



Achieving Universal Primary Health Care Through Health Systems Strengthening: Lesotho's National Primary Health Care Reform

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ACHIEVING UNIVERSAL PRIMARY HEALTH CARE THROUGH HEALTH SYSTEMS
STRENGTHENING: LESOTHO'S NATIONAL PRIMARY HEALTH CARE REFORM

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**Achieving Universal Primary Health Care through Health Systems Strengthening:
Lesotho's National Primary Health Care Reform**

Abstract

This doctoral thesis examines how different aspects of health systems strengthening (HSS), such as human resources, supply chain, service delivery, and governance, can contribute to achieving universal health coverage (UHC). The doctoral thesis contains two key sections: the Analytical Platform, which examines key aspects of the existing literature on this topic, and the Results Summary, which presents a case study from Lesotho.

The Analytical Platform consists of one narrative chapter focused on the role that values can play in setting health system priorities, and two systematic reviews which examine whether different HSS interventions - namely 1) task shifting and 2) improvements to health product procurement and supply chain - can improve health system efficiency in low- and middle-income countries (LMICs). The first review finds that substantial evidence exists for task shifting as a means to generate cost savings for care related to tuberculosis, HIV/AIDS, and various other diseases at the primary health care (PHC) and community levels. The second review finds that substantial evidence exists for pooled procurement as a means to achieve cost savings, and that a wide range of supply chain interventions can increase drug availability in different contexts.

The Results Summary synthesizes Lesotho's experience with a National PHC Reform, which sought to strengthen health systems to create universal access to comprehensive PHC and which can in turn serve as the foundation for broader UHC in the country. The Reform consisted of interventions at multiple levels, including a Village Health Worker (VHW) program,

expanded services at clinics, decentralized management of the district health system, and central oversight of the Reform. Documentation of the Reform noted several key insights. First, in this model, VHWs do not simply have discrete clinical tasks, but rather have cross-cutting activities that aim to increase patient utilization of services across multiple disease areas. Second, by taking a comprehensive approach to improve population health, the Reform model specifically aims to build state capability in strengthening health systems.

The findings from the Analytical Platform and Lesotho's experiences documented in the Results Summary are relevant for policymakers, practitioners, and researchers working to achieve UHC through HSS in LMICs, especially in a post-2015 agenda.

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Introduction

Since the signing of the Alma-Ata Declaration in 1978, public health policymakers, practitioners, and researchers have debated the merits and effectiveness of using a primary health care (PHC)-based approach to achieving universal health coverage (UHC).¹ Since then, dominant approaches to improving public health have vacillated between using “horizontal” approaches to deliver health services (e.g. comprehensive PHC platforms, health systems strengthening [HSS]) and more targeted, “vertical” interventions focused on addressing specific disease areas. For example, shortly after the signing of the Alma-Ata declaration, some practitioners advocated for the implementation of “selective PHC,” which rebranded a focus on select vertical interventions under the label of a PHC approach.^{2,3} Beginning in 2000, the Millennium Development Goals (MDGs) focused on addressing specific disease areas.⁴ Much research and practice has focused on the limitations of using strictly vertical approaches to public health and the need to integrate disease-specific initiatives into health systems and broader HSS efforts.^{5,6}

Sustainable Development Goal 3 (SDG), launched in 2015 as part of the broader SDG agenda, focuses both on disease-specific priorities and overall access to strengthened health systems (through SDG 3.8 – achieving UHC).⁷ Due to the nascent nature of the SDGs at this time, it is difficult to know whether they will provide effective guidance that governments, donors, and other organizations can use to improve population health and other outcomes, or whether this new agenda will create fragmentation and confusion between priorities. Learning early from the experiences of countries aiming to improve population health under the new SDG agenda is critical for understanding both the success factors and challenges associated with these

efforts. Accordingly, Lesotho's health system and ongoing efforts to strengthen it provide a useful case study for understanding how national health reforms are playing out in a post-2015 agenda, and how both evidence and context influence public health practice.

Lesotho is a small land-locked country in Sub-Saharan Africa with a population of approximately 2 million people, and it has some of the worst health outcomes in Sub-Saharan Africa. Lesotho was significantly off-track to meet all health-related MDGs as of 2014.⁸ According to World Bank data, Lesotho has the highest incidence of tuberculosis and the second-highest incidence of HIV in the world. Maternal, newborn, and child health (MNCH) indicators, such as mortality rates for these populations, are similarly poor. Unsurprisingly, both the delivery of health services and demand for these services are also weak. The majority of the country lives in rural areas, and nearly 40% of rural residents report that it takes greater than two hours to reach the nearest health facility by walking. Less than 40% of the population has comprehensive knowledge of HIV/AIDS.⁹ The country faces high loss-to-follow up for HIV and TB patients, and 22% of women who receive at least one antenatal care (ANC) visit do not complete the recommended four.^{9, 10}

This doctoral project and thesis focus on efforts to improve population health in Lesotho through the development of a National Primary Health Care (PHC) Reform. The doctoral project took was hosted by Partners in Health (PIH), a US-based non-profit medical organization that has been working in Lesotho since 2006. The details of PIH's role in Lesotho's health system are discussed further in the Results Statement of this document.

Problem statement

The problem statement for this doctoral project and doctoral thesis is as follows: *Lesotho has poor population health outcomes, especially for high-burden diseases, such as HIV/AIDS,*

tuberculosis, and maternal, newborn, and child health (MNCH). I have chosen to formulate the problem statement this way for several reasons.

First, the problem statement focuses on the “work at the center” and does not speak to any potential competing interests or factions among stakeholders involved in the work.¹¹ Of course, a reform of any kind at the national level will involve many different groups that have different priorities and levels of power, including the government, donors, civil society organizations, the private sector, and the populations receiving these services. However, the ultimate goal of public health work should be to improve population health, so centering the problem statement for this work around population health outcomes can help to focus the work on this topic. The problem statement builds on widely-accepted metrics for measuring health outcomes and burden of disease, which I discuss in the Results Statement.

Similarly, the problem statement specifically avoids “defining the solution into the problem.”¹² There are many ways to improve population health, and I have specifically chosen to avoid naming (the absence of) one of those in the problem statement. For example, it would be tautological to describe the problem statement as the lack of National PHC Reform (and then subsequently describe a theory of change that addresses this problem by implementing a National PHC Reform.) The Results Statement describes the theory of change by which the National PHC Reform aims to address the problem statement.

Finally, I have tried to construct the problem statement to make it amenable to root cause analyses which would help identify appropriate solutions to the problem. For example, one could determine whether supply-side or demand-side factors (or both) present barriers to individuals getting tested for HIV/AIDS and then design interventions to address these barriers.

Relevance for the field of public health

As discussed earlier, the case study of the National PHC Reform in Lesotho provides an early and ongoing case study of a government undertaking a national health reform in a post-2015 agenda. The broad scope of this Reform means that it necessarily builds on theoretical and applied work in public health, social medicine, public administration, political economy, ethics, governance, and other disciplines. The implications the National PHC Reform, some of which are documented in this doctoral thesis, will have relevance for numerous stakeholders, including:

- **Government policymakers looking to improve public health in a post-2015 agenda, especially in low-resource settings:** As already mentioned, the shift from MDGs to SDGs has created a new set of priorities for public health and other development topics. The SDGs list a much broader and comprehensive set of goals. On the one hand, this expansion of priorities may create more opportunities for improving public health, especially by improving HSS efforts and focusing on UHC. However, this broadened set of priorities may also lead to fragmentation of efforts. While SDG 3 presents many priorities, it gives little guidance on the linkages between these priorities or how to organize and sequence efforts to address them. As a member of the UN, Lesotho has committed to achieving UHC and has already made commitments to achieving this goal, including the removal of user fees at public clinics and adopting the national Test & Treat policy to ensure universal access to HIV care.^{13, 14} The National PHC Reform, which aims to strengthen access to and delivery of PHC services for the entire population, provides another step toward achieving UHC. Therefore, understanding both the technical components of this policy and the barriers and enablers to its adoption and implementation can provide useful experience for other countries working to address similar issues.

- **Development partners (e.g. donors, NGOs) aiming to achieve public health goals by building state capability:** While PIH and numerous other development partners participated and have a stake in the Reform, the effort is ultimately government-led. The story of the Reform is one of organizational capability of the state at various levels – community, health clinics, district management health teams, and central government – with various programs and interventions. Therefore, the successes and challenges of this effort can contribute to a growing knowledge base of how to build state capability for improving public health and other development priorities.^{15, 16}
- **Public health practitioners and researchers working on service delivery-related aspects of UHC:** Achieving UHC requires financial accessibility, physical accessibility, and acceptability of health services.¹⁷ While the literature on financial accessibility is very robust,¹⁸ the literature on the delivery-related aspects of UHC is less comprehensive at this time; indeed, as of the time of writing, SDG 3.8 still did not have an official set of indicators to measure progress on its implementation.¹⁹

Sections of this doctoral thesis

This doctoral thesis is organized into an Analytical Platform and Results Statement. The Analytical Platform introduces novel frameworks and evidence relevant for Ministers and other policymakers looking to strengthen health systems and improve population health, especially in low- and middle-income countries (LMICs). Consistent with the goals of the doctoral project of translating knowledge into practices and policies, the sections of the Analytical Platform integrate existing pieces of literature to create an evidence base on select topics that are relevant for policymakers and practitioners in public health. Drafts of all chapters of the Analytical Platform were all presented at the Harvard Ministerial Leadership Program, a forum designed to

strengthen leadership by Ministers of Health, Finance, and Education from LMICs (and which the current Minister of Health of Lesotho has attended). The chapters in this section are as follows:

- **Aligning Values and Outcomes in Priority-Setting for Health:** This article presents a framework for analyzing the role that values play in shaping government priorities as they pertain to health, and how these priorities in turn shape health, economic, and political outcomes. The framework describes specific value sets – utilitarianism, liberalism, and communitarianism – and explains how each value set might lead to a different set of priorities and choice in priority-setting and resource allocation. Although the policymaking process does not usually follow such a linear approach, such a framework can help policymakers and other stakeholders understand and communicate the principles by which they have set their priorities and the intended goals of their decisions.
- **Does task shifting yield cost savings and improve efficiency for health systems? A systematic review of evidence from LMICs:** This systematic review examines the existing evidence base for using task shifting (i.e. shifting clinical or public health tasks to lower-skilled workers) as a means for achieving cost savings and improving health systems efficiency. Previous research has demonstrated the effectiveness of task shifting and the cost-effectiveness of using community health workers (CHWs), and this article builds on that in three ways: 1) it includes all forms of task shifting, rather than just CHWs, 2) it reports cost savings, which serve as a proxy for health systems efficiency, rather than cost-effectiveness thresholds, and 3) it systematically reports changes to program quality when cost savings are achieved. The research finds that substantial

evidence exists for cost savings achieved for task shifting related to TB and HIV/AIDS programs, especially at the PHC and community levels, and additional evidence exists for a wide range of other diseases.

- **Do changes to supply chains and procurement processes yield cost savings and improve availability of pharmaceutical, vaccines, and other health products? A systematic review of evidence from LMICs:** This systematic review examines the existing evidence base for using supply chain and procurement improvements as a means for achieving cost savings. Although much HSS work focuses on these areas, little systematic evidence of its impacts on costs exists. The research finds that centralized procurement and tendering processes can lead to direct cost savings, while different types of supply chain management programs can reduce drug stock outs, thereby possibly leading to indirect cost savings through efficiency improvements.

The Results Statement focuses on the specifics of the health system in Lesotho and the National PHC Reform. This section documents the theory of change of the Reform and how it attempts to address the problem statement. It analyzes the context and technical aspects of the Reform and documents the process of formulating, adopting, and implementing the Reform, both before and up through the completion of the doctoral project. The chapters in this section are as follows:

- **Overview of the National Primary Health Care Reform:** This section defines the problem statement and summarizes the theory of change by which the National PHC Reform sought to address this problem.
- **DEPLESET analysis of Lesotho:** Understanding the context for a major public health reform or other development initiative is critical for its success. This chapter uses the

DEPLESET framework* to analyze the key aspects of the context in Lesotho, both health-related and otherwise, and how these factors might contribute to the success or failure of the Reform.

- **Village Health Workers Activities along the Care Delivery Value Chain: The Case of Lesotho:** This article documents the technical aspects of PIH's Village Health Worker (VHW) model, which served as the basis for the Reform pilot. While much research has focused on the technical skills that VHWs can perform for a specific disease area (e.g. HIV/AIDS, TB), less research exists documenting the activities that VHWs can play across disease areas. Using the Care Delivery Value Chain (CDVC) framework, this article identifies four distinct competency-based activities that VHWs in the Reform model have: 1) community-based demand creation and health facility support, 2) community-based patient identification and diagnosis, 3) patient accompaniment and tracking, and 4) community-based care delivery and support. All four of these activities contribute to the VHW's overall role as an extension of the health system into the community that can help increase utilization of services. Based on this evidence, we suggest that defining VHW skills as a set of competency-based activities rather than clinical tasks for a specific disease area may reorient their training and help better integrate them into broader HSS activities.
- **Building State Capability to Strengthen Health Systems: The National Primary Health Care Reform in Lesotho:** This article documents the process of setting the agenda, formulating, adopting, and implementing the National PHC Reform up to this point. Using analytical frameworks drawn from health systems innovation diffusion

* Demographic, Economics, Political, Legal / Regulatory, Epidemiological, Sociodemographic, Environmental, Technological

theory and problem-driven iterative adaptation (PDIA), this article finds that adoption and diffusion of the Reform did not happen in a simple, linear process, but rather through multiple cycles of iteration that allowed the Reform to gain functionality and legitimacy over time. Adoption of the Reform used several key approaches to building state capability, including: focusing development efforts on locally-identified problems, encouraging ongoing experimental iteration, (re-)establishing authorizing environments over the course of the Reform, and engaging a broad set of change agents. Other key policy lessons identified from this research include the importance of setting the agenda for reform using multiple sources of “data” (including quantitative analysis and observational experience by senior decision-makers), and the importance of building grassroots support for a policy, especially in a shifting political climate.

The conclusion of this doctoral thesis summarizes the key findings from the thesis and highlights key policy and public health implications.

Analytical Platform

Aligning Values and Outcomes in Priority-Setting for Health

Gabriel Seidman and Rifat Atun

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Abstract

Numerous factors and competing interests shape policymaking and budget allocation for health and health systems. In particular, the values and outcomes prioritized by policymakers have important implications for health spending and the impacts they have on populations and countries. Based on Harvard's Ministerial Leadership Program, this article provides an overarching and integrative framework that policymakers can use to explicitly consider the priorities shaping their decisions, the outcomes that result from their decisions, and processes for making these decisions. The framework includes four key questions: 1) What values underlie the government's priorities for the country? 2) Based on these values, what goals for the healthcare system does the government hope to achieve? 3) Based on these goals, where should the government allocate its financial resources for health? 4) How should the government allocate its financial resources for health? The framework also takes into consideration health system, economic, and political outcomes that result from budget allocations.

Introduction

Investments in health and health systems can create value in two distinct but related ways: by generating “value for money” and “value for many”.²¹ Policymakers can prioritize budgets to improve efficiency and effectiveness of health expenditures, thereby generating value for money, and target investments to improve equity and responsiveness to users’ needs, thereby achieving value for many.

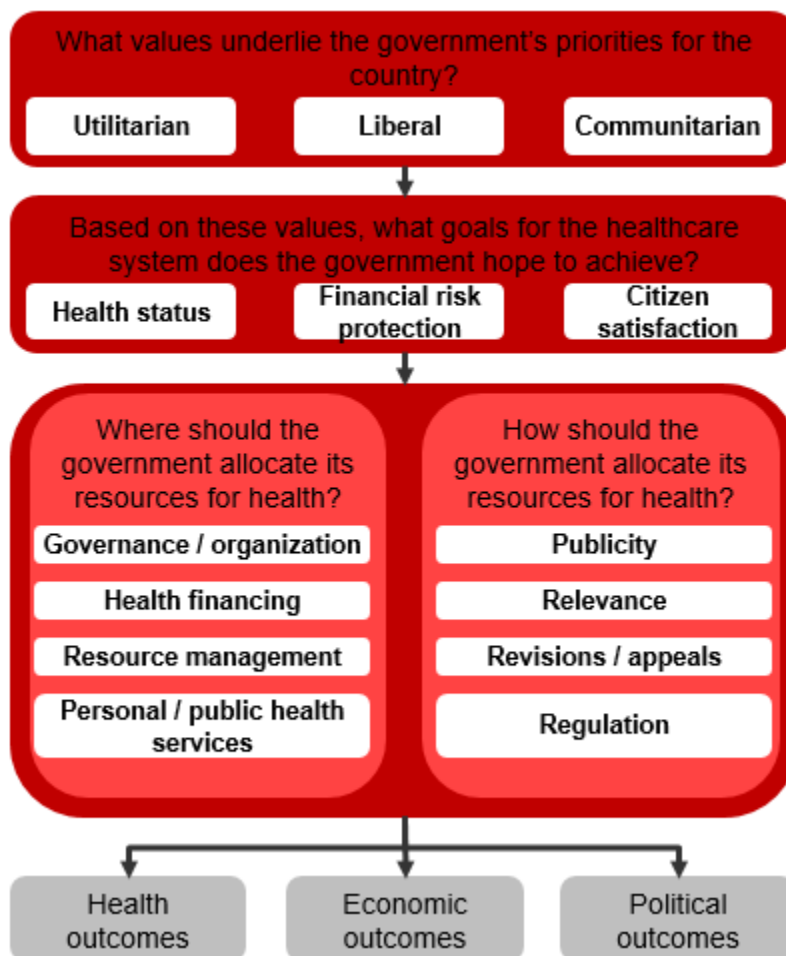
The size and allocation of the health budget directly and indirectly impact population health. Low- and middle-income countries (LMICs) with similar per capita GDP, health expenditures as a proportion of GDP, and per person health expenditure have different outcomes. Investing in health can also bring economic benefits for countries²²⁻²⁵ and political benefits for policymakers who choose to prioritize health (in countries where citizens have electoral power). This article presents a framework (see Figure 1) used at Harvard University’s Ministerial Leadership Program to introduce the roles that values and goals can play in prioritizing health programs and budgets. Based on our experience presenting this framework to several dozen Ministers of Health and Ministers of Finance, we believe it can serve two purposes. First, it can help policymakers explicitly articulate the values, and principles that influence their decisions. Values and beliefs already influence decision-making; as discussed later, policymakers should make these values public and transparent to other decision-makers and the public in order to legitimize their decisions and to invite productive debate. Second, the framework explicitly links the way that different values can impact a policymakers’ priorities, which in turn can lead to different health, economic, and political outcomes. In line with the principles of systems thinking, we believe that by explicitly stating the “mental models” which guide decision-making, individuals and groups can better test their logic *ex ante* and evaluate the impact of their decisions *post hoc*.

The framework includes four guiding questions:

1. What values underlie the government's priorities for the country?
2. Based on these values, what goals for the healthcare system does the government hope to achieve?
3. Based on these goals, where should the government allocate its financial resources for health?
4. How should the government allocate its financial resources for health?

These questions have direct relevance for all policymakers whose decisions impact health.

Figure 1 - Framework for aligning values and outcomes when setting priorities for health



1. What values underlie the government's priorities?

Although a broad range of values can drive the government's approach to resource allocation, these value sets generally fall into three broad categories: utilitarian, liberal, and communitarian.^{22, 26}

Utilitarians typically focus on the value, or utility, that a decision will have. Utilitarians generally believe "the ends justify the means" (assuming "the means" involve ethical and legal decisions). Policy tools such as cost-effectiveness and cost-benefit analysis reflect utilitarian concerns of generating the greatest benefits (utility) using the fewest possible resources. Utilitarians differ in how they choose to measure total utility. Subjective utilitarians argue that individuals must judge happiness for themselves. Objective utilitarians argue that individuals' choices are not always rational and that allocating resources to maximize objective measures of well-being (e.g. Disability-Adjusted Life Years [DALYs] and Quality-Adjusted Life Years [QALYs]) will have the greatest benefit.

Liberals take a rights-based approach to allocation of health resources. Liberals believe that humans have the capacity and obligation to display mutual respect, and this respect endows individuals with rights. Some liberals, known as libertarians, focus on negative rights, which guarantee individual freedom. Libertarians might focus on the rights of the individual to buy health insurance or choose their physician. In contrast, egalitarian liberals emphasize positive rights, or a minimum level of resources and services, which guarantee an individual's ability to exercise free choice. Egalitarian liberals tend to favor redistribution of resources to ensure the entire population has access to positive rights. However, egalitarian liberals differ in their views on whether individuals have a right to health services (i.e. provision of and access to care) or health status (i.e. attaining general well-being).

Communitarians do not focus on the level of the individual in assessing a policy, but on the level of the community or society. They evaluate the merit of a policy based on whether it adheres to a community's value set and whether the policy promotes a society consistent with those values. Communitarians would typically oppose a policy which achieves positive health outcomes using an intervention that defies local norms or values. Communitarians fall into two broad categories: those who believe in a single set of values which would promote a better society (universal communitarians), and those who argue that each society should set its own values based on context-specific factors (relativist communitarians).

These value sets are not mutually exclusive. Policymakers might include both a utilitarian and communitarian perspective in an analysis if they prioritize health interventions based on objective utility but exclude any that defy local norms. Further, governments can modify their ethical values as they learn more about a population's needs and their ability to meet those needs. However, it is important to maintain adequate "coherence and explicitness" when articulating one's values to create transparency for the population.²²

2. Based on these values, what goals for the healthcare system does the government hope to achieve?

Policymakers must consider which outputs and outcomes to prioritize when allocating resources for health. In this context, *outputs* refers to how well the health system performs its functions, whereas *outcomes* refer to the ultimate goals of the health system. In many cases, strong delivery of health systems outputs is necessary but not sufficient for strong health system outcomes.

A policymaker needs to balance four health system outputs:²⁷

- **Equity** refers to the differences in how a policy affects different people. “Vertical equity” evaluates differential impact across different populations, whereas “horizontal equity” evaluates whether the policy treats individuals with the same status the same.²²
- **Efficiency** has many definitions in the fields of policy analysis. For the purposes of health systems analysis, we draw on economic definition of technical efficiency, in which society is producing the most goods and services for the least cost.²²
- **Effectiveness** refers to whether interventions are evidence-based and safe.²⁷ In other words, an effective intervention will achieve the desired health outcomes.
- **Responsiveness** refers to whether the health system meets the public’s legitimate non-medical expectations. Responsiveness is a highly subjective measure and depends on the perceptions among citizens of a health system’s functioning.²⁸

Policymakers’ values will influence which health system outputs they prioritize. For example, pure utilitarians will likely care most about efficiency and effectiveness, and they will less likely prioritize equity. They might also disregard the importance of responsiveness as an objective, unless they believe that a health system’s responsiveness generates value for the population. Liberals, who focus on individuals’ rights, will prioritize equity and responsiveness of the system, with libertarians emphasizing the importance of responsiveness (e.g. choice of health service providers) and egalitarian liberals emphasizing equity in access to positive rights (e.g. basic health services and medicines). Communitarians, who emphasize society’s values, will prioritize the objectives most relevant for achieving the best possible society. Accordingly, they will likely emphasize responsiveness and equity of the system at a societal level, although the emphasis could vary depending on the specific values of the society.

In addition to setting output objectives, policymakers must also pay attention to the health systems outcomes, or the overall goals, of a country's health system: ^{22, 27}

- **Health status** refers to the health of a population. Measurements of population health status include life expectancy, burden of disease, mortality rates for specific groups, and disease prevalence.
- **Financial risk protection** refers to helping people avoid large and unpredictable payments for health, also known as catastrophic (or impoverishing) expenditures. Mechanisms to provide financial risk protection typically involve insurance schemes or tax-funded health systems.
- **Citizen satisfaction** refers to the degree with which users of the health system rate the system as satisfactory.

As with outputs, health systems outcomes derive directly from values. For example, objective utilitarians might concern themselves most with the population's average health status, whereas egalitarian liberals might focus most on the distribution or range of health statuses in the population (as a measure of equity). Egalitarian liberals will also emphasize the importance of financial risk protection as a means for ensuring economic opportunities for all. Subjective utilitarians might place a high value on citizen satisfaction, as would libertarians (in the sense that satisfaction relates to individual choice.)

3. Based on these goals, where should the government allocate its financial resources for health?

Once the government has identified its objectives for the outputs and defined its goals for the health system, it can invest in specific programs or interventions accordingly. A health system has four main functions which a government can prioritize for investment: ²⁷

- **Governance and organization** encompasses the institutions involved in delivering products and services to citizens such as hospitals and primary care clinics.²⁹ Investments in this function include improving accountability or transparency of decision-making, updating management policies and processes at the programmatic level, or changing the system's referral network.
- **Health financing** involves mobilizing, pooling, and allocating financial resources.. A government could choose to invest in health financing by creating a new insurance scheme, expanding coverage of existing insurance to new patient populations, or by expanding the range of services covered under existing schemes.
- **Resource management** entails overseeing the inputs, such as human resources and labor, pharmaceuticals, and medical technologies that produce personal or public health services. The government can invest in the management of resources by purchasing these resources (e.g. procuring medicines), improving systems that oversee and deliver resources (e.g. budgeting tools, supply chain management), or by investing in infrastructure and human resources to strengthen the health system.³⁰

Personal and public health services refer to the activities involved in delivering care to patients. Strong health systems enable delivery of these services. Governments also invest in specific services that generate value, such as by investing in primary health care delivery. Several investment cases have been made for disease-specific “good buys” such as those identified by the Lancet Commission on Investing in Health³¹; UNAIDS HIV Investment Framework³²; STOP TB Strategy³³; the Global Strategy for Women's and Children's Health spearheaded by the UN Secretary General³⁴; interventions identified in

the Global Malaria Action Plan ³⁵, and; the Package of Essential Noncommunicable Disease Interventions (also known as WHO-PEN) ³⁶.

Values will influence how policymakers invest across these four functions. For example, a utilitarian might focus on improving resource management to reduce wastage in the system and improve efficiency. Utilitarians might also focus on the “good buy” interventions described above and choose to invest in those that improve population health for the least cost. By contrast, egalitarian liberals might focus on ensuring equitable access to health insurance and effective health services, especially for marginalized patients such as poor and rural populations, even if these programs are more expensive. Communitarians will focus on implementing these functions to coincide with their society’s values. For example, a society that emphasizes individual responsibility for health might de-prioritize social support for accessing services, while a society that emphasizes the community’s role in promoting health might implement a social health insurance scheme or mobilize the community to raise awareness about disease prevention.

4. How should the government allocate its financial resources for health?

There is no formula for determining which health interventions or areas to prioritize, and limiting analyses to comparisons of cost-effectiveness is insufficient for policymaking.

Without universal consensus on the principles for prioritization, governments need to adopt an approach to allocate resources and justify their policies. Accordingly, ethicists have proposed a framework known as “accountability for reasonableness” (A4R) to guide this decision-making process. A4R, a process grounded in democratic principles aimed at legitimizing decision-making among “ ‘fair-minded’ people who seek mutually justifiable terms of cooperation,” has four conditions ³⁷:

1. **Publicity:** Decisions that establish priorities in meeting health needs and their rationales must be publicly accessible.
2. **Relevance:** Policymakers should provide reasonable rationales which appeal to evidence, reasons, and principles accepted as relevant by fair-minded people when justifying their decisions. Rationale should be relevant for a broad range of stakeholders in decision-making.
3. **Revision and appeals:** There must be mechanisms for challenge and dispute and, more broadly, opportunities for revision and improvement of policies in light of new evidence or arguments.
4. **Regulative:** There must be public regulation of the process to ensure that conditions 1, 2, and 3 are met.

A4R does not identify the priorities for government investments; it establishes a transparent process for publicly and legitimately determining these priorities in order to guide investment decisions. These principles have relevance for policymakers and societies that subscribe to all value sets. Indeed, A4R does not promote a specific value set, but rather advocates for explicitly articulating and linking values and principles to decisions and outcomes, which our framework can help put into practice.

The principles of A4R have influenced health priority-setting in several places: UK, where the National Institute for Health and Clinical Excellence (NICE) takes social value judgments into account when recommending coverage for new treatments ³⁸; Mexico, where decisions about which diseases the public catastrophic insurance should cover involve working groups that evaluate clinical, economic, ethical, and social considerations ³⁹; and Oregon, where,

in 2008, a Health Fund Board made a plan to insure all legal residents of the state involving a wide group of stakeholders and extremely transparent decision-making / information-sharing ⁴⁰.

Outcomes from health spending

The decisions described above can have at least three sets of outcomes.

Health system outcomes

Changes in government health spending can directly impact cause-specific mortality. For example, in low-income countries a 1% decrease in government health spending is associated with an increase of 18 neonatal deaths for every 100,000 live births and 98 deaths before the age of five. ⁴¹ From 1999-2004, a 10% increase in per capita total health expenditure was associated with a 22% reduction in infant mortality rate and 10% increase in per capita public health expenditure was associated with a 21% reduction in infant mortality rate. ⁴² Globally, a 1% increase in government health spending is also associated with a significant decrease in cerebrovascular deaths. ⁴³

However, simply increasing government (or any) spending on health will not necessarily improve health outcomes, especially if funds are not spent efficiently. Evidence suggests that increasing the efficiency of government health spending, without increasing total budget expenditure, could improve population health outcomes. ²⁵ Increasing health spending efficiency among nations below the regional average to the regional average would result in an increase in health-adjusted life expectancy (HALE) by 1.5 years in Africa, 1 year in Asia / Pacific, and 1.3 years in Middle East / Central Asia. In the most extreme example, increasing health spending efficiency in Sierra Leone to the average for Africa could improve HALE by 5.3 years.

Achieving the health systems goal of financial risk protection through universal health coverage (UHC) can also improve population health status. Countries that currently do not have

UHC can improve coverage either by increasing budget allocation to health, or by improving spending efficiency in order to redirect spending to UHC. Cross-country analysis of the influence of insurance coverage on health outcomes suggests that financial coverage has a causal influence on health, especially for low-income individuals, who gain better access to necessary care when they receive coverage.⁴⁴ Individual countries' experiences implementing UHC, including Thailand, Turkey, and several countries in Latin America, supports this finding.^{27, 45-}

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Economic outcomes

Evidence strongly suggests that improved population health has positive economic impacts for a country. Achieving better population health provides a sound “return on investment” in the form of stronger economic output and growth. Evidence for the linkage between health and economic output exists at both the microeconomic and macroeconomic levels.

At the microeconomic level, better health can improve the financial prospects of individuals and households.²³ Malnutrition, frequent illness, and unstimulating home environments can limit the physical and cognitive development of children. Conversely, proper nutrition and health supports adequate physical development and school performance.²³ Interventions targeting specific diseases, such as deworming, nutrition supplements, and malaria prevention can lead to improved education or income outcomes for individuals.²⁴ Among working individuals, illness can negatively impact income due to impoverishing health expenditures, reduced education opportunities, decreased productivity at work, long-term separation from the work force, and disengagement from other economic activities.

Macroeconomic evidence also supports the idea that investing in health generates positive economic returns.²⁴ First, *ceteris paribus*, a healthy workforce will have higher labor productivity than an unhealthy workforce due to increased energy and reduced illness-related absenteeism. Second, a healthy population has increased educational opportunities, and education levels have a direct impact on a country's income growth. Third, populations with high life expectancies tend to save more for the future and likely will have more working years. These increased savings can lead to increased investable capital, an important driver of growth. Fourth, health investments that change mortality and fertility can lead to a "demographic dividend," in which the ratio of working-age to non-working-age people in the country increases and productive capacity increases on a per capita basis. (This demographic dividend accounts for up to one-third of the economic boom that many East Asian countries experienced between 1965 and 1990.)

Political outcomes

Formulating health policy and allocating resources to health depends on and also impacts a country's politics. For example, the transition towards universal health coverage (UHC) has had distinct positive political benefits in many countries.⁴⁸ In addition, health policy in countries such as Turkey, the UK and Brazil has significantly influenced political landscape and political outcomes.

In Turkey, after a regime change in 2002, the government implemented a Health Transformation Program (HTP) with significant commitment from political leadership. This transformation led to increased levels of public satisfaction with the government and influenced voter intentions in favor of the government.⁴⁹

After the re-democratization of the Brazilian government, the 1988 constitution formally defined health as a “citizen’s right and obligation of the state” and established the Unified Health System (SUS), which sought to unify the fragmented care delivery network into a national health system under the MoH. ⁵⁰ Today, 75% of Brazil’s population, or 195 million people, receive services and coverage from SUS. ⁵¹

In the UK, the National Health Service (NHS) receives broad public support, with 89% of the public agreeing with the idea of a tax-funded national health system, which is managed by the government. However, projections show that by 2030, the NHS will have a £65 billion funding gap. Therefore, UK policymakers will have to balance the competing health, financial, and social demands placed on the NHS in order to maintain its relevance going forward.

Framework limitations

Although we believe that this framework can help policymakers make their values more explicit and link values to decisions and outcomes, it has several limitations. First, it presents decision-making as a linear process, whereas decision-making occurs in the context of complicated processes subject to outside forces. Second, the framework does not incorporate decision analysis tools into its approach and cannot and cannot provide a clear-cut answer when making a tradeoff between two different investments. We believe that linking analysis of value-based decision-making with quantitative decision tools is an important next step for study. Finally, because this framework focuses by design on the level of health systems clinicians cannot use it to make individual care decisions.

Conclusion

This article introduces a framework for policymakers to consider how their values influence priority-setting for health and the impacts that these priorities can have on health

systems, economic, and political outcomes. By clearly articulating values and priorities, policymakers can develop a transparent and deliberative process to better discuss and engage their constituents in health systems decisions and to set priorities that create greater value for money by improving efficiency and effectiveness of budget allocation decisions and more value for many by enhancing equity and responsiveness in the health system.

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Does task shifting yield cost savings and improve efficiency for health systems? A systematic review of evidence from Low- and Middle-Income Countries

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Abstract

Background: Task shifting has become an increasingly popular way to increase access to health services, especially in low-resource settings. Research has demonstrated that task shifting, including the use of community health workers (CHWs) to deliver care, can improve population health. This systematic review investigates whether task shifting in Low- and Middle-Income Countries (LMICs) results in efficiency improvements by achieving cost savings.

Methods: Using the PRISMA guidelines for systematic reviews, we searched PubMed, Embase, CINAHL, and the Health Economic Evaluation Database on March 22, 2016. We included any original peer-review articles that demonstrated cost impact of a task-shifting program in an LMIC.

Results: We identified 791 articles, of which 34 were included in our study. We found that substantial evidence exists for achieving cost savings and efficiency improvements from task shifting activities related to tuberculosis and HIV/AIDS, and additional evidence exists for the potential to achieve cost savings from activities related to malaria, NCDs, NTDs, childhood illness, and other disease areas, especially at the primary health care and community levels.

Conclusions: Task shifting presents a viable option for health system cost savings in LMICs. Going forward, program planners should carefully consider whether task shifting can improve population health and health systems efficiency in their countries, and researchers should investigate whether task shifting can also achieve cost savings for activities related to emerging global health priorities and health systems strengthening activities such as supply chain management or monitoring and evaluation.

Introduction

Efficient and effective health systems are critical for managing healthcare costs, addressing rising burden of disease, and providing sustainably universal health coverage. The efficiency of health spending has major implications for the health of the population. In low and middle income countries (LMICs) of Africa, Asia, and the Middle East, increasing the efficiency of health spending could increase health-adjusted life expectancy by 1-2 years.²⁵

Human resources for health (HRH) make up a significant portion of health expenditures; in LMICs, spending on salaried health workers makes up 28.7%-33.2% of total health expenditure.⁵³ Improving the efficiency of spending on HRH can improve the efficiency of health systems, which can free up financial and other resources and ultimately improve health coverage.⁵⁴

According to the World Health Organization (WHO), task shifting “presents a viable solution for improving health care coverage by making more efficient use of the human resources already available and by quickly increasing capacity while training and retention programs are expanded.”⁵⁵ Task shifting can produce equivalent or superior outcomes for many

diseases and health interventions including non-communicable diseases,⁵⁶ HIV/AIDS,^{57, 58} contraceptive distribution,⁵⁹ and others.^{56, 60}

Given the high spend on HRH, the evidence for task shifting as a way to improve population health, and the prominence of task-shifting on the global policy agenda, policymakers should understand the cost and efficiency implications of this approach to health systems strengthening (HSS). Therefore, our systematic review aims to answer the following question: Does task shifting result in cost savings and efficiency improvements for health systems or patients in LMICs?

To our knowledge, only one literature review (Vaughan et al., 2015) has addressed a similar question so far.⁶¹ That review found that community health workers (CHWs) are cost-effective for treating TB and select other disease areas, such as reproductive, maternal, newborn, and child health (RMNCH). Our review builds on the important initial review conducted by Vaughan et al. in three ways. First, our search strategy takes a broader scope in that it reviews other forms of task shifting besides the use of CHWs (e.g. shifting the work of physicians to nurses or the work of nurses to pharmacy technicians), which may contribute to HSS.

Second, our review looks at evidence for efficiency improvements achieved by shifting tasks from one cadre of workers to another, rather than whether an intervention using a specific type of health worker meets a cost-effectiveness threshold. Although cost-effectiveness thresholds (e.g. cost / unit of health improvement above or below a pre-defined benchmark) are an important criterion for prioritizing interventions, cost-effectiveness as measured by an actual reduction in costs without a reduction in programmatic quality is particularly salient for policymakers trying to improve the efficiency of the health system. Therefore, we review whether studies found changes in cost per input / process, output, or outcome as a result of task

shifting. Whereas cost savings on inputs / processes are very likely since the wage for a lower-skilled worker will almost always be lower than that of a higher-skilled worker, cost savings on outputs and outcomes are not as guaranteed since lower-skilled workers might operate less efficiently. A reduction in cost per output or outcome can be interpreted as an improvement in efficiency and therefore a true savings to the health system (with changes in cost per outcome as the stronger indicator), but a reduction in cost per input / process can only be interpreted as an efficiency improvement if it is accompanied by the documentation of no change (or an improvement) in clinical or programmatic quality.

Third, following from the previous point, our review also captures and reports evidence of changes in programmatic or clinical quality as a result of task shifting for each included reference, which Vaughan et al. do not systematically report. Reporting programmatic quality outcomes is important for determining whether a reduction in costs actually indicates an improvement in health systems efficiency.

Methods

This systematic review follows the criteria and methodology described in the PRISMA guidelines on systematic reviews.⁶²

Search process and criteria

This search relied on an internal protocol developed by both authors, with the support of a Harvard University librarian specializing in systematic reviews. The protocol was not registered externally. We searched PubMed, Embase, CINAHL, and the Health Economic Evaluation Database. The main search that was conducted on March 22, 2016 was as follows (for PubMed), with an additional search term for LMICs, and any publication from before that data was eligible for our review:

(task shift*[tiab] OR balance of care[tiab] OR non-physician clinician*[tiab] OR nonphysician clinician*[tiab] OR task sharing[tiab] OR community care giver*[tiab] OR community healthcare provider*[tiab] OR cadres[tiab] OR "Community Health Workers"[Mesh])
AND
("Cost Savings"[mesh] OR "Cost Benefit Analysis"[mesh] OR "Efficiency"[mesh] OR cost[tiab] OR costs[tiab] OR efficienc*[tiab] OR economies of scale[tiab] OR economies of scope[tiab] OR productivity[tiab] OR absenteeism[tiab] OR "Absenteeism"[Mesh])

We also conducted several additional searches based on a review of citation lists from relevant publications, and based on recommendations from public health researchers.

Study selection and eligibility criteria

After conducting our search, all titles were reviewed for relevance. After excluding irrelevant titles, we read all abstracts and, when appropriate, full articles to determine the relevance of the article for our research question. In order to be included in the study, the publication had to meet the following criteria:

- Report on an effort, such as a program or policy intervention, involving task shifting of a clinical activity or health systems-related activity
- Report a comparison of program costs from the task-shifted model for conducting the activity or service to a comparable activity in a model that does not involve task shifting.
- Report results from an actual intervention, rather than a computer model or simulation
- Report results from a low- or middle-income country
- Be original research about an intervention published in a peer-reviewed format (as opposed to an editorial, literature review, opinion piece, interview, etc.)
- Have a complete article available (as opposed to just an abstract)

- Be published in English

Data collection process

In order to extract data for this review, we piloted an Excel-based data collection tool that was used to capture results from a preliminary search, the results of which were presented at the Harvard Ministerial Leadership Program in the summer of 2016. Based on our experience with this initial process, we modified the tool accordingly and finalized a tool which collected the following information: author, year, title, publication, abstract, country, continent, description of the intervention, main indicator, result on relevant indicator, and data on programmatic quality changes resulting from the intervention. Studies were not excluded if they did not have relevant quality comparisons. Results which did not provide evidence of cost changes, such as baseline costing studies, were excluded. GS conducted a first review of all references in the search, and the list was reviewed by RA and other public health researchers in order to identify missing references or references which had been improperly included.

We also retrospectively categorized the included references based on whether the main indicator documented changes in cost per input / process, output, or outcome, using the following definitions:⁶³

- Inputs / processes: Resources required to conduct an activity, or a discrete activity such as a patient visit with a clinician
- Outputs: Direct products of program activities, such as number of individuals treated
- Outcomes: Changes in health status as a result of the program, such as number of patients cured or number of deaths averted

Risk of bias

As with any systematic review, the references and data sources for this review contain the possibility for bias. At the level of individual references, authors are more likely to report cost data if their program resulted in cost savings, especially if costing / cost-effectiveness was not the primary purpose of the study.

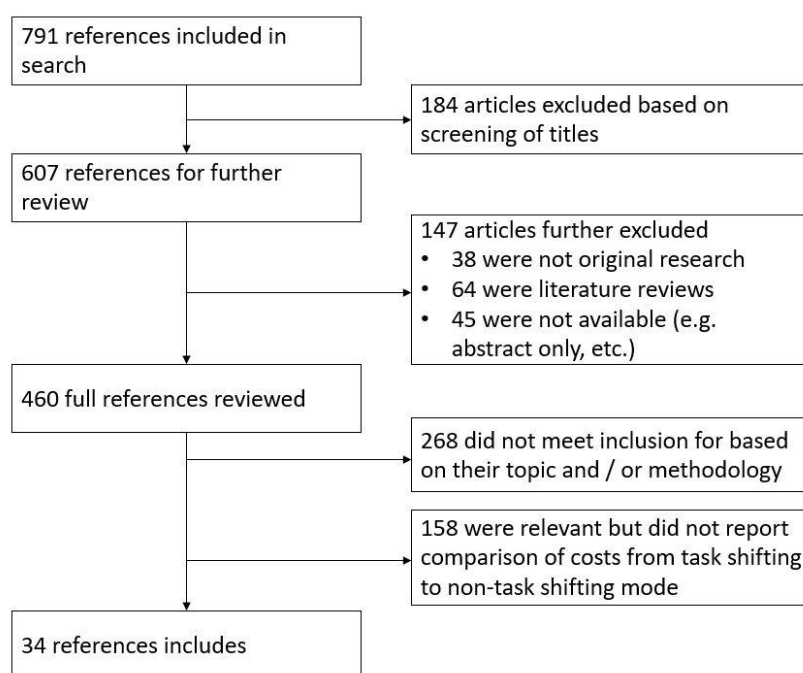
Across all studies, there is also a risk of publication bias and selective reporting within studies, especially if authors more frequently chose to report positive outcomes (such as cost savings). Of course, the decision to implement task shifting in a given context would require extensive analysis of that particular intervention's potential impact, and we caution researchers and policymakers not to interpret the findings from this review as indicative of the results that they can expect to achieve.

Results

Study selection

We reviewed 791 articles and identified 34 references which analyzed the cost implications of task shifting in LMICs – 22 in sub-Saharan Africa, eight in Asia and four in Central or South America. See Figure 2 for the study selection for inclusion in this systematic review. Of the 32 studies included in the review by Vaughan et al., we excluded 17 and included 15, which means that our review also included an additional 19 studies not included in Vaughan et al. Of the 17 references included by Vaughan et al. that we excluded, 12 were excluded because they did not provide comparison of costs between the task shifted model and another model of care,⁶⁴⁻⁷⁵ three reported results from modeling of hypothetical programs rather than actual interventions,⁷⁶⁻⁷⁸ one reference did not have a full article available,⁷⁹ and one reference reported the same data from the same program as another reference already included in our review.⁸⁰

Figure 2 - Study selection for inclusion in the systematic review (task shifting)



Of the 34 studies included in our review, 30 found evidence of a reduction in health costs either to the health system or the patient, and four had a mixed impact, an increase in costs, or no changes in costs.⁸¹⁻⁸⁴ Almost all the studies focused on the effects of shifting clinical or public health tasks related to a specific disease or disease area, while one study focused on task shifting ab HSS activity (mapping of village geographic coordinates).⁸⁵ Only two studies examined task shifting within a hospital, whereas all others examined task shifting from the hospital to the primary health care (PHC) or community levels, or task shifting within the PHC / community levels.

Of the 30 studies that found evidence of cost savings, 10 reported a cost savings per outcome, 13 reported a cost savings per output, and 3 reported a cost savings per input / process coupled with a corresponding maintenance or improvement in programmatic quality. Although cost savings on inputs / processes do not indicate efficiency improvements as strongly as savings on outputs or outcomes, the combined body of evidence from these 26 studies suggests that task

shifting yields cost savings that result in efficiency improvements to the health system, especially at the PHC and community levels. The four citations which reported cost savings on an input / process and which did not report changes in clinical or programmatic quality all reported on tasks related to different disease areas / HSS activities.

The full list of references meeting inclusion criteria can be found in Table 1.

Tuberculosis

Nine studies demonstrated cost savings with task shifting for identification, diagnosis and treatment of tuberculosis. Strategies for reducing costs included task-shifting treatment supervision to health workers in the community,⁸⁶⁻⁹² to home guardians or close relatives,⁹³ laypersons,⁹⁴ and in one case entrusting patients to take medicine without direct supervision.”⁶⁴ Programmatic and clinical indicators, such as treatment success rate, treatment completion rate, and case finding rate, also indicate that task shifting programs maintained programmatic quality comparable or superior to traditional models of care.

HIV/AIDS

Studies in this review revealed cost savings from task shifting prevention and care for a high-risk group (men who have sex with men [MSM]) to community-based organizations⁹⁵, and dispensing of ART from pharmacists to Indirectly Supervised Pharmacist Assistants (ISPA), adherence clubs, or other pharmacy-only refill programs.⁹⁶⁻⁹⁹ Programmatic indicators, such as patient retention, viral load, and mortality also indicate that these programs maintained high-quality of care. These findings indicate that the dispensation of ARTs, especially to clinically stable patients who are very familiar with the routine of taking these drugs, is suitable for task shifting in low-resource (and possibly other) settings. One study examining task shifting of ART dispensation to clinics found both an increase of costs in one state and a decrease in another

state,⁸² and one study examining the task shifting initiation and management of ART treatment found no statistically significant differences in costs.⁸¹

Malaria

Our review identified five articles that identified cost savings related to task shifting for malaria-related programs: CHW management of malaria,^{100, 101} village health worker (VHW) administration of IPT,¹⁰² community-based surveillance and treatment of malaria,¹⁰³ and community-based surveillance and trapping of mosquitoes for vector control.¹⁰⁴ Indicators of program and clinical quality, such as administration of appropriate treatment, treatment completion rate, and average time from examination to initiation of treatment, indicate that the programs also maintained or improved programmatic quality. One study found a minor (9%) increase in the cost of administration of IPT during pregnancy when shifting to a community-based model. Although the evidence is less robust than that for TB or HIV/AIDS, these findings suggest that many malaria-related tasks can achieve cost savings from task shifting.

Other disease areas and activities

Our review identified 11 additional studies which provided evidence of cost savings from task shifting for activities related to other diseases or health systems strengthening. These activities included: controlling blood pressure through a combination of general practitioner and CHW activities,¹⁰⁵ community-based management of severe acute malnutrition,¹⁰⁶ integration of the detection of sleeping sickness into routine CHW activities,¹⁰⁷ treatment for mental health problems by a “collaborative care” team that included a lay health worker and mental health specialist,¹⁰⁸ administration of major obstetric procedures by assistant medical officers instead of physicians,¹⁰⁹ home-based treatment of severe pneumonia by lady health workers,¹¹⁰ integration of surveillance to reduce transmission of Chagas disease by Primary Health Care agents instead

of specially trained professionals,¹¹¹ diagnosis and treatment of schistosomiasis by CHWs,¹¹² treatment of diarrhea by CHWs,¹¹³ community-based integrated child care using volunteers to monitor and maintain growth,¹¹⁴ and geo-mapping activities by CHWs and nurses instead of dedicated GIS teams.⁸⁵

Discussion

This review aimed to identify whether task shifting can result in cost savings and efficiency improvements to health systems. Our results indicate that task shifting is a promising approach to achieving cost savings and improving efficiency in LMICs, and our results build on previous work which concluded that task shifting can be an effective way to improve population health. These findings have significant policy implications, discussed below, as well as important limitations.

1. Task shifting can help achieve cost savings and improve efficiency for activities related to top global health priorities, emerging global health issues, and neglected tropical diseases, but the evidence base is mostly limited to PHC and community-based care

The most robust body of evidence found in this study is for achieving cost savings from task shifting activities related to TB and HIV/AIDS. Given the high-burden of these diseases in LMICs and the longitudinal nature of preventing, treating, and managing these diseases, interventions that can reduce both their economic and health burdens simultaneously are particularly important for the future of global health. Each year there are 1.5 million new cases of tuberculosis, mostly in LMICs, and the global burden of TB amounts to approximately \$12 billion annually.^{115, 116} As of 2015, 36.7 million people were living with HIV, and meeting UNAIDS targets will require nearly \$20 billion annually^{117, 118}. TB treatment using DOTS is a relatively routine activity that occurs over many months and can take place in the community

(when the infection is not drug-resistant). Dispensation of ART to clinically stable patients who know and follow their drug regimens is also a relatively routine process. Therefore, these activities are well-suited for task shifting, and health systems can likely improve their efficiency by undertaking such efforts.

Outside of TB, HIV/AIDS, and malaria, the evidence for cost savings from task shifting was spread across many disease areas, making it difficult to conclude that task shifting activities for a specific disease could result in cost savings. Nonetheless, the fact that programs achieved cost savings from such a diverse set of diseases and across multiple geographies indicates that policymakers and program planners should consider task shifting as one of many potential approaches to improve efficiency in their health systems. The evidence for cost savings came from disease areas such as childhood illnesses, non-communicable diseases (which are receiving increased priority at the global level due to the Sustainable Development Goals), and neglected tropical diseases (NTDs).

Almost all studies identified shifted tasks to or within the context primary health care (PHC) or community-based care. Although several citations identified cost savings by shifting tasks from hospitals to PHC or community care, only one citation found cost savings by shifting tasks within the hospital setting.¹⁰⁹ One additional study within the hospital setting found that shifting surgical care from physicians to clinical officers did not yield cost savings, but it did not analyze the cost-effectiveness of shifting surgical tasks from surgeons to other physicians.⁸⁴ While the body of evidence in this review suggests that task shifting can improve efficiency across multiple disease at the PHC and community levels, more research is needed on the effects of task shifting within secondary, tertiary, and highly specialized care.

2. Models of task shifting involve more than transferring clinical care to CHWs

CHWs play a key role in reducing costs and increasing access to care in the health system. Nonetheless, this research shows that many models of task shifting exist outside of a simple transfer of clinical care to a CHW. Of course, many types of associate health professionals exist, such as pharmacy technicians, lay counsellors, and medical assistants, and the references included in this study reflect this diversity of health professions.¹¹⁹ In particular, the use of different models for dispensing ART to HIV-positive patients was documented in multiple studies. In addition, several studies used models where CHWs or other lower-skilled workers collaborated with clinicians in order to provide a new model of care for the patient.^{105,}

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Interestingly, only two studies identified cost savings from task shifting non-clinical activities: geo-mapping by CHWs, and community-based mosquito trapping and surveillance. Given the importance that many non-clinical health systems functions have on improving population health (e.g. supply chain, monitoring and evaluation), research and program planners should consider the potential that task shifting could have for other health systems-related activities. For example, it is possible that lower-skilled professionals could perform routine tasks related to monitoring the supply chain or tracking patient data without compromising the quality of the activity.

3. The design and benefits of task shifting interventions will vary based on the context

Policymakers and program planners must recognize that task shifting is not a panacea for improving health and efficiency, but rather one of many tools to use in order to improve the efficiency of the health system. This review identified a range of task shifting models which resulted in different types of cost savings. Of course, without proper design, task shifting may actually increase system costs or reduce efficiency, such as by worsening overall population

health due to poor clinical quality or increasing the number of staff in the health care system without changing care-seeking patterns among patients. Interestingly, one study found that the same model of task shifting resulted in both cost increases and cost decreases in two different regions of the same country.⁸² Further, task shifting can also result in task overload for health workers, which could also reduce productivity and worsen health population health outcomes.¹²⁰ The breadth of task shifting models covered in this review is consistent with other findings from the literature which also indicate the need to adapt task shifting models to local contexts and health systems. For example, one systematic review notes a number of factors which can impact the success of lay health worker programs, including acceptability of the model to patients, implementation challenges such as problems with training, and health systems bottlenecks such as challenges with payment.¹²¹ Another systematic review specifically identified strong management of CHW programs as the most important factor in their scale-up.¹²² This body of evidence therefore suggests that designing appropriate task shifting models requires a thorough investigation of the local context, disease burden, and program goals.

Limitations of the evidence, risks, and future directions for research

There are several limitations to the research and its findings. First, this study includes citations that measure changes in cost and efficiency very differently. Of course, looking strictly at cost-effectiveness thresholds, rather than cost savings and programmatic indicators as a proxy for cost-effectiveness, would have helped to standardize these findings to make them more comparable. However, limiting our analysis to cost-effectiveness thresholds would also have negatively altered the evidence base in our review by: 1) eliminating studies which demonstrated savings but did not have a formal cost-effectiveness analysis, and 2) including studies that may have achieved some level of cost-effectiveness but which did not actually achieve savings (i.e.

those in which an intervention by a specific cadre of health worker met a cost-effectiveness threshold). By researching the impact of task shifting on costs to the health system as a proxy measure for efficiency improvements, we have focused on a key aspect of decision-making directly relevant to policymakers.

Second, unlike systematic reviews looking at health outcomes from highly specified clinical protocols, this review cannot predict the implications of a new task shifting program. Numerous factors in a given context will affect the outcomes of task shifting, including the burden of disease, the existing human resources for health, previous task shifting efforts, the social determinants of health, and the political economy of health. We caution that researchers and policymakers should not treat this review as a guarantee that future task shifting efforts will result in cost savings; rather, they should see this review as providing compelling evidence that task shifting can achieve cost savings if there is a need for such an intervention, and it is implemented appropriately.

Third, our search only identified two citations suitable for inclusion that examined task shifting within a hospital setting. Our search did not exclude programs that delivered services at a specific level, and the search included other citations focused on hospitals or specialty care that failed to meet inclusion criteria for other reasons. (See select citations for examples.¹²³⁻¹²⁶) This result suggests that the absence of evidence for task shifting within hospitals is likely due to the limited research on this topic to date. Nonetheless, LMICs have implemented programs to task shift hospital-based care, such as surgical services.^{127, 128} Future research should examine models of task shifting within hospitals and their impacts on health outcomes, costs, and other relevant indicators.

Finally, as already discussed, the methodology of this review is limited by biases in reporting and publication of individual references.

Going forward, we feel that researchers, program planners, and policymakers should continue to collaborate to understand both the financial and health impacts of task shifting. Many new task shifting efforts are underway globally, and ensuring that all these programs report on cost-effectiveness thresholds and changes in costs to the system will increase the evidence base surrounding this important topic. In particular, more programmatic research is needed to confirm the preliminary findings that task shifting for activities related to NCDs, NTDs, and health systems strengthening can result in cost savings, and to understand the role that task shifting can play in hospital and specialty settings. At the same time, researchers should also carefully examine the risk of task overload from task shifting and design ways to prevent and mitigate this risk.

Conclusion

This review examined the evidence for task shifting in improving health systems efficiency in LMICs. The evidence indicates that task shifting for activities across a broad range of diseases, including TB, HIV/AIDS, malaria, childhood illness, NCDs, and NTDs, can result in cost savings without compromising clinical or programmatic quality. This review also revealed that countries have used different approaches to introduce task shifting for management of different conditions, and that task shifting takes on many forms besides simply transferring clinical activities to CHWs. Going forward, researchers, program planners, and policymakers should carefully examine their local context in order to determine whether task shifting can improve health systems efficiency while also maintaining or improving population health.

Table 1 - Full list of citations included in systematic review

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
TB						
Clarke, M., et al. (2006) ⁹⁰	South Africa	Training of lay health workers (LHWs) to support treatment and management of TB on farms, instead of clinic nurses or enrolled (non-professional) nurses	Input / process	Cost per minute of health worker time	91% reduction in cost from clinic nurses (\$0.12 per minute) to LHWs (\$0.01 per minute) and 87.5% reduction from enrolled nurses (\$0.08 per minute) to LHWs	Farms with LHWs supporting had 42% better case finding rate and 10% better cure rate
Datiko, D. G. and B. Lindtjorn (2010) ⁸⁶	Ethiopia	Comparison of Health-Facility based DOT (HFDOT) program for TB compared with community DOT (CDOT) program using health extension workers	Outcome	Cost per successfully treated patient	63% reduction in costs from HFDOT model (\$16.19) to CDOT model (\$6.07)	74.8% cure rate for CDOT compared with 68.2% for HFDOT
Dick, J., et al. (2007) ⁸⁸	South Africa	Evaluation of a lay health worker project overseen by primary healthcare nurses aimed at treating TB on farms	Outcome	Cost per case detected and cured	74% cost reduction to the District Health Authority on farms with LHW program compared to control farms (absolute cost figures not reported)	Treatment completion rate for smear-positive TB patients 18.7% higher in intervention group compared to controls (p<.05)

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
Floyd, K., et al. (2003) ⁹²	Malawi	Community-based outpatient treatment for smear-positive pulmonary patients (instead of inpatient treatment)	Outcome	Cost per patient cured	62% reduction from hospital-based treatment (\$786) to community-based treatment (\$296)	Cure rate was 68% for community-based strategy and 58% for hospital-based strategy
Islam, M. A., et al. (2002) ⁸⁷	Bangladesh	BRAC TB control program using CHWs, compared to government-run program	Input / process; Outcome	Total annual cost for TB control program at the subdistrict (thana) level; Cost per patient cured	31% reduction in total annual costs from government program (\$10,697) to BRAC program (\$7,351); 32% reduction in cost per patient cured	84.1% cure rate in BRAC TB program compared to 82.2% in government program
Khan, M. A., et al. (2002) ⁹¹	Pakistan	Comparison of DOTS by health workers at health centers, DOTS by family members, and "DOTS without direct observation"	Outcome	Cost per case cured	45% reduction from health center DOTS (\$310) to CHW DOTS (\$172); unsupervised DOTS cost \$164	Cure rates were 62% for unsupervised DOTS, 55% for family member DOTS, 67% for CHW DOTS, and 58% for Health Center DOTS
Okello, D., et al. (2003) ⁸⁹	Uganda	Comparison of conventional hospital-based care with community-based care for DOTS, including management by a sub-county public health worker	Outcome	Cost per smear-positive patient successfully treated	57% reduction in costs from conventional care (\$911) to community-based care (\$391)	Treatment success rate for smear-positive cases was 56% for conventional care and 74% with community-based care

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
Prado, T. N., et al. (2011) ⁹³	Brazil	Comparison of DOTS overseen by guardians with standard of care treatment by CHWs	Output	Total cost for DOTS course	28% reduction in costs from CHW DOTS (\$547) to guardian-supervised DOTS (\$389)	98% treatment completion in guardian-supervised DOTS compared to 83% treatment completion with CHW-supervised DOTS (p=.01)
Sinanovic, E., et al. (2003) ⁹⁴	South Africa	Comparison of clinic-based care with community-based observation by lay person with community-based care for smear-positive pulmonary and retreatment TB patients	Outcome	Cost per patient successfully treated	62% reduction in costs for new smear-positive patients from clinic-based care (\$1302) to community-based care (\$392); 62% reduction in costs for retreatment patients from clinic-based care (\$2008) to community-based care (\$766)	80% treatment success rate for community-based care, compared to 54% treatment success rate for clinic-based care
HIV						
Babigumira, J. B., et al. (2011) ⁹⁷	Uganda	Comparison of a Pharmacy-only Refill Program (PRP) to Standard of Care for treatment for HIV/AIDS patients	Output	Cost per person per year from societal and Ministry of Health perspective	21% reduction in societal costs from Standard of Care (\$665) to PRP (\$520) and 17% reduction in MoH costs from	No statistically significant difference in favorable immune response among patients in two groups

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
					Standard of Care (\$610) to PRP (\$496)	
Bemelmans, M., et al. (2014) ⁹⁹	South Africa	Adherence club for ARVs led by lay counselor and offered to all clinically stable patients who had been on ARVs for greater than 12 months; Club met every two months for essential medical tasks (e.g. weighing and health assessment) and distribution of ARVs	Output	Cost per patient per year	46% reduction from mainstream model of care (\$108) to ARV club model (\$58)	<1% mortality at 40 months, and 2.8% loss to follow up at 40 months in ARV club
Fatti, G., et al. (2015) ⁹⁶	South Africa	Indirectly Supervised Pharmacist Assistant () program compared to nurse-managed models for providing ARTs	Input / process	Human resource costs and costs per item dispensed	29% reduction in human resource costs from nurse-managed program (\$1.89 per patient visit) compared to ISPA model (\$1.35 per patient visit); 49% reduction in cost per item dispensed from nurse-managed program (\$0.83) to ISPA model (\$0.43)	Cumulative attrition lower at ISPA sites (20.7% compared to 31.5%); proportion of patients achieving virological suppression higher at ISPA sites (89.6% compared to 85.9%)

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
Foster, N. and D. McIntyre (2012) ⁹⁸	South Africa	Indirectly Supervised Pharmacist Assistant (ISPA) program and nurse-managed models compared to full-time pharmacist for providing ARTs	Input / process	Cost per patient visit	43% reduction in cost from nurse-driven model (\$10.16) to ISPA model (\$5.74) and 12% reduction in cost from full-time pharmacist model (\$6.55)	
Johns, B. and E. Baruwa (2015) ⁸²	Nigeria	Comparison of hospital-based distribution of ART (by doctors) with clinic-based distribution of ART (by nurses and/or community pharmacists) for stable patients who had been on ART for at least 1 year, in two states aiming to decentralize health services	Output	Total cost per person per year	Total costs increased in one State by 31% and decreased in one State by 32%; In both cases, the largest difference in costs between the hospital and clinic sites was staff cost / patient visit	Few statistically significant differences found in service utilization indicators between patients going to clinic sites versus hospital sites; Patients in the state that achieved cost savings had 3.7x more visits per year than in hospitals (p<.01)
Johns, B., et al. (2014) ⁸¹	Ethiopia	Comparison of minimal, moderate, and maximal task-shifting for ARV responsibilities away from physicians with hospital-based ARV	Output	Cost per patient year	No statistically significant changes in cost / patient per year between models of task shifting or between	Almost no statistically significant differences in patient retention from

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
		distribution. Minimal = nonphysicians clinicians (NPC) monitor ART; Moderate = NPC initiate and monitor ART; Maximal = NPCs initiate, monitor, treat side effects, and switch ARTs			all task-shifting models and hospitals	different levels of task-shifting
Yan, H., et al. (2014) ⁹⁵	China	Evaluation of shifting HIV preventive intervention and care for men who have sex with men (MSM) from government facilities to community-based organizations (CBOs)	Outcome	Unit cost per HIV case detected	97% reduction in cost from government health facilities (\$14,906) to community-based organizations (\$315)	Within four years, total % of HIV cases reported increased from ~10% to ~50%, despite "a very low share of HIV tests by CBOs out of the total HIV tests performed each year during the pilot," which indicates effective targeting of HIV patients for tests by CBOs
Malaria						
Chanda, P., et al. (2011) ¹⁰⁰	Zambia	Comparison of home management (using CHW) with facility-based management of uncomplicated malaria	Output	Cost per case appropriately diagnosed and treated	31% reduction from facility-based management (\$6.12) to home management (\$4.22)	100% of cases treated appropriately through home management, and 43% of cases treated

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
						appropriately in facility
Hamainza, B. M., et al. (2014) ¹⁰¹	Zambia	Comparison of CHW program to test and treat malaria with facility-based testing and treatment	Output	Total cost per confirmed case treated	60% reduction in cost from facility-based approach (\$10.75) to CHW approach (\$4.34)	78% of CHW contacts received appropriate testing and treatment, while 53% of facility-based patients received appropriate testing and treatment based on guidelines
Mbonye, A., et al. (2008) ⁸³	Uganda	Community-based administration of intermittent preventive treatment (IPTp) for malaria by traditional birth attendants, drug-shop vendors, community reproductive health workers, and adolescent peer mobilisers	Output	Cost per patient of providing a full regimen of IPTp	9% increase in costs from health center care (4093 shillings) to community-based care (4491 shillings)	
Patouillard, E., et al. (2011) ¹⁰²	Ghana	Comparison of IPT administration by village health workers (VHWs), facility-based nurses working in outpatient departments of health	Outcome	Economic cost per child fully covered and fully adherent to treatment	11% reduction from using facility-based strategy (\$8.51) to VHW strategy (\$7.56)	69.1% of children in VHW strategy completed course, 63.8% of children in facility-based strategy completed course

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
		centers or EPI outreach clinics				
Ruebush, T. K., 2nd, et al. (1994) ¹⁰³	Guatemala	Change to the supervision and distribution model of unpaid Volunteer Collaborators (VC) in the surveillance and treatment of malaria, including treatment for malaria without taking a blood smear, removal of literacy requirement for VC, and reduced supervision from once every four weeks to once every eight weeks	Output	Cost per patient treated	75% reduction in cost per patient treated in modified model of VCs (\$0.61) versus control network of VCs (\$2.45)	Average time from examination to initiation of treatment was 6.6 days in modified model areas, compared to 14.6 days in control areas
Sikaala, C. H., et al. (2014) ¹⁰⁴	Zambia	Community-based (CB) mosquito surveillance and trapping using light traps (LT) and Ifakara tent traps (ITT) compared to centrally supervised quality assurance (QA) trapping teams, including human-landing catch (HLC) teams, for the prevention of malaria	Output	Cost per specimen of <i>Anopheles funestus</i> captured	96% reduction in costs from using QA-LT (\$141) to CB-LT (\$5.3); 83% reduction in costs from using QA-ITT (\$168) to CB-ITT (\$28); QA-HLC method cost \$10.5	

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
Other diseases and health systems strengthening activities						
Aung, T., et al. (2013) ¹¹³	Myanmar	Comparison of costs to treat diarrhea by CHW, government facility, and private provider	Input / process	Total patient cost for consultation and correct ORS	7% reduction from private providers (\$5.40) to CHWs (\$5) and 67% reduction from government facilities (\$15) to CHWs	CHWs provided appropriate ORS and amount of drinking water in 57.6% of cases, private providers in 47.1% of cases, and government facilities in 71.4% of cases
Buttorff, C., et al. (2012) ¹⁰⁸	India	Comparison of "collaborative care" model using full-time physician, lay health worker (LHW), and mental health specialist with "enhanced usual care" by full-time physician only for treatment of depression and anxiety disorders	Output	Average annual cost per subject	23% reduction in costs from collaborative care model (\$177) compared to physician-only care model(\$229)	Patients in collaborative care improved 3.84 points more on the Revised Clinical Interview Schedule (to measure psychiatric symptoms) compared to physician-only care model
Chuit, R., et al. (1992) ¹¹¹	Argentina	Surveillance to reduce transmission of Chagas disease using Primary Health Care (PHC) agents compared to a vertically oriented program run by trained	Output	Cost of surveillance per house	80% reduction in cost from vertical surveillance (\$17) to PHC surveillance (\$3.40)	Surveillance rates and levels of infestation detection were comparable across intervention and control arms

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
		entomological professionals				
Cline, B. L. and B. S. Hewlett (1996) ¹¹²	Cameroon	Diagnosis and treatment for schistosomiasis by CHWs identified by the community	Output	Average cost of diagnosis and treatment of a child	90% reduction in cost from treatment at nearest pharmacy (approx. \$15) to CHW model (\$1.50)	7% prevalence in school children after participating in program, compared to 71% in children who did not participate in program
Fiedler, J. L., et al. (2008) ¹¹⁴	Honduras	Community-based integrated child care (AIN-C) program that uses volunteers to help mothers monitor and maintain adequate growth of young children	Input / process	Cost for one child growth and development consultation	86% reduction from facility-based consultation (105.1 lempiras) to community-based program (14.67 lempiras)	
Hounton et al., (2009) ⁸⁴	Burkina Faso	Training of obstetricians, general practitioners, and clinical officers to lead surgical teams for caesarian sections	Outcome	Incremental cost of one newborn life saved	Compared to clinical officers, one newborn life saved cost \$200 for general practitioners, and \$3,235 for obstetricians	Higher newborn and maternal case fatality rates among clinical officers than other types of practitioners
Jafar, T. H., et al. (2011) ¹⁰⁵	Pakistan	Home-health education (HHE) by CHWs, home-health education plus	Output	Total cost per patient over two years for each group	7% reduction in costs from GP-only group (\$537) to	Decline in systolic BP was highest in the

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
		general practitioner (GP) supervision (combined group), or general practitioner-supervision only to control blood pressure			combined group (\$500); 27% reduction in costs from GP-only group to HHE-only group (\$393)	combined group (p=.001)
Kruk, M. E., et al. (2007) ¹⁰⁹	Mozambique	Comparison of surgically trained assistant medical officers and specialist physicians	Input / process	Cost per major obstetric surgical procedure	72% reduction in costs using assistant medical officers (\$39) compared to specialist physicians (\$144)	
Laveissiere, C., et al. (1998) ¹⁰⁷	Cote d'Ivoire	Detection of sleeping sickness using conventional mobile teams compared to integration of activity into CHW duties	Output	Cost of surveillance per person	81% reduction in costs using CHWs (\$0.10) instead of using mobile teams (\$0.55)	
Puett, C., et al. (2013) ¹⁰⁶	Bangladesh	Community-based management of severe acute malnutrition by CHWs compared to inpatient treatment	Outcome	Cost per DALY averted	98% reduction in costs / DALY averted from observed inpatient treatment costs (\$1344) to community treatment (\$26) and in costs / death averted from from observed inpatient treatment costs	91.9% of children in community treatment area recovered, compared to only 1.4% in inpatient treatment

Author and year	Country	Intervention	Indicator type	Main indicator	Result	Quality data
					(\$45,688) to community treatment (\$869)	
Sadruddin, S., et al. (2012) ¹¹⁰	Pakistan	Comparison of home treatment of severe pneumonia by lady health workers with referred cases treated by other practitioners	Output	Cost per treatment of severe pneumonia	81% reduction in costs using lady health workers (\$1.46) compared to referred cases (\$7.60)	93.4% of cases successfully treated by lady health workers with 5-day course of amoxicillin, and remaining cases referred for further treatment
Munyaneza, F., et al. (2014) ⁸⁵	Rwanda	Use of CHWs and nurses to collect geographic coordinates using GIS systems instead of trained and dedicated GIS teams	Input / process	Total cost of mapping activities	51% reduction in costs from using dedicated GIS teams (\$60,112) to CHWs (\$29,692)	

Do changes to supply chains and procurement processes yield cost savings and improve availability of pharmaceuticals, vaccines, or health products? A systematic review of evidence from low- and middle-income countries

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Abstract

Introduction: Improving health systems performance, especially in low-resource settings facing complex disease burdens, can improve population health. Specifically, the efficiency and effectiveness of supply chains and procurement processes for pharmaceuticals, vaccines, and other health products has important implications for health system performance.

Pharmaceuticals, vaccines, and other health products make up a large share of total health expenditure in low- and middle-income countries LMICs, and they are critical for delivering health services. Therefore, programs which achieve cost savings on these expenditures may help improve a health system's efficiency, whereas programs that increase availability of health products may improve a health system's effectiveness. This systematic review investigates whether changes to supply chains and procurement processes can achieve cost savings and / or improve the availability of drugs in LMICs.

Methods: Using the PRISMA guidelines for systematic reviews, we searched PubMed, Embase, CINAHL, and the Health Economic Evaluation Database to identify.

Results: We identified 1,264 articles, of which 38 were included in our study. We found evidence that centralized procurement and tendering can achieve direct cost savings, while supply chain management programs can reduce drug stock outs and increase drug availability for populations.

Conclusion: This research identifies a broad set of programs which can improve the ways that health systems purchase and delivery health products. Based on this evidence, policymakers and program managers should examine the root causes of inefficiencies in pharmaceutical supply chain and procurement processes in order to determine how best to improve health systems performance in their specific contexts.

Summary box

What is already known about this subject?

- Pharmaceuticals, vaccines, and other health products are an important component of a strong health system. Procurement processes and supply chains are critical for purchasing and delivering these products.

What are the new findings?

- Centralizing procurement for health products can yield cost savings across many contexts.
- Efforts to improve supply chain management can increase the availability of health products in low- and middle-income countries, especially by reducing stock outs. However, there is no single approach to improving supply chains that should be used in all contexts.

What are the recommendations for policy and practice?

- Policymakers and practitioners should consider the root causes of programmatic challenges to purchasing and distributing health products in their context and identify specific interventions that can strengthen these processes.

Introduction

Health systems performance along key outputs, such as equity, efficiency, effectiveness, and responsiveness, has important implications for population health.²⁰ Specifically, maximizing “technical efficiency” of the health system, or the amount of outputs generated by a given cost (or other input), can increase total fiscal space for health in a country, thereby freeing up resources for additional programs or activities.^{20, 22, 130} Improving the effectiveness of the

health system in its delivery of services can improve population health and build trust in the health system.

Pharmaceuticals, vaccines, and other health products constitute a key component of health systems by providing important treatments to populations. Pharmaceutical health expenditures makes up a large share of health spending: in low- and middle-incomes countries (LMICs), the total pharmaceutical expenditure as a share of total health expenditure in 2006 varied from 7.7% to 67.6%.¹³¹ Access to pharmaceuticals, such as Essential Medicines, remains a challenge, with only 61.5% of select Essential Medicines available in select LMICs.¹³²

Improved procurement and supply chain management can reduce costs and address the problem of supply shortages¹³³ which adversely affect health outcomes by interrupting treatment and, in the case of certain drugs, possibly leading to drug resistance. In LMICs, where procurement and supply chain management tends to be complex and fragmented, these types of improvements can be critical for strengthening the health system.¹³⁴ Changes to the procurement and supply chain processes include centralizing or decentralizing purchasing, improving data systems to monitor and inform purchasing (e.g. early-warning systems), improving infrastructure or processes along the supply chain to reduce wastage, and altering the methods for financing purchases, among others.,

Given the high spending on pharmaceuticals, vaccines, and other health commodities and their importance for population health outcomes, this systematic review aims to answer two questions regarding the performance of a health system: 1) Do efforts to improve supply chains and procurement processes yield cost savings for health systems in LMICs, and 2) Do these efforts lead to increased availability of drugs, vaccines, or other health commodities in LMICs? We use these two criteria as evidence for changes to health system performance for several

reasons. Both metrics are objective and captured through routine data collection in the management of many health systems. Any change in spend without a commensurate change in the quantity or quality of products purchased will indicate a change in the technical efficiency of the health system. Changes in supply availability, as measured by a reduction in stock outs or several other measures, is a useful indicator of whether health facilities (e.g. hospitals, clinics, and pharmacies) can effectively deliver certain services to patients.

To our knowledge, no systematic review has attempted to answer these questions, which are critical for policymakers and program managers looking to improve health systems performance and maximize population health outcomes.

Methods

This systematic review follows the criteria and methodology described in the PRISMA guidelines on systematic reviews.⁶²

Search process and criteria

This search relied on an internal protocol developed by GS and RA. The protocol was not registered externally. We searched PubMed, Embase, CINAHL, and the Health Economic Evaluation Database. The main search that was conducted on March 22, 2016 was as follows (for PubMed), with an additional search term for LMICs, and any publication from before that date was eligible for our review:

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("Materials Management, Hospital"[Mesh] OR "Pharmaceutical Preparations/supply and distribution"[Mesh] OR materials management[tiab] OR (supply chain*[tiab] AND (redesign*[tiab] OR improv*[tiab] OR oversight[tiab] OR management[tiab])) OR ((purchas*[tiab] OR procure*[tiab]) AND ("Pharmaceutical Preparations"[Mesh] OR drug*[tiab] OR medicine*[tiab] OR pharmaceutical*[tiab])))
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AND

("Cost Savings"[mesh] OR "Cost Benefit Analysis"[mesh] OR "Efficiency"[mesh] OR cost[tiab] OR costs[tiab] OR efficienc*[tiab] OR economies of scale[tiab] OR economies of scope[tiab] OR productivity[tiab] OR stock out*[tiab] OR stockout*[tiab] OR out of stock[tiab] OR drug suppl*[tiab])

We also conducted several additional searches based on a review of citation lists from relevant publications, and based on recommendations from public health researchers.

Study selection and eligibility criteria

After conducting our search, all titles were reviewed for relevance. After excluding irrelevant titles, we read all abstracts and, when appropriate, full articles to determine both the relevance of the article for our research question and the availability of relevant data for inclusion. In order to be included in the study, the publication had to meet the following criteria:

- Report on an effort, such as a program or policy intervention, aiming to improve or modify the supply chain or procurement processes for pharmaceuticals, vaccines, or other health products. (For the purpose of simplicity, we often refer to all commodities under consideration in this review simply as products or health products.)
- Report on the impact of the program or policy on costs to the health system or availability of pharmaceuticals, vaccines, or other health products. Cost comparisons could be reported using any cost ratio or change in cost figure and could report costs from the provider or patient perspective. Availability of products could be reported as the frequency of stock outs, or an indirect indicator for availability, such as number of emergency orders.
- Report results from an actual intervention, rather than a computer model or simulation

- Report results from a low- or middle-income country
- Be original research about an intervention published in a peer-reviewed format (as opposed to an editorial, literature review, opinion piece, interview, etc.)
- Have a complete article available (as opposed to just an abstract)
- Be published in English

Data collection process

In order to extract data for this review, we piloted an Excel-based data collection tool that was used to capture results from a preliminary search, the results of which were presented at the Harvard Ministerial Leadership Program in the summer of 2016. Based on our experience with this initial process, we modified the tool accordingly and finalized a tool which collected the following information: author, year, title, publication, abstract, country, continent, geographic level of intervention (sub-national, national, or international), description of the intervention, relevant outcome metric, and result on relevant outcome metric. The relevant outcome metric had to involve some comparison or change in costs either from the patient or provider perspective in quantitative terms or change in product availability, and the summary measures for the review follow from these outcome metrics. Results which did not provide evidence of cost changes, such as baseline costing studies, were excluded. GS conducted a first review of all references in the search, and the list was reviewed by all co-authors in order to identify missing references or references which had been improperly included.

Risk of bias

At the level of individual studies, there is the possibility that authors are more likely to report positive outcomes (e.g. programs that resulted in cost savings or reduced stock outs) than negative outcomes. In addition, because many references describe programmatic activities that

do not use experimental designs, it may be difficult to obtain the statistical significance of quantitative findings. Nonetheless, we have chosen to include all studies that report changes in costs as a result of a relevant program in order to demonstrate to policymakers the range of potential impacts that supply chain and procurement projects can have.

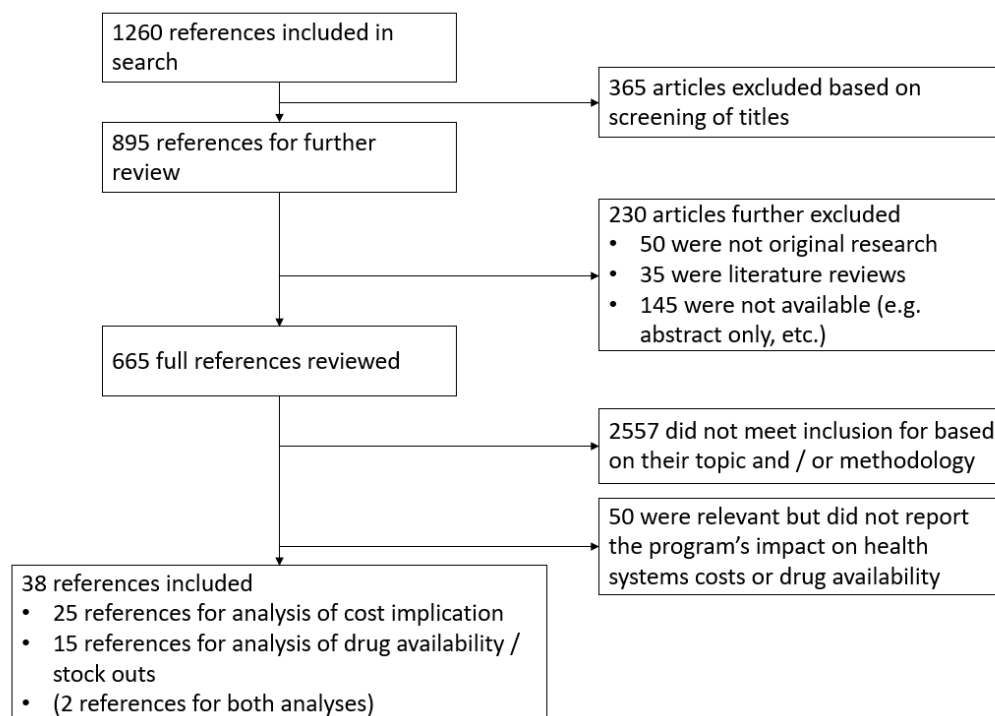
Across all studies, there is also a risk that authors have publication bias or only report selective outcomes for their programs. In addition, there is a risk that the literature under-reports findings from these kinds of programs in general, since the peer-review process may favor rigorous experimental designs, which are not necessarily appropriate for programmatic health systems improvements, over other types of program evaluations.

Results

Study selection

We reviewed 1,264 articles and identified 25 references which specified the cost implications from changing supply chain or procurement practices – 8 from Latin America, 5 from the Middle East / North Africa, 5 from Sub-Saharan Africa, 4 from Asia, 1 from Eastern Europe, 1 focused on a program on multiple continents, and 1 reporting separate results from programs in both Latin America and the Middle East. Of these 25 references, nine reported result from a nation-wide intervention, 10 from an intervention within parts of a single nation (e.g. a city or region), and 6 from an intervention that spanned multiple countries. We also identified 15 studies reporting a change in availability of pharmaceuticals, vaccines, or other health products as a result of these types of programs – 12 from Sub-Saharan Africa, 2 from Asia, and 1 from Latin America. (Of the latter 15 studies, 2 were also included in the 25 reporting cost implications, making for a total of 38 studies included in the review.) See Figure 3 for the study selection for inclusion in this systematic review.

Figure 3 - Study selection for inclusion in systematic review (supply chain and procurement)



Of the 25 references analyzing the cost implications of supply chain or procurement changes, 23 found a reduction in costs to the health system. Of these, 12 focused on cost savings from some form of centralized procurement or tendering process. The other references which demonstrated cost savings included supply chain management projects, comprehensive drug policies at the national, district, or city level, and other types of interventions. Of the two references which did not exclusively demonstrate savings, one reference analyzed centralized procurement processes in multiple Middle Eastern countries and found that some countries achieved cost savings compared to local procurement, while other countries experienced cost increases.¹³⁵ One reference that studied the impact of requiring bioequivalence studies as part of the drug procurement process found that the program resulted in price increases due to an increased failure rate on these studies.¹³⁶

Of the 15 references analyzing changes in health product availability, 13 found improvements, and eight of these were from supply chain management programs. One reference about supply chain management program in Tanzania found a reduction in unaccounted antimalarials and antihelminthics, but an increase in stock outs for ORS.¹³⁷ One reference about a centralized procurement process for antimalarials in Kenya found that a delay in the process, and the awarding of the tender to a relatively new, unknown company, resulted in a nationwide increase in stock outs.¹³⁸

The full list of references meeting inclusion criteria can be found in Table 2 and Table 3.

Comprehensive drug system policies

Three references described comprehensive policies and programs to improve drug procurement and supply chains at either the national or municipal level. In Brazil, a series of policies by the Ministry of Health aimed to promote the use of multi-source drugs (those which can be purchased from multiple manufacturers or distributors), development of the national pharmaceutical industry, and aggressive price bargaining for select drugs, such as ARVs, under the provisions in the TRIPS agreement.¹³⁹ These initiatives resulted in a 79% reduction in the annual cost per person of ARVs in six years (from 1997 to 2003).

In China, the National Essential Medicines Scheme, established in 2009 as part of broader health sector reform, included four components: a National Essential Drugs List, a zero-mark-up policy, reimbursement for drugs on the Essential Drugs List, and public procurement of drugs.¹⁴⁰ An evaluation of this Scheme in three provinces found that it resulted in a 17.5% reduction in cost of drugs needed to treat pneumonia or bronchitis ($p < .05$) and a 48.4% reduction in cost of drugs needed to treat gastroenteritis (statistical significance not reported).

In Delhi, India, a 1997 comprehensive drug policy included the development of an Essential Drugs List, a central pooled procurement system, and programmatic activities to promote rational drug use.¹⁴¹ This policy was found to result in 30% savings on the cost of drugs to the government of Delhi and to increase the availability of key drugs from 40%-70% before the policy's implementation to >90% after its implementation.

Centralized procurement and tendering processes

We found the most references demonstrating cost savings from centralized procurement and tendering processes. These references included joint procurement across multiple countries, including the Gulf Cooperation Council (GCC) of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and UAE,^{142, 143} the PAHO Expanded Program on Immunization (EPI) which included many Latin American countries,¹⁴² and the Eastern Caribbean Drug Service (ECDS) which serviced nine small Caribbean countries.¹⁴⁴ We found references from two countries – Jordan and Mexico – that described centralized procurement at the national level. In Jordan, a Joint Procurement Directorate bids for drugs across four different government agencies, and this program achieved 5.2%-17% cost savings on drugs procured.^{145, 146} In Mexico, a Commission to purchase ARVs and other drugs established in 2008 achieved cost savings of \$52.1 million - \$121.8 million in its first four years, although the prices for ARVs were still above those of other upper-middle income countries.¹⁴⁷⁻¹⁴⁹ At the sub-national level, references found cost savings from an Intermunicipal Health Consortium which coordinated procurement for multiple municipalities in Brazil,¹⁵⁰ and centralized procurement at hospitals or hospital systems in Serbia¹⁵¹ and Brazil.¹⁵² No references found that centralized procurement reduced stock outs or improved availability of health products.

Supply chain / cold chain management

Three references identified cost savings from efforts to improve supply chain management. Of these three references, one program in Nigeria aimed at strengthening laboratory services in hospitals reduced the costs of conducting lab tests by increasing the total volume of tests and then purchasing reagents in bulk at reduced costs. Another reference found that a modification of methods to store and transport vaccines in Tunisia resulted in a 20.16% reduction in energy costs for vaccine storage and distribution. A third reference found that transitioning to a vendor managed inventory (VMI) system, in which customers automatically send inventory information to the supplier who then creates and fills order to replenish the inventory, resulted in an increase in unit costs per vaccine, but reductions in total logistics costs and unopened vial wastage led to an 18% reduction in overall program costs.¹⁵³

An additional eight studies found improvements in availability of health products from supply chain management programs, suggesting that these initiatives can improve health systems performance by ensuring access to products for populations. For example, certain references documented programs to improve data systems or processes to track and monitor drug inventory, including an mHealth application,¹⁵⁴ improved human-related processes and meetings relating to the supply chain,^{155, 156} and a web-based stock management system for rural clinics in Haiti.¹⁵⁷

Three references identified programs that changed the process for ordering drugs: one program in Senegal used an informed Push Model, in which projected demand dictates quantities of drug orders, to reduce stock outs for contraceptives,¹⁵⁸ whereas a Pull Model, which uses clinic or customer demand to inform drug orders, improved drug availability in Tanzania and Uganda.^{137,}

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Other types of programs

In addition to the types of programs listed above, we found limited evidence for the impact of a number of other types of initiatives related to supply chain management or procurement on health systems costs and availability of health products. Three references described revolving drug funds (RDFs), which maintain drug inventory by beginning with an initial donation or free contribution of drugs, and then maintaining inventory by selling these drugs at cost (plus a mark-up in some cases) and then purchasing replacement drugs. One reference found that in South Sudan, drug prices were 40% cheaper in the RDF than those purchased by the Central Medical Supplies Public Organization, and two references found increased availability of vaccines or essential drugs in RDFs in Guinea¹⁶⁰ and Nigeria.¹⁶¹ Two references reported on the Affordable Medicines Facility-malaria (AMFm), which provided subsidies to artemisinin-based combination therapies (ACT) manufacturers at the global level, and which resulted in price reductions for ACTs to consumers¹⁶² and increased availability of ACTs in various countries in Sub-Saharan Africa.^{162, 163} Other references reported cost savings from public procurement of drugs (compared to private sector only) in Mali,¹⁶⁴ the implementation of an IT system to purchase hospital supplies in India,¹⁶⁵ and the direct purchase of drugs from commercial suppliers rather than through government channels in Sierra Leone.¹⁶⁶

Discussion

With this review, we aimed to synthesize the evidence on whether programs to improve supply chain and procurement can achieve cost savings or improve health product availability in LMICs. Our findings indicate that multiple approaches to strengthening purchasing and supply systems in LMICs can improve the system's performance. These findings have significant implications for policymakers, discussed below. They also have limitations, discussed in the next section.

1. Opportunities to improve procurement and supply exist at every level of the health system

The breadth of findings in this review suggests that governments and other organizations can take multiple approaches to improving the procurement and delivery of health products. On the one end of the spectrum, the AMFm represents an example of a comprehensive, international agreement that built on existing global governance structures to improve availability of antimalarials. Our review also included examples of national programs to improve drug supply, such as those in China, Brazil, and Mexico, and initiatives all the way down to the clinic and community levels. These findings suggest that there is no “one-size-fits-all” approach to improving the performance of health systems and the provision of health products. Therefore, we believe that policymakers should use a problem-driven approach to understanding and addressing the root causes of problems in their drug procurement and supply systems.

2. Different supply chain management systems can yield similar results in different contexts

Following from the point above, it is worth noting that our review identified a variety of techniques to strengthen supply chains in different countries, and, in some case, these approaches conflicted with each other. Indeed, our review identified references that demonstrated improved drug availability from both “pull” and “push” systems, which take opposite approaches in how to determine drug order quantities. Similarly, some references focused on using technology to improve inventory management, while others focused on improving teamwork and the human elements of supply chain management, and both types of initiatives achieved positive results. These findings further reinforce our point that policymakers and program managers should examine the specific context of their systems and identify root causes of their inefficiencies in order to determine how to improve them.

3. Centralized procurement has the potential to achieve cost savings across many contexts

In contrast to the first two points, which emphasize that different contexts require different types of interventions in order to achieve improvements in health system performance, we found that centralized procurement / tendering achieved cost savings in the Middle East, Brazil, the Caribbean, Mexico, other parts of Latin America, and several countries in Asia and Africa. It also achieved cost savings when centralizing procurement across countries, within a single country, or across multiple municipalities or health centers. Although centralized procurement is certainly not a panacea for improving health systems efficiency, these findings suggest that by creating economies of scale and improved purchasing power, centralized procurement and tendering can reduce health systems costs in many contexts. This is a particularly noteworthy finding since many countries are moving to decentralize their health systems.^{167, 168}

Limitations of the evidence, risks of bias, and directions for future research

This systematic review has several limitations that are worth noting. First, the studies included in this review used many different types of metrics to quantify the impact of supply chain and procurement programs on health systems costs and product availability. Because of this situation, it is difficult to compare or synthesize findings across studies. When analyzing impacts on health systems costs, references used metrics such as total absolute cost savings, cost savings as a percentage of spend in previous years, and percentage of individual products which had lower costs from one year to another. They also use costs to both the health system and to the patient; changes to costs to the patient may not actually reflect a change to health systems efficiency. Further, since efficiency is achieved by a reduction in costs without a commensurate reduction in (quality of) outputs, or vice versa, but many studies only report total cost savings, it is difficult to determine conclusively that these cost savings result in a true efficiency

improvement to the health system. (On the other hand, studies which demonstrate a reduction in cost per drug or cost per person treated do likely reflect an improvement in efficiency.)

Second, because these findings are context-specific, one cannot predict the impact that a specific program reported in this review would have in another context. Although the body of evidence presented in this study suggests that health systems can improve their performance by undertaking efforts to improve supply chain and procurement processes, policymakers and program managers must keep in mind that the most effective programs tend to achieve improvements when they address the root causes of inefficiencies in the system, so a program that works in one context may fail in another.

Third, reductions in costs and improvements in drug availability both improve health system performance, but in different ways. As already discussed, cost reductions can serve as a proxy indicator for efficiency improvements. On the other hand, increases in availability of products can improve the effectiveness of health facilities providing services. Although stock out reductions may result in indirect cost savings (e.g. by reducing how often patients default from drug treatment), they may also increase costs simply because the health system has to purchase and provide more drugs (paid for either by institutional payers or patients). Weighing the importance of reducing costs versus increasing the availability of health products is the job of practitioners and cannot be determined by this review.

Fourth, even though we find that many programs either reduce costs or improve drug availability, these interventions have other shortcomings which limit their effectiveness as interventions to improve health systems performance. For example, implementation of RDFs has had many challenges, such as fund decapitalization due to unanticipated changes in procurement costs, inflation, or exchange rates, failure to recover costs, and other issues.¹⁶⁹ Centralized or

pooled procurement may require increased coordination and governance arrangements among purchasers, and it may be important to avoid relying exclusively on a single supplier to ensure that alternative supplies are available, especially in the case of emergencies.¹⁷⁰ VMI can lead to challenges, *inter alia*, integrating technologies between customer and supplier, and dependency on the supplier for monitoring inventory.¹⁷¹ Describing the advantages and limitations of each of these types of programs is beyond the scope of this review. We recommend that practitioners consult a reference text, such as MDS-3: Managing Access to Medicines and Health Technologies, for detailed information on the logistical considerations for different types of supply chain and procurement programs.¹⁷²

Finally, as discussed already, biases in the publication of individual studies limit the generalizability of study. In particular, there are very few studies which reported negative outcomes from supply chain or procurement improvement programs; our experience working in health systems in LMICs suggests that it is very unlikely that so few programs fail. Therefore, the results of this study are likely biased by researchers tending only to publish positive outcomes from these types of initiatives. Nonetheless, the research still provides compelling evidence that these types of programs can help improve health systems performance when implemented properly.

In the future, we recommend that researchers, program planners, and policymakers should work together to better understand which types of supply chain and procurement programs can improve health systems performance in which types of contexts. It is also important to understand better the key barriers and enablers of success for these types of programs. Health systems experts should also identify a common set of indicators and metrics for measuring improvements in supply chains in order to standardize reporting and simplify

comparisons across programs. These may include the metrics used in this research, or other key indicators such as the frequency of counterfeit medicines and the frequency of medicine expirations.

Conclusion

This systematic review aimed to determine whether efforts to improve procurement and supply chains for pharmaceuticals, vaccines, and other health products can achieve cost savings and improve drug availability in LMICs. Our findings indicate that many different types of initiatives can achieve these improvements. While the evidence suggests that centralized procurement has the potential to improve efficiency across multiple contexts, other efforts require more context-specific implementation.

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Table 2 - Full list of references with cost implications from programs

Author and year	Level	Country / region	Intervention	Outcome measure	Results
Comprehensive drug system policy					
Chaudhury, R. R., et al. (2005) ¹⁴¹	Sub-national	India	Evaluation of a comprehensive drug policy in Delhi which included development of an Essential Drugs List, a centralized pooled procurement system, and activities to promote rational drug use	Total savings to the Government of Delhi from drug purchases	Approximately 30% cost savings
Homedes, N. and A. Ugalde (2006) ¹³⁹	National	Brazil	Multiple interventions by the Ministry of Health, including promotion of multi-source drugs, the development of the Brazilian pharmaceutical industry, and the use of provisions of the TRIPS agreements to engage in aggressive price bargaining with multinational pharmaceutical manufacturers	Annual cost per person of ARV treatment	Costs reduced from \$4860 in 1997 to \$2530 in 2001 (48% reduction) and to about \$1000 in 2003 (60% reduction, for a total reduction of 79% in 6 years)
Li, Y., et al. (2013) ¹⁴⁰	National	China	Evaluation of the National Essential Medicines Scheme, which included a National Essential Drugs List, a grassroots zero-mark-up policy, reimbursements for drugs on the list, and public procurement of drugs	Total cost of drugs in select districts for treating 1) pneumonia or bronchitis, and 2) gastroenteritis	Costs decreased by 17.5% for patients with pneumonia (p<.05) and 48.4% for patients with gastroenteritis (no significance figure reported)
Centralized procurement / tender					
Adesina, A., V. J. Wirtz and S. Dratler (2013) ¹⁴⁷	National	Mexico	Evaluation of the Mexican Commission for Price Negotiation on the price of ARV drugs	Cost savings from negotiation process for 12 ARV drugs	38% reduction in total spend on ARV drugs (but prices still above those in other upper-middle-income countries)
Alabbadi, I. (2011) ¹⁴⁵	National	Jordan	Joint Procurement Directorate (JPD) of Jordan bids for four government agencies and aims to unify purchases of drugs and medicals applies to reduce the cost of purchased drugs	Savings from joint purchasing for all drugs in first year of JPD	5.2% savings achieved; 17% savings reported when one drug (cephalexin), whose raw material prices doubled that year, excluded from analysis
Al-Abbadi, I., et al. (2009) ¹⁴⁶	National	Jordan	Establishment of a joint procurement system across four different government agencies	Total savings to the four agencies	8.9% reduction in spend on drugs using joint procurement system
Amaral, S. M. and C. R.	Sub-national	Brazil	Intermunicipal Health Consortium used to procure drugs for multiple municipalities after	Number of drugs with reduced unit prices	76% of drugs had a reduction in unit price within two years of program implementation

Blatt (2011) ¹⁵⁰			a government policy decentralizing procurement to the municipality level		
Chaumont, C., et al. (2015) ¹⁴⁸	National	Mexico	Creation of the Coordinating Commission for Negotiating the Price of Medicines (CCNPM) to negotiate prices for drugs, especially antiretroviral treatments (ARVs)	Annual treatment cost for various ARVs in Mexico compared to HICs, UMICs, and LMICs	ARV prices were "higher than those paid by similar upper-middle income countries" and were higher than prices in HICs in some cases
Danzon, P. M., et al. (2015) ¹⁷³	International	Brazil, China, Algeria, Egypt, India, Indonesia, Philippines, Thailand, South Africa, and French West Africa	Tendered procurement by NGOs for cardiovascular and anti-infective drugs (including HIV and TB drugs) in LMIC	Comparison of retail originator drug prices to tendered originators and tendered generic drugs	Price for tendered originators was 42.4% less than the price for retail originators; price for tendered generics was 66.8% less than the price for retail originators
DeRoeck, D., et al. (2006) ^{†142}	International	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates	Gulf Cooperation Council (GCC) group purchasing program which centralized tender and bid processes	Savings on price for vaccines procured through the group purchasing program	4%-46% price reduction on six vaccines
DeRoeck, D., et al. (2006) ^{†142}	International	Latin America	Pan-American Health Organization (PAHO) Expanded Program on Immunization (EPI) Revolving Fund, which purchases vaccines and immunizations on behalf of countries in Latin America and the Caribbean	Savings on price for vaccines procured through Revolving Fund versus those supplied directly to countries before creation of the Fund	70-82% price savings on vaccines and immunizations
Ewen, M., et al. (2014) ¹³⁵	International	Palestine (Gaza / The West	Comparison of different procurement mechanisms for drugs by the United Nations Relief and Works Agency for Palestine	Prices of medicines including antidiabetic medicines, anti microbials,	Syria paid 20% less for drugs procured locally; Lebanon paid 83% more for drugs procured

† Note that these entries refer to the same citation, which reports results from two different programs.

		Bank), Jordan, Lebanon, Syria	Refugees in the Near East (UNRWA); Analysis of price differences when drugs procured using central tender versus locally by each field site	anithypertensives, and antipyretics	locally; and West Bank paying 128% more for drugs procured locally
Gomez-Dantes, O., et al. (2012) ¹⁴⁹	National	Mexico	Introduction of the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (CCPNM) in 2008	Annual direct savings on public expenditure for public medicines since introduction of CCPNM	Annual savings from \$52.1 million - \$121.8 million in the first four years of CCPNM
Huff-Rousselle, M. and F. Burnett (1996) ¹⁴⁴	International	Caribbean	Eastern Caribbean Drug Service (ECDS), which provides pooled procurement services to nine small island nations	Average savings on drugs procured through ECDS after first tender cycle	16.1%-66.1% savings across different countries
Khoja, T. A. and S. A. Bawazir (2005) ¹⁴³	International	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates	Group purchasing agreement among six countries via the Gulf Cooperation Council (GCC)	Total cost savings to member countries	"According to a study performed by GCC Executive Offices in 1992, total of US \$33 million was saved by the 5 GCC states. Furthermore, more than US\$ 11 million was saved by 3 GCC states in 2001."
Milovanovic, D. R., et al. (2004) ¹⁵¹	Sub-national	Serbia	Evaluation of a drug tender process of 479 drug formulations by a university hospital	Cost savings compared to free market price	17.2% cost savings from drug tender compared to free market price for basket of drugs purchased
Sigulem, F. and P. Zucchi (2009) ¹⁵²	Sub-national	Brazil	E-procurement tool used to facilitate joint purchasing of medications by multiple hospitals within a network	Change in unit price of drugs from 1) before joint purchasing to beginning of joint purchasing, and 2) from beginning of joint purchasing to last joint purchase over two-year period	Of 37 drugs included, 34 showed price reductions after implementation of e-procurement system, and 27 showed further decreases in price over the following two years
Supply chain management					
Hamel, D. J., et al. (2015) ¹⁷⁴	Sub-national	Nigeria	Program to strengthen laboratory services in hospitals and clinics, with procurement of more efficient equipment, lab modifications, supply chain management, and trainings;	Reduction in cost / test for specific tests	CD4+ cell count test reduced from \$22 / test to \$2 / test; routine chemistry tests (such as alanine amino transferase) reduced from >\$1 / test to \$0.29

			Program involved securing reduced reagent costs due to high volume of regular lab tests		/ test; viral load tests reduced from \$33 / test to \$14 / test
Lloyd, J., et al. (2015) ¹⁷⁵	Sub-national	Tunisia	Modification of methods to store and transport vaccines, including use of electric utility vehicles for regular deliveries	Energy costs for storage and distribution of vaccines	20.16% reduction in costs after implementation of supply chain improvements
Riewpaiboon, A., et al. (2015) ¹⁵³	National	Thailand	Transition to vendor managed inventory (VMI) system to manage vaccine supply chain	Total cost per dose of vaccine procured	Costs increased from \$1.35 (conventional system) to \$1.43 (VMI)
Other					
Bevilacqua, G., M. R. Farias and C. R. Blatt (2011) ¹³⁶	Sub-national	Brazil	Study of the impact of requiring bioequivalence and/or bioavailability studies as part of the procurement of generic medicines	Change in total procurement cost of the same quantity of 150 medicines before and after the policy	Total costs increased by 87% after implementation of the policy because test failure rates increased from 2.6% before the policy to 56.9% after the policy
Maiga, F. I., et al. (2003) ¹⁶⁴	Sub-national	Mali	Comparison of city (Niono) where public health system regularly supplies drugs with another city (Koutiala) where public health system does not supply drugs, limiting supply to availability in private sector	Cost of drugs to consumers after accounting for the content of transactions (i.e. type and quantity of drugs)	Drugs cost 32% less in city where public health system supplied drugs
Ramani, K. V. (2006) ¹⁶⁵	Sub-national	India	Implementation of a reengineered, IT-enabled system to purchase hospital supplies	Cost to purchase common items	7.7% reduction in cost of purchase for common items after implementation of system
Thuray, H., et al. (1997) ¹⁶⁶	National	Sierra Leone	Procurement of drugs and supplies directly from commercial supplier, rather than through standard governmental channels, by a Preventing Maternal Mortality (PMM) team under the Ministry of Health and with external partner support	Reduction in total costs for drugs and supplies associated with select obstetric procedures in conditions (comparison between PMM costs versus hospital pharmacy costs)	28% price reduction for treating sepsis / induced abortion (non-surgical); 30% price reduction for treating eclampsia; 49% price reduction for obstetric surgery; 54% price reduction for treating post-partum hemorrhage
Tougher, S., et al. (2012) ¹⁶²	International	Ghana, Kenya, Madagascar, Niger, Nigeria, Uganda, and Tanzania	Evaluation of the the Affordable Medicines Facility-malaria (AMFm), which included price reductions through negotiations with manufacturers of quality-assured ACTs (QAACts); a buyer subsidy, via a co-payment by the Global Fund to participating manufacturers, for purchases made by eligible public, private, and non-governmental organization importers; and interventions to	Manufacturer price of QAACts sold to private, for-profit buyers; Median price of QAACts sold in the private, for-profit sector	Manufacturer price reduced 29%-78% depending on package size; Median price to consumers dropped in all seven pilot countries, with a statistically significant drop (p<.0001) for five of seven countries

			support AMFm implementation and promote appropriate antimalarial use		
Witter, S. (2007) ¹⁷⁶	Sub-national	Sudan	Revolving drug fund (RDF) which oversees procurement, distribution, and sale of drugs	Prices of drugs for its list of essential drugs	Drugs 40% cheaper than Central Medical Supplies Public Organization (CMSPO) and 100% cheaper than private sector outlets

Table 3 - Full list of references with drug availability implications from programs

Author and year	Level	Country / region	Intervention	Outcome measure	Results
Comprehensive drug system policies					
Chaudhury, R. R., et al. (2005) ¹⁴¹	Sub-national	India	Evaluation of a comprehensive drug policy in Delhi which included development of an Essential Drugs List, a centralized pooled procurement system, and activities to promote rational drug use	Percentage availability of key drugs (e.g. amoxicillin, cloxacillin) before and after implementation of centralized pooled procurement system	Key drug availability increased from 40%-70% before implementation of system to >90% after implementation
Centralized procurement / tendering					
Tren, R., et al. (2009) ¹³⁸	National	Kenya	Requirement by the Global Fund that Kenya purchase 75% of its annual order for first-line treatment of uncomplicated malaria (ALU) through an international open tender	Availability of ALU after tender process	Due to tender process, which was delayed and which ended up purchasing drugs from a relatively new and unknown company, Kenya "was experiencing wide stock-outs of ALU and had to place emergency orders with the President's Malaria Initiative"
Supply chain management					
Alayande, A., et al. (2016) ¹⁵⁶	Sub-national	Nigeria	UNFPA-supported program to increase distribution of contraceptives, which involved bimonthly meetings attended by reproductive health coordinators, family planning providers, and representatives from the State health team to review commodity inventory and replenish stock	Annual average rate of contraceptive stock unavailability	Reduction from 30% in 2012 to 24.1% in 2013
Berger, E., et al. (2007) ¹⁵⁷	Sub-national	Haiti	Evaluation of a web-based stock management system for rural clinics	Reduction in stockouts (e.g. for ARVs) from initial rollout of system to end of first year	Stockouts reduced from 2.6% to 1.1% (p<.001) in one year
Bukhari, S. K., et al. (2010) ¹⁷⁷	National	Pakistan	Evaluation of 12 guidelines focused on supply and management of essential medicines during emergencies	Percent of donated medicine wasted during a disaster	1.3% wastage per annum in Pakistan, compared to 20-70% in other benchmark disasters
Daff, B. M., et al. (2014) ¹⁵⁸	Sub-national	Senegal	Evaluation of the Informed Push Distribution Model (IPM), which brings deliveries of drugs closer to clients in health facilities	Levels of stockouts for four types of contraceptives: IUDs, implants, injectables, and pills	Stockouts for all four types of contraceptives reduced to 0% within six months from baseline of 14% for IUDs, 86% for implants, 57% for injectables, and 57% for pills

Author and year	Level	Country / region	Intervention	Outcome measure	Results
Mikkelsen-Lopez, I., et al. (2014) ¹³⁷	Sub-national	Tanzania	Evaluation of a transition from a central "push" system for drug delivery to a "pull" Integrated Logistics System (ILS)	Percentage of unaccounted antihelminthics, antimalarials, and ORS before and after system implemented	Unaccounted for antimalarials decreased from 59.8% to 17.8% (p<.05); unaccounted for antihelminthics decreased from 81.9% to 71.1% (p<.05); unaccounted for ORS increased from 63.8% to 80.7% (p<.05)
Namisango, E., et al. (2016) ¹⁵⁴	Sub-national	Uganda	mHealth application used to track supply chain and service delivery information	Reduction in emergency orders after implementing the mHealth application	Reduction from five times per quarter to two times per quarter
Shieshia, M., et al. (2014) ¹⁵⁵	Sub-national	Malawi	Comparison of an Efficient Product Transport (EPT) supply chain intervention, which focused on improving product flow and data flow, with an Enhanced Management (EM) intervention, which focused on product flow, data flow, and improving the effectiveness of the people by promoting team performance	Mean percentage stockout rate over 18 months for six drugs (cotrimoxazole, LA 1x6, LA 2x6, ORS, paracetamol, and zinc)	EM resulted in lower stockout rates for all six drugs (p<.001 for all six drugs)
Steyn, F., et al. (2009) ¹⁷⁸	Sub-national	South Africa	Comprehensive Plan with "investments to upgrade the national drug distribution system at all levels of the health care system," with particularly strict requirements to dispense ARV drugs	Availability of essential drugs and supplies for HIV care other than ARV medication (e.g. antibiotics and anti-TB medications)	At baseline, eight of 15 essential HIV care items not available at all facilities, but two years after intervention, only three of 15 items not available at all facilities
Tumwine, Y., et al. (2010) ¹⁵⁹	Sub-national	Uganda	Implementation of a "pull system" for ordering drugs at a rural hospital, in which health units had to determine the types and quantities of medicines and medical supplies needed	Median days out of stock for drugs, and average % days out-of-stock for drugs (e.g. amoxicillin, diclofenac)	Median out-of-stock days reduced from 94 to 24 (p<.001); average % out-of-stock days reduced from 15.3% to 3.5% (p<.001)
Other					
Knippenberg, R., et al. (1997) ¹⁶⁰	Sub-national	Guinea	Evaluation of the Bamako Initiative - a Revolving Drug Fund (RDF)	Availability of vaccines	Increase from 86% in 1991 to 100% one year later
Sabot, O., et al. (2009) ¹⁶³	Sub-national	Tanzania	Evaluation of impact of subsidy on ex-factory price of ACTs as a pilot to test the AMFm model	Percent of shops stocking ACTs	Increase from 0% of shops stocking ACTs before pilot to 72.2% of shops stocking ACTs one year later (p<.001)
Tougher, S., et al. (2012) ¹⁶²	International	Ghana, Kenya, Madagascar, Niger, Nigeria,	Evaluation of Affordable Medicines Facility-malaria (AMFm) pilot, which included price reductions through negotiations on quality-assured ACTs (QAACTs), a buyer subsidy, and	Achievement of a benchmark to show an increase of 20 percentage points from baseline to endpoint in the availability of QAACT	All eight sites showed an increase in availability of QAACTs, and 5 of 8 sites showed either a statistically significant change of achieving the benchmark or a

Author and year	Level	Country / region	Intervention	Outcome measure	Results
		Uganda, and Tanzania (and Zanzibar as a separate site)	interventions to support AMFm implementation	among all outlets stocking antimalarial treatment	definitive demonstration of achieving the benchmark
Uzochukwu, B., et al. (2002) ¹⁶¹	Sub-national	Nigeria	Evaluation of the Bamako Initiative - a Revolving Drug Fund (RDF)	Number of essential drugs available	Average of 35.4 essential drugs available in Bamako Initiative facilities, compared with 15.3 essential drugs in other facilities (p<.05)

Results Statement

Overview of the Lesotho National Primary Health Care Reform (Problem Statement and Theory of Change)

Building off of the Analytical Platform, the Results Statement focuses specifically of Lesotho’s National Primary Health Care (PHC) Reform. The purpose of this Results Statement is three-fold: 1) it explains the need for the PHC Reform (i.e. the “problem statement”) and the ways that the PHC Reform can address this need (i.e. the theory of change); 2) it documents the key aspects of the PHC Reform, including the core technical aspects of the Village Health Worker (VHW) model; and 3) it analyzes the process by which the Reform diffused and gained functionality and legitimacy over time.

The Results Statement is organized into four sections. This section and the DEPLESET analysis which follow describe the context for the Reform, which helps explain the problem statement, and the key aspects of the Reform, which help explain the theory of change. This section specifically builds on aspects of the Analytical Platform which identified how context and values can influence and intersect with health system priorities. The third section, an article on the VHW model in Lesotho, describes the technical aspects of one aspect of the PHC Reform. This section builds on the section of the Analytical Platform which analyzed the implications of task-shifting for low-resource health systems. The final section of the Results Statement documents all aspects of the Reform pilot, including but not limited to the VHW model, and analyzes the processes which led to its diffusion. This section builds on the sections in the Analytical Platform which analyze the role that context and values can play on priority-setting for health systems and the analysis of task-shifting. One should note that, due to the broad

literature on PHC, health systems strengthening (HSS), and universal health coverage (UHC), the Results Statement also builds on other analytical frameworks and theories which are described later as needed. The Results Statement does not include a discussion of supply chain, a core aspect of the Analytical Platform, because improving supply chain management was not a core aspect of the National PHC Reform (although the Reform did involve hiring pharmacy technicians for certain clinics to dispense pharmaceuticals). Nonetheless, one should note that efforts to improve the supply chain are currently underway in Lesotho and are an important aspect of HSS.¹⁷⁹

Problem statement

As discussed earlier, the problem statement for this doctoral project and doctoral thesis is as follows: Lesotho has poor population health outcomes for high-burden diseases, such as HIV/AIDS, tuberculosis, and maternal, newborn, and child health (MNCH). See the DEPLESET analysis for a more complete burden of disease analysis.

Theory of change

In order to address this problem, the National PHC Reform, to which this doctoral project contributed, aimed to strengthen the primary health care system in Lesotho. These HSS activities included both supply-side and demand-side activities that could contribute to improving access to population health.

Lesotho began a pilot of the Reform in 2014 in four of the country's ten administrative districts. In 2016, the government began an effort to scale the Reform to all ten districts, which involved writing a Policy for the Reform scale-up. The Reform pilot involved four core interventions, which operated at different levels of the health system. These interventions,

summarized below, are described in additional detail in the two sections of the Results Statement analyzing the Reform:

- Strengthened VHW program (community level): The VHW program, which included two cadres of VHWs (one focused on HIV/AIDS and TB, and the other focused on MNCH), aimed to improve linkages between the health center and the population in its catchment area. VHWs conduct tasks such as patient accompaniment, directly observed therapy (DOT), and demand-creation at the community level through patient education and community mobilization efforts.
- Improved services at the health center: The Reform aimed to improve the delivery of specific health services, especially MNCH services. The Reform involved the renovation of maternal waiting homes at all health centers and the provision of commodities such as delivery kits and food for waiting mothers. The Reform implemented a facility-based system for managing the VHWs in its catchment area. The Reform also worked in harmony with other efforts to strengthen health services, such as programs focused on the rollout of HIV testing and treatment. Finally, the Reform involved hiring several new staff at select health centers, such as pharmacy technicians.
- Empowered and capacitated management of the District Health Management Teams (DHMT): Prior to the Reform, management of the district health system was fragmented and ineffective. The Reform undertook specific capacity-building activities and reorganizations at the DHMT in order to strengthen this management and oversight. The Reform also worked with ongoing decentralization efforts in the Government of Lesotho at the time.

- Quarterly reviews of the Reform Pilot (Central MoH level): In order to facilitate oversight of the Reform by the Central Ministry of Health (MoH), the Reform pilot involved quarterly reviews where the DHMTs presented progress on key indicators, challenges, and successes to MoH leadership over the past quarter.

In addition to these interventions, the rollout of the Reform beyond the four initial pilot districts will include:

- Further empowerment of government leaders: In addition to the quarterly reviews, the full National PHC Reform will include awareness-building of the Reform both for technical leaders (e.g. senior MoH officials) and political leaders (e.g. directly elected officials in the central and local governments). This empowerment can help promote accountability and oversight for the Reform.
- Devolution of health system administration: The Government of Lesotho plans to devolve many government services to the country's ten administrative districts. This effort could help localize decision-making and cut through administrative barriers to management of the health system.
- Clear health systems targets: Incorporating clear input, output, and outcome targets into the Reform could help strengthen accountability for the Reform and ensure that all stakeholders, including the DHMT, clinics, donors, and implementing partners are working toward a common set of goals.

DEPLESET Analysis of Lesotho

Introduction

Health systems do not operate in isolation. Rather, they exist within complex national and global contexts which influence their structure and functioning. Health systems reform can have impacts not only on population health outcomes, but also on the country's political and economic landscape, and vice versa.²⁰ Therefore, having a deep understanding of the context in which a health system and health reform exists is crucial for understanding the progress, direction, and results of “health system behavior” and the health system Reform.¹⁸⁰

In order to analyze the context which influences the structure of the Lesotho health system and the outcomes of the National Primary Health Care Reform, I will use the DEPLESET methodology.¹⁸⁰ This approach looks at eight factors that can influence health systems behavior: demographic, economic, political, legal and regulatory, epidemiological, sociodemographic, and technical contexts. This approach has already been used to study various health sector reforms.^{27, 181} However, before undertaking this analysis, it is instructive to formally define to what each of these eight contextual factors refers. For the purposes of my analysis, I will use the following definitions for each contextual factor:

- **Demographic:** Information on the “characteristics of human populations, such as size, growth, density, distribution, and vital statistics”¹⁸²
- **Economic:** Information “of or relating to the production, development, and management of material wealth”¹⁸²
- **Political:** Information “of, relating to, or dealing with the structure or affairs of government, politics, or the state”¹⁸²
- **Legal and Regulatory:** Information regarding rules, law, or principles in the country¹⁸²

- **Epidemiological:** Information related to “the causes, distribution, and control of disease in populations”¹⁸²
- **Sociodemographic:** Information on populations other than demographic and vital information, such as “membership in organizations, household status, interests, values, and social groups”¹⁸³
- **Environmental:** Information “relating to or associated with the [natural] environment”¹⁸²
- **Technological:** Information related to “the application of science, especially in industrial or commercial objectives”¹⁸²

The following sections summarize the Lesotho context based on these eight dimensions, and, where relevant, presents possible high-level implications for the country’s health system and National Primary Health Care Reform. See Table 4 for a comparison on select World Development Indicators between Lesotho, Sub-Saharan Africa excluding high-income countries, Swaziland, and South Africa on select indicators. All data listed in the DEPLESET analysis refer to World Development Indicators unless otherwise specified.

Table 4 - Select World Development Index indicators for Lesotho (LSO), Swaziland (SWZ), South Africa (ZAF), and Sub-Saharan Africa (SSA)⁸

Indicator	LSO	SWZ	ZAF	SSA	Year of data
Demographic					
Age dependency ratio (% of working-age population)	67.3	69.3	52.1	86.1	2015
Birth rate, crude (per 1,000 people)	28.6	29.7	20.7	37.1	2014
Death rate, crude (per 1,000 people)	14.8	14.4	12.5	10.2	2014
Fertility rate, total (births per woman)	3.2	3.3	2.4	5.0	2014
Life expectancy at birth, total (years)	49.7	48.9	57.2	58.6	2015
Population ages 0-14 (% of total)	36.1	37.4	29.2	42.9	2015
Population ages 15-64 (% of total)	59.8	59.1	65.7	54.0	2015
Population ages 65 and above (% of total)	4.1	3.6	5.0	3.1	2015
Population density (people per sq. km of land area)	70.3	74.8	45.3	42.4	2015
Population growth (annual %)	1.2	1.4	1.6	2.7	2015
Population, female (% of total)	50.5	50.5	50.8	50.0	2015
Population, total	2,135,022	1,286,970	54,956,920	1,000,888,081	2015
Rural population (% of total population)	72.7	78.7	35.2	62.3	2015
Rural population growth (annual %)	0.5	1.4	0.2	1.9	2015
Urban population (% of total)	27.3	21.3	64.8	37.7	2015
Urban population growth (annual %)	3.2	1.4	2.4	4.1	2015
Economic					
GDP per capita (constant 2010 US\$)	1227	3061	7604	1647	2014
GDP per capita growth (annual %)	2	1	0	2	2014
Epidemiological					
Health expenditure per capita, PPP (constant 2011 international \$)	276.0	586.8	1148.4	199.8	2014
Health expenditure, public (% of total health expenditure)	76.1	75.7	48.2	42.6	2014
Incidence of HIV (% of uninfected population ages 15-49)	1.9	2.4	1.4	0.3	2015
Incidence of tuberculosis (per 100,000 people)	852.0	733.0	834.0	281.0	2014
Sociodemographic					
Adjusted net enrolment rate, primary, both sexes (%)	80.7	No data	No data	No data	2014
CPIA gender equality rating (1=low to 6=high)	4.0	No data	No data	3.2	2014
Duration of compulsory education (years)	7.0	7.0	9.0	8.0	2014
Literacy rate, adult female (% of females ages 15 and above)	88.3	87.5	93.4	No data	2015

Literacy rate, adult male (% of males ages 15 and above)	70.1	87.4	95.8	No data	2015
Environmental					
Agricultural land (% of land area)	74.2	71.0	79.8	43.9	2013
Arable land (% of land area)	8.2	10.2	10.3	8.8	2013
Technological					
Access to electricity (% of population)	20.6	42.0	85.4	35.3	2012
Access to electricity, rural (% of rural population)	10.2	24.5	66.9	15.3	2012
Access to electricity, urban (% of urban population)	46.9	100.0	96.6	71.6	2012
High-technology exports (% of manufactured exports)	0.0	No data	5.4	4.3	2012
Internet users (per 100 people)	16.1	30.4	51.9	22.4	2015
Mobile cellular subscriptions (per 100 people)	105.5	73.2	159.3	75.7	2015

NB: Political and legal indicators are excluded from this table because they are better analyzed using qualitative than quantitative data for the purposes of this analysis. Additional epidemiological data and health systems data is included throughout the Results Summary.

Demographic factors

In 2015, the population of Lesotho was 2,135,022, with 50.5% of the population being female, and a population density of 70.3 people per square kilometer. 70.3% of the population lives in rural areas, with many rural residents living in remote, mountainous districts, and the majority of urban residents living in the capital district of Maseru. The urban population was growing at 3.2% annually, a rate over six times the rural population growth. In 2014, the crude birth rate (per 1,000 people) was 28.6, and the crude death rate (per 1,000 people) was 14.8. These rates resulted in an annual population growth rate of 1.2%.

As of 2015, 36.1% of Lesotho's population was below the age of 14, 59.8% was between the ages of 15 and 65, and 4.1% was 65 or older. According to the World Bank, this population structure results in an age-dependency ratio of 67.3 dependents for every 100 working-age people.

In 2014, Lesotho had an average life expectancy of 49.7 years, with life expectancy nearly identical for males and females. The total fertility rate in 2014 (TFR, number of births per woman) was 3.185, compared to a wanted fertility rate of 2.3 in 2014.⁹

Collectively, these indicators reflect a relatively young, rural, growing population with a limited life expectancy (due to the epidemiological profile of the country, discussed later). Such a population structure will necessarily influence the types of health services most needed in the country, such as extensive maternal and child health services. They also point to the challenge of providing health and other services to rural populations, especially those living in remote mountainous areas.

Economic factors

As a small, landlocked country, Lesotho has limited economic prospects and relies heavily on South Africa for much of its economic activity (through trade, cross-border labor, etc.)¹⁸⁴ In 2014, Lesotho's GDP per capita in constant 2010 \$US was \$1226.60. In 2015, 7.7% of GDP came from agriculture, 31.6% from industry, and 60.7% from services.¹⁸⁴ Private industry in the country is somewhat weak, with the largest employer being the government, and the largest private employer being the textile industry (which employs approximately 4% of the country's total labor force).¹⁸⁴ The majority of Basotho are subsistence farmers, and agricultural output varies based on weather and climate conditions (see the section on environmental factors for more information). However, the country only produces approximately 20% of the total national demand for food.¹⁸⁴ In addition, at least a third of active male wage earners are employed in South Africa (often in the mining industry).¹⁸⁴ These economic conditions make the Basotho population vulnerable to undernutrition due to the variable availability of food, and

the high rates of migration in and out of South Africa by the labor pool has contributed to the high rates of HIV and TB in the country.

The 2015 Human Development Report categorized Lesotho as having “low human development” and reported the country’s GINI Coefficient as 54.2, the third-highest of all low human development countries (after Haiti and Central African Republic).¹⁸⁵ This high level of inequality has important implications for inequity in health outcomes, described in the section epidemiological factors.

Political factors

Lesotho is a parliamentary constitutional monarchy which gained independence from its status as a protectorate of the United Kingdom in 1966.¹⁸⁴ The chief of state is the king, currently King Letise III, but the king has no “no executive or legislative powers,” thereby making the Prime Minister the head of government.¹⁸⁴ Lesotho governs using a majority-party government, or, when necessary, a coalition government, and the leader of the majority party or majority coalition in the Assembly is the country’s Prime Minister.¹⁸⁴ In the most recent National Assembly elections in 2012, 552,000 valid votes were cast among 18 different political parties. Nearly 90% of the vote went to one of three parties, with the Democratic Congress (DC) receiving 39.58% of the vote.¹⁸⁶

The Lesotho Cabinet consists of 28 members: the Prime Minister, the Deputy Prime Minister, the Minister in the Prime Minister’s Office, and Ministers from each of the country’s 25 Ministries.¹⁸⁷ The line Ministry responsible for health in the country is the Ministry of Health, but other Ministries - such as Agriculture & Food Security, Development Planning, Gender, Youth, & Sports, and Social Development – all have mandates that impact population health. The government’s legislative branch has a bicameral system.¹⁸⁴

In 2014 and early 2015, the Government of Lesotho (GoL) experienced an attempted coup against the then-Prime Minister Thomas Thabane, of the All Basotho Congress (ABC) party.¹⁸⁸ After two elections, the Democratic Congress (DC) party ousted Thabane and GoL swore in Pakalitha Mosisili as Prime Minister, who had also served as Prime Minister from 1998 until 2012.

Legal and regulatory factors

The most relevant aspect of Lesotho's regulatory and administrative environment for understanding the health system is the recent push toward decentralization in the country. In 2014, GoL published its National Decentralisation Policy, which aimed to define and formalize devolution of services from central GoL Ministries to local governments in the country's 10 administrative districts.¹⁸⁹ The Policy specifies that administration of services related to agricultural production & marketing, environment & natural resources, infrastructure, planning, finance & accounts, social development, health, and education would all be devolved to the districts and would each have their own Directorate. These Directorates (in addition to a Directorate of Administration & Support Services) would report to the District Executive Secretary (DES) and would also have a dotted-line to their relevant "Sectoral Ministries," who provide technical oversight and support to each Directorate. On the other hand, the DES would oversee "financial and administrative matters" in the district; this position already existed in the districts prior to the National Decentralisation Policy, albeit under a different name (the District Council Secretariat or DCS). The Policy also codified the role of District, Community, and other Councils with regards to the devolved functions. (The Councils already existed and were functional in the districts, and had been established by the 1997 Local Government Act.)

By using devolution as the approach to decentralization, GoL aimed to shift decision-making for district-level functions to Directorates in the districts, rather than central GoL Ministries. This approach aimed to adhere to a number of standard principles for decentralization, including the principles of subsidiarity (functions and decisions should be performed at the lowest-possible administrative level), local autonomy (independence in making certain decisions at the local level), and the recognition of GoL as a single entity (in order to ensure that plans taken at the local level are harmonized with national plans and consistent with national policies and guidelines). Following from the 2014 National Decentralisation Policy, the 2015 Local Government (Transfer of Functions) Regulations listed the following health functions (as well as functions from other Ministries) to be devolved to local governments: environment health, maternal, newborn, & child health (MNCH), communicable and non-communicable diseases, health education and promotion, procurement and supply of medicines, health legal frameworks and policy regulation, human resource management and information systems, and quality assurance.^{189, 190}

The process of decentralizing any government service, including health services, faces a wide range of decisions. One of the key aspects of decentralizing is choosing which type of decentralization to undertake: devolution, deconcentration, and delegation.^{191, 192}

Deconcentration, the weakest form of decentralization, involves setting up field offices for central ministries; these field offices continue to report to the central government, who tend to set policies and control budgets. Devolution, a political form of decentralization, involves transferring authority and administration for service delivery to quasi-autonomous local government bodies. While Lesotho originally undertook deconcentration of the health system, it is now moving to a devolved model. A third form of decentralization not being undertaken by

Lesotho is delegation, which shifts authority to semi-autonomous agencies. Decentralizing a health system also requires determining how much autonomy the responsibility body has for making decisions related to a number of functions, such as financing, service organization, human resources, access rules, and governance rules.¹⁹²

Epidemiological factors

Lesotho faces a complex and challenging epidemiological and health systems profile. As of 2015, infectious diseases made up the majority of the burden of disease (as measured by Disability-Adjusted Life Year [DALYs]), with HIV/AIDS, tuberculosis (TB), diarrhea, lower respiratory infections, and other common infectious diseases alone making up 55% of the total burden of disease.¹⁹³ Among children under-5, the same two categories also constituted 50% of the burden of disease, and neonatal disorders constituted another 36%. In spite of the fact that infectious diseases dominate the total burden of disease, non-communicable diseases and injuries also account for an increasing share of the country's disease burden. After HIV/AIDS and tuberculosis, the disease areas whose absolute rates of burden of disease increased the most from 1990 to 2015 were 1) self-harm and interpersonal violence (increase of 134%), 2) diabetes, urogenital, blood, and endocrine diseases (90%), 3) transport injuries (69%), 4) and cardiovascular diseases (62%). Therefore, although "Group 1" diseases (communicable, maternal, neonatal, and nutritional) dominate the total disease burden, Lesotho is likely heading toward an epidemiological profile characterized by a double burden of disease. See Figure 4 for a comparison of Lesotho's burden of disease in 1990 and 2015 for the entire population, and Figure 5 for the under-5 population.

Figure 4 - DALYs per 100,000 population, 1990-2015, all ages¹⁹³

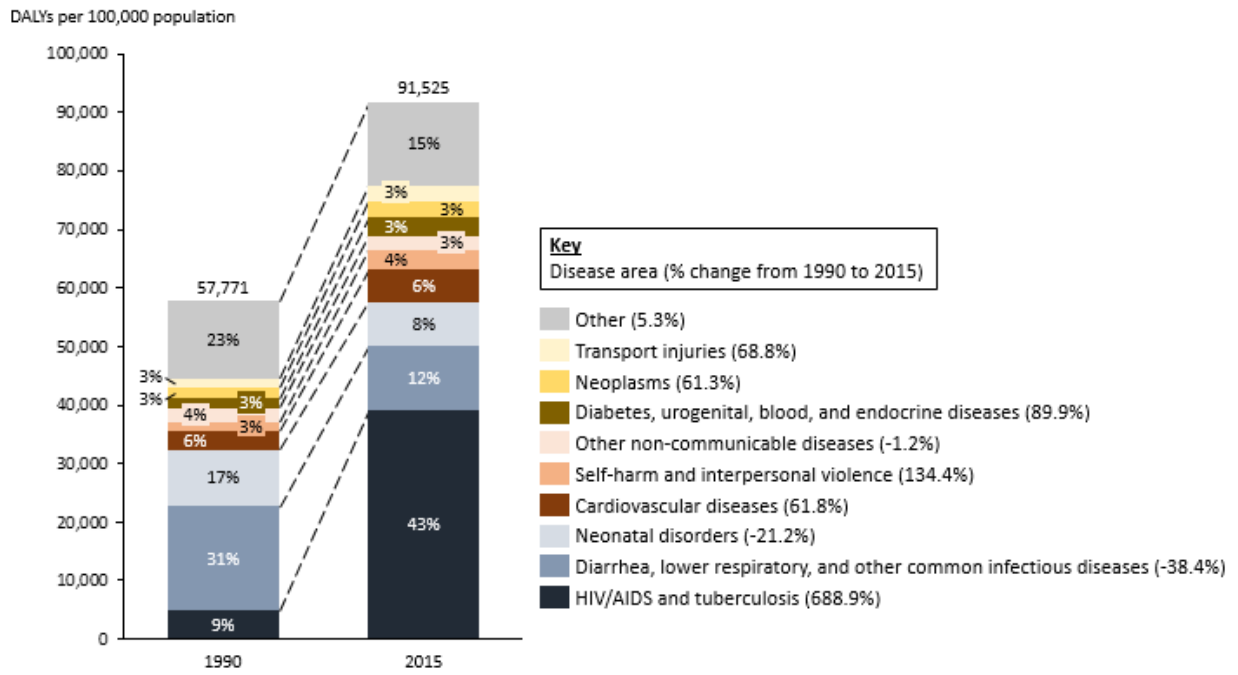
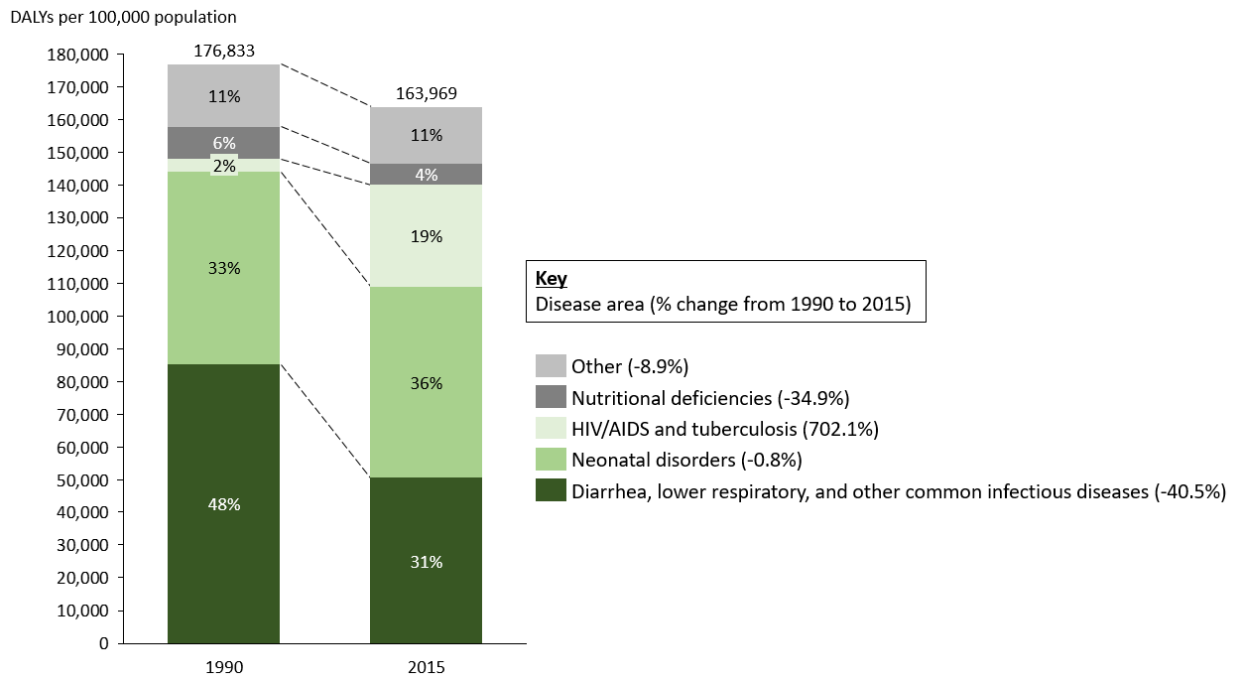


Figure 5 - DALYs per 100,000 population, 1990-2015, Under-5¹⁹³



HIV/AIDS

In 2015, Lesotho had the second-highest incidence of HIV infections in the world, with 1.9% of all uninfected adults becoming infected that year. (Swaziland was ranked first, at 2.4%, and South Africa was ranked third at 1.4%). Accordingly, the HIV prevalence is also very high, with 25% of the population being infected (30% of women and 19% of men).⁹ The epidemic is somewhat geographically concentrated, with the capital district of Maseru and the four most nearby districts having higher prevalence rates (24.7%-28%) than the other five districts (17%-21.2%). This geographic distribution has important funding implications, with PEPFAR funding and overseeing activities in four of the five highest-burden districts (known as the “scale-up” districts), and the Global Fund funding activities in the other five.¹⁹⁴

In 2014, approximately 86% of women and 81% of men reported knowing that HIV transmission can be prevented “by using condoms and limiting sex to one uninfected partner,” an increase from both 2004 and 2009.⁹ However, only 39% of women and 31% of men had comprehensive knowledge of HIV. Stigma associated with HIV/AIDS has decreased slightly from 2009 to 2014, with women and men both reporting attitudes towards HIV-positive people that are considered “accepting”.⁹ Nonetheless, anecdotal evidence from Basotho living in the country suggests that people are often unwilling or reluctant to disclose their HIV status, which can impede treatment-seeking behavior.

One important development in the fight against HIV/AIDS in Lesotho was the launch of the Test & Treat Campaign by the Government of Lesotho in early 2016. This plan aims to achieve universal access to HIV testing and treatment.¹⁴

Tuberculosis

In 2014, Lesotho had the highest incidence of TB globally, at 852 per 100,000 people. (South Africa was ranked second, at 834, and Swaziland was ranked third at 733). Given the high HIV prevalence and incidence, these high rates of TB are not unexpected. Of the total estimated TB cases in 2015, only 45% received treatment, and Lesotho had a TB case fatality ratio of 0.37.¹⁹⁵ Lesotho also had a 70% TB treatment success rate in 2015. Finally, 4.8% of new cases and 14% of previously treated cases were classified as multi-drug resistant (MDR-TB) or rifampicin-resistant (RR-TB).

Maternal Health and Sexual & Reproductive Health (SRH)

The data on maternal mortality, an important indicator of maternal health, is highly variable across data sources for Lesotho. According to the 2014 Demographic and Health Survey (DHS), in 2007-2014, the maternal mortality ratio (MMR) was 1,024 deaths for every 100,000 live births. This figure is slightly lower than during the period of 2002-2009 (1,243 deaths for every 100,000 live births), but higher than during the period of 1997-2004 (939 maternal deaths for every 100,000 live births).⁹ However, according to the World Bank World Development Indicators, the MMR in 2014 was 490, below the average for LMICs in Sub-Saharan Africa (547 deaths for every 100,000 live births). Nonetheless, both MMR estimates are well above the 2015 MDG target of 190 maternal deaths per 100,000 live births.¹⁹⁶

Output and outcome indicators related to maternal health can partially explain the country's high MMR. For example, in 2009-2014, only 74% of women had the recommended four (or more) antenatal care (ANC) visits, and only 62% of women had a postnatal health check within 2 days of delivering.⁹ 77% of women delivered in health facilities, and 78% had skilled assistance with delivery. Further, inequities in access to maternal health services also exist;

women with more education were more likely to deliver in a facility, and wealthier women were more likely to have a skilled provider attending their birth.⁹

With regards to sexual and reproductive health (SRH), 60% of married women used some form of modern contraceptives in 2014, up from just 35% in 2004.⁹ Unmet need for family planning was 18% in 2014 and has also declined since 2014. Only 10% of women aged 14-59 had had a breast cancer screening in the previous 12 months, and only 11% had had a cervical cancer screening. These data suggest that although family planning access continues to increase, access to other SRH services, particularly those for reproductive cancers, are low.

Newborn and Child Health

Neonatal, infant, and under-5 mortality all remained relatively constant from 2004 to 2009 but decreased from 2009 to 2014.⁹ However, significant geographic variation in child mortality exists, with the under-5 mortality rate varying from 59 deaths per 1,000 live births to 111 deaths per 1,000 live births in different districts.

With regards to child health, in 2014 68% of children (age 12-23 months) had received the complete set of basic vaccinations, the same percentage as in 2004.⁹ Of children who had diarrhea, 75% were treated with oral rehydration therapy (ORT).

Non-Communicable Diseases

The four non-communicable diseases examined by the Lesotho Demographic and Health Survey (DHS) are breast cancer, cervical cancer, diabetes, and blood pressure. (Breast and cervical cancer have already been covered under the section on SRH). While the prevalence of hypertension among women has increased from 11% in 2009 to 19% from 2009 to 2014, it remained the same among men at 13% in that interval.^{9, 197} With regards to diabetes, knowledge

of symptoms among the population is low (at or below approximately 50% in 2014).⁹ The prevalence of diabetes in the adult population is approximately 2-3%.⁹

Health service delivery overview

An assessment of the Lesotho health system in 2010 found that “Lesotho does not suffer from an inadequacy of funds, but rather from chronic under-spending of health resources, as well as from a less-than-optimal allocation of health resources.”¹⁹⁸ These findings indicate challenges both in government delivery of priorities and in allocative efficiency. The report also described the HIV rate, poor physical infrastructure, and low human resources for health (HRH) as structural challenges to improving health in the country. The country’s most recent Health Sector Strategic Plan, written in 2013, identified similar constraints, as well as opportunities for strengthening the system going forward, such as: international support for the health sector, abolition of user fees in the country, government’s commitment to the sector, strengthened governance through decentralization, and the existence of public-private partnerships (PPPs) for health.¹⁹⁹ (Implementing good governance through increased financial transparency has faced subsequent challenges.²⁰⁰) The majority of core health indicators in this plan focus on HIV, reproductive health, child survival, and TB control, all of which relate to primary care.

One important and controversial aspect of the health system in Lesotho is the Queen ‘Mamohato Memorial Hospital, built as a public-private partnership (PPP) with support from IFC and the World Bank. Although the facility has high quality and is seeing a high volume of patients, it was also using more than 50% of MoH’s budget in 2014, indicating that it may have been diverting important resources from other health sector activities.^{201, 202} One should note that these challenges validate the concerns of PHC advocates, who have historically criticized the building of urban hospitals in low-resource settings, which “were perceived as promoting a

dependent consumer culture, benefiting a minority, and drawing a substantial share of manpower and funds.”²⁰³

Health financing overview

According to the World Bank, Lesotho spent \$276 per capita on health (PPP, constant 2011 international \$). 76.1% of total health expenditure (THE) came from public sources, and 52.2% of THE came from external resources. According to the IHME, Lesotho received \$158.2 million in development assistance for health (DAH) in 2013, or \$76.44 per capita.²⁰⁴ According to IHME, Lesotho received the fourth-most funding DAH per capita of any country globally. These figures indicate that Lesotho is highly dependent on external aid for financing health care and public health services.

In 2008, Lesotho’s Ministry of Health and Social Welfare (now the Ministry of Health) abolished user fees for outpatient services at the health center (primary health care) level for all government-owned facilities, and reduced fees for outpatient services at health centers run by the Christian Health Alliance of Lesotho (CHAL). This elimination of user fees was expected to result in a 22% increase in demand for outpatient services, and preliminary analyses indicated that eliminating user fees did indeed result in a demand increase.¹³

Sociodemographic factors

Lesotho is a fairly homogeneous country with regards to ethnicity and culture. 99.7% of the population is Sotho, and 80% of the population identifies as Christian (with the other 20% of the country identifying with indigenous beliefs).¹⁸⁴ The majority of the population speaks Sesotho, one of the country’s two official languages (the other is English, which is used for government communications and documents).¹⁸⁴

With seven years of mandatory schooling, Lesotho has some of the strongest education outcomes in Sub-Saharan Africa, and the country is progressing towards universal primary education.¹⁸⁴ In 2014, 80% of primary school-age children were enrolled in primary school. The literacy rate for adults (ages 15 and above) is 88% for females and 70% for males.

International benchmarking indicates that Lesotho performs at least moderately well on indicators for gender equity. The World Bank's Country Policy and Institutional Assessment, which ranks countries' gender equality on a scale from 1 to 6 (with 6 being the highest), rates Lesotho as a 4. The 2015 Human Development Report's Gender Development Index, which measures the ratio of the Human Development for females to males in the country, is 0.953 (a value of 1.0 would indicate complete parity across genders).¹⁸⁵ Education levels and labor force participation are either equitable or superior for women, although women hold only 26.8% of seats in Parliament.¹⁸⁵

Environmental factors

As already discussed, the majority of Basotho live in rural areas. As of 2014, 74.2% of the country's land area was agricultural land and 8.2% was arable land (i.e. land used for temporary crops). In 2015 and 2016, Lesotho was experiencing a significant drought, with rainfall less than 65% of normal levels.²⁰⁵ The negative impacts of this drought are exacerbated by the fact that Lesotho exports its water to South Africa through several dams (and uses these dams to generate electricity for the country.)²⁰⁶ Given that approximately three out of every four rural people engage in subsistence farming and animal herding, this drought has the potential to have particularly severe health and economic consequences.¹⁸⁴

37.3% of the population has access to "improved" sanitation facilities (i.e. flush or pour-flush to a piped sewer system, septic tank or pit latrine; ventilated improved pit (VIP) latrine; pit

latrine with slab; or a composting toilet).¹⁸⁴ In 2015, approximately 81.8% of the population (but only 77% of the rural population) had access to an “improved” drinking water source (i.e. piped water into dwelling, yard, or plot; public tap or standpipe; tubewell or borehole; protected dug well; protected spring; or rainwater collection).¹⁸⁴ These conditions can pose public health challenges in the districts, such as unsanitary living and working conditions and lack of water at health centers.

Technological factors

As of 2012, 20.6% of the population had access to electricity, with only 10.1% of rural residents having access to electricity, and 46.9% of urban residents having access to electricity. 100% of installed electric capacity came from hydroelectric plants (e.g. dams).¹⁸⁴ These conditions can pose public health challenges in the rural districts, such as unsanitary living and working conditions and lack of electricity at health centers.

With regards to communication, there were 105 mobile phone subscriptions per 100 inhabitants in 2015. Although this figure does not necessarily indicate that most people in the country have access to a mobile phone (and many people with mobile phones may not have connectivity at all times), it does suggest that mobile use is high and reaches into the rural areas of the country. For every 100 people, only 16.1 were internet users.

Technology and technological innovation make up a very small portion of the economy. In 2012, <1% of manufactured exports were high-technology exports.

As of 2011, Lesotho had 5,940 kilometers of roadway, of which 18% were paved.¹⁸⁴ However, this figure may have changed since 2011. The low percentage of paved roads can cause challenges accessing health centers, especially for rural populations living in mountainous

areas. It can also present challenges for supply chain, cold chain for vaccines, and emergency transport of patients.

Conclusion

Taken together, these factors present a picture of a country struggling with aspects of governance, service delivery, and high levels of inequity, among other things. These conditions highlight both the challenges and importance of improving access to PHC services and focusing on equity as a key component of the Reform.

Village Health Worker Activities along the Care Delivery Value Chain: The Case of Lesotho

Gabriel Seidman, Joseph Rhatigan, Abera Leta, Likhapa Ntlamelle, Joia Mukherjee, Jesse Bump, Rifat Atun

Abstract

Background: Village Health Workers (VHWs) provide effective and efficient health services in low-resource settings globally. Partners in Health, a US-based non-profit medical organization, has operated in Lesotho since 2006 and has implemented a VHW program which is currently contributing to a National Primary Health Care (PHC) Reform. The purpose of this study is to document what care delivery services VHWs in this model perform, and to determine what competency-based activities they may have across multiple disease areas.

Methods: We conducted ten key-informant interviews and extensive document review to answer these questions. We structured our analyses around the Care Delivery Value Chain (CDVC).

Results: This VHW model staffs two VHWs per village, and includes close management of VHWs at the community and health center levels. VHWs serve as extensions of the health center into the community, and they perform four distinct competency-based activities that span multiple disease areas to fulfill this role: 1) community-based demand creation and health facility support, 2) community-based patient identification and diagnosis, 3) patient accompaniment and tracking, and 4) community-based care support. These activities contribute to tasks for disease areas such as HIV/AIDS, tuberculosis, and maternal, newborn, and child health (MNCH).

Conclusions: Although much research has focused on disease-specific tasks that VHWs can perform, this research identified key activities that VHWs can perform across disease areas, in their role as extensions of the health center into the community. A competency-based approach

to VHW training which emphasizes the VHW's cross-cutting activities, coupled with strong management oversight, may help integrate VHWs into the health system. Demand generation and other VHW activities can complement improvements in service delivery in order to increase service utilization by populations. Future research should evaluate the effectiveness of this model, VHW performance along each of these competencies, and the roles that VHWs play in other national health systems.

Background

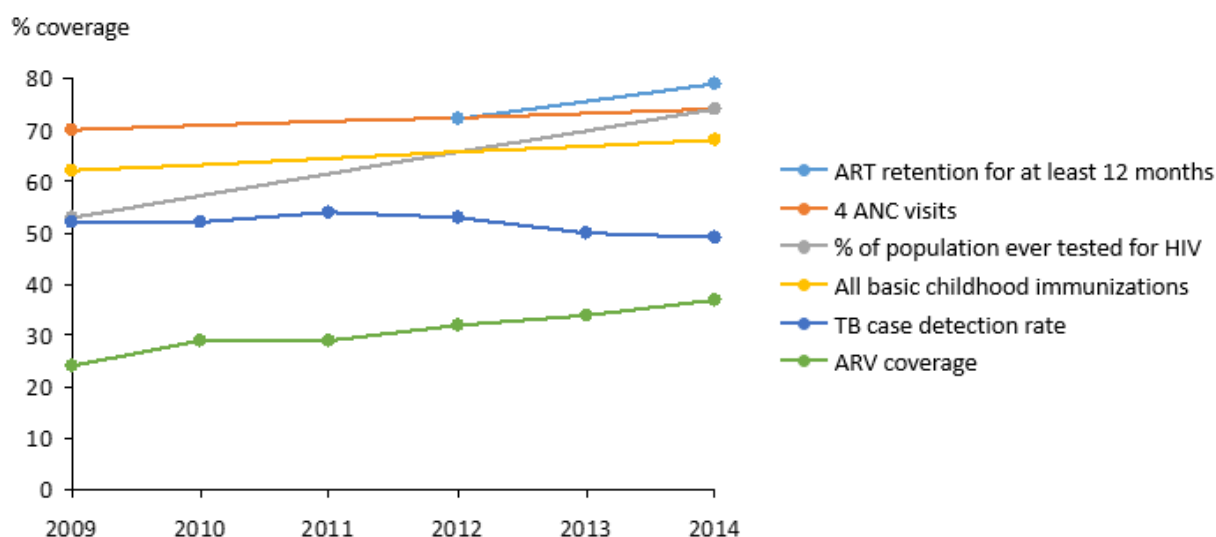
Village Health Workers (VHWs), also known as Community Health Workers (CHWs) in many contexts, provide important health services and care in low-resource settings.[‡] Task shifting to VHWs and other health associate professionals can improve clinical outcomes for patients across a number of diseases.⁵⁶⁻⁶⁰ The importance and cost-effectiveness of these types of workers for improving health systems performance in low-resource settings has also gained attention from a global advocacy perspective.^{207, 208}

Lesotho is a landlocked, lower-middle income country in Sub-Saharan Africa with poor health systems performance and health outcomes. Lesotho was significantly off-track to achieve all health-related Millennium Development Goals (MDGs) when they ended in 2015.⁸ In addition, the population of Lesotho faces significant challenges with regards to health access. 70.3% of the population lives in rural areas;⁸ among rural populations, 31% report that it takes greater than two hours to reach a health facility by the usual means of transportation, and 39% report that it takes greater than two hours by walking.⁹ 42% of women report having at least one problem accessing health care, including 26% citing distance to the health facility, and another

[‡] For the sake of consistency, we use the term VHW to refer to both VHWs and CHWs in this article, except where a citation specifically refers to CHWs. The two terms should be considered interchangeable for the purposes of this analysis. WHO's Classification of Health Workforce Statistics describes VHWs as an example of CHWs.

9% not wanting to go to a health facility alone. Therefore, access to key primary health care services remains low, although Lesotho has seen progress on many of these indicators. The Government of Lesotho (GoL) has committed to increasing access to key health services, including universal access to HIV testing and treatment.¹⁴ See Figure 6 for a summary of coverage rates for key services in Lesotho.

Figure 6 - Coverage rates for select population health indicators



Note: Each dot represents an actual data point from a specific source. Lines that span data points separated by more than one year represent linear interpolation of data. Only one source was used for each indicator to ensure consistency.

Sources: ARV coverage and TB case detection rate⁸; ART retention¹⁰; all other indicators^{9, 197}

Lesotho has used a VHW model to deliver select care since 1974, and in 2008, GoL formalized payments for VHWs.²⁰⁹ As of July 2013, Lesotho had at least 7,000 VHWs.²¹⁰ Due to programmatic challenges, including payment interruptions, lack of clear policies and guidelines for VHW training and management, and fragmentation of implementing partners, Lesotho has failed to achieve a unified, national VHW program.²⁰⁹ Nonetheless, the VHW model used by Partners in Health (PIH), a US-based non-profit medical organization that has worked in Lesotho since 2006, has served as one component of a broader National Primary

Health Care (PHC) Reform led by the Ministry of Health (MoH). This Reform aims to strengthen PHC and district health systems in order to combat mortality and morbidity from HIV/AIDS, TB, and maternal, newborn, & child health (MNCH). MoH piloted the Reform in four rural districts beginning in 2014 with support from PIH, and is currently planning for scale-up to the remaining districts. See Figure 7 for a high-level overview of the Reform model and history.

Figure 7 - Overview of the National PHC Reform

Led by the Ministry of Health and with Partners in Health playing a key technical advisory role, the pilot of the National PHC Reform consisted of three core health systems interventions: a new VHW model focused on highest-burden disease areas, expanded health services at PHC clinics to meet population needs, and empowered and capacitated management of the District Health Management Team (DHMT) to oversee the district's health system, including community, health clinic, and hospital levels. The Reform also included oversight by central MoH through various means, including quarterly review meetings. A pilot of the Reform, which built on PIH's model for running seven remote clinics in Lesotho, began in 2013/2014 in four districts. MoH currently plans to scale the Reform model to all 10 districts in the country. As discussed in the Methods section, a complementary paper on the institutional history of the Reform is also forthcoming.

Given that this VHW model serves as the basis for a national health reform, our research aimed to answer two important questions about the technical aspects of the model: 1) What care delivery tasks do VHWs execute in this Reform Model? and 2) Do VHWs in this model perform competency-based activities that span across multiple disease areas?

To answer these questions, we structured our analysis using the Care Delivery Value Chain (CDVC) as a guiding framework. CDVC is an established framework used to map the key activities needed to prevent, diagnose, treat, and manage a given health condition across the entire cycle of care. The CDVC approach has been used to describe the care continuum for HIV/AIDS in low-resource settings,²¹¹ breast cancer,²¹² acute knee-osteoarthritis,²¹³ clubfoot,²¹⁴ and other conditions.²¹⁵ It has also been used in programmatic work to guide programmatic

decisions about VHWs. However, to our knowledge, no published research has used CDVC to understand the full set of activities that a single cadre of worker in the health system can play across disease areas. Therefore, this research builds on important previous work in global health delivery to articulate how a cadre of health workers can support and strengthen care delivery across a set of disease priorities.

Methods

In order to answer these questions, we conducted ten semi-structured key informant interviews with PIH staff and consultants involved in the design and implementation of the VHW model, as part of a broader research effort on the PHC Reform. We used purposeful sampling with snowballing to identify interviewees based on their experience with some aspect of the Reform, such as its design or implementation. See Figure 8 for a list of the professional titles of participants interviewed. Each interview lasted at least one hour and was conducted between September and December 2016. We used an interview guide based on the Care Delivery Value Chain (CDVC) and other health systems frameworks, and the interview guide and research protocol were approved by the Institutional Review Board at Harvard University. All participants were asked to describe the full list of activities that VHWs conduct across disease areas (HIV/AIDS, TB, and MNCH), and how the activities relate to each other. After completing this list, they were shown the CDVC framework to ensure that they had not missed any activities in the continuum of care. We tailored our interviews to the specific expertise of the interviewees (e.g. clinical aspects of the VHW model, programmatic aspects of the VHW model, challenges to implementing the VHW model and other aspects of the Reform, etc.) We informed participants that interviews were confidential and anonymous but that their statements may be used in research efforts documenting the Reform. With participants' permission, we

recorded all interviews. We also conducted an extensive document review of over 30 documents relating to the VHW Model and PHC Reform in Lesotho. These included policy documents, training guidelines, and reports on the current state of the VHW program in Lesotho.

Figure 8 - List of interviewees' professional titles

- Program Director
- Reform Technical Advisor (former)
- Reform Technical Advisor (current)
- Clinical Director
- Community Director
- Maternal & Child Health Manager
- Quality Assurance & Improvement Manager
- Statistician
- Senior Consultant
- Principal Consultant

To analyze our interviews, we used directed content analysis guided by the CDVC framework described earlier. Content analysis was iterative in order to account for new, complementary, or conflicting findings from subsequent interviews. We used our document review to complement, triangulate, and verify statements and opinions by the interviewees in order to get a clear record of the tasks that VHWs perform, and the broader history of the Reform. See Figure 9 for a list of select documents relevant for the VHW model that were reviewed for this research.

This research was also used to document the nature of the National PHC Reform and the institutional history of its adoption, which is the subject of a forthcoming complementary paper.

- Lesotho Ministry of Health (publicly available documents)
 - Draft VHW Policy (2013)²¹⁶
 - Lesotho PHC Revitalisation Plan, 2011-2017²⁰⁹
 - Lesotho Village Health Workers' Profiling and Mapping Exercise²¹⁰
 - PHC Revitalisation: 2014 Village Health Worker Draft Policy Framework - Towards ONE Village Health Worker Programme²¹⁷
- Partners in Health Lesotho (internal documents)
 - Protocols

- Accompagnateur Training Guide²¹⁸
- Conducting a Pitso Checklist²¹⁹
- VHW Trainings
 - Conducting “Healthy Family Visits”²²⁰
 - Conducting a Pitso²²¹
 - Encouraging Clinic Attendance²²²
 - Factors that Affect Families’ Health and Actions²²³
 - Good Communication²²⁴
 - The Health Reform²²⁵

Figure 9 – List of select VHW-related documents reviewed for this research

Results

The Reform Model for VHWs uses two cadres of VHWs with overlapping activities: one focused on HIV/TB, and one focused on maternal and newborn health (known as Maternal Mortality Reduction [MMR] workers).²¹⁶ Both cadres also focus on health for children under-5 and for general population health in the community. These disease areas were selected because they represent the majority of the disease burden in Lesotho.¹⁹³ The model used two cadres focused on different disease areas rather than one cadre due to the significantly different nature of follow-up required for HIV/TB and MNCH. At the onset of the Reform, each cadre received training separately but from the same training team.

The Reform model specifies that there should be at least 2 VHWs per village, and a community-based VHW supervisor oversees approximately 15 VHWs. These supervisors report to a VHW Coordinator based at the health facility, who oversees the entire VHW program within the health center’s catchment area. This management structure for the VHWs, which is based at the health center but extends into the community, helps ensure that VHW activities are integrated into the health system’s operations and that the VHWs’ activities can be closely monitored.

We structured our Care Delivery Value Chain (CDVC) for analyzing VHWs’ tasks around four generic stages in patient treatment: prevention, diagnosis / assessment, initial treatment, and ongoing management and support. (For maternal and newborn health, antenatal

care [ANC] was considered part of diagnosis / assessment, whereas postnatal care [PNC] was considered part of ongoing management and support.) Within this framework, we found that VHWs have an overall role of serving as an extension of the health center into the community, and they have perform four distinct, cross-cutting activities to fulfill this role: 1) community-based demand creation and health facility support, 2) community-based patient identification and diagnosis, 3) patient accompaniment and tracking (during diagnosis, treatment, and disease management), and 4) community-based care support. See Figure 10 for a complete schematic of these roles and their application to relevant disease areas.

VHW overall role	Serve as an extension of the health center into the community					
CDVC	Prevention	Diagnosis / assessment		Treatment	Management	
VHW competency-based activities	Community-based demand creation and health facility support	Patient identification and community-based diagnosis support	Patient accompaniment	Patient accompaniment	Patient accompaniment and tracking	Community-based care support
HIV/AIDS	<ul style="list-style-type: none"> Educate community on HIV prevention and treatment; promote “Test & Treat” campaign 	<ul style="list-style-type: none"> Track which patients have been diagnosed as HIV-positive 	<ul style="list-style-type: none"> Accompany patients to facility for HIV testing 	<ul style="list-style-type: none"> After patient receives diagnosis from nurses, link with patient for ongoing care 	<ul style="list-style-type: none"> Track and record patients, including defaulters Accompany (defaulted) ART and pre-ART patients to health center for refills, appointments Report community deaths 	<ul style="list-style-type: none"> Provide DOT for ART and ensure that the patient has sufficient food to take medication Answer basic treatment-related questions (e.g. drug side effects) and provide psychosocial support Promote adherence for people in denial of status
Tuberculosis	<ul style="list-style-type: none"> Educate community about TB prevention and treatment 	<ul style="list-style-type: none"> Identify suspected TB patients (i.e. cough, night sweats, weight loss, chest pains, bloody sputum) by going door-to-door Conduct contact tracing (i.e. check whether other household members have cough) 	<ul style="list-style-type: none"> Accompany patients to facility for testing (e.g. sputum collection) 	<ul style="list-style-type: none"> Stay with patient during treatment initiation Answer basic treatment-related questions (e.g. drug side effects) 	<ul style="list-style-type: none"> Track and record patients, including defaulters Accompany patients to health center for refills, appointments, and sputum collection after 2 months of treatment Report community deaths 	<ul style="list-style-type: none"> Provide DOT for TB medications, record DOT, and ensure that the patient has sufficient food to take medication Answer basic treatment-related questions (e.g. drug side effects) and provide psychosocial support
Maternal / Newborn Health	<ul style="list-style-type: none"> Educate patients about common problems during pregnancy, benefits of HIV-testing and PMTCT, and family planning 	<ul style="list-style-type: none"> Identify suspected pregnancies (i.e. women with a missed menstrual cycle) by going door-to-door Screen pregnant women in community for symptoms of high-risk pregnancy (i.e. bleeding, regular vomiting, decreased fetal movement) 	<ul style="list-style-type: none"> Accompany women for pregnancy test And four ANC visits 	<ul style="list-style-type: none"> Accompany women and ensure they enter maternal waiting home as directed by nurse-midwife (typically at 38th week of pregnancy) 	<ul style="list-style-type: none"> Accompany HIV-exposed infants to facility for DNA-PCR Accompany mothers for PNC at one, six, and 14 weeks Record patient accompaniments Report community deaths 	<ul style="list-style-type: none"> Conduct follow-up visits at home to mother / neonate during first seven days after delivery Check to see if mothers are properly breastfeeding and burping Check for danger signs for maternal and infant health
Child Health	<ul style="list-style-type: none"> Educate communities about child health and importance of nutrition Mobilize the community for National Immunization Days 	<ul style="list-style-type: none"> Identify under-5 children that should attend Under-5 Clinics (i.e. for immunizations) Monitor growth of children in the community using salter scale every month Identify malnourished children in the community using growth trend graphs 		<ul style="list-style-type: none"> Accompany children for vaccines and growth monitoring during scheduled appointments Accompany malnourished children for treatment 	<ul style="list-style-type: none"> Track patients and number of accompaniments Report community deaths 	
Other activities	<ul style="list-style-type: none"> Convene community meetings for health facilities (“pitos”) Participate in health outreach campaigns by health facilities Report health hazards in the community 	<ul style="list-style-type: none"> Participate in investigations of communicable disease outbreaks 				<ul style="list-style-type: none"> Provide counseling bereavement support as needed

Figure 10 - VHW competency-based activities and tasks along the CDVC

1) Community-based demand creation and facility support

In order to generate demand for health services, VHWs educate community members on the priority disease areas under their purview and mobilize them to address these disease areas. VHWs received an initial 10-day training, followed by monthly one-day trainings from their health center on a given health topic, which serves a form of continuing education. They are expected to hold a community gathering, known as a “*pitso*” in Sesotho, at least one time per month, where they address an important health topic.²²¹ Clinical staff at the health center may also attend the *pitso* at the invitation of the VHW and the village chief, who helps organize the meeting. VHWs can hold *pitsos* on a wide range of topics. These meetings serve as one way to mobilize the community around a specific health issue. For a representative list of topics suggested for *pitsos*, see Figure 11.

Figure 11 - Suggested topics for a *pitso*

- Services offered at the clinic for adults, children, and pregnant women
- Importance of having only one sexual partner
- Importance of using condoms and where you can get them
- Importance of regular testing for HIV
- Stages of HIV (key message: you can't tell if someone has HIV by how they look)
- Importance of adhering to HIV and TB medications
- Signs and symptoms of TB
- Importance of attending the ANC clinic early in pregnancy
- Benefits of delivering at the clinic and the disadvantages of delivering at home
- Importance of PNC
- Types of contraception available and their benefits
- Signs and symptoms of STIs and the importance of treating them
- Household hygiene
- Importance and steps of proper hand washing

Source: Partners in Health²¹⁹

During monthly health family visits, VHWs also conduct health education on the following topics as relevant, where they speak with different individuals / groups:²²⁰

- With the entire family: Child immunizations, signs of child malnutrition (serious weight loss; stunted growth; wasting of muscles; being extremely thin; severe hunger; discolored hair that is falling out; swelling of feet, face, eyelids, and hands; lightening of skin with blackish spots; loss of appetite; dehydration due to diarrhea), and child health services available at the facility
- With each woman individually: The importance of condom use, family planning methods, side effects of contraception (irregular bleeding; nausea; cramps; headache; weight gain / loss), the importance of receiving a pregnancy test after a missed period, and the importance of ANC visits
- With each man individually: The importance of condom use

In addition, as extensions of the health center into the community, VHWs can help mobilize communities to participate in health outreach days (when health facility staff provide clinical services in the community) and report health hazards in the community to the health facility staff.

Notably, these demand creation activities do not operate in a vacuum and are complemented by the availability of quality, reliable services at the facility. In other words, demand creation at the community level was part of a broader strategy to increase utilization of health services in the community and at health centers.

2) Community-based patient identification and diagnosis

In the Reform model, VHWs are expected to identify the following individuals in the community to initiate testing or treatment:

- Pregnant women (based on last missed period; asking about pregnancy status in Lesotho is considered taboo, so asking about last missed period is a culturally sensitive way to identify pregnant women)
- Women with high-risk pregnancies (based on vaginal bleeding, regular vomiting, decreased fetal movement)
- Individuals who do not know their HIV status
- Suspected TB cases (based on cough for more than two weeks, night sweats, weight loss, chest pains, and bloody sputum) and their contacts (i.e. other household members with possible exposure)
- Malnourished children (based on the symptoms listed in the previous section and growth chart in patient booklet)
- Children who are due for immunizations
- Other ill patients requiring medical attention

VHWs identify these patients primarily during home health visits, but can also identify them based on their ongoing interactions with the community, during *pitsos*, and by word-of-mouth from other community members. They also conduct monthly growth monitoring for all under-5 children in the village using a salter scale and track the child's weight on a growth chart; VHWs should be able to identify when a child's weight is outside the normal range and bring or refer them to the clinic.

3) Patient accompaniment and tracking

Patient accompaniment, or physically escorting patients to the health centers, occurs across most stages of the CDVC. Physically accompanying patients to the health center helps address concerns such as not wanting to travel to the health center alone or feeling nervous about

the visit. VHWs track and record all instances of accompaniment, and the VHW Coordinator records these instances of accompaniment in a register. VHWs will also report any community deaths.

Patient accompaniment begins with bringing patients to the health center for diagnosis and care initiation after patient identification. This stage includes HIV testing, TB screening and testing for patients with symptoms or with possible exposure, and pregnancy testing / first ANC visits. Accompanying patients for diagnosis / treatment initiation provides support at an early stage of care and brings patients into the health center who might not even know that they require medical care or have a clinically addressable condition. VHWs will also re-accompany patients back to the health center to receive their diagnostic results (if they are not provided immediately). Having a VHW available at the health center during treatment initiation ensures that patients link with VHWs and that VHWs know the basic medical attention that patients will need to receive at the health center. (In the case of newly diagnosed HIV patients, the health center will only disclose the patient's status and link them with a VHW with the patient's consent). VHWs also accompany pregnant mothers when they are ready to move to the maternal waiting home (typically at the 38th week of pregnancy, though possibly earlier for high-risk pregnancies or those living very far from the facility).

VHWs also track and accompany patients for ongoing management and care – i.e. ART refills, CD4 / viral load testing, TB medication refills, subsequent ANC and PNC visits, routine vaccinations, and outpatient treatment for child malnutrition. Given that many of the most important health issues in Lesotho require ongoing care, tracking patients to ensure that they come for follow-up visits as scheduled is critical for managing both individual and population health. When a patient misses an appointment, either a nurse or the VHW Coordinator notes the

missed appointment, and the VHW Coordinator contacts the VHW to investigate the situation. The VHW will then accompany the patient back to the health center to make up the missed appointment.

Patient accompaniment faces cultural and implementation challenges in Lesotho, and acceptance of the accompaniment model varies based on factors such as geographic setting (urban versus rural) and patient demographics. For example, patients who do not want to disclose their HIV or pregnancy status may resist accompaniment to the health center for ART refills or ANC visits, respectively. Clinically stable patients who have been on ART for a long time and feel they know how to manage their illness may also resist accompaniment because they feel that they do not need additional support. In urban settings, where travel to the health center may involve paying for transport via taxi or public bus (because patients do not want to walk), accompaniment may incur additional costs for the VHW. Some patients may resist accompaniment because they do not trust the VHW or fear that s/he will gossip about the patient's health with other community members. On the other hand, many patients appreciate accompaniment, and experience with its rollout in Lesotho suggests that it can reduce loss-to-follow-up and patient non-adherence.

4) Community-based care support

VHWs provide select, limited care services at the community level. They provide directly observed therapy (DOT) for TB patients every day for six months and record these observations in a TB card (which the clinic nurse can then check for missed days). They also provide DOT for select ART patients, such as new ART patients, patients experiencing complications, and those who are non-adherent. VHWs will also monitor for severe side effects from drugs, such as vomiting from ART or TB medications, extreme rashes, psychotic symptoms

from ART, or other serious negative reactions, and will accompany sick patients to the health center where a clinician can make a more formal assessment of the patient's condition. (VHWs do not know the detailed side effects of every drug). VHWs should also know common mild side effects, such as TB patients' urine turning red (from rifampicin), and can counsel patients that these are not serious. They may also remind patients to take their drugs with food if they experience gastro-intestinal side effects. VHWs check on new mothers and infants for the first seven days after discharge from the health facility and promote proper breastfeeding and burping. During these postnatal checks, they should be able to identify danger signs for the infant's health, such as reduced sucking, high temperature, and excessive crying, and for the mother's health, such as profuse bleeding.

As members of the community, VHWs can also provide limited counseling and psychosocial support for patients. For example, VHWs can explain to non-adherent ART patients the importance of their drugs and remind them why they initiated treatment in the first place. After the death of a VHW's patient, the VHW will join with other community members to console the family and offer emotional support, and they will also let the family know that they can continue their support as a linkage to the health center.

Challenges to the VHW Reform Model

The main challenge raised during this research involved the issue of cultural resistance to accompaniment (i.e. VHWs physically escorting patients to the health center). Basotho culture does not reject accompaniment outright, and many patients seem to accept and even welcome accompaniment. However, patients seem to reject the idea of mandatory accompaniment and insist that they should have the right to choose whether or not to receive accompaniment. As discussed previously, individuals such as HIV-positive or pregnant patients, clinically stable

patients with experience managing their own care, and individuals concerned about VHWs gossiping about their health status, may reject accompaniment.

Our research did not identify having too many different clinical activities as a major challenge for VHWs. This is likely because VHW activities are divided across two cadres, so their clinical scope is somewhat limited. However, several interviewees stated that keeping detailed records and accompanying many patients did represent a significant workload for VHWs simply due to the number of patients. Other challenges discussed mostly involved logistical (rather than clinical) aspects of implementing the program, such as ensuring sustained payments and maintaining up-to-date lists of active VHWs.

Discussion

Our research identified four cross-cutting VHW activities that address Lesotho's major disease areas in a primary health care setting. These cross-disease activities are consistent with the formal definition for VHWs given by the WHO Classification of Health Workforce Statistics, which state that VHWs "provide health education, referral and follow up, case management, and basic preventive care and home visiting services to specific communities. They provide support and assistance to individuals in navigating the health and social services system."¹⁹ We summarize here several key policy and programmatic implications from these findings.

VHW activities address the root causes of poor population health in Lesotho A

The four roles performed by VHWs are especially critical to address the root causes of poor population health. Health education can address poor knowledge of key disease areas: only 31%-39% of Basotho have comprehensive knowledge of HIV, and 10%-20% of Basotho cannot name any symptom associated with TB.⁹ Patient identification can help address the low coverage of key health services: 35% ART coverage for HIV-positive people (as of 2015),¹⁰ 45%

treatment coverage for TB patients,¹⁹⁵ and 68% of children fully immunized.⁹ Tracking patients and community-based care / DOT is also critical due to high loss-to-follow-up / defaulting rates: 21% of ART patients are lost before 12 months,¹⁰ 13% of TB patients default,²²⁶ and 22% of women who receive their first ANC visit do not complete the recommended four visits.⁹ Accompaniment, or physically escorting patients to the health center, works in conjunction with other support services provided by the VHWs, such as providing social support and adherence support for treatment.

Further, VHWs focus on select disease areas which dominate the burden of disease in Lesotho. HIV/AIDS and tuberculosis made up 43% of Lesotho's disease burden in 2015, and neonatal disorders, maternal disorders, and other communicable and nutritional diseases affecting the under-5 population constituted another 17%.¹⁹³

Competency-based approach to defining VHW's activities can make their skill set relevant across disease areas and possibly create a distinct professional identity for VHWs

The most comprehensive report on CHWs from WHO extensively details the services and trainings for different cadres of CHWs that address different disease areas.²²⁷ While it is important to understand the individual, disease-specific tasks that VHWs can perform, our findings suggest that defining and articulating VHW cross-cutting activities is equally relevant for designing programs. Rather than thinking about VHWs as providing disease-specific services, the PIH Lesotho model trains VHWs to perform general activities for a specific set of priority diseases (e.g. HIV/AIDS, TB, MNCH). While “specialized” VHWs may contribute effectively to a vertical program focused on one disease area, using a competency-based approach to VHW training may allow programs to integrate these workers into broader health systems strengthening and service delivery. Because VHWs work as an extension of PHC

services, structuring their work around competencies could allow for transferability of skills as disease priorities shift (e.g. during an outbreak or with the rise of non-communicable diseases in the population.) This approach has the potential to create a distinct professional identity for VHWs which focuses on the competency-based activities that they can be expected to perform in a health system.²²⁸

Of course, policymakers and program managers must also take care not to overload VHWs with too many tasks or diseases.¹²⁰ Experience with this model suggests that segregating different disease areas to different VHW cadres, while maintaining the same competency-based activities across all cadres, can prevent clinical task overload.

Strong management of VHWs helps integrate them into the health system

Global guidance on best practices for CHWs suggests that they should be integrated into national health workforces and plans.²²⁹ A systematic review of CHW program scale-up and sustainability found that the most frequently cited enabling factor of success is “consistent management and supervision of CHWs and CHW program.”¹²² The model in Lesotho, where a paid Coordinator at the health center oversees the activities of all VHWs in the catchment area and where VHW skills focus on the same disease areas as the services provided by the clinics, reflects this approach. Because VHW activities such as patient tracking contribute to data collection, strong management of the program is important not only for impacting population health but also for monitoring and evaluating the program.

Linking demand generation to improvements in service delivery can provide a holistic approach to improving service utilization

This VHW model diverges from the approach promoted by integrated community case management (iCCM), where CHWs directly provide treatment such as antibiotics at the

community level.^{230, 231} A recent evaluation of iCCM practices in three countries found that, in the case of Burkina Faso, where the iCCM program did not have strong management, clinical quality was poor.²³² In the other two countries, Ethiopia and Malawi, stronger management led to better quality of care, but the expansion of access to iCCM did not lead to increased care-seeking or increased coverage of treatment (i.e. utilization of services) for childhood illness.^{233,}
²³⁴ The authors of these evaluations list a number of factors which could have led to this limited impact on service utilization, including lack of demand generation activities, lack of transport for CHWs, low acceptability of CHWs by the population due to poor quality during an early period of the program, and CHWs not actually residing in their catchment area or spending sufficient time there. These findings suggest that although CHWs can provide quality clinical care for select services, a more comprehensive approach to strengthening the health system in the local area, including demand generation activities tied to improvements in the supply of services, is necessary to improve service utilization. The Lesotho model, which links demand generation by VHWs to the care support activities they provide and the services offered at the health center, presents one such approach.

Limitations of this research

This conceptual analysis of a specific VHW model has several key limitations. First, this research does not provide conclusive evidence for the effectiveness of this model. Rather, it provides a framework for understanding the VHW model which could serve as the basis for a later evaluation. This research does not provide a definitive model for implementing VHW programs in other settings. Rather than trying to copy this model, policymakers and practitioners could consider how they can adapt this model to their own settings, particularly after more thorough evaluations of its effectiveness.

We were only able to interview staff and consultants associated with PIH for this research, which could introduce considerable bias in favor of the PIH model into our research. Indeed, further qualitative research should examine other stakeholders' perspectives on the model. These stakeholders include GoL policymakers, the District Health Management Teams (DHMT), health center clinical staff, patients, and the VHWs themselves. Nonetheless, conceptualizing and framing the VHW model which is serving as the basis for a national health reform serves as an important first step in documenting and evaluating the best practices and challenges of this model.

Further, this paper does not document the political or institutional processes which led to the development of the VHW model; the CDVC framework is not designed to support such an analysis. However, as discussed in the Methods section, a forthcoming complementary paper on the National PHC Reform documents the processes that led to the development of the VHW model and other aspects of the Reform.

Future directions for research on this topic include formally evaluating the effectiveness of this VHW model (and the National PHC Reform) in Lesotho and mapping the activities of VHWs in other contexts along the CDVC in order to compare and contrast this experience with other contexts.

Conclusion

VHWs provide an important basis for increasing access to health services in low-resource settings. Extensive research has already documented the effectiveness of this type of health worker for working in specific disease areas. This research examined a specific VHW model in Lesotho to determine whether VHW cadres also perform activities that cut across disease areas and which can serve as the basis for training (and possibly professionalizing such a cadre).

Using the Care Delivery Value Chain, we identified four distinct activities – creating demand at the community level, patient identification, patient accompaniment / tracking, and community-based care support – which VHWs in this model perform across multiple disease areas, and which allow them to fulfill their ultimate role of serving as extensions of the health center into the community. This approach can help policymakers, practitioners, and VHWs themselves think more holistically and integratively about how they fit into the health system and how their work contributes to improving population health. Going forward, researchers and policymakers should evaluate the Lesotho VHWs’ performance along these four activities and the effectiveness of this model for improving population health.

Declarations

Ethics approval and consent to participate: The Harvard IRB approved this research and the interview guide used for this article. All interviewees consented to participating both verbally and in writing.

Consent for publication: Not applicable

Availability of data and material: Links to all publicly available data are included in the References section of this article.

Competing interests: GS served as an independent consultant for Partners in Health. This research separate from his consultancy, and payment for his consultancy was not contingent upon the research, findings, or publication of this article. JR, AL, LN, and JM are employees of Partners in Health. Their employment was not contingent upon the research, findings, or publication of this article.

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Building State Capability to Strengthen Health Systems: The National Primary Health Care Reform in Lesotho

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Abstract

Background: Achieving universal, comprehensive primary health care in low-resource settings has been a global health priority at various points over the last four decades. With the recent increased focus on universal health coverage on the global agenda, a primary health care-based approach may help low-resource countries achieve this and other health systems goals. Lesotho, a small country in southern Africa with one of the highest HIV rates in the world, poor health outcomes, and a weak health system, has recently undertaken a National Primary Health Care Reform with the support of Partners in Health, a US-based non-profit medical organization. The purpose of this research is to document the nature of this Reform and the institutional and historical processes which led to the Reform.

Methods: We conducted 10 semi-structured interviews with PIH staff and reviewed over 30 documents related to the Reform, and we analyze the institutional history of the Reform using health systems innovation diffusion theory and the framework of problem-driven iterative adaptation.

Results: The Reform pilot included four sets of interventions: implementation of a Village Health Worker model, improved service delivery at health clinics based on alignment of human resources, supply chain, and infrastructure with an assessment of the disease burden in the population, capacity-building and empowerment of the District Health Management Teams, and quarterly reviews of the pilot with the central Ministry of Health. Formulating, adopting, and

implementing the Reform took place over a series of iterative steps to continually increase both the functionality and legitimacy of the Reform.

Conclusion: The theory of PDIA argues that effectively building state capability in development initiatives involves addressing locally-identified problems, continuously iterating on solutions, working within a clear authorizing environment, and engaging a broad set of change agents; our research finds that the approach to formulating, adopting, and implementing the Reform took all four of these approaches in some form. Experience with this Reform also suggests the importance of building support for policy interventions among multiple constituents with multiple types of data. Directions for future research include an impact evaluation of the Reform, and further theoretical and empirical work on the linkages between strengthening primary health care delivery and achieving universal health coverage.

Introduction

Practitioners and researchers have identified and debated the benefits of using a primary health care-based approach to achieve universal health coverage (UHC) for many years. In 1978, the Alma-Ata Conference described primary health care (PHC) as an approach to achieving health for all by 2000, and the 32nd World Health Assembly endorsed this declaration.^{3, 203, 235} More recently, the 2008 World Health Report focused on PHC and how it could contribute to universal coverage and equity, and World Health Assembly resolution 62.12 in 2009 reaffirmed the Alma-Ata declaration and urged Member States to prioritize PHC as a means to increase access to health services and improve population health.^{236, 237} Since then, WHO priorities have continued to focus on UHC and health systems strengthening (HSS) as horizontal approaches to improving population health.^{18, 238, 239} Although the health-related Millennium Development Goals (MDGs) focused on a select set of priority diseases, there was

recognition by governments and partners that HSS was necessary to contribute to the efficiency and sustainability of achieving the MDGs.²³⁸

As the era of the MDGs drew to a close in 2015, UN member states adopted a broader approach to improving public health with Sustainable Development Goal (SDG) 3. SDG 3.8 specifically lists achieving UHC as a target. Given that PHC can address 90% of health care demands, using a PHC approach can help achieve UHC and some of the challenges faced by the UHC agenda.²⁴⁰ For example, health systems globally will have an estimated deficit of 12.9 million skilled health professionals by 2035.²⁴¹ Task shifting to lower-skilled workers in the context of PHC can provide equivalent or superior outcomes for a number of diseases and is often a cost-effective way of doing so.^{52, 56, 58-61, 242} Financing for UHC also provides challenges, both on the supply side (i.e. the high cost of delivering services to an entire population), and on the demand side (i.e. the possibility of incurring catastrophic financial expenditure from receiving services).¹⁸ However, health systems oriented toward PHC tend to reduce costs and increase patient satisfaction, in addition to being generally more equitable and accessible, especially for poorer populations.²⁴³

Many of the health challenges faced by countries in southern Africa, including Lesotho, are directly addressable by PHC. Lesotho had the second-highest HIV prevalence in the world in 2015 (after Swaziland),²⁴⁴ the highest incidence of TB in 2014,⁸ and high rates of maternal, newborn, and under-5 mortality.⁹ In 2009, a nurse-driven, community-supported PHC approach to distributing antiretroviral treatment (ART) in Lesotho more than doubled ART enrollment in two years without a major increase in human resources.²⁴⁵ Introduction of a lay maternal health worker program and basic improvements to maternal health services in rural clinics in Lesotho in 2009 resulted in an increase in antenatal care (ANC) visits, facility births, and emergency

referrals for births with complications to hospitals.²⁴⁶ The introduction of maternal waiting homes also led to an improvement in access to maternal health services.²⁴⁷ GoL has recently committed to universal access to testing and treatment for HIV/AIDS, an important step toward UHC.¹⁴

Nevertheless, the PHC system in Lesotho faces challenges which directly contribute to the country's poor health outcomes. As of 2014, 70% of health facilities had staffing shortages, the majority of PHC clinics did not receive their allocated budgets, health information systems did not collect routine data, and less than 15% of Village Health Workers (VHWs) reported receiving their payments on time.²⁴⁸ Further, Lesotho's Ministry of Health (MoH) has invested in Queen 'Mamohato Memorial Hospital, a controversial investment into the country's tertiary care system built as a public-private partnership with support from the World Bank. Although the facility has strong clinical quality and sees a high volume of patients, it used over 50% of MoH's budget in 2014, indicating that it may have diverted important resources from PHC.^{201, 202}

Given the importance of PHC and the challenges faced by the system, MoH undertook the pilot of a National PHC Reform in 2014. In partnership with Partners in Health (PIH), a US-based non-profit medical organization, MoH piloted the Reform model in four of the country's ten administrative districts and currently plans to scale the Reform model to the rest of the country. This research has two purposes. First, we aim to document the nature of the Reform model used during the pilot. Second, using several theoretical frameworks, we aim to understand the institutional processes which led to the initiation, adoption, and diffusion of the Reform. This research can contribute to a growing body of literature on how to structure health systems to achieve UHC in low-resource settings.

Methods

We conducted ten semi-structured key informant interviews with PIH staff and consultants involved in the design and implementation of the Reform. The interview guide and research protocol used for these interviews were approved by the Institutional Review Board at Harvard University. We used purposeful sampling with snowballing to identify interviewees based on their experience with some aspect of the Reform, such as its design or implementation. See Figure 12 for a list of the professional titles of participants interviewed. We asked certain questions across all interviewees, including their understanding of the origins of the Reform and the challenges and successes to date. However, we also tailored our questioning to benefit from the unique knowledge that each participant may have had regarding a specific aspect of the Reform (e.g. technical aspects of the VHW model, institutional change within MoH, etc.) We informed participants that interviews were confidential and anonymous but that their statements may be used in research efforts documenting the Reform. With participants' permission, we recorded all interviews. We also conducted an extensive document review of over 30 documents, including but not limited to publicly available documents about Lesotho's health system.

Figure 12 - List of interviewees' professional titles

- Program Director
- Reform Technical Advisor (former)
- Reform Technical Advisor (current)
- Clinical Director
- Community Director
- Maternal & Child Health Manager
- Quality Assurance & Improvement Manager
- Statistician
- Senior Consultant
- Principal Consultant

To analyze our interviews, we used directed content analysis guided by two theoretical frameworks described in the next paragraph. Content analysis was iterative in order to account for new, complementary, or conflicting findings from subsequent interviews. Our review of documents pertaining to the rollout of the Reform, and of the Lesotho health system more broadly, allowed us to complement, triangulate, and verify statements and opinions provided by the interviewees. They also provided a clear historical record of the activities that have taken place to formulate and implement the Reform. These interviews and document review also served as the basis for a forthcoming complementary paper which describes the Reform VHW model in detail.

Theoretical frameworks provide useful guidance for understanding the diffusion of an innovation or policy. For this analysis, we draw on the theories of innovation diffusion in health systems²⁴⁹⁻²⁵¹ and problem-driven iterative adaptation (PDIA),^{252, 253} Health systems innovation theory provides a useful model for describing the different factors contributing to the Reform, such as the nature of the innovation itself and factors which may have contributed to (or impeded) its diffusion. However, this framework does not take into account the timeline or sequence of events, which are important for a historical understanding of the Reform. PDIA describes the process of successfully implementing an intervention in international development as a series of steps designed to increase both the intervention's functionality (the ability of the intervention to technically achieve its desired outcomes) and legitimacy (support and authorization for the intervention by relevant constituencies). PDIA argues that without achieving both functionality and legitimacy, development interventions will fail. The theory argues that to successfully build state capability to perform a specific function, development initiatives should 1) focus on addressing specific problems in local contexts, 2) encourage

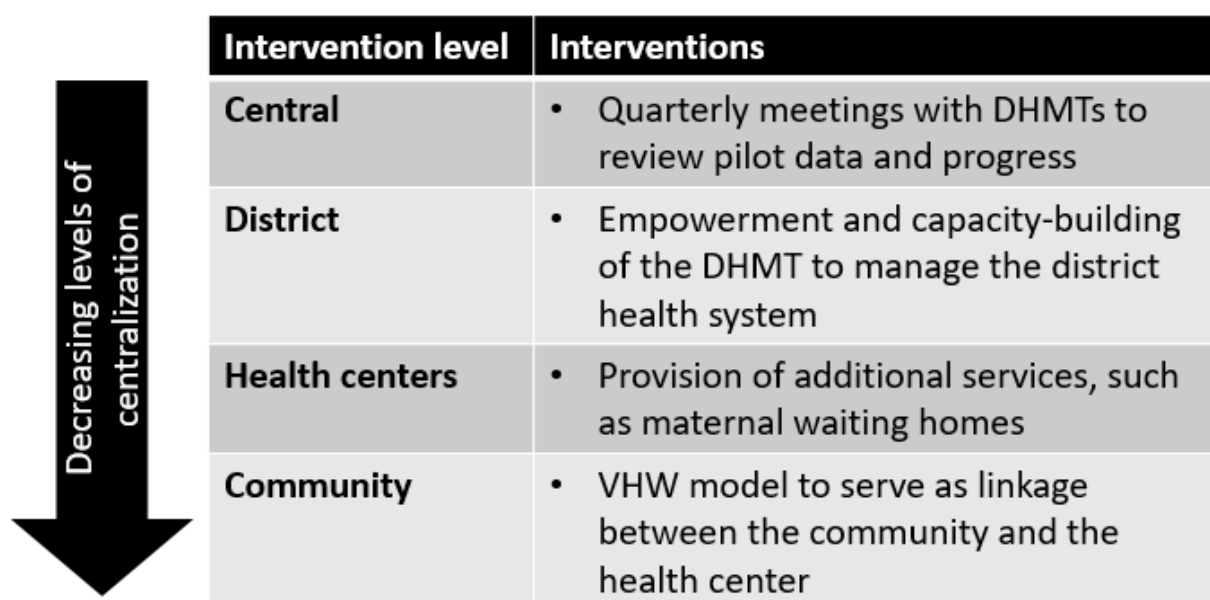
ongoing experimental iterations, 3) establish a clear “authorizing environment” for the work, and 4) engage a broad set of change agents.

Results

Innovation characteristics

The Reform pilot consisted of four distinct but interrelated interventions operating at different levels of the health system. Overall, the Reform sought to increase utilization of facilities by implementing supply-side interventions (which were prioritized based on Lesotho’s disease burden) at the health center level, and by generating demand at the community level using the VHWs and civil society engagement; it sought to improve health systems performance by strengthening and decentralizing management, data for decision-making, and financial management at the district level. See Figure 13 for an overview of the Reform Pilot components.

Figure 13 - Summary of Reform pilot interventions at different levels of the health system

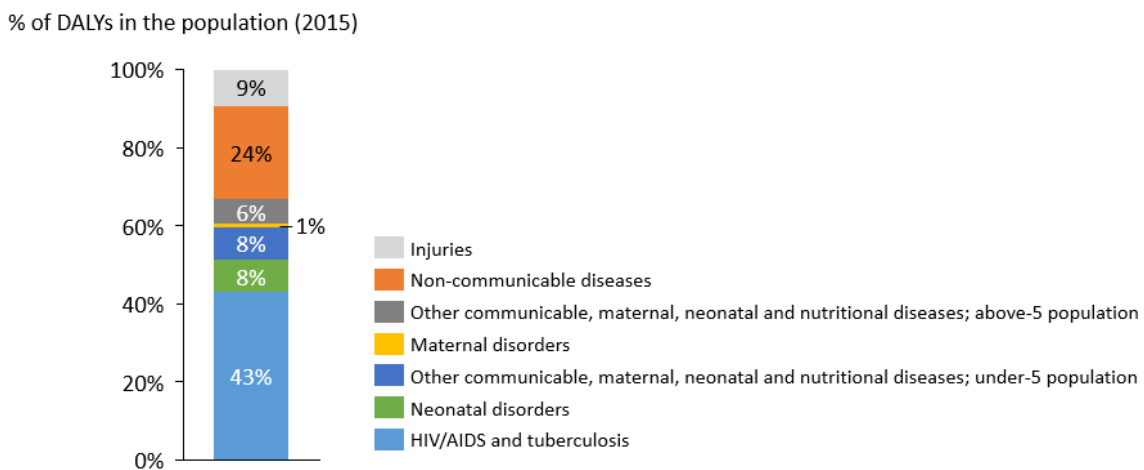


Intervention level	Interventions
Central	<ul style="list-style-type: none"> Quarterly meetings with DHMTs to review pilot data and progress
District	<ul style="list-style-type: none"> Empowerment and capacity-building of the DHMT to manage the district health system
Health centers	<ul style="list-style-type: none"> Provision of additional services, such as maternal waiting homes
Community	<ul style="list-style-type: none"> VHW model to serve as linkage between the community and the health center

At the community level, the pilot introduced a new VHW model consisting of two cadres – one focused on TB/HIV and one focused on maternal and newborn health (with both cadres

also focusing on child and general population health). These two cadres were selected based on Lesotho’s burden of disease, which is dominated by HIV/AIDS, TB, and maternal, newborn, and child health (MNCH). See Figure 14 for a summary of Lesotho’s disease burden. VHWs were trained to physically accompany certain patients to the health facility (e.g. pregnant women for ANC visits, suspected TB cases) and to perform community-based directly observed therapy (DOT) for TB and HIV patients. A VHW coordinator at each health center oversees the VHW program and manages a team of VHW supervisors, who each oversee 7-15 VHWs. The origins and technical aspects of this VHW model are described extensively elsewhere, including the complementary paper mentioned in the Methods section.^{254, 255}

Figure 14 - % of total DALYs in Lesotho's population (2015)¹⁹³



At the health center level, the pilot used a similar analysis of disease burden to align staffing, infrastructure, and supply chain inputs to match the population health needs. This required renovation of maternal waiting homes at all health centers and provision of the supplies needed for 100% of women to deliver at facilities (e.g. delivery kits, food for waiting mothers). Each health center also recruited one or two local community members who owned a car that a nurse could call to provide emergency transport to the nearest hospital for emergency obstetrical

care, and PIH paid these drivers for the service. The pilot also worked in synergy with other efforts to improve service delivery at the clinic level. The Millennium Challenge Corporation (MCC), a US government foreign aid agency, funded the renovation of all public health centers in the country prior to the Reform pilot, donors such as PEPFAR and the Global Fund invested heavily in increasing access to ART and other clinical services, and, more recently, the Government of Lesotho (GoL) launched the Test & Treat campaign for HIV/AIDS.^{14, 256}

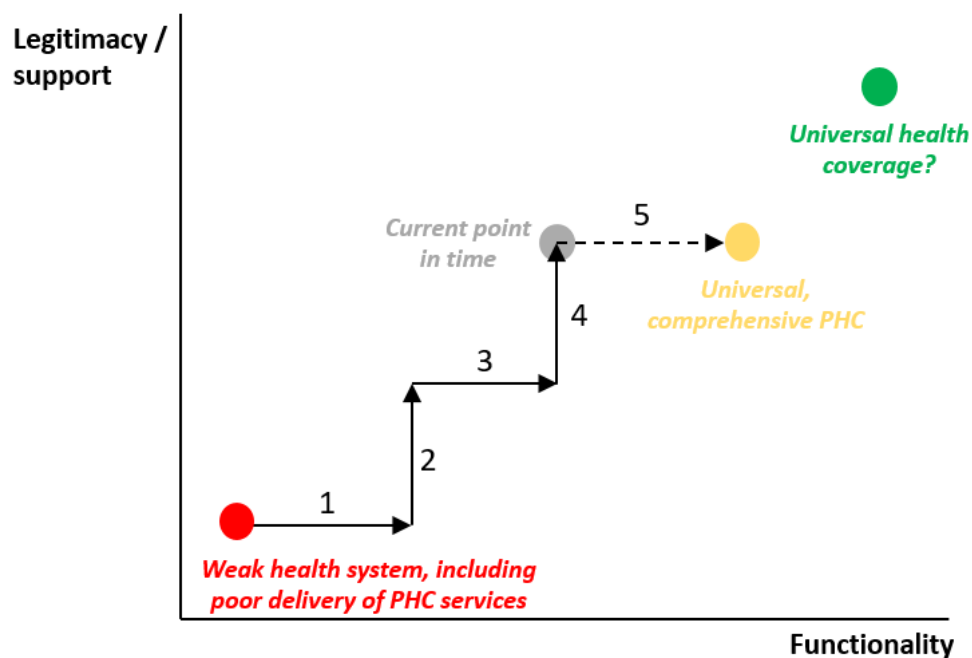
At the district level, the pilot aimed to improve management of the district health services through organizational redesign and capacity-building of the District Health Management Team (DHMT). Prior to the introduction of the pilot, the district hospital and district PHC team (who oversaw clinics and community health) reported separately to Central MoH, meaning that no single individual or team had oversight or management control over the district health system. Given the need for coordination between the community, clinics, and the hospital for providing patient care and managing population health, this fragmented reporting presented challenges for administering an efficient system. The Reform pilot established a single DHMT that consists of both hospital and PHC management teams, as well as support services such as pharmacy, labs, and administrative activities. This model clarified roles, responsibilities, and reporting lines for each of the DHMT members. Under the pilot, PIH also provided capacity-building services to the DHMTs so they could develop and oversee their own district-level work plans, address district-level problems locally whenever possible, improve coordination for use of resources and activities (such as scheduling transport for supportive supervisions to clinics), implement a standardized set of health indicators for monthly review, hold regular meetings to review data, and coordinate implementing partners (e.g. NGOs) so that the partners' plans fit with district-level objectives and activities.

Although most aspects of the pilot focused on the district level or below (more information on this in the next section), the pilot also introduced one intervention at the central level. Each quarter, the District Health Managers from each pilot district would convene for a quarterly meeting with the leadership of central MoH in order to report progress on key indicators, challenges, and successes over the past quarter. These meetings were designed to help increase central MoH visibility into activities at the district level and empower the DHMTs to take ownership of their progress.

Stages of Reform diffusion

Diffusion of the Reform model across Lesotho has taken place over a series of four steps, which, consistent with the theory of PDIA, have contributed both to its functionality and legitimacy. See Figure 15 for a schematic of these steps using the PDIA framework. The approach taken to formulate, adopt, and implement the Reform also used all four approaches noted by PDIA as useful for successfully implementing development initiatives (described in the Methods section). See Figure 16 for a summary of the PDIA approach to development initiatives and how the Reform model used each of these approaches.

Figure 15 - Schematic of steps in the Reform process using the PDIA framework



- 1) Introduction of the PIH delivery model for 7 rural clinics;
- 2) Formal articulation of the delivery model and authorization by MoH for a health sector Reform Pilot;
- 3) MoH-led Pilot of the Reform in four districts;
- 4) Translation of the Reform Pilot into a National Primary Health Care Policy;
- 5) Implementation of the National Reform

Figure 16 - Summary of PDIA approach to development initiatives and approach taken by the Reform

PDIA approach to successfully implementing development initiatives	Reform approach
Address locally identified problems within context	<ul style="list-style-type: none"> • Lesotho’s burden of disease (e.g. HIV/AIDS, TB, and MNCH) directed clinical and operational priorities • PIH began operations by delivering services at a limited number of sites, focused on a specific local context
Encourage ongoing experimental iterations	<ul style="list-style-type: none"> • Original rural sites served as the basis for a broader Reform only after demonstrating success • Ongoing iteration with various elements of the Reform model, including VHW responsibilities and structure of the DHMT
Establish a clear “authorizing environment”	<ul style="list-style-type: none"> • Formal authorization for the Reform by the Ministry of Health at all stages • Gradually expanding scale of the Reform model (from 7 clinics to 4 districts to all 10 districts) only as far as the authorizing environment could or would support at any given time
Engage a broad set of change agents	<ul style="list-style-type: none"> • Engagement of stakeholders such as Prime Minister’s Office, senior leadership and technical directors in Ministry of Health, local leaders and chiefs, VHWs, and patient populations in order to generate support for the Reform at various stages in the process

First, in 2006, at the request of GoL, MoH established a Memorandum of Understanding (MoU) with PIH to run seven rural clinics in the mountainous regions of Lesotho.²⁵⁵ These clinics, which provide care for some of the most hard-to-reach and underserved Basotho, originally aimed to increase access to HIV/AIDS treatment and later expanded into maternal, newborn, and child health services. They incorporated both the community- and clinic-level innovations described in the previous section. By starting with a discrete operation focused on providing services for a clear sub-section of the population, and by choosing clinical and

operational priorities based on the burden of disease, PIH could focus on a very specific problem within its local context.

Second, after five years, a number of activities increased the legitimacy of this model and led to its adoption as the basis for the Reform pilot. Although PIH clinics had a reputation for providing high-quality care, MoH and partners also perceived the PIH program as expensive and therefore unsustainable and unsuitable for scale-up in a low-resource setting. However, two sets of analyses, one as part of the five-year evaluation of the Reform by donor agencies, and one by an independent consulting firm, determined that on a per capita basis, PIH clinics provided services more cost-effectively and with better patient outcomes than MoH clinics. (Costs were partially lower on a per capita basis due to high utilization rates at PIH clinics, which resulted from community mobilization efforts and the population's ability to rely on the clinics for provision of quality services.) Shortly thereafter, in 2013, senior GoL leadership visited these clinics with PIH leadership to observe how the clinics operated; one interviewee noted that the Minister of Health at the time remarked that the PIH clinic "looked like a puzzle" where all the pieces fit together.

These quantitative data and observations led MoH to commission an independent consulting team to determine what lessons from the PIH model could inform a national reform of the district-level health system. Over several months, the team designed the Reform model, which included the key components described above, as well as a reorganization of Central MoH. Although senior MoH leadership supported the Reform proposal, it also initially generated considerable resistance from government counterparts and implementing partners for a number of reasons, including: possible loss of budget and power by central MoH due to decentralized management of the health system to empowered DHMTs; lack of complete

understanding of the Reform model, possibly due to fragmented communication and the large scope of the Reform; and perceptions that PIH was advocating for a “PIH Reform,” rather than a government-led Reform with PIH providing technical support. Given these challenges, MoH leadership and PIH decided to begin the Reform with a pilot in four districts, without making any changes to central MoH initially. In order to strengthen the legitimacy of the Reform at the district and community levels, the pilot commenced with an effort to mobilize Lesotho’s chiefs, who make up a robust structure of traditional leadership throughout the country. This effort helped ensure that politically powerful stakeholders at the grassroots level understood the importance of the Reform and supported it before the pilot undertook major changes to the functioning of the health system.

Third, having gained enough legitimacy for the Reform to pilot in four districts, MoH engaged PIH in a second MoU to serve as the technical advisor for implementing the Reform. This effort involved visiting all 73 health centers in the pilot districts to assess their service delivery, training over 4,000 VHWs across these health centers, performing capacity-building for the DHMT, and providing select supplies and services to clinics, as described earlier. During this pilot period, ongoing quarterly reviews of data with the DHMT and central MoH not only increased the functionality of the Reform by providing a forum to address challenges and share best practices, but also increased its legitimacy by highlighting to senior MoH leaders the progress made by the districts. Similarly, at the district level, chiefs and community councilors (members of the local government) participated in quarterly meetings at the DHMT and health centers both in order to address ongoing problems and to track the progress of the Reform.

Fourth, after two years, GoL decided to scale the Reform to all ten districts. However, the process of achieving legitimacy and political support up for this step faced considerable

challenges. Most notably, GoL experienced significant changes in leadership since the initiation of the Reform, with the Prime Minister and Minister of Health both changing during that time, and other senior positions in MoH changing more than once. However, the early support from chiefs, who are not elected to their positions, increasing support from DHMTs, clinic staff, and populations actually benefitting from the Reform, and the longitudinal nature of the MoH-PIH MoU, all helped maintain momentum for the Reform even as senior political leadership changed, such that PIH had enough of an “authorizing environment” to continue to work on the Reform in the pilot districts. Direct observation of the increased functionality of the health system in the pilot districts also helped to garner support for the Reform by senior technical staff within MoH. Accordingly, in mid-2016, the Office of the Prime Minister requested from PIH follow-on consulting services to develop a policy and implementation plan to scale-up the Reform to all ten administrative districts.²⁵⁷ In addition to legitimizing the Reform at the national level, this policy exercise also allowed GoL to reconsider and iterate on aspects of the Reform, including challenges to the VHW accompaniment model and the structure of the DHMT.

At this point, having achieved legitimacy at the national level through endorsement by senior political and technical leadership, the Reform now aims to achieve fully-scaled functionality across all ten districts.

Ongoing challenges to the Reform

As with any major public sector reform, the National PHC Reform in Lesotho still faces considerable challenges. With regards to its functionality, poor health information systems in both pilot and non-pilot districts make data collection difficult, thereby limiting potential claims of causality about the Reform’s impact on population health. Presentations at quarterly meetings by DHMTs are not always standardized, sometimes making it difficult to compare progress

across districts. MoH and PIH continue to debate and iterate on the most effective approach to deploying VHWs. Given that donors such as the US Government (through PEPFAR) typically only fund vertical programs, and MoH has committed a large share of its budget to the country's tertiary care system, identifying sustainable sources of funding for the Reform also presents a challenge.

With regards to the legitimacy of the Reform, the historical turnover of the country's leadership makes it difficult to ensure continual support for the Reform from "the top." As recently as January 2017, Lesotho was facing rising political tensions which could lead to a shift in the country's political leadership.²⁵⁸ Continuing to transfer management authority from central MoH to DHMTs and increasing the role that local government plays in administering the health system could lead to additional challenges associated with decentralization efforts.

Discussion

The efforts to develop a functional PHC model which also has national legitimacy among GoL leadership, health system staff, implementing partners, and the Basotho population have considerable policy implications for national health reforms, especially those aiming to achieve universal, comprehensive PHC and UHC. We summarize here three preliminary learnings from this experience.

Achieving a functional and legitimate Reform occurs non-linearly and requires constant iteration

Theories of the policy process and policy cycles that distinguish between agenda-setting, policy formulation / adoption, and policy implementation often present these activities in a sequence of orderly steps.²⁵⁹ However, many scholars have critiqued these frameworks as being overly linearized.²⁶⁰ Our research indicates that the activities for reforming PHC in Lesotho

occurred in an iterative, back-and-forth process of continually (re-)setting the agenda, (re-)formulating the nature of the Reform, and (re-)implementing aspects of the Reform model. A confluence of stakeholders, including civil society organizations and donors, participated in this non-linear process, although senior government officials ultimately decide whether or not to formally adopt a policy.²⁵⁹

Berlan et al. identify seven distinct steps involved in the policy formulation process.²⁵⁹ Of these, PIH and the consultancies to whom they outsourced pieces of work participated in six: generation of policy alternatives, deliberation and / or consultation, advocacy of specific policy alternatives, lobbying for specific alternatives, drafting the enactment of policy, and guidance / influence of implementation. (Our research did not identify any PIH activities that involved direct financial negotiations relating to the policy.) However, this process did not involve formulating the policy *ex ante* and then implementing it. Rather, setting the agenda and formulating the policy for the Reform often occurred *through implementation activities*, which then influenced later versions of the Reform through an iterative process. For example, by designing quarterly review meetings to track the DHMT's progress in the pilot districts, PIH and the Reform pilot efforts continually focused attention on PHC reform and kept this topic as an important agenda item for MoH. Similarly, the sequence in which an existing VHW program served as the basis for the Reform pilot, and then as the basis for the national policy, indicates that implementation of certain aspects of the Reform actually occurred before the formulation of the policy. In other words, the policy formulation resulted from past experience with program implementation and iteration on this model, rather than vice versa.

Both quantitative analysis and observational experience can build momentum for policy adoption

No single analysis, assessment, or evaluation in the Reform’s history definitively led to its adoption at a single point in time. Rather, an accumulation of data – both in the form of quantitative analyses and actual experience with the success of the model – led to its gradual enactment and implementation. The decision to explore the possibility of a PHC Reform (pilot) came from both quantitative analyses demonstrating the potential financial and health impacts of strengthening PHC, and direct observation of this model by the most senior political leadership in the country which resulted from a series of ongoing conversations and relationships between MoH, PIH, donors, and other implementing partners. These experiences are consistent with theories of agenda-setting in the political process, such as the “issue-attention cycle.”²² As advocates and policymakers consider how to generate support for their programs or policies, they should consider the importance of convincing other constituents of their potential impact by visibly demonstrating these possibilities, or “showing them the future.”²⁶¹

Grassroots support for reform or other policies can sustain momentum, even under shifting political leadership

WHO, the World Bank, other major global organizations, and researchers have all recognized and articulated the importance of political leadership and commitment to achieving health systems goals, including UHC.²⁶²⁻²⁶⁴ However, as the case of Lesotho shows, turnover in political leadership can make sustaining this momentum difficult. However, in truly representative democracies where political leaders have incentives to support the priorities of their constituents, generating sustained commitment for health reform from those at “the top” may be best achieved by creating demand from those at “the bottom.” Our interviewees noted that, although DHMTs and clinic staff recognized that the Reform had issues, they supported the effort and saw its value. Although populations in pilot districts did not always understand that

improvements in health service delivery resulted from a distinct set of initiatives bundled under a specific reform, they did take note of these changes. As mentioned earlier, the traditional leadership of the country also supported the Reform due to an extensive awareness-building campaign during the early stages of the pilot. Therefore, our interviewees argued that failing to continue with Reform efforts, or, worse, allowing the health system to regress, could lead to a significant negative response toward elected government officials. These experiences suggest that policymakers, practitioners, and advocates looking to strengthen health systems can gain legitimacy and authorization for their efforts by empowering beneficiaries of the Reform who can hold political leadership accountable for policy adoption and implementation.

Limitations of this research

This research has several key limitations. First, limiting our interviews to PIH staff and associated consultants has the potential to introduce bias into the analysis, possibly overstating the benefits of the Reform or PIH's role in it. By focusing on the history at the country level, this research also cannot incorporate the way that broader global trends, such as changes in development financing or global advocacy for health, affected Lesotho's health system. On the other hand, however, PIH staff provide the most longitudinal perspective on the Reform because many have participated in these efforts since they began. Further, our document review aimed to triangulate claims made by interviewees in order to document the historical process as accurately as possible.

In addition, as an institutional history of the Reform, this research does not provide any evidence of its effectiveness at improving health systems or population health. Our analysis does not document quantitative changes in the performance of Lesotho's health system or the associated costs of undertaking this Reform. Rather, we aim to provide a historical perspective

in order to describe the key components of the Reform and generate lessons for policymakers and practitioners working on similar topics.

Finally, this analysis is necessarily limited by the frameworks chosen to understand the institutional processes involved in the Reform. Other theories and frameworks may lead to complementary or even conflicting conclusions. We would welcome researchers and practitioners building on these limitations with future work, as discussed in the next section.

Areas for future research

An impact evaluation of the Reform and its different components would provide evidence for the success, or lack thereof, of the Reform. Such an evaluation could strengthen any claims about the Reform's functionality, identify key barriers and enablers of success, and lead to productive iteration on the model going forward.

In addition, this research would benefit from additional perspectives on the history and nature of the Reform in Lesotho. Different stakeholders likely have different perspectives on this history of the Reform, which could complement, triangulate, or even contradict the results presented here. Analyzing the Reform through additional theoretical frameworks could also lead to new insights about the policy process and its implications for other countries.

Finally, at a more abstract level, the experience in Lesotho highlights the importance and potential of using a PHC-based approach to achieve equity and access to health services, key aspects of UHC. Further theoretical and empirical work identifying the strengths and limitations of using universal, comprehensive PHC as a foundation for UHC could help countries understand how best to achieve the targets listed in SDG 3.

Conclusion

Successful diffusion of an innovation throughout a health system requires that the innovation achieves both functionality to achieve its goals and legitimacy among the constituents who have to authorize, implement, and utilize the innovation. This research documented the key components of and iterative steps taken to achieve an innovation for strengthening Lesotho's health system: the National PHC Reform. This Reform included interventions at all levels of the system, and benefitted from an iterative approach which sought to increase its functionality and legitimacy at multiple steps in the policy process. Experience with this Reform further suggests that generating political support for policies can come from multiple sources of "data" – including direct observation by political leaders of the problem and solutions – and can result from broad support for the effort by its beneficiaries.

Conclusion

This doctoral project and doctoral thesis focused on HSS activities relevant for health systems reform in low-resource settings, and on the process of formulating a policy and approach to bringing Lesotho's National Primary Health Care Reform to all ten of the country's administrative districts. It built on extensive work by the Government of Lesotho, the Ministry of Health, Partners in Health, and other donors and implementing partners working in Lesotho. The conclusion contains a summary of the problem statement and theory of change, the key findings from each of the five main analytical chapters of the doctoral thesis, the main analytical takeaways relevant for different stakeholders, and areas for further programmatic work and research.

Summary of the problem statement and theory of change

This doctoral thesis began with the following problem statement: *Lesotho has poor population health outcomes, especially for high-burden diseases, such as HIV/AIDS, tuberculosis, and maternal, newborn, and child health (MNCH)*. This problem statement draws on several theoretical approaches within public health, including theories of health systems which define population health as a primary goal of health systems, and methodological approaches to measuring burden of disease, such as approaches to measuring national and global burden of disease. Briefly, several pieces of data which provide evidence for this problem statement include:

- The total burden of disease per capita in Lesotho has increased by 58% between 1990 and 2015¹⁹³
- The burden of disease per capita for HIV/AIDS has increased by approximately 700% for the entire population and the under-5 population¹⁹³

- Lesotho has the second-highest incidence of HIV and the highest incidence of tuberculosis globally⁸
- Maternal, newborn, and under-5 mortality all remain very high⁹
- High levels of inequity in access to health services exist: Among rural populations (who represent 70% of the population), greater than 30% report that it takes over two hours to reach the nearest health facility by means of usual transportation, and nearly 40% report that it takes over two hours to reach the nearest health facility by walking⁹
- The burden of disease for non-communicable diseases such as diabetes and cardiovascular disease have increased substantially between 1990 and 2015¹⁹³

Further, the country context described in the DEPLESET analysis emphasizes challenges related to governance, service delivery, and inequities in Lesotho. Lesotho has experienced political instability since the coup in 2014, with frequent turnover in political leadership and appointees. The population lacks access to basic infrastructure such as electricity, water, and sanitation, especially in rural regions. The country faces high levels of inequity, as indicated by its extremely high GINI coefficient. These factors highlight both the challenges and importance of taking an equity-based approach to improving population health services through a PHC-based approach.

This doctoral project and doctoral thesis did not design Lesotho's National PHC Reform. Indeed, one of the strengths of the Reform is that the government (and implementing partners) did not try to bring a *de novo* intervention to scale, but rather continually iterated with the Reform model to improve its functionality and legitimacy. Rather, this doctoral project focused on a specific activity in the evolution of the Reform, namely developing an approach to scale the Reform from its pilot phase in four administrative districts to adoption in all 10 districts.

The Reform, and by extension this doctoral project, aimed to address the problem statement by addressing both supply- and demand-side aspects of access to population health services. The theory of change for the Reform focused on implementing an interrelated set of interventions at all levels of the health system. In particular, the Reform pilot implemented:

- **A strengthened Village Health Worker program** at the community level which served as a linkage between the health center and the community. VHW competencies include creating demand for health services, identifying patients needing diagnosis or treatment, accompanying patients to the health center and track them, and providing limited community-based care.
- **Improved services and management at the health center level**, including the renovation of maternal waiting homes, the provision of select commodities, and the implementation of systems for providing emergency referrals for deliveries and oversight for the VHW program.
- **Empowered and capacitated District Health Management Team (DHMT)**, who, among other things, oversees all aspects of the district health system (including the community, health clinics and district hospitals), manages this system using a decentralized approach, coordinates implementing partners, and conducts supportive supervisions to all health centers on a regular basis.
- **Quarterly DHMT reviews** which allowed Central MoH to continually monitor the Reform and DHMTs to report their progress on key indicators, challenges, and successes from the previous quarter

In addition to these four key interventions involved in the Reform pilot, the national scale-up of the Reform will also include:

- **Further empowerment of government leaders**, especially non-technical political leadership, to oversee the Reform, monitor its progress, and hold technical stakeholders accountable for the performance of the health system
- **Devolution of district health systems management to the DHMT**, which builds on efforts to decentralize the health system already undertaken during the pilot and which is consistent with the National Decentralization Policy¹⁸⁹
- **Clear targets for health systems performance**, particularly for inputs, outcomes, and outcomes, in order to develop clear service assurance standards for the health system and to provide leaders with clear metrics by which they can oversee the health system and hold implementers accountable for health system performance

These interventions work in harmony to build state capability to oversee the health system and ultimately improve population health. Further, while only one intervention (the VHW model) works directly on generating demand for health services, the approach to improving supply at the health facility level by improving service assurance and building trust in the clinics' ability to deliver quality care can indirectly improve demand over time as well.

Key findings from the doctoral project

This section summarizes the key findings from each of the five main analytical chapters of the doctoral thesis, and highlights some of the intersections from key takeaways across various chapters.

Aligning Values and Outcomes in Priority-Setting for Health

When setting priorities and allocating resources for public health and health systems, a multiplicity of factors come into play. This chapter presents a framework for describing and understanding the ways that values can influence policymakers' and advocates' priorities for the

health system. It then describes how these priorities may in turn affect not only population health outcomes, but also economic and political outcomes for a country, which are of course very relevant for policymakers and elected officials. Although the framework presents a linear approach to understanding the role that values play in setting priorities that does not necessarily reflect a chronological sequence of events in the policymaking process, it nevertheless can help policymakers clearly articulate their values, priorities, and intended outcomes, such as the equity-based approach taken in the National PHC Reform.

Does task shifting yield cost savings and improve efficiency for health systems? A systematic review of evidence from Low- and Middle-Income Countries

While much research has shown the effectiveness of task shifting as an approach to improve population health, there is limited research to date on its impact on health financing or systems efficiency. One literature review has demonstrated that using community health workers (CHWs) for select diseases can be cost-effective. This review builds on that research to look at the cost implications of all forms of task shifting. This research uses cost implications, rather than cost-effectiveness thresholds, to analyze the impacts of task shifting on systems efficiency in order to make the research directly relevant for policymakers considering different approaches to health systems strengthening. This review finds substantial evidence for achieving cost savings when using task shifting to address HIV/AIDS and TB, particularly through CHWs and laypeople for performing directly observed therapy (DOT), and pharmacy assistants for refilling ARVs for clinically stable HIV-positive patients. There is also a substantial number of publications that provide evidence for cost savings from task shifting across a number of other diseases, including malaria, neglected tropical diseases, and childhood illnesses.

Given Lesotho's limited financial resources available for PHC, using VHWs as an approach to link patients to health centers may present a cost-effective approach to improving population health. Although implementing a national VHW program would likely represent an increase in costs to the health system given currently low levels of access to health care providers, using VHWs could help achieve universal access to care for lower costs than an approach without this cadre of human resources. Notably, the evidence from this research is strongest for TB and HIV/AIDS, two of the top health priorities in Lesotho, and at the PHC and community levels, the focus of the National PHC Reform.

Do changes to supply chains and procurement processes yield cost savings and improve availability of pharmaceuticals, vaccines, or health products? A systematic review of evidence from low- and middle-income countries

Although the procurement and provision of pharmaceuticals is a critical component of a functioning health system, little research has attempted to systematically document evidence for the role of supply chain improvement efforts for HSS. This research found evidence for three comprehensive drug system policies in Brazil, China, and Delhi, India, all of which led to cost savings and improvements in drug delivery. In other settings, centralized procurement and tendering had the effect of directly saving costs by lowering purchase prices of drugs, and supply chain management efforts had the effect of reducing stock outs, thereby potentially leading to indirect savings for the health system through efficiency improvements. This review and the wide variety of approaches to improving provision of drugs demonstrates that HSS can occur at multiple levels within the health system.

With the exception of the staffing of additional pharmacy technicians in select health center, Lesotho's National PHC Reform did not specifically focus on efforts to improve supply

chains and provision of drugs. Nonetheless, provision of drugs is an important activity and challenge for Lesotho's health system.

Village Health Worker Activities along the Care Delivery Value Chain: The Case of Lesotho

This chapter documents the technical components of one key aspect of the National PHC Reform: the VHW model. Although much programmatic work has focused on the roles that VHWs play in health systems, little published research has looked at their roles across different disease areas. This chapter maps VHWs' competency-based activities across key disease areas using the Care Delivery Value Chain (CDVC), a framework which describes the sequence of steps needed to prevent, diagnose, treat, and manage diseases. This research finds that VHWs in Lesotho have four distinct competency-based activities which cut across multiple disease areas: 1) community-based demand creation and health facility support, 2) community-based patient identification and diagnosis, 3) patient accompaniment and tracking, and 4) community-based care delivery and support. They perform these activities for multiple disease areas, including HIV/AIDS, TB, and MNCH, and these activities allow them to fulfill their role as extensions of the health clinic into the community. Focusing on the competency-based activities that VHWs perform, rather than disease-specific tasks, highlights potential synergies for integrating their roles into a broader PHC-based approach to care delivery. It may also facilitate easier re-training of VHWs to meet changing public health needs, such as in the event of an acute outbreak of an infectious disease, or with the rise of non-communicable diseases in the population.

Building State Capability to Strengthen Health Systems: The National Primary Health Care Reform in Lesotho

Using the theories of health systems innovation diffusion and problem-driven iterative adaptation (PDIA), this chapter describes the main technical components of the Reform and the stages of its implementation to date. The Reform has three main components at the community, health center, and district levels which have already been discussed. Consistent with the theory of PDIA, implementation of the Reform took place in four stages which served to incrementally build both its functionality and legitimacy: 1) operation of seven rural clinics by PIH, 2) formalization of the Reform model, 3) pilot of the Reform modal in 4 districts, and 4) development of a National PHC Reform which would serve as the basis for scale-up to all 10 districts. Formulating and implementing the Reform had a number of approaches which contributed to its achieving both functionality and legitimacy, such as the focus on local problems in context, stages of experimental iteration, respect for an authorizing environment to guide the work, and engagement of broad set of change agents.

Main analytical takeaways

As discussed in the Introduction to this thesis, the programmatic work and research involved in the National PHC Reform has relevance for several different stakeholder groups working in public health. This section integrates analytical takeaways relevant for improving public health in a post-2015 agenda especially in low-resource settings and building state capability to strengthen health systems.

Structuring VHWs' work within the context of broader health systems strengthening activities, and linking demand generation to improved service delivery at health centers, can serve as an approach to increase utilization of services

The VHW model in the Reform contrasts with other VHW models, such as those used in iCCM, because these VHWs deliver very limited clinical care. Rather, they serve as extensions

of the health clinic into the community, where their activities link patients to health center services across the continuum of care. Therefore, they are an essential component of the health center operations, and strong service delivery and service assurance at the health center fully complement their work. Further, facility-based management of the VHWs further ensures strong linkage between VHW activities and care provided by the facilities.

Comprehensive, universal PHC can serve as the foundation for a UHC delivery strategy

Although WHO and other organizations have put out clear guidance on financing UHC, the service delivery aspects of UHC are still not fully defined. The National PHC Reform takes an approach to achieving UHC by creating a strong foundation in community- and PHC-based services, which can then link to secondary and tertiary care through a clear referral system. The Reform specifically focused priorities for community and clinic care on the disease areas which form the majority of Lesotho's burden of disease, all of which can be addressed through a PHC approach: HIV/AIDS, TB, and MNCH. This strong PHC-based health systems foundation can also expand into other clinical priorities, such as control of a specific outbreak or management of non-communicable diseases, as the country's epidemiological profile changes.

Building state capability to promote population health requires multiple, interrelated interventions that operate at multiple levels

As with the linkages between the community and the health center via the VHW program, other aspects of Lesotho's PHC Reform work together, rather than in silos, in order to strengthen the health system. The Reform involved capacity-building of VHWs, clinic staff, the DHMT, and central MOH (to oversee the Reform). Data collection at all levels contributed to monitoring of the Reform during quarterly reviews, and DHMT supervision of health centers aimed to ensure quality service delivery at the clinics. In other words, the Reform model's

approach to health system strengthening aimed to go beyond merely strengthening one level of the system or one delivery of one clinical priority; instead, it aimed to build the capability of the state overall to manage and deliver the public health and clinical services.

Areas for further programmatic work and research

This section integrates relevant areas for further programmatic work and research which could build on the findings, experiences, and questions raised in this doctoral thesis.

Impact evaluation of the Reform and its multiple interventions

As with any major public health or development intervention, formally evaluating the impacts of the Reform can establish claims of causality for the Reform's impact on population health, identify key success factors and challenges to implementation of the Reform, and allow for programmatic improvements to the Reform going forward. Given the sequenced rollout of the Reform, it would likely be possible to conduct a difference-in-differences analysis of population health outputs, outcomes, and impacts across districts. In addition, more specific evaluation efforts could look at specific parts of the Reform, such as evaluating the competencies of VHWs and improvements to management of the district health system by the DHMT.

Documentation of other countries' experience with health reform in a post-2015 agenda

SDG 3 includes a much broader health-related agenda than the MDGs did. While the main diseases covered in the MDGs are also part of SDG 3, it also includes targets for noncommunicable diseases, substance abuse, injuries, reproductive health, environmental health, as well as various HSS activities (e.g. access to medicines, human resources for health, and the implementation of International Health Regulations). Given this breadth and the focus on HSS, it will likely be very difficult for countries to achieve progress on SDG 3 only with targeted, disease-specific interventions. However, targeted interventions can be integrated into health

systems along a number of dimensions - including stewardship / governance, financing, planning, service delivery, monitoring and evaluation, and demand generation – and most interventions are neither fully integrated nor fully “stand-alone.”²⁶⁵

The shift from a focus on few specific, high-burden diseases to multiple disease areas, risk factors, and HSS will likely create both challenges and opportunities for countries looking to improve population health. This thesis documented early experiences with Lesotho’s approach to achieving UHC. Continuing to learn from Lesotho and other early experiences with national (or sub-national and regional) approaches to this broader public health agenda will help determine whether it is actually achieving the outcomes it targets. Indeed, practitioners and researchers should consider, *inter alia*, whether countries are actually taking up this agenda, whether they are converting targeted interventions into more integrated approaches, whether these approaches have long-term sustainability, and the implications for organization of the health system along multiple dimensions, such as financing, service delivery, and governance. It will also be important for policymakers, practitioners, and researchers to understand whether and how approaches to building state capability can lead to improved management of the health system.

Formal definition of a service delivery approach to UHC

World Health Report 2010 provided a formal definition and guidance to countries on the various ways to achieve adequate financing for UHC.¹⁸ However, no comparable definition of best practices for organizing service delivery to achieve UHC exists, although much research and practice has addressed questions of service delivery as they relate to access, equity, efficiency, and health systems impacts. As of the completion of this thesis, SDG 3.8 – achieving UHC – did not have a formal set of indicators to track UHC.¹⁹

This thesis aimed to articulate one approach for working toward UHC in Lesotho – namely, using a strong primary health care system as the foundation for achieving universal access to a key set of services. This approach, defined through the model of the National PHC Reform, has several distinct advantages, including the ability to integrate community-based interventions with services at the clinic (through the VHW program), a focus on highest-burden diseases, and comprehensive management and governance of the system at multiple levels and by multiple actors. While a formal evaluation of the Reform and its impacts on population health can provide evidence of its effectiveness (or lack thereof), further theoretical and empirical work from multiple countries can further add to the evidence base surrounding PHC as an approach to achieving UHC. Formally defining this approach and associated best practices could provide guidance to countries, especially in low-resource settings, hoping to achieve UHC as part of the SDG agenda.

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