

THE MEASUREMENT OF PNEUMONIA INCIDENCE AND MORTALITY IN MALAWI IN
CHILDREN UNDER FIVE

By
Karen Elizabeth Finnegan, MPH

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Abstract

Background

Globally, pneumonia is a leading cause of death in children under-five. Although pneumonia is responsible for nearly a million under-five deaths worldwide each year, there is limited information on community-level pneumonia incidence. To guide data-informed policies and resource allocation, policymakers require nationally representative, regularly available, sub-national estimates of disease incidence and mortality. We explore the use of available health sector data, including routine data captured in Malawi's Health Information System (HIS) and survey data, to construct sub-national estimates of pneumonia incidence and mortality. As an initial step in this process, we explore the quality of routine HIS diagnosis data.

Methods

Our methods vary by research questions. In Chapter 2, we estimate district-level pneumonia mortality in children 1-59 months using the Lives Saved Tool (LiST). We estimate district-level coverage of preventive and curative health sector interventions to determine how change in intervention coverage has impacted pneumonia mortality over time and across districts. In Chapter 3, we use a mixed methods study to explore the quality and use of routine HIS data. Guided by the World Health Organization data quality metrics, we describe the quality of routine acute respiratory infection (ARI) data collected through the HIS. We use qualitative methods to understand how the data collection process contributes to quality and use of the ARI data. In Chapter 4, we use Bayesian estimation methods to estimate district-level pneumonia incidence. Bayesian estimation techniques allow us to use available health sector information—the ARI data that we explored in Chapter 3, the intervention coverage data that we used in Chapter 2, and census data on under-five population—to estimate community-level pneumonia incidence, an unknown quantity.

Results

Pneumonia mortality has declined from 2000 to 2014 across all districts in Malawi. The decline is attributed to preventive interventions (*Haemophilus influenzae* type B and pneumococcal vaccines), treatment of pneumonia with antibiotics, and reductions in stunting and wasting. Pneumonia mortality is <4 per 1,000 children under-five in all districts in Malawi in 2014. We estimate community-level under-five pneumonia incidence to be 66.5 per 1,000 (SD: 23.2 per 1,000) across Malawi's 28 districts in June 2015. Pneumonia incidence increases slightly over time and demonstrates seasonal variation. Routine data on ARI diagnosis in children under five, used to estimate pneumonia incidence, is available, complete, and consistent over time. However, data in the HIS are an overestimate of number of cases recorded in the register as verified by our study team (mean difference in number of cases: 94.0).

Conclusion

We demonstrate that Malawi's available health information includes information that can be used to create sub-national estimates of incidence and mortality. District-level variation and trends over time can be used for the directed allocation of resources and to identify and respond to areas of above-average disease burden.

Committee of thesis readers

Committee members:

Melissa A. Marx, PhD (Advisor)

Assistant Professor
Department of International Health

Shannon Frattaroli, PhD

Associate Professor
Department of Health Policy and Management

Maria Merritt, PhD

Associate Professor and Associate Chair for Student Matters
Department of International Health

Scott Zeger, PhD (Chair)

Professor
Department of Biostatistics

Alternate committee members:

Abdullah H. Baqui, MBBS, DrPH, MPH

Professor
Department of International Health

Judith K. Bass, PhD

Associate Professor
Department of Mental Health

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Abbreviations

ARI	Acute respiratory infection
ART	Antiretroviral therapy
CLHP	Child Lung Health Program
CMED	Central Monitoring and Evaluation Division
DHIS-2	District Health Information Software, version 2
DQA	Data quality assessment
ETAT	Emergency triage assessment and treatment
GNI	Gross national income
HIS	Health information system
HIV	Human immunodeficiency virus
Hib.	<i>Haemophilus influenzae</i> type B
HSA	Health surveillance assistant
IIP	Institute for International Programs
IMCI	Integrated management of childhood illness
LMIC	Low and middle income country
LRI	Lower respiratory infection
MDHS	Malawi Demographic and Health Survey
MICS	Multiple Indicator Cluster Survey
MOH	Ministry of Health
NEP	National Evaluation Platform
NSO	National Statistical Office
OPD	Outpatient department
PCV-13	Pneumococcal conjugate vaccine
UNDP	United National Development Programme
UNICEF	United Nations Children's Fund
URI	Upper respiratory infection
WHO	World Health Organization

Chapter 1. Introduction

Health information is one of the fundamental building blocks of a health system. The World Health Organization (WHO) asserts, “A well-functioning health information system is one that ensures the production, analysis, dissemination and use of reliable and timely information on health determinants, health systems performance and health status” (World Health Organization, 2007). It is imperative that we understand the quality, limitations, and uses of available data for epidemiologic research and evaluation.

In 2015, Handley et al deemed called for the creation of stronger, more robust, and transparent data collection systems to be available as an essential component of monitoring and evaluating the Sustainable Development Goals (Handley, Boerma, Victora, & Evans, 2015). In fact, they called for the continued examination and use of existing data sources, including routine data collected as part of a country’s health information system (HIS) and survey data. Data stored in health information systems (HIS) represent an available, nationally representative source of information on health sector utilization and activities with information that can be examined at many levels of the health system. Although there have been concerns about using HIS data for research and evaluation (Gloyd, Wagenaar, Woelk, & Kalibala, 2016), interest in using these routinely collected data grows as resources become increasingly constrained.

HIS capture data on services delivered at health facilities and by community-based health care workers, including diagnosis and treatment of pneumonia among children under five. As the leading cause of under-five mortality in Africa, pneumonia presents a substantial disease burden in low- and middle-income countries (LMICs). Global attention is given to the prevention, diagnosis, and treatment of pneumonia (Rudan et al., 2015; WHO, 2013; WHO & UNICEF, 2008; Zar & Ferkol, 2014). Given the limited availability of data sources—most data on pneumonia incidence and mortality comes from small sub-national studies which may not be

representative of the country or region—we must turn to the HIS. In a call to action, Campbell and Nair, stated,

At a time when child pneumonia mortality has fallen substantially in almost all low-income and middle income countries, any remaining national inequities, such as disadvantaged communities in which progress has lagged behind, must be identified. Much of our understanding of childhood pneumonia in these countries comes from a relatively limited number of hospitals and research centres... Routine data collection has to be scaled up to better understand child pneumonia in these settings. (Campbell & Nair, 2016)

HIS and survey data form the backbone of the health information system. We explore their application in the field of pneumonia throughout this dissertation.

Rationale

Globally, pneumonia is a leading cause of death among children under five (Liu et al., 2016; Walker et al., 2013). In Malawi, as in other low and middle income countries, the introduction of pneumococcal conjugate vaccine (PCV-13) and *Haemophilus influenzae* type B (Hib) vaccine, in addition to increased treatment with antibiotics, have led to decreased rates of under-five pneumonia mortality (McCollum et al., 2017; Theodoratou, Johnson, et al., 2010; Wahl et al., 2018). However, national trends may not be consistent across all districts. This research attempts to quantify district-level variability in disease incidence and mortality using available data sources. In addition to assessing sub-national disease burden, we explicitly explore the use of routine health information, collected through the DHIS-2, to quantify disease incidence.

This work is part of the National Evaluation Platform (NEP), a project funded by Global Affairs Canada, and by Johns Hopkins University's Institute for International Programs (IIP). This research was completed in collaboration with the Government of Malawi's Central Monitoring and Evaluation Division (CMED), Acute Respiratory Infection (ARI) unit, and

National Statistical Office (NSO). The work is intended to provide guidance on implementation and use of national health information data to the Ministry of Health (MOH) and National Statistical Office (NSO) of Malawi.

Background

Global burden of disease

Globally, pneumonia represents a leading cause of death among children under five. In 2015, it was estimated that pneumonia was responsible for 920,000 under-five deaths worldwide, second only to pre-term birth complications as the leading cause of death, and the leading cause of death among children in Africa (Liu et al., 2016). Pneumonia has persisted as a leading cause of death among children under five in LMICS (Bhutta et al., 2013; Niederman & Krilov, 2013). It is estimated that 81% of pneumonia deaths occur among children under two years of age (Walker et al., 2013) and most deaths from pneumonia occur before twelve months (Billings, Deloria-Knoll, & O'Brien, 2016; Walker et al., 2013).

In 2010, it was estimated that pneumonia incidence among children under five was 0.28 episodes per child-year (Theodoratou, Johnson, et al., 2010). This is a decrease from 1990, when researchers estimated that ARI incidence in developing countries ranged from 12.7 to 16.8 new episodes per 100-child weeks and that lower respiratory infection (LRI) incidence ranged from 0.4 to 8.1 new cases per 100 child-weeks (Selwyn, 1990).

Pneumonia mortality is associated with malnutrition and both HIV infection and HIV exposure (Iroh Tam et al., 2018; von Mollendorf et al., 2015). Additionally, pneumonia incidence is associated with poverty, poor sanitation, unclean drinking water (Bhutta et al., 2013; Sonogo, Pellegrin, Becker, & Lazzerini, 2015), and malnutrition, including low rates of breastfeeding (Rudan et al., 2013; World Health Organization, 2015). Air pollution from indoor cooking and exposure to secondhand smoke are also associated with an increased risk of mortality from pneumonia (Sonogo et al., 2015; World Health Organization, 2015).

Pneumonia can be caused by bacteria, viruses, or fungi. The most common bacterial cause of pneumonia is *Streptococcus pneumoniae* (Feikin, Hammitt, Murdoch, Brien, & Scott, 2018; Webster et al., 2011). In 2000, *S. pneumoniae* was responsible for an estimated 3.81 million cases of pneumonia in the African WHO region (O'Brien et al., 2009). The most common viral agent is Respiratory Syncytial Virus (RSV) (Lanata, 2004; Sonogo et al., 2015). *Haemophilus influenzae* type B (Hib) was responsible for an estimated 16% of pneumonia-related deaths in 2000 (Rudan et al., 2015; Watt et al., 2009).

Pneumonia is an air-borne disease spread through droplets when an infected individual coughs or sneezes. Pneumonia can also be spread through blood; neonates are susceptible to blood-borne infection during and immediately after birth (World Health Organization, 2015). Children infected with pneumonia remain at risk for long term sequelae, including restrictive lung disease, obstructive lung disease, bronchiectasis, chronic bronchitis, asthma, and other respiratory disease or abnormal pulmonary function (Edmond et al., 2012).

Diagnosis of pneumonia

In most low and middle income countries, including Malawi, diagnosis of pneumonia is made based on signs and symptoms at presentation and caregiver report. Diagnosis is based on IMCI guidelines, which were first developed in 1999 and intended to be used in countries with under-five mortality rates higher than 40 per 1,000 live births (World Health Organization, 2017b). The IMCI guidelines support the diagnosis, classification, and treatment of common childhood illnesses, especially in settings where children may present with multiple co-morbidities, and where diagnostic capacity may be limited (World Health Organization, 2017b). Diagnostic guidelines and disease classification for pneumonia are summarized in Table 1. IMCI guidelines were intended to have a high level of sensitivity of diagnosis, reducing the number of missed cases and to encourage antibiotic treatment of possible bacterial infection (World Health Organization, 1991, 2014).

Even in high resource settings, differential diagnosis of pneumonia can be challenging. Confirmed clinical diagnosis of pneumonia requires laboratory confirmation (Rudan et al., 2013; Satzke et al., 2013). Radiology is most commonly used to diagnose pneumonia in adults, but pneumonia in children is not always detectable by x-ray and x-ray services are often limited in LMICs (Scott et al., 2012). WHO continues to work to establish guidelines for diagnosis of pneumonia using chest radiographs for clinical diagnosis and for use in determining study outcomes (Mahomed et al., 2017). Without advanced diagnostic capacity, pneumonia and other respiratory infections—bronchitis, bronchiolitis, reactive airways disease—may often all be diagnosed as pneumonia (Lanata, 2004). Additionally, pneumonia symptoms and those of other common childhood illnesses—including upper respiratory infection, anemia, malaria, and sepsis—are similar, which can lead to misdiagnosis (Feikin et al., 2018; Scott et al., 2012).

Prevention and treatment

The pneumococcal conjugate vaccine and Hib vaccine serve as key components the in prevention of pneumonia (Bliss et al., 2008; O'Brien et al., 2007; Saokaew, Rayanakorn, Wu, & Chaiyakunapruk, 2016; Theodoratou, Johnson, et al., 2010). It is estimated the introduction of these two vaccines decreased pneumococcal deaths by 51% from 2000 to 2015 (Wahl et al., 2018). Developed in 2000, the most common pneumococcal vaccine, PCV-7, protects against seven of the most common serotypes found in North American pneumonia cases (Flasche, Le Polain de Waroux, O'Brien, & Edmunds, 2015; Webster et al., 2011). In 2009, PCV-10 and PCV-13 were introduced to provide coverage against additional serotypes and are estimated to provide coverage against 70% of serotypes in all regions of the world (Johnson et al., 2010; Webster et al., 2011). Hib vaccine has been shown to reduce radiologically-confirmed pneumonia incidence by 18%, with decreases also seen in severe pneumonia (6%) and pneumonia-specific mortality (7%) (Bhutta et al., 2013). Additionally, measles vaccination reduces measles incidence and with it, the development of secondary infections, including pneumonia (Bhutta et al., 2013).

In most LMICs, treatment of pneumonia is in accordance with IMCI guidelines (World Health Organization and United Nations Children’s Fund, 2012). The IMCI guidelines, updated in 2010 and 2012, advise home care and counseling for the caregiver if a child is diagnosed with a cold; oral amoxicillin for the child and counseling for the caregiver if the child is diagnosed with pneumonia on the basis of fast breathing and/or chest indrawing, and; first dose of an antibiotic and referral to a secondary or tertiary facility for children with severe or very severe pneumonia and any of the danger signs (unable to drink, vomiting, convulsions, lethargic or unconscious, stridor, severe malnutrition) (World Health Organization, 2014).

Implementation of the IMCI guidelines has been shown to statistically significantly increase antibiotic treatment of pneumonia, decreasing ARI mortality and all-cause mortality (Lassi et al., 2014; Sazawal & Black, 2003; Theodoratou, Al-jilaihawi, et al., 2010) The program has demonstrated a 42% reduction in pneumonia-specific mortality among those aged 0-1 months and a 49% reduction in ages 1-4 years (Das, Lassi, Salam, & Bhutta, 2013).

Oxygen therapy is recommended for children presenting with hypoxemic pneumonia at facilities (P. Enarson, La Vincente, Gie, Magangad, & Chokanie, 2008). Introduction of oxygen systems may reduce pneumonia-specific mortality, although the impact of oxygen therapy is dependent on appropriate patient identification, correct administration, and ongoing monitoring of the therapy (Catto et al., 2011; Subhi et al., 2009). Oxygen therapy can reduce pneumonia mortality by 20% (Catto et al., 2011).

Quality and use of routine data

Given the disease burden presented by pneumonia in children under five, quantifying the disease and its variability is of vital importance. Sub-national estimates may be most useful for identifying areas of above-average incidence and mortality. We now turn our discussion to a review of routine data with an emphasis on quality and use.

Routine health sector data, collected through the HIS as part of the provision of care, represent a readily available, ongoing data source and document health sector activities, including

diagnosis and treatment. The WHO identified health information as a fundamental building block of a health system and defined a data quality framework which incorporates four dimensions (World Health Organization, 2007, 2017a):

1. Completeness and timeliness
2. Internal consistency
3. External consistency
4. External comparison of population data.

These four dimensions can be applied at many levels of the health system, including facility, district, and nation. For example, one can identify the completeness of data in the national DHIS or the completeness of a register at a specific facility. Additionally, the dimensions can be adapted to be used with a range of indicators and across clinical areas.

As interest grows in the use of routine data, there has been increasing attention to the quality of data collected as part of the HIS. A summary of studies focused on the assessment of HIS data quality can be found in Table 2. Methods of assessment vary, although most rely on quantitative assessment of available data and draw from statistical principles related to the assessment of data quality (Chen, Hailey, Wang, & Yu, 2014). Most studies have found high levels of availability of registers, reports, and other source documents. Completeness of registers and reports have been high, although missing data are common. Quality of routine data—defined as reliability, validity, accuracy, or concordance depending on the study—has varied across country contexts, facilities, programs, and indicators.

Previous data quality work in Malawi assessed the quality of select indicators at facilities and districts using a data quality assessment (DQA) (O’Hagan et al., 2017); results from related work are included in Chapter 2. In brief, the researchers found that data quality varied by clinical area, with a high verification ration (VR), a measure of the agreement between two different sources, for family planning, antenatal care, and HIV services. Recent supervision was associated with increased data availability. Data use by the facility was also associated with improved availability and completeness of data (O’Hagan et al., 2017). Review of the quality of data from

Malawi's community-based IMCI program, found that HSA registers and reports were available (>93% of all audited reports available) and HSA registers were complete. There were gaps in completeness of reports at the facility-level (61-82% completeness with variability by metric and district) and in documentation of supervision (Yourkavitch, Zalisk, Prosnitz, Luhanga, & Nsona, 2016). An audit of the quality of antiretroviral therapy (ART) data found high rates of agreement in documentation in the patient's treatment card and the facility register with a 1.2% discrepancy rate for patient outcomes and a 0.4% discrepancy rate for treatment regimen (Hedt-gauthier et al., 2012).

Varied activities and systems have been put in place to improve the quality of routine data.

These activities may include training, data quality audits, supervision, on-the-job mentoring, and data dashboards. The evidence of the impact on these activities has been mixed (Braa, Heywood, & Sahay, 2012; Gimbel et al., 2017; Nutley & Reynolds, 2013; O'Hagan et al., 2017; Wagenaar et al., 2015).

Country context

The Republic of Malawi is a sub-Saharan country in the east of Africa. Bordered by Mozambique, Tanzania, and Zambia, Malawi is landlocked with an area of 118,484 square kilometers. The country is composed of 28 districts and three regions (Figure 1). Approximately 20% of the country is covered by Lake Malawi (Malawi National Statistics Office & Macro, 2011). In 2016, Malawi's population was estimated to be 18.1 million (The World Bank Group, 2018).

Malawi is a low income country, with an estimated GNI of US\$320 per capita in 2016 (International Monetary Fund, 2017; The World Bank Group, 2018). Poverty is pervasive in Malawi; 50.7% of the population lives at or below the national poverty line (United Nations Development Programme, 2015). In fact, 25.0% of the population lives in extreme poverty,

defined as the inability to purchase sufficient food (International Monetary Fund, 2017). In 2013, the United Nations Human Development Report ranked Malawi as the 18th least developed country in the world (United Nations Development Programme, 2015). Malawi's economy is largely driven by agriculture, with tobacco, tea, and sugar as the primary exports (Malawi National Statistics Office & Macro, 2011), and, therefore, is vulnerable to recent drought and low crop yield (United Nations Children's Fund (UNICEF), 2017).

Malawi's health profile

Life expectancy is 61 for males and 67 for females (World Health Organization, 2018). In 2017, it was estimated that the under-five mortality rate is 63 deaths per 1,000 live births and the infant mortality rate is 42 deaths per 1,000 live births (National Statistical Office (NSO) & ICF, 2017). Under-five and infant mortality have declined from 1992 when the rates were 234 deaths per 1,000 live births and 135 deaths per 1,000 live births, respectively (National Statistical Office (NSO) & ICF, 2017). This decrease is largely due to a decline in deaths among those aged 1-59 months; neonatal mortality has not shown as substantial a reduction (Kanyuka et al., 2016).

In the two weeks preceding the 2015/2016 Malawi Demographic Health Survey (MDHS), 5.4% of children under five had symptoms of acute respiratory infection (ARI), 28.8% had fever, and 21.7% had diarrhea. Care-seeking for advice or treatment varied by condition: 77.6% of children with ARI sought care from a formal or informal care provider, whereas 66.8% of those with fever and 65.8% of those with diarrhea did (National Statistical Office (NSO) & ICF, 2017). Malnutrition, measured by rates of stunting and wasting, have improved since 2000. In the most recent MDHS, 37.1% of children under five were stunted and 2.7% were wasted (National Statistical Office (NSO) & ICF, 2017). In 2000, rates of stunting and wasting were 49.0% and 5.5%, respectively (National Statistical Office [Malawi] & ORC Macro, 2001).

It is estimated that 825 neonates and 4,596 children aged 1-59 months died from pneumonia in Malawi in 2015 (Liu et al., 2016). This is a decrease from 2000, when an estimated

1,182 neonatal deaths and more than 12,000 deaths in children aged 1-59 months were attributed to pneumonia (Liu et al., 2015, 2016). A recent study in two districts in Malawi, Chikwawa in the south and Karonga in the north, estimated pneumonia incidence to be 15.67 (95% CI: 15.06, 16.28) per 100 child-years (Mortimer et al., 2017). A study in one town in the district of Mangochi determined annual prevalence of ARI to be 32.6%, with higher prevalence among children with a sibling with ARI and those with acute malnutrition (Cox et al., 2017).

A study of the impact of PCV-13 found that introduction of the pneumococcal vaccine in 2011 reduced hypoxemia by 47% (p-value=0.031) and pneumonia-related hospital deaths by 36% (p-value=0.047), in two districts in central Malawi (McCollum et al., 2017). Total pneumonia cases increased by 47% (p-value= 0.154) and fast breathing cases increased by 135% (p-value=0.0154) (McCollum et al., 2017). A national study of the case fatality rate among children hospitalized with pneumonia in Malawi demonstrated improvement as well; the overall case fatality rate at district and central hospitals declined from 15.2% (95% CI: 13.4-17.1%) in 2001 to 4.5% (95% CI: 4.1-4.9%) in 2012 (Lazzerini et al., 2016). Mortality rates remained highest among those with very severe pneumonia, severe undernutrition, and severe acute malnutrition (Lazzerini et al., 2016).

Malawi's ARI program

Malawi's Ministry of Health oversees the prevention, diagnosis and treatment of ARI, generally, and pneumonia, specifically, at primary and secondary care facilities and within the community (Figure 2).

In 2008, the Ministry of Health trained a cadre of community health workers, called Health Surveillance Assistants (HSAs) to provide care at village-based health clinics and health posts. HSAs were trained in international community case management protocols for common illnesses in children under five and were deployed in hard-to-reach areas located more than 8 kilometers from a health center. HSAs diagnose, classify, and treat pneumonia, malaria, and

diarrhea. Severe or persistent cases are referred to the health center for follow-up. HSAs diagnose suspected pneumonia based on caregiver report and presenting symptoms, including cough for an extended period of time and fast or difficult breathing (Gilroy et al., 2013; Nsona et al., 2012). Suspected pneumonia is treated with antibiotics, cotrimoxazole or amoxicillin as available, and children are followed up after three days to ensure that there has been improvement in symptoms. Children with danger signs are referred directly to the nearest health center (Nsona et al., 2012).

Children with suspected pneumonia may also seek care at health centers and district hospitals. At the health center, children are examined and the practitioner completes a medical history. Based on symptoms, children are diagnosed with pneumonia, simple pneumonia, severe pneumonia, or another acute respiratory infection. Children diagnosed with any of these conditions may be prescribed antibiotics, most commonly cotrimoxazole or amoxicillin, depending on drug availability (World Health Organization, 2014). Children with severe pneumonia are referred directly to the district hospital for care and do not receive treatment at the health center.

Historically, hospital-based treatment of pneumonia has been delivered in accordance with the Child Lung Health Program (CLHP) guidelines and standards, which were first implemented in 1999 with support from the International Union against Tuberculosis and Lung Disease (P. M. Enarson, Gie, Enarson, & Mwansambo, 2009). The CLHP focuses on treatment of children presenting at hospital pediatric wards with severe or very severe pneumonia. CLHP began as a pilot project in five district hospitals and by 2004 was scaled up to 22 of 28 district hospitals and two of four central hospitals (P. M. Enarson et al., 2009). CLHP provided case management protocols for pneumonia treatment at hospital-level, training and supervision of health workers, prioritization of limited resources for children at risk of death, strengthened supply chains for antibiotics and oxygen, and improved data collection systems (P. Enarson et al., 2008). In 2009, Emergency Triage Assessment and Treatment (ETAT) was introduced to district hospitals. ETAT is one component of the international guidelines related to Integrated

Management of Childhood Illness (World Health Organization and United Nations Children's Fund, 2012) and supports the streamlined diagnosis and treatment of children presenting at the outpatient department (OPD). The ETAT program, part of the Ministry of Health's Child Health Unit, oversees outpatient and inpatient care of children with pneumonia, malaria, and diarrhea (Robison et al., 2011).

There is mixed evidence on the quality of pneumonia diagnosis and care at all levels of Malawi's health system. A nationally representative survey of health facilities found that health workers completed 30% of IMCI guidelines in each encounter and only 21% of children who met IMCI criteria for pneumonia were diagnosed with the condition (Uwemedimo et al., 2018). These findings are consistent with an earlier study, conducted at one outpatient clinic, that found less than 1% of patients were evaluated on all 16 elements of the IMCI assessment, and 30% of children with IMCI-defined pneumonia were correctly diagnosed (Bjornstad et al., 2014). Following diagnosis, children may not receive the correct treatment; 68.2% of children diagnosed with pneumonia received antibiotics in a study of quality of case management by health care workers (Kobayashi et al., 2017). However, clinicians were found to have necessary equipment, and relatively high levels of knowledge of IMCI guidelines (75% score on knowledge test) (Kalu, Lufesi, Havens, & Mortimer, 2016). Within the community, HSA compliance with IMCI guidelines is similar to that of facility-based health care workers. HSAs assessed fast breathing in 71% of children presenting with cough and provided antibiotics to 52% of children with suspected pneumonia (Gilroy et al., 2013).

Research overview

In 2013, Malawi joined the National Evaluation Platform (NEP), a project funded by Global Affairs Canada to support comprehensive sub-national evaluation using available data and recognizing the simultaneous scale-up of support from diverse partners and stakeholders. This work is funded by Global Affairs Canada through the NEP and explores the application of

available data to determining the incidence of pneumonia and the pneumonia-specific rate of mortality at a sub-national level across Malawi. The following sections provide additional information on the project and the conceptual framework which guided the project.

Aims and questions

The overall aim of this research is to understand and use available data to determine the incidence rate of ARI and pneumonia mortality. Specifically, the research questions are:

Question 1: How does intervention scale-up vary across Malawi's districts and impact pneumonia mortality rates?

Question 2: What is the quality of ARI data collected as part of Malawi's health information system (HIS)?

Question 3: Using routinely available data, what is the prevalence of pneumonia at the primary care and community level?

Conceptual framework

The pathway by which children become sick with suspected pneumonia and seek care at a facility is outlined in Figure 3. Ultimately, children either recover or perish from pneumonia-specific mortality. This figure serves as the conceptual framework guiding the research.

Chapter 2 is an examination of pneumonia outcomes, namely disease specific mortality, which appear in green. We model the impact of changing rate of intervention coverage (not included in Figure 3) to determine the impact on pneumonia mortality in children aged 1-59 months by district.

Chapter 3 is an exploration of the pink boxes, assessing the collection of data and translation of health service statistics into information. When children become ill with pneumonia and seek care at a health center or from an HAS, how is that action translated into available information? This is the focus of Chapter 3.

In Chapter 4, we explore the blue oval, estimating pneumonia incidence. We use information from the steps following illness, namely the decision to seek care and documentation of the sick child in the HIS, to estimate pneumonia incidence.

In each chapter of this dissertation, we examine a different step in this pathway to arrive at a more complete understanding of pneumonia morbidity and mortality in Malawi its districts.

Defining the outcome for this research

This work focuses on the measurement of pneumonia incidence and mortality in Malawi. As discussed, differential diagnosis of pneumonia is challenging in many settings, and especially so in a country like Malawi where diagnostic capacity is limited. Diagnosis is based on symptoms at presentation using the WHO IMCI algorithm, a definition intended to have high sensitivity in order to increase treatment rates and decrease child mortality. Diagnosis based on clinical presentation may be called pneumonia or suspected pneumonia in the literature. I have chosen to use the term pneumonia.

When referring to data collected through Malawi's HIS, I refer to the diagnosis as ARI, which is the term documented on the reporting form. In Chapter 3, I discuss the collection and reporting of ARI data, to reflect what is being requested via report and the diagnostic ambiguity that we explore in the research. In Chapter 4, I use the term pneumonia; the outcome that we model adjusts available ARI data for misdiagnosis and is the best available approximation of pneumonia incidence. These distinctions are consistent with definitions used by other researchers (Cox et al., 2017; Lazzerini et al., 2016; Mortimer et al., 2017).

Organization of dissertation

The remainder of this document includes four chapters, three of which contain individual manuscripts:

Chapter 2: District variability in reduction of pneumonia-specific mortality in Malawi, 2000-2014 (Paper 1)

Chapter 3: “ARI means lots of things”: exploring the quality of child respiratory infection data in Malawi’s health information system (Paper 2)

Chapter 4: Using routine data to estimate pneumonia incidence at the district level (Paper 3).

The final chapter (Chapter 5) is a summation of the findings and draws parallels between the three prior chapters. Additionally, there are appendices which include data collection instruments and other study documents.

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Tables and Figures

Table 1. Pneumonia classification in Malawi

Age	Signs and symptoms	Classification
<2 months	Cough and/or difficulty breathing Lower chest indrawing or fast breathing for age (>60 breaths per minute) No danger signs	Severe pneumonia
2-59 months	Cough and/or difficulty breath Fast breathing for age: >50 breaths per minute for ages 2-11 months, >40 breaths per minute for 12-59 months No lower chest indrawing No danger signs	Non-severe pneumonia
2-59 months	Cough and/or difficulty breathing Lower chest indrawing No danger signs Possible fast breathing for age	Severe pneumonia
0-59 months	Cough and/or difficulty breathing At least one danger sign Possible fast breathing for age Lower chest indrawing	Very severe pneumonia

Adapted from World Health Organization and United Nations Children's Fund, 2012

Table 2. Summary of data quality assessment activities from literature review

Author	Country	Metrics	Methods	Findings
(Bosch-Capblanch, Ronveaux, Doyle, Remedios, & Bchir, 2009)	41 countries	DPT3 immunization rate	Data quality assessment	21 countries had VR <80% (over-reporting of immunized children relative to assessment of primary data source)
(Gimbel et al., 2011)	Mozambique	First ANC, institutional birth, DPT3	Adapted Global Fund bottom-up audit to assess availability, reliability, and validity with population-level estimates	98% report availability 80% concordance between facility reports and registers Strong correlation with population estimates (R=0.73)
(Hong, Hoa, Walker, Hill, & Rao, 2018)	Vietnam	Cause of death	Capture-recapture to assess completeness and reliability of death records	Death records were 90% complete Reliability varied by cause of death (kappa=0.11 for pneumonia, kappa=0.69 for road traffic accidents)
(Ahanhanzo et al., 2015)	Benin	Maternity, outpatient, laboratory, immunization, malaria, financial management	LQAS to assess completeness, reliability, accuracy	Low completeness, reliability, and accuracy Data best quality for immunization and financial reporting
(Chiba, Assistant, & Oguttu, 2012)	Kenya	Childbirth register	Availability, completeness, and accuracy	>20% of fields incomplete Data fields in register did not match report

Author	Country	Metrics	Methods	Findings
(Dhillon, Subramaniam, Mulokozi, Rambeloson, & Klemm, 2013)	Tanzania	Vitamin A supplementation coverage	Cross-sectional household survey to validate routine data	Data validity varied by field in register Survey estimated Vitamin A coverage to be 30% lower than immunization tally sheets
(Hussain, Ansari, Salman, Khan, & Ashgar, 2016)	Pakistan	Number of ARI cases	CDC guidelines on evaluating health surveillance including review of completeness, timeliness, system's sensitivity	83% of districts submitted reports on time 94% of estimated ARI cases were included in system
(Nicol, Dudley, & Bradshaw, 2016)	South Africa	Prevention of mother to child transmission: ANC HIV testing, ANC initiation on medication, infant HIV testing, infant initiation on medication	PRISM tools used to assess completeness, accuracy	Data 91% complete at facility and 96% at district 51% agreement between register and report, 84% agreement between report and database
(Nisingizwe et al., 2014)	Rwanda	10 indicators, including ANC1, ANC4, number of OPD visits, number of under-five visits	WHO data quality report card framework	High completeness (>95%) of reports and individual indicators (>88%) 0% moderate and extreme outlier values >87% agreement between ANC registration and DPT1 administration
(O'Hagan et al., 2017)	Malawi	4 indicators: ARI, HIV testing, ANC, family planning	Availability, completeness, verification ratio (VR)	Registers were available and complete

Author	Country	Metrics	Methods	Findings
				Quality varied by clinical area with ARI lowest (VR: 0.78), HIV and ANC highest (VR:1.0)
(Puttkammer et al., 2016)	Haiti	HIV electronic medical records data including patient demographics, visit dates, ART status, CD4 test value	Completeness, accuracy, and timeliness of electronic medical record data	Completeness varied by indicator: age (99% complete), height, pregnancy, ART status (60-80% complete) <3% of data flagged for check based on male sex, CD4, visit date
(Sharma, Rana, Prinja, & Kumar, 2016)	India	Maternal and child health services	Cross-sectional household survey to validate coverage estimates from routine data, completeness	High completeness (88.5%) of HIS data Discordance of coverage estimates varied by indicator (2%-41%)
(Yourkavitch et al., 2016)	Malawi	Community-based IMCI	Adapted PRISM tools to assess completeness, VR	High levels of register and report availability Completeness of data varied by indicator VR varied by indicator, new cases (VR:0.9), stock outs (VR:2.19)
(Wagenaar et al., 2015)	Mozambique	First ANC, institutional birth, DPT3	Concordance	Concordance increased from 56.3% at baseline to 87.5% following data quality intervention

Figure 1. Map of Malawi

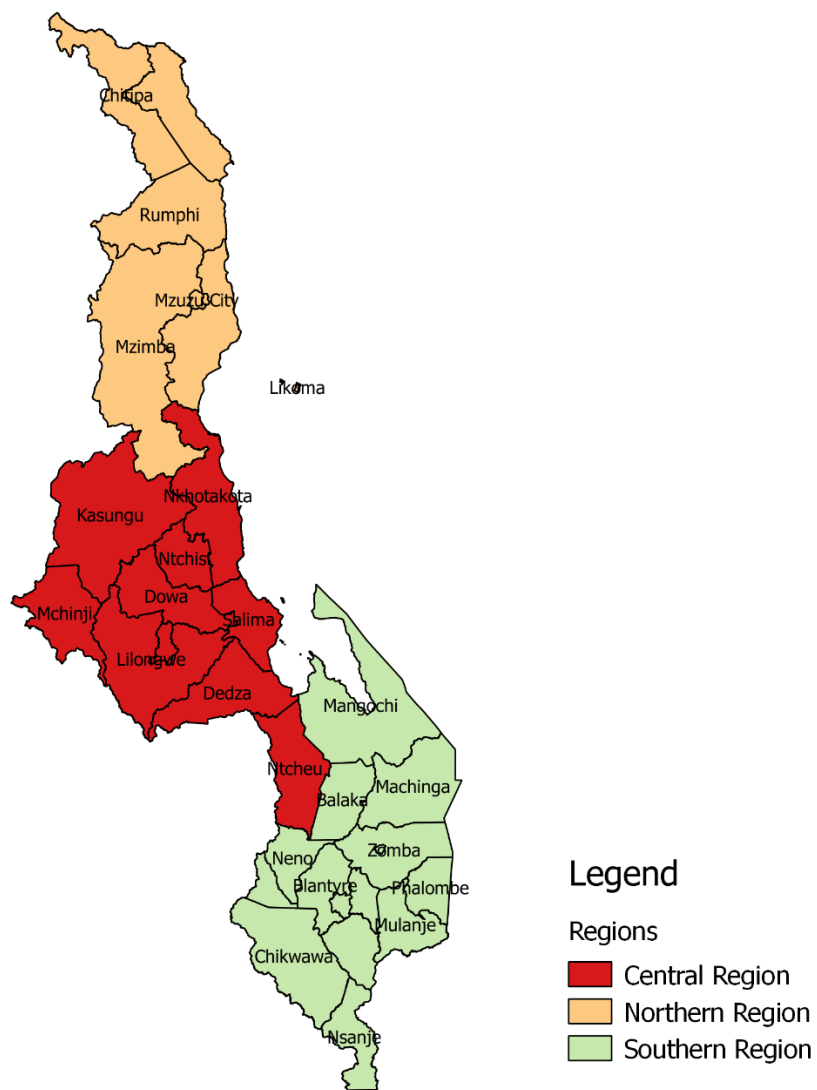


Figure 2. Timeline of Ministry of Health prevention, diagnosis, and treatment activities for pneumonia

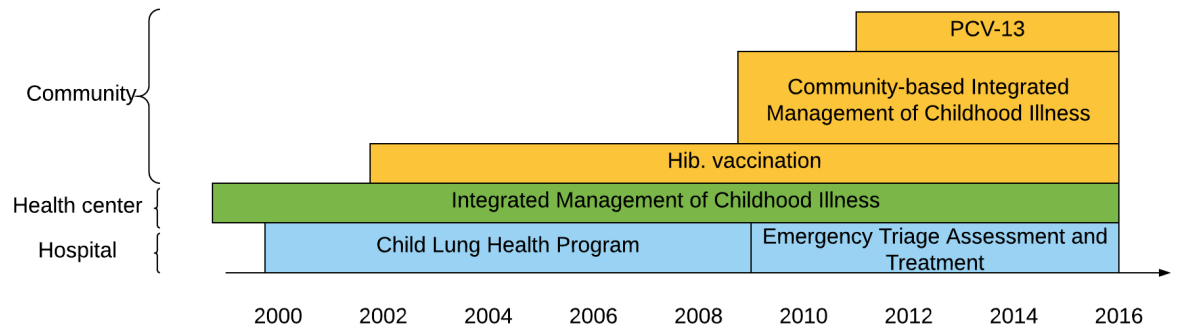
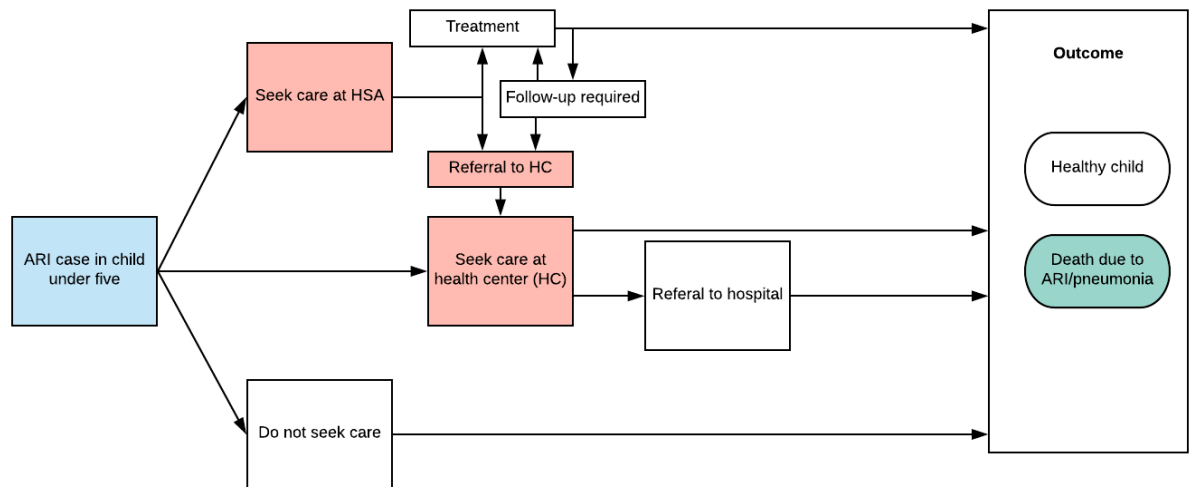


Figure 3. Conceptual framework of dissertation research.



Chapter 2. District variability in reduction of pneumonia-specific mortality in Malawi, 2000-2014

Karen E. Finnegan, Norman Lufesi, Mercy Chimbalanga, Patrick Naphini, Ernest Kaludzu, Lewis Gombwa, Bethred Matipwiri, Amos Misomali, Neff Walker, Melissa A. Marx

Abstract

Worldwide, pneumonia is a leading cause of under-five mortality. Malawi demonstrated a substantial decline in under-five mortality from 2000 to 2014, driven, in part, by a decline in pneumonia-specific mortality, but it is not known if all districts had similar improvements or if there was district variability. We model how district-level coverage of interventions shown to prevent and treat pneumonia have influenced changes in district-level rates of under-five pneumonia mortality.

We estimated district-level intervention coverage rates using population-based household surveys, the Malawi Demographic Health Survey (MDHS) and Multiple Indicator Cluster Survey (MICS). We input these district estimates of intervention coverage into the Lives Saved Tool (LiST) to model how changing rates of intervention coverage across districts led to changes in pneumonia mortality in children aged 1 to 59 months from 2000 to 2014.

Intervention coverage varied across districts and over time. Coverage of antibiotic treatment ranged from 13.0%-36.2% in 2000 and from 51.4% to 79.3% in 2014. All districts had *Haemophilus influenzae* type b (Hib) vaccination rates above 80% in 2014; mean coverage of PCV-13 was 89.7% in 2014. Stunting and wasting decreased across districts all districts; rates of exclusive breastfeeding for infants <1 month and children 1-5 and 6-12 months increased. Across districts, health sector interventions averted more than 45,000 pneumonia-related deaths among children 1-59 months. The relative contribution of interventions to the decline in mortality varied across districts. Proportion of pneumonia deaths averted due to vaccines ranged from 14.5%-57.5% across districts. Mean proportion of deaths averted due to oral antibiotic treatment was 26.7% (SD: 10.0%). Between 2000 and 2014, all 27 districts reduced the absolute number of

pneumonia deaths. The percentage of deaths attributed to pneumonia ranged from 10.1% to 17.6% across districts in 2014.

Intervention scale-up varied across districts, impacting the number of lives saved due to reductions in pneumonia mortality. Sustaining high levels of intervention coverage are essential to reducing pneumonia mortality in children ages 1 to 59 months. Districts with low coverage and high mortality are able to improve health over a short period of time.

Key words: under-five mortality, pneumonia mortality, district

Background

Globally, pneumonia is a leading cause of under-five mortality, with an estimated 15% of child and infant deaths attributed to the disease (World Health Organization, 2015). In Malawi, it is estimated that there were approximately 684,000 cases of clinical pneumonia in children under five and more than 7,800 deaths in 2010 (Rudan et al., 2013). By 2015, the estimated number of pneumonia deaths had fallen to less than 5,500, including 825 in neonates and approximately 4,500 aged 1-59 months (Liu et al., 2016). Malawi was one of the few low and middle income countries to achieve Millennium Development Goal 4, reducing child mortality by two-thirds—from 247 deaths per 1000 live births in 1990 to 71 in 2013 (Kanyuka et al., 2016). This decline was due, in part, to an estimated 14% reduction in pneumonia mortality nationally (Liu et al., 2015).

A national analysis of the drivers of the reduction in Malawi's under-five pneumonia mortality found that the decline in mortality was the result of increasing vaccination rates and antibiotic treatment, as well as a reduction in stunting and wasting (Lufesi et al., n.d.). Although Malawi's national pneumonia mortality rate fell sharply, there is some evidence of district-level variability in program implementation and in the magnitude of the decline in pneumonia-specific mortality (Gilroy et al., 2013; Kanyuka et al., 2016; Kobayashi et al., 2017; Lazzerini et al., 2016; Uwemedimo et al., 2018).

District-level assessments of pneumonia incidence and mortality provide evidence of improvement, however, most studies are limited in scope to a subset of districts or one component of the health system. A study of mortality data at 40 of 41 hospitals found that among inpatient pediatric cases diagnosed with pneumonia, the case fatality rate fell from 15.2% in 2001 to 4.5% in 2012 (Lazzerini et al., 2016). A study in two districts in Central Malawi, found that hospital deaths from pneumonia decreased by 36% from 2012 to 2014 following introduction of pneumococcal conjugate vaccine (PCV-13) (McCollum et al., 2017). Additionally, there was a slight increase in diagnosis of fast-breathing at facilities and by community-based Health Surveillance Assistants (HSAs); this was accompanied by a decrease in reported rates of hypoxemia (McCollum et al., 2017). While national trends show evidence of improving health, sub-national variability in mortality and program implementation has not yet been fully explored and has been limited in scope to a sample of districts or facilities (Cox et al., 2017; Mortimer et al., 2017).

The Government of Malawi conducts programs to prevent, diagnose, and treat under-five pneumonia at community, health center, and hospital levels (Lufesi et al., n.d.). The diagnosis and treatment of children with pneumonia at health facilities and by community-based health surveillance assistants (HSAs) is in accordance with World Health Organization Integrated Management of Childhood Illness (IMCI) protocols (World Health Organization, 2014; World Health Organization and United Nations Children's Fund, 2012) and emphasizes diagnosis based on symptoms at presentation, and treatment with antibiotics if pneumonia is suspected. Additionally, Malawi has focused on childhood vaccination. *Haemophilus influenzae* type b (Hib) and pneumococcal conjugate vaccine, PCV-13, were introduced in 2002 and 2011, respectively. Malawi's IMCI program and treatment guidelines have previously been described elsewhere (Bjornstad et al., 2014; Kalu, Lufesi, Havens, & Mortimer, 2016).

To inform program implementation and the prioritization of resources across districts in Malawi, we used district-level changes in intervention coverage rates to model pneumonia-specific mortality among children under five.

Methods

The Lives Saved Tool

We modeled the impact of change in intervention coverage and disease risk factors on pneumonia-specific mortality rates among children 1-59 months of age across Malawi's districts from 2000 to 2014 using the Lives Saved Tool (LiST) (Johns Hopkins School of Public Health, n.d.). Briefly, LiST estimates how changes in rates of coverage of community and health sector interventions affect maternal, neonatal, and child mortality (Fox, Martorell, Broek, & Walker, 2011; Walker, Tam, & Friberg, 2013). The model includes data on more than 70 maternal and child health interventions, both preventive and curative, and takes into account simultaneous scale-up of interventions (Walker et al., 2013). LiST calculates lives saved by first attributing the change in mortality to preventive interventions and then calculating the impact of curative interventions on children who remain at risk (Walker et al., 2013). Intervention impact is ordered sequentially from peri-conception, pregnancy, delivery, and then through sequential age groups from youngest to oldest; this process is repeated for curative interventions (Walker et al., 2013). Cause-specific estimates of effectiveness for LiST's interventions were obtained from peer-reviewed studies and reviewed by the Child Health Epidemiology Reference Group (CHERG) (Bhutta et al., 2013; Catto et al., 2011; Das, Lassi, Salam, & Bhutta, 2013; Lamberti et al., 2013; Nair et al., 2013; Theodoratou et al., 2010). LiST has been described in detail previously (Fox et al., 2011; Victora, Barros, Malpica-Ilanos, & Walker, 2013; Walker et al., 2013).

The model underlying LiST assumes that mortality rates and cause of death distribution are statistically predictable and that any change in these is the result of a change in intervention coverage. Changes in less proximate variables—increasing GDP, change in crop yields, maternal

education—affect mortality by impacting coverage or risk factors but are not directly included in the model.

LiST Inputs

We estimate intervention coverage using data from the Malawi Demographic Health Survey (MDHS) and Multiple Indicator Survey (MICS) (Malawi National Statistics Office and ICF Macro, 2011). These population-based surveys collect information on care-seeking and treatment for a range of childhood illnesses, including suspected pneumonia. We use data from the MDHS and MICS to estimate intervention coverage. Proximate and distal interventions that impact pneumonia mortality are detailed in Figure 1. Figure 1 also outlines risk factors for pneumonia mortality, including poor birth outcomes, and malnutrition as measured through rates of stunting and wasting.

Coverage of key interventions are assessed through population-based household surveys. The methods of ascertainment of coverage for interventions and risk factors that affect pneumonia mortality are presented in Table 1. We exclude neonatal pneumonia mortality from our outcomes because limited information is available on intervention coverage for children younger than 30 days.

Creating district projections

To model under-five pneumonia-related deaths and lives saved, we create 27 district-level projections, one for each district in Malawi. Although Malawi currently has 28 districts, we calculate lives saved and present results for the 27 districts that were defined in 2000, our baseline year. We present results for Mwanza District, which was split into Neno and Mwanza Districts in 2003, to allow analysis of time trends from 2000.

The underlying population pyramid in LiST is drawn from the World Population Programme's population projections, which provide national estimates of population by age group for countries worldwide (Fox et al., 2011). We use data from Malawi's 2008 census to identify district-level population estimates and modify LiST's population estimates by adjusting

the projection's population numbers with district population estimates from the census (National Statistical Office, 2008). We then input district-level estimates of intervention coverage.

To estimate district-level intervention coverage over time, we first address changing survey sampling methods. Prior to 2006, only 40% (11/27) districts were representatively sampled to allow for the calculation of district-specific estimates of coverage; the remaining districts were included in data collection, but were not sampled to allow for stable district-level estimates of coverage. For the 16 districts which were not representatively sampled in 2000 by the MDHS, we estimate district-level intervention coverage for 2000 to 2005 by computing the ratio of the district estimates in 2006, the first year that all districts were representatively sampled, and apply this ratio to the regional coverage estimates for 2000. This calculation provides an estimate of district-level baseline intervention coverage for our model. We do no such adjustment for the 11 districts that were representatively sampled in 2000.

We estimate stunting and wasting for age groups (0-5 months, 6-11 months, 12-23 months, and 24-59 months) by district. We apply the same district to regional ratio used above to our estimates of stunting and wasting to obtain coverage estimates for our baseline year. We input these estimates of stunting and wasting by age group directly into LiST; this forces the model to use our estimated coverage levels rather than the model-estimated levels based on the scale up of other interventions. We include appropriate breastfeeding in children as a risk factor in our projection. We define appropriate breastfeeding as initiation of breastfeeding within 1 hour of birth, exclusive breastfeeding through 6 months, and continued breastfeeding through 24 months.

We input our estimates of intervention coverage into the LiST model and calculate outcomes related to pneumonia-specific under-five mortality.

MDHS data were accessed through the DHS Program website (ICF, n.d.); MICS data were downloaded through the MICS website (UNICEF, n.d.). District-specific estimates of intervention coverage were calculated using Stata 14.2 (StataCorp, 2015). This work was

determined to be not human subjects research by the Johns Hopkins University Institutional Review Board.

Results

District-level intervention coverage

Intervention coverage varies over time and by district (Figure 2). Care-seeking for treatment of pneumonia, ranged from 51.4% to 79.3% across districts in 2014. This was an increase from 2000, when care-seeking ranged from 13.0% to 36.2%. Figure 3 displays the increase in care-seeking over time by district. Similarly, there have been substantial increases across districts in vaccination rates. Consistently high rates of Hib vaccination coverage (>80%) were noted across all districts in 2014; district coverage rates ranged from 89.3% to 97.1%. The proportion of children who received pneumococcal vaccination has remained high since it was introduced in 2011; mean coverage ranged from 74.0% to 97.0% in 2014. In 2014, district-level estimates of the percentage of children stunted (>2 z-scores from the WHO median standard height-for-age) ranged from 31.4% to 58.3%, with a mean of 45.0% for children ages 12-23 months. Among children aged 24-59 months, stunting rates were similar (mean: 45.5% range: 37.4-53.0%). Rates of wasting (>2 z-scores from the WHO median standard weight-for-height) ranged from 1.7% to 11.8% (mean: 5.5%) among children 12-23 months and from 1.0% to 6.9% among children aged 24-59 months. Most districts achieved high rates of appropriate breastfeeding among children <1 month in 2014 (mean coverage 95.9%, range 66.2% to 100.0%) and high rates of extended breastfeeding among older children (mean coverage: 80.3%, range: 64.9%-95.1%). The variability in intervention coverage by district is displayed in Figure 4. There are few outlying districts with extremely high or low coverage. Districts with extremely high or low values, defined as above or below 1.5 times the interquartile range of the district estimates of coverage, are labeled in the figure.

Outcomes

Across districts, preventive and curative interventions contributed to avert more than 45,000 pneumonia-related deaths among children 1-59 months of age in the study period. From

2001 to 2014, all of Malawi's 27 districts saw a reduction in the absolute number of deaths due to pneumonia. In 2014, we estimated that, across districts, an average of 13.1% (SD: 1.7%) of deaths in children 1-59 months were due to pneumonia. The percentage of deaths due to pneumonia ranged from 10.1% to 17.6% across districts.

We calculated the number of pneumonia deaths per under-five population (Figure 5). In 2000, pneumonia deaths per 1,000 children under five ranged from 3.6 in Lilongwe to 7.4 in Mulanje. Mulanje, Thyolo, and Phalombe, all in the Southern Region, had the highest rates of pneumonia mortality per under-five population in Malawi in 2000. By 2014, all districts had achieved a pneumonia mortality rate less than 4 deaths per 1,000 under-five population. Rates remained the highest in Thyolo at 3.2 per 1,000 children under five in 2014, but demonstrated a substantial decline from the district's rate of 7.1 per 1,000 in 2000.

The impact of interventions varied across districts. Figure 5 displays the proportion of deaths averted by intervention by district. Both Hib and pneumococcal vaccination played a key role in all districts in reducing pneumonia mortality. The percentage of lives saved due to vaccination implementation ranged from 14.5% in Kasungu to 57.5% in Mulanje. This variation was driven largely by differences in Hib vaccination rates over the 12 years that the vaccine was available during the study period.

We saw similar variation in the impact of oral antibiotics. Oral antibiotic use was responsible for more than a quarter of lives saved (26.7%, SD: 10.0%) over the 14 year study period, ranging from 11.3% to 49.5% across districts.

Nutrition-related interventions, including reductions in stunting and wasting, reduced pneumonia mortality by 34.5% (SD: 10.0%).

Discussion

From 2000 to 2014, all of Malawi's 27 districts reduced the pneumonia mortality rate among children aged 1 to 59 months; however, as hypothesized, we see variability across districts in the contributions of interventions to this achievement. The reduction in deaths was driven by

treatment of pneumonia with oral antibiotics, prevention of disease through vaccination, and improvements in rates of stunting and wasting. Even in districts that had higher rates of pneumonia-specific child mortality in 2000, intervention coverage increased to achieve a decline in pneumonia mortality. These higher mortality districts were able to achieve rates of pneumonia mortality similar to districts with lower mortality rates in 2000.

Malawi's district-level changes in pneumonia mortality demonstrate the importance of sustaining high levels of coverage of proven interventions. Districts which have a high disease burden can, over a relatively short period, increase coverage of effective interventions and demonstrate declines in disease-specific mortality similar to those seen in initially healthier districts. Our results demonstrate the importance of implementing preventive and curative interventions in reducing pneumonia-specific mortality; vaccines and treatment with oral antibiotics are essential in reducing pneumonia mortality across all districts. However, equally important are reductions in malnutrition, which may be achieved through specific interventions and improvement in related risk factors (diarrhea incidence, pre term birth, low rates of breastfeeding). Our results highlight the importance of sustained coverage of proven interventions.

We find evidence of increases in intervention coverage over time. Care-seeking for suspected pneumonia increases across all districts of Malawi. This may suggest an increase in accessing care or it may suggest an increase in ARI incidence.

LiST relies on a linear deterministic model, which calculates the decline in pneumonia morbidity and mortality for each district independent of other districts. It is likely that estimates of mortality would be improved if Bayesian estimation techniques could be applied to use information from geographically proximate districts; this is not possible using the current LiST version, where each district's regression is run independently of others. Additionally, we assume that intervention coverage changes linearly between survey years. Without additional primary data collection this is the best option to estimate coverage change between survey years.

Household surveys provide the best available data on intervention coverage, but are not without challenges. Care-seeking for pneumonia and other childhood illnesses is especially hard to capture accurately (Campbell et al., 2015; Hazel, Requejo, David, & Bryce, 2013) and this estimate drives the reduction in district-level pneumonia mortality in Malawi. We assume that coverage estimates reflect receipt of high quality care, and the questions in household surveys are predicated on that assumption. In fact, there is evidence that quality of care is mixed in Malawian clinics. A small study in two districts in Malawi found that clinicians had materials needed to diagnose children according to IMCI guidelines, had good knowledge of the guidelines, and completed most evaluation steps in diagnosing sick children (Kalu et al., 2016). However, a study of quality of care in one public sector hospital in Lilongwe district in 2010 found that clinical officers completed all evaluation steps in only 6% of observed visits, resulting in misdiagnosis and low treatment rates (Bjornstad et al., 2014). Linking facility and household surveys could help to explore the assumption of quality. We use both MICS and DHS surveys as sources for intervention coverage estimates; we do not adjust for differences in methodology or sampling technique when inputting the estimates into the LiST model. Differences in sampling, data collection practices, and timing of surveys may contribute to inconsistencies in estimation of intervention coverage (Hancioglu & Arnold, 2013). Both MICS and DHS offer limited information on coverage of interventions which address neonatal morbidity and mortality. Given the limited information on intervention coverage, we are unable to model the change in pneumonia mortality among children <1 month in age. In 2018, the 2015/2016 MDHS was released, with updated estimates of intervention coverage. Those estimates are not included in the current analysis due to discrepancies that we have identified. Our estimates of stunting differ by 5.6% from the MDHS report; our estimates of wasting differ by 17.8%. We are currently working with ICF, the international implementer of the DHS program, to address these challenges.

Despite these limitations, LiST presents an accessible tool for modeling declines in sub-national district-level pneumonia mortality and uses readily available data. In light of limitations

in nationally representative death and cause of death data, LiST analysis offers an approachable method for calculating district-level declines in overall and cause-specific mortality.

Given limited district-level data on pneumonia morbidity and mortality in low and middle income countries, modeling offers an opportunity to estimate overall and disease-specific mortality and to observe the effect of varied intervention coverage. This study demonstrates that there was district variability in pneumonia mortality in children aged 1-59 months and that intervention mix varied across districts. Districts with higher levels of disease-specific mortality can “catch up” to healthier districts through increased intervention coverage and these gains can be realized over a short period of time.

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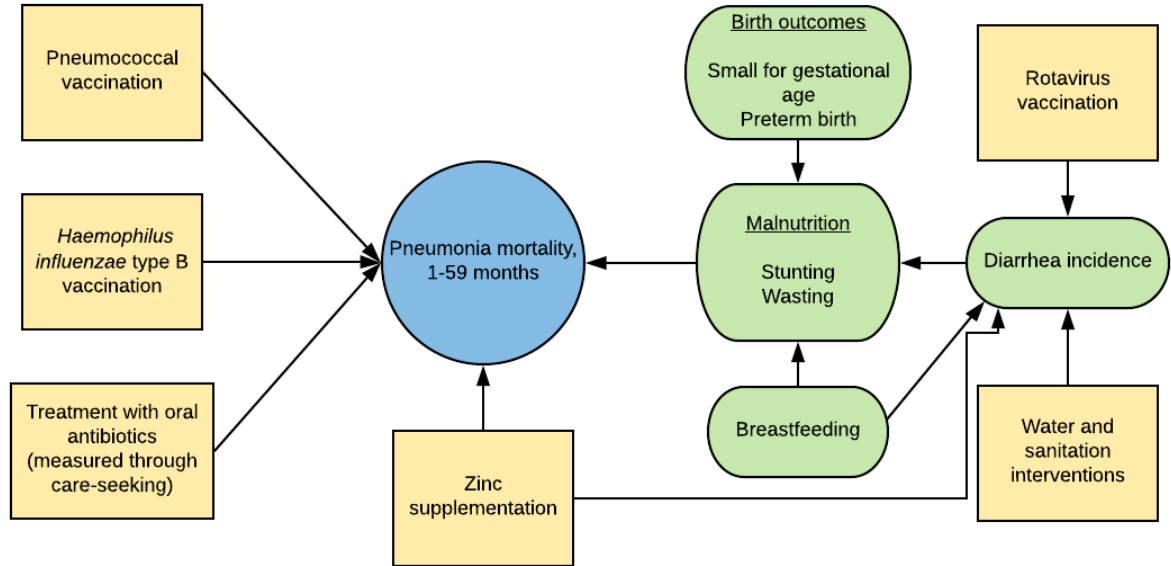
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Tables and Figures

Figure 1. Conceptual framework of interventions and risk factors impacting pneumonia mortality, age 1-59 months



Interventions are in yellow boxes and risk factors are in green; the outcome, pneumonia mortality, is in blue.

Table 1. Assessment of interventions and risk factors associated with reduction in pneumonia mortality in children 1-59 months

Intervention	Method of ascertainment
<i>Preventive</i>	
Breastfeeding (exclusive, predominant, and partial by age group)	Series of questions asked of caregiver
Pneumococcal vaccine	Children who have received 3 doses of PCV-13 based on caregiver report and/or review of vaccination card
<i>Haemophilus influenzae</i> type B vaccine	Children who have received 3 doses of Hib vaccine based on caregiver report and/or review of vaccination card
<i>Curative</i>	
Antibiotic treatment for suspected pneumonia or other ARI	Series of questions asked of caregiver about child's symptoms in two weeks preceding the survey; follow-up questions about if care was sought and location of care for those indicating cough or difficulty breathing Care-seeking for recognized symptoms of ARI is a proxy measure for treatment with antibiotic
<i>Risk factor</i>	
Stunting and wasting	Anthropometric assessment of children <5 including measurement of height and weight

Figure 2. Intervention coverage from 2000 to 2014 for select preventive and curative interventions, district and national estimates

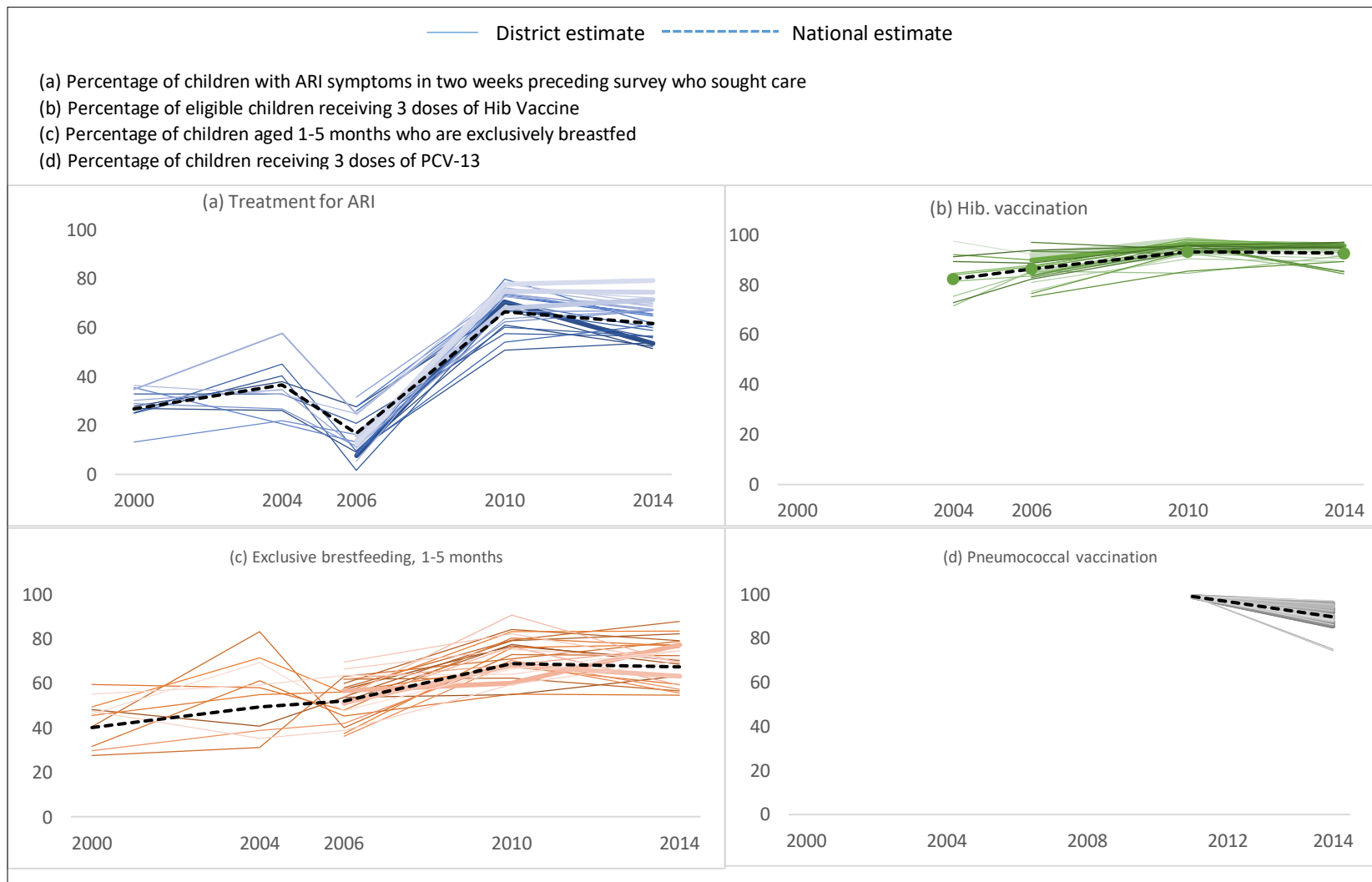


Figure 3. Percentage of children with ARI symptoms (cough, difficulty breathing) in two weeks preceding the survey who sought care according to caregiver report, by district, 2000-2014

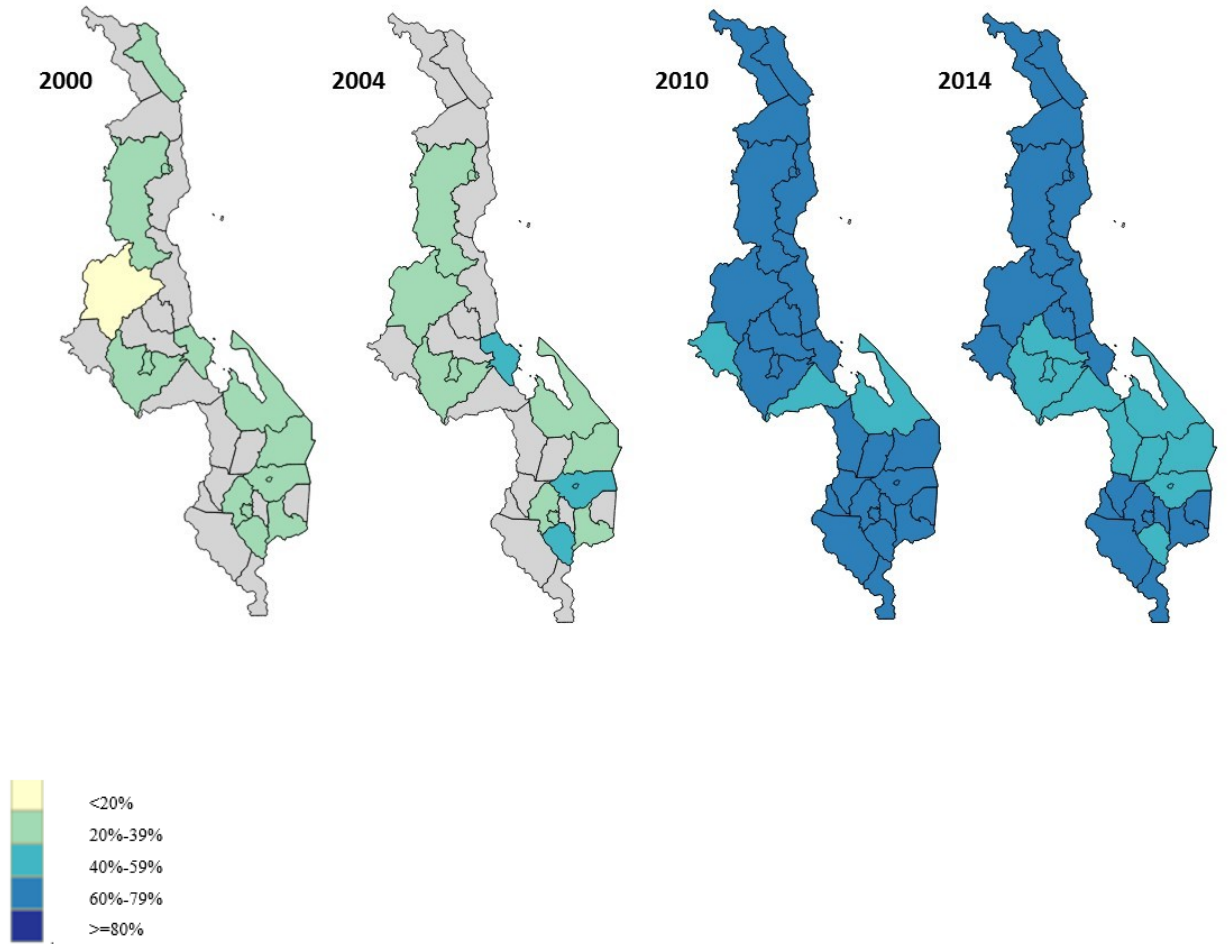


Figure 4. District variability in intervention coverage, 2014

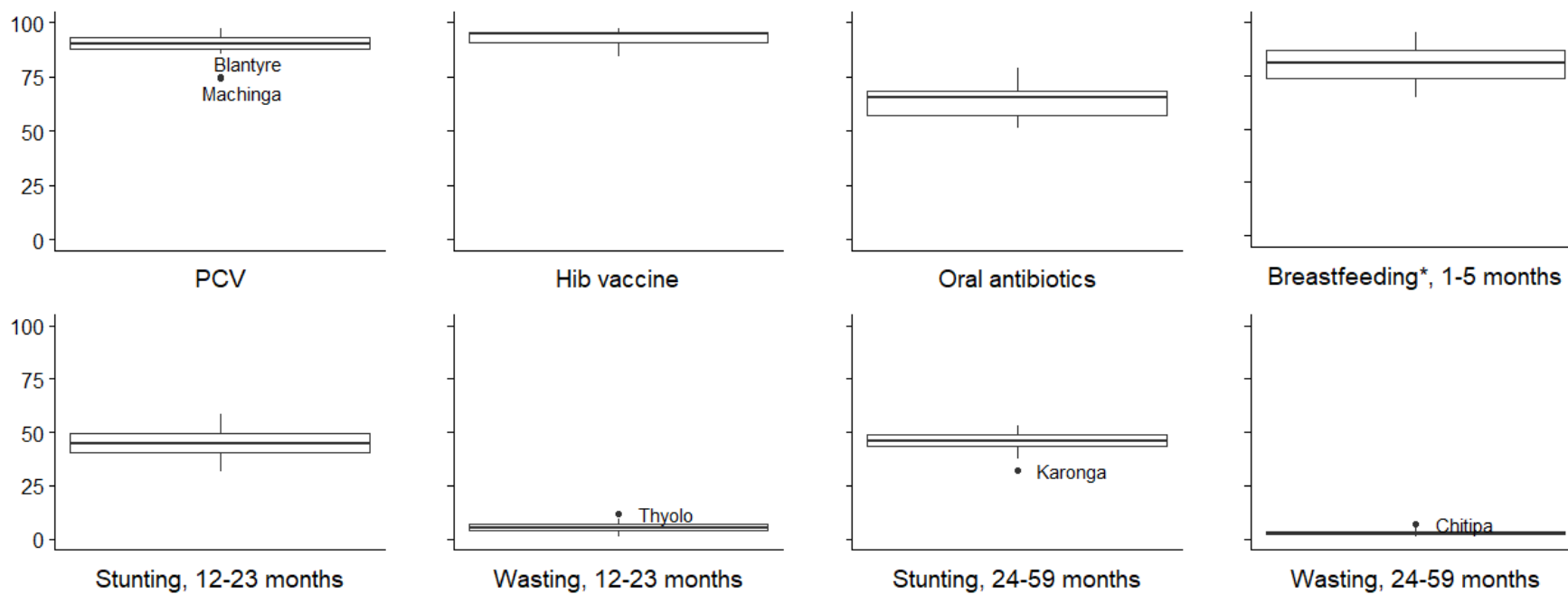


Figure 5. Pneumonia deaths per 1,000 children under five by district, 2000 and 2014

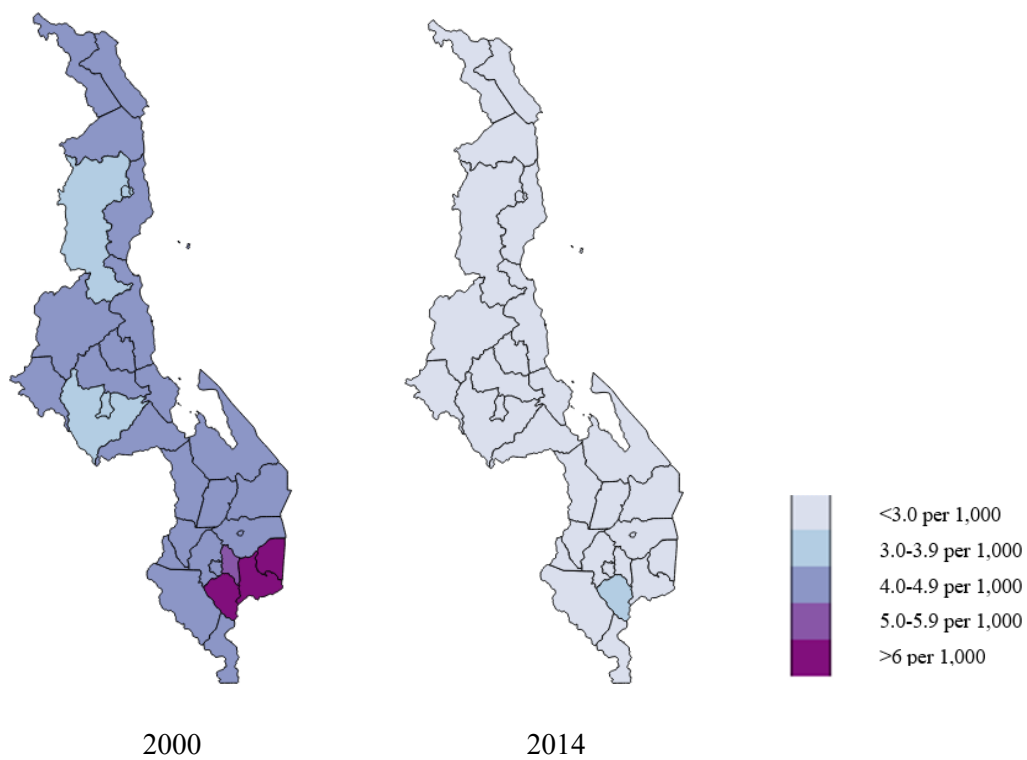
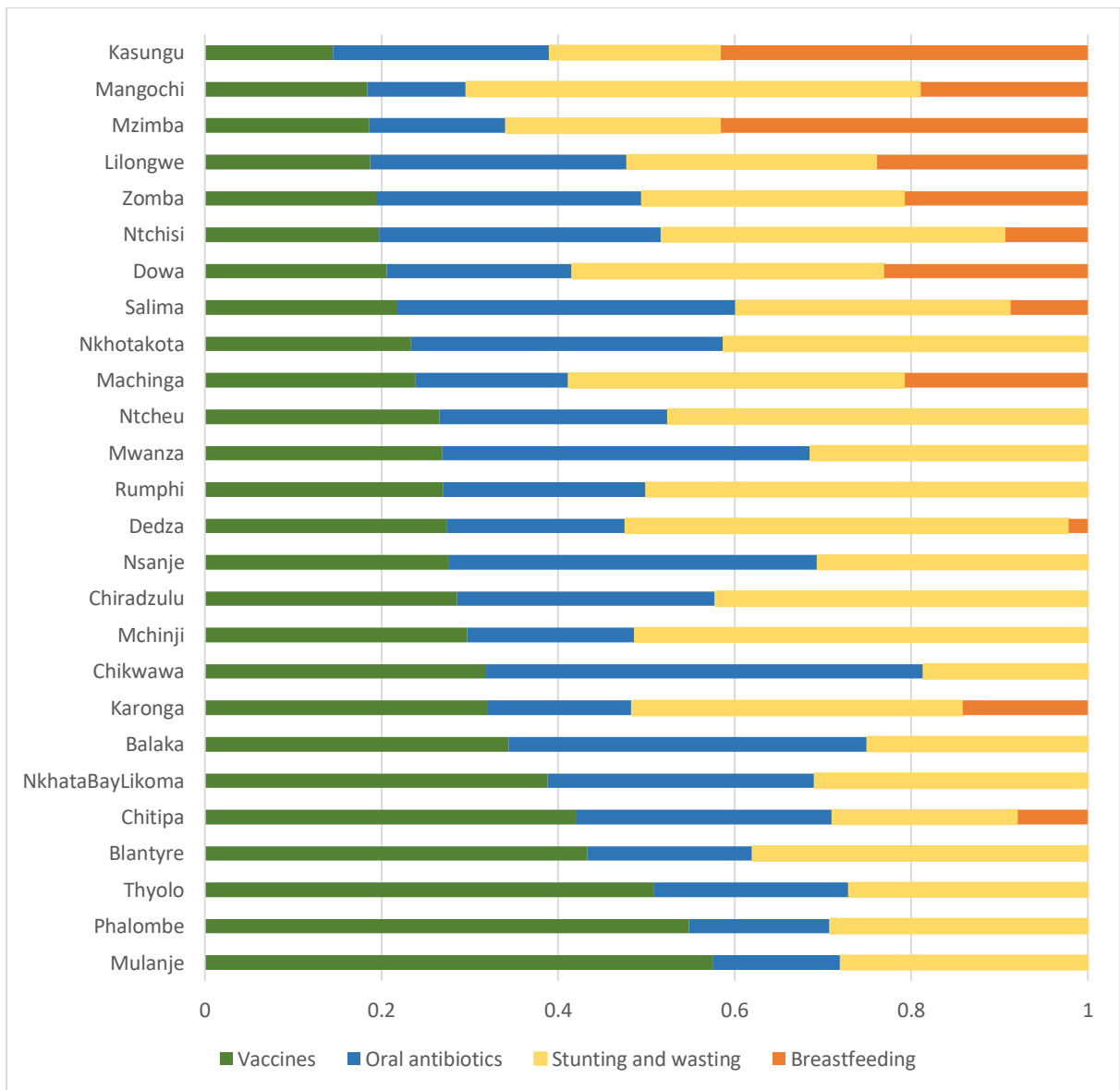


Figure 6. Relative contribution of interventions by district in preventing pneumonia deaths in children aged 1-59 months, 2000-2014.



Chapter 3. “ARI means lots of things”: A mixed methods study of Malawi’s routine acute respiratory infection data

Karen E. Finnegan, Ernest Kaludzu, Brian Malunga, Richael O’Hagan, Patrick Naphini, Sautso Wachepa, Emily Wilson, Lois Park, Ashley Sheffel, Melissa A. Marx

Abstract

Low and middle-income countries use electronic District Health Information Software (DHIS) to capture data on health sector utilization and diagnosis patterns. The DHIS represents a potentially rich and cost-effective data source for research and evaluation, but there are concerns about data quality. We evaluated the quality and use of acute respiratory infection (ARI) data and described how they are influenced by the collection and reporting processes.

We conducted a mixed methods study, including a Data Quality Assessment ((DQA); N=106 facilities in 16 districts) and focus groups (N=4; N=46 participants) and in-depth interviews (N=6) with Ministry of Health (MOH) staff. Using the DQA we assessed the availability, completeness, consistency over time, and consistency across sources of ARI data. We conducted four focus group discussions (FGDs) with health center-based statistical clerks and supervisors of Health Surveillance Assistants (HSAs). In each of the four districts where we conducted an FGD, we also conducted an in-depth interview (IDI) with the Health Management Information System (HMIS) Officer in that district. We also conducted six IDIs with national-level MOH staff.

We examined the completeness, availability, and consistency of ARI data. ARI data had high levels of completeness and availability. Data in the monthly reports and DHIS had good internal consistency (mean difference in number of ARI cases: 0.1), but varied between DHIS and register (mean difference in number of cases: 94.0). Stakeholders’ impressions from interviews and focus groups supported these findings, highlighting challenges with aggregation, materials shortage, and data use.

Findings indicate that ARI data in DHIS are available, complete, and consistent over time, but improvements are needed to ensure better consistency across sources.

To improve quality and increase use of DHIS data, the Ministry of Health's Central Monitoring and Evaluation Division (CMED) should standardize the definitions of ARI cases for monthly reports, support collection of indicators with a high caseload, and use regular quality assurance and periodic audits to identify and solve quality issues. Nevertheless, with caveats, the DHIS data should be considered for use in evaluation, research, and programmatic decision-making.

Introduction and Background

Many low and middle-income countries use electronic, centralized databases to capture aggregated information on health sector activities. National governments rely on District Health Information Software (DHIS) or other electronic databases to collect routinely aggregated information on health delivery including utilization data, counts of patients by disease or condition, number of tests conducted and results, and drugs dispensed (AbouZahr & Boerma, 2005; World Health Organization, 2011). Although data are not generally available at the individual patient level, the DHIS provides insight into the functioning of the health system and may represent the only consistent source of health sector data in the country. There are concerns, however, about the quality of routine health information system (HIS) data: data may be missing, incomplete, or implausible; the user may have limited oversight of collection; definitions and data collection practices change over time; and existing data may be limited in scope (Gloyd, Wagenaar, Woelk, & Kalibala, 2016).

Despite these limitations, researchers and public health officials have used HIS data to guide practice and improve services (Amouzou et al., 2013; Chanda et al., 2012; Gething et al., 2007; Mitsunaga et al., 2013; Wagenaar, Sherr, Fernandes, & Wagenaar, 2015). For example, HIS data have been used in Rwanda to estimate the burden of diarrhea at health facilities prior to rotavirus implementation (Ngabo, Gatera, Karema, & Donnen, 2014). Similarly, in Zambia,

malaria diagnosis data were used to determine the impact of a national malaria control program (Bennett et al., 2014).

Globally, DHIS systems typically capture data on the number of children under five diagnosed with acute respiratory infection (ARI) and pneumonia. In Malawi, a country of 18.1 million people that is the 18th poorest country in the world (Index Mundi, 2017; The World Bank Group, 2018), pneumonia was a leading cause of death, second only to malaria, and responsible for 13% of under-five deaths from 2000 to 2013 (Liu et al., 2015). It is estimated there were approximately 684,000 cases of pneumonia in Malawian children under-five in 2010 (Rudan et al., 2013). Pneumonia was estimated to be responsible for more than 5,000 deaths in children under-five in Malawi in 2015 (Liu et al., 2016).

In Malawi, children with suspected pneumonia may be examined and treated or referred by community-based Health Surveillance Assistants (HSAs) or clinicians at health centers. Patients are diagnosed and treated according to international IMCI guidelines (World Health Organization and United Nations Children’s Fund, 2012). When patients seek care, data about the consultation are documented on a patient’s “health passport”, which patients keep, and entered into a facility-based register. The data entered into the register are tallied and summarized monthly and reported to the districts using a form known locally as the “HMIS-15” form. The HMIS-15 form summarizes facility activities, including the number of ARI cases identified in children under five per month. These paper reports are entered monthly into an electronic system, DHIS-2, by district health office staff. Data entered into the DHIS are reported to the national level, but may also be used to monitor programs, health, and disease; and to inform health priorities at the district.

A decline in pneumonia-specific mortality in Malawian children was described in a 2016 study (Lazzerini et al., 2016) using specially-collected hospital data. Even so, it has been acknowledged that trends in pediatric pneumonia diagnosed and treated in health centers and

community-based sites are largely unknown in Malawi and globally (Campbell & Nair, 2016). Recently, prevalence of ARI was reported using health passport data, but for only one zone (a section of a district) and for a twelve-month period (Cox et al., 2017). Studies on ARI and pneumonia in Malawi have so far required specialized data collection, which is expensive and necessarily time-limited. DHIS is the only continuous, nationwide routine source for these data and could be used to analyze and report trends of ARI and pneumonia in children under five.

Concerns about data quality and lack of access to DHIS have precluded its use to describe ARI or pneumonia to date. Assessments of the quality of DHIS data have been conducted in Malawi previously for specific diseases and health interventions (Hedt-gauthier et al., 2012; Yourkavitch, Zalisk, Prosnitz, Luhanga, & Nsona, 2016). Antiretroviral therapy (ART) data were determined to be of high quality with minimal discrepancy between treatment card and registry (Hedt-gauthier et al., 2012), whereas the community-based integrated Community Case Management program was found to under-report referrals and stock-outs (Yourkavitch, Zalisk, Prosnitz, Luhanga, & Nsona, 2016). There are also increased efforts globally to describe and improve data quality (Gimbel et al., 2017). In responses data quality concerns, the World Health Organization (WHO) developed a data quality tool for the DHIS. The application identifies potential errors, encourages staff to address them, and, ultimately, improves data quality (Haugen, Geir, & Poppe, 2017; Health Information Systems Programme (HISP), 2018). The DHIS data quality application was being piloted in Malawi at the time of our study.

To determine whether and how DHIS data could be used to describe trends of ARI and pneumonia in children under five in Malawi, and to identify ways to address gaps in quality, in this paper we: 1) describe the quality of pneumonia and ARI service utilization data, and 2) explore the underlying collection, reporting, and use practices that contribute to the quality of these data.

Methods

We use a mixed methods approach, combining quantitative and qualitative methods for a more nuanced understanding of the research questions (J. Creswell, 2013; J. W. Creswell, Klassen, Plano Clark, & Clegg Smith, 2011). Mixed methods research includes the identification of a research question which necessitates understanding of context and multiple perspectives; rigorous application of quantitative and qualitative methods; and the intentional integration of methods to draw upon the strengths of each (J. W. Creswell et al., 2011). We use quantitative methods to describe the quality of ARI data in the HIS and qualitative methods to understand how data are collected and used from the perspectives of the creators and users of the data. We used a convergent parallel design; we collected quantitative and qualitative data at the same time and compared and contrasted the results during analysis and synthesis. The convergent parallel design allowed us to triangulate methods and findings from both the qualitative and quantitative study components (J. W. Creswell et al., 2011). Mixing of results informed the analysis of the qualitative data and provided context for the quantitative results. Mixed methods have been used previously to explore data quality and the data collection process, and we used these studies to inform our own (Chiba, Assistant, & Oguttu, 2012; Hahn, Wanjala, & Marx, 2013; Yourkavitch et al., 2016).

Quantitative data collection and analysis

We randomly sampled 25% of public sector health centers from 16 districts to be included in a data quality assessment (DQA; described in detail previously (O'Hagan et al., 2017). Briefly, we used stratified sampling to select the districts to ensure representation of Malawi's five administrative zones (Figure 1). The main hospital was purposively selected in each sampled district. Additionally, we collected data at district health offices in each sampled district. In the facilities, we reviewed facility registers and reports, and data in the DHIS-2. We used a version of the World Health Organization (WHO) DQA tool (World Health Organization, 2015) that we adapted for our setting and enhanced with questions from the PRISM tool (Aqil,

Lippeveld, & Hozumi, 2009; Measure Evaluation, 2017). We added questions on the collection and reporting of ARI and pneumonia data and used the tool to collect data on health system functioning and data quality for select indicators. Data available at the facility were then compared with data for the same period that were entered into the DHIS.

The quality of ARI data was described using metrics informed by the World Health Organization data quality framework: availability, completeness, consistency across data sources, and consistency over time (World Health Organization, 2008). Table 1 summarizes the four quality measures and the quantitative evaluation methods used for their assessment. Specifically, we assessed the availability of two forms of primary source documents used for recording identification of ARI and pneumonia: 1) the outpatient department (OPD) register, and 2) the HMIS-15 form. We reviewed the OPD register and tallied the number of ARI cases and the number of pneumonia cases for a three-month period (March-May 2016). To determine consistency of data across sources we compared our register tally of ARI cases in children under five with the health center-tally of the same indicator reflected on the HMIS-15 form and data from the same indicator as entered into the DHIS. To assess completeness and consistency over time, we reviewed available data for March 2015-February 2016 for all selected facilities. We identified outliers, which were defined as an extreme (more than ± 3 standard deviations from the district mean for the month of interest) or moderate (± 2 standard deviations from the district mean for the month of interest), consistent with WHO definitions (World Health Organization, 2017). Descriptive statistics were calculated for each metric using R version 3.3.2.

Qualitative data collection and analysis

We purposively sampled district-based and national Ministry of Health staff for focus group discussions (FGD) and in-depth interviews (IDI). Staff members working in districts included in the DQA were eligible for inclusion in qualitative data collection activities and four districts were selected based on the quality of their ARI data in the DHIS for a 12-month review

period. Specifically, drawing upon the idea of maximum variability (J. Creswell, 2013; J. W. Creswell & Creswell, 2018), districts were selected to represent a range of quality in the ARI program indicator included in the DQA: number of children under five diagnosed with ARI. Of the 16 districts included in the DQA districts, we selected one high performing district with little missing data and no extreme values for the indicator of interest; one low performing district with substantial missing data; and two average performing districts with moderate missing data and outliers. Within selected districts, all HMIS officers were sampled for participation in interviews, and statistical clerks and HSA supervisors were purposively selected for participation in FGDs based on proximity to the interview location. The Central Monitoring and Evaluation Division (CMED) provided contact information for participants and study staff contacted them via phone and text message. Participants were provided with a transportation stipend and snack. We interviewed 4/4 HMIS officers and 46/105 statistical clerks and HSA supervisors across the four districts. These cadres were chosen because they are responsible for reporting of routine health systems data. We also selected national MOH program managers responsible for child health programs related to ARI and staff from the Central Monitoring and Evaluation Division (CMED), the unit that oversees collection and use of routine HIS data, including senior leadership and staff responsible for oversight and use of ARI data.

We used a semi-structured guide for focus group discussions and interviews. FGD and IDI participants were asked about data collection, reporting practices, data use, factors influencing the quality of ARI data during the data collection process, and their understanding of the term “data quality.” FGDs and IDIs were conducted primarily in English and were audio-recorded; recordings were transcribed for analysis. All data collection activities were completed in a private or semi-private room. This study was determined to be not human subjects research by the Johns Hopkins Institutional Review Board and determined exempt by Malawi’s National Health Science Research Ethics Committee.

Questions and probes were modified as we gained understanding of the topic and to follow-up on the areas of technical expertise of the individual participants. Following each data collection activity, the team debriefed, identified key messages, and compared emerging themes across cadres and districts. Qualitative data were analyzed using the framework analysis method (J. Creswell, 2013; Gale, Heath, Cameron, Rashid, & Redwood, 2013) and were organized in Excel. The framework analysis method is well-suited to applied research which aims to provide policy recommendations (Gale et al., 2013).

A subset of transcripts was open-coded to generate the themes used in creating the framework for analysis. The categories were then refined based on a literature review. Analysis of the transcripts was an iterative process that captured developing ideas, the relationships between respondents and the relationship between the quantitative and qualitative data. A summary of our major themes and codes are presented in Table 1. Ultimately, we organized responses as they related to the WHO data quality metrics assessed during the DQA, allowing the qualitative results to provide context for quantitative findings (WHO (World Health Organization), 2008). Preliminary coding was completed by a team of five researchers, followed by a synthesis by the first author. We discussed preliminary results with CMED leadership. Their initial response to the results indicated that our findings were consistent with their understanding of the data collection process and that our interpretation was fair. After preliminary analysis, results of the qualitative analysis were shared with stakeholders for feedback; their responses helped guide the final analysis and interpretation of results.

Results

The quantitative data quality assessment was completed at 106 health facilities, 105 of which provided information on diagnosis of ARI in children under five. One facility did not provide ARI services. We completed four FGDs with 46 district-based statistical clerks and HSA

supervisors, four IDIs with district-based HMIS officers, and six IDIs with central MOH staff. A description of the quantitative and qualitative study populations are presented in Table 2.

We report results below by WHO data quality metric. A summary of our results by WHO data quality metric are in Table 3.

Availability

At the time of the assessment, 97.0% of OPD registers for the study period (March-May 2016) were available for review. Paper copies of the monthly HMIS-15 report were available for 77.5% of the audited reports (March-May 2016). In 17 health facilities staff reported that no paper copies of HMIS-15 reports were available.

Although statistical clerks cited insufficient materials (e.g. inadequate number of registers or forms) as a common problem for data collection and reporting, the DQA found most materials available for the collection of ARI data. Financial or material support by partner organizations often provided resources when there were shortages of forms and registers. Statistical clerks highlighted the lack of dedicated storage space, which limited their ability to archive old registers and reports in accordance with national policy. There was concern among clerks about the maintenance of historical records:

[T]he pages of the registers are being torn out... when you come back, you find that other pages have been removed. – Statistical clerk

Indeed, this was reflected in the DQA, where only 44% of respondents indicated that there was adequate space for the storage of records.

In response to the same concern, a central program manager described information loss and how they helped retrieve lost hospital data.

We used to store [hospital] data, and when they lost their data we brought it back; we can photocopy it and bring it back. –Central program manager

Completeness

At the facility-level, ARI data were missing in the DHIS for an average of 1.2 months (SD 2.1) of the 12-month review period. In total, 9% of months during the 12-month review period were missing ARI data in the DHIS; however, 17% of the facilities reported a value of 0 for at least one month in the same period. In interviews, HMIS Officers indicated that zeros are sometimes used to indicate missing data during data entry but could also mean that there were no cases recorded.

Resource constraints and logistical challenges were reported to affect the timely and complete submission of reports, including HMIS-15. Statistical clerks discussed having to pay out of pocket to transport monthly reports to the district office when they were unable to send the reports by ambulance or other courier. Additionally, there were challenges in submitting reports on time when distance or geographical barriers made the process difficult. Malawi is predominantly rural and health centers are separated from the district health office by mountains, rivers, and/or unpaved roads.

Statistical clerks reported having developed mechanisms for improving the completeness of data recorded in the register, including ascertaining missing age data from the caregiver, verifying that treatment aligned with diagnosis, and asking the clinician to clarify if data were missing or seemed inconsistent. Clerks reported improving completeness of data through follow-up with clinical staff.

Sometimes in my case when I find that the clinician has just written symptoms without diagnosis I take that health passport back to him or her, [and ask] what is the diagnosis here? what do I put in my book? – Statistical clerk

However, efforts to improve data quality varied by facility and by individual. When confronted with missing age data, required to report the number of ARI cases under five, one clerk stated:

At our facility we just leave it out because if it is missing under-five or above-five we don't count it. – Statistical clerk

Data quality improvement activities were not limited to register completion. In one district, the HMIS officer developed a tallying tool to aid in the extraction of numbers for reports from complicated hospital registers.

I design my own data collection tool that helps. I don't have to carry all of the reporting forms... I put each indicator into the data collection tool that I design. It may happen that one indicator may be appearing in different sections [of the facility], so I go in all sections [of the facility] and collect the figures and then I sum them and enter the figure in the report. –Statistical clerk

Despite their efforts to improve data quality, statistical clerks voiced concern that during the busy first days of the month, when they were tallying the previous month's utilization data, completeness of data was impacted:

Our duty is collecting, analyzing, and reporting of data. So when it comes to time for reporting, it means that we are supposed to collect the data as well. It becomes a challenge to collect data as well as to report during the month's end. – Statistical clerk

This was a common concern voiced during the focus groups. Reports are due to the district by the fifth of the following month, which leaves minimal time for quality checking and a heavy workload at the beginning of the month.

The DQA is unable to quantify the magnitude of patients who were never recorded in the register. Patients who present as emergent cases requiring immediate transfer to the hospital or those who present when facilities are short-staffed, when the clerk is tallying registers for the HMIS-15, and at night or on weekends—may not be documented completely, or at all, in health facility registers. Respondents in FGDS reported this quality issue consistently.

During night hours, most clinicians just write [the diagnosis] into the health passport without documenting anywhere, so when you come in the morning, you find nothing. -

Statistical clerk

Consistency across sources

During focus group discussions, participants noted confusion among providers in differentiating ARI and pneumonia during diagnosis and reporting often using the terms interchangeably. Patient data were occasionally recorded without a diagnosis, but with symptoms such as, “cough” or “fever”. Clerks indicated that when diagnosis was missing they sought clarification from clinicians. Statistical clerks were confident in their ability to transcribe patient age, diagnosis, and treatment from the patient’s health passport to the register. They felt that because they were responsible for recording data in the register and the monthly report, consistency between the two documents was high. However, they were less confident that diagnosis was accurately recorded in the health passport by the clinician.

There is ARI and pneumonia-- maybe some of the clinicians don't know how to separate them. I feel like most of them are putting these two things into the category of ARI, rather than diagnosing pneumonia. So lots of the ARI cases must be pneumonia. – Statistical clerk

Health centers reported inconsistently whether ARI and pneumonia cases were aggregated together when completing the reports or if the two diseases were reported separately. During the DQA, we asked health center staff which diagnoses from the register they included as “ARI” when they completed the monthly HMIS-15 report. Results were mixed; 63% of respondents included pneumonia, 48% cough/difficulty breathing, 48% upper respiratory infection, 29% lower respiratory infection, and fewer than 25% included diagnoses of cold, bronchitis, bronchiolitis, sinusitis, epiglottitis, laryngitis, or other conditions when summing ARI cases. When asked about reporting on number of pneumonia cases, a FGD participant indicated:

[I]t is rare to find pneumonia in the registers, we report very little, so ... [my colleague] asks the health center in-charge if there are really pneumonia patients in that particular month and the in-charge told him that he should take the number of ARI cases and add them to pneumonia. -- Statistical clerk

Yet others indicated that the two diseases were reported separately and the tally of ARI cases never included pneumonia cases.

Each disease is given a code and at the end of the month there are numbers from the page summaries... so we just add those numbers to come up with the one number representing ARI in under five. Pneumonia has its own code. – Statistical clerk

In one district, the confusion has been addressed through training, but this training did not appear to have occurred in other districts. There were also specific instances of clinical staff providing guidance on diagnosis and reporting for ARI.

It wasn't me [an HMIS officer] giving the guidelines but the [clinical] coordinator and her deputy. –HMIS Officer

However, this varied by district. Having clinical support for reporting was not commonly reported.

It was noted that clinicians are pressured by patients to provide diagnoses that require antibiotics, further complicating efforts to determine accuracy of reporting.

Most of the time they would give antibiotics. So, in the process of pleasing the mother, the best way is just to say ARI. Because when they write ARI, you go... to see whether they gave the antibiotics or not. -Clinical program manager

Among the 105 facilities with data available for audit during the DQA, the mean number of monthly ARI cases per facility register for March-May 2016 was 380 (SD 466), 527 (SD 647)

from the HMIS-15 report, and 643 (SD 732) from the DHIS-2 system. Despite considerable variability across facilities, on average, there was no difference between the report and the DHIS (mean = 0; range: -780 to 481). The DHIS reflected more cases than the HMIS-15 (mean=-94; range: -1108 to 375). There was minimal variability in differences between sources across months. Figure 2 displays differences in register, report, and DHIS values for the three-month review period.

Consistency over time

In a review of DHIS data from the twelve months preceding the DQA, the mean number of ARI cases among children under five was 218 (SD 264). Of the reported data, 5% were moderate outliers and 2% were extreme outliers. Fluctuations in number of cases were consistent with the expected seasonal variation in disease burden. Indeed, statistical clerks used seasonal variation to informally validate ARI data and expected seasonal variation in the numbers that they reported.

Sometimes [ARI cases] increase or decrease, it depends on the season... – Statistical clerk

Clerks also discussed the role of external factors in influencing reporting over time. Statistical clerks noted that clinicians' attendance at a refresher training in diagnosis of childhood illness changed the clinicians' recording of diagnoses in the health passport.

[C]urrently we are not having much ARI... 'cause it was seen that there was a combination [of ARI and pneumonia] before [an IMCI refresher training]. Some clinicians were combining cough, some cough and breathing, some cough and fever, and taking it as ARI. Since they attended the trainings, there has been a drop in cases of ARI. It's like they were not differentiating between pneumonia and ARI.- District HMIS Officer

This IMCI training was not held in all districts. Statistical clerks did not receive training on updated diagnosis and reporting practices, which led to confusion about tallying when clinicians returned from training. The DQA did not detect any systematic change in the number of reported ARI cases following the training.

Data use

MOH staff reported that data use affects data quality and perceptions of data quality influence use. Although data are entered into the DHIS by a team of HMIS officers based at the district health office, use of the ARI data at the district level is limited. ARI cases are collected in the HMIS-15 report, and responsibility for presentation of the HMIS-15 data lies with the HMIS Officer. No HMIS Officer reported that they routinely graphed or otherwise considered the number of ARI cases or shared the data during monthly district health medical team meetings. The Emergency Triage Assessment and Treatment coordinators, who oversee ARI care at the district, focus on inpatient pneumonia data from the hospital, with a primary emphasis on patient outcomes. They do not regularly look at ARI diagnosis burden data from the health centers.

At the national level, MOH staff reported that there is minimal use of the ARI DHIS data because of limited availability of staff to review and interpret data, challenges accessing the DHIS, perceptions of poor quality of data, and the limitations of the available data, namely that DHIS data are focused on counts of children diagnosed and the program is interested in outcomes. District-based Emergency Triage and Assessment (ETAT) coordinators submit data on patient outcomes and quality of care for patients hospitalized with pneumonia and ARI. The national ARI program relies heavily on these data, not on DHIS, to understand what is going on in the districts. Program managers from child health programs expressed concerns about using the routinely collected data from the DHIS because it is not verified or checked for quality concerns.

This other data [DHIS], hasn't been verified, so it is difficult to trust. -Clinical program manager

Discussion

ARI data are available, complete, and consistent over time, however, there were discrepancies between sources, specifically the DHIS and register, indicating problems with data quality. DHIS data are an accurate reflection of data recorded on monthly reports, but DHIS values are higher than those obtained during our register review.

Data collectors and users expressed concern regarding the accuracy of the data and its ability to correctly quantify cases and distinguish pneumonia and ARI. Additionally, we identified systemic challenges to the reporting of quality data: limited resources for transportation of forms, a heavy reporting burden, and minimal use of the data. Given the potential uses of the DHIS data for resource allocation, planning, evaluation, and research, it is important to understand these quality limitations and address them.

The challenges we found in reporting on cases of ARI in children under five are not unique to this particular indicator, but are more pronounced than for other metrics (O'Hagan et al., 2017). In addition to assessing ARI, the DQA examined discrepancies across data sources for counts of positive HIV tests and dispensed injectables for family planning. Both indicators were found to be consistent across register re-count, monthly reporting form, and DHIS, although they had similar challenges with report availability and document storage (O'Hagan, 2017).

Our assessment found that routinely available electronic ARI data in the DHIS overestimate the number of ARI cases relative to the register. Data quality challenges could reasonably be largely attributable to diagnostic ambiguity and its impact on aggregation. Aggregation requires determining which conditions “count” and tallying across pages in a register. Clinically, it is difficult to differentiate pneumonia, a specific condition, from other ARIs, a more general disease category. Pneumonia is a subset of ARI, a diagnosis that also encompasses upper respiratory infection, lower respiratory infection, cold, bronchitis, bronchiolitis, sinusitis, epiglottitis, and laryngitis (Feikin, Hammitt, Murdoch, Brien, & Scott,

2018, Malawi Ministry of Health). With limited diagnostic capacity in Malawi, children presenting at health facilities may be identified as having ARI, pneumonia, or another respiratory infection. District staff reported this diagnostic ambiguity, and attributed it to inconsistent practices in defining ARI for the register.

Our results were consistent with findings from studies conducted in other settings to assess quality of HIS data across disease conditions and clinical areas. A study of HIV data in two districts in South Africa found that differences between register and report were larger than those between report and DHIS (Nicol, Dudley, & Bradshaw, 2016). Similarly, Nicol and colleagues identified collation, referred to as aggregation in this study, as a major challenge. In Kenya, the quality of antenatal care data varied by facility and service (Hahn et al., 2013). In Zambia, researchers identified limited use of data from HIV and condom programs as a challenge (Munthali et al., 2017).

Limitations

This study has some key limitations. Employing mixed methods allowed us to identify and explore data quality issues more fully; we used the qualitative data to contextualize the quantitative findings, but because we collected DQA and qualitative data concurrently, we missed the chance to inform the quantitative DQA data collection instrument with the qualitative findings. In particular, if the qualitative analysis had been conducted first, we would have included questions in the DQA to explore the aggregation process more fully and systematically. While the staff members of these two studies communicated during the data collection period, modification of quantitative tools was not possible or advisable after DQA data collection started. Nonetheless, we were able to use early findings from the quantitative study to inform ongoing qualitative data collection. Despite these limitations, our results are strengthened by the triangulation of and similarities between the quantitative and qualitative findings. The results

from the quantitative and qualitative activities both indicate that data collection processes, especially disease definition and aggregation, are the areas of greatest concern for ARI data.

Ensuring rigor

We took steps to ensure rigor throughout the design, data collection, and analysis phases of this study. Following each FGD and IDI, the research team debriefed. This included a discussion of the most salient points of the data collection, an opportunity to contrast the findings with other data collection activities, and a time to reflect upon the data collectors' perspective and biases. We attempted to limit the use of jargon during data collection and asked respondents to define "data quality" during all interviews and focus groups to help minimize bias in interpretation of results. We improved the credibility of results by debriefing with national CMED staff and validating our findings early in the analysis process. Triangulation of our quantitative and qualitative results was an important part of the analytic process.

Conclusions

Based on our findings, we recommend that Malawi's Central Monitoring and Evaluation Division (CMED) take the following action:

1. Provide reference documents that offer guidance for the recording of diagnoses, especially of conditions, like ARI, which may be an umbrella term for a series of illnesses. Clinicians could be encouraged to use standard diagnoses for the most common illnesses using a list of possible diagnoses rather than the free text box of the health passport, which must then be translated to a standard diagnosis by clerks without clinical training. CMED should provide universal guidelines on how to count diagnoses for routine reporting to limit the influence of diagnostic ambiguity.
2. Support data collectors in the aggregation process through the development of daily or weekly aggregation sheets, which can then be summed at the end of the month for use completing the monthly report. For high-burden indicators, like number of children diagnosed with ARI in a month, this will reduce the burden of monthly aggregation.

3. Support those facilities that have challenges with reporting— because of distance from the central office, lack of supplies, or infrastructure – through targeted funding or prioritization when additional funding becomes available.
4. Implement regular quality monitoring by trained in-charge nurses to identify data quality issues early in the reporting process, before data are reported from health facilities to districts.
5. Implement regular, periodic data quality assessments that include data verification on a range of indicators. Post results of the assessments on DHIS or another publicly available platform so that users can quantify and account for the quality of available data in their analyses. The findings of these assessments would complement the data quality application built by the WHO for the DHIS, which assesses completeness and consistency of data already in the DHIS as a desk review, but cannot account for problems earlier in the data collection and reporting pathway (Haugen et al., 2017; Health Information Systems Programme (HISP), 2018). The assessments could help to identify districts and facilities most in need of targeted support as outlined in the third recommendation (see above).

Improving quality and sharing the results of data quality audits will ultimately encourage data use, leading to a virtuous cycle of improved data quality and increased data use. Although we identify areas of intervention to improve the quality of ARI data, the changes described above will strength the HIS as a whole. Some recommended changes are specific to ARI data collection and reporting, while others are relevant for all HIS activities. These recommendations are summarized in Figure 3.

Results from this mixed methods assessment can help CMED improve the quality of ARI data in DHIS-2, but they can also help potential users decide whether and how to use these data to elucidate trends and inform program improvement. The ARI data stored in Malawi's DHIS2

system are updated monthly, do not require additional data collection and, despite challenges with consistency across sources, are consistent over time. Further research is needed to develop and implement ways to account for the data quality issues identified in the analyses. But despite remaining challenges, DHIS-2 remains a rich source of continuous, on-demand, nationally representative, facility-level data. With adjustment for quality issues, these data should be used for research and program evaluation to inform how and where programs are implemented and ultimately to improve the health of populations.

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Tables and Figures

Figure 1. Districts selected for inclusion in the quantitative DQA and qualitative assessment
Districts shaded in dark blue were selected for inclusion in the DQA only; districts shaded in light blue were selected for qualitative data collection and the DQA.

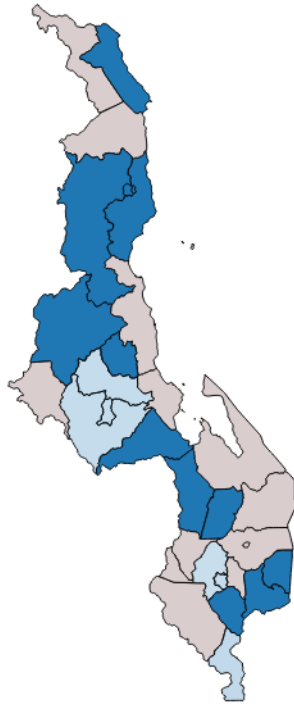


Table 1. Qualitative analysis themes and codes

Major theme	Sub-theme	Codes
Quality	Availability	Physical space Source documents DHIS
	Completeness	Innovation Logistics Systems challenges Information loss
	Consistency across sources	ARI vs pneumonia Innovation to improve data quality
	Consistency over time	Change in process Training Form or document change
Data use	Barriers	Data quality perception Parallel reporting DHIS
	Facilitators	

Table 2. Description of quantitative and qualitative study population

	N	%
<i>Quantitative sample</i>		
Districts	16	
Facilities		
Health center	90	84.9%
Hospital	16	15.1%
Location		
Urban	4	3.8%
Rural	102	96.2%
ARI cases	218 (SD 264)	
<i>Qualitative sample</i>		
Districts	4	
Data collection activities		
FGDs (groups)	4	
FGDs (participants)	46	
IDI with district-based HMIS officers	4	
IDI with central-level MOH staff	6	
Male (IDI and FGD participants)	43	76.8%
Years experience (FGD only)	4.5 (SD)	

Table 3. Measures of quality and methods for the quantitative analysis

Measure of quality	Method of assessment	Source
Availability	Availability of register and HMIS-15 report at health facility and district, March-May 2016	DQA
Completeness	Percentage of facilities reporting ARI and pneumonia data for 12 months preceding DQA	DHIS review
Consistency across sources	Comparison of register recount with HMIS-15 report and DHIS value, March – May 2016	DQA
Consistency over time	Moderate (+/-2-3SD) and extreme values (+/- >3SD) for 12 months preceding DQA	DHIS review

Figure 2. Number of ARI cases in children under 5 across data sources for March-May 2016, by facility

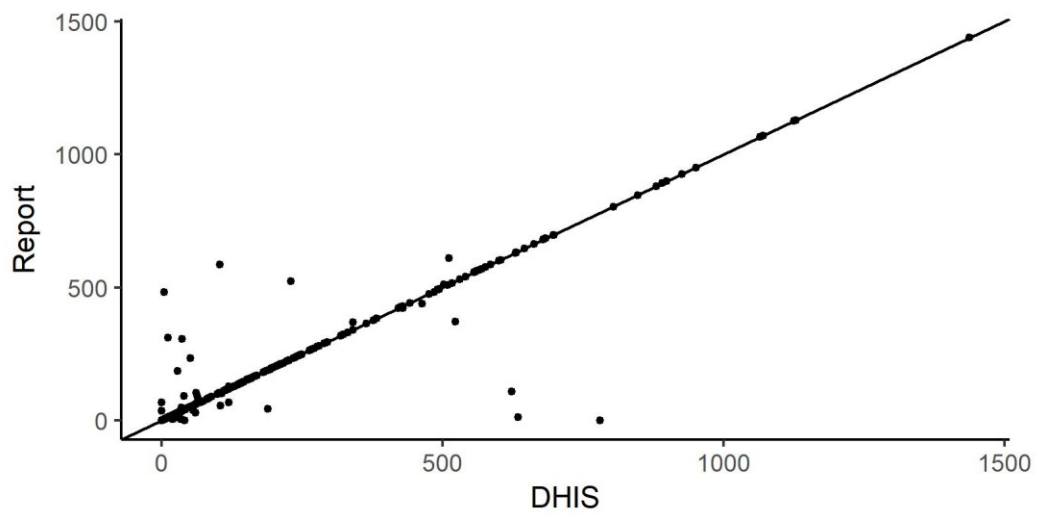
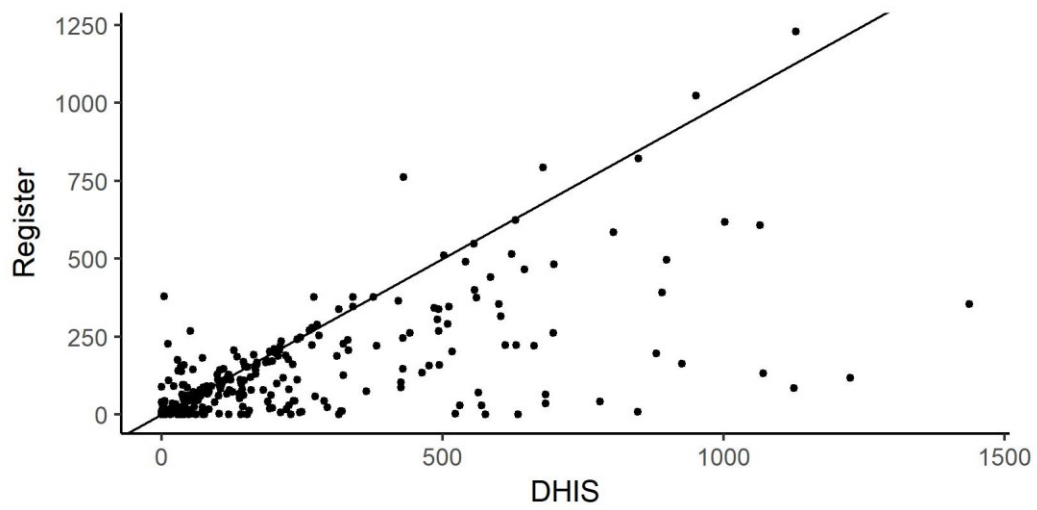
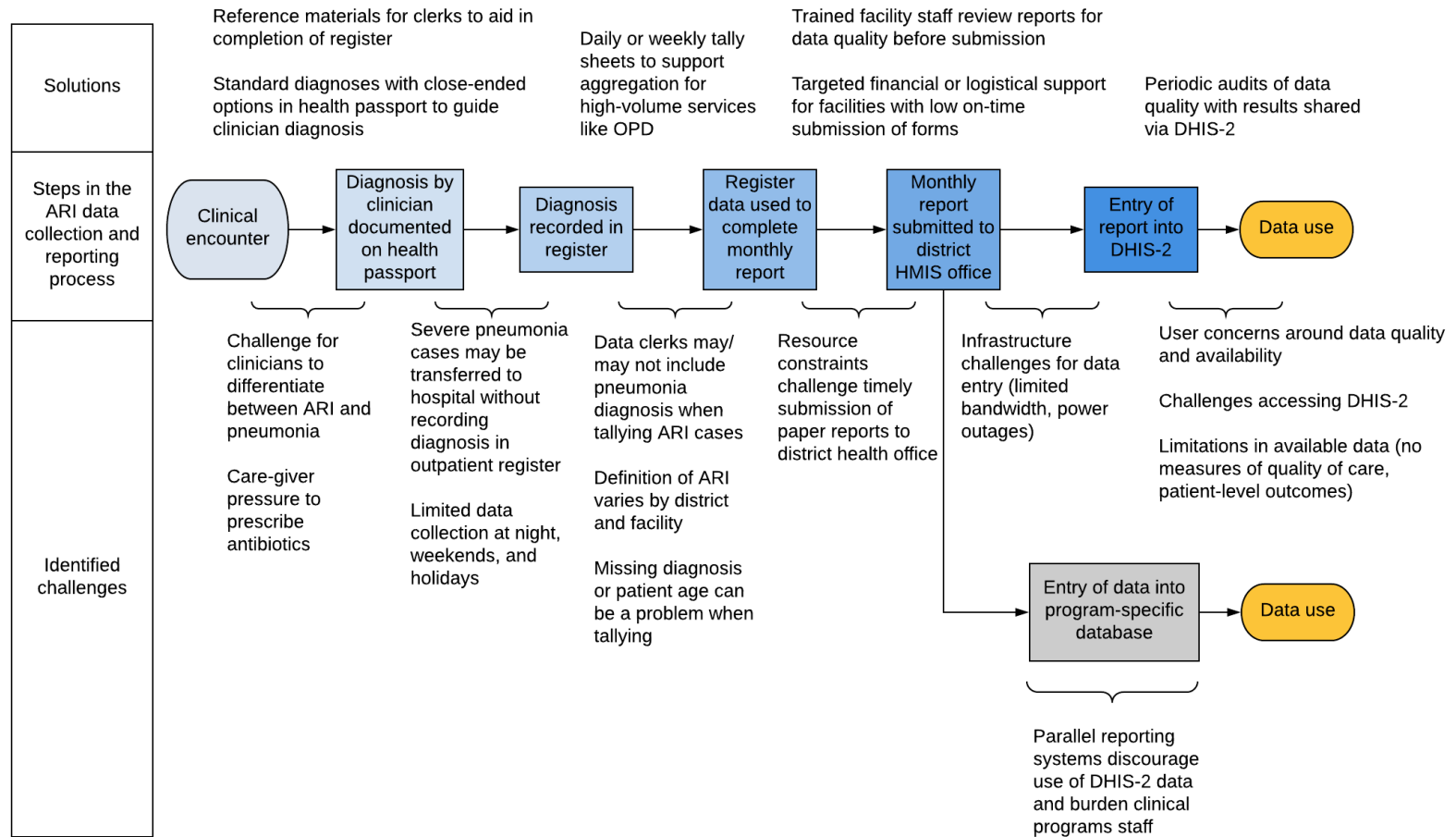


Table 4. Summary of data quality findings from quantitative and qualitative analysis by World Health Organization data quality metric

Measure of quality	Quantitative results	Qualitative results
Availability	Availability of resources at time of audit: 97% of OPD registers 77% of HMIS-15 reports 16% of facilities had no HMIS-15 reports	Register and report availability bolstered by partner support Limited storage for maintenance of historical records
Completeness	91% of all monthly ARI indicator data available in DHIS 17% of facilities reported a 0 value for at least one month	Patients not entered into register when they arrive at night Urgent cases transferred by ambulance without record Report submission constrained by limited resources
Consistency over time	5% of monthly reported number of ARI cases were moderate outliers, 2% were extreme outliers	Training for staff in childhood illness protocol changed diagnosis patterns for ARI
Consistency of ARI reporting across sources	Register recount: 380 (SD 466) cases Report summaries: 527 (SD 647) cases DHIS: 643 (SD 732) cases	ARI and pneumonia may be conflated when reporting on conditions and guidance is not uniform across districts

Figure 3. Factors influencing quality of ARI data along the data collection and reporting pathway with proposed recommendations to improve the quality of ARI data



Chapter 4. Using routine data to estimate pneumonia incidence at the district level

Karen E. Finnegan, Melissa A. Marx, Normal Lufesi, JiSoo Kim, Emily Wilson, Patrick Naphini, Amos Misomali, Mercy Kanyuka, Scott Zeger

Abstract

Globally, pneumonia is a leading cause of death among children under five. There is limited information on pneumonia incidence at a sub-national level for all districts or regions of a country; most estimates of incidence are informed by global modeling activities, which result in national incidence estimates, or by vaccine studies and small-scale research projects that are time-limited and cover only a small area of a country. Lazzerini et al documented a decline in the case fatality rate among hospitalized pediatric pneumonia cases in Malawi, but there remain gaps in understanding disease incidence in the community. We used Malawi's routine health data to estimate monthly district-level pneumonia incidence from 2012-2015.

To estimate pneumonia incidence we use diagnosis counts from the District Health Information System (DHIS-2), care-seeking for suspected pneumonia from the Malawi Demographic Health Survey, and district under-five population estimates from the 2008 Malawi Census. We combine these available data using Bayesian estimation methods that integrate multiple sources of information while accounting for uncertainty in their estimates.

We estimate community-level pneumonia incidence to be 66.5 per 1,000 (SD: 23.2 per 1,000) across Malawi's 28 districts in June 2015. Pneumonia incidence varies over time and by district; seasonal variation is evident in the routine data.

We demonstrate that available routine data can be used to estimate pneumonia incidence at the community-level, producing a result that is consistent with other estimates of disease burden in Malawi and sub-Saharan African countries. Our methods may be applicable to other diseases or conditions captured in the DHIS-2. With continuous, sub-national estimates of

pneumonia incidence, the Government of Malawi can better allocate resources and identify possible epidemics.

Introduction

Pneumonia was a leading cause of death among children under five and the leading cause of death among children under five in the World Health Organization's (WHO) Africa region in 2015 (Liu et al., 2016). Globally, pneumonia was responsible for 13% of deaths in children 1-59 months in 2015 and 3% of neonatal deaths; this translates into an estimated 920,000 deaths due to pneumonia in 2015 (Liu et al., 2016).

The WHO estimated pneumonia incidence to be 0.22 cases per child-year in low- and middle-income countries (LMICs) in 2010 (Rudan et al., 2013). In WHO's Africa region, pneumonia incidence was estimated to be 0.27 cases per child-year for the same time period (Walker et al., 2013). Despite the prevalence of pneumonia and its global disease burden, disease incidence is rarely reported by country or sub-nationally. Estimates of pneumonia incidence, like those from WHO, draw from global models of disease burden to generate country-specific estimates, and do not produce sub-national estimates of incidence (Barendregt, Van Oortmarssen, Vos, & Murray, 2003; Kovacs et al., 2015; Walker et al., 2013). Sub-national estimates of pneumonia incidence are often drawn from clinical studies of vaccine effectiveness, which may be limited in geographic scope and time (Rudan et al., 2013). Clinical trials may provide incidence estimates for a handful of districts, for a finite period of time, minimizing the utility of the data for sub-national comparisons and trend analyses.

In response to this dearth of accessible sub-national data, Campbell and Nair called for better estimates of community-level disease incidence in their commentary about the persistent burden of pneumonia and lack of high quality community-level data (Campbell & Nair, 2016). Existing studies on pneumonia incidence and prevalence in Malawi are limited in geographic

scope, service provision level, and time (Cox et al., 2017; Lazzarini et al., 2016; McCollum et al., 2017).

Globally, there is increasing interest in the potential of Health Information Systems (HIS) data for research, evaluation, and planning (Bennett et al., 2013; Gloyd, Wagenaar, Woelk, & Kalibala, 2016; Ngabo, Gatera, Karema, & Donnen, 2014; Wagenaar, Sherr, Fernandes, & Wagenaar, 2015). Although the quality of HIS data varies by country and disease area (Gimbel et al., 2011; Hedt-gauthier et al., 2012; O'Hagan et al., 2017; Yourkavitch, Zalisk, Prosnitz, Luhanga, & Nsona, 2016), pneumonia-related ARI data in Malawi are routinely collected, consistent over time, and accessible (Finnegan et al., 2017). Recent work in the field of malaria has explored the use of routine data to create comprehensive sub-national estimates of incidence, but this work has not expanded beyond this single clinical area (Bennett et al., 2013).

Since 2007, all public sector facilities in Malawi have been required to submit monthly aggregated counts of services using standard Ministry of Health reporting templates. These data include the number of children under-five diagnosed with suspected pneumonia and acute respiratory infection (ARI) during the review month. Additionally, facilities submit reports on activities of health surveillance assistants (HSAs) who are associated with the facility. HSAs report monthly on the number of children diagnosed with suspected pneumonia based on presentation with cough, difficulty breathing, and fast breathing. These aggregated data have been entered into an electronic database since 2007; the country transitioned to DHIS-2 in 2011. Although these data are subject to misdiagnosis, misclassification error, incompleteness, and other challenges of routine data (Finnegan et al., 2017; Gloyd et al., 2016), DHIS-2 data are available on an ongoing basis and do not require additional funding for collection or access. Diagnosis of pneumonia in Malawi is based on WHO Integrated Management of Childhood Illness (IMCI) guidelines and is not radiographically confirmed (Kalu, Lufesi, Havens, & Mortimer, 2016).

The Malawi Demographic and Health Survey (MDHS), is a population-based household survey which contains information on care-seeking for symptoms of possible pneumonia. Collected every two to five years, MDHS data are only available periodically, but provide national and sub-national estimates of intervention coverage. Although subject to issues of caregiver recall bias and difficulty recognizing symptoms of pneumonia, they are widely used as the best available measure of care-seeking (Bryce et al., 2013; Campbell et al., 2015; Luque, Whiteford, & Tobin, 2008; Noordam, Carvajal-Velez, Sharkey, Young, & Cals, 2015; Tuhebwe, Tumushabe, Leontsini, & Wanyenze, 2014).

In this manuscript we describe and explore trends in pneumonia incidence among children seen at primary care facilities or by community-based health workers, using readily available secondary data sources.

In the general methods section below, we will give an overview of our methods. In the methods subsection titled “Data sources and estimating approach” we will review the data included in our model. As we discuss each data source, we will describe the analytic approach required to prepare the data for inclusion in the final model. As a final step, we will describe the process of estimating the posterior distribution of district-level pneumonia incidence. In the “Results” section, we will review the findings from each of our analytic steps and our outcome of interest, pneumonia incidence. We check our model using available data on seasonal rainfall patterns, an important predictor of pneumonia incidence. In “Discussion”, we discuss the limitations, and review the implications of this work for district-level analysis of pneumonia incidence and consider how this work transforms routine data into a usable format for epidemiologic research and impact evaluation.

Methods

To estimate pneumonia incidence, we combine multiple sources of available data and literature summaries, each of which has specific strengths and limitations. We start with routine data. To address limitations associated with data quality, we impute missing DHIS-2 values and

adjust ARI case counts by a misdiagnosis rate drawn calculated from the literature. We account for the uncertainty in the misdiagnosis rate. We acquire district-level care-seeking for symptoms of pneumonia from the Malawi Demographic and Health Survey (MDHS) and use Empirical Bayes estimation methods to shrink estimates toward a regional mean, gathering information from neighboring districts to improve our estimates. We combine these data using Bayesian estimation methods to approximate the posterior distribution of monthly pneumonia incidence for each of Malawi’s 28 districts. We use these Bayesian estimates of ARI visits, and care-seeking behavior, combined with under-five population—to estimate monthly pneumonia incidence among children under-five, conditional on our observed count data (Carlin & Louis, 2000; Gelman et al., 2014; Gelman & Hill, 2007).

Data sources and approach to estimation

To fit our model, we first conceive of a deterministic model that assumes all variables are known with certainty, the number of pneumonia diagnoses in children under-five in a given month in a specified district is a function of those who are correctly diagnosed with the disease at the facility or community (true positive) and those who are misdiagnosed (false positives). The true positives are a function of the disease incidence (π_{ij}), care-seeking for symptoms of pneumonia ($CARI_{ij}$), and the under-five population (N_{ij}). False positives are a function of the rate of misdiagnosis (OC_{ij}), specified below as a proportion of the total children diagnosed with pneumonia. This relationship can be represented by the following equation:

$$\mu_{ij} = (\pi_{ij} * CARI_{ij} * N_{ij}) + (\mu_{ij} * OC_{ij}).$$

To solve for pneumonia incidence among children under-five in a given district for a given month (π_{ij}):

$$\mu_{ij} - (\mu_{ij} * OC_{ij}) = (\pi_{ij} * CARI_{ij} * N_{ij})$$

$$\pi_{ij} = \frac{\mu_{ij} - (\mu_{ij} * OC_{ij})}{CARI_{ij} * N_{ij}}$$

$$\pi_{ij} = \frac{\mu_{ij} * (1 - OC_{ij})}{CARI_{ij} * N_{ij}}.$$

That is to say, incidence is the ratio of the number of true cases diagnosed in the health system divided by the population that seeks care. The former equals the children diagnosed with pneumonia in a given district for a given month, reduced by the fraction of false positives. The denominator is the total population multiplied by the fraction that seeks care.

We used data on facility diagnoses of ARI in children under-five from Malawi's DHIS-2 and care-seeking information from periodic household surveys to estimate annual district-level pneumonia incidence in children under-five adjusted for care-seeking behavior. We used a Bayesian approach to integrate the multiple sources of information to estimate the incidence and its uncertainty. For each of the unknown quantities, we used available data and then estimated the quantity and its approximate posterior distribution. We assumed that each unknown comes from independent data sources and that the joint posterior distribution is equal to the product of the posterior distributions as defined below. Below, we detail the estimation of our parameters.

ARI diagnosis (μ_{ij}):

To estimate ARI diagnoses, we used the number of children under-five diagnosed with acute respiratory infection at the facility or by community-based health surveillance assistants from January 2012 through December 2015 from the DHIS-2. Our analysis focused on the 2012 to 2015 time period because data completeness varied considerably before DHIS-2 implementation.

We used existing DHIS data to impute missing values using a quasi-Poisson model (details in Appendix) and calculated a smoothed curve of monthly, district-specific number of children diagnosed with ARI. We assumed that μ_{ij} is the expected district-specific number of children diagnosed with ARI and estimated μ_{ij}^* , a simulated value drawn from a Poisson distribution which varies around μ_{ij} .

We adjusted μ_{ij}^* for under or over-reporting of ARI using a verification ratio (VR_i) estimated from a data quality assessment conducted and reported separately (O'Hagan et al., 2017). VR_i is the ratio of reported number of ARI cases in the DHIS-2 and the number obtained during a register audit during the 2016 data quality assessment. VR_i is a constant value and varies by district.

Care-seeking given ARI symptoms ($CARI_{ij}$):

We used data from the Malawi Demographic Health Survey (MDHS) from 2010 and 2015 to estimate district-specific monthly care-seeking for symptoms of ARI. Data were based on caregiver's report of whether their children exhibited signs of pneumonia (cough and/or difficult breathing) in the two weeks preceding the survey and if they sought care (Malawi National Statistics Office and ICF Macro, 2011; National Statistical Office (NSO) & ICF, 2017).

To estimate a district-specific monthly rate of care-seeking by children under-five with pneumonia symptoms despite small sample sizes in smaller geographic regions, we used Empirical Bayes estimation methods (Carlin & Louis, 2000). By using Empirical Bayes estimation to combine district-level data with region-level data, we obtain district-specific estimates that minimize the aggregate error across all districts. When there are fewer data in a district, we rely more heavily on the regional data. This method trades off variability in the estimate from small numbers with bias from borrowing data from larger regions.

We estimated care-seeking given caregiver recognition of pneumonia symptoms using the 2010 and 2015 MDHS data and assigned the care-seeking estimates to the first month of

MDHS data collection. We then estimated a monthly rate of care-seeking between surveys by calculating a linear slope between points sampling from a Gaussian distribution to mimic likely variation in care-seeking from month-to-month. This produced a simulated value, $CARI_{ij}^*$, for each district for each month.

Other care-seeking (OC_{ij}):

We incorporated an estimate of the proportion of children incorrectly diagnosed with pneumonia after presenting with non-specific symptoms of other childhood illnesses. This estimate was derived from a review of the literature where estimated rates of misdiagnosis of pneumonia among children with other common childhood illnesses ranged from 23.0% to 5-6% (Druetz et al., 2015; English et al., 2003). The MDHS estimated that 29% of children had fever in the two weeks preceding the survey (National Statistical Office (NSO) & ICF, 2017) and malaria prevalence was estimated to be 33% in 2014 (National Statistical Office, 2014; Zgambo, Mbakaya, & Kalembo, 2017). Care-seeking for these conditions may lead to incorrect diagnosis of pneumonia as there is overlap in clinical presentation.

We estimated that the mean rate of misdiagnosis (OC_{ij}) was 10% and allowed OC_{ij} to vary, following a beta distribution with parameters 1, 9. We estimated OC_{ij}^* 1000 times to use in the integrated estimate of pneumonia incidence as described below. The beta distribution is a common choice for describing the uncertainty or variation in rates defined on the interval (0,1). This estimation of OC_{ij}^* reflects that incorrect diagnosis may vary across facilities and over time, depending on prevalence of other illnesses and capacity of staff to correctly diagnose ARI.

Under-five population (N_{ij}):

We used the under-five population from the 2008 Census obtained from the National Statistical Office (NSO) (National Statistical Office, 2008). We estimated the monthly district-specific population using Malawi's annual district population estimates, assuming linear growth

over time. We assumed that the under-five population was a known value without uncertainty in the monthly population. See the appendix for population data by district.

Incidence of pneumonia (π_{ij})

We estimated the monthly district-level incidence of pneumonia in children under five 1,000 times using Equation (1) above where the simulated values were specified as defined in the steps above. A summary of the estimation process is in Table 1. We arrived at district-level estimate of the posterior distribution of pneumonia incidence. Our final model is specified below:

$$\pi_{ij}^* = \frac{\mu_{ij}^* - (OC_{ij}^*)}{N_{ij} * CARI_{ij}^*}$$

We simulated this estimation 1,000 times per district and obtained a mean monthly estimate of incidence for each district. We allowed the parameters of care-seeking ($CARI_{ij}^*$) and misdiagnosis of pneumonia when children have other illnesses (OC_{ij}^*), to vary according to set parameters, as described above. We sampled the number of children diagnosed with pneumonia (μ_{ij}^*) from a Poisson distribution. We calculated incidence for each district separately.

Results

The DHIS-2 included data on 893 unique facilities that reported between January 2012 and December 2015; we removed the 87 hospitals to limit our analysis to diagnosis at community and primary care sites. We then removed an additional 231 facilities that did not provide ARI diagnosis and treatment; this exclusion was based on guidance from Ministry of Health staff. Removing these facilities, which included dispensaries and military and police facilities, resulted in 575 facilities providing data for our analysis. Data from the 575 remaining facilities from across Malawi's 28 districts (average of 20.5 facilities per district (IQR 12)) were included in this analysis.

Facilities provided primary care for children and adults and reported an average 1985.8 (SD 2014.7) outpatient visits per month during the study period (January 2012-December 2015).

Facility staff diagnosed a mean of 161.9 (SD 215.6) cases of ARI per month and community-based HSAs affiliated with the facility diagnosed a mean of 132.9 (SD 466.1) cases during this period. After adjustment for missing data, a mean of 4157.3 ARI cases (SD 3751.2) were diagnosed at facility and community per month per district. The mean number of cases reported varied over time and by season (Figure 1).

In 2010, we estimated that on average, across districts, 74.4% (SD 6.7%) of children sought care for cough or difficulty breathing. Over the study period, care-seeking ranged across districts from 51.3% to 86.5% (Figure 2).

In 2012, Malawi's total under-five population was an estimated 2.7 million. Over time, the under-five population increased by approximately 2.9% per year, as estimated by the National Statistical Office. District under-five population ranged from an estimated 1,500 in Likoma, an island in Lake Malawi, to more than 400,000 in Lilongwe in 2015.

We estimated mean community-level prevalence of ARI (total number of ARI cases reported by facilities and HSAs divided by under-five population) to be 35.1% (SD: 13.5%) in 2012 across Malawi's 28 districts. In 2015, we estimated mean prevalence to be 56.4% (SD: 15.9%). From 2012 to 2015, mean prevalence increased by 21.3%.

The mean monthly incidence of pneumonia in children under five was estimated to be 55.4 per 1,000 (SD 25.3 per 1,000) from January 2012 to December 2015, based on 1,000 replications per district. There was variability in estimates of incidence across districts and over time. Mean incidence was estimated to be 43.1 per 1,000 (SD 30.3 per 1,000) in January 2012 and 60.4 per 1,000 (SD 30.1 per 1,000) in January 2015. Community-level pneumonia incidence was 66.5 per 1,000 (SD: 23.2 per 1,000) in June 2015. Estimates of incidence increased slightly over time, and demonstrated a seasonal pattern of increasing incidence during rainy season (approximately January-April) (Figure 4).

Figure 5 displays mean estimated incidence by district over time and the uncertainty in our estimate. Mean incidence is highest in districts in the central region, although there is variability across districts. There is seasonal and geographic variation in pneumonia incidence.

Discussion

This paper describes a rigorous approach to using available routine data alongside other reliable sources to estimate pneumonia incidence. We use statistical methods to address the limitations of available data and create a credible estimate of monthly district-level pneumonia incidence. Our estimate is 66.5 (SD: 23.2 per 1,000) community-level pneumonia cases per 1,000 children across Malawi's 28 districts in June 2015, an increase from June 2012 when pneumonia incidence was estimated to be 38.0 per 1,000 (SD: 17.6 per 1,000). The data show the expected variability in pneumonia incidence over time and by season. Additionally, with these methods we were able to show variation in pneumonia incidence by district and over time.

Our study fills the gap left by clinical studies, which have so far been the main source of pneumonia estimates globally and for Malawi. We complement the Lazzerini study that identified declining pneumonia case fatality rate and included only hospitals in Malawi (Lazzerini et al., 2016). Using data from that study (provided by Tim Colburn via personal communication), we added the number of hospital cases to our community and facility counts, and calculated 34.4% prevalence (SD 13.2%) of pneumonia among children under five in 2012 across 23 of Malawi's 28 districts. These results are consistent with a study in one district in Malawi where they reviewed child health passports to estimate the prevalence of acute respiratory infection and found the annual prevalence of ARI to be 32.6% over a one-year study period (Cox et al., 2017). We limit our analysis to pneumonia, and Cox et al estimate the prevalence of ARI, so our findings may overestimate pneumonia incidence. However, Cox estimated prevalence for 2014; we are only able to calculate prevalence for 2012 due to data availability, which may contribute to the difference in our estimates. We calculate pneumonia prevalence by assigning pneumonia cases to the district of treatment; it is possible that severe pneumonia cases seek care at a hospital

in a neighboring district and are incorrectly attributed in our estimate which may also contribute to an overestimation of prevalence. McCollum et al estimated the impact of PCV-13 in two districts in central Malawi and found that incidence was highest in January to February 2013, July 2013, and March 2014 (McCollum et al., 2017). These peaks coincide with rises in incidence in our data (Figure 4). Additionally, McCollum et al study found a 45% increase in the number of pneumonia cases when comparing January to June 2012 with January to June 2014; we found an increase of 80% in number of cases for the same time period across Malawi. McCollum et al calculated incidence at all levels of the health system, including both hospital and community diagnoses.

A study in South Africa estimated the incidence of severe pneumonia to be 20.7 per 1,000 children under five prior to pneumococcal vaccine implementation and 5.4 per 1,000 following implementation (von Mollendorf et al., 2015). It is estimated that severe pneumonia account for approximately 6-12% of all pneumonia cases (Rudan, Tomaskovic, Boschi-Pinto, & Campbell, 2004). Our study examines incidence in Malawi after pneumococcal vaccine implementation only and finds rates roughly ten times higher than the study in South Africa, consistent with our inclusion of both severe and non-severe pneumonia in our incidence estimation.

There has been increasing interest in using routine data for monitoring, evaluation, and research. Concern about data quality has historically been cited as the primary reason for not using HIS data for these applications (Gloyd et al., 2016). Nevertheless, some people have tried. In Rwanda, researchers determined that diarrhea data from health facilities could be used to determine the impact of the introduction of rotavirus vaccine on diarrhea (Ngabo et al., 2014). Researchers in Zambia used facility counts of malaria diagnoses to estimate the impact of the malaria national control program (Bennett et al., 2014). This analysis included a variable that measured proportion of facilities reporting each month, an important metric of data quality. Indeed, much of the research into using routine data for research and evaluation has used malaria

data (Ashton et al., 2017). Our work expands the clinical areas in which routine data has been used for applied epidemiologic research and included a measure of data quality.

It is important to consider the limitations of this analysis. Pneumonia, more than other childhood illnesses, is plagued by diagnostic uncertainty. The diagnosis of pneumonia is based on symptoms at presentation and caregiver recall, not laboratory or radiography confirmation (Clancy, 2016; Feikin, Hammitt, Murdoch, Brien, & Scott, 2018; Rudan et al., 2013; Scott et al., 2012). This diagnostic uncertainty was identified during mixed methods research of collection and use of ARI data in Malawi (Finnegan et al., 2017). We address this in two ways in this analysis: 1) we adjust our estimate using a verification ratio, a value which compares the number of reported ARI cases with the number of identified pneumonia cases based on record review (O'Hagan et al., 2017); 2) we include information on misdiagnosis rate, drawn from values in the literature, in our model. Including information on data quality lends strength to the estimate of the number of ARI cases as reported in the DHIS-2; however, we assume that our assessment of data quality is representative of the entire study period. One of the main strengths of this analysis is the use of available and accessible data, however, a DQA does require primary data collection if not already implemented as part of routine health sector activities. Routine data are also limited in their use for individual-level analyses. Because routine diagnosis data are reported as counts, we are unable to track individual children over time, and cannot report outcomes which require longitudinal follow-up of individuals, such as cases per year and case fatality rate.

Our analysis estimates district-level monthly pneumonia incidence, although some of our data are available at a more granular level. To apply similar methods to sub-district geographic units, a researcher or policy maker would need to consider methods relevant for small area estimation. We touch upon these methods with our estimation of $CARI^*_{ij}$, but they are not fully explored in this work. Application of this analysis method to small geographic units should be approached with caution.

The analytical methods used to analyze these routine data are complex. Substantial statistical support would be required to support monitoring and evaluation officers in LMICs to conduct similar analyses. It is likely that more simplified analyses can be useful for countries, even if some there is some loss of validity in results. More research is needed to identify the optimal mix of rigor and simplicity for the field.

The similarity in estimates between these comprehensive but resource-intensive studies and our analysis of routine data demonstrate that routine data can be a reliable source for estimation of disease incidence. However, there is a need to validate this method in other settings, using other diseases or conditions, and over time.

By estimating monthly district-level pneumonia incidence, we provide the Government of Malawi with information needed to improve the health of children under-five. With better, more available information, the Ministry of Health is able to target the allocation of resources, and identify and respond to an epidemic.

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Tables and Figures

Figure 1. Estimation of pneumonia incidence, an unknown quantity, using available data

$$\pi_{ij}^* = \frac{(\mu_{ij}^*) * (1 - OC_{ij}^*)}{N_{ij} * CARI_{ij}^*}$$

Where:

π_{ij}^* = Estimated incidence of pneumonia in children under five for district i in month j

μ_{ij}^* = Expected number of pneumonia diagnoses in children under five for district i in month j

N_{ij} = Under-five population for district i in month j

$CARI_{ij}^*$ = Care-seeking among children under five with pneumonia-like ARI symptoms for district i in year j

OC_{ij}^* = Fraction of diagnosed ARI cases for which children had other illnesses.

Table 1. Steps in the estimation of monthly district-level pneumonia incidence

Steps in estimating monthly district-level pneumonia incidence	Estimate obtained
<p>1. Using DHIS-2 data on number of cases of ARI diagnosed by facility by month, remove facilities not expected to report (i.e. identify where data are missing and where data are expected to be absent).</p> <p>2. Impute missing facility-level data on number of ARI cases reported by month using a log-linear generalized model with month and facility as predictor variables.</p> <p>3. Estimate district-level expected number of ARI cases per month using a quasi-Poisson model. We estimate this as a smoothed curved with 16 degrees of freedom.</p>	μ_{ij}^*
<p>4. Using MDHS data, estimate district-level care-seeking for suspected pneumonia borrowing strength from regional estimates of care-seeking, using Empirical Bayes methods for one month in 2010 and one month in 2015.</p> <p>4. Calculate a linear slope from 2010 to 2015, allowing value to vary around a normal distribution.</p>	$CARI_{ij}^*$
<p>5. Estimate the misdiagnosis rate using a beta distribution with parameters 1,9.</p>	OC_{ij}^*
<p>6. Estimate monthly under-five population assuming linear change from 2012 district estimates; assume these values are known with certainty.</p>	N_{ij}
<p>7. Using all information defined above, estimate district-level monthly pneumonia incidence using the equation outlined in Figure 1. Repeat this 1,000 times for each district to obtain a measure of uncertainty around the estimate.</p>	π_{ij}^*

Figure 2. Monthly number of ARI cases in children-under 5 by district by month, 2012-2015, as recorded in DHIS-2

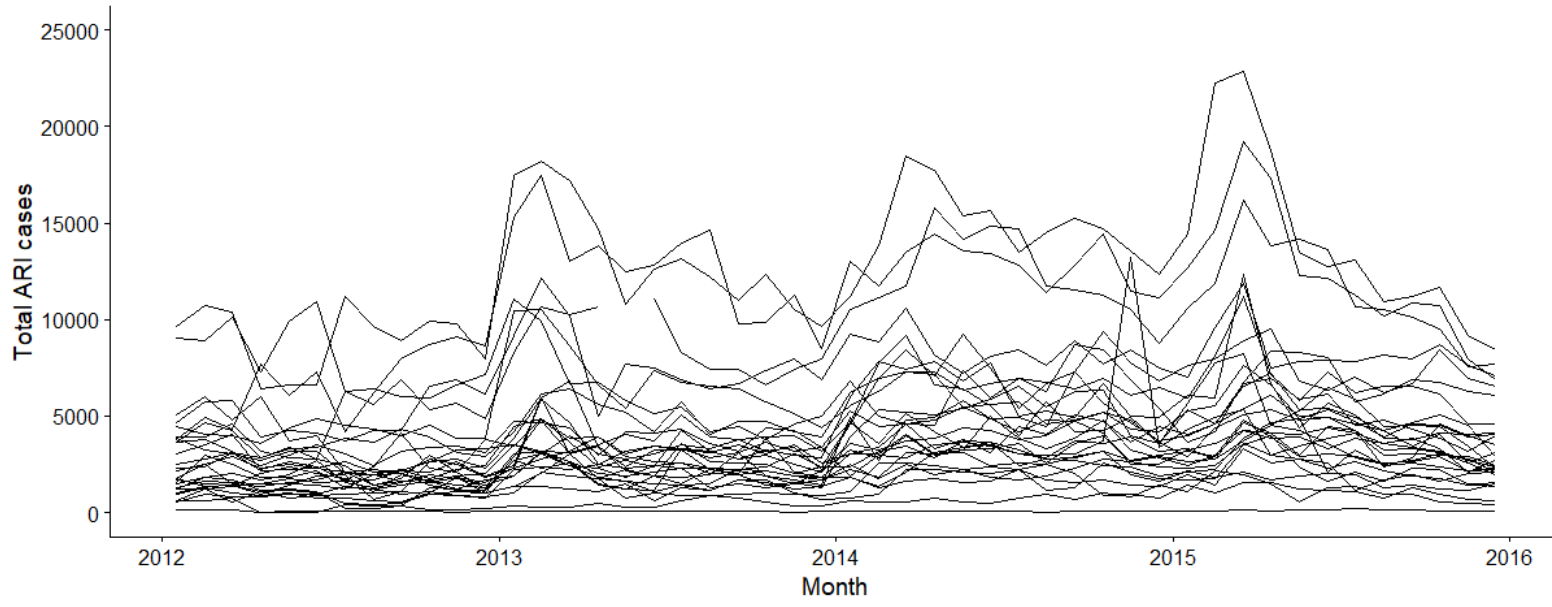


Figure 3. Empirical Bayes estimation of care-seeking for pneumonia by district with 95% confidence interval, 2010 and 2015/2016

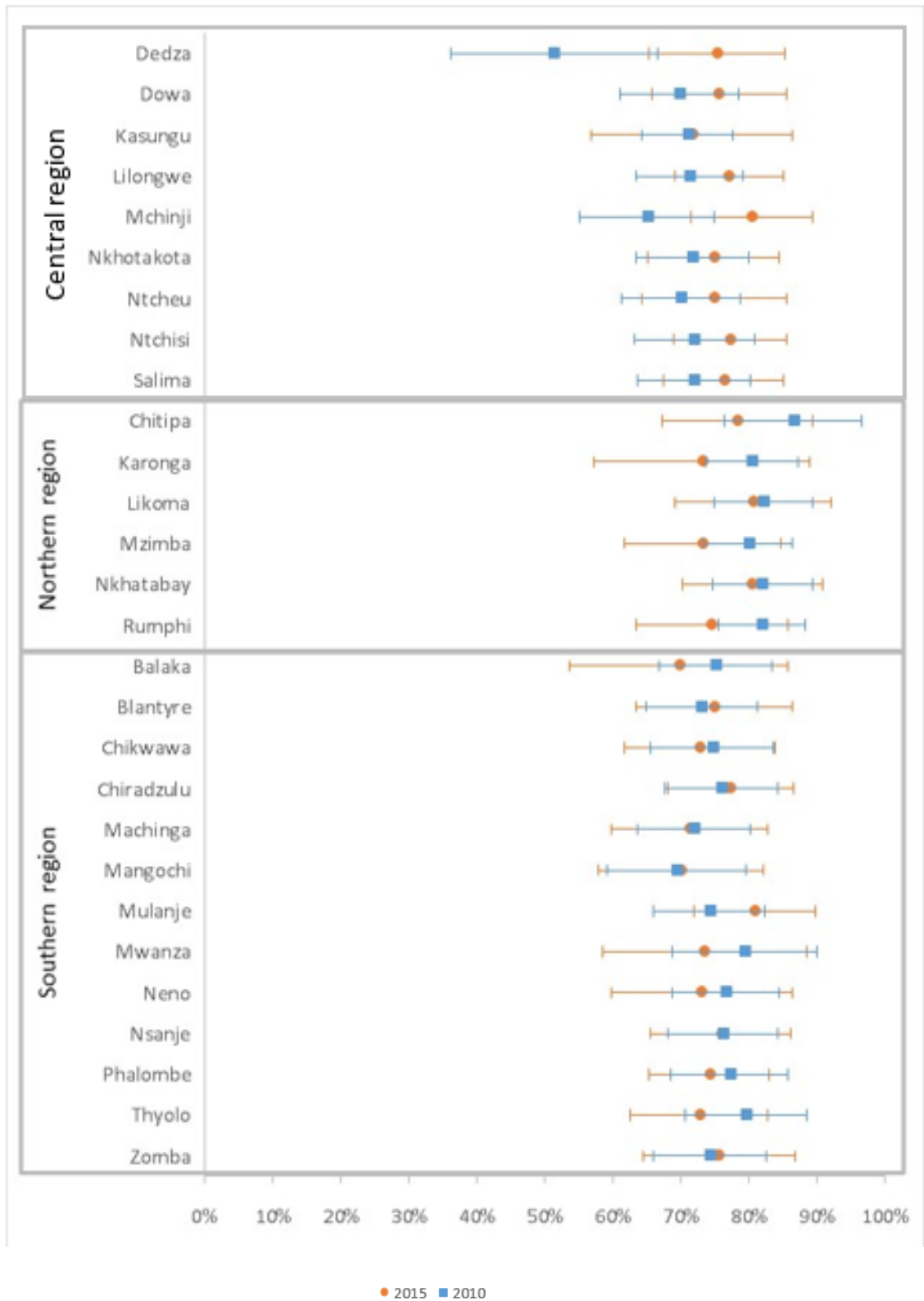


Figure 4. Mean estimated monthly incidence of ARI in children under-five by district and total rainfall (mm)

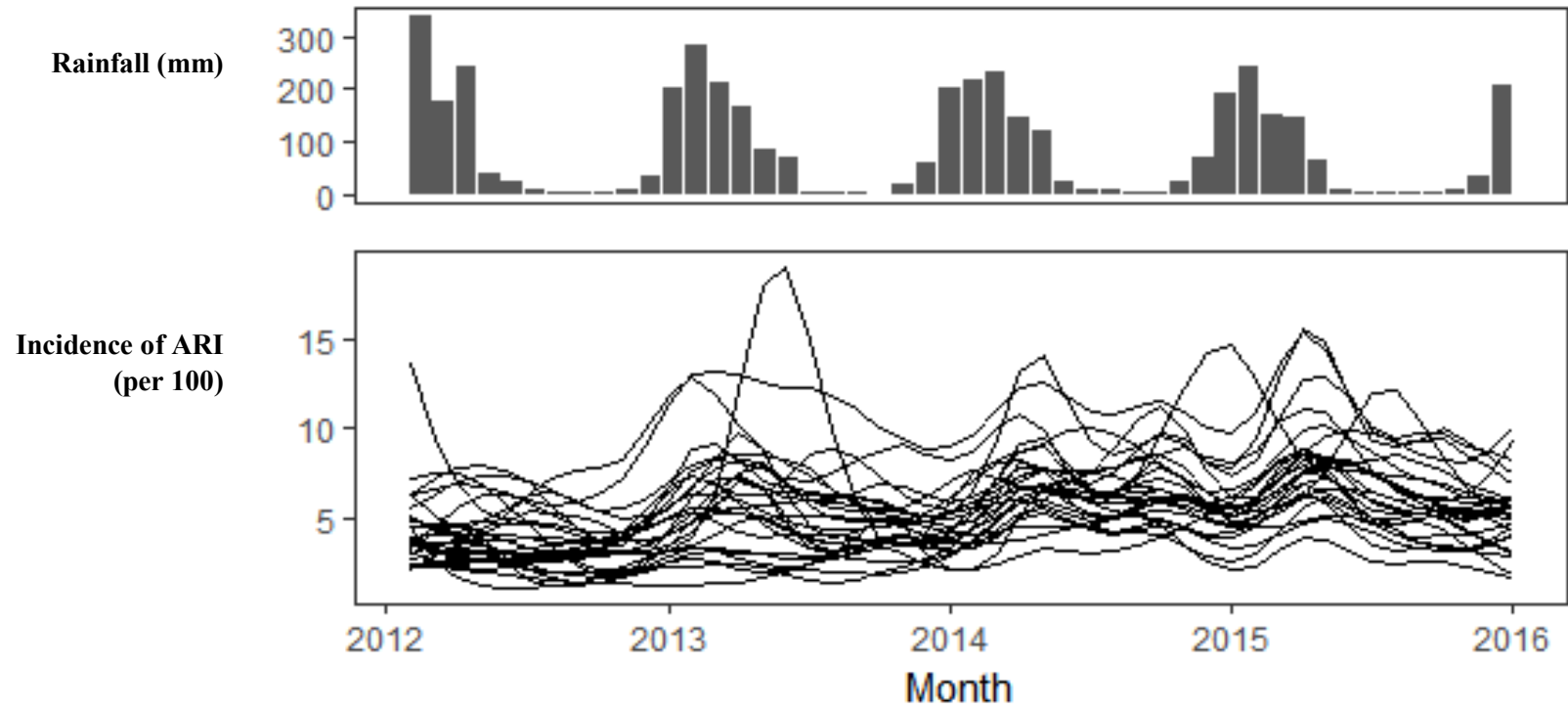
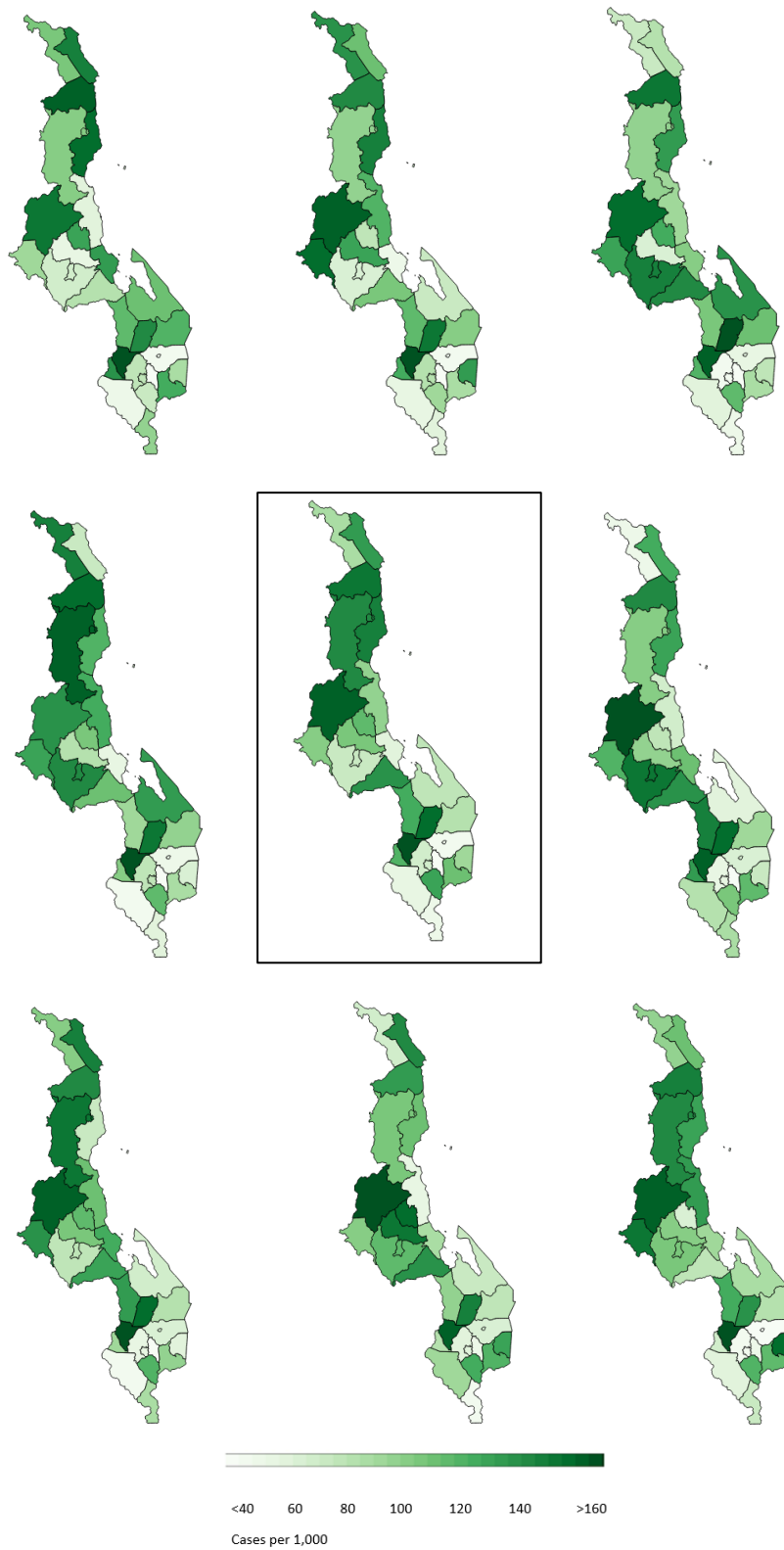


Figure 5. Mean estimated incidence (center) and 8 randomly selected incidence estimates, by district, March 2015



Chapter 5. Summary and policy implications

Summary of findings

Despite declining numbers of pneumonia deaths in children under five, pneumonia remains a leading cause of death in this age group. Malawi has demonstrated a substantial decrease in the number of deaths due to pneumonia among children aged 1-59 months since 2000 (Kanyuka et al. 2016; Liu et al. 2016). However, much of the evidence of this progress relies on global modeling efforts. Global models provide regional or national estimates of morbidity and mortality and are informed by data from international databases (Liu et al. 2016; Rudan et al. 2013; Wahl et al. 2018). These regional and national estimates limit our ability to identify variation across districts. To develop district-level estimates of disease incidence and mortality rates, we must turn to Malawi's available health sector data. Malawi's health data includes periodic population-based surveys and routine service utilization data collected through the country's HIS.

Population-based surveys, namely the Malawi Demographic and Health Survey (MDHS) and Multiple Indicator Cluster Survey (MICS), are the only nationally representative data sources on intervention coverage, including vaccinations rates and care-seeking. They can be used to determine national or district-specific estimates of intervention coverage and used to assess trends over time. Researchers have demonstrated that caregiver report of care-seeking are affected by recall bias and difficulty identifying symptoms (Bryce et al. 2013; Campbell et al. 2015). However, these are the best available data on care-seeking and represent an important information source on trends over time in care-seeking and treatment. We demonstrate in Chapter 2 that MDHS and MICS data can be used to explore district-level implementation of interventions and their impact on changes in pneumonia mortality. Over the 14-year study period, we see that districts are able to rapidly scale-up interventions and that intervention mix is essential to decreasing pneumonia mortality in children aged 1-59 months and maintaining health gains. Both

curative and preventive treatments play key roles in reducing pneumonia mortality. We would be unable to explore this change in district-level pneumonia mortality without district-level estimates of intervention coverage collected over time and using a nationally representative sampling frame.

In Chapter 3, we provide evidence that pneumonia and ARI diagnosis data in the DHIS-2 are available, complete, and consistent over time. We identify that these data are prone to misclassification, a common challenge in low- and middle-income countries that rely on clinical presentation rather than laboratory confirmed test results to diagnose pneumonia (Feikin et al. 2018; Mahomed et al. 2017). Diagnostic ambiguity is a common challenge in pneumonia research (Hammit et al. 2017). Data quality is also affected by lack of resources, aggregation errors, a heavy workload for data collectors, and challenges with data submission. These challenges are not unique to ARI data, nor are they unique to Malawi (Chiba, Assistant, and Oguttu 2012; Couralet et al. 2012; Gimbel et al. 2011, 2017; Hahn, Wanjala, and Marx 2013; O’Hagan et al. 2017; Yourkavitch et al. 2016). Despite these challenges, data in the DHIS-2 remain a consistently available, easily accessible, and geographically representative source of information about ARI diagnoses at health facilities and by community-based HSAs.

Although there are some data quality concerns with Malawi’s ARI data, there are concrete steps which the Government of Malawi can take to improve data quality. We suggest that the Central Monitoring and Evaluation Division (CMED) of the Ministry of Health provide aggregation guidance to statistical clerks, train facility-based leadership in data quality checks, implement periodic audits of data quality, and use the results of the audits to inform the allocation of targeted support and resources. Additionally, we propose that CMED make the results of these audits publicly available through DHIS-2, informing users of quality concerns that may not be captured in a desk review of the data. Even without these improvements, we are able to use the ARI data for applied research.

Both survey data and HIS data have documented challenges. However, in Chapter 4, we apply Bayesian estimation methods to combine these imperfect data sources and estimate an unknown quantity, district-level monthly pneumonia incidence. Bayesian estimation methods allow us to use available information to estimate an unknown quantity, accounting for uncertainty in our estimate. In our work, this is district-level monthly pneumonia incidence occurring in the community and at primary care sites. This work is in response to Lazzerini et al who documented a declining case fatality rate in Malawi's hospitals, but who were limited in their ability to quantify incidence trends outside of the hospital (Campbell and Nair 2016; Lazzerini et al. 2016). In the 2017 MDHS, 77.6% of children with cough or difficulty breathing in the two weeks preceding the survey sought care (National Statistical Office (NSO) and ICF 2017). However, among those who sought care, 11.9% of them reported that they sought care at a public or private hospital. Given the low prevalence of care-seeking at hospitals, it is important to characterize incidence at the primary care level to arrive at a more complete understanding of pneumonia morbidity.

The work in Chapters 2 and 4 demonstrate the important role that imperfect, yet readily available, data sources can play in understanding variation in sub-national morbidity and mortality. Researchers have documented that the quality of IMCI care varies by district in Malawi (Kalu et al. 2016; Kobayashi et al. 2017; Uwemedimo et al. 2018). Additionally, in Chapter 2, we provide evidence that intervention coverage varies by district. Given this variation in coverage and implementation quality, it is essential that we understand district-level variation in health outcomes. Improving national trends may obscure district-level variation in health outcomes.

In Figure 1, we compare findings from Chapters 2, 3, and 4. These maps reveal the similarities and differences in our findings. There is some overlap in districts with the highest proportion of deaths in children 1-59 months due to pneumonia and our estimates of incidence. This is particularly true in Nkhatabay (see Figure 2 for a map labeled with district names). We

expect some difference in these estimates as high incidence does not necessarily imply high mortality, which is a reflection on health care access, quality of care, and treatment availability.

We also see overlap in data quality and incidence. In the Central Region, areas with high data quality (C) have higher estimates of incidence (B). Ntchisi and Kasungu are examples of this phenomenon. In districts with more discrepancy between DHIS-2 and the register recount, we estimate lower incidence; although this pattern is not universal. This is an interesting observation; it would require the ongoing implementation of data quality audits to understand if there is a true association between the two.

In this work, we demonstrate the use of available data to examine sub-national variation in morbidity and mortality.

Policy implications

We demonstrate that available data can be used to estimate incidence and mortality. Sub-national analyses are essential to providing countries with information for data-informed decisions about intervention implementation, intervention effectiveness, resource allocation, and planning. HIS data are a cornerstone for these data-informed decisions. We demonstrate that even imperfect data can be used to generate evidence about sub-national rates of disease.

Overall, Malawi has improved rates of under-five child mortality and reduced pneumonia mortality (Kanyuka et al. 2016; Lazzerini et al. 2016; McCollum et al. 2017). However, there is evidence that there is sub-national variation in the implementation and quality of programs (Bjornstad et al. 2014; King et al. 2016; Uwemedimo et al. 2018). Indeed, our findings in Chapter 2 provide evidence that intervention coverage varies across districts as does the relative importance of interventions in reducing pneumonia mortality. This variation leads to district-level variability in improvements in health outcomes. Limiting analyses to the assessment of national outcomes will encourage policymakers to overlook sub-national disparities. This is evidence that understanding sub-national levels of coverage are essential. We demonstrate the importance of

implementing a suite of intervention activities to reduce pneumonia mortality in children 1-59 months and of assessing both coverage and outcomes over time.

An understanding of district-level change and differences in health outcomes are essential for planning and resource allocation. In 2015, Malawi spent 9.3% of gross domestic product on health spending (World Health Organization 2017), or an estimated \$590 million. Given limited resources, the Government of Malawi must prioritize resources and identify areas of greatest needed. This is not possible with analyses which do not look at sub-national variability. By using available data to identify differences in incidence and mortality, our findings can guide resource allocation.

Although this work makes use of available HIS data, which limits research costs, HIS data are not free for the countries that collect them. It is estimated that LMICs will require \$1 billion per year to implement data collection systems and ensure adequate statistical support to monitor the Sustainable Development Goals (Sustainable Development Solutions Network 2015). The Global Fund estimates that adoption of a new DHIS-2 system will cost a country approximately \$1.8 million over three years, including start-up, equipment, and training costs (The Global Fund to Fight Aids Tuberculosis and Malaria 2018). Additionally, Bloomberg Philanthropies has dedicated \$100 million over four years to improving data for health (Bloomberg Philanthropies 2018). The collection of HIS data are essential, and there is funder interest in insuring that high quality data are available. It is imperative that researcher capitalize on this available data and wring as much information as possible from existing sources. We make the best use of this substantial investment by LMICs when we use the HIS data in as many ways as possible to identify meaningful estimates of coverage, disease incidence, and morbidity.

We make concrete recommendations in Chapter 3 for how Malawi can insure the quality of ARI data collected in the DHIS-2. Our findings emphasize the capture and aggregation of data, but do not confront the diagnostic ambiguity of pneumonia diagnosis in LMICs. Data are only

able to reflect that which is knowable and in Malawi, confirmed diagnosis of pneumonia is impossible. Researchers in Malawi continue to work to advance the diagnosis of pneumonia in low-resource settings (Mahomed et al. 2017); improved certainty of diagnosis can only strengthen available data.

Future research

This work focuses on the use of routine health sector data, including data collected as part of the HIS and population-based household surveys. Future research should explore 1) continued understanding of the quality of HIS and survey data; and 2) applications of routine data for estimation of pneumonia and other disease outcomes.

We find that ARI data are available, complete, and consistent over time. However, we identified that data are not consistent across sources; there are differences between register recount and the value reported in the DHIS-2. As data stored in the DHSIS-2 are the data that are available and accessible, this has implications for analysis. We use the information on the discrepancy between the register recount and the DHIS-2 to adjust our estimate of incidence in Chapter 4. However, a data quality assessment (DQA) can be cost-prohibitive. We propose that future research explore if data quality metrics collected solely through desk review (completeness, consistency over time, magnitude of reported data, clinical area), can be used to predict data consistency across sources. Using available data can we estimate the expected difference between the data that we have in the DHIS-2 and what appears in the register? This would minimize the need for ongoing DQA activities.

We explored the quality of the ARI data through mixed methods research. Our findings identified systems issues which impact all HIS data, as well as challenges unique to the collection and reporting of ARI and pneumonia diagnosis data. It is possible that similar challenges exist in other clinical areas, but were beyond the scope of our study. Further research could replicate our study to identify if there are challenges unique to the collection of other specific clinical data.

Our estimates of pneumonia mortality in Chapter 2 rely on our estimates of intervention coverage and effectiveness, drawn from survey data and the literature, respectively. We limit our analysis to mortality in children aged 1-59 months because of limited information about coverage and quality of neonatal interventions. Most pneumonia deaths occur in children younger than 12 months (Billings, Deloria-Knoll, and O'Brien 2016; Walker et al. 2013). Limited information on one-twelfth of that time at risk, limits our ability to fully understand effective interventions to reduce pneumonia mortality. This lack of information is due to survey design (questions on interventions and quality of care are not included in the survey) and collection on such activities be challenges because of the rarity of events (Carvajal-Aguirre et al. 2017). This analysis, and the information available to policymakers, could be strengthened with better available data on neonatal interventions.

In Chapter 4, we use routine data to estimate pneumonia incidence. This estimate is complicated by the diagnostic ambiguity inherent in the diagnosis of pneumonia in LMICs. We propose expanding this work to include other measures of illness (malaria, diarrhea, HIV), all of which are subject to less diagnostic uncertainty. These diseases are also included in the DHIS-2 and care-seeking for these services are collected through population-based household surveys like the MDHS and MICS. It would be feasible to expand the methods to other conditions and construct similar district-level estimates of disease incidence.

In our estimation of pneumonia incidence, we estimate district-level monthly pneumonia incidence using minimal information from surrounding districts. It is only in our calculation of intervention coverage using MDHS data that we borrow information from other districts using Empirical Bayes methods. We could consider the application of this method for the estimation of pneumonia incidence; this would assume that districts near each other have more similar pneumonia incidence rates than districts far from each other and use nearby data to inform a district's incidence estimate. This is an area that merits further exploration.

Additionally, our analysis focused on district-level estimation of pneumonia incidence. Our focus on the district as the unit of analysis is an artifact of real-world policy (districts are administrative health units and as such programs and resources are deployed to districts) and convenience (census, utilization, and MDHS data are available at the district-level with minimal manipulation). With advanced statistical support it may be possible to use small area estimation methods to estimate outcomes at a sub-district level, although one would need to map enumeration areas from the MDHS to health facility catchment areas.

Concluding thoughts

HIS data represent a valuable source of information. In Malawi, they are the only available data on health sector utilization which are updated monthly and available across the country and for smaller geographic units. These data have their challenges. Likewise, survey data provide periodic insight into the health behaviors of the population. Each of these data sources are imperfect. However, by understanding the quality gaps and limitations of these data, we are able to shape them into something useful and meaningful.

Pneumonia is an enduring cause of childhood death, despite declines in the absolute number of cases of pneumonia mortality. It is essential that we continue to strive to understand where intervention could reduce pneumonia mortality and use that information to target the allocation of support and resources.

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Tables and Figures

Figure 1. Maps comparing pneumonia mortality (a), pneumonia incidence (b), and data quality (c), by district

(A) Proportion of under-five mortality due to pneumonia, 2014

(B) Estimated pneumonia incidence, December 2014

(C) Data quality (difference in DHIS-2 number of ARI cases and register recount)

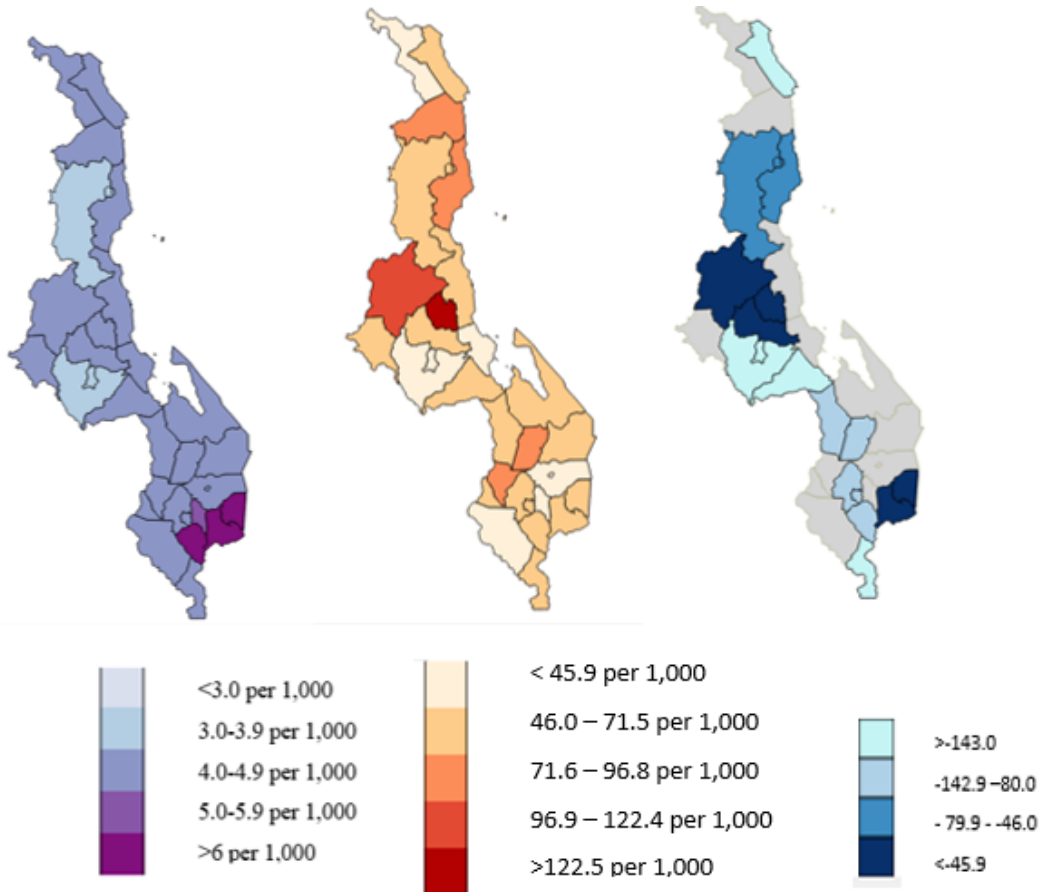


Figure 2. Malawi districts



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Appendix

A. Interview guide for District HMIS Office

Thank you for taking the time to speak with me today. As you may know, I am here as part of the National Evaluation Platform project, a collaboration between the Malawian National Statistical Office, the Ministry of Health, and Johns Hopkins University. Everything you say today will remain confidential. Today we will talk about the routine data collected by the health sector, this is sometimes referred to as the District Health Information System (DHIS). This refers to the data which are reported by health centers, village health clinics, and hospitals on their activities.

Background

1. To begin, could you start by stating your job title and your educational qualifications?
 - a. As part of your training at school, what instruction did you receive on mathematics or statistics?
2. What are the major responsibilities of your position?
3. When you first began in your position, did you receive any training?
 - a. If yes: Tell me about it. Probe for training on reporting, data collection, data use.
 - b. If no: Have you received any training since starting? If so, in what?

Understanding of routine data

4. Tell me about the data reporting process for your district.
 - a. Probe: How many reports do you receive and what are they?
 - b. Probe: What do you do if reports are not submitted by the facilities?
 - c. Probe: How do you document that reports have been received on time? What deadlines are in place?
 - d. Probe: What do you do when you receive the reports? Can you tell me about the review process?
 - e. Probe: What happens if data are missing?
5. How do you use the data that you report?
 - a. How would you like to use the data?

DHIS-2

6. I'd like to ask you some questions about the DHIS-2. Are you the one who enters data into the system?
 - a. If yes: Which programs or reports do you enter data for?
 - b. About how long does it take you to enter data for the district and how many facilities are included in your catchment areas?

7. What has been your experience with the District Health Information System (DHIS-2)?
 - a. What do you know about the data quality app that is part of the DHIS-2?
 - b. How do you use the dashboard and data visualizer sections of DHIS-2?
8. I have been told that the DHIS-2 has data checks in place and you will get an error message if a value that you enter is invalid. What do you do if the value on the report triggers an error message?
9. What feedback do you receive from the central level or district leadership on the data which you submit?
 - a. What do you do when you receive feedback?

Data quality concerns

10. I want to ask you specifically about information from the outpatient register and HMIS-15 report, number of ARI cases in children under-five.
 - a. When you look at this information, do you think it shows the truth about ARI in your district? Why?
 - b. Can you tell me about any problems that you see with this information?
 - c. Who do you discuss the ARI data with? (Probe: Is there a clinical program officer at the district?)
 - d. How do you use the ARI data?
11. I'm going to ask you a bit about data quality. What does that term, data quality, mean to you?
12. What do you think about the quality of the ARI data?
 - a. How do you know if the data are good or bad quality?
 - b. What does good quality data look like?
13. What do you do when you think that the data that you report are incorrect or you are worried about the quality of the data?
 - a. Are there ways to edit or correct the data?
14. Tell me about a time that you had concerns about data quality. What did you do?
15. What feedback do you receive from district or central level on data quality?

Systems issues

16. Overall, not just for ARI, how well does the data that you report show what is going on in your district?
 - a. What changes could be made to reporting to better show what is going on in the district?
17. What information does your district need that you don't currently collect?
18. Are there trainings that you could receive that would make your job easier or make you better at your job?
 - a. Probe: What are they?
19. As we conclude, are there any other thoughts that you would like to share on data, data collection, reporting, or quality?

B. Focus group guide for statistical clerks

Thank you for taking the time to speak with me today. As you may know, I am here as part of the National Evaluation Platform project, a collaboration between the Malawian National Statistical Office, the Ministry of Health, and Johns Hopkins University. Everything you say today will remain confidential. Today we will talk about the routine data collected by the health sector, this is sometimes referred to as the District Health Information System (DHIS). This refers to the data which are reported by health centers, village health clinics, and hospitals on their activities.

Before we begin, we should establish a few rules for our discussion so that everyone has a chance to speak and I am able to hear all of your answers. Does anyone have any suggestions for rules? (*Wait for suggestions. If none, ask that everyone silence their phones, only one speak at a time, allow everyone the opportunity to speak, keep all things discussed confidential.*)

Background

1. To begin, could we start by stating your job title and how long you have been in your position.
 - a. As part of your training at school, what instruction did you receive on mathematics or statistics?
2. When you first began in your position, did you receive any training?
 - a. If yes: Tell me about it. Probe for training on reporting, data collection, data use.
 - b. If no: Have you received any training since starting? If so, in what?

Understanding of routine data

3. Tell me about the data reporting process at your facility for the district.
 - a. Is the process the same at all of your facilities?
 - b. Who is responsible for aggregation?
 - c. Is the report reviewed before submission? By who? For what?
 - d. What happens if data are missing?
 - e. What deadlines are in place?
4. What are some of the challenges in reporting?
5. How does your facility use the data? What examples can you provide for how the data is used by the in-charge or other facility staff?
6. What changes in data collection tools have taken place over time? How has reporting changed since you began in your position?
 - a. Probe: Were you trained when these changes were made?
7. What feedback do you receive from the district or central level on the data which you submit?
 - a. Probe: Who gives feedback? How often?

8. What has been your experience with the District Health Information System (DHIS-2)?

Data quality concerns

9. I want to ask you specifically about something from the outpatient register, number of ARI cases in children under-five. Can you tell me how you report on this each month?
 - a. What diagnoses in the outpatient register are counted as an ARI case?
 - b. What do you do if the age of the patient is missing?
 - c. What do you do if you can't read the diagnosis?
 - d. What do you do if the diagnosis is pneumonia? Is it counted as an ARI case?
 - e. Can you think of cases where children are diagnosed with ARI but not included in the register? Tell me about these examples.
10. Tell me about any changes over time with how you sum the ARI data.
11. We're going to talk about data quality. How do you understand data quality?
12. What are the data quality issues with the ARI data?
 - a. Probe: How do you know if the data are good or bad quality?
13. Overall, how well does the data that you report show what is going on in your facility?
 - a. Which data are the most challenging to collect and report?
 - b. Which data have the most problems?
14. What do you do when you think that the data that you report are incorrect?
 - a. Are there ways to edit or correct the data?
 - b. Tell me about a time that you had concerns about data quality. What were the problems? What did you do?
15. What feedback do you receive from district or central level on data quality?
16. What data collection or quality training activities have you participated in?
17. Are there trainings that you would like to receive?
 - a. Probe: What trainings or skills could make your job easier?
 - b. Probe: Are there things that you would like to do but need more training on?

Systems issues

18. What tools could make the reporting process easier?
19. What information does your district or facility need that you don't currently collect?
20. We brought you here because of your responsibility for summing data to complete monthly health reports. What other tasks are you responsible for?
 - a. What are the pressures of the job?
21. As we conclude, are there any other thoughts that you would like to share on data, data collection, reporting, or quality?

C. Interview guide for interviews with clinical programs national staff

Thank you for taking the time to speak with me today. As you may know, I am here as part of the National Evaluation Platform project, a collaboration between the Malawian National Statistical Office, the Ministry of Health, and Johns Hopkins University. Today we will talk about the routine data collected by the health sector, this is sometimes referred to as the Health Management Information System (HMIS), the Health Information System (HIS), or the District Health Information System (DHIS). All of these terms refer to the data which are reported by health centers, village health clinics, and hospitals on their activities.

Background

1. To begin, can you tell me what your position is in the Ministry of Health and what your job involves?
2. What training do you have in data use, statistics, or reporting?
 - a. Did you receive this training as part of your job?

Understanding of routine data

3. What data does your program collect?
 - a. Probe: Is it all included in DHIS-2?
 - b. If no, What data does your program collect that is not included in DHIS-2?
4. What has been your experience with the District Health Information System (DHIS-2)?
 - a. Probe: Specifically, how do you use the data that is stored in the DHIS-2? What do you use that data for?
 - b. What are the most challenging aspects of using the routine data?
 - c. What are the best parts of using the routine data?
 - d. If response is that DHIS-2 is not used: Where do you get information on how your programs are doing? How is that data collected and transmitted? Have you ever considering using DHIS-2?
5. Tell me more about the data that you use that is not in the DHIS-2?
 - a. What information is it? Who enters it? What do you do with it? Why is it not in the DHIS-2?
6. Probe: Your program collects information on (*insert specific indicators here*). What do you do with that information?
 - a. What analyses, reports, or projects would you like to do with your data?
 - b. With whom do you share this data?
 - c. What reporting is required of your program?

Data quality concerns

7. How do you decide if the data that you report/receive are good quality?
 - a. What does good quality data look like?
8. What do you do when you think that the data that you report/receive are incorrect?
9. Tell me about a time that you had concerns about data quality. What did you do?
 - a. How do you share feedback on data quality and with whom?
 - b. Are there things that you would like to do that you have been unable to implement? Why?
 - c. What would make you feel more confident in the quality of routine data?

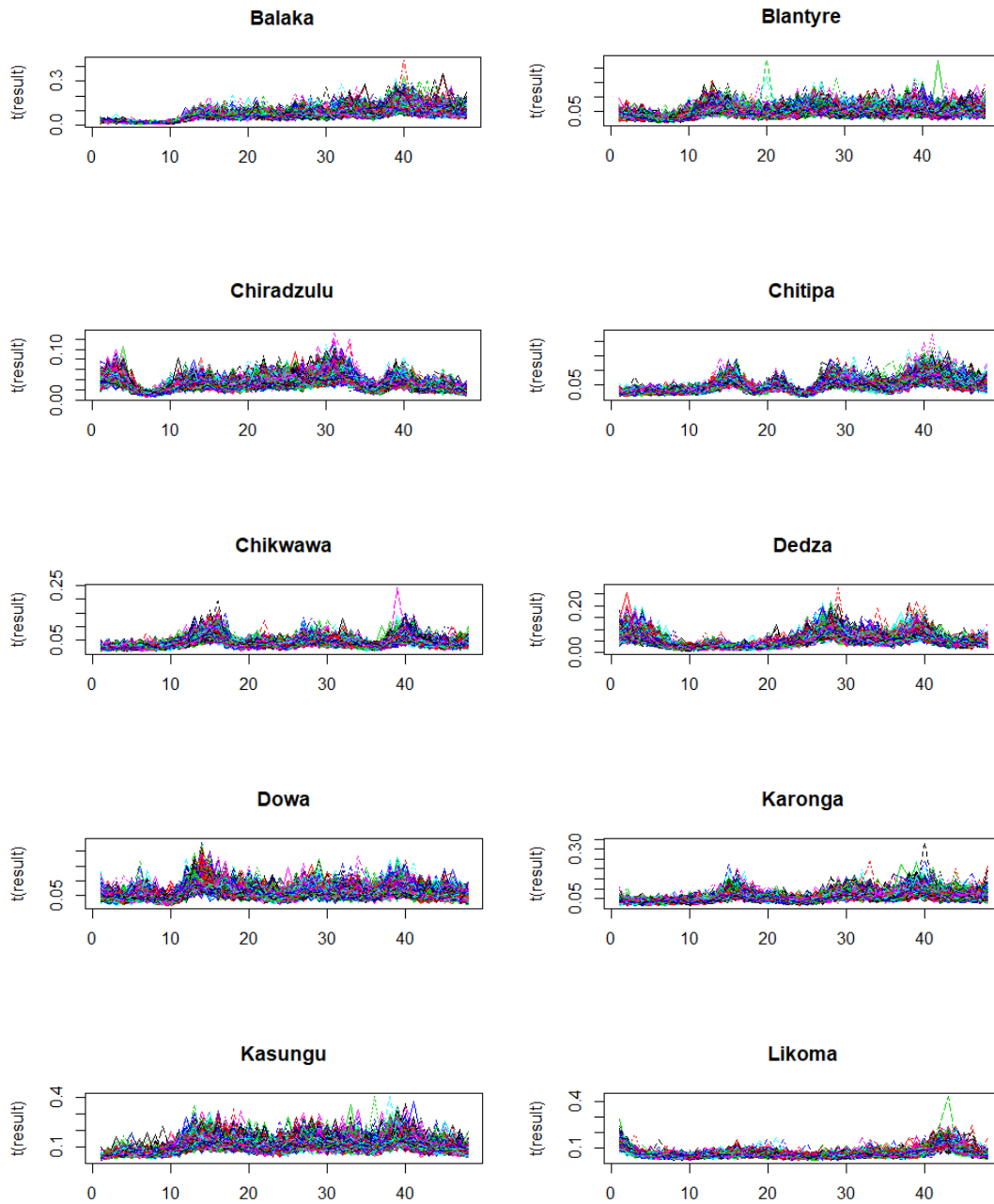
10. What data collection or data quality activities have you participated in?

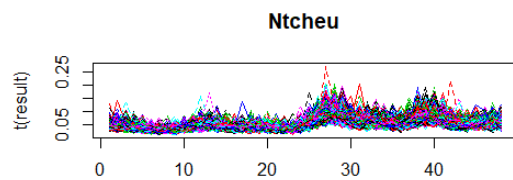
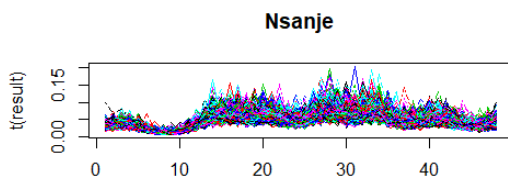
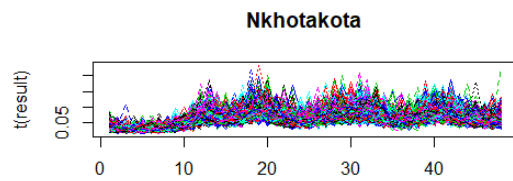
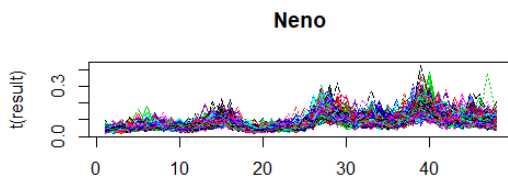
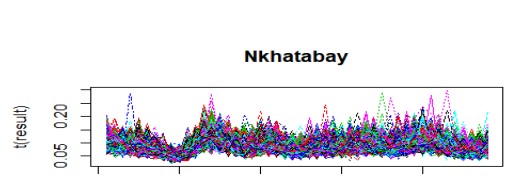
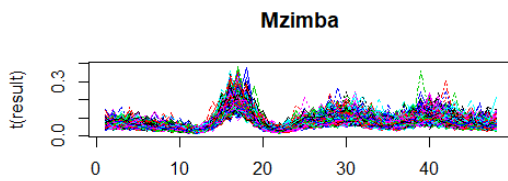
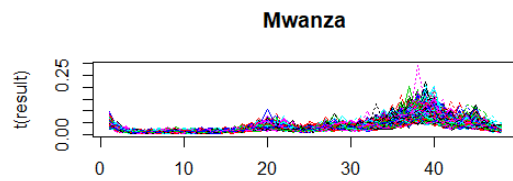
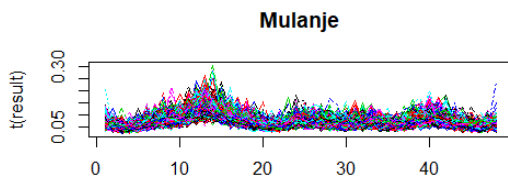
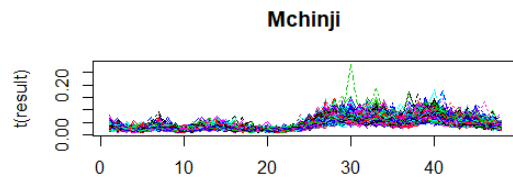
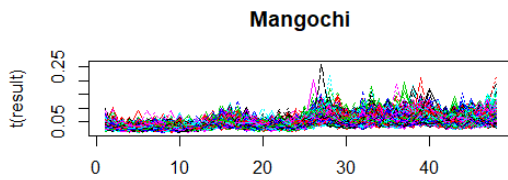
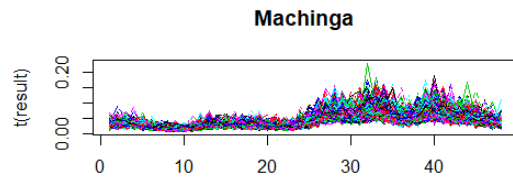
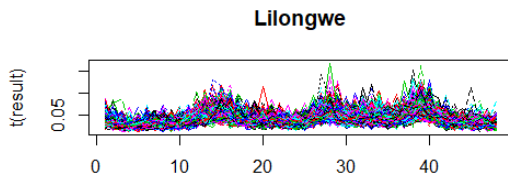
Systems Issues

11. How are [program area] data currently used for national policy or planning?
 - a. What data do you wish that you had for policy and planning?
12. What proportion of current indicators included in the DHIS are useful for your program area?
 - a. Are there indicators that you would like to add?
13. CMED has been working with clinical programs to revise indicators. What indicators have you settled on? What will you do with that data? Is there other information that you will collect and how do you decide if it is included in the list of revised indicators?
 - a. How are they defined and how will they be collected?

D. Supplementary material for Chapter 4

Figure 4. Estimated incidence of pneumonia by district over time, 1000 replications of estimation process.





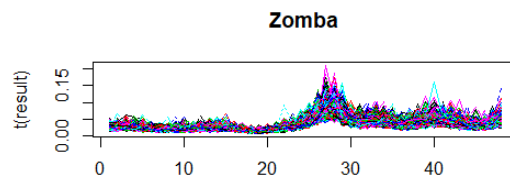
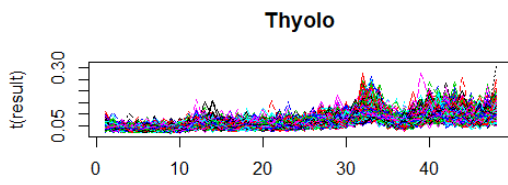
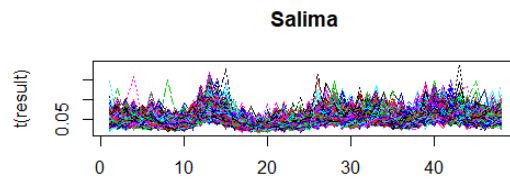
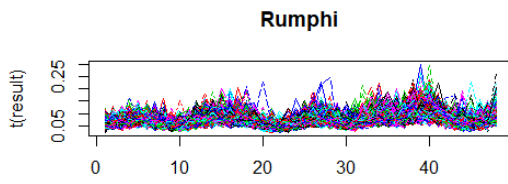
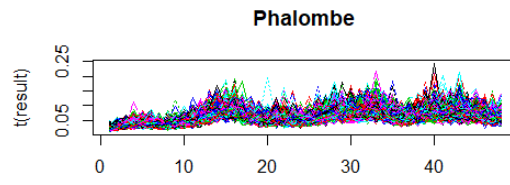
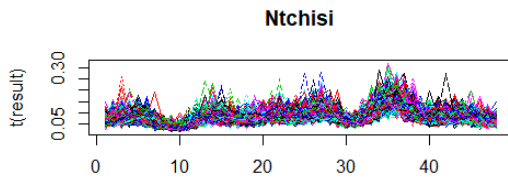
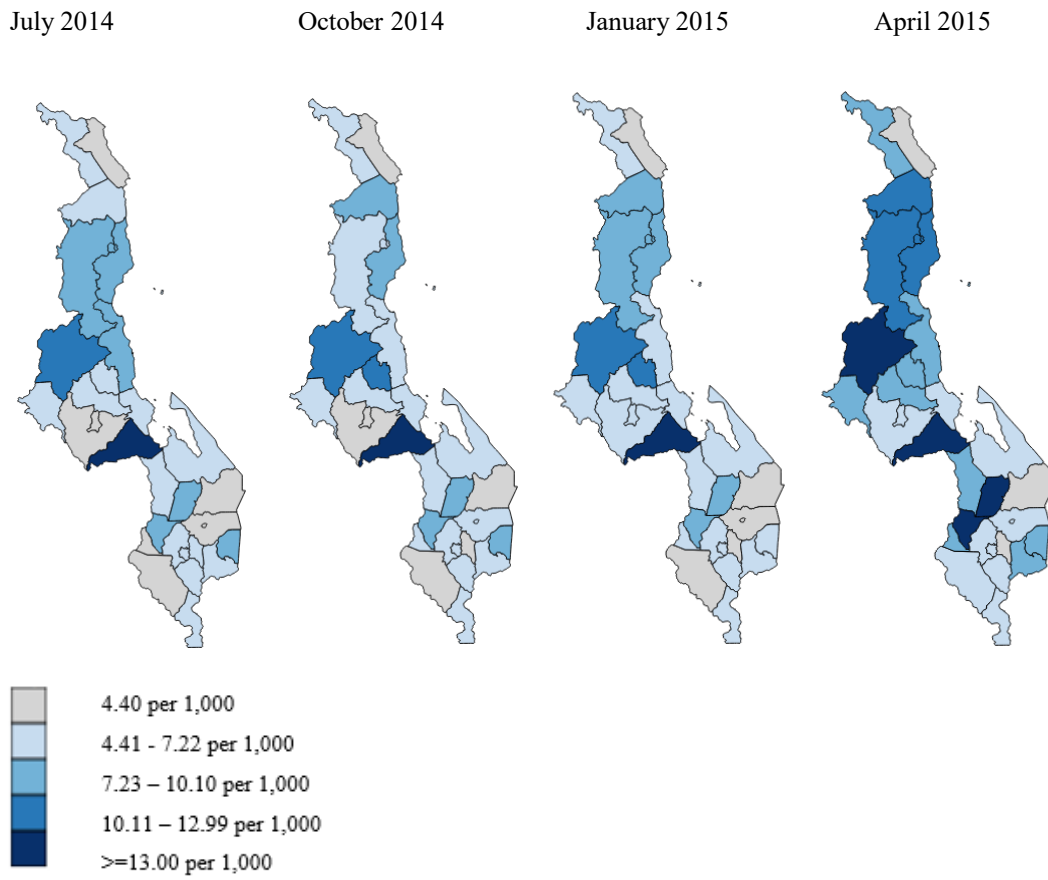


Table 3. Under-five population by district, 2010

	Under -five population	Total population	Proportion of population under- five
Central Region			
Dedza	127,387	686,636	0.19
Dowa	133,845	671,075	0.20
Kasungu	149,302	735,836	0.20
Lilongwe	410,726	2,225,089	0.18
Mchinji	107,520	530,218	0.20
Nkhotakota	67,136	345,495	0.19
Ntcheu	102,425	528,088	0.19
Ntchisi	54,316	258,499	0.21
Salima	75,044	383,421	0.20
Northern Region			
Chitipa	40,684	200,061	0.20
Karonga	58,260	307,216	0.19
Likoma	1,619	10,420	0.16
Mzimba	183,338	1,000,987	0.18
Nkhatabay	42,794	244,537	0.18
Southern Region			
Rumphi	35,306	192,307	0.18
Balaka	67,466	360,252	0.19
Blantyre	198,399	1,156,139	0.17
Chikwawa	90,007	489,030	0.18
Chiradzulu	51,953	305,692	0.17
Machinga	107,336	554,840	0.19
Mangochi	174,595	916,274	0.19
Mulanje	93,850	550,721	0.17
Mwanza	18,892	99,434	0.19
Neno	24,936	130,611	0.19
Nsanje	44,122	244,468	0.18
Phalombe	64,039	346,639	0.18
Thyolo	101,603	612,676	0.17
Zomba	128,094	720,235	0.18

Figure 5. Quarterly estimated incidence of ARI by district



Estimation of ARI diagnosis

Outlined below are additional details around the estimation of each of the components that contribute to the estimation of ARI diagnosis.

ARI diagnosis (μ_{ij}): To calculate a smoothed monthly, district-specific number of ARI diagnoses from facilities, we did the following:

1. Calculated the total number of children under-five diagnosed with ARI by facility by month.

We summed the number diagnosed with ARI from the facility HMIS report and the HSA report to determine the total number of children under-five diagnosed with ARI within a given month for each facility.

2. We then identified inconsistent values in the summed total. Data from facilities that reported a value for monthly diagnosis of ARI cases less than 10% of the time were inspected before inclusion in the analysis with input from Ministry of Health Staff; DHIS-2 includes information on all public sector health facilities, although not all are expected to offer ARI diagnosis and treatment. The majority of facilities that reported data fewer than 10% of the time (i.e. facilities that provided data for 5 or fewer of the 48 months in our study period) reported data erroneously. After removing facilities that were not expected to report (N= 223) or which did not report at all during the study period, we remained with 575 facilities across 28 districts.

3. We then adjusted for missing diagnosis data. Among the 575 facilities, on average, facilities were missing data for 6.04 (SD 10.31) months of the 48-month review period. To adjust for missing data, we modeled the expected monthly ARI district diagnosis counts using a quasi-Poisson regression model. A quasi-Poisson model assumes that variance is a linear function of the mean, relaxing the assumption of a Poisson model that the variance and mean are equal. The regression model to obtain a monthly adjusted value for ARI is defined in Equation 1:

$$\text{Eq 1. } \mu_{ijk} = B_0 + HC_{ijk} + \text{Time}$$

Where μ_{ijk} is the expected number of cases diagnosed per month for a given facility nested within a district, HC_{ijk} is the monthly count data for a facility within a district as it comes from DHIS-2 and time is an indicator of month. Using this model, we estimated an expected district-specific number of ARI cases for each of the 48 months.

4. We used the expected number of cases diagnosed for each facility for each month to estimate a smoothed curve of ARI diagnosis. We estimated a smoothed curve for district-level ARI diagnosis. We used time (defined as month from January 2012-December 2015) as our predictor variable and included a linear spline with 16 degrees of freedom, 4 degrees of freedom for each of the four years included in analysis.
5. The estimation produced predicted values of number of children diagnosed with ARI in a district in each month for 48 months (μ_{ij}), a vector of 17 coefficients, and a variance-covariance matrix. We simulated μ_{ij} using the design matrix and coefficients, and allowed the value of μ_{ij}^* to vary according to a Poisson distribution.

Curriculum Vitae

KAREN E. FINNEGAN, MPH

PhD Candidate in International Health with a focus on health systems research, primary health care, health systems strengthening, maternal and child health, implementation research, and translating evidence to action.

EDUCATION

Johns Hopkins Bloomberg School of Public Health **Baltimore, MD**
PhD Candidate, International Health (Health Systems) Expected 2018
Dissertation: The measurement of pneumonia incidence and mortality in children under five in Malawi

Rollins School of Public Health, Emory University **Atlanta, GA**
Master of Public Health: Epidemiology May 2008
Thesis: The role of Healthy Start participation in modifying interpregnancy interval in South Central Health District, Georgia

Bowdoin College **Brunswick, ME**
Bachelor of Arts in Latin American Studies and Spanish May 2003
Thesis: The paradox of Pincochet's rule: Patriarchal ideology and women in the workforce

PROFESSIONAL EXPERIENCE

Institute for Community Health **Malden, MA**
Research and Evaluation Scientist (April 2017 –)

- Principal investigator for teen pregnancy prevention and Lawrence data use projects
- Lead epidemiologist and provide oversight for quantitative analysis team

Johns Hopkins University **Baltimore, MD**
Graduate Research Assistant, National Evaluation Platform (December 2013- March 2017)

- Supported Malawi and Mozambique NEP programs with technical assistance, including development of research proposal, training, and analytic support

Pivot **Madagascar**
Technical Assistance in Monitoring and Evaluation (August 2013-January 2017)

- Supported development of monitoring and evaluation plan, including development of data collection tools, databases, and reports

Partners In Health Rwanda **Rwanda**
Associate Director of Research, Monitoring and Evaluation (January 2011-May 2013)

- Supported evaluation of health systems strengthening intervention, including data collection and analysis, survey development, research oversight, and supervision of data team

Data Analyst (January 2010-January 2011)

- Developed databases and conduct quantitative analyses of health and social intervention data

Abt Associates

Bethesda, MD

Senior Analyst, Monitoring and Evaluation (June 2008 – January 2010)

- Provided technical assistance in monitoring and evaluation for USAID-funded projects focused on strengthening family planning, reproductive health and HIV/AIDS services

Rollins School of Public Health

Atlanta, GA

Healthy Start Research Assistant (February 2007- May 2008)

- Linked Healthy Start data with Georgia State records to evaluate birth outcomes
- Prepared data for submission for federal grant renewal

Partners In Health

Boston, MA

Institute for Health and Social Justice Intern (June 2007- August 2007)

- Analyzed TB/HIV patient data to determine health outcomes for cohort study
- Evaluated data on perceived stigma among HIV patients for validation of a shortened Berger stigma scale

Geiger Gibson Community Health Center

Boston, MA

Case Manager (September 2005 – July 2006)

- Liaised with medical and behavioral health departments to meet social service needs of patients

Massachusetts League of Community Health Centers

Boston, MA

Community Health Corps Fellow (December 2004 – September 2005)

- Served as health advocate and educator at Geiger Gibson Community Health Center

PUBLICATIONS

1. Zallman L, **Finnegan K**, Roll D, Todaro M, Oneiz R, Sayah A. Impact of medical scribes in primary care on productivity. *Journal of the American Board of Family Medicine*. 2018 Jul-Aug; 31(4):612-619. doi: 10.3122/jabfm.2018.04.170325.
2. Thomson DR, Amoroso C, Atwood S, Bonds MH, Rwabukwisi FC, Drobac P, **Finnegan KE**, Farmer DB, Farmer PE, Habinshuti A, Hirschhorn LR, Manzi A, Niyigena P, Rich ML, Stulac S, Murray MB, Binagwaho A. Impact of a health systems strengthening intervention on maternal and child health outputs and outcomes in rural Rwanda: 2005-2010. *BMJ Global Health*. 2018 Apr 9;3(2):e000674. doi: 10.1136/bmjgh-2017-000674. eCollection 2018.
3. O'Hagan, R., Marx, M. A., **Finnegan, K. E.**, Naphini, P., Laija, K., Wilson, E., ... Mleme, T. National Assessment of Data Quality and Associated Systems-Level Factors in Malawi. *Global Health: Science and Practice*. 2017 5(3), 367–381.
4. Guenther T, Sadruddin S, **Finnegan K**, Wetzler E, Ibo F, Rapaz P, Koepsell J, Khan IU, Amouzou A. Contribution of community health workers to improving access to timely and appropriate case management of childhood fever in Mozambique. *Journal of Global Health*. 2017 Jun;7(1):010402.

5. Iyer H, Kamanzi E, Mugunga JC, **Finnegan K**, Uwingabye A, Shyaka E, Niyonzima S, Hirschhorn LR, Drobac PC. Improving district facility readiness: a 12-month evaluation of a data-driven health systems strengthening intervention in rural Rwanda. *Global Health Action*. 2015; 8.
6. Iribagiza MK, Manikuzwe A, Aquino T, Amoroso C,.. **Finnegan K**,... Hedt Gauthier, BL. Fostering interest in research: evaluation of an introductory research seminar at hospitals in rural Rwanda. *Public Health Action*. 2014; 4(4): 271–275.
7. Drobac PC, Basinga P, Condo J, Farmer PE, **Finnegan K**, Hamon J, Hirschhorn LR, Kakoma JB, Lu C, Murangwa Y, Murray M, Ngabo F, Rich ML, Thomson D, Binagwaho A. Comprehensive and Integrated District Health Systems Strengthening: The Rwanda Population Health Implementation and Training (PHIT) Partnership. *BMC Health Services Research*. May 2013; **13**(Suppl 2):S5.
8. Hirschhorn LR, Baynes C, Sherr KG, Chintu N, Awoonor-Williams JK, **Finnegan K**, Philips JF, Anatole M, Bawah A, Basinga P. Approaches to Ensuring and Improving Quality in the Context of Health System Strengthening: A Cross-Site Analysis of the Five African Health Initiative Partnership Programs. *BMC Health Services Research*. May 2013; **13**(Suppl 2):S5.
9. Muñoz M, **Finnegan K**, Zeladita J, Caldas A, Sanchez E, Callacna M, Rojas C, Arevalo M, Sebastian JL, Bonilla C, Bayona J, Shin SS. Community-based DOT-HAART accompaniment in an urban resource-poor setting. *Journal of AIDS Behavior*. June 2010; 14(3):721-3.
10. Franke MF, Muñoz M, **Finnegan K**, Zeladita J, Sebastian JL, Bayona JN, Shin SS. Validation and abbreviation of an HIV stigma scale in an adult spanish- speaking population in urban Peru. *Journal of AIDS Behavior*. February 2010;14(1):189-99.

PRESENTATIONS

1. **Finnegan KE**, Touw S, Himmelstein D, Woolhandler S, Zallman L. Immigrants contributed \$25.1B more to private insurance than they took out in 2014. Oral presentation at: Academy Health Annual Research Meeting; 2018 June 24-26; Seattle, WA.
2. Zallman L, **Finnegan KE**, Roll D, Todaro M, Oneiz R, Sayah A. Impact of medical scribes on productivity, face to face time, and patient comfort with scribes in primary care. Poster presented at: Academy Health Annual Research Meeting; 2018 June 24-26; Seattle, WA.
3. **Finnegan KE**, Marx MA, Kaludzu E, Malunga B, O’Hagan R, Simeon Y, Dambula I. Barriers and Facilitators of Data Quality and Use in Malawi’s Health Information System. Poster presented at: 8th Annual Conference of Global Health of the Consortium of Universities for Global Health; 2017 April 4-6; Washington, DC.
4. **Finnegan K**, Lufesi N, Chimabalanga M, Naphini P, Kaludzu E, Gombwa L, Matipwirir B, Misomali A, Walker N, Marx MA. District trends in under-five pneumonia mortality in Malawi, 2000-2014. Oral presentation at: American Society for Tropical Medicine and Hygiene; 2016 November; Atlanta, GA.
5. Manzi A, Mezzacappa C, Magge H, Pace L, Saint-Fleur J, Fung Chaw C, **Finnegan K**, Cyamatare F, et al.. Integrated mentoring and enhanced supervision to improve the quality of maternal health care delivery in resource-limited settings. Poster session

presented at: Global Maternal Health Conference; 2013 January; Arusha, Tanzania.

6. Drobac PC, Nsanzimana S, Mpundu R, Umugwaneza P, Amoroso C, Rwabukwisi Cyamatara F, Niyigena PC, Hamon JK, Hedt B, **Finnegan K**, et al. Community-based HIV treatment: retention outcomes of 3,024 patients receiving antiretroviral therapy in rural Rwanda under a model of accompaniment and high treatment support. Poster presented at: International Aids Conference; 2012 July; Washington, DC.
7. **Finnegan K**, Zeladita J, Muñoz M, Caldas A, Sanchez E, Callacna M, Rojas C, et al. Preliminary outcomes of DOT-HAART accompaniment in an urban resource-poor setting. Poster presented at: International Aids Conference; 2008 August; Mexico City, Mexico.
8. **Finnegan K**, Manikuzwe A, Ndagijimana JD, Shumbusho D, Habimana D, Hirschhorn LR. Strengthening routinely collected data for monitoring and evaluation. Oral presentation at: Second Global Symposium on Health Services Research; 2012 October; Beijing, China.

TEACHING EXPERIENCE

Tufts University School of Medicine, Instructor

Boston, MA

- Public Health Evaluation

2018

Johns Hopkins University, Teaching Assistant

Baltimore, MD

- Training Methods and Continuing Education for Health Workers (online) Summer, 2015-2016
- Introduction to International Health (online), Term 4, 2014-2015
- Health Systems Research and Evaluation in Low and Middle Income countries, Term 3, 2014-2015
- Introduction to International Health, Term 1, 2014-2015

PROFESSIONAL MEMBERSHIPS

Academy Health

2018-2019