* project (Barrington et al 2010a) which monitors weekly stock-levels via a mobile phone Short Messaging System (SMS) on all four dose levels of the ACT *Coartem* in 35 health facilities in Ulanga, of which eight were also covered by the Ifakara HDSS. Of these eight, we excluded two as they were in the same village and therefore could not be associated with individual catchment households resulting in a total of six health facilities included (five dispensaries and one health centre). We identified the number and pattern of weeks where they were stocked out of all four doses of ACT. ACT stock-out was defined when all four ACT doses were stocked out since health workers cope with a stock-out of one dose by dividing blister packets from others. If in a given week the health worker did not respond to the SMS, this was considered a stock-out only if it was preceded or followed by a reported stock-out. From (and including) November 2009 until (and including) August 2011, there were 576 health facility weeks of data of which 82 (14%) reported total stock-out.

Informed consent was obtained for this study from the Tanzania National Institute for Medical Research (NIMR/HQ/R.8a/Vol.IX/998).

Univariate logistic models were fitted to assess the effect of predictors on household expenditure during care seeking for fever and whether these varied across wealth quintiles. All analysis was done using Stata 10.

We defined non-compliance for user fee charges in the public sector as charging patients user fees contrary to policy (i.e. for patients who were under the age of five or over the age of 60 or who were covered by health insurance) or when individuals who did not qualify for one of the above exemptions were charged over TZS1,000 (using the higher user fee). Non-compliance for medicines management was defined as cases where a fee of more than TZS1,000 was charged in the public sector for medicines as ACTs were supposed to be dispensed for TZS300 (or free), and a combination of antipyretic and other basic medicines would cost no more than TZS1,000. Non-compliance for medicines management was also defined in cases when a monotherapy (SP or quinine) was dispensed, either in the public or private sector, apart from when this was given for free in a public sector facility to a female of reproductive age, according to Standard Treatment Guidelines for women in their first trimester of pregnancy who should receive quinine for the treatment of uncomplicated malaria (Ministry of Health and Social Welfare Tanzania 2007b). Referral to the private sector to purchase medicines during stock-in periods was also considered non-compliant behaviour by health workers. Fever cases not receiving an antimalarial were not considered as non-compliant as there may have been other symptoms that suggested another diagnosis, or a negative test from a Rapid Diagnostic Test. We believe that ACT stock-outs in the public sector are in part a result of the inability of healthcare workers to reliably ensure that medicines are ordered appropriately and on time (in addition to non-compliant behaviour of individuals higher up on the supply chain) and therefore incidents of care seeking during an ACT stock-out were also attributed to non-compliant behaviour of health workers. Furthermore, we believe that it is reasonable to assume that the cost of non-compliant behaviour in the public sector resulting in stock-outs also results in costs experienced by households seeking care (purchasing ACTs) in the private sector if these occurred during an ACT stock-out. This is because only 9% of

total care seeking chose the private sector during times when the public sector was stocked in, as well as the fact that news of public sector ACT stock-outs spreads quickly in times of frequent stock-outs of commonly sought products. Some patients may therefore go directly to nearby private sector facilities for treatment. While these costs may not have arisen directly as a consequence of non-compliant health worker behaviour, they nonetheless would not have arisen if health staff and others in the procurement and supply chain system had been 'compliant' with their own policies and processes to avoid stock-outs. Finally, the cost to the household of non-compliance may be defined as the difference between the average direct cost for compliant behaviour and the average direct cost for the non-compliant behaviour.

Section 6.04 **Results**

General characteristics

There were 439 INESS fever interviews in the Ulanga District between November 2009 and August 2011. From these, we excluded respondents whose closest health facility was not one of the six, or who sought treatment from another source such as from a friend or family, or a traditional healer. We also excluded respondents who went to a hospital as this involved cases of complicated malaria requiring inpatient care. Two outliers were removed as they reported excessively high costs (TZS12,000 on medicines). Of the remaining 333 fever cases, 192 (58%) sought initial care from the public sector and 141 (42%) from the private sector. The most common private sector outlets were Accredited Drug Dispensing Outlets (ADDOs) (62%); others went to private pharmacies and shops.

86% of fever cases received an antimalarial (ACT, quinine or SP) (see Figure 6.1) of which the most common was ACT (72%). The rest took an antipyretic such as aspirin, panadol, ibuprofen or diclofenac.

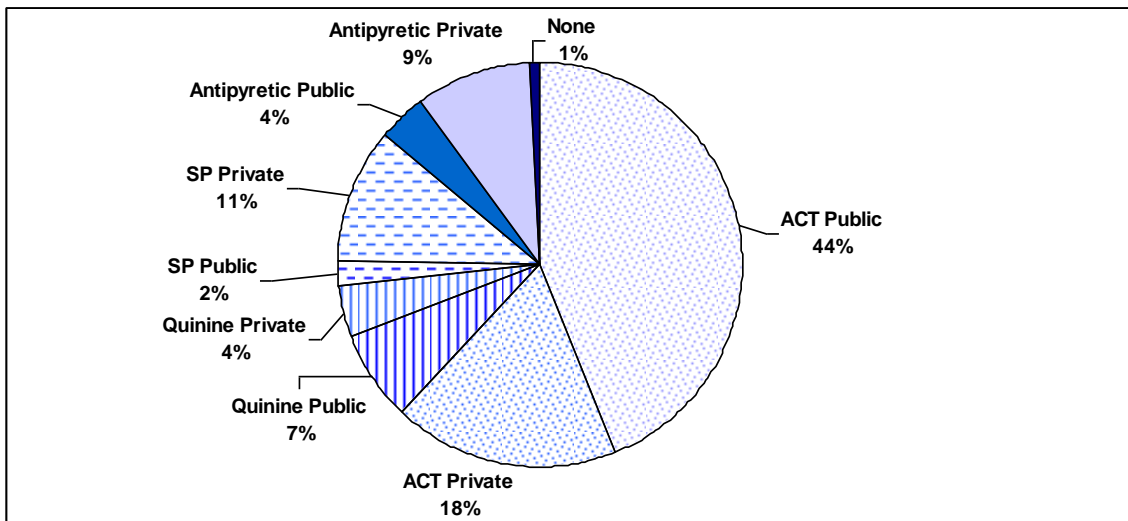


Figure 6.1: Distribution of medicines taken for fever, by source, in the Ulanga district, Tanzania, November 2009 – August 2011

ACT and quinine were most commonly obtained from the public sector, whilst SP was predominantly obtained in the private sector. The majority (58%) of those who received SP were men, against policy.

The costs experienced by respondents seeking treatment in each of the two sectors (private and public) are illustrated in Figure 6.2.

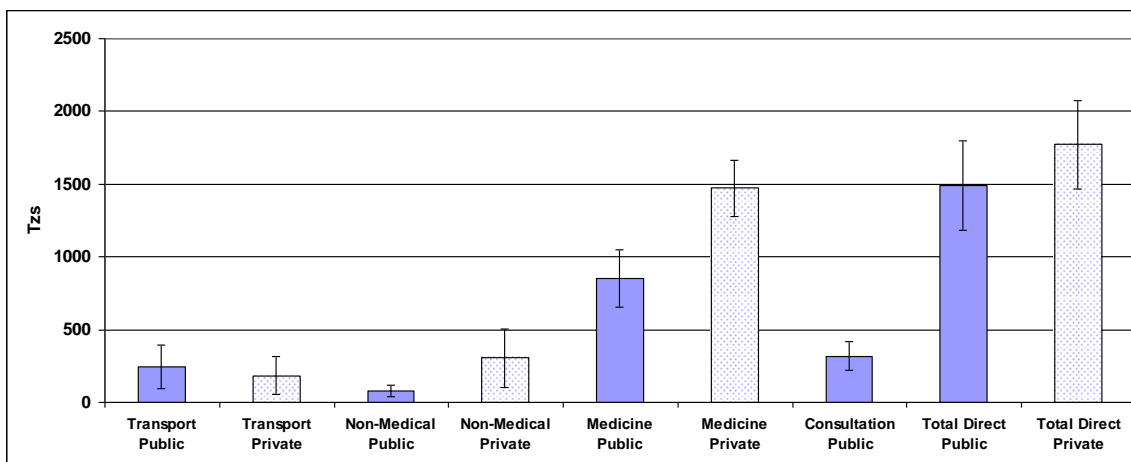


Figure 6.2: Cost (TZS) of fever treatment in both the public and private sector, Ulanga, Tanzania, November 2009 – August 2011

Note: Non medical costs include: food, water, lodging, phone, gift payments.

TZS 1,434 = USD1 (average exchange rate during the study period 2009- 2011). Source: Bank of Tanzania. There were no consultation costs in the private sector

The total direct cost of seeking treatment for fever was TZS285 (19%) higher in the private than in the public sector (95% CI: 139 – 857). This was largely due to higher (73%) average medical costs where the difference between both means was TZS736 (95% CI: 428 – 1044). Non medical costs were also nearly four times higher (95% CI: 124 – 448) in the private sector compared to the public sector, although transport costs were lower. In addition, patients seeking care in the private sector were not charged a consultation fee, which made up about one-quarter of the direct public sector treatment.

A more detailed breakdown of these costs, showing cases which were subjected to non-compliant behaviour of any sort by health care workers can be seen from Figure 6.3. Non-compliant behaviour was relatively more common in the public sector, with over-charging for medicines being the most common form.

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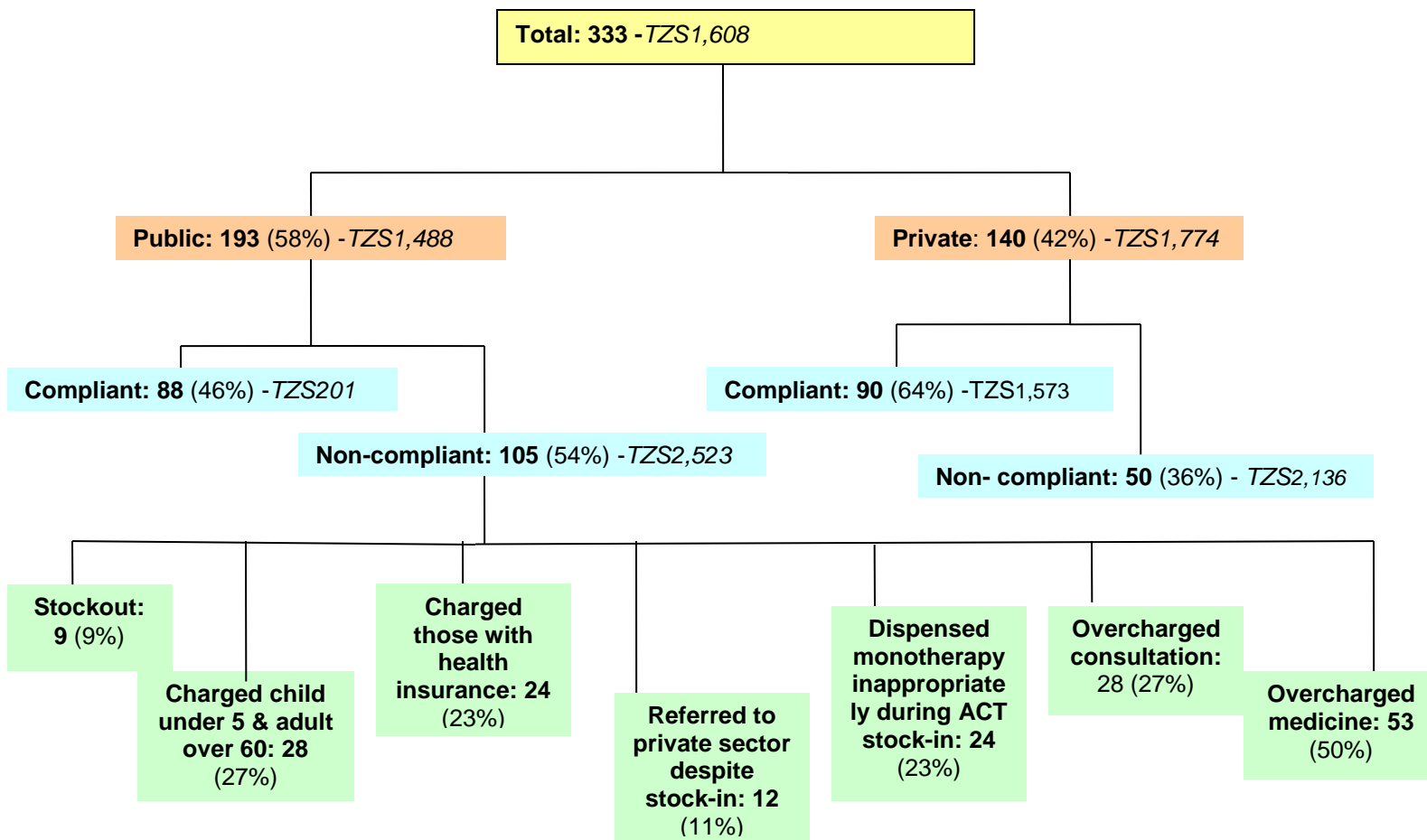


Figure 6.3: Care seeking and average direct costs during fever episodes in Ulanga, Tanzania, November 2009 – August 2011

*Note that the number of non-compliant cases in the public sector does not sum to total non compliant cases due to some individuals experiencing more than one non -compliant behaviour at the health facility during fever treatment

Cost of non-compliant behaviour

The cost of non-compliant health worker and health system behaviour in the Ulanga District for those seeking fever treatment in the period 2009-2011 is estimated as USD1.62 or TZS2,322 per episode of fever. When health-workers and shop workers are compliant, the cost is lower in the public sector than the private sector (USD0.96, TZS1,372).

However, in non-compliant cases, the reverse is true with the cost of care being marginally lower in the private sector compared to the public sector (USD0.27, TZS387).

Stock-out analysis

Out of the total sample, 7% of respondents sought treatment for fever during an ACT stock-out and their direct costs were 21% higher at TZS1,921 (95% CI: 1251, 2590) compared to those who sought treatment during a stock-in [TZS1,584 (95% CI: 1353, 1815)]. The majority of these patients (79%) received their medicines from the private sector which explains the high direct costs. Of these, 53% obtained an ACT. Due to the small sample size of respondents seeking care during an ACT stock-out, we were unable to confirm whether the increase in costs during fever seeking was statistically significant ($p = 0.44$).

PCA scores were available for 286 households and regression analysis suggested that those in the higher socio-economic quintile tended to use the private sector more, although the difference was not statistically significant. The consumption of antimalarials did not vary significantly across socio-economic quintiles, although the poorest were more likely to take a (cheaper) antipyretic. Healthcare seeking expenses did not vary significantly across socio-economic quintiles, although those in the higher socio-economic quintile tended to spend more (TZS126, 95% CI: -14.78 – 267.14, $p = 0.08$).

Limitations

The INESS data included hospitalization costs which were a lump sum of medical costs, laboratory costs and bed costs. As some respondents who went to a dispensary reported only hospitalization costs, we distributed these costs between medicines (80%) and consultation (20%) on the basis of the observed average distribution among respondents

who incurred both costs. There were also inconsistencies in the household data where for example, people going to a private shop reported having bed costs, or reporting no cost. Also, it is likely that the two week recall of respondents would have affected data quality. Finally, *SMS for Life* includes long periods of non-reporting; for example, in 2011, more than one in three weeks (37%) had missing data. Furthermore, *SMS for Life* only counts boxes in the store room, not in the dispensing room, therefore ACT stock-out rates could be inflated.

Section 6.05 ***Discussion***

The frequent ACT stock-outs which have occurred in Tanzania have not been well documented in the literature. The aim of this case-study was to better understand household behaviour and expenditures during care-seeking for fever in the Ulanga District and whether they varied during an ACT stock-out. However, from our results stock-outs accounted for a relatively small proportion (less than 10%) of the non-compliant behaviour in the system experienced by respondents when attending the public health facilities for treatment. By far, the largest contributor to non-compliant behaviour was overcharging for medicines and/or consultations and not respecting health insurance status, as also noted in Tanzania by others (HERA 2006; Laterveer et al. 2004; Maestad and Mwisongo 2007). Non-compliant health worker behaviour has also been found in other African countries such as Uganda (McPake et al 1999; Zurovac et al 2008) Ethiopia (Lindelow and Serneels 2006) and Zambia (Zurovac et al 2007b).

Over charging for services or goods that are supposed to be free could be an outcome of various dysfunctional elements across the health system. Within the information system, over charging could be a result of lack of information among patients who may be under informed on their rights and entitlements. Indeed, during our field visits, we did not observe

any posters displayed at health facilities stating the fee for service or patient rights. Similarly, lack of information could be occurring on the supply side where health facility staff are unaware of the fee-for-service guidelines. Health system stewards could consider strengthening information flows by designing interventions aimed at increasing health worker training on user fee policies followed by reminder messages using mobile phones.

Overcharging could also be occurring due to weaknesses in the financing system especially with regards to payment of salaries to health workers, who may be overcharging as a coping mechanism, either because of salary delays or because funding to the health facility is irregular and limited. If this is the case, then stewards would need to review the remuneration system for health workers and streamline the flow of funds to health facilities. Another potential intervention could be to allow more access to funds received at the health facilities through cost sharing schemes such as insurance funds which could then be used to purchase medicines from other sources when needed. This would reduce the frequency of stock-outs and informal charges, empower the health workers, and build trust in the health care system among the community.

Over-charging for health care services results in a dual burden to the health system, both by potentially discouraging patients from receiving care, and possibly impoverishing them when they do seek care. Considering that the commodity supply cost of ACTs together with other technologies used to prevent malaria such as bed nets and Rapid Diagnostic Tests are nearly fully donor funded in Tanzania, it is perhaps surprising that the 2009/2010 National Health Accounts found that approximately 40% of total malaria expenditure came from households (Ministry of Health and Social Welfare Tanzania 2010b). This is particularly concerning as out-of-pocket costs for medicines tend to be the second largest family expenditure item after food in developing countries (Cameron et al. 2009), resulting in equity and impoverishment implications, together with creating barriers for universal coverage. Socio-economic considerations are important as our results indicated that the

least poor tended to use the private sector more than the poorest households. There could be a combination of demand and supply factors that contribute to this observation, on the demand side, the least poor may want to avoid long queues and therefore go directly to the private sector to purchase medicines. On the supply side, unpublished work from the Ifakara HDSS running in this district has geo-positioned all households and has socio-economic status of a large sample of households, it shows that the least poor quintile is more commonly located in the centre of large villages (merchants, teachers, other elites, etc) while the poorest are more scattered and distributed in and between small villages (peasant farmers, etc.)^a. The implication of this is that the poor rely on the public health care system to provide health services, and when these are either not available, or not accessible, it becomes an indicator of health system failure.

At just under 10% of the non-compliant behaviour observed in our study, ACT stock-outs are a serious issue for those experiencing them, especially when they concern essential medicines for a leading cause of a life threatening condition. Stock-outs are a result of a combination of governance challenges and weak system design. The design of the current system is such that Tanzania relies entirely on donor support for its ACTs, most of which comes from the Global Fund and President's Malarial Initiative (PMI) (Ministry of Health and Social Welfare Tanzania 2008b). Relying on donor support puts Tanzania at risk of having to abide by external bureaucratic requirements. For example, a report by the Local Fund Agent for the Global Fund in 2009 reported stock management issues which resulted in the Global Fund withholding around USD 1.2million for the purchase of ACTs (The Global Fund to Fight AIDS Tuberculosis and Malaria 2007). A delay in Round 7 application was a consequence of having to restructure the grant to host the innovative financing mechanism 'Affordable Medicines Facility for malaria' (AMFm) which aimed to lower the price of ACTs (AMFm Independent Evaluation Team 2012). This resulted in Tanzania only

submitting their proposal in June 2009 and signing the AMFm a year later (Independent Evaluator team 2012;The Global Fund to Fight AIDS Tuberculosis and Malaria 2011).

Another health system design feature which would have contributed to the ACT stock-out was the nature of the supply chain system which is based on a 'pull' system. That is, medicines availability is entirely based on whether health facilities order the correct amount of medicines at the right time from MSD.

Tanzania could consider redesigning the medicine supply system to simplify the way that funds are transferred to the MSD for procurement. Understanding the resource constraints of health budgets in developing countries, Tanzania could take the opportunity of subsidised ACTs through the AMFm program (first orders were received July 2011) to allocate a small portion of domestic funds to co-finance ACT purchases, including creating a buffer stock which would mitigate future stock-outs. With the introduction of Rapid Diagnostic Tests to accurately diagnose malaria, fewer ACT doses will be required. Health system stewards could also consider carrying out an external assessment of the medicines quantification, procurement and supply system to identify and address barriers, potentially considering moving towards a system which did not rely entirely on health workers placing medicines orders in on time.

There are also a range of governance challenges centred around lack of accountability and transparency which can contribute to stock-outs. Tools like *SMS for Life* can greatly increase transparency of medicines stocks and identify where the barriers are, but this is only if they are being widely accessed, which at present it is not due to the website being password protected. Therefore, many involved in the forecasting, procurement and delivery of ACTs may be unaware of stock-outs at the dispensary level as they only monitor stock levels in the national or zonal warehouse. If there was more transparency, perhaps accountability would increase along the supply chain and which may reduce any unjustifiable referral to the private sector, especially when ACTs are in stock.

Our results indicate that in a stock-out period household expenditure during care seeking for fever increased (this was not statistically significant). However, average district ACT stock-out rates are increasing. For 2009, 2010, and 2011, district ACT stock-out rates were, respectively, 8.3%, 11.4% and 34.1%, and so a district analysis today may yield statistically significant increases in household expenditure results. The predominant periods of ACT stock-outs were November 2009; July to August 2010; and the most severe was between March – August 2011, corresponding to the peak period of malaria transmission. Thus, in addition to the economic consequences of ACT stock-outs, it would not be unreasonable to expect severe health consequences in affected communities, although this remains to be established.

The irregular public sector ACT availability could have been one of the principal factors contributing to nearly half the respondents going to the private sector for fever treatment, especially since cost of care in the private sector for fever treatment was only slightly higher (19%) than in the public sector. Our case-study does not examine the private sector ACT stock, which may have been higher following the earlier introduction of AMFm funded ACTs compared to the public sector. Another factor dissuading patients from seeking care at public health facilities was the prevalent practice of over-charging. Over charging (an average, per case, of TZS200 per patient) was also reported in a GIZ 2011 study on the availability of medicines which found in one district that health facilities were overcharging patients to pay for security services (GIZ and Tanzanian German Programme to Support Health TGPSH 2011b).

Our overall costing results differ from those of Somi *et al.* (2007) who calculated the direct cost of fever/malaria treatment in the same Ifakara HDSS site in 2004 and found the public sector to be 61% more expensive than the private sector (Somi *et al.* 2007). Using GDP deflators from the World Bank, the average direct cost in 2004 was TZS1,184, 50% or so higher than the average cost during our study (TZS767). A direct comparison is difficult

because in 2004 the first line antimalarial was SP which was at the time much more inexpensive than ACT. Chloroquine was also still popular in the shops and very inexpensive.

The annual number of malaria cases reported in public health facilities in Tanzania is estimated at between 14 – 18 million (USAID 2012). If over half of these cases experienced additional costs (USD1.62) due to the non-compliant behaviour of health system employees, the estimated total additional expenditure born by households would be between USD12.2 - USD15.7 million. This represents about 3.6 - 4.6% of the total health expenditure on malaria in Tanzania (USD340 million (Ministry of Health and Social Welfare Tanzania 2010b)). Furthermore, an estimated 68% of the population in 2007 live on less than USD1.25 a day (World Bank 2011) suggesting that their daily income was consumed entirely due to governance failures for each fever episode.

Section 6.06 **Conclusions**

We investigated the behaviour and expenditure of households during fever seeking in the Ulanga district in Tanzania in 2010 -2011 when the district, like the rest of the country, was experiencing frequent periods of ACT stock-out. The main governance issue affecting the proper delivery of health services during a fever episode observed in our case-study was non-compliant health worker behaviour at public health facilities. Among other things, this results in decreasing the cost gap between the private and public sector. Had the public sector workers been fully compliant, treatment costs in the private sector would be significantly larger than those in the public sector. In addition to over charging for medicines and services, another element of public sector worker non-compliant behaviour was ACT stock-outs, which we estimate increased the cost of care during fever treatment by 21% compared to treatment costs during a stock-in. For those seeking care during an ACT stock-out, the majority went to the private sector. Costs in the private sector were

19% higher than the public sector which would explain the higher costs for those seeking treatment during an ACT stock-out.

As the ACT stock-out rate in our case-study was low compared to the district average, we were unable to fully assess its impact. However, our results demonstrated that there are other important governance challenges in the health system that increase household expenditure during care-seeking for fever. Now that *SMS for Life* is operating at a national level and as other household costing data sources become available, we encourage a larger scale study to assess the national impact on household expenditures of an ACT stock-out. Furthermore, an investigation into the long term health consequences of people not accessing the first line antimalarial would be important for health services management policy. With potential ACT resistance, it is imperative that Tanzania secures a stable ACT supply with adequate buffer stock and implements the use of Rapid Diagnostic Tests to provide the population with an affordable treatment against one of the major public health concerns and work towards the goal of universal coverage for malaria treatment.

Competing Interests

The authors declare that they have no competing interests.

Endnote

^aMasanja, H. et al (2005) Ifakara Health Institute, Dar es Salaam

Authors' contributions

DDS, IML and FT contributed equally to the conceptualisation and design of the approach. RK and FM led the work in the field. FM, MN, GA, BA and IML managed and analyzed data. IML, FT, and DDS wrote the manuscript and all authors reviewed, contributed to, and approved the final manuscript.

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PART 7

DISCUSSION AND CONCLUSIONS

“If you want to go quickly, go alone. If you want to go far, go together”

- African Proverb



7. Discussion

This body of research has identified that the lack of attention to developing strong health systems in Tanzania has resulted in high levels of unaccounted essential medicines, and stockouts of a fully donor-funded, life-saving antimalarial. More generally, this thesis has explored the issue of governance in the health system with the aim of contributing to a better understanding of the health system challenges in Tanzania that prevent the adequate supply of essential medicines to public health facilities, and has attempted to quantify the impact on household expenditure when the supply of medicines fails. In addition, the findings should inform a more general discussion on supply chain barriers. This chapter begins with a review of methodological approaches, followed by a discussion that synthesizes the main research findings with reference to the original objectives described in chapter two. Finally, the overall implications of these results for the supply of essential medicines in resource constrained environments are discussed and recommendations for further research and development are made.

Section 7.01 *Methodological issues*

The research for this thesis was carried out within two rural districts in Tanzania, both being part of the Tanzanian HDSS system (Armstrong Schellenberg et al 2002). The HDSS provides a unique opportunity to collect valuable information from repeated household surveys and integrate them using common household codes. However, the long-standing presence since 1996 of researchers in the area may influence the way people answered survey questions. As households are regularly visited, it is possible that they become tired of answering routine questions, with implications for the consistency of data quality. The possibility of a “Hawthorne effect” (Roethlisberger and Dickson 1939)

also needs to be considered whereby the respondents may adapt their behaviour or responses as a consequences of the increased attention they receive by being part of the HDSS or the *SMS for Life* project. Consequently, the observations made in this thesis may not be representative of the situation in other districts. However to date, there has been no evidence of a Hawthorne effect in any of the studies from these districts.

In parallel to our study there was also significant investment being made by the US government in training staff for the supply chain system and strengthening service delivery for certain programs (President's Malaria Initiative 2011; President's Malaria Initiative 2012) which could have influenced the way health workers respond. It is uncertain which districts these programs were rolled out in; however if they were carried out in our study districts they may have resulted in health workers performing better in terms of requesting medicines, and thus this thesis may underestimate the true governance issues which we set out to explore.

Whether the findings in this thesis can be extrapolated to the rest of Tanzania depends on each component. The initial framework developed to assess governance (chapter 3) is not Tanzania-specific and could certainly be applied to any country and to any health system concern. For the analysis comparing both medicines delivery systems in the Rufiji District (chapter 4), the results may provide an optimistic assessment as during the 1999 data collection the Rufiji District was part of the *Tanzania Essential Health Interventions Project* which involved significant interaction with health facility workers. This could mean that the findings on the accountability of medicines in 1999 were in fact better than the national average. Regarding malaria (see chapters 5 and 6), it is likely that malaria awareness and therefore treatment is better in the study area than the rest of Tanzania due to the activities of the HDSS. For example, from the 2012 Tanzania HIV/AIDS and

Malaria Indicator Survey, the national percentage of children under five with fever who took an ACT was 33.6% whilst in the Morogoro Region (where the Ulanga District is) this was 52% (no results for Pwani Region which include the Rufiji District) (Tanzania Commission for AIDS (TACAIDS) et al 2012). Therefore the results presented for fever-seeking treatment in chapter 6 of this thesis may in fact be more optimistic than the reality in the country. In the same section, we report that only 7% of respondents sought care for fever during an ACT stockout; this is much lower than the district average of 39% and the national average of 29%. Therefore our estimate of the additional costs associated with stockouts of 21% could be an underestimate. Finally, we define an ACT stockout as a stockout of all four doses of ACT, as a fully functioning well governed system should always provide access to all four doses. However, there may be periods when a health facility is stocked out of one dose of ACT requiring the health worker to divide or combine other pack sizes. While this coping mechanism is undesirable, it would not be reflected as a stockout in this thesis. Therefore the estimated stockout rates presented in this thesis would under-report those expected to prevail in a fully functioning health system.

The costing element of this thesis (chapter 6) relies entirely on secondary data collection, including ACT stock reports from health workers, cost of health care seeking during fever and routine reports from health facilities. As such, it is prone to errors in data quality: we have attempted to correct these wherever possible, such as health facility workers reporting the number of doses in stock instead of boxes, or field interviews reporting hospitalization costs when going to a dispensary.

Section 7.02 ***Contribution to understanding health system governance***

Based on the specific objectives defined for this thesis, the following section reviews the contributions that this research has made to improving our understanding of health system governance. We also discuss how this framework can be empirically applied to other areas of the health system.

7.2.1 Objective 1 - To define a framework for the assessment of governance within a health system

The initial contribution of this thesis was to develop a framework to assess governance in the health system (chapter 3). The framework developed was based heavily on contemporary literature including the WHO 2007 framework where the six health system building blocks were first defined (WHO 2007), as well as the governance elements outlined in Siddiqi *et al.* (2009) (Siddiqi et al 2009). The framework presented in this thesis rearranges the building blocks to better represent the various interactions in the health system, whereby service delivery is seen as the central point where the health system interacts with patients and governance is the overarching building block influencing the other four building blocks (human resources, medicines and technology, information and financing). Other frameworks have been developed to assess governance in health systems (Islam 2007; Lewis and Pettersson 2009; Siddiqi et al 2009; WHO 2008b), often proposing a check list of questions to answer, which are in some instances more idealistic than realistic. The framework presented in this thesis differs from these efforts in that it highlights the dynamics between the building blocks, stressing the importance of feedback information flows as highlighted in Paina and Peters (2012) (Paina and Peters 2012). The framework proposes a practical tool to assess governance across the health system. It does not define a set of questions to ask. Instead, the important difference compared to

other frameworks is that it is designed to start from a certain governance issue which constrains the health system and guides the evaluator to assess comprehensively various elements of the governance failure across the system to identify the most promising entry points for system-level governance interventions. In summary, our framework suggests that a well governed health system should have clear goals based on a certain degree of participation of relevant stakeholders, especially those who provide the services as well as from disadvantaged groups who may have less power to influence policies, and from which transparent policies are designed and adhered to by promoting accountability and reducing the risk of corruption.

7.2.2: Objective 2 - To empirically apply the framework in Tanzania

The framework developed as part of this thesis is really only of value if it can be applied empirically. The application of the framework requires identification of a governance issue which constrains the health system from operating effectively to act as a starting point. This thesis applies the framework developed under Objective 1 to the issue of irregular supply of essential medicines, with a particular focus on stockout of antimalarials, as the availability of medicines at health facilities is a crucial element of service delivery quality. Stockouts of essential medicines are a barrier to the health system achieving its goals of improving both the overall level of health and health equality whilst at the same time protecting people from financial hardship and responding rapidly to the legitimate health needs of the population. Using the framework, we identify serious weakness across the health system in providing essential medicines at the point of service delivery (Figure 7.1).

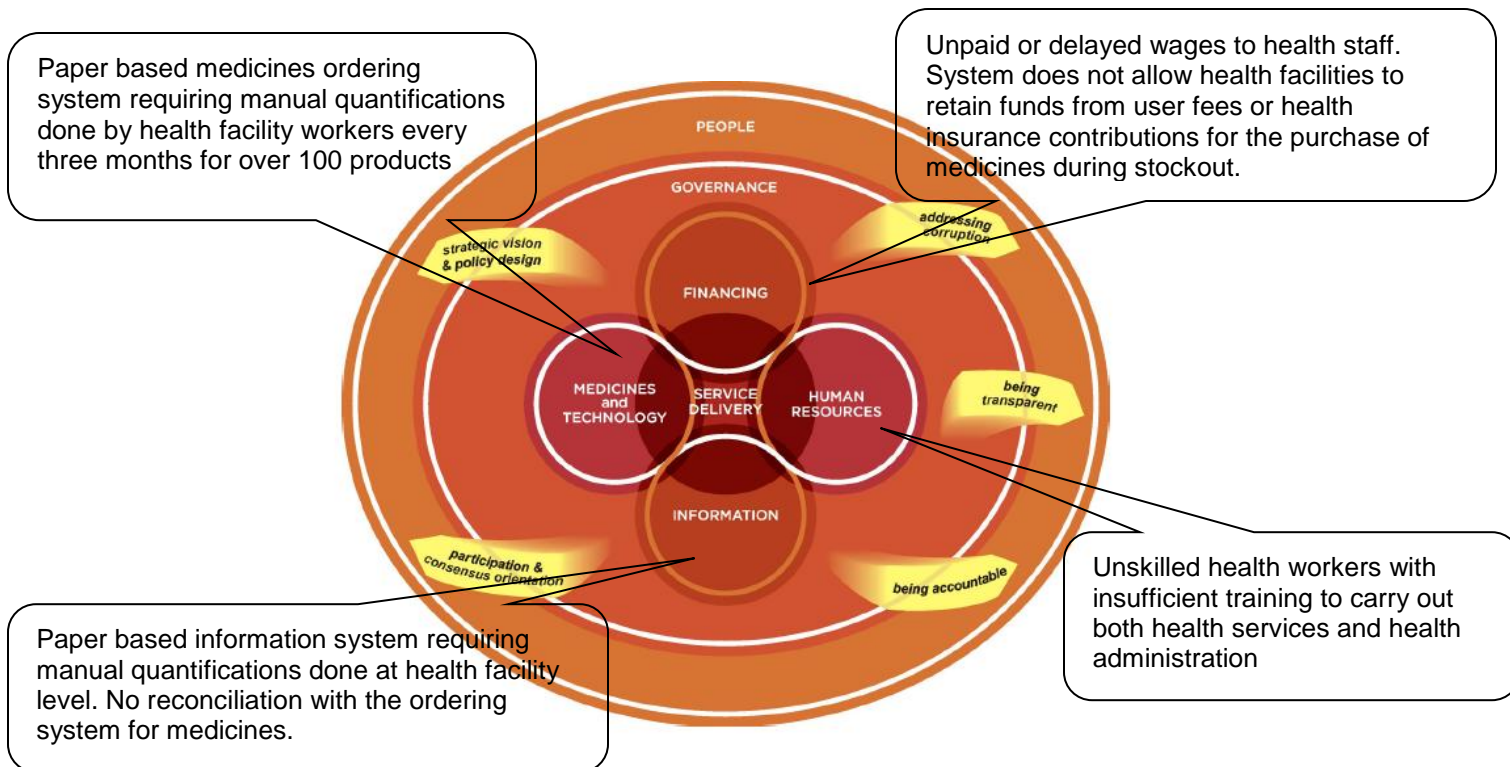


Figure 7.1: Application of health system governance framework to the issue of stockout of essential medicines in Tanzania

The first key finding of this thesis is that the recently developed ‘pull’ system rolled out in 2009 has not resulted in an overall improvement in accountability of essential medicines in the public system in Tanzania. In addition, Tanzania has been experiencing stockouts of the first line antimalarial, ACT. Possible reasons for this are illustrated in Figure 7.1 across the various areas of the health system. These barriers are also interconnected; so, for example, unskilled health workers have an impact on the quality of the information system; late payment of wages would be expected to be a disincentive for health workers to complete ordering forms for medicines on time and may result in higher absenteeism rates across health facilities. There are also importance feedback loops whereby the stockout of medicines can influence the performance across the system. For example, health workers may be less inclined to spend time on lengthy medicines order calculations if they have not received feedback from their previous orders. The end result of these barriers identified in Figure 7.1 and the complex and dynamic nature of the health system is that if

orders are not placed in time, then health facilities will not receive the delivery of medicines that they require.

Underlying all of these issues discussed across the four health system areas is governance, of which probably the most important factor that would explain the lack of medicines availability, is accountability. This thesis found limited accountability across the health system which resulted in the persistently high percentage of unaccounted essential medicines. For example, within human resources, health workers are not held accountable when medicines orders are not submitted, nor are DMOs held accountable when medicines orders are submitted to the central MSD with errors in calculations. Health workers are not held accountable when they do not submit yearly booklets containing health information statistics and districts are not held accountable when health information booklets are missing from their records. The cumulative result of this lack of accountability is that it becomes increasingly more difficult to account for medicines consumption by reconciling data from the HIS and ILS tools, as demonstrated in chapter 2 of this thesis. Within the information function of the health system, tools like *SMS for Life* have been designed to improve transparency (which is needed for better accountability). However, as of now, no one has been held to account for the persistent stockout of ACT in Tanzania as *SMS for Life* is not widely accessed. There is limited accountability in the financing system at the highest level when funds from the Ministry of Health are not transferred in time to the MSD for the purchase of medicines, which has resulted in a large debt accumulation at the MSD. The MSD is in turn unable to hold the Ministry of Health to account due to its parastatal status. At the international level, donors are putting more pressure on countries like Tanzania to account for funds spent and increasingly request progress reports. Questions could be raised as to whether institutions such as the Global Fund should be

held to account for piloting programs like the AMFm in Tanzania which ultimately slowed down the local funding application process for ACTs.

These constraints are, by and large, all interconnected, with bottlenecks and failures in one part of the system (e.g. the health information system) having a clear impact on the ability of other parts of the system (e.g. medicines delivery; financing) to function effectively. While this may make the design of interventions more complex, it also means that efforts to improve governance in one area of the health system by addressing specific concerns are likely to have flow-on benefits in other areas.

An important contribution of this thesis is to highlight that even though the stockout of essential medicines is an issue central to the 'medicines and technology' function, as defined by the health system, there are many other contributing factors across the health system which both influence, and are influenced by, medicines availability. The findings of this thesis on medicines availability are similar to what was found by the German Development Agency (GIZ) in their 2011 report (GIZ and Tanzanian German Programme to Support Health TGPSH 2011a) which identified limitations in health worker capacity, and also to that of McPake and colleagues (1999) who found that medicines leakages resulted in reduced availability of health workers at the point of service, reduced health service utilization rates and reduced medicines availability in Uganda in 1996 (McPake et al 1999). This thesis did not look into issues of corruption; however, incidents of medicines theft have been reported in the press (Siyame 2012a;The Citizen 2011).

Having identified areas of weaknesses in the design and governance of the medicines supply system, we focused on the availability of the first line antimalarial ACT, for two reasons. Primarily, because malaria is second only to HIV/AIDS in terms of its contribution

to disease burden in Tanzania and antimalarials for children are a life-saving intervention. Second, because since 2005 Tanzania has been receiving funds from the Global Fund to purchase ACT in the public sector.

The second major finding of this thesis was to capture the extent of the ACT stockout in Tanzania over a study period of 15 months, using results from approximately 4000 health facilities who provided data through the *SMS for Life* tool. We found an average of 29% of health facilities at any one point in time were stocked out of all four doses of ACT. These results are disappointing considering that the pilot program demonstrated promising results, whereby stockouts of three out of the four ACT were greatly reduced or eliminated after the 21 week pilot study period in three districts (Barrington et al 2010a). A similar pilot study undertaken in Kenya in 87 health facilities across 26 weeks from mid 2011 – mid 2012 found that at the start of the *SMS for Life* program there was only a 5% ACT stockout which was completely eliminated at the end of the pilot (Githinji et al 2013). Considering ACT are both life saving and available to Tanzania through various donor assistance programs, these long and persistent stockouts surely highlight an unacceptable situation and evidence of a severe and prolonged health system failure to which there appears to have been no response at the local, national or global level. In addition, during the period of study under this thesis, there have been no initiatives taken to improve the transparency or ownership of *SMS for Life*, potentially on purpose to avoid public scrutiny and demands for information about the reasons behind the ACT stockout.

In addition to the health system design features of the medicines delivery system discussed at the start of this section, the frequent prolonged periods of ACT stockout identified in this research can be largely attributed to the design of the ACT supply system. Tanzania relies entirely on donors for the financing of all ACT (the Global Fund and the

President's Malaria Initiative) and therefore is at the mercy of donor priorities and procedures to obtain funds for procurement. The perils of this volatile relationship were highlighted during the 2008 Global Financial Crisis when donors reigned in their commitments and required greater transparency about the use of funds, even setting the precedent of installing a set of conditions which Tanzania was required to fulfil before the release of each round of funding. As seen in Figure 7.2, changes in Global Fund funding for ACTs through the introduction of the AMFm resulted in severe grant funding delays and a serious disruption to supply of medicines as a result of the significant delay in the signing of the Round 7 grant.

Year Quarter	Global Fund				Doses (M)	PMI Emergency doses (M)	Comment
	R4	R7	AMFm	R9			
2004 Q1							Global Fund Grant Status
2004 Q2							Submitted
2004 Q3							Signed
2004 Q4							ACT orders
2005 Q1							
2005 Q2							
2005 Q3							
2005 Q4							
2006 Q1					0.53		
2006 Q2					1.08		
2006 Q3					2.54		
2006 Q4					4.86		
2007 Q1					2.56		
2007 Q2					10.95		GF withholds US\$1.2m due to stock management issues
2007 Q3					1.62		
2007 Q4						0.52	
2008 Q1					6.56	0.15	
2008 Q2					5.8		Local Fund Agent warns against stockouts in report
2008 Q3							PMI report predicts stockout: Q3 2009 - Q3 2010
2008 Q4					3.23		
2009 Q1					3.42	0.52	Global Fund Round 7 Reprogrammed to host AMFm
2009 Q2					3.22		AMFm and Round 9 grant proposals both warn about ACT stockout Q4 2010
2009 Q3					7.53		
2009 Q4						3.48	
2010 Q1							PMI report predicts stockout Q3 2011
2010 Q2					4.76		
2010 Q3						3.65	R7 reprograms USD 5M ACT from private sources for emergency public sector use
2010 Q4						3.57	
2011 Q1						1.53	
2011 Q2					2.71		
2011 Q3					2.21	2.52	
2011 Q4						2.52	
2012 Q1					1.65	1.48	
2012 Q2					3.27	0.74	
2012 Q3						3.78	
2012 Q4							
Totals					68.5	24.46	
					93.0		

Figure 7.2: Chronology of ACT supply in Tanzania, 2004 – 2012

In parallel with bureaucratic delays at the international level, officials from the NMCP have blamed the reduced capacity of suppliers to produce sufficient ACT (The Citizen 2012). Despite these challenges, Tanzania could have mitigated some of the impact of ACT stockouts had it possibly taken a more proactive approach to the warning given by the Global Fund and the PMI in 2008 that stockouts were imminent (as seen in Figure 7.2).

The design features of the supply of ACT as discussed above, both at the international and national level, have undoubtedly contributed to the persistent stockout of ACTs since 2009. Prolonged periods of ACT stockout raise governance questions as to who and why the system was designed in this way, and why so little has been done to correct system failures? A possible explanation for the inertia in the design of the system is the inherent value of ACT which may increase the risk of leakage. This thesis did not carry out an indepth analysis into ACT leakages, but did find that approximately 90% of ACTs shipped from Novartis were accounted for in the *SMS for Life* system in 2012. Leakages, however, have been reported in **The Wall Street Journal** (31/08/2010) (Bate 2010) and **The Citizen** (21/05/2012) (The Citizen 2011). To understand why the barriers to the regular supply of ACT have not been addressed, one would need to assess who benefits from the weak design, and what interventions could be designed to strengthen it, for example, by increasing the wages of staff involved in the supply of medicines in order to reduce incentives to sell public sector-bound ACT to supplement their unpaid or low wages.

This being said, changes in the design of the ACT supply system are being made in Tanzania. Significant steps have been taken recently to curb any possibility of medicines leakage by requesting that ACT supplies are delivered by the manufacturer directly to the MSD (and not at the port of entry), accompanied by a manufacturer representative until hand over. This is in addition to changes in top management at the Dar es Salaam port

and Tanzania Ports Authority (Mwakyusa 2013). This path towards greater accountability and transparency is one that Tanzania should continue to follow and accelerate at all levels of the health system, including ensuring that health facility workers are equipped with the knowledge and capacity to complete medicines orders correctly and on time, that the MSD is provided with sufficient resources to deliver medicines directly to health facilities, and that districts are given, and trained in the use of, appropriate tools to better oversee trends in medicines consumption and availability in their districts. Evidence of a promising shift in policy in this direction is the design of a national mHealth strategy which includes routine health facility data collection as part of the HIS, as well as health logistics monitoring and health worker communication and training modules. In addition, the MSD is now rolling out a direct delivery of medicines to health facilities to build a stronger contact with their clients.

One of the consequences of irregular ACT availability in the public sector is that households may seek treatment for fever in the private sector. We identified the frequent use of private pharmacies as the first point of service when seeking treatment for fever, with nearly 42% of respondents seeking care in the private sector. In addition, (and the third key finding of this thesis) there is a high frequency of non-compliant behaviour among public sector health workers, usually in the form of overcharging for care and medicines which we calculate as an extra USD1.62 per case of fever, on average, borne by the household which is above the estimate USD0.98 per capita daily income level in the rural areas. Cumulatively, this non-compliant health worker behaviour results in an estimated annual cost of USD12.2 million – USD15.7 million at the national level (based on the number of malaria cases going to the public sector), or between 3.6%- 4.6% of total health expenditure on malaria in Tanzania. Non-compliant health worker behaviour can result in ACT stockout in so far as health workers, through lack of training, fail to correctly order

medicines, thus resulting in shortages. We find that when health facilities were stocked out of ACT, households in their catchment area experienced an increase in direct costs of about one-fifth (21%) compared to those who sought treatment during an ACT stock-in period at their predicted health facility. This increase in household expenditure was predominantly due to an increase in medicines costs experienced by about two-thirds of households who sought treatment from the private sector (which was found to be 19% more expensive than in the public sector).

In summary, exploring and understanding the role of governance in the health system is crucial as public officials, donors and researchers strive to understand how to improve the performance and functioning of health systems. The results of this research have demonstrated that when little effort is paid to resolving issues of governance, well meaning interventions such as donor funding for ACT and the development of a new medicines supply system can fail. In order to provide some insight into potential ways to strengthen health system effectiveness, we first proposed a practical framework to assess governance in the health system. We then explore the findings from applying the framework to the issue of availability of essential medicines in Tanzania, and study the implications of health system failures on household expenditures due to care seeking for fever. We find that ACT stockouts are due to both international and national governance and procedures, and system design failures. We strongly recommend that these are systematically addressed to reduce the economic burden on households of having to seek treatment in the more expensive and less regulated private sector. In addition, with Tanzania following WHO guidelines and moving away from presumptive treatment towards using RDTs, the complexity of having to manage an additional malaria product will increase the pressure on an already fragile system.

The global financial crisis has put pressure on donor funding and, as is evident in Tanzania, donor funding cannot always be relied upon. With the AMFm resulting in a price reduction for ACT and as the economy of Tanzania continues to grow, there is no reason why Tanzania should not allocate a portion of its malaria budget to procure ACT treatments to create a buffer stock. This will require bold public policies, strong political leadership and a more systematic approach to medicines supply and financing, including possible reallocation of the health budget. Indeed, in the march towards malaria elimination, Tanzania may need to explore new ways to allocate funding for ACTs and RDTs. An interesting option might be to levy more taxes on tourists, as suggested by Sir Richard Feachem in his “Call for Action” (Feachem et al. 2010b). Even as malaria endemicity declines, Tanzania needs to ensure a well governed malaria programme, including long term planning. Tanzania has the tools available for prevention, diagnosis and treatment of malaria, what is now required are strong health systems, including strengthening skills of workers and health professionals to deliver effective and sustained malaria control programmes to the poorest and more remote areas of Tanzania, based on the recognition that treating malaria is a public good.

Section 7.03 ***Recommendations and future research***

7.3.1 Recommendations for health system strengthening

The key implication of our findings is that if health system stewards in Tanzania wish to improve the availability and accountability of essential medicines across the public sector, they will need to take a health systems perspective aimed at strengthening elements across all areas of the health system. We find five key implications of this research for health system strengthening in Tanzania:

- 1) health worker capacity needs to be addressed with regular training on ordering medicines and updating health facility booklets;
- 2) the health information system should be simplified and reoriented so that it is able to capture basic data on outpatient numbers for various diseases and injuries as well as on births and causes of death. This might be most efficiently done using mobile phones to report vital events which could even provide information on vital event happening outside of the health facility in the community through community health workers;
- 3) financing flows should allow more autonomy for health centres to be able to purchase medicines from qualified private supplies to prevent stockouts;
- 4) the medicines delivery system should be simplified into a mixture of 'push' and 'pull' levers whereby medicines quantification should only happen once a year and, based on this quantification, regular medicines kits should be "pushed" out, factoring in an inflation for medicines such as antimalarials which will have seasonal variations; and
- 5) accountability and transparency need to be strengthened across the system, perhaps by creating stronger incentives and disincentives, and by making efficient tools like *SMS for Life* open access for the public. Greater participation by health workers should also be facilitated in the design of the first four of these suggested areas of health systems strengthening, and in order to make them better aware of the health development advantages of strengthening the fifth.

Strategies and interventions to strengthen one health system function will only be truly successful if thought has been given as to how these actions may influence other building blocks. Programs like *SMS for Life* have shown the potential to greatly increase transparency and real-time information flow yet the impact of this simple but highly effective initiative has not been fully appreciated by those in charge. The power of using mobile phones needs to be leveraged and expanded across all essential medicines to

improve the accountability of resources. Nonetheless, technology is not the entire solution; while text messaging can strengthen the flow of data toward the centre, it may not ultimately improve services unless there is regular, and relevant, feedback. Finally, as people play a central role in health system performance, both in terms of paying for health care and contributing to the need for health care, they are in effect owners of the health system and should be encouraged to play a larger role in the design of new interventions to improve it.

7.3.2 Recommendations for future research

Further research is needed to support future improvements in service delivery, to strengthen the evidence base for disease control and poverty reduction strategies, and to achieve better health outcomes. This thesis investigated the impact on household expenditure during an ACT stockout which is important when considering the need for financial protection against catastrophic health expenditure. However, we did not assess the indirect costs of seeking care for fever which would include the loss of income. Therefore, future research might consider looking into issues of income protection during unstable medicines supply. In addition to financial protection, another health system goal is improve overall levels of health. A second recommendation of this thesis for further research is thus to better understand the health impacts of stockouts of essential medicines (antimalarials, antibiotics, vaccines). For example, do stockouts increase incidence and mortality from malaria, especially among children? This is perhaps as important as information on financial effects on households in building the case for better disease control programs. Given the basic function of health systems to promote health and prevent premature death, reliable evidence about this probable effect would be a critical lever to accelerate action to prevent stockouts.

From a provider-perspective a key area for future research might be identifying new models and approaches to designing the supply of essential medicines, or new ways to manage the inputs and responsibilities of key stakeholders, including donors. This focus on system design would require a better understanding of both financial and behavioural factors that influence health workers and what tools could be built into the system to strengthen accountability. Research into ways to improve the health information system, making it more transparent, increasing data quality and accessibility, and designed in a way that it can be automatically reconciled with other data bases, for example on the supply and consumption of medicines, would also strengthen the capacity of stewards of the health system to better manage disease control programs.

Section 7.04 ***Conclusion***

The findings of this thesis underline the importance of recognising the complexity and dynamics among various health system functions, and the need to take a comprehensive system-wide approach to analysing and improving access to essential medicines in Tanzania. This body of research suggests that although efforts aimed at strengthening the delivery of technologies such as medicines (or in other cases, bed nets and vaccines) are of value, to be maximally effective they need to be embedded in a well designed health system which includes attention to human resources, information and supply chains. More recently, donors such as the Global Fund and GAVI have been investing in these elements, but responsibility for their integration and strengthening rests with national governments, particularly the Ministries of Health, Finance and Education including how interactions between them could be strengthened under complex political pressures. Health system stewards, for their part, need to take a broader perspective when assessing

health system performance by looking at outcomes in terms of population health gains and distribution, improvement in service delivery, patient satisfaction and financial protection. But, probably the greatest challenge to health system strengthening is to embed the significance of health systems thinking into the planning process and daily activities of health system stewards, so that they understand the importance of strategic vision, evidence based decision making, and accountability. For, as concluded by Julio Frenk in 2010, *“without leaders, even the best designed systems will fail”*.

End.

8. Bibliography

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9. CV

Inez MIKKELSEN-LOPEZ

Australian/Danish

2005, University of Queensland, **BEcon**

2007, University of Queensland, **MHEcon** (Advanced)

2013, University of Basel, **PhD Epidemiology**

Language Skills: English, French, Spanish, Kiswahili

Country Experience: Papua New Guinea, Tanzania, Madagascar, Thailand

Contact: E-mail: inezmlopez@gmail.com

Results-driven, effective Program Manager with over ten years of international health experience focusing on health systems and health economics. Familiarity with field work in the Pacific, Sub-Saharan Africa and East Asia with an international health and social sector consulting group, the World Bank and academia. Quantitative research skills and peer-reviewed publications.

WORK EXPERIENCE

Abt JTA (Port Moresby, Papua New Guinea)

August 2013 – Present

Monitoring and Evaluation Manager

Leading the monitoring and evaluation activities of a large Australian-aid health program in Papua New Guinea:

- Developing monitoring frameworks for numerous local non-governmental organizations receiving grants from the Australian Government
- Providing capacity support to local monitoring and evaluation staff
- Creating and managing a knowledge management system to capture all reporting

Merck Serono (Geneva, Switzerland)

April 2012 – June 2013

Program Manager

Overseeing and coordinating the Access to Health function within the Global Health Department of the pharmaceutical company Merck Serono:

- Developing a pilot study to assess supply chains in Africa and how they could be strengthened
- Elaborating a tiered pricing strategy to increase access to medicines in low and lower-middle income countries
- Designing a monitoring and evaluation platform to assess 'Access to Health' initiatives across the company
- Representing the company in various industry association meetings and global health forums

The World Bank (Washington DC, USA)

August 2007 - March 2009

Junior Professional Associate

Rotating experience across different functions in the Health, Nutrition and Population Unit, including:

- Madagascar health portfolio

Team member of the World Bank mission to Madagascar to assess the status of the health system and the impact of World Bank-funded programs, particularly those related to HIV. Collaborated on the design of a results-based financing (RBF) pilot to increase immunization

- Monitoring & Evaluation

Core member of the Monitoring & Evaluation team reporting to senior management on status of the health portfolio

- Health equity data evaluation study

Collaborated on a multi-country analysis of microeconomic inequalities in health service (public and private) utilization

- Global Monitoring Report 2009, Chp 3

Co-authored chapter on the contribution of the private sector in health towards attaining the Millennium Development Goal targets

- Cambodian health information system

Contributed to an analysis of the health information system in Cambodia and the role of the Health Metrics Network

Abt JTA (Brisbane, Australia)

February - July 2006

Research Assistant

Contributed to an AusAid funded project on HIV in Papua New Guinea:

- Analysed costing data for community health centres in Papua New Guinea
- Estimated costs of HIV treatment as an input to the medium term expenditure figures

Ministry of Public Health, Thailand (Bangkok, Thailand)

November 2005 - January 2006

Research Assistant

Collaborated on a multi-institution project assessing trends in under-five mortality according to income and household assets for Thailand using 1990 and 2000 census data – funded by the Wellcome Trust, UK

Queensland Centre for Population Research (Brisbane, Australia)

June - October 2005

Research Assistant

Contributed to the analysis of mortality differentials across various countries using Demographic and Health Survey data

EDUCATION

The University of Basel

Swiss Tropical and Public Health Institute – SwissTPH (Basel, Switzerland) *April 2009 – July 2013*

Ph.D. Epidemiology

Thesis title: *Health System Governance in Tanzania: How does it impact service delivery in the public sector?*

Supervisors: Prof. Don de Savigny, SwissTPH and Dr. David Evans, WHO

See section on publications

Courses taken: Health Technology Assessment and Economic Evaluation; Health Planning in Low Income Countries; Inequalities in Health and Health care; Health Policy and Politics; Epidemiological concepts; Epidemiological methods.

University of Queensland (Brisbane, Australia)

July 2005 - June 2007

Master of Health Economics (Advanced)

Thesis title: *Determinants of health and avoidable health inequalities.* Modeling cross-national data to investigate the influence of a series of variables including living standards, socioeconomic status, human capital and health interventions on health levels and inequalities.

University of Queensland (Brisbane, Australia)

July 2002 - June 2005

Bachelor of Economics

AWARDS

- Selected as finalist in the ‘Young Voices in Research for Health’ 2011 competition – Global Forum for Health Research
- Selected to join the World Bank Junior Professional Associate program 2007
- Dean’s commendation list for high achievement, Faculty of Business, Economics and Law, University of Queensland, 2007
- Dean’s honour roll, Faculty of Business, Economics and Law, University of Queensland, 2005
- Dean’s commendation list for high achievement, Faculty of Business, Economics and Law, University of Queensland, 2004

SKILLS

- Fluent in English, excellent knowledge of French, basic knowledge of Spanish and Swahili
- Fully proficient in Microsoft Office, the data analysis and statistical software Stata, and GIS Mapping platform ArcGIS

PUBLICATIONS & PRESENTATIONS & ADDITIONAL COURSES

- Mikkelsen-Lopez, I., Tediosi, F., Abdallah, F., Njozi, M., Amuri, B., Manzi, F., de Savigny, D. (2013). Beyond antimalarial stock-outs: implications of health provider compliance on out-of-pocket expenditure during care seeking for fever in South East Tanzania. *BMC Health Services Research*.13:444
- Mikkelsen-Lopez, I., Cowley, P., Kasale, H., Mbuya, C., Reid, G. and de Savigny, D. (2013). Essential medicines in Tanzania: Does the new delivery system improve supply and accountability? *Health Systems*.1-8
- Mikkelsen-Lopez, I., Wyss, K. and de Savigny, D. (2011). Governance in Health Systems: towards a new assessment. *BMC International Health and Human Rights*. 11:13
- Mikkelsen-Lopez, I. (2010). Is Universal Coverage the Right Goal? In: *Global Forum for Health Research, Young Voices in Research for Health*. Geneva: Global Forum for Health Research, pp 89 - 93
- Fidler, A. and Mikkelsen-Lopez, I. (2010). Health System Reform in Slovenia. In: *From Tolar to Euro*. Ljubljana: Centre of Excellence in Finance, pp 23- 45
- ‘Towards a new approach for assessing Health Systems Governance’. Presentation at the Global Health Forum, Geneva, April 2010
- Mikkelsen-Lopez, I., Sango, W., Barrington, J., Ziegler, R., Smith, T. and de Savigny, D. ‘The challenge to avoid anti-malarial medicine stock-outs in an era of funding partners: the case of Tanzania’ (*accepted by Malaria Journal 29/04/2014*)

Additional Courses Completed

- E-learning course on Reproductive Health: from Advocacy to Action 2. The World Bank Institute. 6th February – 19th March, 2014