Improving the quality of primary care delivery and health worker performance in rural Rwanda using the W.H.O. Integrated Management of Adolescent & Adult Illness (IMAI) guidelines

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Declaration by candidate

I have read and understood the School's definition of plagiarism and cheating given in the Research Degrees Handbook. I declare that this thesis is my own work, and that I have acknowledged all results and quotations from the published or unpublished work of other people.

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Abstract

To-date primary care delivery – defined here as first-contact patient care delivered at the first level of health systems - in low-and middle-income countries (LMICs) has been an under-researched topic, with researchers tending to focus on specific diseases or vulnerable groups (e.g. children, pregnant women). Yet as vertical programs have evolved and expanded in the past two decades, interest in primary care has been renewed, specifically as operational challenges to delivering integrated care have surfaced. There is also growing recognition that vertical interventions benefit from a basic foundation of general clinical quality, which in turn, requires integration at the point-of-care.

One of the few notable, yet comparably under-researched, efforts to advance integrated primary care delivery in LMICs, is the World Health Organization (WHO)'s Integrated Management of Adolescent & Adult Illness (IMAI). IMAI consists of simplified protocols addressing common adult and adolescent illness and targeted at health workers at first-level facilities. Unlike the better-known Integrated Management of Childhood Illness (IMCI) for children under-five, however, IMAI lacks an evidence base either for its validation or its impact on care. This thesis addresses this gap and describes an implementation research trial – using a pre- / post-intervention plausibility design - of the impact of IMAI training combined with a program of sustained mentoring and supervision, on the quality of care and on the

performance of primary care nurses in one district in rural Rwanda.

The main finding of this trial is that IMAI training and sustained supervision leads to significant improvements in basic quality indicators and behaviors such as taking of vital signs and screening and counseling for priority conditions, while also resulting in a greater than two-fold increase in the odds of agreement in diagnosis and treatment decisions by nurses, when compared to the reference standard. This effect remained for diagnosis with exposure to supervision alone, but in the absence of classroom-based didactic IMAI training, highlighting the importance of sustained mentorship to improving health worker performance and quality.

This study is one of the first of its kind to focus specifically on the quality of integrated primary care delivery in itself, rather than through the lens of a specific proxy disease or population subgroup. It is also the first study to provide impact data on IMAI, and thus offers early evidence of its utility as an organizing protocol to improve integrated primary care delivery in LMICs.

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Foremost I would like to thank my supervisors, Steve Lawn and David Mabey. Their unyielding (though not untested!) support and patience with my journey through this research was fundamental; they truly provided professional guidance and supervision in its truest sense. I am especially thankful to them given that this thesis spans a period of considerable professional growth, from public health and non-profit professional, to medical student, to house physician, and now to public health and medical faculty member – all simultaneous to this dissertation. All the while Steve and David provided frank advice, helping me to navigate the challenging balance between my competing demands. I am especially grateful for Steve's guidance, support, and friendship over the past year. His courage and professionalism in difficult circumstances is remarkable, as is his good humour and spirit. I am deeply impressed and in awe of your strength, Steve, and my deepest thanks to you and to your family for allowing me to have a bit of your time and attention for this thesis.

Research - especially implementation research such as this – is only as strong as the quality of collaborations and partnerships. For this I am eternally grateful to my colleagues at Partners In Health and the Brigham & Women's Hospital in Rwanda and Boston, as well as at the Ministry of Health in Rwanda. I thank them for the privilege of conducting research in such a beautiful and rich country, and for their continued support despite the challenge of balancing the needs of patient-oriented service work, with those of research. Special thanks go to Manzi Anatole, my friend and collaborator, without whom this project would not have been possible. In the

face of long odds and many hurdles, Manzi's field-level support and guidance was instrumental to the success of this work, as was his loyal friendship and support. *Murakoze neza.* Others to thank in this regard are Michael Rich, who brought me to Rwanda from Lesotho, Jill Hackett, who was a consistent voice of support for me at PIH, Sandy Gove at WHO for her remarkable work in developing IMAI and IMCI as well as for her mentorship, and KJ Seung, Gene Bukhman, and Peter Drobac who recognized the relevance of this work and in turn, provided necessary support and advocacy. Special thanks go to Katie Vasey for her editorial support and encouragement in the final stages, as well as to Jim Todd at LSHTM, who instigated my PhD enrollment from Uganda, and offered important statistical support. And a final note of thanks to Paul Farmer and to Jim Yong Kim who gave me my start in global public health, and who continue to serve as inspirational mentors today.

Most importantly, I wish to thank my family for their abiding support and love. To my parents, whose courage to leave India all those decades ago for greater opportunity, and who then created a life for me without want and without boundaries, made this possible. To my sister, whose strength and commitment to social justice and her ability to rebound from adversity, is inspirational. And finally to my wife, Johanna, with whom I share my deepest thanks and love for her unwavering support and counsel through many ups and downs. I can think of no better person with whom to share my life.

This thesis is dedicated to my daughter, Amaya, and to my soon-to-arrive son. You bring me much happiness and joy, and are a constant reminder of what truly matters.

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List of acronyms

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Clinic
ART	Anti-Retroviral Therapy
CDC	Centres for Disease Control
CHW	Community Health Worker
CD4	CD4+ lymphocyte
CHW	Community Health Worker
CRF	Case Recording Form
DBS	Direct Budget Support
DPT	diphtheria/pertussis/tetanus
DDCF	Doris Duke Charitable Foundation
FFF	Food supplementation, Female literacy, and Family planning
GOBI	Growth, Oral rehydration, Breastfeeding, and Immunization
HC	Health Centres
HCW	Health Care Worker
HIV	Human immunodeficiency virus
HRH	Human Resources for Health
ID	Infectious Diseases
IMAI	Integrated Management of Adult and Adolescent Illness
IMCI	Integrated Management of Childhood Illness
IMB	*Inshuti Mu Buzima*
IMEESC	Integrated Management of Emergencies and Essential Surgical Care
IMPAC	Integrated Management of Pregnancy and Childbirth
IRB	Institutional Review Board
I-TECH	International Training & Education Centre for Health
IQR	Inter-Quartile Range
LMIC	Low- and Middle-Income Country
LSHTM	London School of Hygiene and Tropical Medicine
MESH	Mentoring and Enhanced Supervision at Health centres
MDGs	Millennium Development Goals
MOH	Ministry of Health
MSM	Men who have Sex with Men
NCD	Non-Communicable Disease
NHS	National Health Service
NURSPH	The National University of Rwanda School of Public Health
OPD	Out-Patient Department
PAL	Practical Approach to Lung Health
PALSA	Practical Approach to Lung Health, South Africa
PCP	Phencyclidine
PHIT	Population Health Implementation and Training
PMTCT	Prevention of Mother to Child Transmission
PLHIV	People Living with HIV
PIH	Partners In Health
PIH-IMB	Partners In Health-Inshuti Mu Buzima

QI	Quality Improvement
RCT	Randomized Controlled Trial
RN	Registered Nurse
SEATEC	Southeast AIDS Training and Education Centre
SIS	*Système Informatique Sanitaire*
STI	Sexually Transmitted Infection
TB	Tuberculosis
TRAC-Plus	Treatment and Research for AIDS Centre-Plus
UK	United Kingdom
US	United States
UNICEF	United Nations International Children' s Emergency Fund
USAID	United States Agency for International Development
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

Preface

This thesis is divided into three sections, as follows:

I: Section I describes the conceptual basis of the design of the trial intervention, specifically that of Integrated Management of Adolescent and Adult Illness (IMAI) training followed by mentoring and supervision. Chapter 2 describes the conceptual origins, strengths, and limitations of IMAI in the context of the history of primary health care in the post-Alma Ata era. This is presented in two papers, one a short Commentary piece, and the second a full critical analysis and narrative review of IMAI. Chapter 3 is a comprehensive review of support and performance improvement initiatives for primary health care workers in low and middle-income countries (LMICs), which establishes the rationale for combining IMAI training with a comprehensive mentoring initiative.

II: Section II presents background data on the service and training setting for primary care delivery in rural Rwanda. Chapter 4 describes the baseline in-service training and practice environment for primary health care workers in the study area in southeast Rwanda. Chapter 5 is a baseline quality assessment of the level of care and of nurse performance under routine conditions at the study sites.

III: Section III describes the intervention, beginning with a detailed description of the field-testing and adaptation of the global IMAI guidelines to the Rwandan context in Chapter 6. Chapter 7 presents the intervention plausibility trial.

The thesis is preceded by a general Introduction in Chapter 1, which presents an overarching rationale for the thesis topic along with a description of the study

setting, and the thesis ends with general Conclusions, presented in Chapter 8.

In accordance with the London School of Hygiene and Tropical Medicine (LSHTM) Research Degrees Regulations, the majority of the thesis is presented as a series of published, accepted, or submitted research manuscripts. Together the thesis represents a coherent body of new scientific material and new contribution to the field of global health, primary care, and implementation or operations research. The presentation of the work as a series of stand-alone manuscripts has, expectedly, required repetition of some background information. Varying editorial conventions and requirements between journals may result in inconsistencies in terminology and formatting.

I conceived all the presented research, drafted all the research protocols and data collection instruments, submitted all protocols for ethical approval, implemented the studies, and supervised all the field work and data collection, in conjunction with colleagues from partner institutions described below. I either analyzed data personally, or was closely involved in any statistical analyses that were led by collaborators. Where colleagues have contributed to statistical aspects of the work this is clearly acknowledged.

Research by foreign academic individuals and institutes within Rwanda must be conducted in partnership with a local lead partner institution; in the case of the work comprising this thesis, as with all health research, the main partner was the Ministry of Health of Rwanda, here supported by Partners In Health – *Inshuti Mu Buzima* (PIH-IMB). The work presented here was conducted under the Population Health Implementation and Training (PHIT) grant partnership between the Ministry of Health (MOH), the National University of Rwanda School of Public Health (NURSPH), Partners In Health (PIH), and the Brigham & Women's Hospital/Harvard

Medical School, and funded by the Doris Duke Charitable Foundation (DDCF). I received additional supplementary funding from the World Health Organization and Partners In Health. This research was approved by the Institutional Review Boards of PIH-IMB, NURSPH, Partners Health Care (Harvard/Brigham), and the London School of Hygiene & Tropical Medicine.

Chapter 1

Introduction

1. Background

1.1 *Primary care*

The concept of 'primary care' is often thought to originate with the Dawson Report of 1920, written by Lord Dawson of Penn to Parliament (Ministry of Health, 1920). The report described a network of 'primary health care centres that should function as decentralized, and thereby readily accessible, loci of health services across the United Kingdom (UK). It intended to lay out a vision for the provision of medical and allied health services in the UK, and was a critical reference point in the development of the National Health Service (NHS) in 1948, and the growth of the 'general practitioner' as the primary care provider (Webster, 2002). Since this time, primary care has evolved into the backbone of health care delivery in most functioning health systems, regardless of the income level of the country (Starfield, 1994) and strong primary care systems have, in turn, been shown to be associated with improved population health (Starfield et al., 2005, Macinko et al., 2003).

While there is little consensus on an exact definition of primary care, general themes can be identified. Primary care is delivered at the front lines, or 'first level' of health systems, which means it should be located close to where people live in communities, and thus be widely available and easily accessible (Schoen et al., 2006). An essential component of primary care is 'first contact' service, noting that primary

care providers should be the first destination for the patient during an new illness episode or for other health care needs (Forrest and Starfield, 1996). In addition, primary care addresses common conditions in an integrated manner, without privileging one illness or set of illnesses over another, and serves to coordinate care when consultation with other providers and other levels of the health system is necessary (Frenk, 2009a, Simoens and Scott, 2005). Finally, primary care strives to provide person-centred, rather than disease-oriented care, and thus attempts to address the 'first causes' of illness, or the upstream social determinants of health (Starfied, 2009, Frenk, 2009a, Leiyu et al.), as well as the illness itself.

1.2 Primary care and the developing world

While primary care was established in higher-income nations in the global North during the mid-to-late 20th century, in low-and middle-income countries (LMICs), or developing nations, primary care has struggled to evolve in a similar fashion. By the 1970s, health and development efforts in poor countries, supported largely by bilateral and multilateral aid flows, were largely structured around targeted, or 'vertical' programs - each with their own funding, administration, procedures and protocols. Some examples of common vertical programs from that era were for malaria control or eradication of vaccine-preventable diseases such as smallpox (Cueto, 2004). As a reaction to these programs, in an effort to enhance a rights-based and person-centred approach to health, and in order to address 'health' holistically rather than simply 'health care,' the 1978 Declaration of Alma Ata (World Health Organization, 1978) represented a seminal event in global public health. It declared an aspirational target of 'health for all' by the year 2000, and also defined the scope of 'primary health care' as based on human rights and participatory

community engagement. As a result, 'primary care' was largely relegated to a concept of clinical and health services alone.

Against this backdrop the concept of 'selective primary care' (Walsh and Warren, 1979) took root. Selective primary care was initially proposed as an interim solution towards the vision of Alma Ata and was targeted at public health programs in developing countries that struggled with resource limitations and the lack of a clear operational plan in the aftermath of Alma Ata. Selective primary care was a framework based on disease burden, impact, and cost-effectiveness, intended to address the issue of difficult choices, and to assist policy makers and implementers operating in an environment of socioeconomic scarcity (Evans et al., 1981). Advanced largely by North American foundations and aid agencies, as well as by the World Bank, selective primary care was - intentionally or unintentionally - pitted in direct contrast to the comprehensive vision of primary health care put forth in Alma Ata, (Marcos, 2004, Finnemore, 1997, Knowles J. H. to C. Wahren, 1997). Over the next 25 years, influenced by the selective primary care framework, global public health became further entrenched in vertical efforts to address sentinel diseases and programs targeted at particular vulnerable populations

1.3 Integrated care in LMICs

In the succeeding two decades after Alma Ata, attention and resources were dedicated to select priority campaigns, diseases, and populations in the developing world. Particular attention was paid to infant and early childhood illness, nutrition, and immunization, which were thought to be cost-effective and easy to evaluate, and therefore made it easier to leverage donor funding (Cueto, 2004). These programs became a priority focus through the Growth, Oral rehydration, Breastfeeding, and

Immunization (GOBI) package advanced by the United Nations International Children's Emergency Fund (UNICEF), which later grew into GOBI-FFF which added Food supplementation, Female literacy, and Family planning (UNICEF, 1983, Warren, 1986, Warren, 1988, Bellamy et al., 2001), later framed as the 'child survival revolution' (Werner et al., 1997).

At that stage, there were only few limited attempts to design integrated programs in LMICs. The WHO tried to emphasize the need for integrated district-based health services, but this gained little traction in the 1980s or 1990s (Smith and Bryant, 1988). Specific programs in integrated lung health (Practical Approach to Lung Health (PAL))(Murray et al., 2006), intended to improve TB diagnosis and treatment at primary care facilities, and integrated antenatal and obstetric care (Integrated Management of Pregnancy and Childbirth,(IMPAC))(World Health Organization, 2003), were also developed by WHO during this time, but were not launched until after the turn of the century. It was not until late in the 1990s that specific focus was given to integrating the multiple successful interventions for childhood illness including GOBI-FFF, simplified treatment of acute respiratory illness and malaria, amongst others, into an integrated guideline for use by primary care providers (Tulloch, 1999). Entitled the Integrated Management of Childhood Illness (IMCI) this WHO and UNICEF joint program created a single, protocol-driven system of care that targeted non-physician front-line health workers, and addressed prevention and treatment of priority illnesses in children under-five years of age. IMCI used an integrated case management approach comprised of evidence-based interventions from specific vertical programs, structured into symptom-based 'syndromes' which the health worker could evaluate in a single clinical encounter (Gove, 1997). After extensive validation and impact evaluation (Bryce and Victora,

2005), IMCI would go on to be implemented in over 100 countries in the developing world, forming the basis of many ambulatory pediatric care systems.

1.4 The development of IMAI in the context of HIV/AIDS

Given the success of IMCI and its approach to integrated care, the WHO began the development of an analogous guideline for adults and adolescents, entitled the Integrated Management of Adolescent and Adult Illness (IMAI). As with IMCI, IMAI (World Health Organization, 2004) presented an integrated and syndromic approach to the clinical management of adult and adolescent illnesses that are commonly observed at front line primary care facilities in LMICs, including malaria/fever, cough/TB, diarrhoea, sexually transmitted infections, and others. Given the wide array of common conditions in adults and adolescents, unlike in children, IMAI also included protocols for identification, triage, and management of emergencies, and new approaches to the screening and initial management of human immunodeficiency virus (HIV) and chronic non-communicable diseases (NCDs) such as chronic lung and heart disease (World Health Organization, 2004).

At the time of the development of IMAI, the pressing public health issue was the HIV pandemic and access to antiretroviral therapy (ART) (Montaner et al., 2006). Understanding the shifting landscape of political will and funding behind HIV/AIDS and ART programs, the WHO strategically aligned IMAI within the Department of HIV/AIDS (Gilks et al., 2006b). The WHO focused attention on orienting the *Acute Care* protocols of IMAI (World Health Organization, 2009) to the identification of HIV-related opportunistic infections, and even developed IMAI guidelines for the provision of chronic HIV care with ART at the front lines of LMIC health systems (World Health Organization, 2007a). As a result, the general primary care approach

to IMAI was deferred in favor of an HIV-focused program, and in turn, the core IMAI protocols were subject to little rigorous investigation, research, or systematic improvement initiatives.

2. Objective and Rationale of thesis

The objective of this thesis was to test the hypothesis that IMAI training, when combined with a program of sustained mentoring and supervision, will lead to significant improvement in the quality of care and the level of performance of primary health care workers in rural Rwanda. This thesis begins to fill the evidence gap for IMAI by measuring its impact on primary care delivery in a lower HIV prevalence setting, and evaluating IMAI as it was originally intended, rather than the HIV-focused applications it has taken to-date. This is especially topical as efforts to scale up antiretroviral therapy -- which equate to chronic, longitudinal ambulatory care of people with HIV -- have reinforced the need to integrate vertical HIV programs within a foundation of effective general primary care delivery and strong health systems (Peterse and Swartz, 2002, Dongbao et al., 2008, Biesma et al., 2009). This is the first formal evaluation of IMAI and the first evaluation to specifically address quality improvement of ambulatory primary care in an integrated and general context, rather than from the perspective of a specific disease or diseases, or a vulnerable population group.

The main intervention described in this thesis is a program of didactic, classroom-based IMAI training, supported by a system of on-site, post-training supportive supervision and mentoring of primary health care workers in IMAI. The structure of this performance and quality improvement initiative has previously been described in detail (Manzi et al., 2013). It involves a system of routine site visits

by a district-based clinical mentor in IMAI and outpatient primary care, which includes practice-based mentoring and preceptorship, observation of case management, and tailored on-site didactic teaching. The structure also involves routine clinical and systems-based data collection used in health worker performance review and feedback, as well as for site- and systems-based quality improvement. The structure of the intervention is based largely on evidence that didactic training may be necessary for health worker performance and quality improvement, but is often insufficient (Smits et al., 2002, World Health Organization, 2000, Rowe et al., 2005c). It is also based on evidence that the conventional model of sporadic, managerial and audit-based supervision may be sub-optimal for improving quality (Brown et al., 1991, Fritzen, 2007a, De Geyndt, 1995, Dieleman et al., 2009). In its place, more frequent and sustained supervision, focused on support, mentoring, and feedback, leads to better performance (Hansen et al., 2008, Rowe et al., 2010a, Loevinsohn et al., 1995a). This is specifically true for the mentoring program described in this thesis, which has been shown to improve the quality of care and fidelity to IMCI in a similar study population in Rwanda (Magge et al., 2014a).

3. Methods

3.1 Background and overview of study design

This thesis is situated within the discipline of operations research or implementation research. These terms specifically acknowledge that such research is conducted, to the greatest extent possible, within the routine operating conditions of health services. In addition, such research does not attempt to control exposure or covariates beyond what would be expected under conditions of routine program

implementation. In this case, the IMAI training intervention described in this thesis was conducted as a pilot, as it was not yet adopted as a Ministry of Health (MOH) standard operating protocol for primary care in Rwanda. The mentoring initiative, however, was a part of routine operations in the study district, and officially adopted by the MOH.

The principle component of this thesis is a plausibility trial, which is based on a quasi-experimental study design. Despite lacking randomization, plausibility designs maintain the objective of drawing causal inference via observation and comparison (Habicht et al., 1999). In this case, the trial is organized as a pre- / post-intervention study, where the comparator is the same or a similar population as prior to the implementation of the intervention. Plausibility designs have been increasingly advocated for in global public health at the expense of formal randomized control trials (RCTs), especially in operations research. The reason for this is because causal pathways for programs in poor settings can be complex and multi-dimensional (Victora et al., 2004), and hypotheses of their effectiveness often lack the clinical equipoise that is the hallmark of RCTs, given that global health interventions are largely based on known standards of care from the industrialized world (Farmer, 2013).

3.2 General description of study setting

The research in this thesis was conducted in Rwanda, a small, but densely populated, land-locked nation of approximately 12 million people (World Health Organization, 2015). Rwanda is located in East-Central Africa and bordered by Uganda to the North, Democratic Republic of Congo to the West, Burundi to the South, and Tanzania to the East (Figure 1). The country is organized into five

provinces (Northern, Southern, Eastern, Western, Kigali), and subdivided into 30 districts. Since the 1994 genocide, which left approximately 800,000 to one million people dead, and over two million homeless (National Institute of Statistics of Rwanda and ORC Macro, 2006, Uvin, 1998), Rwanda has undergone a dramatic transformation in its population health and socioeconomics, particularly since the year 2000 when mortality returned to pre-genocide levels (National Institute of Statistics of Rwanda and ORC Macro, 2006, Drobac et al., 2013b). Gross domestic product (GDP) has more than tripled in the last decade, and life expectancy grew by nearly 30 years, to 56 years, by 2012 (Farmer et al., 2013, National Institute of Statistics of Rwanda, 2012b). In the decade from 2000 to 2010, for example, maternal mortality fell by nearly 60% (World Health Organization et al., 2012), and under-five childhood mortality by over 70%, (World Health Organization et al., 2012, United Nations Children's Fund et al., 2012) well out-pacing its regional counterparts and similar low-income countries (LICs), while approaching global averages (Farmer et al., 2013). Some have estimated that should current trends persist, Rwanda could be the only country in East Africa to achieve the health-related Millennium Development Goals (MDGs) by the close of 2015 (Farmer et al., 2013).

Many reasons have been postulated to explain Rwanda's dramatic public health transformation, including increases in public sector expenditure on health, strong political will from central government, and the adoption of approaches that prioritize integration of primary care and vertical programs as well as integration of social support programs with health programs, including a system of community-based social insurance called *Mutuelle de Sante* (Farmer, 2013, Farmer et al., 2013, Logie et al., 2008). The distribution of these gains remains uneven however, with rural districts experiencing fewer gains across indicators, compared to urban areas

(Drobac et al., 2013b). As a result, the Government of Rwanda (2009) embarked upon a new Health Sector Strategic Plan (HSSP-II). In addition to setting strategic priority areas (financial and geographic accessibility, human resources for health, medical supplies and logistics, service quality, institutional capacity, specialization and research capacity) that integrate the six building blocks of the WHO approach to health systems strengthening (World Health Organization, 2007b), the MOH prioritized improving population health in rural areas (Government of Rwanda Ministry of Health, 2009).

3.3 Specific description of study site and health system context

In line with the MOH priority for improving rural health outcomes, the intervention described in this thesis occurred in one of the poorest rural districts in the country, southern Kayonza District, which has a population of approximately 190,000 and forms part of Rwanda's southeast border with Tanzania (Figure 2). Southern Kayonza is one of two districts (along with Kirehe) that comprise the intervention area of the Population Health, Implementation and Training (PHIT) Partnership between the MOH, Partners In Health-*Inshuti Mu Buzima* (PIH-IMB), The National University of Rwanda School of Public Health (NURSPH), and Brigham & Women's Hospital/Harvard Medical School (Drobac et al., 2013b). The PHIT partnership is part of a seven-year grant from 2009-2016 from the Doris Duke Charitable Foundation (DDCF). The overall aim of the grant was to examine the impact on population health of an integrated program of health systems strengthening that targets first-level facility and community based health care delivery and quality improvement. One of the main pillars of this intervention was the Mentoring and Enhanced Supervision at Health centres (MESH) program

(Anatole et al., 2012). MESH complements didactic training of health centre nurses – as described in this thesis for IMAI – with a program of routine on-site mentoring and supervision of nurses in their practice area. The on-site mentoring and supervision focuses on the improvement of clinical skills through structured observation and feedback and tailored on-site didactic education, as well as data collection for health worker performance improvement and facility-based and systems-based quality improvement. The MESH program is the basis for the mentoring and supervision initiative described in this thesis.

The Rwandan health system is organized in a manner typical of post-colonial LMIC health systems. There is a network of hospitals, divided into National Teaching Hospitals, Regional Hospitals, and District Hospitals, in descending order of size, staffing, and specialization. This hospital network is underpinned by a front-line system of facility-based care at health centres and in communities. Each village has three appointed community health workers (CHWs) that offer basic health education, family planning, and basic preventive and curative services. These CHWs are linked to a health centre, each of which has an approximate catchment area of 20,000 people. Health centres provide acute care, basic immunizations and childhood care, family planning and reproductive health services, which include uncomplicated labor and delivery services, and diagnosis and treatment of HIV, tuberculosis and malaria. Health centres themselves are staffed entirely by nurses of different cadres, classified as 'A0', 'A1', or 'A2', official Rwandan nursing designations that indicate the level of pre-service education. An A2 nurse has a secondary school education (12 years) with the final two years focusing on nursing science, human physiology, health and human behavior. An A1 nurse has an additional two years of pre-service nursing training and practica. After completing A1 qualifications, an A0

nurse chooses a specialty (e.g. Advanced Nursing, Public Health, Research, etc.), which may require an additional one to two years of pre-service and in-service training. The majority of nurses that staff front line health centres in Rwanda are classified as A1 or A2, and the majority of nurses in this study area were A2. The MOH is currently in the process of phasing out the A2 designation by upgrading all A2 nurses to A1 through a system of distance learning and short-course practica and didactic education. This program had not yet commenced when this research was conducted.

Health centres are, in turn, organized into a series of clinical services. All health centres have an outpatient department, or OPD, which is usually the first point of contact at the facility and where the majority of adult and adolescent acute care takes place. Health centres in southern Kayonza also have a separate clinic for children under-five, which exclusively use the IMCI guidelines, but in other parts of the country this care is also provided through the OPD. Additionally, health centres have antenatal clinics (ANC), which operate at least two to three times a week, depending on staff availability. In addition to a laboratory, as well as an administrative office, many health centres have limited inpatient capacity where patients can be observed overnight or treated for acute, urgent or emergent illness before being transferred to a district hospital. In southern Kayonza, health centres also have a separate 'Infectious Diseases' (ID) clinic that manages HIV and TB exclusively. This is true of many districts in Rwanda where external partners support HIV and TB services, but some health centres operate these services out of the OPD. This thesis focuses exclusively on the implementation of IMAI training and mentoring at health centre OPDs.

Southern Kayonza and Kirehe Districts in the Eastern Province, along with

Butaro District in the Northern Province, are the three districts in Rwanda supported by Partners In Health (PIH) a US-based non-governmental organization affiliated with Harvard University and the Brigham & Women's Hospital in Boston. At the invitation of the Government of Rwanda and in partnership with the William J. Clinton Foundation, PIH – through its local sister organization *Inshuti Mu Buzima* (IMB) - has supported the MOH in the delivery of health services in these districts since 2005. PIH-IMB's specific clinical emphasis has been on improving the quality of care at district hospitals, as well as strengthening primary care through their 'Four Pillars' approach (Walton et al., 2004), which includes voluntary counseling and testing (VCT) and community-based management of HIV with ART, active case finding and treatment of TB and STIs, and women's health services including family planning, antenatal care, and improved midwifery services. PIH-IMB's support to MOH includes extramural support for facility improvements and construction, hiring and human resources administration, additional salary support, training for clinical and non-clinical MOH staff, and support for improved logistics and supply chain management, amongst other areas. The PHIT grant, under which this study occurred, is part of a joint strategic effort of the MOH and PIH-IMB to extend their partnership activities to the front lines of the health system. Specifically, this entails increased support to health centres and to CHWs, and a broadened focus of work beyond hospital care and the four pillars described above, towards strengthened primary health care which includes general adolescent and adult ambulatory services described in this thesis.

The institutional relationships governing this research are illustrated in further detail in Figure 3. The main implementer of clinical services in southern Kayonza is the MOH; specifically for this research, district health workers at

outpatient health centers in southern Kayonza, operating under the supervision of the District Health Unit (DHU) of Kayonza. As described above, implementers were supported by PIH-IMB, who provided supplemental clinical training, equipment, drugs and supplies, as needed, as well as infrastructure and communications upgrades to district health centers. The majority of the funding for this health center support came from the PHIT grant, which was a unique combination of an implementation and research grant in one. PHIT funding was also responsible for the design and implementation of the MESH intervention.

The main research objective of the PHIT grant was to assess the impact on maternal, neonatal, and child morbidity and mortality, using DHS survey data, of the entire program of district health services delivery in southern Kayonza and Kirehe districts, a partnership between MOH and PIH-IMB. This was designed as a pre- post-intervention, stepped-wedge, quasi-experimental study, with the intervention districts aggregated and compared to control districts of similar population size, demographics and epidemiology, who were not exposed to activities under the MOH/PIH-IMB partnership.

As previously described, prior to the PHIT award the MOH/PIH-IMB partnership focused mainly on acute care at district hospitals and ambulatory HIV, TB, and malaria care at health centers, but did not address general primary care services or broader strengthening of first level health facility operations. As such, PHIT funding was aimed at establishing a comprehensive package of health systems strengthening activities at all levels of district health care delivery, and specifically, these funds were directed towards improving access, quality, and scope of care at first level health centers in the study districts.

Within this larger research and implementation trial, specific research studies

were designed to assess the impact of the MESH intervention on health worker performance and quality. As described in greater detail in Chapter 7, the MESH intervention involved supervision of front-line health workers at district health centers, across clinical services including MNCH, HIV, NCDs, and adult and adolescent general primary care, as studied in this thesis. Specific evaluations were designed for each of these disciplines, including a published evaluation of IMCI in the PHIT study area (Magge et al., 2014). These studies were executed largely by faculty from Harvard, Brigham & Women's Hospital, and PIH, with colleagues from the MOH and NURSPH. In the case of the research presented in this thesis, specific arrangements were made for the PhD Candidate to link the PHIT project, and specifically the evaluation of IMAI-MESH, with the PhD program at LSHTM, including ethical approvals and satisfaction of degree requirements. The Candidate served as a Co-Investigator on the PHIT grant, and the Principal Investigator of the sub-study that forms the thesis. This was a unique institutional arrangement made as a concession to the Candidate for years of prior service work at PIH.

4. Outline and contribution of papers

4.1 Research Papers 1 and 2

Research paper 1 has been published (Vasan et al., 2013c) and is a succinct commentary describing IMAI and its relevance to primary care delivery in LMICs and why IMAI serves as a useful reference from which to refocus attention on improving the quality of primary care delivery in these settings. This is followed by a more detailed narrative review of IMAI (Vasan et al., 2014a). This paper describes the evolution of IMAI in the aftermath of Alma-Ata, and provides a critical review of its strengths, weakness, and limitations as an approach to strengthening primary care

delivery in LMICs. This is followed by a discussion of the way forward with respect to the need for more rigorous and thorough research and investigation of IMAI, as well as primary care delivery, more generally. These are the first papers of their kind on the topic of IMAI, specifically, and the first to offer the reader an understanding of where IMAI is positioned relative to vertical interventions, as well as against attempts at integrated care for other population groups.

4.2 Research paper 3

This paper has been submitted for publication and is under review (Vasan et al., 2015c). The paper is a narrative review of support and performance improvement initiatives for front-line primary health care workers. It is the first review of its kind to focus specifically on this population of health workers, instead of performance improvement initiatives more generally across health worker groups or at different levels of the health system. It also offers insight into the conceptual basis and rationale for the design of the MESH initiative that forms a core piece of the intervention described in this thesis.

4.3 Research paper 4

Research paper 4 has been submitted for publication and is under review (Vasan et al., 2015b). It describes a survey of health workers in the PHIT intervention districts, with respect to their current exposure to training courses, how their mix of training matches their current practice responsibilities, and their desire for future training courses and skills. This is the first study of its kind to examine the appropriateness and structure of didactic training against the realities of every day practice and service at rural primary health centres in LMICs.

4.4 Research paper 5

This paper 5 has been published (Vasan et al., 2013a) and is a baseline assessment of the quality of care and health worker performance at health centre OPDs in southern Kayonza, with specific focus on adult and adolescent ambulatory care. The study describes the current practice environment prior to the design and implementation of IMAI intervention, and is the first of its kind to describe the quality primary care delivery from a generalist perspective, without regard to a specific disease or disease group.

4.5 Research paper 6

Research paper 6 has been submitted for publication and is under review (Vasan et al., 2015a). It presents the results of the IMAI intervention trial, designed as a pre/post-intervention plausibility study, of the impact of IMAI training and mentoring on the quality of adult and adolescent primary care and the performance of primary care nurses at the eight government health centres in southern Kayonza. This is the first study of its kind to evaluate the impact of IMAI on quality of primary care delivery. It also presents results of the impact of an innovative system of mentoring and supervision – MESH (as described above) -- on quality and performance, both in conjunction and in the absence of IMAI didactic training.

This final research paper is preceded by a narrative linking chapter (Chapter 6) that describes the process of field-testing and adaptation of the global IMAI guideline, to the specific context of Rwanda and the MOH-PIH/IMB partnership described above. This chapter describes the pragmatic process of field-based testing and adaptation of a generic guideline and application to the specific context described in this thesis.

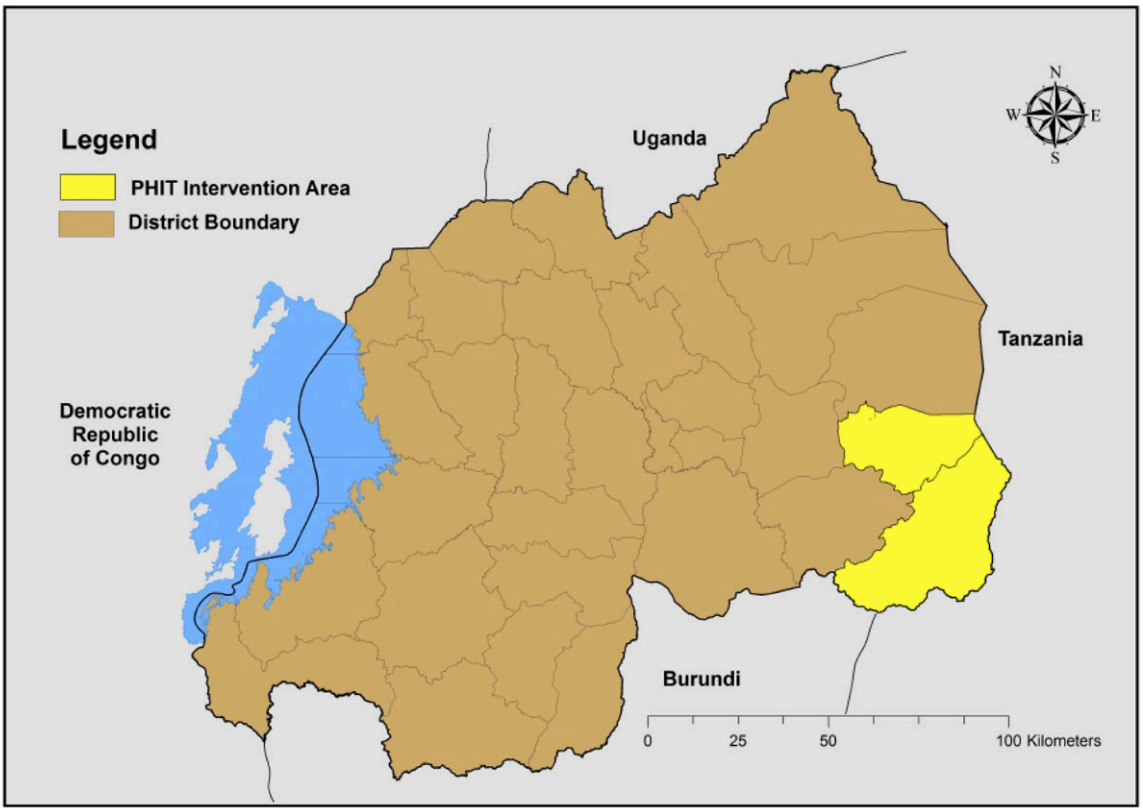

Figure 1: District and PHIT intervention area, Rwanda.

(Source: Government of Rwanda Ministry of Public Works, Transport and Communications, Centre for Geographic Information System and Remote Sensing of the National University of Rwanda, National Institute of Statistics or Rwanda. 2005 [http://giscentre.nur.ac.rw/spip.php?rubrique32]. Created by Fabien Munyaneza, 2012, and adapted from Drobac et al. BMC Health Services Research 2013; 13(Suppl 2):S5)

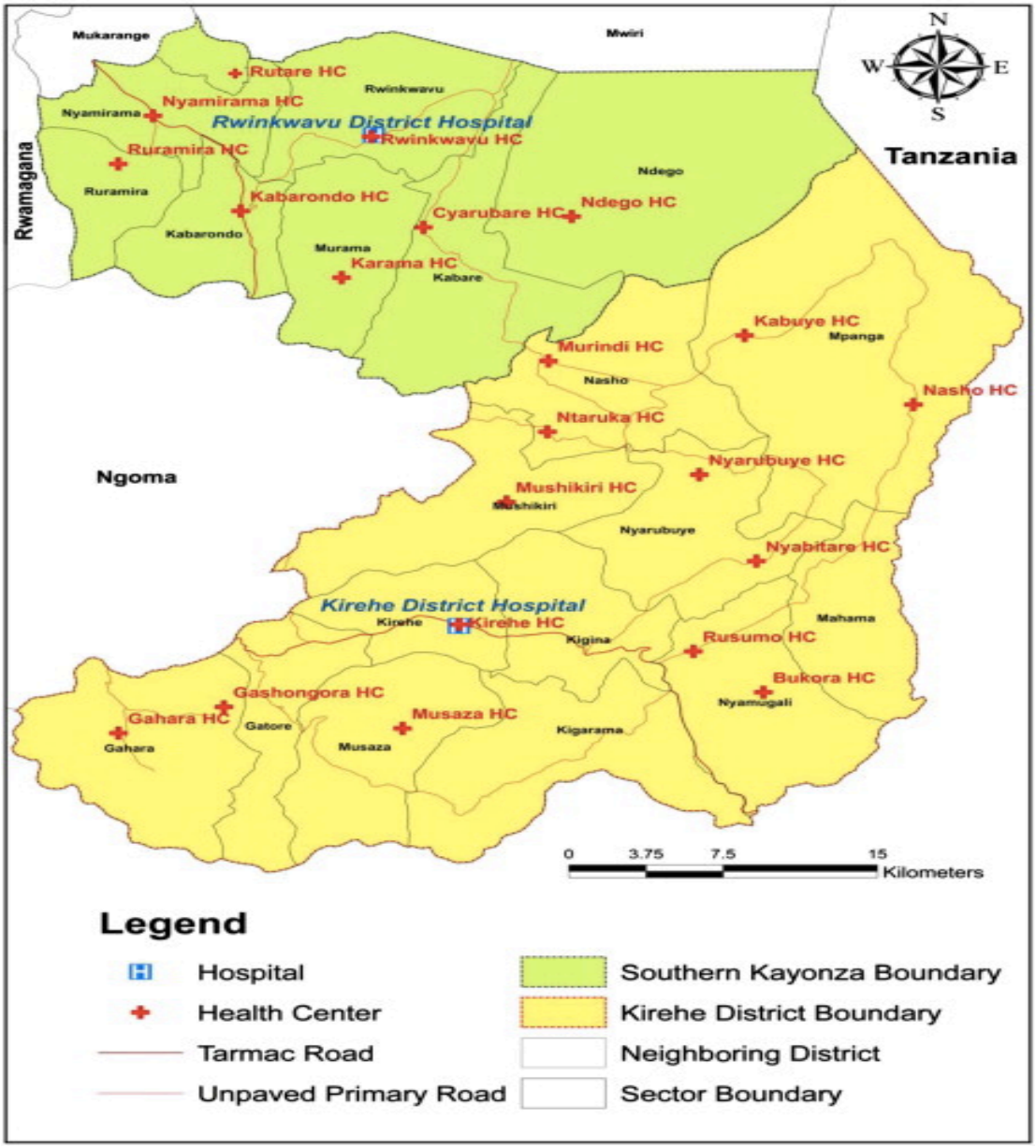

Figure 2: Geographic distribution of HCs and district hospitals in Southern Kayonza and Kirehe districts, 2012.

(Source: Geographic information systems, Partners In Health/Inshuti Mu Buzima, 2012; adapted from Anatole et al, Nursing Outlook 61, no. 3 (2013): 137-144.)

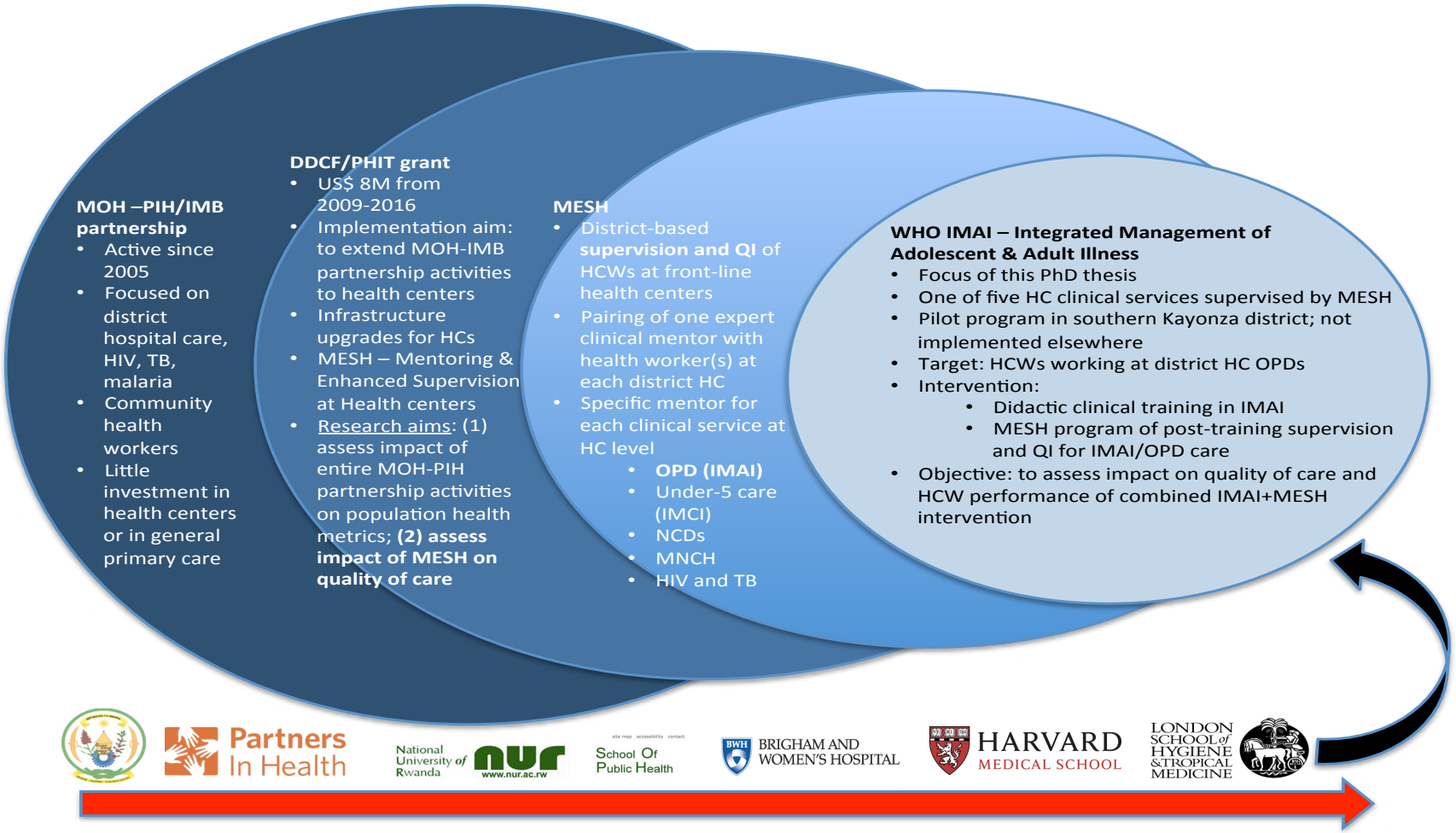

Figure 3: Institutional and programmatic hierarchy in relation to PhD thesis research

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Chapter 2 (Part 1)

Research paper 1

Title: Strengthening of primary-care delivery in the developing world: IMAI and the need for integrated models of care

Author(s): Ashwin Vasan, Andrew Ellner, Stephen D Lawn, Neil Gupta, Manzi Anatole, Peter Drobac, Tom Nicholson, Sandy Gove, Kwonjune Seung, David Mabey, Paul Farmer

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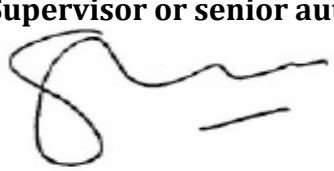

Dr Stephen D. Lawn

Strengthening of primary-care delivery in the developing world: IMAI and the need for integrated models of care

September, 2013, marked the 35th Anniversary of the 1978 Declaration of Alma-Ata, an agreement in which WHO member states outlined a comprehensive vision for primary health care that addressed provision of medical services and wider structural and community needs.[1] More than three decades later, effective, high-quality primary care is still an elusive goal for most countries. This status partly shows a failure to develop practical, operational models of primary-care delivery in the developing world in the wake of Alma-Ata. Instead, the global health community turned to programmes smaller in scope and thus deemed more feasible, rapid, and measurable.[2] This choice is partly why primary care and its attendant metrics often refer to targeted initiatives—eg, immunisation campaigns or childhood interventions for children younger than 5 years—rather than more generalised, systems-based interventions.

When *The Lancet* revisited Alma-Ata on its 30th anniversary in 2008, editors and contributors recommended a recommitment to primary care, broader global-health targets, and better integration.[3-6] Similarly to primary care, integration has several layers, including the integration of multiple social and economic sectors that affect primary care, integration of structures and programmes on the health-systems level, and, clinically, integration of services for multiple diseases into essential packages of care.[7] Published studies suggest that concise integrated management guidelines can help to improve quality of comprehensive primary-care delivery,[8] much as standardised protocols have improved quality within disease-specific programmes.[9] Several examples exist of successful integration of services for one disease programme (eg, tuberculosis,[10] sexually transmitted infections,[11] non-communicable diseases,[12] and family planning[13]) with a second programme (commonly HIV[14]), whereas other groups have proposed so-called diagonal approaches[15] to service integration around, for example, women's health. Perhaps most notably, the WHO/UNICEF Integrated Management of Childhood Illness (IMCI) framework has been widely implemented and has proven successful in integrating treatment for multiple specific diseases (eg, acute respiratory infections, anaemia, diarrhoea or dehydration, and malaria) to improve overall quality of care for children younger than 5 years, when delivered by well-trained and well-supported multipurpose health workers. Despite equivocal findings from long-term effectiveness studies,[16] IMCI leads to reductions in childhood mortality and overall cost-savings to health systems.[17,18]

Also developed by WHO, the Integrated Management of Adult and Adolescent Illness (IMAI)[19] is an analogous guideline that integrates discrete vertical interventions into a single operational model at the point of care. Although IMAI has received little attention or examination, we propose that, with adequate support, research, and iterative improvement, it could have an important role in improvement of primary-care delivery in low-income settings.

Apart from specific programmes for maternal health, HIV, tuberculosis, malaria, and other (mainly infectious) diseases, adult and adolescent ambulatory care in the developing world is neither standardised nor well

Panel: Implementation of and research priorities for Integrated Management of Adult and Adolescent Illness (IMAI)

1. Needs assessment: Few data exist that define quality of care for adult ambulatory acute care at outpatient departments. A baseline assessment of outpatient department care has recently been done in Rwanda (Vasan, unpublished data), but this must be replicated in multiple settings with varying epidemiology to establish quality gaps and better define the specific role of IMAI in different environments.
2. Implementation: IMAI's implementation as a strategy to drive quality improvement for outpatient departments and adult ambulatory acute care must be supported. As with IMCI, IMAI will need strong training programmes, implementation support from Ministries of Health and non-governmental partners, and a robust follow-up involving mentoring, supervision, and quality improvement infrastructure to ensure that post-training increases in quality are sustained.
3. Validation: Questions still exist regarding whether the IMAI case-management guidelines provide valid approaches to triage, screening, diagnosis and assessment, and management and referral. IMAI must undergo rigorous validation studies against gold-standard assessment and treatment, and in this way the guidelines can be adjusted and improved to emphasise those protocols that prove most useful in approximating causal diagnosis and management.
4. Assessment and effectiveness research: A multicountry assessment of IMAI is needed, in the same way as for Integrated Management of Childhood Illnesses. After sustained implementation we must define and measure IMAI's effect on quality of care, nurse performance, and short-term outcomes for specific illnesses, and its effect on the health system—eg, the triage of severely ill patients, screening for and integration with chronic disease programmes, establishment of a robust referral network from health centres to district hospitals, and generation of efficiencies and cost savings to the health system.

integrated. Especially in low-income countries with tiered health systems, most adult and adolescent primary care is delivered through outpatient departments.[7] These departments deliver general care and some specialty care together while principally addressing acute problems. Apart from disease-specific protocols in national guidelines, however, little reference material exists for use during general patient consultations at outpatient departments. Charting is often minimum, typically in a single-line register format specific to that encounter, which indicates a pattern of acute, episodic, and often suboptimum care. Little is known of whether nurses provide adequate screening or prevention counselling. Perhaps most importantly, attempts at iterative changes or improvements are often not mentioned. Ironically, this paucity of data and literature limits further investment and examination, perpetuating a cycle of ignorance about an important area of health-care delivery.

Building on the success of IMCI and recognising the needs in adult primary care, WHO developed IMAI as a series of simplified, syndromic protocols to diagnose and manage common adult illnesses in low-income settings. Using the universal approach to the patient history and physical examination, each protocol classifies patients according to clinical severity and disease chronicity for a presenting symptom complex—eg, fever, diarrhoea, or cough. The protocols then provide prescriptive algorithms for appropriate treatment, follow-up, and referral, as well as counselling and prevention recommendations. Like IMCI, IMAI integrates proven disease-specific clinical protocols, including for malaria, HIV/AIDS, sexually transmitted infections, pneumonia, and tuberculosis. By targeting nurses and other multipurpose health workers, IMAI is aimed at improvement of care at the front line of the facility-based health system through service integration, and is the first guideline of its kind to do so for adult and adolescent primary care.

Because IMAI was developed in parallel with the movement to expand antiretroviral therapy for HIV/AIDS, WHO also produced the IMAI *Chronic HIV Care with ART* handbook,[20] which has been the focus of most published research on IMAI.[21,22] The small amount of literature on the IMAI Acute Care protocols[23] has shown mixed but generally promising results, suggesting the potential for IMAI to positively affect general adult acute primary care[24] (Simoes E and colleagues, unpublished data; Seung KJ and colleagues, unpublished data). Certainly, in view of the scarcity of data, further investigation is warranted.

By contrast with the robust implementation and research agenda for IMCI—which has been the subject of more than 200 studies and papers since its inception—the only available research on IMAI is as mentioned. There are several reasons for this paucity of data: first, a syndromic case-management approach—which is particularly useful in children who present with overlapping clinical signs and who often cannot relate detailed histories—is of less value in adults who present with a wide spectrum of symptoms, diseases, and underlying causes. Second, the population affected by adult and adolescent illness is hard to isolate, and without a clear target—eg, children younger than 5 years—rallying the necessary advocacy and funding becomes more challenging. When launched, IMCI effectively integrated the few existing interventions targeting children younger than 5 years—eg, programmes for immunisation, nutrition, and diarrhoeal disease. The myriad vertical programmes broadly targeting adults and adolescents make integration more complex, and thereby make measurement of the effect of IMAI on overall adult survival more difficult than measuring the effect of IMCI on child survival. Finally, IMAI does not address the community health and policy interventions necessary for comprehensive primary health care as outlined at Alma-Ata. Apart from HIV-focused guidelines on community-based palliative care and patient self-management, the present version of IMAI does not deal explicitly with the integration of facility and community-based care.

Despite the challenges and potential limitations, we contend that models such as IMAI can ignite a dialogue about the use of protocols to develop standards and to improve the integrated delivery of primary care. IMAI uses proven clinical approaches for specific illnesses and integrates them into a single guideline. This type of integration streamlines services for the patient and harmonises the monitoring, evaluation, and reporting of these conditions. IMAI also provides a beginning framework of integrating acute care with care for chronic, non-communicable diseases, which have long been recognised as integral to reform of primary care in the face of demographical and epidemiological transitions.[25] Specifically, IMAI does this by incorporating screening for HIV, tuberculosis, cardiovascular disease, and chronic respiratory disease into its standard and

integrated approach to the patient encounter, and gives clear follow-up and referral protocols to help distinguish between an acute event and an acute exacerbation of an underlying chronic illness. In this way, a system of primary-care delivery organised around IMAI provides a clear entry-point for patients with chronic disease who could be missed in the present model designed for acute care and episodic patient contact.

Finally, through its general prophylaxis section, IMAI also makes a first attempt to integrate preventive care in a standardised and operational way by addressing topics such as insecticide-treated mosquito nets, screening for alcohol abuse, and safe-sex practices.

Comprehensive and integrated primary health care encompasses more than the ambulatory services delivered to adults and adolescents and addressed by models such as IMAI, but improvement of primary-care delivery in poor countries will necessitate rigorously tested operational models. A paradigm shift is needed to give health-care providers a more sophisticated and standardised approach to the patient which integrates acute and chronic care, and prevention and treatment. Definition and implementation of a standard of primary-care delivery will serve as the basis for ongoing quality-improvement efforts. To achieve its potential in contributing to a vision of integrated global primary care, IMAI—or any such model—will need support (panel). We recognise that disease-specific health initiatives are, and will continue to be, an integral part of the fabric of global primary care; such initiatives should complement, not compete with, one another. IMAI provides a clearly-defined approach to integrated primary-care delivery in the developing world that can be implemented, tested, analysed, iterated, and improved on. With a robust evidence base, we can deliver on the promise made by Alma-Ata more than 30 years ago.

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We declare that we have no conflicts of interest.

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Chapter 2 (Part 2)

Research paper 2

Title: Integrated care as a means to improve primary care delivery for adults and adolescents in the developing world: a critical analysis of Integrated Management of Adolescent and Adult Illness (IMAI)

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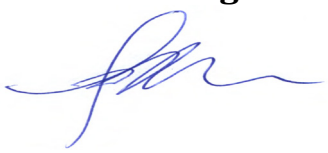

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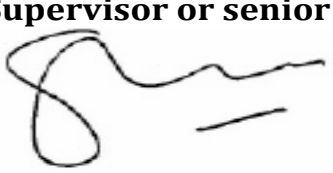

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Integrated care as a means to improve primary care delivery for adults and adolescents in the developing world: a critical analysis of Integrated Management of Adolescent and Adult Illness (IMAI)

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Abstract

Background: More than three decades after the 1978 Declaration of Alma-Ata enshrined the goal of 'health for all', high-quality primary care services remain undelivered to the great majority of the world's poor. This failure to effectively reach the most vulnerable populations has been, in part, a failure to develop and implement appropriate and effective primary care delivery models. This paper examines a root cause of these failures, namely that the inability to achieve clear and practical consensus around the scope and aims of primary care may be contributing to ongoing operational inertia. The present work also examines integrated models of care as a strategy to move beyond conceptual dissonance in primary care and toward implementation. Finally, this paper examines the strengths and weaknesses of a particular model, the World Health Organization's Integrated Management of Adolescent and Adult Illness (IMAI), and its potential as a guidepost toward improving the quality of primary care delivery in poor settings.

Discussion: Integration and integrated care may be an important approach in establishing a new paradigm of primary care delivery, though overall, current evidence is mixed. However, a number of successful specific examples illustrate the potential for clinical and service integration to positively impact patient care in primary care settings. One example deserving of further examination is the IMAI, developed by the World Health Organization as an operational model that integrates discrete vertical interventions into a comprehensive delivery system encompassing triage and screening, basic acute and chronic disease care, basic prevention and treatment services, and follow-up and referral guidelines. IMAI is an integrated model delivered at a single point-of-care using a standard approach to each patient based on the universal patient history and physical examination. The evidence base on IMAI is currently weak, but whether or not IMAI itself ultimately proves useful in advancing primary care delivery, it is these principles that should serve as the basis for developing a standard of integrated primary care delivery for adults and adolescents that can serve as the foundation for ongoing quality improvement.

(Continued on next page)

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Summary: As integrated primary care is the standard of care in the developed world, so too must we move toward implementing integrated models of primary care delivery in poorer settings. Models such as IMAI are an important first step in this evolution. A robust and sustained commitment to innovation, research and quality improvement will be required if integrated primary care delivery is to become a reality in developing world.

Keywords: Primary care, Integrated management, Integration, Quality improvement, Health care delivery, Health systems, IMAI

Background

The 1978 Declaration of Alma-Ata [1], where member states of the World Health Organization (WHO) declared 'health for all' by the year 2000, remains a significant, if elusive, goal in global health. Spurred by limited successes in community-based primary care delivery in India, China, and elsewhere, health ministers and policymakers from 134 countries gathered at the International Conference on Primary Healthcare at Alma-Ata (now Almaty, Kazakhstan) to express their commitment to bringing primary care services to scale around the globe [2]. That vision of comprehensive global primary care, while still unrealized, informs our current concept of primary care as a system that encompasses the provision of basic medical services and also accounts for community needs [3]. Alma-Ata also explicitly acknowledged the often overlooked links between primary care and broader issues of social protection such as clean water and sanitation, nutrition, and food security [4]. As we continue to combat global health inequalities, we can learn from Alma-Ata and from the subsequent implementation (or lack thereof) of primary care programs in resource-poor countries [5-8].

The decades since Alma-Ata have witnessed dramatic shifts in priorities, political will, and funding in global health. Amidst such shifts, there have been limited successes, including encouraging improvements in child survival and immunization coverage for vaccine-preventable diseases [9]. The Millennium Development Goals (MDGs), particularly the health-related goals on child survival, maternal health, HIV, tuberculosis, and malaria, laid out benchmarks for primary health systems performance. The proliferation of global health initiatives for vertical, disease-specific programs could, and should, be leveraged for wider systems improvement [10,11]. Despite Alma-Ata's clarion call, primary care continues to attract too few resources. The health-related Millennium Development Goals remain out of reach for many countries in the developing world, particularly in sub-Saharan Africa where shortages of doctors, nurses, and community health workers threaten the advances that have been made [12,13]. This paper first attempts to outline several sources of the persistent dissonance between primary care theory and practice as they apply to effective global primary care delivery. Secondly, this paper examines the role of service integration and integrated models of care and their potential to revitalize and strengthen primary care delivery in poor settings. Finally, the paper examines the WHO's Integrated Management of Adolescent and Adult Illness (IMAI) as one example of such a model that is deserving of consideration as a method to improve basic primary care delivery.

Discussion

Alma-Ata and the politics of language

Despite advancing the primary care discourse as a whole, Alma-Ata lacked a clear implementation plan and failed to bring about operational consensus, instead focusing entirely on 'primary healthcare' as a high concept encompassing intersectoral approaches with a distinct community and sociopolitical focus [1]. In this vacuum, artificial distinctions emerged between 'primary healthcare', as above, and 'primary care' as simply front-line clinical services [2,14-16]. Some have subsequently tried to bring clarity to primary care's role as both a discipline and a practice. Frenk, for example, differentiates three uses of the word 'primary' [17] as (1) first contact: the point of first contact between the patient and the formal health system, (2) first level: the preventive and curative services delivered at the front line of a health system, and (3) first causes: the social determinants of health and the interdisciplinary approaches to addressing basic public health needs [18]. Starfield and Shi suggest that the distinction between primary care as a service within the broader schema of primary healthcare is critical in order to mobilize societal actions towards health equity [19] and Gilson *et al.* put forward that good primary care delivery is dependent on robust primary healthcare [20]. More recently, others have tried to cast primary care as a distinct medical specialty, a set of functions within the health system, or a way to orient health systems through regional-level or area-level aggregates [21]. It would appear that none of these distinctions have achieved broad consensus.

As academic circles debated the theoretical definitions of primary care, funders, policymakers, and implementers shifted away from Alma-Ata's broad and systems-oriented vision in favor of programs more limited in scope and thus deemed more feasible, rapid, and measurable [22]. This is, in part, the reason that 'primary

care' often refers to targeted initiatives (immunization campaigns, for example) as opposed to more complex systems interventions.

Integration and gaps in adult and adolescent primary care

In recent years, calls have been made to capitalize on the successes of vertical interventions by increasing investment in broader global health targets [23], particularly better integration. Integration, like primary care itself, has been defined from multiple perspectives: from the perspective of the multiple government sectors and academic disciplines that impact primary care, from the perspective of the health system, and from the perspective of disease, meaning the combination of clinical services for specific diseases or groups of diseases into integrated, essential packages of care. However, from any perspective, the challenge remains in delivering front-line primary care services that optimize both coverage and equity without compromising quality of care.

The literature suggests that concise and integrated clinical management guidelines can play a role in improving the quality of comprehensive primary care delivery [24], much as standardized guidelines and protocols have improved quality within individual global health initiatives [11]. In many instances, this type of integration has involved integrating HIV/AIDS services into other existing programs. For instance, integration of HIV care with tuberculosis (TB) and sexually transmitted infection (STI) services in Haiti showed demonstrable increases in patient access, uptake of testing and case detection, enrollment in antiretroviral therapy (ART), and even benefits in unrelated programs such as vaccine coverage [25-27]. Similar results with TB/HIV integration have demonstrated improved rates of screening [28,29] increased enrollment in antiretroviral treatment programs [30], and even improved TB treatment outcomes in one cohort in Ghana [31], but a recent systematic review of TB/HIV integration suggested that more robust downstream outcome measures should be emphasized in future research [32]. Research has also been conducted on integration of HIV care and treatment services with programs such as Prevention of Mother to Child Transmission (PMTCT) [33] and family planning services [34-36], with generally positive results with respect to patient access, and patient and provider perceptions. But not only are these outcomes limited in scope and generalizability, these integrated programs also benefit from the fact that HIV is coincident or closely related with these conditions/services and as such binary integration of two or several related programs may not be applicable to the wider primary care setting. There are several studies examining integrated HIV care with routine primary care services [25,37,38], but again most examine access, uptake, and systems metrics without reporting impact on clinical care and treatment for other general primary care conditions, or overall patient outcomes. Finally, there have been numerous examples of binary program integration between non-HIV disease programs and routine primary care, previously and comprehensively reviewed [39-41], but many do not report quantitative outcomes or outcomes that enable robust comparisons and conclusions about integration as a quality improvement strategy.

A more general approach to integration has been implemented and studied, however, with some successful examples. Based on an early version of IMAI and initially designed as an intervention to integrate acute respiratory conditions and HIV care into routine primary care services in South Africa [42,43], the Practical Approach to Lung Health in South Africa (PALSA) was expanded to include a range of common primary care conditions [44] and rigorously tested and scaled up nationally to over 10,000 nurse-led primary care teams (M Zwarenstein, Institute for Clinical Evaluative Sciences, University of Toronto personal communication) and internationally in Malawi [45,46] where ongoing testing continues. Results from implementation of this program has shown not only gains in specific outcomes such as rates of cotrimoxazole prophylaxis for PCP and increase rates of TB diagnosis in the primary care setting [47], but also improved provider perception of care [44,48] and even cost effectiveness [49].

Another notable example of integrated clinical management at the point of delivery is the WHO/United Nations International Children's Emergency Fund (UNICEF) Integrated Management of Childhood Illness (IMCI) for children under 5. The IMCI framework has proven successful in integrating treatment for specific diseases (for example, acute respiratory infections, anemia/malnutrition, diarrheal disease, malaria) and preventive interventions into a single integrated guideline with the aim to address the major causes of childhood mortality in children under 5, when delivered by well-trained and well-supported multipurpose health workers. In addition to improving outcomes for specific conditions such as pneumonia [50], the implementation of IMCI has also led to reductions in overall childhood mortality and overall cost savings to the health system [51,52]. Although the multi-country evaluation of IMCI raised concern about health system limitations to expanding IMCI implementation and the lack (then) of community tools [53] and while there has been debate around issues of inadequate ongoing support and missed opportunities for quality improvement [54], newer long-term data from Egypt also suggests that under-5 care based on IMCI leads to durable mortality reductions [55], and more than 100 countries continue to implement IMCI as a key component of primary care delivery to children under 5 years of age.

In general, the impact of integration on primary care delivery is poorly understood, particularly for adults and adolescents. While the data above suggest that integrated clinical and program management for specific (and often related) conditions could be an important strategy in improving quality of primary care delivery, the overall quality of data is generally poor and, often based on incomparable outcomes. Definitive reviews have explicitly called for expanded and improved research in the field [39-41]. In addition, little study has occurred on how to implement a standard and integrated approach to the initial general patient assessment and screening in primary care clinics in poor settings. Such a standard approach could serve as the basis for the delivery and ongoing quality improvement of integrated primary care for populations in these settings.

The state of adult and adolescent primary care delivery

Particularly in low-income nations with tiered health systems, the majority of adult primary care is delivered in outpatient departments (OPDs), a legacy often attributed to structural recommendations initially put forth in the UK Dawson Report of 1920 [17] (see Box 1). In many resource-limited countries, particularly in rural areas, these departments serve as catchalls, delivering general and limited specialty care together while focusing on management of acute conditions. The care provided to adults and adolescents in outpatient departments, however, often lacks the necessary standardization and integration, apart from disease-specific services delivered within OPDs. Beyond protocols in national guidelines, there is little reference material available for use during the general patient consultation and when available, these materials are usually disease specific. Charting is often performed in a single-lined register, which reflects a troubling pattern of minimal data collection, and only acute, episodic, and a very limited scope of care. Little is known of whether nurses appropriately screen for sexually transmitted infections or for tobacco or alcohol abuse, for instance, or provide appropriate counseling on prevention and lifestyle changes. So, as expected, there has been little rigorous study on the quality of adult and adolescent primary care delivery in the developing world from either the clinical or operational perspective, with most research focusing instead on self-reported or self-perceived performance [56], or using metrics from children under 5 as a proxy for overall effectiveness of primary care within the health system [57]. Perhaps most importantly, there is often no mention of attempts at iterative changes or improvements. It is ironic that this paucity of data limits the resources devoted to further examination, perpetuating major gaps in understanding in this important area of healthcare delivery in poor settings.

Box 1: Functions of the OPD in the health system*

- Triage and referral or admission of acutely ill patients.
- Diagnosis and management of acute, non-severe illness that does not require hospitalization or higher-level care (for example, diarrhea, pneumonia, malaria).
- Screening, diagnosis, and management or referral of chronic illnesses (for example, HIV or non-communicable chronic diseases) that may require longitudinal specialty care from a clinic or service that deals with these conditions specifically.
- Provision of health behavior messages and prevention services, including for family planning, STI and HIV prevention, nutritional counseling and support, as well as lifestyle modification for chronic disease prevention.

*Some variation by particular setting or country.

IMAI as an example of integrated primary care for adults and adolescents

We are neither the first to recognize the need for standardization and integration in adult primary care delivery, nor the first to propose the development and implementation of essential packages of care [9]. Capitalizing on the success of IMCI, WHO developed IMAI in a similar fashion, first as a series of simplified, syndromic case management protocols to diagnose and manage common adult illnesses in resource-poor settings, and then integrated into a single clinical management guideline [58]. The IMAI acute care protocols are structured around presenting symptoms, and classify the patient according to clinical severity and disease chronicity using a syndromic approach structured around a simplified version of the universal patient history and physical examination. This is followed by simple and prescriptive algorithms for syndromic treatment as well as follow-up and/or referral recommendations. Like IMCI before it, IMAI draws upon proven approaches to the screening, diagnosis, and management of specific diseases including malaria, HIV/AIDS, STIs, pneumonia, diarrheal disease, and tuberculosis. IMAI was introduced to improve acute care through better integration of delivery at a single point-of-care, usually health center or hospital OPDs. It was designed to target nurses and other providers delivering care at the front lines of health systems. It was the one of the first guidelines of its kind to address adult primary care in both general and integrated fashions, and to take proven interventions for priority diseases and present them within a unified strategy.

With unprecedented attention and funding for HIV/AIDS at the time of IMAI's initial development, IMAI's implementation was absorbed within the broader movement to increase access to antiretroviral therapy. WHO developed the IMAI *Chronic HIV Care with ART* handbook [59] to build health worker capacity in managing HIV disease with antiretroviral therapy (ART), using a simplified format analogous to the original IMAI protocols, and this handbook quickly became the most visible and widely implemented component of the IMAI package, particularly in southern and eastern Africa. It did not offer new management protocols *per se*, but rather incorporated existing WHO clinical staging, chronic HIV care, antiretroviral therapy and prevention guidelines into a simpler format targeting nurses and multipurpose healthcare workers operating within decentralized ART scale-up programs [60,61],. It was based on applying the general principles of good chronic care [ref], derived from review of the experience with non-communicable disease programs, and was innovative in its use of PLHIV expert patients, both on the clinical team and as trainers.[ref]. Currently, more than 40 countries are in various stages of adaptation or implementation of IMAI for use in their HIV treatment programs.

Building on the lessons learned in scaling up AIDS treatment and care, the original IMAI *Acute Care* guidelines continued to evolve and expand, yet have not been implemented with nearly the same support. Consequently, the majority of available research on IMAI to date has focused on the *Chronic HIV Care* guidelines, which does not offer insight into IMAI's potential to improve primary care delivery through integration [62,63]. The limited available literature on the original *Acute Care* components of IMAI has shown mixed but generally promising results, though they remain mostly unpublished. For example, an unpublished 2003 validation study using the cough and/or difficulty breathing algorithm showed a sensitivity of 72% in detecting severe pneumonia, but was insensitive (0% to 22%) in detecting other causes of respiratory illness, and non-specific in its detection of chronic pulmonary conditions [Simoes E, Todd J, English R, Sepulveda R, Ottomani SE, Gove S: Preliminary Analysis of IMAI Validation Studies. 2003. Unpublished.]. A 2009 multicenter study utilizing the acute care algorithms in an HIV-positive cohort at Ethiopian government health centers demonstrated greater than 85% sensitivity and greater than 92% specificity in diagnosing upper respiratory tract infection, pneumonia, tuberculosis, and dysentery [64]. The algorithm performed poorly, however, in assessing the severity of illness and in the diagnosis and assessment of anemia. Finally, a recent study from Lesotho showed that a number of specific symptoms and clinical signs from the algorithm were significant predictors of different disease states (for example, chronic vs acute respiratory conditions, tuberculosis, pneumonia), but overall only moderately sensitive and specific [Seung KJ, Rigadon J, Finch M, Gove S, Vasan A, Ramangoaele L, Satti H: Evaluation of integrated management guidelines for patients with respiratory symptoms. 2011. Unpublished]. The only known research on IMAI *Acute Care* to date, these three studies, while certainly revealing some mixed results, indicate the potential for the IMAI algorithms to positively impact general adult acute primary care. Nevertheless, this is certainly a limited evidence base and further investigation is paramount.

Limitations and opportunities for integrated care and IMAI

There are a number of possible explanations for why IMAI has struggled to achieve programmatic or research relevance in the wider public health and primary care implementation and research agenda. The first hurdle is clinical and technical, reflecting limitations of the basic IMAI syndromic approach. Use of a syndromic management in adults and adolescents is fraught with challenges when compared with children, where it is effective precisely because children frequently present non-specifically and with overlapping clinical signs, where IMCI could focus on a limited number of conditions causing a significant proportion of mortality, and because children are often incapable of providing reliable and detailed histories. Adults, by contrast, usually present with more complex spectra of diseases and etiologies, thus decreasing the utility of broad-spectrum diagnosis and management and increasing the complexity of an integrated clinical algorithm, and limiting the generalizability of a single-integrated guideline across settings with varying epidemiology and demographics, without rigorous adaptation.

The second challenge is that the 'adult and adolescent' population is difficult to isolate, both politically and programmatically. It becomes challenging to generate the necessary advocacy and funding for implementation, quality improvement, and research without a clear and defined target population, such as 'children under 5' or 'patients with HIV'. Introduced in the wake of the so-called 'child survival revolution' of the 1980s [9], IMCI integrated the major important vertical interventions targeting the under-5 population (nutrition, immunization, acute respiratory infection, malaria, and diarrheal disease programs, for example), thus making it a circumscribed and attractive target for funders, implementers, researchers and policymakers alike and may explain why even today under-5 metrics are often used to describe overall health system performance [65,66]. Moreover, as previously suggested above, the 'integration' of closely related or coincident conditions may not be of relevance for a more generalized

approach. The numerous and varied vertical programs broadly targeting 'adults and adolescents' and impacting primary care delivery, make service integration in this population much more complex, and thus measuring the impact of an intervention such as IMAI on 'adult survival' is harder than corresponding interventions for under 5 s, for example.

Third, while IMAI addresses healthcare delivery at the facility level, it does not address the community health and policy interventions necessary for comprehensive primary healthcare as outlined at Alma-Ata. Community health programs and community health workers have been shown to play a critical role in reducing maternal and neonatal morbidity and mortality, as well as in more complex programs such as tuberculosis control and therapy, and ART delivery [67-76]. Additionally, large-scale global efforts are underway to recruit, train, and retain community health workers towards achieving the health-related MDGs [77]. But aside from guidelines on community-based palliative care, patient self-management and ART treatment supporters, the current version of IMAI does not deal explicitly with the integration of facility and community-based primary care nor the training of community health workers to support integrated primary care delivery.

Finally, we must return to the issue of persistent confusion around the aims, definitions, and scope of global primary care. The inability of the public health community to achieve a common operational understanding of primary care, especially for adults and adolescents, has predictably led to inertia in program implementation and difficulty generating a policy consensus, advocacy platform, and funding base. Interventions such as IMAI struggle to find programmatic footing in such a climate [78].

Despite the challenges and potential limitations, we contend that specific models such as IMAI can and should stimulate dialogue regarding the wider use of integrated clinical guidelines to improve primary care delivery in developing countries (see Box 2). Specifically, attention should be given to those models that offer realistic approaches for healthcare workers to provide integrated management for a range of conditions at a single point-of-care. Integrated clinical models such as IMAI take proven clinical approaches for specific illnesses in specific populations and integrate them into a single guideline implemented at a single point-of-care. This type of integration streamlines services for the patient and harmonizes the monitoring, evaluation, and reporting for these conditions. As such, it could be an important catalyst in developing a common standard of global primary care delivery that can serve as the basis for ongoing quality improvement.

Box 2: Specific ways in which IMAI could advance primary care delivery

1. Integration of services for existing vertical programs
   - Integrate proven clinical protocols for specific illnesses such as malaria, STIs, and pneumonia.
   - Advance towards healthcare worker in multipurpose settings managing a range of conditions.
   - Streamline patient services with potential increase in patient satisfaction and uptake of care.
   - Harmonize monitoring, evaluation, and reporting for these conditions.
2. Expanded standardization/protocolization of care
   - New, rigorously-developed syndromic protocols for common illnesses such as adult headaches, oral and throat problems, and skin conditions that do not currently have vertical programs.
   - Additional chronic care guidelines and training tools for decentralized management of important chronic non-communicable diseases including diabetes, hypertension, and heart failure.
3. Integration of acute and chronic care
   - Integrated chronic disease (chronic infections and NCDs) screening within each protocol (for example, HIV, TB, heart disease, chronic lung disease).
   - Well-defined entry point into health system for patients with NCDs.
   - Guidelines for follow-up of acute illness, moving away from episodic to longitudinal care.
4. Integration of prevention and treatment
   - Integrated screening and prevention messages within each protocol, such as tobacco cessation for smokers with chronic cough and respiratory conditions.
   - Section on general prophylaxis and behavior modification for routine use, including topics such as condoms and safe sex practices for HIV and STI prevention, tobacco and alcohol cessation, family planning, and use of bednets for malaria prevention.
   - Section on prevention in special populations, including adolescents and men who have sex with men (MSM).

IMAI in its current form outlines a preliminary model for integrating acute and chronic care by incorporating screening for HIV, tuberculosis, cardiovascular disease, and chronic respiratory conditions, for example. Long recognized as integral to a comprehensive primary care reform

strategy [79], non-communicable disease (NCD) interventions have been integrated into existing vertical delivery for TB [80,81], HIV [82] and reproductive health services [83], but these have been limited in scope and have yet to tackle the more general integration of acute and chronic care into a single approach. Employing integrated and systematic screening for NCDs within a standardized approach to the patient offers a clear and operational entry point into care for patients with chronic diseases who may otherwise be overlooked in a system designed principally for acute care and episodic patient contact. Additionally, the IMAI *General Principles of Good Chronic Care* [84] was developed to draw on the experience of non-communicable disease control to support HIV/AIDS treatment scale up by reorienting existing health worker practices and communication toward longitudinal patient care, but these principles could readily be extended to care for other chronic NCDs going forward. Models such as IMAI could improve follow-up care and referral services by advising providers on when and how to follow an episode of acute illness longitudinally, especially if they are concerned that persistent symptoms may indicate an underlying chronic illness. Finally, IMAI *Acute Care* contains a general prevention section, encompassing such topics as safe sex practices, immunization and the use of bed nets to prevent the transmission of malaria, and thus takes the first practical steps toward integrating prevention and treatment across a range of conditions within a single structured protocol.

The way forward

There is no doubt that the evidence base for IMAI is weak. And, as previously noted, even the literature on integrated care more generally has significant limitations. But in itself these limitations should not preclude further examination of integrated primary care as a strategy to improve primary care delivery. However flawed, the evidence base for integrated care in under 5 s and in leveraging HIV programs as an entry point to integrated care, at least offers some initial promise for more robust analysis of general primary care approaches. The following specific areas of implementation and research are critical to improving our understanding of the potential of integrated primary care models to improve quality:

1. Describing the baseline: in our review of the peer-reviewed and grey literature we were unable to identify any current data that define quality of care for general adult and adolescent ambulatory acute care at outpatient departments using quantitative approaches. Our group has completed a baseline assessment of OPD care at eight health centers in one district in southeast Rwanda [85], but this must be replicated in multiple settings with varying epidemiology in order to establish quality gaps and to better define the specific role of integrated care in different environments.
2. Implementing the models: robust support must be given for implementing integrated models of care to drive quality improvement for adult ambulatory acute care in primary care clinics. This will require strong didactic training programs, implementation support from Ministries of Health and non-governmental partners working together, and a robust follow-up, supervision, mentoring and quality improvement apparatus to ensure that post-training improvements in quality are sustained. In our project in Rwanda, for example, an integrated mentoring and supervision infrastructure has been implemented to support a range of primary care service delivery at rural health centers in three districts [86].
3. Validating the models: one of the strengths of the syndromic approaches offered in IMCI, for example, is in the range and quality of the validation research undertaken prior to multicountry analysis [87-94] whereas only one published validation study of IMAI Acute Care has been done. More validation work is needed in a range of epidemiological settings, to improve the adult and adolescent integrated syndromic protocols for the care and treatment of common primary care conditions. Thus, IMAI and all integrated models should undergo rigorous validation against gold-standard assessment and treatment, thereby identifying the most sensitive and specific protocols, and highlighting opportunities for developing new approaches where gaps or weaknesses exist.
4. Multicountry evaluation: to be brought to scale and to have maximum impact on patient and population outcomes, integrated models of care must be implemented in a range of settings with varying epidemiology, health infrastructure and health workforce dynamics. Subsequently we must measure and define the impact of these models on the quality of care, health worker performance and process outcomes, and short-term outcomes for specific illnesses. More importantly, long-term effectiveness studies must be employed to define the impact of integrated clinical management on overall morbidity and mortality.
5. Cost and efficiencies: as with any successful program, we must examine the costs of implementing integrated models of primary care in poor and rural health systems in the developing world. As with many interventions based on education and feedback [8], we would anticipate that the cost effectiveness of such models to be high, but this requires specific study. Additionally, research must be performed to examine gains in efficiency in health

system performance, such as in the identification and triage of severely ill patients to higher levels of care, screening for and integration with chronic disease programs, establishing a well-functioning referral network from health centers to hospitals at the district, and creating integrated electronic medical records and health information systems to support the delivery of high-quality primary care. As well, studies should be performed on the requisite staffing and human resources required to successfully implement integrated models of care such as IMAI.

6. Strengthening the integrated system: the success of integrated primary care delivery rests on its ability to function within a well-performing and integrated health system. Thus efforts to strengthen clinical care through integrated management must be complemented by a broader operational and policy strategy that addresses, for example, the use of information technology in the primary healthcare system to support delivery of care, the strengthening of management and administration capacity at facilities and district/regional public health authorities, the systematic integration of community health workers with health-center-based teams, and further upstream, the integration of financing of healthcare delivery at the front lines of the health system. Without these parallel interventions, any integrated clinical model cannot realize its full potential impact in improving primary care more broadly.

Summary

In the developed world, integrated primary care is a given. Primary care providers are expected to be able to triage, screen for, diagnose, and manage a wide range of conditions, and when they cannot, to know when and to whom to refer for specialty consultation or more advanced or intensive care. This expectation is set by society, and reflected by the profession through the education and training of front-line providers. It is towards this model that we should aim globally, and perhaps most vitally in the poorest and most rural of settings where structural inequality and relative geographic isolation make high-quality, front-line primary care even more necessary.

We recognize that disease-specific programs are essential components of global primary care. And of course, comprehensive primary healthcare cannot be reduced to the ambulatory clinical services provided to a select population. But neither can efforts to strengthen the quality of primary care delivery in the developing world continue to rely on vertical programs alone to drive improvement. Instead, a paradigm shift is required that will give providers a sophisticated and standard way to approach each patient; one that offers robust and sensitive screening methodologies, that integrates care for acute and chronic conditions as well as prevention and treatment, and that strengthens referral and follow-up patterns as systems transition toward longitudinal care of the patient. Integrated models of primary care such as IMAI provide a clear approach that can be iterated and improved upon to that end. Going forward, successful integrated models of care must come from the people and places where they will be delivered, given the proximity of primary care delivery to the communities served. Thus with a commitment to innovating, implementing, and improving upon models of integrated care, including IMAI, we can finally deliver on the promise of Alma-Ata.

Abbreviations

AIDS: Acquired immune deficiency syndrome; ART: Antiretroviral therapy; HIV: Human immunodeficiency virus; IMAI: Integrated Management of Adult & Adolescent Illness; IMCI: Integrated Management of Childhood Illness; MDGs: Millennium Development Goals; NCD: Non-communicable disease; OPD: Outpatient department; PALSA: Practical Approach to Lung Health in South Africa; STI: Sexually transmitted infection; TB: Tuberculosis; UNICEF: United Nations International Children's Emergency Fund; WHO: World Health Organization.

Competing interests

All authors declare that they have no competing interests, financial or otherwise, in relation to this research or production of this manuscript.

Authors' contributions

AV led the initial design and conception of the manuscript with support from SDL and DCM and led the writing of the first and all subsequent drafts of the manuscripts, including incorporation of coauthors' edits. AE worked directly with AV on design and conception of the manuscript and contributed significant written and editorial inputs to the manuscript at every stage. SDL supported AV and AE in the design and conception of the manuscript and contributed substantive editorial inputs to early drafts of the manuscripts. NG and MA worked together and contributed significant research and substantive editorial inputs to early drafts of the manuscript, especially the Background. PD and TN contributed substantive editorial inputs to later drafts of the manuscript especially the Discussion. SG and KS contributed significant research and editorial input to the Discussion, especially the sections on IMAI, with SG also contributing to the sections on IMCI and NCDs. DCM and PEF served as the senior authors on the manuscript, providing overall editorial guidance to the lead authorship team and contributing significant editorial and intellectual content to later drafts of the manuscript. PEF in particular contributed significant edits to the final version. All listed authors gave final approval to the manuscript.

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Chapter 3

Research paper 3

Title: The design and effectiveness of programs to support and improve the performance of primary health care workers in low and middle-income countries: a comparative review.

Author(s): Ashwin Vasan, David C. Mabey, Helen-Anne Epstein, Stephen D. Lawn

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Supervisor or senior author's signature to confirm Candidates role:

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TITLE: The design and effectiveness of programs to support and improve the performance of primary health care workers in low and middle-income countries: a comparative review.

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ABSTRACT:

Primary health care workers (HCW) in low- and middle-income settings (LMIC) often work in challenging conditions in remote, rural areas, in isolation from the rest of the health system and particularly specialist care. Much attention has been given to the design and implementation of interventions to support quality and performance improvement for workers in such settings. However, little is known about the optimal design of such initiatives and which approaches are most effective. We aimed to distil and clarify the evidence on these approaches to inform decision-making and design of programs intended to support health workers in these settings. We systematically searched the literature for articles addressing this topic, and undertook a comparative review to document the principle approaches to performance and quality improvement for primary HCWs in LMIC settings. We identified 40 eligible papers reporting on interventions that we categorized into five different approaches: (1) supervision and supportive supervision; (2) mentoring; (3) tools and aids; (4) quality improvement methods, and (5) coaching. The variety of study designs and quality/performance indicators precluded a formal quantitative data synthesis. The most extensive literature was on supervision, but there was little clarity on what defines the most effective approach to supervision or delivery of supervision programs. The mentoring literature was largely focused on clinical skills building and educational strategies. A substantial literature exists on tools, but variation in approaches makes comparison challenging. We found examples of effective individual projects and designs in specific settings, but there was a lack of comparative research across approaches or across settings, and no systematic analysis within specific approaches to provide evidence with clear generalizability. Future research should prioritize comparative intervention trials to establish clear

global standards for performance and quality improvement initiatives. Such standards will be critical to creating and sustaining a well-functioning health workforce and for global initiatives such as universal health coverage.

BACKGROUND

Primary HCWs in LMICs typically work in challenging environments. They are frequently stationed in remote, rural areas and charged with working on the front lines of their country's health system as the first point of patient contact. They have often received inadequate or incomplete education and training, and have limited resources and tools at their disposal. And yet, the role of primary health care workers remains critical to health care delivery in LMICs, especially as complex, longitudinal care interventions are implemented and scaled up. Such interventions, including antiretroviral therapy for HIV/AIDS, have increasingly employed a decentralized health systems approach to coverage (Suthar et al., 2014), relying on task-shifting to non-physician cadres of health workers to achieve access at scale (Lazarus et al., 2014). This approach is a direct result of attempts to cover a large population within the constraints of significant health workforce shortages. Such shortages are notorious barriers to the delivery and quality of health care in LMICs (Haines et al., 2007). Primary HCWs are thus required to do more and to provide greater complexity of care. Robust support mechanisms to maintain high standards of quality and performance are therefore required.

Traditionally, poor performance by health workers was considered a result of poor education and a lack of knowledge and skills, and that as long as providers knew the correct care and decisions to make, they would implement them (Brugha and Zwi, 1998). The majority of interventions to improve health worker

performance have, therefore, focused on education, training, and dissemination of evidence-based guidelines through didacticism. But this singular approach has had mixed, if not disappointing, long-term results (Oxman et al., 1995). A review of health worker performance in low-resource settings, found that dissemination of written materials and guidelines alone – often through in-service training courses – without additional post-training support interventions, was usually ineffective in improving performance and quality (Rowe et al., 2005a). It was noted that supervision with audit-and-feedback techniques usually proved an effective complement to training, and that multi-pronged support interventions were more effective than single interventions. This suggested that a broader approach to health worker support was needed. Fritzen (2007b) and Bach (2001) have noted that typical training of health personnel emphasizes factual and specialized medical knowledge, but in order to perform their job adequately, they have to identify and analyze problems in real-time, supervise and audit of other workers and processes, as well as coordination across multiple levels of the health system, including communities.

Interventions to support and improve health worker performance and quality of care have taken on myriad forms, functions, and structures, and have been known by various names, including 'supervision', 'mentoring', and 'quality improvement.' There is no clear consensus on what distinguishes these approaches from one another, nor agreement on which approach is more effective. In an attempt to provide some clarity for the design and implementation of programs aimed at supporting primary health care workers in LMICs, we conducted a systematic literature search and a comprehensive narrative review of the literature identified. Our objective was to offer definitional and operational rigor and explanation as to

how these approaches to HCW support and performance improvement interventions are designed, and what distinguishes them from one another. We also aimed to establish a basic understanding of general and unifying principles of support programs intended to improve quality and performance of primary HCWs in LMICs.

METHODS

Search strategy

Using a pre-defined search strategy, we systematically searched the literature for relevant articles. Databases searched included MEDLINE, OVID, Web of Science, EMBASE, EBSCOHOST, and PubMed, restricted to publications in English. To identify relevant unpublished grey literature, we also searched Google and Google Scholar, as well as websites of the World Health Organization (WHO), Department of Human Resources for Health, The Global Health Workforce Alliance, Human Resources for Health (HRH), Global Resource Centre from the United States Agency for International Development (USAID), and the International Training & Education Centre for Health (I-TECH) at the University of Washington. With assistance from a research librarian, a comprehensive search string was created to systematically identify publications reporting on interventions to support health workers in low and middle-income nations (Table 1). Terms were truncated to alternative spellings or tenses and no methodological or study design filters were applied given the wide range of observational, experimental and quasi-experimental study designs used in research of large-scale health interventions, especially in LMICs. After reviewing results, additional targeted searches in PubMed were conducted by frequently published authors or institutions, by reviewing the bibliographies of included studies and by studies known *a priori* to the authors.

Study selection

The primary search was conducted by the first author with approval of the search criteria and screening methodology from the remaining co-authors. Results of the electronic database search were first screened by title and abstract for relevance. Studies from high-income settings were excluded, along with studies that contained some of the search terms but did not explicitly address the question at hand, which was to propose, describe, implement or evaluate a performance support or improvement program for primary HCWs in LMICs. Letters to the Editor, Response to Authors, short editorial articles and short commentary pieces that did not report data were also excluded, although narrative reviews were included. Otherwise no particular preference for inclusion was given to any specific study design or writing format.

The second stage of screening involved a detailed reading and review of the remaining articles and an attempt to group the articles by topic. Inclusion criteria included studies that explicitly addressed topics of supervision, supportive supervision, performance and/or quality improvement, mentoring and clinical mentoring, or coaching. Studies that did not explicitly address these issues, or that included one or more of these techniques packaged within a larger intervention, were excluded. Primary health care was defined as care provided at the first level of the health system, whether in a facility- or community-based setting, and focused primarily on ambulatory care. Exclusion criteria included articles that focused on hospital-based, inpatient management, articles that addressed performance and quality in procedural, laboratory, or radiology-based skills, as well as articles that targeted pre-service or in-service training as the primary intervention without

adequate description of a program of sustained follow-up, support or re-training, and discussion or analysis of its impact. Such studies do not address the question of ongoing, sustainable in-service practice support and performance improvement of trained primary health care workers. Articles simply describing the level of quality of care, without attention given to health worker support and performance improvement, were also excluded.

Categorization and evidence review

Articles included in the review were grouped into general topic areas. Three primary categories of literature emerged: (1) Supervision and supportive supervision; (2) Mentoring and clinical mentoring; (3) Tools and Aids. Two secondary categories, with more limited literature, were also identified: (4) Quality and performance improvement, and (5) Coaching and peer-review strategies. In cases where an article had obvious overlap between more than one category and where articles did not distinctly fit in one category, the authors decided by consensus review on the best fit.

RESULTS

The overall results of the literature search and study selection are shown in Figure 1. In total 347 articles were identified in our search, 114 were included for full-text review, and 40 were included in the review and categorization exercise. Of these 40 papers, 13 papers used cross-sectional survey study designs based on pre-/post-intervention plausibility design. Eight papers involved qualitative research using a variety of methods (realist evaluation, focus group discussion, key informant interviews). Seven papers described randomized controlled trials (RCTs) or studies

nested within RCTs, and another seven papers were Reviews, three of which were systematic reviews with or without meta-analyses. Other study designs included were four program evaluations (using routinely collected data not under research conditions), and one time-use study. Twenty-three of the 40 studies included in the review (57.5%) were categorized under 'Supervision or Supportive Supervision,' ten studies (25%) fell under 'Tools, and Aids,' three studies (7.5%) were included under 'Mentoring or Clinical Mentoring' and four under 'Quality Improvement,' and finally only one study was found for 'Coaching and Peer Review Strategies' (Table 2).

Supervision and supportive supervision

Of all of the strategies to support primary HCWs in LMICs, supervision is the most studied and referenced, but also has the greatest diversity of definitions and implementation. Terms commonly used to describe supervisory activity in the health sector include 'supervision,' 'supportive supervision,' and 'managerial supervision' or 'clinical supervision,' each with distinctions in approach and aims. Nonetheless, these terms are generally used to describe a range of activities where a more senior professional, or a supervisor from a higher level in the health system, audits and/or directly observes the work of a primary HCW to ensure that the correct activities are being performed, that they are done effectively. In addition, appropriate guidance and support is given, aimed at helping staff to become more competent, knowledgeable and effective in their work.

Clements et al. (2007) describe traditional supervision as focused on inspection and oversight of behavior and practices for the purposes of finding fault, with little guidance on improvement. They regard this, in part, as a vestige of colonialism, where foreign supervisory structures were designed in a hierarchical and often

punitive manner aimed at local staff, and where a worker higher-up on the administrative chain was responsible for oversight of a lower-level worker and charged with ensuring that the lower level worker executed their duties appropriately. Marquez and Kean (2002) have similarly noted that the goal of supervision was geared towards 'inspection and control' by external actors, based on the premise that front-line workers require strong controls to induce satisfactory performance, as they tended to be unmotivated and lacking incentive for high performance.

In its primary oversight function, supervision has largely focused on administrative tasks such as facility inspection, use of resources, supply logistics, review of records, and communication of information and directives from higher to lower levels of the health system (Simmons, 1987). Problem solving within this type of system tended to be reactive and episodic, with little attention to empowering front-line staff to identify, report, and solve problems proactively. In turn, supervisors were expected to deal with a broad range of problems at the facility, yet they often lacked the necessary skills and capacity. Thus, their function was largely in monitoring alone, with little emphasis placed on training and support of front-line providers, and teamwork or communication improvement. The typical mode of implementation of such a supervisory structure involved the 'site visit' as the primary episode of contact, where an external supervisor would make a fleeting visit to a facility, largely to complete forms and checklists.

Previous attempts to modify supervisory structures have focused largely on increasing the frequency and/or duration of these site visits and introducing tools, including supervisory guidelines and checklists, in order to highly structure the site visit. Effectiveness of supervision is generally measured by changes in the numbers

or frequency of activities performed during the site visit or based on records review, but is rarely linked to actual HCW behavior, practice improvement, or health outcomes themselves (Centre for Human Services, 1987, 1990).

In the post-colonial era, particularly in sub-Saharan Africa, supervision has shifted from its discrete oversight function towards a broader concept of supportive supervision. It has been described as 'a process that promotes quality at all levels of the health system by strengthening relationships within the system, focusing on the identification and resolution of problems, and helping to optimize the allocation of resources promoting high standards, teamwork, and better two-way communication' (Marquez & Kean 2002: p 12). Others have described supportive supervision as involving direct, personal contact, on a regular basis to guide, support, and assist designated staff to become more competent in their work (Djibuti et al., 2009). Marquez and Kean (2002) note that supportive supervision incorporates self-assessment and peer-assessment, as well as community input, in the process of performance improvement. In doing so, they argue, supportive supervision shifts the locus of supervision from a single official to the broader workforce as a whole. Multiple actors, including officially designated supervisors, informal supervisors, peers, and health providers themselves, implement it. The multiple lines of responsibility and accountability has the potential to promote quality throughout the system through stronger communication, better problem-solving, facilitation of teamwork, and the necessary leadership and support to empower primary HCWs to monitor and improve their own performance as well as of those around them (Marquez & Kean 2002). In general, this suggests that supportive supervision moves a step beyond supervision alone by focusing on broader performance improvement (Children's Vaccine Program at PATH, 2003).

Another core paradigm shift from supervision to supportive supervision is in changing the focus of improvement from tasks to performance, and from activities to individuals. Stinson and colleagues (1998) describe supportive supervision as emphasizing joint problem-solving, mentoring, and two-way communication between supervisors and those being supervised, which is usually based on a sustained, longitudinal relationship between supervisor and supervisee. They also note, for example, that while supportive supervision may include some element of audit and performance review, it refers to an ongoing relationship between providers and supervisors, a characteristic that is usually not captured in traditional supervision programs based on single site visits (ibid:. 1998). Working through this dyadic relationship between supervisor and HCW, some of the major functions are to set clear expectations, to monitor and assess performance, to identify problems and opportunities, and to take action on these issues as needed. Additionally, there is a role for setting individual HCW performance objectives and for monitoring and managing performance problems as they arise, in addition to motivation, feedback and guidance in problem solving, on-site training, and assistance with managing resources and logistics (ibid:. 1998).

This model of supervision, based on a sustained relationship between supervisor and supervisee, also serves an important human function by connecting often remote and isolated facilities and providers to the wider health system. Valdez and colleagues (1990) emphasize the importance of sustained supportive supervision within the context of increasing health service decentralization and strengthening of rural care. In light of increasing decentralization, they argue that the lower and more remote levels of the health system need more capacity building and connection with ongoing supervisory and management structures as they are

burdened with a heavier work load and with the need for improved quality (Mills et al. 2001). Senunn and colleagues (2006) also emphasize the role of supervision in connecting rural and urban levels of the health system, emphasizing the role of urban supervisors in connecting peripheral facilities and ensuring adequate managerial oversight, but also in facilitating communication and improving quality at the front lines of health systems.

There is extensive agreement that supervision forms an important part of human resources management for the delivery of health services (Simmons, 1987). This was corroborated, for example, in a survey of sixteen field-based organizations by USAID, who agreed on the importance of supervisory structures in ensuring quality care (Marquez and Kean, 2002). But what remains in question is whether effective supervision in itself can definitively and in a generalizable way, improve the quality of health care and patient outcomes (Kilminster and Jolly, 2000). Perhaps the most conclusive review of supervision was a Cochrane review of managerial supervision – defined as any effort at supervision linking higher levels to lower, more peripheral levels of the health system – in order to improve primary health care in LMICs (Bosch-Capblanch and Garner, 2008, Kilminster and Jolly, 2000). This review included randomized controlled trials, pre-/post-intervention studies, and interrupted time series studies, with only nine papers meeting criteria, highlighting the paucity of high quality evidence. Amongst the papers included in the review, the evidence for an effect of supervision on quality was equivocal (Table 2).

Despite this uncertain result from a comprehensive and stringent review, multiple individual studies suggest that supervision can improve quality of care and primary HCW performance. Randomized trial evidence has shown positive effects of supervision on care for children under-5 using IMCI (Hoque et al., 2014, Pariyo et al.,

2005b, Kayemba Nalwadda et al., 2013, Amaral et al., 2004b) for general primary care (including vaccination, vitamin A distribution, family planning, antenatal care, and costs per capita) (Loevinsohn et al., 1995c) and primary eye care (Okwen et al., 2014). Plausibility trial evidence also supports the association of increased or enhanced supervision with quality of immunization services (Djibuti et al., 2009), STI services (Mugala et al., 2010a), malaria care and treatment (Zurovac et al., 2004), management of childhood diarrhoea (Pham DM et al., 2013), and correct use of pharmaceuticals from front-line dispensaries (Ross-Degnan D et al., 2007). Additionally, a time use study from Ghana showed that increased supervision led to increased HCW 'productivity', defined as time spent directly on patient care activities as a measure of quality (Frimpong et al., 2011), while a study from Mexico found that supervision increased health services efficiency, equity, and cost-effectiveness (Kroeger and Hernandez, 2003). Only one study showed an overall non-significant result for increased supervision on the quality of malaria care in Malawi (Osterholt et al., 2006).

Similarly, qualitative research has shown that supervision is associated with improved HCW knowledge, perception of their work and professional satisfaction and motivation, across a number of settings including Tanzania (Manongi et al., 2006), Zambia (Mugala et al., 2010b), Guatemala (Hernández et al., 2014), and Uganda (Kaye et al., 2011). The positive associations of supervision on HCW motivation have also been repeated in multi-country studies (McAuliffe et al., 2013, Willis-Shattuck et al., 2008, Ahmed et al., 1993). Lack of supervision or poor quality supervision has been shown in India (Mohan et al., 2011) and South Africa (Suri et al., 2007) to be associated with poorer performance, inferior fidelity to protocols, and even treatment failure and poor patient outcomes, respectively. These country-

specific findings echo policy statements that have also emphasized the need for supervision, in addition to training and other investments in primary HCW performance and quality of care, to not only improve motivation and performance but also to achieve broader global health targets (Gouws et al., 2005, Pariyo et al., 2005a, Haines A et al., 2007, Rowe et al., 2005b, Teasdale et al., 2001).

With respect to patient outcomes, a study from Rwanda showed that over a two year period, a system of task-shifting to nurses to deliver antiretroviral therapy (ART) at rural health centres, combined with weekly supervision visits guided by supervision checklists, led to greater than 90% patient retention, significant increases in mean CD4 counts, and patient weight over the follow-up period, which compares favorably to other ART cohorts in sub-Saharan Africa that do not employ such a model (Shumbusho et al., 2009). The challenge of this study, along with many others, is in separating out the effect of supervision in relation to the intervention as a whole, which included training, new clinical protocols, improved infrastructure, and systems of patient monitoring and reporting. Though found in our systematic search, this study was not included in our formal review, because although the supervision system was described clearly, it was part of a system-wide intervention, and thus attribution would be impossible. We found no other studies exploring the impact of supervision on patient or clinical outcomes, let alone morbidity and mortality.

While supervision is thought to have a positive impact on performance and care, there is little empirical agreement as to the optimal amount or timing of supervision. Some studies argue that more supervision generally improves performance, provided that supervision time is used on productive, high-yield activities (Loevinsohn et al., 1995c). A systematic review and meta-analysis of

Integrated Management of Childhood Illness (IMCI) effect on health worker performance observed a stronger association across all domains of quality within studies that reported more supervisory visits (RR=1.11, CI 103-1.20) (Nguyen et al., 2013). Rowe and colleagues (2010a) in Benin documented the rise and fall of supervision visits for IMCI using record review, focus groups, interviews, and surveys, and found that only 29% of needed supervision visits actually occurred overall, blaming poor coordination and lack of integration of supervision systems as possible explanations for these poor results; but overall quality improved with supervision, despite sub-optimal implementation of the supervision system. While a controlled trial in Brazil found that reducing the frequency of supervision for community-based contraceptive program reduced costs significantly, it had no impact on quality or primary HCW performance (Foreit and Foreit, 2015). In general, more supervision is considered better, but the evidence is weak to support this and there is certainly no guidance on optimal 'dose' of supervision.

Mentoring and Clinical mentoring

Few studies were found that explicitly addressed mentoring or clinical mentoring as the principal intervention to improve health worker performance, though it appears that mentorship – like other categories found in this review – can encompass a range of often overlapping activities to support health worker performance and delivery of care. The International Training & Education Centre for Health (I-TECH: p3) based at the University of Washington, defines clinical mentoring as a 'sustained, collaborative relationship in which a highly experienced health care provider guides improvement in the quality of care delivered by other providers and the health care systems in which they work.' The World Health

Organization (WHO) (2005) defines clinical mentoring as '…a system of practical training and consultation that fosters ongoing professional development to yield sustainable high-quality clinical care outcomes.' The WHO regards clinical mentors as highly-experienced clinicians who provide mentoring to less-experience health workers in the form of review of clinical cases, feedback, and direct assistance in managing complex cases. Andrews and Wallis (1999) and Marquez and Kean (2002) have suggested that clinical mentoring is founded on collaboration and focuses on clinical teaching in the setting of direct patient care. The goal of clinical mentoring is to enhance knowledge, build confidence, and maintain adherence to protocols in less-experienced providers of care. Usually this is through direct, side-by-side case observation, targeted specifically at improving the clinical skills of the less experienced health care worker. This is achieved through the provision of individualized feedback and in response to provider-driven queries, mostly related to clinical reasoning, diagnosis and management, and physical examination skills, though this seems to vary widely. Clinical mentoring can been thought of as a follow-on activity to initial didactic training, involving both on-site mentoring and distance-based consultation and communication utilizing technology (Department of Health Republic of South Africa, 2011).

While these definitions may seem broad, there is agreement that mentoring improves skills through direct, on-site observation of case management and the provision of targeted and individualized feedback to the provider. While clinical mentoring is most commonly part of a multi-faceted performance improvement and support intervention, there are examples of small observational studies that have examined the effectiveness of mentoring alone, or as the distinct and primary intervention, on the performance of health care workers and on program outcomes

(Anatole et al., 2013b, Magge et al., 2014b, Workneh et al., 2013b, Fatti et al., 2013) and on HCW motivation (Songstad et al., 2012).

Tools and Aids

While much of the literature focuses on interpersonal or educational strategies to support health worker performance in LMICs, as described above, a separate, but important body of work focuses on the implementation of specific tools and aids that can support HCWs. These tools generally complement one of the educational approaches described above, or are implemented using teaching and educational practices, but have also been studied alone. These tools can take the form of checklists that HCWs and/or supervisors or mentors can use to monitor performance; job aids, guidelines, or protocols to provide real-time decision-support and guidance during the patient consultation; or mobile technology or e-Health tools to facilitate improved record-keeping and increased communication between less experienced or rural providers and supervisors, consultation with specialists, etc.

Checklists can target primary HCWs directly and can aid them with the provision of high-quality care through decision support during patient care, or through retrospective review of cases. Checklists can also be aimed at mentors and supervisors to measure HCW performance and to identify gaps in care, thus serving as a basis for ongoing quality improvement efforts. It is this latter approach that has been increasingly studied, for example in Nigeria for childhood diarrhea management (Zeitz et al., 1993), in Uganda for CHW diagnosis and treatment of pediatric malaria and pneumonia (Mukanga et al., 2011), for delivery of essential birth practices in India (Spector et al., 2012), and surgical safety procedures in Moldova (Kwok et al., 2013). Each of these studies showed that the implementation

of a checklist led to improvements in quality of services and HCW performance of key activities.

Job aids, guidelines, protocols, and/or charts that provide real-time decision support to providers during the patient encounter have also been widely studied. These tools describe in detail, often in a prescriptive and standardized manner, the steps to implement a particular standard of care for a disease, set of diseases, or a particular population group during the consultation. For example, multiple studies have shown that using decision support tools and job aids to structure supervisory visits of HCWs leads to faster reactions by supervisors to changes in health worker behavior (Armstrong Schellenberg et al., 2004, Derenzi et al., 2011). Clinical job aids also lead to improved HCW satisfaction (Sodhi et al., 2011). Wall charts have been used successfully to improve clinical decision-making in multiple settings (Zurovac et al., 2004, Nicholas, 1991). Nevertheless, one older study showed an unexpected inverse correlation between the presence of a fever wall chart and correct treatment in children with fever in Central African Republic, 25% of HCWs in this study identified lack of supervision as a barrier to providing correct treatment, rather than the wall chart itself (Rowe et al., 2000).

Technology, in the form of mHealth or eHealth tools targeted at primary health care workers, is also being used more widely in performance improvement and quality assurance for primary HCWs, though it has been little studied. Short message service (SMS) reminders have been shown to improve pediatric malaria case management with artemisinin combination therapy (ACTs) for instance (Zurovac et al., 2011), while a study from India showed that computerized decision support system and job aid for primary health care workers was associated with significant improvement in patient satisfaction and perceived quality of care (Peters

et al., 2006).

Simulated patient cases are another tool that has been used to evaluate and improve health worker performance. This usually involves the presentation of a case scenario to a health worker either through a trained human actor or mannequin aimed at mimicking a patient case scenario, or through clinical vignettes presented in a classroom setting. Simulated cases are a potentially important tool for performance improvement because they reduce the potential of likely positive bias that occurs during conspicuous observation by a supervisor or mentor, otherwise known as the 'Hawthorne Effect' (Leonard and Masatu, 2006a). Few studies were found that specifically tested these approaches in the primary care setting in LMICs, but they have been used effectively in Myanmar (Aung et al., 2012). In Benin, direct case observation of IMCI was associated with higher HCW performance than a simulated client method which the authors attributed to the Hawthorne Effect (Rowe et al., 2012b). This effect was similar to other studies comparing conspicuous observation to patient interviews and to patient registers (Rowe et al., 2006)

Quality improvement / quality of care

While quality improvement (QI) itself is often described as the underlying objective of interventions to support primary health worker performance, it has also been studied as an intervention or set of interventions unto itself, often combining multiple aspects of the approaches and tools described above. Despite an extensive literature on quality improvement in LMICs, the heterogeneity of intervention types makes it challenging to separate out which interventions were specifically targeted at primary HCW performance, versus larger systems improvement that include HCW performance as one dimension of quality. Quality improvement is often framed as a

sequence of steps to assist health workers and managers to identify and solve problems of poor or inadequate health worker performance. Rowe and colleagues (2005a) have described the process of QI as similar to that implemented by clinicians in longitudinal care of chronic illness, including periodic assessments, identification and diagnosis of new problems, treatment of those new problems, follow-up of the problem to see if the recommended treatment had the intended effect, and if not, attempting another therapy and repeating the cycle. They have also highlighted how QI can demonstrate how particular interventions like supervision and job aids – amongst others – fit together into the larger process of managing a health system and the health workers within it. Rowe (2009) has also described the use of integrated continuous surveys and quality management techniques to support scale-up of health interventions, which revolved around a continuously-implemented quality survey similar to DHS (Demographic and Health Surveys) in its implementation (Eriksen et al., 2007). Other than these, however, no additional studies meeting the inclusion criteria that looked specifically at quality improvement as the intervention itself were found. Rather, most studies that made reference to 'quality improvement' initiatives either were not specifically targeted at improving HCW performance, or actually tested one or more of the groups of interventions described above and thus were included in those categories.

Coaching and peer-review strategies

Finally, the least known and studied approach to health worker performance and quality improvement is coaching. Only one paper was found, a narrative review from the grey literature, that dealt specifically with coaching as a strategy for performance improvement in the settings we studied (Steinmann and Bosch-

Capblanch, 2011). Coaching was defined as a one-on-one activity where a coach attempts to induce change in the coachees to boost performance in a particular sector, which shares some specific attributes with mentoring but remains distinctly different in approach. Whereas a coach facilitates learning by enhancing the client's behavioral change through self-awareness and/or by achieving higher levels of skill performance, the authors argue that mentoring is rather based on a stable, longitudinal, and dyadic relationship where an experienced person fosters a junior protégé using his/her superior professional and social experience, knowledge, and connections to advance the overall development of the mentee. Whereas a coach does not necessarily come from the same technical or professional background as the coachee, but rather focuses on general professional issues, a mentor is generally from higher up on the professional hierarchy within the same field of work, if not the same organization. The authors argue that the evidence for the effectiveness of coaching is strong within the business and private sector, but in general, available studies are of low quality and often biased, and they argue for the need for higher-quality evidence. They also suggest that what little evidence exists from the health sector suggests that coaching is minimally effective, and they conclude that there is no strong evidence for coaching overall or clear guidance on optimal design.

DISCUSSION

During this literature review, we identified several major themes concerning performance and quality improvement for primary HCWs in LMIC settings:

(1) Lack of comparative evidence: Despite decades of implementation of performance improvement initiatives for primary HCWs in LMICs, there remains insufficient evidence regarding which specific approaches are most

effective for improving quality. We were unable to find any clear comparative trials. As such, those responsible for program design and planning remain without clear guidance on how best to design interventions for post-training HCW support, to what extent they should rely on supervision, mentoring, or other strategies, or what combination of approaches would be beneficial.

(2) Ambiguous approaches to supervision: supervision was the approach for which the published literature is currently most extensive. Based on results from the individual studies reviewed here, supervision is likely to be a beneficial intervention for HCW performance and quality improvement in primary care settings in LMICs. What remains unclear, however, is what type(s) of supervision are optimal for performance improvement (e.g. clinical, managerial, etc.) and what is the optimal 'dose' and frequency of supervision to achieve and to sustain durable gains in quality and HCW performance. What also remains ambiguous is whether the optimal supervision strategy would differ based on disease or based on covariates such as previous health worker experience, education level, or the local epidemiology and case mix.

(3) Repositioning the role of mentoring in the health care delivery system: Mentoring has been inadequately tested and must be evaluated with more breadth and rigor. If, as the literature suggests, mentoring is highly focused on a particular educational approach to clinical quality improvement, it could benefit from falling under the auspices of the health educational system, such as nursing, medical, and health sciences schools, rather than public health and health care delivery authorities. This would be similar to

preceptorship or mentorship strategies employed by medical and nursing training programs in high-income settings, where individual mentorship and improvement of clinical skills is the responsibility of degree-granting training programs, post-training certificates and continuing medical education programs. More study is needed in this regard, as well as ways to better describe how clinical mentoring initiatives dovetail with pre-service education and training provided by medical and nursing education institutions.

(4) Unclear role of coaching: Insufficient evidence exists to draw conclusions on coaching as a performance improvement strategy; because of the dearth of evidence, it is not clear that coaching is indeed an applicable strategy for primary HCWs in LMICs, and thus its inclusion may not be necessary in any future analyses of strategies to improve HCW performance. However, more review of the corporate and business school literature from health care is probably warranted to closely examine health workforce performance improvement initiatives, and whether there are particular operational principles of these programs that could be applicable or adapted to primary HCWs working in LMICs, such as team-based approaches and cooperation, communication strategies, and performance reviews.

(5) Further investment in tools and technology: Tools and technology are an important area of ongoing and future investment and research to support HCW performance. This is especially true for primary health care workers who work in remote areas, often poorly supported with inadequate infrastructure, connectivity and communication with the rest of the health system, and with urban areas where specialized care and consultation exists.

Preliminary evidence is mixed, although singular successes do exist, as described above in multiple settings (Kwok et al., 2013, Eriksen et al., 2007, Mukanga et al., 2011, Spector et al., 2012). We note that despite a growing literature on eHealth interventions, most did not meet inclusion criteria because they did not address HCW performance improvement specifically, or were not targeted at primary health care delivery. More data and research are required to outline exactly which tools should be used as in-service job aids by primary HCWs, and which tools can be used by supervisors and mentors. As well, more research is needed on the design and impact of eHealth interventions on performance and quality improvement metrics. Specifically, the impact of eHealth tools on fidelity to treatment or decision protocols, HCW practice behavior and self-perception of care, as well as patient perception of quality, would be important to systematically study and review.

(6) Further study on operational approaches: Finally, little is known about the optimal approach to delivering any of the interventions discussed in this review. As noted, the traditional model of delivery of any supervision, mentoring, QI or other performance improvement intervention has typically involved a short site visit. This model is typical because supervisors are often based at higher levels of the system or come from external agencies outside of the public sector due to donor structures and financing. This structure is also a reaction to evidence that suggests that workshops and didactic training sessions that pull HCWs out of practice are both costly and often ineffective. However, one can assume that the short site visit may not be the optimal model for achieving durable gains in quality and performance, and

rather alternative models such as week-long intensive visits, longitudinal embedded supervision, or HCW learning exchanges between facilities could be explored. Dedicated study of these alternative models is thus warranted.

The approach to this review had a number of strengths and limitations. The principal strength of this approach was in the comprehensive scope of the review. Most systematic and narrative reviews of performance improvement initiatives have typically addressed one particular intervention (e.g. supervision, quality improvement, etc.) using restrictive definitions. In this review, a comprehensive search strategy was employed to simultaneously identify a wide range of interventions across the five different categories studied. The goal was to provide some comparative evidence across these categories and to establish some clarity as to what distinguishes these approaches from one another in theory and in practice. The limitations of this review were in the restrictions we placed on the setting of study. Our search terms, while expansive across different categories and approaches to performance and quality improvement, were restrictive with respect to countries studied and the particular level of the health system targeted. Therefore a number of studies may not have been captured in our search that describe performance improvement initiatives at district, regional, or national hospitals in LMICs, or that targeted primary HCWs in high income countries, that probably could have been instructive in our analysis, but were beyond the geographic scope of this review. Additionally, and despite a systematic search, the limitations of the data and differences in outcomes and study design precluded any form of quantitative synthesis within or across categories, given our expansive inclusion criteria and definitions of specific performance improvement approaches.

CONCLUSION

This review is one of the first of its kind to engage in a comparative examination of a range of approaches to performance and quality improvement programs targeted at primary health care workers in low- and middle-income countries. Primary HCWs in these settings are often the most in need of accompaniment and support due to their geographic isolation and lack of ancillary support, and thus it is important to especially focus quality improvement efforts on these workers and on the front lines of health systems in the developing world. Whether referred to as supervision, mentoring, quality improvement, or otherwise, it is critical that policy-makers and planners are equipped with strong evidence as to which approaches are most effective at achieving significant and sustained gains in front-line health worker performance and quality of care. Further comparative analysis trials are warranted to rigorously examine which specific approaches are more effective than others.

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Table 1: Search String

Search String
"developing world" OR "developing countries" OR "rural" OR "low middle income" AND ("health worker" OR "health care worker" OR "nurse" OR "nursing" OR "community health worker" OR "physician" OR "human resources" OR "personnel" OR "worker") AND ("mentor" OR "support" OR "train" OR "supervision" OR "advise") AND ("tools" OR "checklist" OR "curriculum" OR "guideline") AND ("evaluation" OR "appraisal" OR "validation") AND ("delivery of health care" OR "quality of health care" OR "quality improvement" OR "quality assurance")

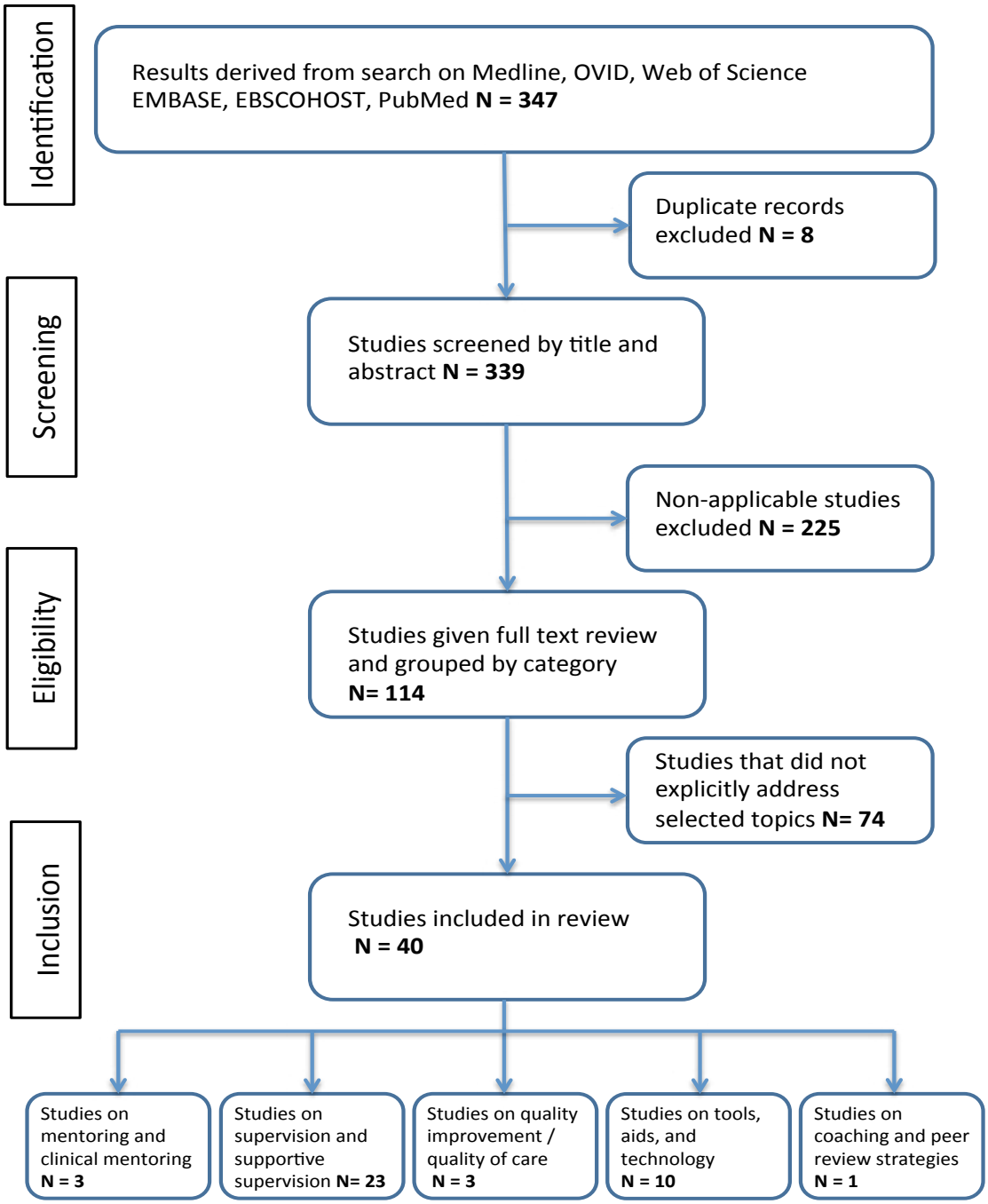

Figure 4: Results of systematic search protocol

Table 2: Summary of intervention studies for the three principal article categories under review: supervision and supportive supervision, mentoring and clinical mentoring, and tools and technology

Study Category	Authors	Type of study	Country	Setting	Intervention	Relevant Measured Outcomes	Impact/ Relevant Findings
Supervision and supportive supervision	Hoque et al. 2013	Randomized Control Trial	Bangladesh	First-level primary health centres	IMCI training + monthly supervision w/ case observation	• HCW performance - IMCI assessment - Case management	• >30% gain in correct assessment of children using IMCI • Results sustained at 3 and 5 years from baseline • Equivalent performance of HCWs w/ 18 months vs. 4 years of pre-service education
	Loevinsohn et al. 1995	Randomized Control Trial	Philippines	Primary care health posts and health centres	Enhanced monthly supervision, supported by checklist	• Prenatal care • Immunization rates • Midwife knowledge on vitamin A	• >75% increase in correct ANC record-keeping at 6 mos • >30% increase in >3 prenatal visits at 6 mos • >87% increase in midwife knowledge of vitamin A dose/schedule • No change in infant immunization
	Okwen et al. 2014	Randomized Control Trial	Tanzania	Primary health care facilities / dispensaries	Routine vs. Enhanced supervision for eye care after training	• HCW knowledge • Vision testing performance • Total primary eye care (PEC)	• 80% improvement in PEC knowledge in intervention group vs. 59% improvement in control • Vision testing score higher (1.8 vs. 0.88, p=0.03) • Total PEC score not significantly different
	Kayemba Nalwadda et al. 2013	Randomized Control Trial	Uganda	CHWs	Enhanced supervision system after training (monthly, then quarterly visits, case observation, feedback)	• CHW knowledge of identification and referral of sick newborns	• 68% CHWs passed the knowledge examination • 74% able to identify the five major newborn danger signs • 98% recognized sick vs. not sick in case vignettes • 96% completed referral forms correctly • 63% passed the caregiver communication skills examination
	Minh et al. 2013.	Pre/post intervention plausibility design	Vietnam	Front line pharmacists	Quarterly supervision after initial training	• Pharmacist knowledge and management of childhood diarrhoea and emergency contraceptive	• Knew ≥ 3 danger signs of diarrhoea (OR 15.9, CI 9.1-29.1) after 18 mos • Knew ≥ 3 dehydration symptoms (OR 32.4, CI 19.7-53.7) after 18 mos

						pills (ECP)	• Knew when to use ECP (OR 8.4, CI 5.5-12.9)
	Mogasale et al. 2010	Pre/post intervention plausibility design	India	State STI clinics	Quarterly supervision supported by checklist/tool	• STI service coverage • Quality of care, prevention support, effective drugs • Referral into care • Community involvement	• 3- to 7-fold increase in all indicators over 45 month observation period at 292 STI clinics in 7 states
	Osterholt et al. 2006	Pre/post intervention plausibility design	Malawi	Government and private non-profit front line health facilities	Routine and enhanced supervision for malaria	• Effective treatment with anti-malarial drugs	• Supervision type (w/ or w/o clinical observation) or frequency was not significantly associated with improved quality of malaria treatment
	Djibuti et al. 2009	Pre-/post-intervention plausibility design	Georgia	Primary health care providers and managers of immunization programs	Continuous, structured supportive supervision	• Immunization service delivery coverage	• Significant increase in DPT-3, Polio, Hep B coverage after 1 year (p=0.000, 0.000 and 0.002, respectively) • Significant reduction in vaccine wastage for DPT, OPV, Hep B (p=0.016, 0.029, and 0.022, respectively)
	Zurovac et al. 2004.	Pre-/post-intervention plausibility design	Kenya	Front line dispensaries, health centres, and small hospitals	Routine government supervision for IMCI and malaria	• Quality of care of uncomplicated malaria (error rates)	• Children treated by HCWs supervised 4-10 times in past 6 months significantly less likely to receive inappropriate treatment (major errors) vs. zero visits (OR 0.28, 0.12-0.66)
	Frimpong et al. 2011	Time-use study	Ghana	Primary health care facilities	Routine government supervision	• HCW productivity	• Supervision within last month associated with higher proportion of time spent on direct patient care (OR=1.57, CI 1.26-1.96)
	Hernandez et al. 2014	Qualitative; Realist evaluation	Guatemala	Primary health posts	Routine government supervision	• HCW perceptions of supervision	• Primary focus on managerial control • Move toward approach of *humanized support* focused on HCW as integral actors, attentive and actively engaged and supportive supervision • Leads to improved HCW recognition, initiative, and shared vision
	Suri et al. 2007	Qualitative survey and focus group	South Africa	Community health workers	Routine government supervision	• CHW perceptions of supervision and administrative support	• Poor monitoring and accountability mechanisms • Lack of support or supervision from community health facilitators • Lack of emotional and moral support from supervisors

	Manongi et al. 2006	Qualitative; focus group discussion	Tanzania	Primary health care facilities	Routine government supervision	• HCW perceptions of supervision, feedback, and training	• More negative comments received than positive about supervision • Little supervision, the irregular supervision from DHMT not supportive • No written or oral feedback • Issue of poor central planning for supervision
	McAuliffe et al. 2013	Quantitative & qualitative survey	Multi-country (Malawi, Tanzania, Mozambique)	Front-line HCWs providing obstetric care	Routine government supervision	• HCW perception and survey of supervision	• 28.7% HCWs in Malawi had no supervision at all; 21.4% in Tanzania, 9.6% in Mozambique • Only 35% HCW in Malawi have formal obstetrics supervision • < 10% of HCWs report supervision is available on request • ~20% had only negative feedback to report on supervision • Lack of supervision significantly correlated with intention to leave job $p<0.01$
	Mugala et al. 2010	Quantitative & qualitative survey	Zambia	Front line facility HCWs trained in IMCI	Supervision for HIV guidelines in IMCI	• Use of HIV guidelines in IMCI algorithm	• 90% respondents received at least 1 supervision visit for IMCI • All respondents reported supervision visits were helpful in better understanding the HIV guideline
	Mohan et al. 2011	Program evaluation using routine data	India	Primary health care	Supervision for IMCI (IMNCI) in 7 states	• Implementation quality of supervision	• 6 of 7 districts assessed to have poor supervision
	Rowe et al. 2010	Mixed methods (records review, FGD, key informant interviews, cross-sectional survey	Benin	Public and private outpatient front-line facilities	IMCI supervision, supported by job aids and non-financial incentives	• Frequency and quality of supervision within RCT of IMCI	• Supervision took at least a quarter to kick off after training despite small HCW number • After 5 year follow-up, rate of supervision (at least 1 visit in past 6 mos) almost twice in intervention district vs. control (88.1% vs. 47.8%) • 97.2% of supervision checklists had most important section (observation and feedback) completed
	Bosch-Capblanch et al. 2011	Systematic review and meta-analysis (Cochrane)	Global (LMICs)	Primary health care workers	Managerial supervision	• Effect of managerial supervision on quality of primary health care, including:	• Only nine studies met inclusion criteria • GRADE quality of evidence was “low” or “very low” • Mixed results; authors are uncertain

						- Adherence to guidelines - Service coverage - Provider knowledge and satisfaction	about the effect of supervision on PHC service quality
	Nguyen et al. 2013	Systematic review & meta-analysis	Global (LMICs)	Primary health care centres	IMCI training and supervision	• Effect of IMCI supervision visits on: - IMCI classification - Medication administration - Vaccination - Nutrition assessment - Caregiver counseling	• IMCI trained HCWs w/ ≥ 1 supervisory visit in last 6 months vs. < 1 visit, associated with improved (versus untrained HCWs): - IMCI classification (RR 2.09 vs. RR 1.88) - Medication administration (RR 1.91 vs. RR 1.73) - Nutrition assessment (RR 5.97 vs. RR 2.64) - Caregiver instructions (RR 3.18 vs. RR 1.79) - Worsening in vaccination rates (RR 1.11 vs. RR 1.81* (not significant)
	Bosch-Capblanch et al. 2008	Systematic review	Global (LMICs)	Primary health care workers	Supervision (general review)	N/A	• Supervision focused mainly on checklists and administration • Usually focused at district level visiting peripheral HCWs • Some evidence of benefit on performance, but evidence is limited
	Clements et al. 2007	Narrative Review	Global (LMICs)	Primary health care	N/A	N/A	• Call for new model of supportive supervision based on problem-based learning and continuous feedback • Need to institutionalize supervision
	Haines et al. 2007	Narrative review	Global (LMICs)	Community health workers	N/A	N/A	• Supervision as a performance improvement intervention for CHWs deserves special attention • Important factors: two-way flow of information between supervisor and CHW, supervisor acts as role model • Challenge is scaling up successful supervision programs to national programs • Supervisors may be the only formal link of CHWs to health system in rural areas • Important potential of peer support as well •

	Marquez and Kean 2002	Narrative review	Global (LMICs)	N/A	General review of supervision	N/A	• Shift from traditional supervision emphasizing "inspection and control" to supportive supervision • Supportive supervision shifts responsibility and activity from one supervisor to the wider health workforce • Requires continuous implementation of supervision for sustained performance improvement
Mentoring and Clinical mentoring	Fatti et al. 2013	Pre-/post-intervention plausibility design	South Africa	Front-line primary health facilities (ANC and birthing sites)	Implementation of Quality Nurse Mentor (QNM)	• Improvement in outcomes and processes for PMTCT including: - % of HIV negative women retested at 32 weeks - % new diagnosed women receiving CD4 testing - % of HIV positive women, not on ART, receiving antenatal ZDV - uptake of infant HIV testing at 6 weeks, 18 mos	• Increased HIV re-testing at 32 weeks from 38.5% to 46.4% (RR=1.2, p<.0001) • ZDV uptake for eligible women increased from 80.9% to 88.1% (RR=1.09, p<.0001) • Infant testing at 6 weeks increased from 68.5% to 76.7% (RR 1.12, p<.0001) • Infant testing at 18 months increased from 12.4% to 22.9% (RR 1.84, p<.0001)
	Workneh et al. 2013	Program evaluation; retrospective chart review	Botswana	Rural HIV clinics	Outreach clinical mentoring	• Completion of chart for key indicators of quality pediatric HIV care, including: - Weight, height, growth curve - Pill count and adherence assessment - Recent CD4 and viral load - Use of co-trimoxazole prophylaxis - Correct ART dosing	• Significant improvements in all indicators at 1 of 4 sites, after one year of mentoring (p<0.0001) • Other site with improvement only in CD4, VL and pill counts (p<0.0001)
	Anatole et al. 2013	Descriptive report/program evaluation	Rwanda	Rural primary health clinics/nurses	Enhanced district-based nurse-led mentoring	• Interim program progress	• Significant increases in mean proportion of assessments completed per consultation for IMCI, IMAI, and ANC after 1 year (p<0.0001) • Significant increase in correctly classified patients for IMCI after 1 year (53.3% vs. 34.6%, p<0.0001) and IMAI (53.5% vs. 40.5%, p<0.0001)

Tools and technology	Sodhi et al. 2011	RCT; qualitative survey	Malawi	Rural primary health clinics/HCWs	Job aid (w/ training) integrating guidelines for HIV, TB and other condition into single tool	• Effect of PALM PLUS tool on staff satisfaction and quality	• HCW worry that tool could slow down patient consultations • Time pressures dissuaded routine use of tool • Not used as checklist for in-consultation decision-making • No difference b/w intervention and control in job satisfaction or likelihood to quit in next 12 months, not all non-significant effects
	Zurovac et al. 2011	RCT	Kenya	Rural health facilities	Text messages (SMS) for malaria case management	• Correct treatment of malaria with arthemeter-lufemantrine • Dispensing and counseling	• Correct treatment improved in the intervention arm immediately by 23.7% (p=0.004) and by 24.5% at 6 months (p-0.003) • Sig improvement in counseling on side effects (vomiting) immediately (p=0.0017) and at 6 mos (p<0.0001)
	Peters et al. 2006	RCT	India	Primary health care facilities	Computer-assisted decision-support tool for patient screening	• Increase in patient throughput • Global patient assessment of care • HCW perceptions	• Sig difference of differences of 430 patient visit in intervention vs. control sites (p=0.005), with 18% increase in intervention vs. 5% increase in control • Sig increase in difference of differences in patient assessment of care (mean 7.9, p<0.001) • Did not affect HCW attitudes or perceptions of their work
	Rowe et al. 2012	Cross sectional survey	Benin	Primary health facilities	Simulated Client (SC) vs. Conspicuous Observation (CO) for IMCI	• HCW performance per IMCI protocol	• HCW performance measured by CO was moderately and significantly higher than by SC (median 16.4 point differential)
	Aung et al. 2012	Cross sectional survey	Myanmar	Primary health facilities	Observed simulated patient (OSP) vs. direct observation	• HCW performance in treatment of pediatric malaria	• Agreement >90% in all areas of HCW performance between direct observation and OSP approach, exp for history taking on past anti-malarial use
	Rowe et al,.2000	Cross sectional survey	Central African Republic	Outpatient health facilities	Fever treatment chart	• Predictors of high quality treatment of children with fever	• Inverse association of use of fever chart and correct treatment (OR=0.19, CI 0.01-0.91)
	Zeitz et al. 1993	Chart review and cross-sectional	Nigeria	Rural primary health clinics	Quality assurance tools (flow charts,	• HCW performance in history-taking, examination, disease	• Significant improvements seen 6 of 9 history questions, 2 of 4 examination skills

		survey, pre/post			decision trees, checklist)	classification, treatment, and counseling	• Sig improvement in disease classification and treatment of childhood diarrhoea
	Spector et al. 2012	Pre-/post-intervention	India	Sub-district birth centre	WHO Safe Childbirth Checklist	• Impact of checklist on HCW's frequency of performing essential birth practices	• Significant improvement in 28 of the 29 measured essential birth practices • Overall improvement in proportion of essential birth practices performed from 10/29 (9.4-10.1) to 25/29 (24.6-25.3) p<0.001
	Derenzi et al. 2011	Narrative review	Global (LMIC)	CHWs	Review of mobile technologies to support CHW performance	N/A	• Identified 6 main health system functions impacted by mobile technology and relevant to CHW - Data collection - Training and access to reference material - Communication amongst HCWs - Job aids and decision support - Supervision - Promoting healthy population behaviors
	Songstad et al. 2012	Qualitative survey and focus groups	Tanzania	Rural HCWs	Open performance assessment tool (OPRAS) and pay-for-performance scheme	• HCW motivation and performance self-appraisal	• Recognition of good performance important for HCW motivation • Lack of regular feedback on their work • Concern about OPRAS tool and its relevance, impact on performance • OPRAS not linked to actual feedback • Encouraged by potential impact of P4P scheme

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Chapter 4

Research paper 4

Title: Baseline survey of training and practice of rural primary health care workers in Rwanda.

Author(s): Ashwin Vasan, Emily Hall, Karen Finnegan, Manzi Anatole, Corrado Cancedda, Stephen D. Lawn, David C. Mabey, Lisa Hirschhorn

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Candidate's signature:

Supervisor or senior author's signature to confirm Candidates role:

Dr Stephen D. Lawn

TITLE: Baseline survey of training and practice of rural primary health care workers in Rwanda.

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Abstract

Background: Training of primary health care workers in low-and-middle income settings (LMICs) is critical to addressing health workforce shortages. The growing responsibilities placed on front-line providers as a result of task-shifting, requires dedicated attention to the content, timing, and quality of training for these providers. However, little is known about the mix of training that primary health care workers are receiving and how it reflects their practice responsibilities and needs. This research describes the self-reported training exposure, practice environment, and desired training and skills of primary health care nurses in rural Rwanda.

Methods: We conducted a cross-sectional survey of nurses and health centre managers at twenty (20) rural health centres in two districts in southeast Rwanda. Anonymous surveys were distributed and collected on the same day and key informant interviews were conducted with health centre managers. Descriptive frequencies are reported.

Results: One hundred and fifty-one nurses, or approximately 86% (151/175) of current nurses in practice, responded to the survey. Thirteen (15.9%) were nurse health centre managers. Twenty three point five percent of nurses (35/151; 23.5%) reported receiving training in HIV/AIDS management, followed by TB (14/151; 9.3%), and prevention of mother-to-child transmission of HIV (13/151; 8.6%). Only 29.7% of nurses who received training in these three categories reported ever receiving a post-training supervisory visit. The most common clinical service to which nurses were allocated was the primary care outpatient department at the health centre (43.1%) followed by labor and delivery maternity services (19.2%). Almost 90% of nurses treating malaria and 75% of nurses working in childhood

malnutrition had never received training on these subjects.

Conclusions: The training environment for primary care nurses in Rwanda is of variable content and quality, with training often not matching responsibilities and not reflecting the specific gaps and aspirations of these workers. Greater attention must be given to issue of the appropriateness, relevance, and acceptability when strategically planning training programs for front-line health workers in LMICs.

Background

The crisis of available human capital within the health workforce, and imbalances in the appropriate skillset of the existing health workforce in low and middle-income countries (LMICs) has been well documented (Aluttis et al., 2014, Frenk et al., 2010, Chen et al., 2004, Chen, 2010, World Health Organization, 2010). These deficits not only mitigate efforts to improve the access, coverage, and quality of prevention, care, and treatment of specific illnesses such as HIV (Kober and Van Damme, 2004, Marchal et al., 2005, World Health Organization et al., 2008), TB, malaria (Blanas et al., 2013, Woyessa et al., 2013), but threaten to compromise the growth and quality of integrated primary care. In response, the World Health Organization (WHO)(World Health Organization, 2008) and others (Lekoubou et al., 2010, Lehmann et al., 2009) proposed 'task-shifting' – transferring specific tasks from more highly qualified health workers to health workers with less formal education and fewer qualifications to make efficient use of available human resources for health – as a short- to medium-term solution. Examples include shifting tasks from physicians to nurses (Sanne et al., 2010), nurses to community health workers, and community health workers to lay providers and family members. This is a widely implemented approach in HIV programs (Iwu and Holzemer, 2014, Suzan-Monti et al., 2015, Gilks et al., 2006a, Samb et al., 2007, Ivers et al., 2011), especially in sub-Saharan Africa where the human resource deficits are significant. Task-shifting has been shown to be effective in maintaining quality care while addressing the human resource gap (Callaghan et al., 2010b, Vasan et al., 2009, Sherr et al., 2010). Growing evidence supports this model of care in a range of clinical services, with task-shifting now employed – albeit with varying levels of effectiveness - in approaches to male circumcision across Africa (Ford et al., 2011),

pharmaceutical management (Wiedenmayer et al., 2015) and emergency obstetrical surgery in Tanzania (Pereira et al., 2011), cataract surgery in Kenya, Malawi and Tanzania (Eliah et al., 2014), maternal mental health in South Africa (Selohilwe et al., 2014), major general surgery in Malawi (Wilhelm et al., 2011), hypertension and diabetes management in Cameroon (Labhardt et al., 2010), and even gastrointestinal endoscopy in Malawi (Wilhelm et al., 2012). It has even been used effectively in primary care settings across Europe (Martínez-González et al., 2015).

Yet despite increasing responsibility placed on nurses and other non-physician clinicians (NPCs) and their critical role in the face of an inadequate supply of health workers in LMICs, relatively little attention has been given to the assessment of their specific educational and training gaps and needs, nor how the training environment does or does not meet the needs of their everyday clinical practice. Nurses and other NPCs are expected to function in roles that their education and experience does not necessarily prepare them for. Greater focus is required to establish balance between their general skills and training needs, and the short-term goals of targeted training courses for specific diseases and vertical programs. In addition, an improved understanding is needed to account for the social, economic, and psychological issues NPCs face as more responsibility and expectations are placed upon them, and the impact of task-shifting on their perceived self-efficacy and job satisfaction (Iwu and Holzemer, 2014). One such qualitative study examined motivation of NPCs in Tanzania (Chandler et al., 2009), and found unsurprisingly that salary was a primary prerequisite to improved motivation, and called for the professionalization of NPCs, while another study from Uganda highlighted the resistance of health managers and policy makers to task-shifting due to concerns of poor supervision and overwork (Baine and Kasangaki,

2014).

Few assessments exist that report the existing task mix of primary care workers as well as specific exposure to training and their specific training needs and desires. This is particularly important in light of myriad vertical programs that typically conduct separate trainings for the same primary health care workers at the front lines of LMIC health systems, but often do not address baseline deficits or gaps arising from pre-service training. One of the few needs assessments specific to training and focused particularly on antiretroviral therapy in Uganda (Lutalo et al., 2009), described heterogeneity and dissonance between training needs for different health worker cadres and the content and quality of the actual training delivered. Others have suggested that more rigorous information on the most effective training methods is needed (Callaghan et al., 2010a). The objective of this research is to describe the composition of current practice, the prior exposure to training, training needs, and training desires of primary care nurses working at the front line of the health system in rural Rwanda. The aim is to better understand the nature of the existing work and training landscape in this region from the perspective of those at the front lines of the health system in order to aid the design of strengthened training interventions. It also aims to highlight the views and needs of health workers with respect to their existing demands, the training and skills they have received, and their desired training and skills.

Methods

Study Setting

The research was conducted in southern Kayonza and Kirehe districts in the Eastern Province of Rwanda, with an estimated population of 530,000 (National

Institute of Statistics of Rwanda, 2012a). Rwanda's health system consists of front-line health centres -- staffed largely by nurses with a secondary school certificate in health behavior and nursing science -- district hospitals, provincial/regional hospitals, and university teaching hospitals (Drobac et al., 2013a). The research was conducted at all 20 government health centres in the two study districts. The survey was conducted as part of a baseline assessment of health worker training within the Population Health Implementation & Training (PHIT) implementation research program of the Ministry of Health of Rwanda, Partners In Health, (PIH), Harvard Medical School, and the Brigham & Women's Hospital, funded by the Doris Duke Charitable Foundation.

Study Population

The survey was exclusively targeted at health care workers – nurses and health centre managers, also called *Titulaires* -- who hold advanced nursing degrees. Nurses in Rwanda are graded according to their level of education as A2, A1, or A0 in increasing order of rank. An A2 nurse has a secondary school education (12 years) with the final two years focusing on nursing science, human physiology, health and human behavior. An A1 nurse has an additional two years of pre-service nursing training and practica. The majority of nurses that staff front line health centres in Rwanda are classified as A2 or A1, though the Ministry of Health is currently in the process of upgrading all A2 nurses to A1 through a combination of distance learning and certificate courses. An A0 nurse then chooses a specialty (e.g. Advanced Nursing, Public Health, Research), which requires an additional one to two years of pre-service and in-service training. The inclusion criteria for health workers for this study were any staff member providing any official clinically related service on the

day of the study team visit to the health centre. Per government regulations, each health centre in Rwanda is allocated 15 full-time nurses, though due to documented shortages in available staff and high rates of turnover, few sites have the full complement working at any given time, though official estimates per site vary. There are no medical doctors permanently staffed at health centres in Rwanda.

Study Design

This study describes a cross-sectional survey of nurses and nurse managers. Both quantitative and qualitative data were collected through deployment of a survey instrument and through interviews. This study presents the results of the quantitative data collection.

Data Collection

The survey data from all nurses (including *Titulaires)* were collected through a standardized, self-administered questionnaire distributed to all practicing health workers at the study health centres on the day of the study team visit. Participating health workers completed the survey independently and not under direct observation, and returned the completed surveys to the study team on the same day. Additional data were collected from health centre managers through in-person, key informant interviews, though the results of these data are not included in this paper. Nurses and managers were explained the purpose of the survey and provided written informed consent to participation. No identifiable nurse or patient information was collected as part of the study.

Tools and outcomes

The self-administered survey was designed using examples from the National Evaluation Centre for the United States AIDS Education and Training Centres (Southeast AIDS Training and Education Centre (SEATEC)). The questionnaire for health workers contained four sections on (i) Demographics, including professional responsibilities and titles, (ii) Educational background, (iii) Training courses attended in the last two years, and (iv) Actual duties and responsibilities, including work experience, use of clinical resources, and desired areas of additional training and skills to help improve the quality of their care. Health centre managers were asked a total of 12 questions divided into three categories regarding: (i) Training, (ii) Health centre workflow, and (iii) Reporting. These questions included specific information on training courses attended by the health centre nursing staff in the preceding 12 months, selection criteria for individual nurses for particular training courses, and specific content and skills needs for the health centre team that could be addressed by additional training. In addition, managers provided details of staff scheduling procedures, routine data collection and reporting of training courses for their nursing staff.

Data analysis

Survey questionnaires were coded and double entered into a Microsoft Excel database, and then into Microsoft Access. Descriptive frequencies for key outcome variables were reported. Data were analyzed using SAS v9.2 (Cary, NC, USA).

Results

Baseline characteristics

In total 151 nurses completed the survey, 90 (59.6%) from Kayonza and 61 (40.4%) from Kirehe. This represents 86.3% (151/175) of nurses currently employed at the study sites at the time of the survey, with the missing 24 nurses not scheduled to work on the day of the survey. Demographics on these nurses were unavailable and thus we are unable to assess whether they may have systematically differed from the 151 surveyed nurses. Fifty-nine (39.1%) nurses came from health centres that had received extramural support from PIH, while 92 (60.9%) came from sites that had never received any PIH support. Of these nurses, 114 (75.5%) identified themselves as active clinical nurses, 24 (15.9%) identified themselves as laboratory-based nurses, and 13 (15.9%) were nurse managers. One hundred and forty-two (94%) nurses were designated as A2 level, as described above, and the remaining nine (6%) A1 level. Nurses reported having an average of 5.5 (0.02-33) years of work experience as a nurse, and reported and average of 26.7 (0.5-324) months working at their current health centre.

Task allocation

Nurses identified 15 different clinical and non-clinical tasks that they performed at the health centre in the six-month period prior to the survey (Table 3). Sixty-five nurses (43.1% of total respondents) reported working in the Outpatient Department, or OPD, which provides general acute ambulatory care and typically serves as the first entry-point into the health system for adult and adolescent patients presenting to the health centre. Ninety five percent of the surveyed health centres had at least one nurse who reported working in the OPD in the six months prior to the survey, and the OPD was the most common service clustered with other services reported by the same nurse (e.g. OPD and Maternity, OPD and under-five

care/IMCI, OPD and PMTCT, etc.). Family Planning (21.2%), Maternity/Labor & Delivery (19.2%), and Voluntary Counseling and Testing (VCT) for HIV (18.0%) were the next most frequent clinical activities reported. In addition, 28 nurses (18.5%) reported working in the health centre laboratory, 25 (16.6%) reported working in the pharmacy, and 14 (9.3%) reported having some non-clinical administrative duties in the six months prior to the survey. The mean number of different tasks at the health centre reported by nurses was 2.1 (range: 1 – 7 tasks).

Previous training and post-training supervision

Nurses reported 27 different topics on which they had been trained in the last two years prior to the survey (Table 4). The most frequent topic was HIV care and treatment, on which 65 nurses (23.5% of total responses) reported receiving training in the last two years. The next most frequent topics reported were TB care and treatment (9%), PMTCT (8.7%), Family Planning (7.9%), and Maternal, Newborn and Child Health (MNCH) (6.5%). The longest average duration of training was for MNCH and Interpersonal Violence training courses, averaging 12.4 and 11.4 days, respectively. The mean duration of training for all courses was 5.4 days, suggesting that nurses were pulled away from practice on average for an entire working week or more for each training.

For the most frequent training courses (HIV, TB, PMTCT, and Family Planning), 29.7%, 32%, 29.2%, and 31.8% of nurses, respectively, reported having ever received a follow-up or supervision visit after the initial classroom-based didactic training course. The highest follow-up rates reported were for Counseling/Social Work training courses, and for Management and Administration training courses (both 100%), but only eight (5.3%) and one (0.03%) nurses

reported previous training in these topics, respectively. The lowest rates (0%) for follow-up were for training in Non-Communicable Diseases (NCDs), Direct Budget Support (DBS), Data Management, HIV Electronic Medical Records, Hematology/Oncology, Medication Use and Prescription, Neglected Tropical Diseases, and VCT.

Origin and support for training courses

Seventy-two point four (72.4%) percent of training courses were supported directly by the Ministry of Health of Rwanda. Twelve point four percent (12.4%) were supported by PIH, in conjunction with the Rwandan government, and 6.6% by IntraHealth International, a US NGO affiliated with the University of North Carolina, Chapel Hill, and funded by the U.S. Agency for International Development (USAID). In total, in the two districts surveyed, 21 different training providers were identified, including the Ministry of Health.

Matching of training with practice responsibilities

Eighty-nine point five percent (89.5%) of nurses that conducted malaria diagnosis, care, and treatment, reported receiving no specific training in that area. Seventy-five (75%) percent of nurses dealing with childhood malnutrition also reported that they had received no specific training on how to manage these conditions. Fifty-four point five (54.5%) percent of nurses working in the under-five/IMCI clinic also reported never having been trained in IMCI formally, and 42.1% of nurses working in PMTCT had not received any formal training. Similarly, 26.3% of nurses working in the HIV clinic reported they had not received any specific HIV-related training.

Use of job aids and references in daily practice

One hundred and thirty-three (88.7%) nurses reported that they currently use reference materials or other decision support tools or job aids in their daily work. This frequency was approximately the same for clinical nurses (88.6%) and laboratory nurses (82.6%). Of the different choices of reference materials, the most frequently used were official Ministry of Health publications (76.7%), followed by textbooks or desk reference books (54.7%) and specific clinical decision tools (21.3%) such as posters and flip charts. Fifty-five (36.7%) nurses reported that they commonly ask another health centre nurse colleague when a clinical question arises, while 36 (24%) reported that they use the internet, when available, to answer clinical questions. Of the 20 sites surveyed, only those eight supported by PIH (40%) had access to an internet connection at the facility.

Work environment

Eighty-nine (59.3%) of surveyed nurses reported nursing shortages and lack of adequate clinical training and skills, respectively, as the most frequent barriers to provision of the highest quality care (Table 3). Other reasons frequently cited were high patient loads (41.9%), lack of resources at the health centre (38.3%) including necessary drugs, diagnostics tests, equipment, and infrastructure, and patients' underlying poverty and socioeconomic status (28.9%). When queried on factors that improve the quality of their work, 129 (85.4%) nurses cited effective teamwork and 90 (59.3%) nurses cited good communication between staff. Fifty-five percent of nurses cited that their own training was a factor helping them to provide the best quality of care possible.

Desired skills and training

Nurses reported twelve different practice domains in which they would like to acquire additional training and skills (Figure 1). Computer skills and information technology was most frequently cited by all three groups of nurses (clinical, laboratory, managers), while clinical diagnosis skills (52.6%), physical examination skills (43.9%), and psychosocial evaluation and counseling (41.2%) were frequently reported by clinical nurses. Among the specific clinical topics most frequently reported as desired additional training by all nurses, were HIV (33.1%), General Labor and Delivery (31.1%), IMCI (30.5%), Women's Health (28.5%), and Obstetrical emergencies (25.2%). General primary care topics and non-communicable disease topics (including asthma, hypertension, cardiac disease, and diabetes) were cited in approximately 19% of the total nurse responses.

Discussion

These data show that the training environment for primary health care nurses in Rwanda is diverse and heterogenous, but often not reflective of their everyday demands or their aspirations. These data also show that nurses have a number of concrete goals in terms of building additional skills and expertise, which could be addressed in part by training, and that lack of training and skills is the primary barrier they perceive to high quality care.

Nurses were exposed to training in 28 different topic areas, offered by 21 different training providers, which could pose a challenge to appropriate coordination and harmonization with government standards and protocols. And as illustrated by examples of malaria, malnutrition, IMCI, PMTCT, and HIV, where a

surprising number of nurses working in these services were untrained in these topics, training content often did not match the nurse's current practice responsibilities. As well the mix of training exposure did not always adequately reflect the task mix of front-line providers, who, as a result of absolute deficits in the health workforce, are required to assume generalist roles and as shown in these data, are responsible for staffing multiple different clinical services at the health centre.

These data also call into question the effectiveness of training, as supported by the lack of post-training support and supervision. There is substantial evidence that training alone may be necessary, but is insufficient to improve quality of care and health worker performance (Fritzen, 2007a, Rowe et al., 2005f, Pariyo et al., 2005c). And thus the relative lack of supervision – particularly for the topics in which training courses were most frequently received (HIV, TB, PMTCT) - is an area in need of attention and improvement for the health sector going forward.

These data also suggest that training courses in general primary care are infrequent and in need of strengthening and advocacy to more appropriately match the responsibilities of primary health care nurses. The most frequent reported training courses were in HIV, TB, and PMTCT, which reflects priorities of vertical global health funding and reporting. Yet less than five percent of nurses received training in adult general medicine, community health, or NCDs, which are core primary care topics. This is particularly concerning given that the most frequent clinical service through which nurses had rotated in the past six months was the OPD, where the bulk of general adult, adolescent, and pediatric ambulatory primary care is delivered. This need for additional primary care and generalist training is also supported by the fact that that approximately half the nurses surveyed

identified physical examination and clinical diagnosis skills – two of the core tools of general medical practice – as common areas of desired additional training.

Eighty-nine percent (89%) of nurse responses identified lack of training as a barrier to high quality care, suggesting that training should be more frequent and of higher quality. Yet the workshop or classroom model of training that predominates in LMICs and requires costly logistical expenses, may not be most effective to increasing the dose and strengthening the quality and durability of the training these nurses receive. Instead, novel attempts to shift the locus of training to a practice-based, mentoring and supervision-driven model that includes quality improvement methods, have produced good early results, particularly in Rwanda where a decentralized program of mentoring and supervision (Anatole et al., 2013a) in these same two research districts has proven effective in improving the quality of IMCI care for children under-five (ref) and has improved health worker motivation and satisfaction (Magge et al., 2015b). Further innovation in the delivery of training is needed to better meet the educational needs and desires of front-line providers working in challenging conditions, and so as to avoid removing already-scare human resources from the health system.

This study has several limitations. It was run as a small cross-sectional survey as part of routine preparatory data gathering for the PHIT grant, rather than formal hypothesis testing, and therefore we did not assess statistically whether there were significant differences in responses based on covariates such as nurse education level, years of experience, health centre and gender. Despite the fact that over 85% of currently practicing nurses in the study area were surveyed, we do not know whether results could have been altered by the ~15% of nurses that were unavailable on the day of survey or who opted out of the study. Finally, we did not

collect data on the perceived quality of the training courses received, and measures of health worker satisfaction with the training environment.

Despite these limitations, these data highlight the need for increased nurse and health worker participation in the design of comprehensive training strategies. These data contribute to a very limited literature on the perceptions and needs of LMIC health workers with respect to training and how it matches to their practical duties and responsibilities. Training continues to reflect donor priorities and funding streams as well as current domestic and international political affairs. This is sometimes at the expense of the critical skills and content that nurses and other front-line providers need to provide the highest quality and most systemically and epidemiologically-relevant clinical care within their practice environments. In addition, the current structure of training does not adequately address the innate aspirations of primary care nurses toward higher performance and building new skills, particularly with respect to the use of information technology and general primary care skills and knowledge. As such, policy-makers, implementers and health system administrators alike would be well-served to not only address vertical interventions and donor programming, but also to account for health worker perceptions and needs in planning future training. They also need to adopt a longer-term view of strategic training to address the core educational needs of primary health care workers in order to strengthen health systems and clinical quality.

Table 3: Allocation of health centre tasks in the six months prior to the survey among nurses

Task/service at the health centre	Number of nurses who reported performing the task	% Nurses who reported performing the task	% Health centres with at least one participant who reported performing the task
Outpatient Department (OPD)–adult & adolescent care	65	43.1	95
Under-5 Clinic (IMCI–Integrated Management of Childhood Illness)	11	7.3	45
Antenatal Clinic (ANC)	17	11.3	50
Infectious Disease Clinic (HIV, TB, STIs)	19	12.6	60
Non-communicable Diseases (NCD) Clinic	8	5.3	30
Vaccination	11	7.3	45
Family Planning	32	21.2	80
Malnutrition	4	2.7	20
Maternity/Labor & Delivery	29	19.2	65
Prevention of Mother-to-Child Transmission (PMTCT) clinic	19	12.6	60
Inpatient services	12	8.0	50
Pharmacy	25	16.6	75
Laboratory services	28	18.5	85
Administrative tasks	14	9.3	60
Voluntary Counseling & Testing for HIV	27	18.0	70

Table 4: Area of training in the two years prior to the survey reported by nurses

Topic of Training	Number of nurses who reported receiving training	N%	Mean duration of training (days)	% Nurses who reported receiving follow-up after training
Adult medicine (general)	11	4	7	45.5
Non-communicable diseases (NCDs)	3	1.1	3.7	0
Community Health	8	2.9	3.9	37.5
Counseling and patient education	1	0.4	5	100
Direct Budgetary Support	10	3.6	4.5	0
Data Management	1	0.4	2	0
HIV Electronic Medical Records (EMR)	1	0.4	1	0
Family Planning	22	7.9	7.9	31.8
HIV	65	23.5	8	29.7
Hematology/Oncology	2	0.7	9.5	0
IMCI	14	5.1	5.7	14.3
Maternal & Child Health	18	6.5	12.4	38.9
Malaria	9	3.6	4.2	40
Management/Administration	1	0.4	3	100
Medication use/prescription	3	1.1	4.3	0
Nutrition	6	2.2	2.8	16.7
Other	6	2.5	6.3	14.3
Performance-Based Financing (PBF)	4	1.4	5.3	50
PMTCT	24	8.7	6.4	29.2
Pediatrics (general)	5	1.8	5.8	40
Pharmacy Management	4	1.4	4.8	25
Tuberculosis	25	9	5.4	32
Tropical/Neglected Diseases	11	4.3	1.5	0
Training-of-Trainers	7	2.5	4.9	28.6
Voluntary Counseling & Testing	1	0.4	5	0
Vaccination	7	2.5	3.4	42.9
Violence (interpersonal)	5	1.8	11.4	20

Table 5: Common barriers to high quality care reported by nurses

	Overall		Job Title					
			Laboratory Nurse		Clinical Nurse		Nurse Manager	
Obstacle to care	**Number of nurses who reported the obstacle to care**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
High patient loads	62	41.9	5	22.7	53	46.5	4	33.3
Poverty/ patient's underlying socio-economic status	43	28.9	2	8.7	39	34.2	2	16.7
Lack of tools/ resources at the health centre (drugs, diagnostics, equipment, infrastructure)	57	38.3	9	39.1	41	6	7	58.3
Too few nurses on staff	91	61.5	7	31.8	75	65.8	9	75
Lack of training, knowledge or skills	89	60.1	14	60.9	67	59.3	8	66.7
Poor communication between nurses and patients	4	2.7	0	0	3	2.6	1	8.3
Complexity of patient illness	10	6.7	2	8.7	8	7	0	0
Inefficient patient flow at the health centre	6	4.0	0	0	4	3.5	2	16.7
Lack of teamwork	6	4.0	0	0	5	4.4	1	8.3
Other	67	44.4	15	62.5	56	49.1	4	30.8

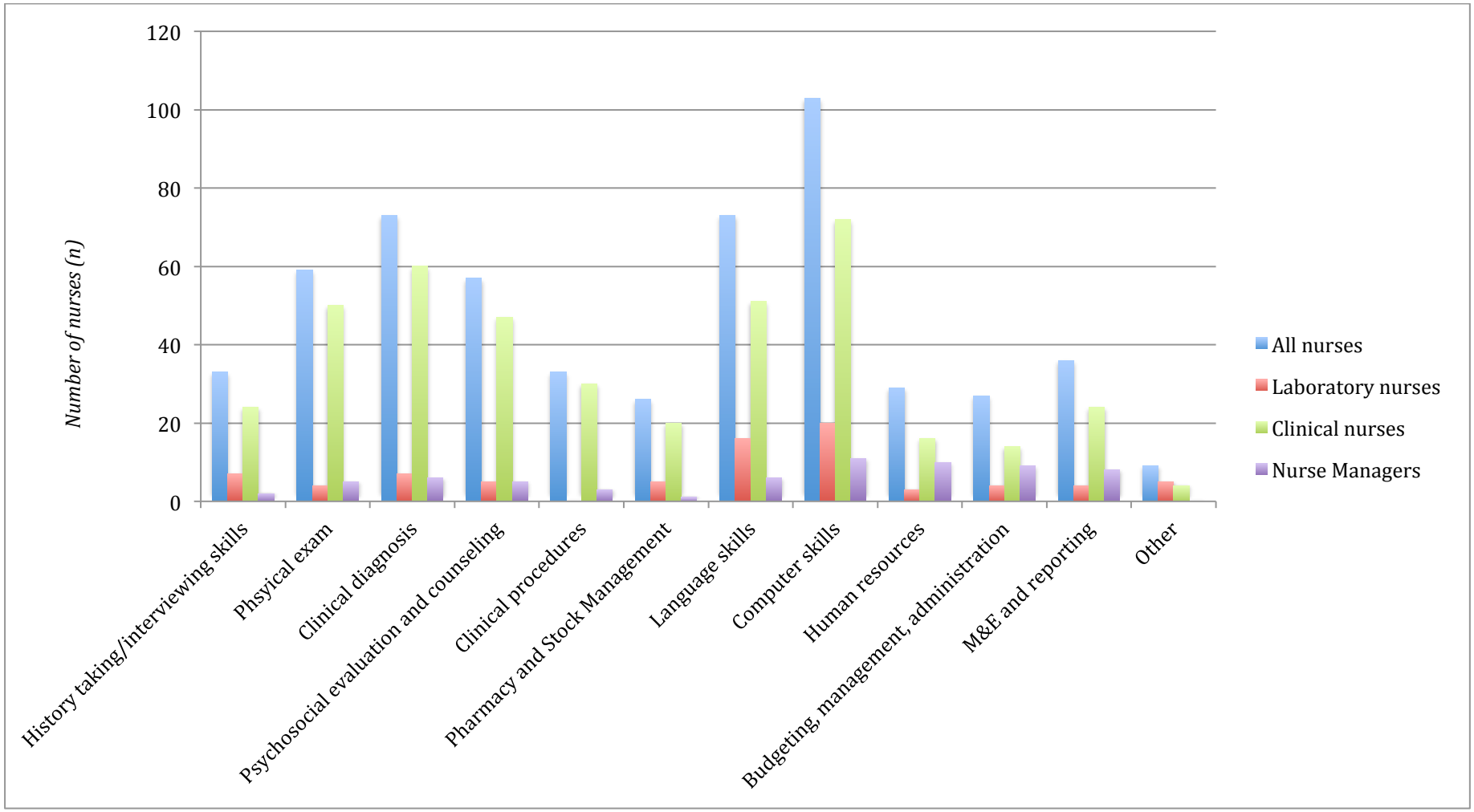

Figure 5: Topics of desired additional skills and training by nurse classification

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Chapter 5

Research paper 5

Title: Baseline assessment of adult and adolescent primary care delivery in Rwanda: an opportunity for quality improvement

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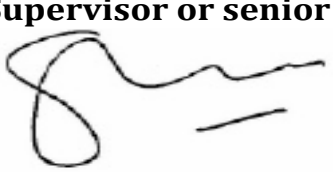
Candidate's signature:

Supervisor or senior author's signature to confirm Candidates role:



Dr Stephen D. Lawn

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RESEARCH ARTICLE Open Access

Baseline assessment of adult and adolescent primary care delivery in Rwanda: an opportunity for quality improvement

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Abstract

Background: As resource-limited health systems evolve to address complex diseases, attention must be returned to basic primary care delivery. Limited data exists detailing the quality of general adult and adolescent primary care delivered at front-line facilities in these regions. Here we describe the baseline quality of care for adults and adolescents in rural Rwanda.

Methods: Patients aged 13 and older presenting to eight rural health center outpatient departments in one district in southeastern Rwanda between February and March 2011 were included. Routine nurse-delivered care was observed by clinical mentors trained in the WHO Integrated Management of Adolescent & Adult Illness (IMAI) protocol using standardized checklists, and compared to decisions made by the clinical mentor as the gold standard.

Results: Four hundred and seventy consultations were observed. Of these, only 1.5% were screened and triaged for emergency conditions. Fewer than 10% of patients were routinely screened for chronic conditions including HIV, tuberculosis, anemia or malnutrition. Nurses correctly diagnosed 50.1% of patient complaints (95% CI: 45.7%-54.5%) and determined the correct treatment 44.9% of the time (95% CI: 40.6%-49.3%). Correct diagnosis and treatment varied significantly across health centers ($p = 0.03$ and $p = 0.04$, respectively).

Conclusion: Fundamental gaps exist in adult and adolescent primary care delivery in Rwanda, including triage, screening, diagnosis, and treatment, with significant variability across conditions and facilities. Research and innovation toward improving and standardizing primary care delivery in sub-Saharan Africa is required. IMAI, supported by routine mentorship, is one potentially important approach to establishing the standards necessary for high-quality care.

Keywords: Primary care, Africa, Resource-limited settings, Quality improvement, Training, Integration, IMAI, Outpatient department, Nurses

Background

The growing success in resource-limited settings of disease-specific interventions for HIV, TB, malaria and other conditions has led to renewed focus on primary care. Integration of disease-specific services into primary care settings has emerged as a strategy to harness specific gains for more generalized improvement in health care delivery, with HIV and reproductive health care most commonly studied [1-7]. Despite this work, relatively little attention has been paid directly to strengthening primary care services for adults and adolescents – the core services with which disease-specific programs should integrate. In many developing-world health systems, particularly in sub-Saharan Africa, the majority of general adult and adolescent ambulatory care occurs in the outpatient department (OPD), which typically operates within front-line health centers (HCs) or as auxiliary clinics to district or regional hospitals. In many settings, the OPD is the first point-of-contact with

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formalized health infrastructure for patients who are not already enrolled in other specialized ambulatory services (e.g. antenatal or TB care), or care for specific chronic diseases (e.g. HIV). As such, the OPD serves a critical function in the health system through triaging for life-threatening conditions, screening for chronic diseases and modifiable risk factors, diagnosis of acute illness, and appropriate management of both acute and chronic conditions. However, there are currently no benchmarks or targets established to define quality of care for adults and adolescents for most conditions in this primary care setting.

Few rigorous studies have been done on how to develop a standardized, integrated approach across conditions for the initial adult patient screening and work-up in resource-limited settings [8,9]. The few existing studies suggest that standardization and integration could be an important component of improving primary care and health worker performance [10-14], but more research is needed. Aside from disease-specific analyses and one qualitative survey [15] a literature review did not identify any reports describing the quality of general ambulatory primary care for adults and adolescents in any resource-limited setting.

Many tools have been developed for services for *selected* conditions delivered within OPDs, including malaria, STIs, and TB. In addition, an integrated guideline for respiratory disease was developed and tested in southern Africa [16-18]. The World Health Organization (WHO) and partners have attempted to standardize *general* adult and adolescent primary care services, called IMAI – the Integrated Management of Adolescent & Adult Illness [19]. Building off the success of the Integrated Management of Childhood Illness (IMCI) for children under-five years [20], IMAI is targeted for use by front-line health care workers, and consists of simplified, syndromic clinical protocols within a single integrated guideline for common presenting illnesses in adults and adolescents. Like IMCI, these syndromic protocols are organized around symptoms (e.g. fever, cough, diarrhea, etc.) and include a simplified approach to patient history and physical exam. These protocols then provide prescriptive guidance on the management (triage, screening, diagnose, treatment, and follow-up and referral) for a variety of conditions commonly seen in adult outpatient care. Unlike IMCI [21-26], IMAI has undergone little study, with limited, mostly unpublished validations from South Africa Simoes E, et al: *Preliminary Analysis of IMAI Validation Studies.* data.], Ethiopia [27], and Lesotho [Seung KJ, et al: Validation of Integrated Management of Adolescent and Adult Illness (IMAI) guidelines for patients with respiratory symptoms in Lesotho. Unpublished.].

The objective of this study is to describe the routine quality of care for adults and adolescents at OPDs in a rural district in Rwanda in order to document the current quality of care, identify needs for improvement, and propose possible interventions going forward.

Methods

Study setting

The study was conducted in southern Kayonza District, in Rwanda's Eastern Province, with an estimated total population of approximately 190,000 people [28]. The study was conducted at all eight of the Ministry of Health (MOH) health centers that fall under the district hospital catchment area, and all of which receive support from Partners In Health-*Inshuti Mu Buzima* (PIH-IMB). PIH-IMB is a non-governmental organization partnering with the MOH since 2005 to strengthen health systems in three rural districts in Rwanda. Rwandan HCs are generally staffed by nurses holding the equivalent of a secondary school education in nursing. These nurses undergo no specific training in adult and adolescent primary care aside from their degree program and practice experience. There are, however, a number of disease-specific didactic trainings provided by the MOH and partners that some nurses may attend. Routine documentation of delivery of care is done in the OPD register, a standard lined registry that contains basic demographic, diagnostic and treatment data.

Study population

The study was conducted between February 1, 2011, and March 31, 2011. Consecutive patients 13 years or older presenting to the OPD were eligible for the study. There is no clearly defined age cut-off between childhood and adolescence in Rwanda [29]. Age 13 was chosen for this study based on definitions used by the United States' Centers for Disease Control (CDC) [30]. Data at each health center were collected over one week, with all centers visited in eight successive weeks.

Data collection

Data were collected by a clinical mentor, employed by the MOH and assigned to train and supervise OPD nurses as part of a larger initiative to improve quality of care at health centers in the district [31]. Supervision and clinical mentoring activities had not yet begun at the time of baseline data collection. The clinical mentor had the equivalent of a bachelor's degree in nursing with five years of relevant clinical experience. The clinical mentor underwent extensive didactic and practical training in the adapted IMAI protocols, mentoring and quality improvement. The standard WHO-IMAI protocols [32] were previously adapted and translated by the study staff and district MOH partners through consensus guideline review and pilot testing so as to adhere to Rwandan

national treatment guidelines and reflect local epidemiologic priorities.

Data were collected by direct observation of routine clinical consultations using a standard data collection tool developed to document critical components of the clinical encounter. This observation checklist was structured upon the WHO-IMAI Case Management Observation Form, and included the standard triage checklist for emergency conditions contained within the IMAI Quick Check protocol, part of the larger IMAI guideline [19]. IMAI had not been formally introduced in Rwanda at the time of the study and study nurses had not received training in the adapted IMAI protocols.

The clinical mentor was present in the room during the consultation but was instructed to not intervene in patient care, with the exception of a critically ill patient requiring immediate action. Data collected in the observation checklist are summarized in Table 1. Formal diagnostic and management decisions made by the nurse were recorded by the clinical mentor from observed actions and review of the OPD register.

The clinical mentor recorded information on up to three chief complaints for each patient consultation. For each patient complaint the nurse, following MOH standards, selected from the 57 MOH *Système d'Information Sanitaire* (SIS) diagnosis codes used in routine practice. The clinical mentor recorded the SIS diagnosis selected by the nurse and selected his own SIS diagnosis based on his clinical expertise and additional training in IMAI.

Table 1 Summary of data categories within the study Observation Checklist

1. Demographics
2. Vital Signs
   - Height
   - Weight
   - Pulse
   - Respiratory Rate
   - Temperature
   - Blood pressure
   - BMI (optional)
3. Triage and Identification of Emergency Conditions
   - Based on IMAI Quick Check triage protocol within WHO-IMAI guideline
4. Screening
   - Chronic cough
   - Malnutrition
   - Anemia
   - Genital/anal lesions
   - Discharge/other genitourinary symptoms in males with genital lesions
   - Previous HIV testing
   - Mosquito net
   - Tobacco use
   - Alcohol use
   - Sexual activity
   - Pregnancy in eligible females
   - Family planning in females
5. Chief Complaint(s)
6. Diagnosis
   - Based on MOH SIS diagnostic codes
7. Treatment
   - 100% agreement, including labs, medications, and other treatments ordered
8. Referrals
   - Including follow-up visits to the OPD, if any
   - Patient Age and Sex
   - Start and end time of consultation
   - Health center
   - Nurse education level
   - Years of OPD experience of nurse

Data analysis

The primary outcome of interest was correct diagnosis of patient illness, defined as agreement in diagnosis between the nurse and the clinical mentor, with patient complaint as the unit of observation. For example, a patient complaining of both cough and back pain would receive one diagnosis for each complaint, and contribute two observations to the sample. Cases where the nurse found no appropriate diagnosis within the SIS codes for a given patient complaint were excluded from analysis of diagnosis agreement. Chief complaints were defined as the primary complaint either: (1) offered by the patient voluntarily, (2) given by the patient in response to direct questioning by the nurse, or (3) selected by the nurse independently at any point during the consultation.

Correct treatment of each complaint was also evaluated, defined as 100% agreement between the nurse and clinical mentor in all elements of treatment plan, including labs/diagnostic tests ordered, medications prescribed, referrals or transfers made, and follow-up recommendations. The nurse treatment plan reflected their routine practice, while the clinical mentor's treatment plan was based on the modified IMAI protocols. Observations where the nurse diagnosis was incorrect were not automatically excluded from the treatment analysis, so as to capture those cases where the nurse may have selected an incorrect diagnosis but still made a correct treatment plan.

Data were double-entered into a Microsoft Access database and analyzed using SASv.9.2 (Cary, NC, USA).

The sample was described using frequencies for categorical variables and means for continuous variables. Patient assessment by nurses was described using frequencies of vital sign measurement, triage, and screenings. The primary outcomes – frequencies of correct nurse diagnosis and correct nurse treatment – were calculated for each complaint, along with corresponding 95% confidence intervals. A secondary analysis was conducted to identify factors associated with the quality of nurse case management. Relationships between correct diagnosis and treatment and health center and duration of nurse experience in OPD dichotomized at four years (the sample median) were assessed using Pearson's chi-squared tests.

Ethics

This study was approved by the Rwandan National Ethics Committee and the Institutional Review Boards (IRB) at Partners Healthcare and the London School of Hygiene & Tropical Medicine. Data were collected as part of routine program monitoring of an ongoing mentorship and quality improvement intervention in the study district. No identifying nurse or patient information was collected. As such, the IRB approved a waiver of informed consent under the routine use of program monitoring data. However, patients were explained the purpose of the data collection and could opt-out if desired.

Results

A total of 470 patient consultations were observed (range 53–69 per health center). The median duration of consultation was six minutes (Interquartile Range (IQR): 5–8 minutes) Approximately two-thirds (68.4%) were female and mean patient age was 35.3 years (standard deviation: 15.9 years). All nurses performing the consultations had the nursing education described above. The median practice experience of the nurses was four years (IQR:3–6 years) (Table 2).

Table 2 Sample characteristics and distribution of patient complaints

Number of observed consultations	470
Nurse years of experience in OPD, median (IQR)	4 (3–6)
Duration (minutes), median (IQR)	6 (5–8)
Patient sex, n (%)	
Female	319 (68.4%)
Male	147 (31.6%)
Patient age (years), mean (s.d.)	35.3 (15.9)
Patients asked why they came to OPD, n (%)	61 (13.1%)
Total number of patient complaints	585
Zero (0) complaints	5 (1.1%)
One (1) complaint	354 (75.3%)
Two (2) complaints	102 (21.7%)
Three (3) complaints	9 (1.9%)
Back or joint pain	44 (7.5%)
Cough or difficulty breathing	83 (14.2%)
Diarrhea	31 (5.3%)
Epigastric pain	65 (11.1%)
Fever	58 (9.9%)
Genital or anal sore, ulcer, or wart	5 (0.9%)
Genitourinary symptoms	
Female	88 (15.0%)
Male	32 (5.5%)
Headache or neurological condition	52 (8.9%)
Hypertension	3 (0.5%)
Lower extremity edema	6 (1.0%)
Mental problem	6 (1.0%)
Mouth or throat problem	37 (6.3%)
Skin problem or lump	32 (5.5%)
Other	43 (7.4%)

Chief complaints

The majority of patients (75.3%) had one chief complaint, with 21.7% (n = 102) reporting two complaints, 1.9% (n = 9) reporting three complaints, and 1.1% (n = 5) with no complaint recorded. The most common chief complaints were female genitourinary issues (15.0%), cough (14.2%), epigastric abdominal pain (11.1%), and fever (9.7%). Of note, only 13.1% (n = 61) of patients were asked directly for a chief complaint by the nurse (Table 2).

Vital signs

At least one of six vital signs was recorded by any staff at 70.9% of visits, with no visits having all seven vital signs taken (Table 3). At least one vital sign was taken by a registration clerk prior to seeing the nurse in 56.0% of visits, and in 11.5% of patient visits, more than one provider collected vital signs. Weight was the most commonly taken vital sign (62.6%). Temperature was recorded for 27.5% of patients, and 16.2% had blood pressure recorded. No patient had height, respiratory rate or pulse recorded, nor body-mass index (BMI) calculated. One HC had no available registration clerk during any of the patient care sessions observed.

Triage

Only seven (1.5%) patients were fully screened and triaged based on the standard triage protocol within IMAI. Five patients (1%) required higher level of care per the clinical mentor, of whom four were appropriately diagnosed and managed by the nurse (Table 3).

Table 3 Quality Indicators – Consultations with Vital Signs, Triage and Screenings by Outpatient Department nurse (N = 470)[a]

Vital signs collected by:	
Registration clerk	209 (44.5%)
Outpatient Department nurse	118 (25.1%)
Other	75 (16.0%)
Multiple providers	54 (11.5%)
None	14 (3.0%)
Blood pressure recorded	76 (16.2%)
Temperature recorded	129 (27.5%)
Weight recorded	294 (62.6%)
Height recorded	0
Respiratory rate recorded	0
BMI recorded	0
Pulse recorded	0
Triage	
Triaged using basic skills in assessment of severe illness	7 (1.5%)
Diagnosed with emergency condition by nurse	4 (0.9%)
Screening	
Chronic cough	45 (10.0%)
Malnutrition	1 (0.2%)
Anemia	8 (1.8%)
Genital/anal lesions	17 (3.8%)
Discharge/other genitourinary symptoms in males with genital lesions (n = 129)	12 (9.3%) penile 1 (0.8%) scrotal
Previous HIV testing	7 (1.8%)
Mosquito net	3 (0.7%)
Tobacco use	2 (0.4%)
Alcohol use	2 (0.4%)
Sexual activity	32 (7.3%)
Pregnancy in eligible females (n = 300)	66 (22.0%)
Family planning (n = 268)[b]	10 (3.7%)

[a]unless otherwise indicated.
[b]only women aged 15–49 eligible for screening per adapted IMAI protocol.

All four patient emergencies identified by the nurse were referred to the district hospital; three with high fevers greater than 38°C and one who was convulsing. One patient, identified only by the clinical mentor, was in circulatory shock and with mentor intervention, resuscitation measures were employed.

Routine screening by history

Low rates were observed for routine screening for a wide range of conditions (Table 3). Only 10% (45) of patients were screened for TB (cough greater than 2 weeks). Among male patients, 10.1% were screened for genitourinary/STI symptoms. Twenty-two percent (66 of 300) of eligible female patients were screened for pregnancy or asked about their last menstrual period. Only 7.3% (32) of patients were asked about current sexual activity, and only 1.8% (7) screened for HIV status. Less than 1% of patients were screened for any of the following: anemia, alcohol use, tobacco use, use of mosquito nets at home or nutrition.

Diagnosis and treatment

In the 470 consultations observed, patients reported a total of 585 complaints. Of these, forty-nine categorized as "Other" (n = 43) and "Mental problem" (n = 6) were not captured by the disease categories included in the checklist and were excluded from analysis. Seven additional complaints (1.2%) had no corresponding diagnosis in the SIS codes, and 32 (5.5%) were missing any recorded diagnosis information, leaving 497 complaints with a diagnosis available for analysis. In addition to the 49 excluded complaints described above, 33 (5.6%) observations were missing information on correct treatment, leaving 503 complaints with available treatment data for comparison (Table 4).

Nurse diagnoses were in agreement with the clinical mentor 50.1% of the time (95% confidence interval 45.7%–54.5%), with the highest diagnosis agreement seen for epigastric pain (90.0%), skin problems or lumps (83.9%), mouth or throat problems (70.3%), and diarrhea (70.0%). Lowest rates of diagnosis agreement were seen for fever (8.2% correct), headache or neurological

Table 4 Correct nurse diagnosis and treatment of patient illnesses*

	N	Nurse diagnosis n = 497 % (95% CI)[‡]	Nurse treatment n = 503 % (95% CI)
Total agreement		249	226
		50.1% (45.7 - 54.5)	44.9% (40.6 - 49.3)
Back or joint pain	42	59.5% (44.7 - 74.4)	71.4% (57.8 - 85.1)
Cough or difficulty breathing	80	31.3% (21.1 - 41.4)	33.8% (23.4 - 44.1)
Diarrhea	30	70.0% (53.6 - 86.4)	36.7% (19.4 - 53.9)
Epigastric pain	59	90.0% (82.4 - 97.6)	18.6% (8.7 - 28.6)
Fever	49	8.2% (2.3 - 19.6)	78.6% (67.8 - 89.3)
Genitourinary symptoms			
Female	80	48.8% (38.0 - 59.6)	35.0% (24.6 - 45.5)
Male	30	53.3% (35.5 - 71.1)	26.7% (10.8 - 42.5)
Headache or neurological condition	44	20.5% (8.5 - 32.4)	77.3% (64.9 - 89.7)
Mouth or throat problem	37	70.3% (55.5 - 85.0)	43.2% (27.3 - 59.2)
Skin problem or lump	31	83.9% (70.9 - 96.8)	45.2% (27.6 - 62.7)

*Limited to complaints with n > 5 observations.
[‡]95% CI calculated using the exact binomial distribution.

conditions (20.5%) and cough or difficulty breathing (31.3%). Agreement varied significantly between HCs, ranging from 35.6% to 60.0% (p = 0.03). There was no association between nurse experience in OPD and correct diagnosis.

The nurse treatment plan was in agreement with the clinical mentor less than half the time (44.9%, 95% confidence interval 40.6% - 49.3%). Complaints of fever (78.6%), headache (77.3%), and back or joint pain (71.4%) had the highest proportion of agreement. Lowest agreement was seen for epigastric pain (18.6%), genitourinary symptoms (26.7% for males, 35.0% for females), cough or difficulty breathing (33.8%), and diarrhea (36.7%). Treatment agreement varied from 32.1% to 58.9% across HCs (p = 0.04), but did not vary with duration of nurse experience in the OPD (Table 5).

Discussion

This is, to our knowledge, the first study assessing the general quality of care and clinical decision-making for adults and adolescents at rural OPDs in a resource-limited setting. Every aspect of routine care that was measured, including triage for life-threatening conditions, screening for chronic disease and modifiable lifestyle risk-factors, diagnosis of acute illness, and appropriate management and treatment, were found to be in need of strengthening and quality improvement. The study demonstrated infrequent collection and use of vital signs, infrequent screening for common illnesses (such as HIV, TB, STIs), and low rates of prevention counseling (such as malaria control with ITNs, and alcohol and tobacco use). With a lack of available standards to support quality, compounded by relatively little investment in general primary care for adults and adolescents, it is unsurprising that the results reflect a great need for improvement of front-line delivery.

Table 5 Factors associated with correct nurse diagnosis and treatment of patient illness

	Nurse diagnosis			Nurse treatment		
	N	Percent correct	p	N	Percent correct	p
Health center			0.03			0.04
A	54	51.9% (38.5 - 65.2)		56	58.9% (46.0 - 71.8)	
B	61	37.7% (25.5 - 49.9)		61	42.6% (30.2 - 55.0)	
C	62	58.1% (45.8 - 70.4)		64	43.8% (31.6 - 55.9)	
D	65	60.0% (48.1 - 71.9)		65	32.3% (20.9 - 43.7)	
E	68	58.8% (47.1 - 70.5)		69	50.7% (38.9 - 62.5)	
F	59	35.6% (23.4 - 47.8)		59	52.5% (39.8 - 65.3)	
G	55	49.1% (35.9 - 62.3)		56	32.1% (19.9 - 44.4)	
H	73	46.6% (35.1 - 58.0)		73	46.6% (35.1 - 58.0)	
Nurse OPD experience			0.26			0.66
4+ years	264	51.5% (45.5 - 57.5)		265	43.8% (37.8 - 49.8)	
0-3 years	220	46.4% (39.8 - 53.0)		225	45.8% (39.3 - 52.3)	

Nurse diagnosis and treatment decisions were in agreement with the clinical mentor approximately half of the time or less. Agreement in diagnosis and treatment for the same conditions (e.g. fever, epigastric pain) often varied widely, suggesting large variations in individual practice. Poor decision-making could be influenced by a number of long-term structural and health system needs, including gaps in infrastructure, supplies and human resources [33-36]. However, other factors could be addressed in the shorter-term and could lead to an initial rapid improvement in the quality of adult and adolescent primary care.

As noted, aside from selected disease- or condition-specific protocols there are few decision-support tools available to help OPD providers simplify and standardize their decision-making and care. These tools, particularly for children under-5 and for HIV/AIDS, have been shown to improve quality and health worker performance [37-42]. While experiential learning is the primary foundation of practice improvement in Rwandan OPDs, the results show there was no significant increase in the quality of the decision making with increasing years of nursing experience.

The data also highlight needs with respect to nurse training and standardization of care. The low frequencies in our data across the measured areas of clinical practice suggest that the nurses in our sample need additional support in basic clinical skills, including history-taking, completion and interpretation of vital signs, and screening for chronic conditions, in addition to clinical reasoning and decision-making. While it was beyond the scope of this study to isolate whether these gaps originated in pre-service education, pre- or post-service training, and/or other structural factors such as infrastructure, lack of protocols or time constraints, clinical training of nurses in primary care has been shown to at least modestly improve quality of care for acute respiratory tract infections [43] and medication prescription [44]. The data demonstrate that nurses manage some illnesses better than others, and that performance differs significantly between sites, suggesting that standardization of care, as well as performance measurement coupled with mentoring and systems-based quality improvement are needed. In addressing issues of decision support, integrated training, and standardization of care, protocols such as IMAI could represent an important part of a toolkit for developing a common standard of OPD care for adults and adolescents, and improving quality of these services.

While implementation of care based on protocols such as IMAI is necessary, it is not sufficient to support the delivery of high quality of care. A critical component is ensuring durable knowledge and practice improvement

through routine and sustainable mentorship of health care workers. Though there are differences in definition and structure of supervision programs [45], mentorship in primary care has been shown to improve and sustain improvements in nurse performance [46-48]. In Rwanda, robust efforts are now underway to implement a system of routine on-site mentorship to health center nurses in all clinical services [31].

There are a number of limitations to our study. First the clinical mentor was not blinded and therefore could have been influenced by observing nurses' decisions in real-time, thus biasing the results and possibly overestimating the level of agreement. Having an observer in the room may have also influenced the nurses to perform better or differently than they would in normal circumstances [49]. Given the low level of consistency found, it is unlikely that either potential bias considerably altered the results. Also, clinical decision-making could not be assessed for approximately 15% of patient complaints due to missing data. Approximately half (n = 43) of complaints missing from the analysis were classified as "Other" complaints that did not fall into the conditions selected for study *a priori*. The remainder of missing diagnosis or treatment information (approximately 7% of the total sample) was distributed across complaints and is unlikely to have had meaningful impact on the results. We have also presented clinical decision-making on diagnosis and therapeutics as a proxy for quality of care, but these are only two key components. We did not measure clinical outcomes, nor define current costs, infrastructure, and human resources which all impact or help define quality and which could be pursued in future research. Finally, IMAI has yet to be formally validated, particularly in low-HIV prevalence settings such as Rwanda, which represents an important next step in establishing a standard of general adult and adolescent primary care delivery.

Conclusions

This study describes the baseline quality of adult and adolescent primary care at Rwandan health center OPDs and demonstrates a clear need for improving the quality and consistency of care. Care based on IMAI or other integrated protocols, accompanied by a robust system of mentorship and supervision that focuses on individual performance as well as systems-level gaps, could be an important approach to simplifying and standardizing the delivery of care for common acute presentations for adults and adolescents in the ambulatory setting. Refining and validating these protocols is needed. Only these coordinated efforts can ensure that high quality and effective primary care is available for all adults and adolescents in resource limited settings.

Competing interests

All listed authors declare that there are no competing interests – financial or otherwise – with respect to the design or execution of this study, or the writing or publication of the manuscript.

Authors' contributions

AV led the principle design of the study including development of data collection tools, data analysis plan, and served as overall co-lead supervisor for the study with MA, and was responsible for writing the first and all subsequent drafts of the manuscript in tandem with MA as well as incorporating authors' editorial comments. MA was the co-lead supervisor for the study working directly with AV on the study design, and served as the principle field coordinator and field supervisor for the study, refining of data collection tools and techniques, and was responsible with AV for drafting the first and all subsequent drafts of the manuscript, especially the Results and Discussion. CM served as the principal data analyst for the study, developing the study database and leading data entry, and conducted the main data analysis for the study according to the analysis plan, and as well contributing significant inputs to early and all subsequent versions of the manuscript, especially the Methods and Results. BLH was the principle statistician for the study, supporting data collection and analysis, and making significant written and editorial inputs to later versions of the manuscript, especially the Methods, Results, and Discussion. LRH is the Co-Principal Investigator for the larger DDCF research grant, and on this study served both as the senior technical advisor to the lead authors of the study, but also provided significant editorial inputs to all sections of later versions of the manuscript. FN served as the lead district MOH representative on the study and was involved in review and approval of the study protocol and all related study tools and procedures, and played an instrumental role in educating staff at participating sites on the study, while also contributing significant editorial inputs and approval on later drafts of the manuscript. MH was the senior nurse clinical mentor and principal data collector on the study, was involved in development and field-testing of all data tools, and contributed significant editorial inputs to later drafts of the manuscript, especially the Methods section. AN served as the deputy field coordinator for the study under MA and was the principle point of contact for all study staff on the ground and managed all of the study logistics, especially for the data collection and study implementation teams; he also contributed significant editorial inputs and approval for later versions of the manuscript. FRC served as the principle clinical lead on the study, working directly with the nurse mentor during the field testing and data collection stages, and also worked closely with the lead authors on design and field testing of the data collection tools, while also contributing significant editorial inputs and approval for later drafts of the manuscript. BN was the central MOH representative for the study, was instrumental in securing national ethics approval in Rwanda, and was involved particularly at the early stages of the study during design, approval and establishment of district partnership for the study, while also contributing significant editorial inputs to later drafts of the manuscript. PD is also a Co-PI on the larger DDCF grant, and served as the principle organizational lead on the study, involved particularly in the conception and design phases working directly with the lead authors, and provided significant editorial inputs and approval to later drafts of the manuscript, especially the Background, Results, and Discussion. NG served as the senior advisor on the study, involved at all stages of the study working in close collaboration with the lead authors, from design and conception to implementation and data management, and was instrumental in providing editorial inputs and approval to all drafts of the manuscript including the first draft. All authors read and approved the final manuscript.

Authors' information

Ashwin Vasan and Manzi Anatole are joint-first authors to this manuscript.

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Chapter 6

Field test and adaptation of WHO-IMAI Acute Care to Rwanda MOH standards of care and to specific protocols used in districts supported by the MOH-PIH/IMB partnership

6.1 Background

The WHO developed IMAI as a series of simplified, syndromic case management protocols to diagnose and manage common adult illnesses into a single clinical management guideline. The IMAI Acute Care (WHO, 2009) protocols are structured around presenting symptoms, and classify the patient according to clinical severity and disease chronicity using a syndromic – as opposed to etiologic - approach structured around a simplified version of the universal patient history and physical examination. These diagnostic guides are followed by simple and prescriptive algorithms for syndromic treatment, along with follow-up and/or referral recommendations. IMAI draws upon proven approaches to the screening, diagnosis, and management of specific diseases including malaria, HIV/AIDS, STIs, pneumonia, diarrheal disease, and tuberculosis. IMAI was introduced to improve acute care through better integration of delivery at a single point-of-care, usually health centre or hospital OPDs.

The efficacy and applicability of the IMAI guidelines can be explored through field-testing and adaptation to specific epidemiology and to health system

environments. In the context of IMAI, and as with similar efforts to adapt IMCI or other global protocols advanced by WHO, adaptation refers to the process of assessing and then making the specific changes required to ensure that the guidelines are appropriate for the circumstances of individual countries and individual settings within those countries. This is generally done through a process of facility-based field-testing and consensus guideline review to ensure that the guidelines conform to national standard of care and treatment protocols, and also to specific practice environments.

This chapter reflects the recommended adaptations to the global, or 'generic' IMAI guideline based on review and field-testing of protocols at government health centres in Rwanda. This is not a hypothesis-driven research study, but rather a description of the pragmatic process of testing and adapting a guideline developed globally at WHO Headquarters in Geneva, to a real-world practice environment in an LMIC health system. The adaptations made to the generic guideline, and described in this chapter, reflect data from four major sources: (1) national standards of care established by the Rwandan MOH in their primary care and disease-specific protocols in use at health centre OPDs; (2) supplemental protocols developed by PIH and used at MOH facilities in PIH-supported districts; (3) quantitative and qualitative data gathered during the field-test, combined with the observational experience of clinicians during the field test, and (4) the clinical experience and judgment of the field test clinicians. The process of adaptation of the global IMAI guideline reflects consensus guideline review conducted by the field-testing clinicians along with MOH and PIH officials, or data from sources 1 and 2 described above, as well as practice-based data gathered from a set of limited clinical encounters, described as source 3 above. Finally many of the adaptations listed

below are based on the clinical acumen and best clinical judgment and experience of the physicians and nurses leading the field test, described as source 4 above.

6.2 Methods

6.2.1 Study setting

IMAI Acute Care (WHO, 2009) was field tested in the Eastern Province (southern Kayonza and Kirehe Districts) of Rwanda from November 2009 to January 2010. The guidelines were tested at six health centre outpatient departments (OPDs) including in Rwinkwavu, Ndego, Mulindi, Nyarabuye, Rusumo, and Kirehe. Data were collected during on-site visits by the field test team over the course of one week (five working days) at each site.

6.2.2 Inclusion criteria

Field-testing sites were selected based on the existing availability of sufficient human resources and flexibility of staff to support the field test. Specifically, each eligible health centre was required to have more than one nurse regularly scheduled to work in the OPD during the field test week, which allowed delegation of a single nurse dedicated to supporting field testing while minimizing disruption to normal clinic operations as much as possible. Adult and adolescent patients aged 13 and older were eligible for the field test study. As the exact age of the start of adolescence is not officially defined in Rwanda, we selected the definitions used by US Centres for Disease Control (Centres for Disease Control and Prevention, 2008a). The purpose of the field test was explained to eligible patients. They provided oral informed consent and could opt-out of the field test if they desired. Patients who declined to

participate in the field test, were evaluated by the other OPD nurse(s) not participating in the field test. No unique patient identifiers were collected.

6.2.3 Staffing

The field test team consisted of three currently practicing physician-researchers affiliated with Partners In Health and trained in Internal Medicine and Primary Care. Each had at least three years of experience practicing Internal Medicine in the US and in Rwanda. At each of the six health centres one OPD nurse was designated as the field-test nurse, dedicated to supporting field test activities during the week-long site visit. These nurses were all designated as 'A2', which is an officially designated cadre of nurses who possess a secondary school degree in nursing science, human physiology and health behaviour. This cadre of nurses routinely staffs health centres and health centre OPDs.

6.2.4 Data collection and analysis

Consecutive and eligible adult and adolescent patients who consented to participation and presenting to the health centre OPD, were seen by the field test physician using the generic WHO-IMAI protocol. They were assisted by the field test nurse who provided real-time translation and were responsible for conducting routine care prior to the physician consultation as well as advising the field test physicians on implementation of current standards of care. The global IMAI Acute Care Case Recording Form (Figure 1) was used by the study physician as a guide for working through the algorithm. An electronic Case Log in Microsoft Excel was maintained by the observing physician to record and manage data, though paper-

based notes were also employed. The case logs from each site were then aggregated and cleaned in a single database, also in Excel.

For each patient encounter, the field test nurse responded to the patient's chief complaint as they typically would in daily consultation, including ordering laboratory investigations and prescribing treatment. Next, the observing physician addressed the chief complaint using the specific IMAI syndromic algorithm relevant to the complaint. Classifications were made according to the algorithm, but recorded diagnoses corresponded to current Ministry of Health reporting and diagnostic codes, also known as SIS or *Systeme Informatique Sanitaire*. The field test physician then completed the remaining portions of the IMAI algorithm, including the routine screening questions, prevention and follow-up on any complaints not directly volunteered by the patient. All final treatment decisions were made by the nurse per routine practice, with the study physician serving only in an advisory capacity when requested by the nurse, or in the case of an acutely ill patient.

In addition to implementing the IMAI algorithm, routine vital signs were collected to observe their utility in identifying sub-clinical illness not explicitly volunteered by the patient, or by providing objective correlates to the patient's symptoms and/or complaints. In addition to weight, which is routinely collected at health centres in Rwanda, height, temperature, pulse, blood pressure, and respiratory rate (only in patients complaining of cough and/or difficulty breathing) were measured.

Finally, targeted physical examination skills were taught to the nurses by the field test physicians. These examination skills corresponded to those included in the IMAI algorithms, but nurses were also advised on auscultation of the chest, abdominal examinations, and musculoskeletal examinations for common complaints

like cough, abdominal pain, and joint/back pain, respectively.

6.3 RESULTS

6.3.1 General description and demographics

A total of 223 patients were seen during the field test. The mean age was 34 years, with the median age 30 years (range of 7-79 years). Fifty three percent (53%) of patients were female, and 47% male. The distribution of conditions found during the field test is shown in Figure 1. The most common condition, either reported by the patient or found on routine screening, was headache or neurological condition, followed by fever. Nineteen percent (19%; 43/223) of patient encounters had a primary complaint or diagnosis that was not represented in the IMAI Acute Care algorithm, and this category was the third most common amongst all conditions. The most frequent of these conditions/complaints included: 1. Epigastric pain (n=14); 2. Joint pain or Arthritis (n=5); 3. Musculoskeletal complaint (n=4); 5. Back pain (n=3); 6. Accident/trauma (n=3); 7. Eye problem / conjunctivitis (n=3). Other complaints reported once each were: abdominal mass, ear problem, lower extremity oedema, hematuria, hypertension, lipoma, mastitis, penile foreskin problem, post-partum infection, allergic rhinitis, sexual impotence.

6.3.5.12 Recommended general adaptations to IMAI guideline

Based on the large number of complaints not addressed by the guideline, we recommend the development of new syndromic algorithms for epigastric pain (Figure 3) and musculoskeletal pain / back pain / arthritis (Figure 4), as this would increase coverage of the IMAI protocols from 81% to 93% of chief complaints based on the findings in this field test population, Although infrequent, we also recommend

the development of a syndromic algorithm for oedema (Figure 5), given its importance as a sign or underlying chronic illness.

6.3.2 SECTION I – Triage and approach to the patient

6.3.2.1 Blood Pressure

Overall, 19% (40/209) of patients were found to have systolic blood pressure (SBP) ≥140 mmHg, 25% (52/209) had diastolic blood pressure (DBP) ≥90 mmHg, 33% (68/209) with either SBP≥140 mmHg or DBP≥90 mmHg, and 11% (24/209) had both SBP≥140 mmHg and DBP≥90 mmHg. Using more strict criteria for elevated blood pressure (Stage II HTN), 3% (6/209) of patients were found to have SBP≥160 mmHg, 4% (8/209) with DBP≥100 mmHg, 6% (13/209) with either SBP≥160 mmHg or DBP≥100 mmHg, and 0.5% (1/209) with SBP≥160 mmHg and DBP≥100 mmHg. No cases of hypotension were found. During this field testing, patients determined to meet criteria for hypertension (as defined by NCD guidelines) were asked to follow up for repeat measurements in order to confirm diagnosis, and if repeat testing was high, the patient would be referred for further evaluation to the hospital or Chronic Care Clinic at Rwinkwavu Hospital.

6.3.2.2 Pulse

In total, 24% (50/208) patients were found to have a tachycardia (>100 beats per minute [bpm]) and 26% with >110 bpm. Although generally a sensitive indicator of acute illness (both patients found in the assessment to have very severe febrile illness had a heart rate (>100 bpm)), it is also very non-specific. In addition, 6% (13/208) had a bradycardia (<60 bpm), all of which were asymptomatic.

6.3.2.3 Temperature

Thirteen percent of patients (26/196) were found to be febrile; body temperature [T]≥37.5°C and 9.2% (18/196) with T≥38°C.

6.3.2.4 Respiratory Rate

Only patients with the complaint of cough or difficulty breathing were screened. No abnormal respiratory rates were found.

6.3.2.5 Weight and height

For the majority of patients weight was taken by standing scale by the clerk at the time of registration, per routine health centre procedures. It was noted on several occasions that the weight was grossly inaccurate and needed to be repeated, though this was not systematically documented. Height is not routinely measured for adult visits. All sites did have balances equipped with a height ruler or a separate wooden height ruler. Essential in calculating body mass index (BMI), height can most likely be measured by the registration clerk with the appropriate training (like weight, this value does not require interpretation).

6.3.2.6 *Body mass index (BMI)*

BMI was calculated for all patients with both height and weight recorded. The average BMI was 20.6 kg/m^2 (N=125). In total, 13% (16/125) of the patients had BMI <17; however, nine of these 16 patients were under 17 years of age. There were no patients with BMI > 30. The major limitation to calculating BMI is training of nurses to either calculate or use of standard BMI tables, which are not adjusted to the Rwandan or sub-Saharan African context. PIH routinely uses BMI tables in both

the HIV/TB clinic and the Chronic Care/NCD clinics, and this information is a useful measure of systemic illness. Nurses will require significant training and mentoring on BMI calculation, interpretation, management, and follow up. Finally, adolescents require age-specific BMI tables for correct interpretation; therefore, for the purposes of near-term implementation, we recommend restricting BMI calculation only to adults over 20 years of age. Traditionally, undernutrition for ≤20 years is defined as <5th percentile and therefore relative to national growth standards and requires additional tables or calculation tools. See the section 'Undernutrition' for interpretation and comparative value of BMI.

6.3.2.7 Mid-Upper Arm Circumference (MUAC)

The average MUAC was 244 mm. See 'Undernutrition' below for interpretation and comparative value of MUAC with BMI.

6.3.2.8 Recommended Adaptations to Vital Signs

We recommend routine vital signs screening on all consultations including BP, pulse, temperature, weight, and height. Nurses are indeed capable and interested in improving their understanding of how vital signs correlate with clinical signs and diagnoses. Accurate measurement of respiratory rate is important, but will require longer training and follow-up of nurses and can initially focus on clinical signs of respiratory distress. Significant effort must be made in the initial training and mentoring plans of IMAI Acute Care to emphasize the role of the taking and interpretation of vital signs in clinical diagnosis and management.

6.3.2.9 Physical examination

In general, OPD nurses rarely, if ever, utilize the physical examination to make or to confirm a diagnosis. In the limited cases observed when a physical examination was performed, it was done in a focused manner, based on a primary complaint, and it often aided the nurse's diagnostic reasoning. In general, the field test nurses had little to no experience with core examination techniques such as the cardiopulmonary examination, abdominal examination, or musculoskeletal examination. They do appear to have greater experience, however, in skills such as examination for pallor and jaundice, and examination of the skin.

6.3.2.10 Recommended Adaptations for Physical Examination

The following focused clinical examinations were found to be helpful and should be incorporated into routine nursing training and technical support:

- Targeted screening of conjunctival pallor useful in high-risk groups – pregnant women, febrile patients, suspected malaria cases.
- Eye examination including visual acuity for eye complaints.
- Ear examination including otoscopy for ear complaints.
- Oropharynx or nasopharynx examination for complaint of mouth or throat pain.
- Auscultation of the lungs for cough or difficulty breathing.
- Auscultation of the heart, especially in cases of peripheral or pulmonary oedema, respiratory distress, or suspected cardiomyopathy.
- Abdominal examination for epigastric pain, abdominal pain or mass, penile or vaginal discharge, severe febrile illness, oedema or suspected cardiomyopathy. Nurses should be instructed in the detection of hepatomegaly and splenomegaly, but this should not necessary be incorporated as routine screening.

- Bimanual examination for complaint of vaginal discharge to assess for cervical motion tenderness and nature of discharge.
- Joint or back examination targeted to location of specific pain.
- Skin examination targeted to location of skin complaint.

6.3.3 SECTION II – Quick Check for Emergency Signs

The Quick Check for Emergency Signs is a simplified identification, triage, and management protocol for emergency conditions included in the IMAI Acute Care guidelines. It is based on the larger Quick Check algorithm (WHO) developed by WHO and partners. In this experience, five (2.2%) patients were admitted for inpatient care based on the Quick Check. Three of these patients had severe febrile illness (Quick Check: Fever from Life-Threating Cause), one with severe pneumonia (Quick Check: Airway and Breathing), and one with abdominal trauma (Quick Check: Pain, Shock). One patient was assessed by the field test physician to have an urgent condition, but ultimately treated as an outpatient with community health worker follow-up, due to logistical concerns. Many patients presented with HR > 110 bpm, but no other signs of distress, thus not qualifying them as having an emergency illness.

6.3.3.1 Recommended Adaptations to Quick Check in IMAI protocol

No specific adaptations recommended. Emphasize nurse training on Quick Check protocols to determine triage status and referral to higher level of care or inpatient admission.

6.3.4 SECTION III - Assess Acute Illness / Classify / Identify Treatments

6.3.4.1 Cough or difficult breathing

Twelve percent (12%) (26/223) of patients reported cough or difficulty breathing as a chief complaint. Of the 197 patients who did not volunteer cough as an initial complaint, 7% (13/197) reported it on routine screening questions. Of these, 5/13 (38.5%) had at least one of the following signs/symptoms: reported duration of cough greater than two weeks, night sweats, chest pain, or weight loss. As a result, 3% (5/197) of patients were detected by routine screening to have significant cough not otherwise detected on routine history, and were referred for further tuberculosis investigations. The overall incidence of TB in Rwanda is low (Incidence 69/100,000) (WHO), but given the referral rate of approximately 3% by routine screening, we would recommend maintaining this question as part of in routine screening in the IMAI guideline.

6.3.4.2 Recommended Adaptations to Cough or Difficult Breathing Algorithm

The following should be incorporated into nursing training and technical support for the Cough or Difficult Breathing algorithm :

- Ask: Add "Have you lost weight?"
- Look and Listen: vital signs should be incorporated into normal triage (see above).
- Look and Listen: include auscultation for crepitations, consolidation, or wheezes.
- Pneumonia Signs: add fever 38°C or above
- Possible Chronic Lung or Heart Problem signs: Add wheezing.
- Possible Chronic Lung or Heart Problem: add 'or Suspected Tuberculosis.'
- Possible Chronic Lung or Heart Problem signs: include weight loss and night sweats.

- Possible Chronic Lung or Heart Problem treatment: Consider referral to NCD clinic.
- Pneumonia and Severe Pneumonia: delete 'If on ARV therapy, this could be a serious drug reaction.' Patients on ART in this setting are not managed in the OPD.
- No Pneumonia (Cough/cold or bronchitis): change to 'Upper Respiratory Tract Infection or Bronchitis.'
- No Pneumonia (Cough/cold or bronchitis) treatments: add analgesic/antipyretic (paracetamol or ibuprofen) and 'Give hydration instructions.'

6.3.4.3 Undernutrition

In total, 16% (35/223) of patients responded that they had experienced some degree of subjective weight loss in the past six months. Often weight loss was confirmed by the patient's hand-held patient record booklet, however, often the patient's report of weight loss did not correlate with recorded weights. Overall, 2% (5/223) of patients were noted to have some degree of clinical wasting (2/5 had subjectively reported weight loss). Of the 38 patients who either reported weight loss or wasting, 50% (19/38) had associated symptoms of chronic illness, such as chronic cough, fevers, night sweats, oropharyngeal or oesophageal complaints, or weight loss > 10%. All patients with weight loss were referred for VCT or confirmed to have a recent documented HIV test. Based on its importance as a marker of chronic illness, we would recommend maintaining this question as a part of routine screening in the IMAI guideline.

MUAC was not highly correlated with BMI (N=108, linear regression R^2=0.58). Although efficient and likely easier to measure than BMI, MUAC has never been

validated as a screening marker for undernutrition in adults or adolescents. The five patients who were noted to have some degree of wasting each had a BMI <17, but their MUAC ranged from 205mm to 218mm, which would not have indicated clinical undernutrition by the current IMAI protocol. It is important to note that BMI may not be applicable for adolescents <20 years old. We would recommend replacing MUAC for patients with suspicion of undernutrition with routine screening of BMI.

In addition, nutrition advice was not routinely given. Further assessment is needing in terms of how patients should be counselled regarding: 1) how to improve nutritional status, 2) what weight loss workup should entail, 3) what patients should do if they do not experience an improvement, and 4) the possibility for social services (Ready-to-Use Therapeutic Food (RUTF), food supplements, agricultural training, social services).

6.3.4.4 Recommended Adaptations to Undernutrition Algorithm

- ASK: delete 'what medications are you taking' – this was an extremely low yield question, both because patients were rarely on chronic medications, and those patients that were on medications rarely knew the names of these drugs.. The patient's hand-held chart booklet is generally a more reliable source for this information. This statement can be adapted to 'Is the patient taking any medications?'
- Look and Feel: Delete question about loose clothing.
- Look and Feel: Replace MUAC with BMI.
- Signs: Replace MUAC with BMI <17 kg/m^2 for severe undernutrition (can maintain current physical examination findings) and BMI <20 kg/m^2 for 'Significant Weight Loss'.

- Signs: Add Weight Loss >10% for 'Severe Undernutrition'.
- Signs: Delete 'loose clothing'.
- Under 'Significant Weight Loss, Treatments': Delete 'diabetes mellitus'; Consider excess alcohol and substance abuse.
- Add an additional box for 'Nutrition Recommendations:' Counsel on well-balanced diet of locally available energy- and nutrient- rich foods for adults with undernutrition or persistent diarrhoea, which may include: maize meal, sorghum, kidney beans, casava, sosoma (soya, sorghum, maize), palm oil, eggs and peanuts.

6.3.4.5 Anaemia

All nurses appeared comfortable with screening accurately for conjunctival pallor. Overall, 4% (9/223) of patients were reported to have some degree of pallor. Of these, six were found on initial physical examination by the nurse, and three were found later on routine screening. No patients were classified as having severe anaemia. Given the high prevalence of anaemia (27% anaemia in women of reproductive age) (Ministry of Health (MOH) [Rwanda] National Institute of Statistics of Rwanda (NISR) and ICF Macro, 2009) conjunctival pallor is a useful screening tool, especially in high-risk patients like pregnant women or patients with suspected malaria. Rapid hemoglobin testing using HemoCue (HemoCue AB, Angelholm, Sweden) was available at most health centres per MOH standards, and was used primarily in the setting of acute malaria.

6.3.4.6 Recommended Adaptations to Anaemia Algorithm

- Divide table for anaemia and malnutrition into two tables for ease of use and clarity.

- Under 'If pallor' look and feel: 'feel for splenomegaly' and 'add check haemoglobin.'
- Severe anaemia signs: Include Hb<7 g/dL.
- Some anaemia signs: Include Hb<10 g/dL.
- Some anaemia: Delete 'ARV drugs… can cause anaemia.' ARVs not managed routinely in OPD setting in study districts.
- Under 'some anaemia treatments': If chronic or recurrent anaemia or presence of splenomegaly, consider referral to NCD clinic.

6.3.4.7 Genital or anal sores, ulcers, warts

Four percent (4%, 9/223) of patients reported past or present genital or anal lesions. Four of these patients presented this as their chief complaint (two cases of haemorrhoids, one case perianal abscess, one case of suspected syphilis). Upon routine screening for genital or anal lesions, three patients were found to have previous, inactive lesions. One of these patients was found to be HIV-positive on further questioning, and another was found to have an HIV-positive partner and an unclear history of HIV testing. Finally, two patients were found on routine screening to have genital or anal complaints. However, neither patient had significant physical examination findings. Overall, routine questioning identified five possible cases (5/219), two of which were extremely important in alerting the clinician to established HIV infection or exposure that would have been otherwise undetected. It is important to note that all health centres included in this study have regular HIV/TB clinics for established HIV-positive patients. Although this is a low-prevalence HIV setting (<3% national; 2.5% Eastern Province) (WHO, Ministry of Health (MOH) [Rwanda] National Institute of Statistics of Rwanda (NISR) and ICF

Macro, 2009) with a relatively low prevalence of STIs, ease of questioning by nurses and specificity of findings make routine screening reasonable in this population.

6.3.4.8 Recommended Adaptations to Genital or anal sores, ulcers, warts Algorithm

- Treatment for Genital Ulcer: Alternative to Benzathine Benzyl PCN: Erythromcyin x 14 days (recommended adaptation per Guide Therapeutique Standard) (Ministry of Health Rwanda, 2007),
- Treatment for Genital Ulcer: Alternative regimen: Doxycycline + Ceftriaxone.
- Treatment for Inguinal Bubo: Change doxycycline to 7d. Add alternative regimen: Erythromycin x 14 days + Ceftriaxone x 1.
- Add note 'For detailed instructions, refer to Guide National de Prise en charge des Infections Sexuellement Transmissibles, TRAC plus, MoH Rwanda, January 2010', or Guide Therapeutique Standard, MOH Rwanda, 2007)

6.3.4.9 Male genitourinary symptoms and abdominal pain

Four percent (4%; 4/104) of male patients were found to have genitourinary (GU) symptoms or lower abdominal pain on routine screening or on questioning after presenting with another chief complaint such as fever. No male patients volunteered GU symptoms as their chief complaint. Three of the four cases had lower abdominal pain or dysuria in the setting of more significant constitutional illness, and were therefore not pursued under this protocol. One male patient was found to have penile discharge, and was treated for STI and referred for VCT. Given the ease and effectiveness of screening, we recommend asking specifically for penile discharge along with genital or anal lesions as part of routine screening.

6.3.4.10 Recommended Adaptations to Male genitourinary symptoms and abdominal pain Algorithm

- For Urethral discharge or urination problem: add a new section with signs of dysuria, urinary frequency, suprapubic tenderness → Classification: Urinary Tract Infection or Prostatitis → send urinalysis or urine dipstick if possible, and treat with trimethoprim/sulfmethoxazole or ciprofloxacin.
- Under scrotal swelling or tenderness, new classification: Scrotal Mass. Signs include painless mass in scrotum or inguinal area, change in mass with position or valsalva, no evidence of incarcerated hernia. Treatment: referral to surgical centre.
- Add note 'For detailed instructions, refer to *Guide National de Prise en charge des Infections Sexuellement Transmissibles* (WHO, 2005b), Guide Therapeutique Standard (Ministry of Health Rwanda, 2007)

6.3.4.11 Mouth or throat complaints

Two percent (2%; 5/223) of patients reported some degree of throat or tongue pain on routine questioning, although all subsequent physical and laboratory examinations were negative. Four of the five patients were referred for VCT (the fifth was not determined to be a significant complaint). We found that nurses had little familiarity or experience with conducting the oropharyngeal physical exam, and thus it was not routinely done. There were no cases detected of oropharyngeal thrush. Overall, seven patients were diagnosed with dental caries or tooth decay, either by chief complaint or by screening examination. There were two patients diagnosed with suspected streptococcal pharyngitis and three with non-streptococcal pharyngitis. However, these were all in patients who self-reported throat pain.

Based on our observations, routine screening oropharyngeal examination would most certainly detect a high caseload of tooth decay and cavities, but in this low HIV-prevalence population there may be low yield for oropharyngeal thrush. Cases of streptococcal pharyngitis would most likely be reported by the patient, and not detected on routine examination. Therefore, we would recommend overall preventive and dental services for oral health, but given the time limitations of the general OPD consultation, these efforts may need to take place outside the IMAI screening algorithm (but including a section on this in both 'Acute Care' and in 'Prevention' may be considered).

6.3.4.12 Recommended Adaptations to Mouth or throat complaints Algorithm

- Remove routine oral and throat examination from the screening section, and replace it with 'If patient has mouth or throat problem' in the Acute Care section.
- Treatments: include page numbers for medication reference.
- For all thrush categories: Instead of fluconazole, must include 'nystatin suspension or ketoconazole (may give fluconazole, if available)' (Fluconazole not available in health centres per MOH formulary).
- Oral Leukoplakia: recommend abstinence from tobacco/alcohol use.
- Tonsillitis and Streptococcal Sore Throat signs: include fever (T >37.5°C) and absence of cough.
- Streptococcal Sore Throat: give benzathine penicillin OR penicillin V if patient able to swallow.
- Sore throat treatments: include paracetamol OR anti-inflammatory medication for pain.

- For severe gum infection treatment: delete 'if on ARV therapy' and edit 'Trial acyclovir, *if available.*'
- For gum/mouth ulcers: edit, 'acyclovir, *if available*' and delete 'if on ARV therapy.'
- For tooth decay treatments: Add: 'counsel on dental hygiene.'

6.3.4.13 In all patients, ask: are you in pain?

In this limited field test experience, patients were reliable in volunteering pain as part of their chief complaint.

6.3.4.14 Recommended Adaptations to 'Pain' section

- Delete this as a routine screening question.

6.3.4.15 In all patients ask: Are you taking medications?

In our context, patients taking ARV or TB medications generally present to the ID clinic, and not to general adult consultation. Most other patients are not taking chronic medications and those few who are on medications are generally unreliable in reporting their names.

6.3.4.16 Recommended Adaptations

Recommended Adaptations to 'Medications' section

- Remove this as a general question for all patients. Emphasize in nurse training to be cognizant of medications in the patient's hand-held chart booklet that the patient may have been recently prescribed.

6.3.5 SECTION IV - Respond to volunteered problems or observed signs

6.3.5.1 *Fever*

Fever was included in the chief complaint in 40% (89/223) of patient encounters. Malaria was suspected by the nurse in 43% (96/223) of patient encounters, including all cases in which fever reported as the chief complaint, and diagnosed by the IMAI algorithm in 31% (70/223) of these encounters. In the few cases where the nurse diagnosed malaria, but which did not agree with the IMAI algorithm, the physician felt that there was a more significant chief complaint and likely alternative diagnosis. Malaria smear was obtained in all cases of suspected malaria per MOH standards. Laboratory follow up and treatment were not recorded in all cases, due to varying laboratory workflow at each site, but *at least* 17% (16/96) of suspected malaria cases were confirmed smear-positive for *Plasmodium*. Given these statistics, the prevalence of fever as the chief complaint and relative malaria burden are high for this endemic malaria region, and malaria should generally be the leading diagnosis for this syndrome. Of note, the field testing was conducted at the end of the autumn rainy season in November, and into the short winter dry season in December, so as to assess the algorithm in periods of higher and lower malaria incidence.

6.3.5.2 Recommended Adaptations to Fever Algorithm

- ASK: under 'Any other problem,' add bullet points for possible localizing symptoms with associated cause: Cough? Rhinorrhea or nasal congestion? Sore throat? Abdominal pain, diarrhoea, or dysuria? Skin lesion? Headache or stiff neck?
- Look and Feel: remove 'Headache? For how long?'

- Look and Feel: remove 'Do malaria smear or rapid malaria test' to outside of Look and Feel box, categorize based on malaria test results.
- Look and Feel: assess for pallor.
- Look and Feel: Focus examination based on symptoms (i.e., throat, lungs, abdomen, skin, joints).
- Look and Feel: Consider haemogram, urine, or stool examination depending on symptoms.
- Delete High, Low, and No Malaria Risk categories. Classify all adults with fever into 4 categories:

Very Severe Febrile Disease

- Maintain as currently displayed under high malaria risk.
- Add fever >39°C under signs.
- Delete artemether (quinine only).
- Treatment: Give paracetamol if able to take medication.

Fever – Malaria

- Move smear positive for malaria to top of signs (remove 'dipstick,' not used).
- Signs: conjunctival pallor.
- Treatment: Give paracetamol.
- Treatment: Give treatment for anaemia if indicated.

Fever – Malaria unlikely or other apparent cause

- Delete final point 'If no apparent cause and fever for 7 days, send sputum for TB' – this will be included in persistent fever.
- delete 'consider fever related to ARV use.'

Persistent Fever

- Treatment: Move 'If no apparent cause…' to bottom. Add 'Consider other causes of prolonged fever' and 'Obtain testing related to symptoms, such as repeat malaria smear, urinalysis, stool analysis, etc.'
- Delete 'consider fever related to ARV use.'

6.3.5.3 Diarrhoea

Six percent (6%; 13/223) of patients presented with diarrhoea as part of the chief complaint. Of these, one patient was diagnosed with diarrhoea with some dehydration, and five with diarrhoea without dehydration. No patients were assessed to have severe dehydration or persistent diarrhoea. By contrast, many more patients presented with the chief complaint of epigastric or lower abdominal pain (see below).

5.3.5.4 Recommended Adaptations to Diarrhoea Algorithm

- Ask: 'Is there fever?' 'Is there vomiting?'
- Look and Feel: Add 'Is the pulse greater than 120 beats per minute?'
- Look and Feel: Add 'Does the mouth appear dry?'
- Look and Feel: Add 'If bloody diarrhoea, examine the anus for haemorrhoids, fissure, or lesions.'
- Severe Dehydration: Add 'Consider HIV-related illness (see pg 54).'
- Signs: for Severe Dehydration, include 'Pulse greater than 120 beats per minute' and 'Severely dry mouth.'
- Severe Persistent Diarrhoea: Add 'If HIV related illness, refer urgently to hospital' and 'Consider HIV-related illness.'

- Severe Persistent Diarrhoea and Persistent Diarrhoea: Replace 'Give appropriate empirical treatment…' with 'Treat with Metronidazole for possible Giardia infection' and 'Consider treatment for possible bacterial enteritis with Ciprofloxacin or Co-trimoxazole.'
- Persistent Diarrhoea: delete 'If on ARV treatment…'
- Dysentery: Oral antibiotic recommended for *Shigella* is Ciprofloxacin or Co-trimoxazole. Add, 'If no improvement, treat with metronidazole for possible amoebic dysentery or giardia' Add 'Treat all dysentery with Mebendazole for possible parasitic infection.'

6.3.5.5 *Female genitourinary: STIs, menstrual problems, UTI and lower abdominal pain*

Twenty seven percent (27%; 32/119) of women reported lower abdominal pain, dysuria, and/or vaginal discharge or bleeding as part of the chief complaint. Of these, 17 were given a primary diagnosis within this algorithm (Gastroenteritis or other GI problem - eight, candidal vagnitis – three, PID – two, STI/cervicitis – two, UTI – two, pregnancy related vaginal bleeding – one). In general, health centre nurses lacked a consistent approach to clarifying the etiology of lower abdominal complaints. Abdominal and/or bimanual examinations were rarely performed.

Although not routinely asked as a part of screening, several women did volunteer a complaint of vaginal discharge later, during the screening questions. Considering higher HIV prevalence in women vs. men (3.6% vs. 2.3%), the higher number of lifetime sexual partners (between 1-9 partners) in women vs. men (Institut National de la Statistique du Rwanda (INSR) and ORC Macro, 2006), and that only 19.7% of women reported condom use with last non-regular partner vs.

40.9% males (Institut National de la Statistique du Rwanda (INSR) and ORC Macro, 2006), inclusion of screening for female STI with routine questioning may be warranted.

6.3.5.6 Recommended Adaptations to Female genitourinary: STIs, menstrual problems, UTI and lower abdominal pain Algorithm:

- Under Ask: delete 'Any bleeding on sexual contact?'
- Look and Feel: add to 'If you are able to do bimanual examination, feel for cervical motion tenderness or adnexal tenderness or mass.'
- Look and Feel: under 'If burning or pain on urination…' include perform urinalysis or urine dipstick.
- Change classification of 'Gastroenteritis or other GI or Gyn problem' to 'Other GI or Gyn problem.'
- Gastroenteritis or other GI or Gyn problem – Under treatment include 'If epigastric pain, see p.__.'
- Gastroenteritis or other GI or Gyn problem – Add 'Consider mebendazole for possible intestinal parasite.'
- Irregular Menses or Very Heavy Periods – Under treatment include 'If heavy active bleeding (or evidence of major blood loss), refer to hospital.'
- Irregular Menses or Very Heavy Periods – Add 'Consider referral to women's health clinic, if available.'
- Candida Vaginitis – Under treatment, change to 'treat with nystatin or fluconazole 150mg x 1. Consider treatment for bacterial vaginosis and trichomonas.'

- Bacterial Vaginitis or Trichomonas- Add 'Consider treatment for candidal vaginitis also' and Add second-line therapy.
- Bladder infection – Under treatment, refer to page number of treatments.
- Kidney and Bladder Infection – Under signs, include urine examination or urine dipstick positive for infection.
- Add note 'For detailed instructions, refer to Guide National de Prise en charge des Infections Sexuellement Transmissibles, TRAC plus, MoH Rwanda, January 2010' (Ministère de la Santé, 2010).

6.3.5.7 Skin problem or lump

Four percent (4%; 9/223) of patients were given a primary diagnosis of skin condition. Four of these were classified as *Tinea* infections, three were soft tissue infection or folliculitis, and two were impetigo or minor abscesses. There were no diagnoses of enlarged lymph nodes. Knowledge amongst nurses regarding appropriate treatment was generally good, but knowledge of appropriate antibiotic for staphylococcal coverage varied.

6.3.5.8 Recommended Adaptations to Skin problem or lump Algorithm

- Reactive Lymphadenopathy: Change to 'Lymphadenitis.'
- Reactive Lymphadenopathy: Add to signs: 'Fever >37.5°C" and "Tender to touch.'
- Persistent Generalized Lymphadenopahy: Under treatment, include 'Consider TB' and 'Refer for evaluation and management at district hospital.'
- Scabies: Add 'benzyl benzoate *or permethrin.'*
- For all acyclovir, add '*if available, or refer to district hospital for treatment.*'
- For Herpes Zoster, delete amitriptyline.

- Warts treatment: add 'if available' before first bullet point.
- Consider cross-referencing to WHO Integrated Management of Emergencies and Essential Surgical Care (IMEESC) for management of burns.

6.3.5.9 Headache or neurological problem

Headache was the most common chief complaint, included in 42% (93/223) of patient encounters. Most were part of a constitutional syndrome (malaria, URTI, etc.) and not addressed in isolation. With no other isolating symptoms, 5% (11/223) of patients were diagnosed with tension headaches using the IMAI protocol, and most were treated symptomatically with paracetamol or a non-steroidal anti-inflammatory agent. This diagnosis tended to be a diagnosis of exclusion after a negative malaria smear and absence of fever. No cases of 'serious neurological problem' or 'sinusitis' were diagnosed, and migraine was suspected in only one case. Nurses were generally unfamiliar with differences in headache classifications or management. No cases of neuropathy or cognitive problems were identified.

6.3.5.10 Recommended Adaptations to Headache or neurological problem Algorithm

- ASK: Arrange into three categories:

  1) If Headache- Place this category on top. Maintain current questions. Also move into this section the following questions: 'Do you have weakness in any part of your body? Have you had an accident or injury involving your head recently? Have you had a convulsion? Add the following questions on top: Have you had fever? If yes, classify according to fever algorithm? Do you have nasal congestion or discharge?'

2) If Leg Pain- add questions, 'What type of pain do you have?', 'Is there a sensation of burning or numbness?', and 'Is there swelling? (see leg oedema section).'

3) If Cognitive Problem- include all other questions

- Look and Feel: Arrange into same three categories as above.

  1) If Headache- include here Look at Face: 'Feel for stiff neck, measure BP, Is patient confused?, flaccid on one side?, Problem walking?, Problem talking? Problem moving eyes?, Feel for sinus tenderness, Flaccid arms or legs? If weakness, test strength (currently redundant). If fever, use fever algorithm and consider malaria test.'

  2) If Leg pain- examine legs for strength, sensation, and presence of skin ulcers or lesions.

  3) If cognitive problem- include mental status examination questions here (from the ASK section). Delete the sentence 'If confused or disoriented, look for physical cause…'.

- Sinusitis- in Signs, add Fever and add Nasal Discharge. Make this 'If two of the below:'
- Tension Headache: under Treatment add paracetamol or anti-inflammatory medication. Also add: 'If greater than two months and no apparent cause, consider referral to hospital for evaluation.'
- Painful Leg Neuropathy: delete 'treat with low dose amitryptiline' – to be done at district level.
- Painful Leg Neuropathy: under Signs include foot ulcerations or other lesions.

6.3.5.11 Mental health problems

Two patients were suspected of anxiety disorder, one with possible co-existing depression. One patient was referred to mental health services.

Recommended Adaptations to Mental health problems Algorithm

At the time of writing, national guidelines for psychiatric care at the health centre level are under development.

- Under ask: move 'Do you have less energy…' to next set of bullet points and change 'if yes to any of the above *two* questions.'
- Under Major Depression: Change start amitriptyline to 'consider amitriptyline, if available' and delete 'if patient is taking EFV…'.
- Under minor depression: delete 'Give amitriptyline…'.

6.3.6 SECTION V - Consider HIV Related Illness

The table listed in IMAI is a comprehensive list of HIV-related illnesses and should trigger HIV testing. Along with the screening questions listed above and general questions for sexual activity and last HIV test, the goal of IMAI in Rwanda should be targeted screening of patients with HIV-related signs and symptoms, patients diagnosed with other sexually transmitted infections, all pregnant women, all patients requesting voluntary counseling and testing, and patients in areas of high prevalence (Guide National de Prise en charge des Infections Sexuellement Transmissibles, TRAC plus, MoH Rwanda, January 2010.)

6.3.7 SECTION VI - Prevention: Routine Screening and Prophylaxis

6.3.7.1 Advise use of insecticide-treated bednet (ITN)

The prevalence of patients *without* a functioning insecticide treated bed-net

was 33% (46/141).

6.3.7.2 Recommended Adaptations to ITN screening

Given the known preventive benefit of ITNs in this setting, which is highly malaria endemic, we strongly recommend screening for bed-net use in all patients. Patients without bed-nets should be advised to obtain them and connected to resources to provide them through social work.

6.3.7.3 Educate on HIV / Counsel on Safer Sex / Offer HIV testing and counseling / Offer family planning

We found that a consolidated approach to questions and counseling on sexual activity and HIV most appropriately addressed the key points of HIV education and testing, as well as contraceptive methods and family planning. Patients were first routinely asked regarding sexual activity. Patients that were sexually active in the past year were then asked questions regarding contraceptive use and family planning techniques. Women not currently using contraception were offered referral to the Family Planning clinic. Pregnant women were referred to the ANC, and men were given instructions on appropriate condom use. All patients were then asked if they had received HIV testing in the past, as well as the date and result of that test. If the patient was not tested in the past six months, he/she was referred to VCT. Over 75% of patients (168/223) reported having received an HIV test in the past six months, which is likely to be due to intensive screening efforts in these districts supported by PIH. In general, basic awareness of HIV was high.

5.3.7.4 Recommended Adaptations to sexual activity and HIV screening

Final adaptation suggested for IMAI guide:

Is patient sexually active (past 1 year)? If so…	
Does the patient use barrier protection?	Counsel on condom use.
Does the patient use family planning?	Educate regarding family planning and refer to family planning clinic.
When was the patient's last HIV test? What was the result?	If no HIV test in past 6 months (or one year), refer to VCT.
Is the patient pregnant?	If pregnant, refer or confirm that patient receives antenatal care.
Is the patient an adolescent?	If adolescent, see page __

6.3.7.5 Counsel to stop smoking

Four percent (4%; 6/141) of patients were found to have a past or present history of smoking or tobacco use. . Given the clear adverse effects of smoking, relative efficiency of screening question and response, and known benefit of health provider initiated smoking cessation counseling, we would recommend incorporating a simple smoking screening section within the IMAI consultation.

6.3.7.6 Recommended Adaptations to smoking cessation screening

Maintain current IMAI format.

- Include 'Brief Intervention Guidelines for Tobacco and Alcohol Use' (WHO, 2005a) in the IMAI guidelines.

6.3.7.7 Counsel to reduce or quit alcohol

In total, 18% (25/141) of patients reported any alcohol use on routine

screening. This usually did not relate to chief complaint and accurate estimation of quantity and degree of use as suggested by IMAI proved challenging. One reason is that "drinks" as listed in IMAI does not necessary translate to discrete quantities in this context, where home-brewed banana-based liquors predominate. However, no alcohol abuse or long-term clinical sequelae of excess alcohol use were identified during the field test.

6.3.7.8 Recommended Adaptations to alcohol screening

- Under ASSESS: if patient drinks alcohol, ask 'How many drinks per week?'
- Under TREAT: If more than 21 drinks per week for man or 14 drinks per week in woman, assess further and counsel to reduce or quit.'
- Include 'Brief Intervention Guidelines for Tobacco and Alcohol Use' (WHO, 2005a) in the IMAI guidelines.

6.3.7.9 Exercises, lifting skills to prevent low-back pain

Overall, 13% (18/141) patients reported backache as part of the chief complaint. Of the remaining patients, 9% (11/123) reported back pain on routine screening. These patients were given basic instructions on back exercises and proper lifting/bending techniques. However, it is important to note that amongst these patients, most back pain was part of constitutional illness and NOT the primary complaint (similar to headache as noted above). Back pain still represents an important morbidity and work limitation in this population based on our limited experience.

6.3.7.10 *Recommended Adaptations to back pain screening*

We recommend removing back pain from routine screening and instead address this as a 'volunteered problem.

6.3.7.11 Do BP screening yearly

Recommended Adaptations

See the section above on Blood Pressure. See PIH-NCD guide for proposed HTN protocols to be implemented in IMAI.

6.3.7.12 For women and girls of childbearing age

Tetanus Toxoid (TT) immunization – This is routinely given during pre-natal consultation in the antenatal clinics. Can delete from routine IMAI care.

Mebendazole – This is routinely given during pre-natal consultation in the antenatal clinics. Can delete from routine IMAI care.

If pregnant, link to antenatal care – currently done.

6.3.7.13 Special prevention for adolescents

This section emphasizes questions regarding adolescent sexual activity. Given the constraints of time for routine consultation and the baseline training of nurses, the level of detail requested here may be unrealistic and not pragmatic for routine inclusion. But guide does serves as a good resource or reference for nurses if time allows or as appropriate. There are no recommended adaptations.

6.3.8. SECTION VII. Follow-up Care for Acute Illness

Given the nature of outpatient care provided in the OPD, which is structured upon episodic, acute care of a particular illness, nurses did not routinely schedule

follow-up visits. We did observe, however, that patients often did return for follow-up if there was little or no improvement in symptoms. Nurses should be trained on the importance of designating a follow-up appointment, and following up an illness episode to its conclusion, as appropriate.

6.3.8.1 Recommended Adaptations to Follow-up Care

Follow-up TB: See *Manuel Technique de la Tuberculose*, July 2005, 5th Edition, TRACplus. (Programme National Intégré de Lutte contre la Lèpre et la Tuberculose, 2005)

Follow-up fever:

- Follow up in 2 days.

  If fever continues, repeat malaria testing and consider other testing based on associated symptoms, such as urinalysis and stool examination.

  If fever >7 days, see section on "Persistent Fever". Consider HIV-related illness, sputum examination for TB, and consider referral to district hospital.

- New section for follow-up malaria: Include the following points:

  Follow up in 48 hours.

  If there is no improvement after 48 hours of treatment, verify whether the patient swallowed the drugs correctly, re-examine the patient carefully and do another peripheral blood smear or rapid diagnostic test. If one of the diagnostic tests is **positive**, change the treatment to oral quinine sulphate as 10 mg/kg body weight per dose, taken three times a day over seven consecutive days.

  If the peripheral blood smear is **negative,** exclude and treat other causes of illness and/or refer the patient to the nearest district hospital;

  If there is no improvement after 48 hours of treatment with quinine, refer the

patient to the nearest district hospital as there is suspicion of other associated pathologies other than malaria.

- New section for follow up epigastric pain:

  If improvement in pain, continue with aluminum hydroxide or H2-blocker (cimetidine). If no improvement, increase therapy to PPI (omeprazole) and consider treatment for H.pylori. If no improvement after treatment for H.pylori, consider referral to district hospital for further evaluation.

- New section for Follow-up Headache:

  If headache persists after 7 days, ask if patient has taken the prescribed medication appropriately.

  If prescribed paracetamol, consider trial of ibuprofen for one week.

  If no improvement after ibuprofen, assess for warning signs and consider alternate classification such as migraine, sinusitis, visual problem, febrile illness or mental health problem.

  Consider referral to district hospital if severe headache for >2 weeks.

- New section for Follow-up Back or Joint pain:

  Follow up in 14 days.

  If no improvement and previously on paracetamol, increase analgesia to ibuprofen.

  If pain stable, continue rest and symptom management.

  If new associated symptoms or worsening pain, consider referral to district hospital.

6.3.9 SECTION VIII- Treatment

6.3.9.1 Medications

All adaptations to recommended medications in the IMAI guideline were made to harmonize treatments with the Rwanda National Essential Medicines List (EML) (Ministere de la Sante, 2010) and with all relevant treatment guidelines, as referred to above.

6.3.9.2 *Supportive care*

- Fluid plans for diarrhoea

No change (can keep infant section, guidelines are consistent with IMCI).

Refer urgently to hospital

If referral refused, ensure that both patient and family understand interventions that can and cannot be provided at health centre. Ensure that family understands the additional interventions that could be provided at the referral centre and how those may affect the patient's care.

6.3.9.3 Essential Emergency Supplies to Have During Transport

Change artemether to quinine only

6.3.9.4 Advice and Counseling

Patients identified for HIV testing from general consultation were referred to VCT for advice and counseling. Some were tested directly from consultation without structured pre-test counseling. Negative results also did not always prompt post-test counseling.

6.3.9.5 Recommended Adaptations to Advice and Counseling section

While an essential component of HIV testing, it is unclear whether detailed protocol on general advice and counseling should be included in the IMAI protocol itself, moved to an appendix, or provided in a separate guideline, for example. In part, this is due to time considerations as observed by the field test clinicians

6.3.9.6 Laboratory Tests

Laboratory norms for each level of the health system from MOH and PIH currently under revision. This section will not be included in the adapted IMAI guidelines.

6.3.9.7 Recommended Adaptations to Laboratory Tests section

- Consider listing the laboratory section as an appendix or separate laboratory guidelines; technical information does not necessarily need to be included in IMAI protocol.
- Rapid test for HIV – Include pertinent test only depending on which rapid test is used in Rwanda health centres.
- Insert instructions for other lab tests that are routinely performed at health centres, including:
    - Hemoglobin
    - Urine dipstick for sugar and protein
    - Blood sugar
    - Urinalysis (ECBU)
- Stool ova and parasites
- Wet prep for vaginal discharge

6.3.10 SECTION VIII - Case Recording Form / Desk Aid

The IMAI Case Recording Form (CRF), included as an appendix to the generic IMAI guideline, was used throughout the field testing experience to structure the consultation. Nurses generally reported their appreciation for a desk aid to guide consultation. Nurses preferred to address and manage volunteered complaints first, followed by the screening questions and preventive counseling. Often, screening questions were volunteered by the patient as part of the chief complaint (e.g. cough) and did not need to be repeated. Additionally, the CRF included all questions to be asked for every chief complaint, without their corresponding classification or treatment tables, which made the tool cumbersome for nurses, as it required them to simultaneously refer to the IMAI guidebook as they used the CRF. Nurses also had difficulty finding classification and treatment guidelines in the IMAI protocols in a timely fashion.

6.3.10.1 Recommended Adaptations to the IMAI CRF (See Figure 2)

- Start recording form with asking for patient's primary problem, then conducting routine screening and prevention after the primary complaint has been addressed and classified.
- Include clinical decision support for screening questions and prevention, but for primary problem refer to flow charts or desk aids that can display syndromic protocol, classification, and treatment.
- Adapted Case Recording Form closely models the IMCI recording form.

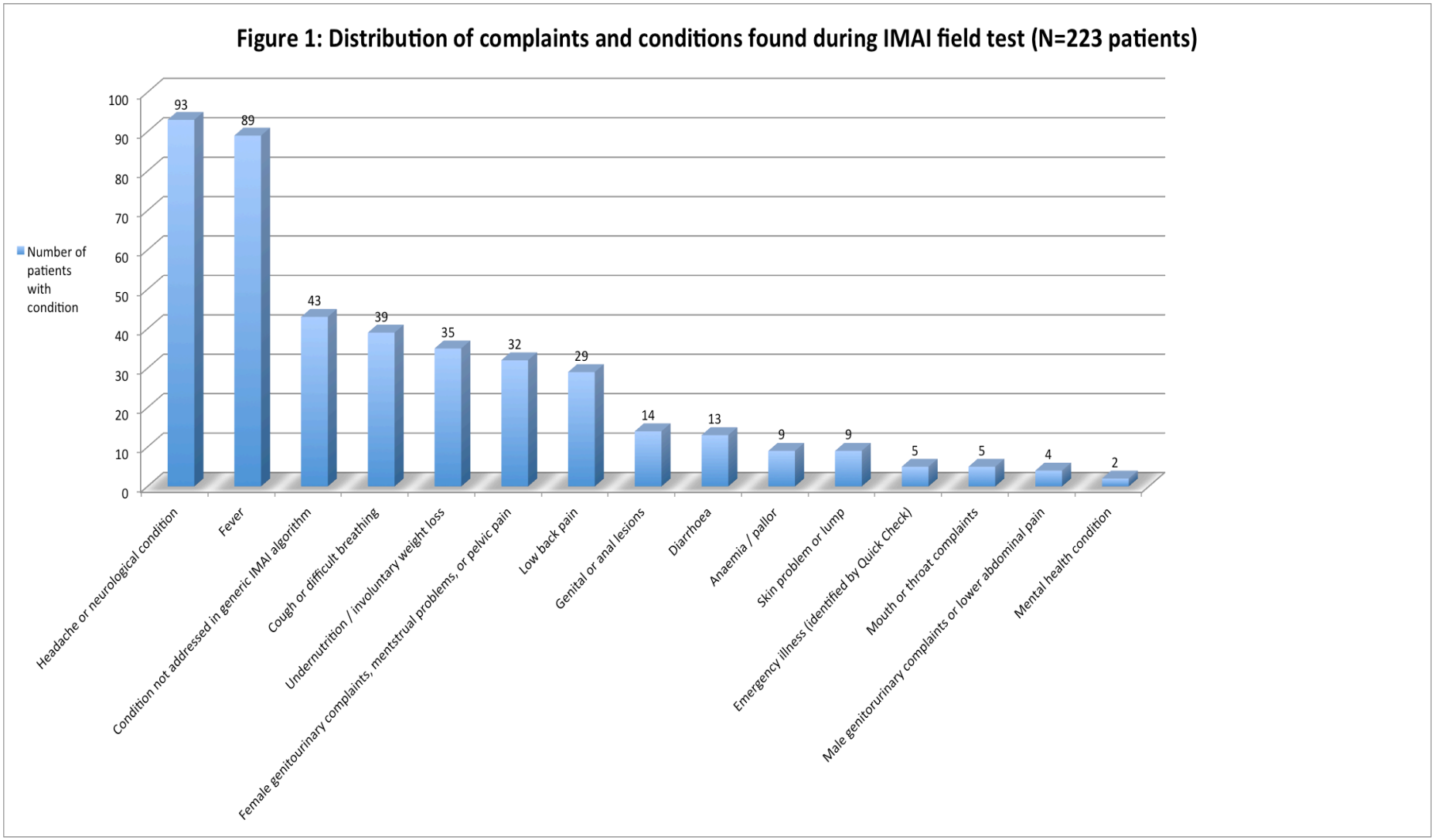

Figure 6: Distribution of complaints and conditions found during IMAI field test (N=223 patients)

Figure 7: Adaptions to IMAI Case Recording Form (CRF)

ASSESS: Check in ALL patients:

DOES THE PATIENT HAVE? If yes, check all boxes that apply.		CLASSIFICATION	TREATMENT
Chronic cough (>3 weeks) If yes, ask: □ Chronic heart or lung problem? □ Weight loss? □ Night sweats? □ Recurrent episodes? □ Occur with exercise?	YES NO □ Respiratory rate elevated? □ Uncomfortable lying down? □ Crepitations or wheeze?		
Undernutrtion BMI ____. If <18 kg/m^2, ask: □ Have you lost weight? □ Weight loss ___%. Is it >10%? □ Diet problems?	YES NO □ Look for severe wasting? □ Sunken eyes? □ Lower extremity oedema?		
Anaemia – is pallor present? If pallor: □ Blood in stools? Black stools? □ Blood in urine? □ If menstruating: Heavy periods?	YES NO □ Respiratory rate elevated? □ Splenomegaly? □ Measure Hgb:___		
Genital/anal lesions? □ Genital or anal sores? □ For men, penile	YES NO □ Examine for sores or lesions		

discharge? □ For men, pain in your scrotum?		

Consider HIV-related illness (□ If patient already HIV seropositive, check here and skip to 4)

Does this patient's problems indicate possible HIV-related illness? YES NO

If Yes, will the patient have HIV testing or be referred to VCT? YES NO

Identify treatments – Enter treatments for problems above

Routine screening and prophylaxis

Does the patient use a mosquito net?	**YES NO**	If No, counsel on obtaining and using a mosquito net
Does the patient smoke tobacco	**YES NO**	If Yes, counsel on tobacco use
Does the patient use alcohol? If so, how many times per week? __	**YES NO**	If Yes, counsel on alcohol use
If female, is the patient sexually active? If yes, is the patient pregnant? LMP:__/__/__ If yes, does the patient use family planning?	**YES NO**	Request pregnancy test if necessary. Result:_ Refer to prenatal care if pregnant. Refer to family planning if necessary.
If sexually active, has the patient had an HIV test in past 12 months?	**YES NO**	If No, obtain HIV test or refer to VCT if patient desires.

Determine follow up care and referrals. Circle below:

Follow up in: 3 days / 7 days / 14 days / 1 month / 3 months / No return needed

Referrals: Prenatal Care / VCT / ID clinic / NCD clinic / Mental Health Clinic / other specialist /

District Hospital / Social Worker / NO REFERRAL

Signature _____

Figure 8: Proposed new algorithm for epigastric pain

If patient has epigastric pain:

If yes, ask:

Pain greater than two weeks?

Does the pain improve or worsen after meals?

Do you have a burning sensation in your chest?

Do you drink alcohol?

Do you take anti-inflammatory medications?

Has there been black stools (melena)?

Look and feel:

Feel for mid-epigastric tenderness. If tenderness:

- Is it epigastric or lower abdominal (cross-reference lower abdominal pain)

- Is there rebound or guarding?

- Can you feel a mass

Signs	Classify As:	Treatments:
Hypotension or tachycardia Rebound and guarding Vomiting blood Presence of black stools	Perforated or bleeding ulcer	Refer to surgical centre
Symptoms > 2 weeks Pain improves with meals	Peptic Ulcer Disease	Prescribe therapy for Helicobacter pylori eradication: p.
Mid-epigastric pain without the above symptoms	Gastritis / GERD	Aluminum Hydroxide H2-blocker (cimetidine) or proton pump inhibitor (omeprazole) if no improvement Discontinue alcohol use Avoid anti-inflammatory medications Anti-reflux precautions

Figure 9: Proposed new algorithm for back or joint pain

If patient has back or joint pain:

If yes, ask:

Where is the pain?

When did the pain begin?

Does the pain worsen with movement?

Is the pain worse in the morning or the evening?

What do you do for work (for example, bending and lifting)?

Do you have fevers, chills, weight loss, or other general symptoms?

If back pain primarily:

> Do you have shooting pains, weakness or numbness in the legs?
>
> Do you have urinary or fecal incontinence?
>
> Any fever or TB risk factors?
>
> Do you have pain with urination?

Look and feel:

Can you move the painful joints?

Is there warmth, tenderness, or swelling in the joints?

If back pain primarily:

> Is there a physical deformity of the spine?
>
> Is the strength and sensation of the legs normal?

If dysuria, obtain urinalysis for possible kidney infection.

If Joint pain primarily:

Signs	Classify As:	Treatments:
Warmth or swelling (effusion) over single joint Tenderness over single joint Fever >38°C Acute onset	Possible septic arthritis	Give IV/IM antibiotics Refer to district hospital
Pain with physical activity Multiple joint involvement Chronic condition	Likely rheumatism, osteoarthritis, or musculoskeletal pain	Prescribe -inflammatory medication Recommend rest from repetitive physical activity

If back pain primarily:

Signs	Classify As:	Treatments:
Persistent fever or Tb risk factors Physical deformity of the back Weakness or numbness in legs Urinary or fecal incontinence Focal midline tenderness over the spine	Non-musculoskeletal back pain	Refer to district hospital
Pain with physical activity	Musculoskeletal back pain	Prescribe anti-inflammatory medication Recommend rest from physical activity Teach safe bending and lifting practices

Figure 10: Proposed new algorithm for lower extremity oedema

If patient has lower extremity oedema:

If yes, ask:

How long has the swelling existed? Does it come and go?

Is the oedema unilateral or bilateral?

Do you have yellowing of the eyes or skin?

Do you have a cough?

Do you have difficulty breathing with exertion or when you lay down?

Do you have right upper quadrant abdominal pain?

Have you had any fevers?

History of alcohol use?

Look and feel:

- Is there periorbital or facial oedema?

- Is there jaundice of the skin or eyes?

- Are the neck veins distended?

- Is there a cardiac murmur?

- Are there crackles in the lungs? If so, unilateral or bilateral?

- Is there dullness to precussion at the lung bases?

- Is there hepatosplenomegaly?

- Is there ascites?

- How extensive is the oedema? Is it pitting?

Signs	Classify As:	Treatments:
Unilateral oedema only	Unilateral lower extremity oedema	Consider Tb if cough, fevers, or history of exposure Consider HIV-related disease such as (Kaposi's sarcoma) Consider parasitic infection such as filiriasis Consider venous thrombus, refer for ultrasound
Bilateral oedema Distended neck viens Heart murmur Bilateral crackles in the lungs Dyspnea with exertion Presence of tachycardia	Possible Cardiomyopathy	Give Lasix Refer to non-communicable disease clinic
Evidence of jaundice Right upper quadrant tenderness History of alcohol use Presence of ascites	Possible Liver Disease	Refer to non-communicable disease clinic
Periorbital or generalized oedema BP>160/100 mmHg Decreased urine output	Possible Renal Disease	Obtain urine protein Refer to NCD clinic

Figure 11: Proposed new algorithm for hypertension

If patient has elevated blood pressure:

If yes, ask:

-Does the patient have a history of high blood pressure?

-Does the patient have a history of diabetes, stroke, or cardiac or renal problems?

-Does the patient have any visual changes?

-Does the patient have a headache?

Look and feel:

-Verify BP in opposite arm. Repeat with manual cuff if necessary.

-Is the patient lethargic, confused, or unresponsive?

-Is there respiratory distress?

-Is there a murmur?

-Is there weakness or numbness of any extremities (signs of stroke)?

[1] High Risk Features include tobacco use, age > 65 and BMI > 25 kg/m[2]

[2] Danger signs include acute dyspnea, visual changes, headaches

Initiation of Hypertension Treatment According to Stage and Risk Factors			
Stage	**Blood pressure range**	**Treatment**	**Clinic follow up**
Stage 3 with danger signs[2]	>180/110 +	Initiate therapy listed in Table 3.1, inpatient management	Transfer to district hospital for
Stage 3 without danger signs[2]	>180/110 +	Start first and second line medications at lowest dose	1-2 weeks in NCD clinic
Stage 2	160/100 - 180/110	Start first and second line medications at lowest dose	3 months in NCD clinic
Stage 1 **with (1)** diabetes, renal failure, or (2) [3] 2 high risk features, and **failed** 6 month trial of lifestyle modification	140/90 - 160/100 (130/80 - 160/100 if diabetes)	Start first line medication at lowest dose	3 months in NCD clinic
Stage 1 **without** diabetes, renal failure, but [3] 2 high risk features[1], no trial of lifestyle modification	140/90 - 160/100	Do not start medications. Counsel on salt intake and weight loss if indicated.	6 months in acute care
Stage 1 **without** diabetes, renal failure, or more than 1 high risk feature[1] (Lone Hypertension)	140/90 - 160/100	Do not start medications. Counsel on salt intake and weight loss if indicated.	12 months in acute care

Table 6: Recommended Hypertension Medication and Dosing for Most Adult Patients

Recommended Hypertension Medications and Dosing for Most Adult Patients				
First Line	**Starting Dose**	**Dose Increase By**	**Maximum Dose**	**Notes**
Hydrochlorothiazide	12.5 mg 1x/day	12.5 mg 1x/day	25 mg 1x/day	Can cause hypokalemia. Not effective in the setting of severe renal failure (creatinine > 300 μmol/L)
Second Line				
Amlodipine	5 mg 1x/day	5 mg 1x/day	10 mg 1x/day	Can cause lower extremity oedema
Third Line				
Lisinopril	5 mg 1x/day	5 mg 1x/day	20 mg 1x/day	Contraindicated in pregnancy and advanced renal failure (creatinine > 200 μmol/L). Can cause cough
Captopril	12.5 mg 3x/day	12.5 mg 3x/day	50 mg 3x/day	
Fourth Line				
Atenolol	25 mg 1x/day	25 mg 1x/day	100 mg 1x/day	Contraindicated if heart rate < 55 bpm Use with caution in renal failure as is renally cleared
Fifth Line				
Hydralazine	25 mg 3x/day	25 mg 3x/day	50 mg 3x/day	Safe in pregnancy. Headache common side effect
Methyldopa	250 mg 2x/day	250 mg 2x/day	500 mg 2x/day	Safe in pregnancy

(Bukhman and Kidder, 2010)

Table 7: Recommended Medications for Management of Hypertensive Emergency (Adult Dosing)

Recommended Medications for Management of Hypertensive Emergency (Adult Dosing)		
Medication	**Dosing**	**Notes**
Nifedipine (immediate release)	10 mg PO	
Captopril	25 mg PO	Contraindicated in pregnancy and severe renal failure (Cr >200 mmol/dl)
Hydralazine	25 mg PO	
Furosemide	40 mg PO or 20 mg IV	If evidence of pulmonary congestion

(Bukhman and Kidder, 2010)

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Chapter 7

Research paper 6

Title: The effect of Integrated Management of Adolescent & Adult Illness (IMAI) training plus enhanced mentoring and supervision on the quality of primary care delivery and health worker performance in Rwanda.

Author(s): Ashwin Vasan, Manzi Anatole, Bethany Hedt-Gauthier, Christopher Boyer, Neil Gupta, David C. Mabey, Lisa Hirschhorn, Stephen D. Lawn

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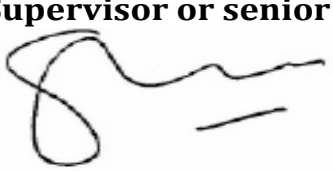
Candidate's role: Data were collected with support from the Population Health Implementation & Training grant which supported my thesis and on which I was a Co-Investigator. I led the principle design of the study including development of data collection tools, data analysis plan and data analysis itself, along with writing all drafts of the manuscript. CB provided support for data analysis through counseling and advice on SAS programming.

Candidate's signature:

Supervisor or senior author's signature to confirm Candidates role:



Dr Stephen D. Lawn

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Running title: Integrated Management of Adolescent & Adult Illness (IMAI) training on quality of primary care delivery in low and middle income countries

Abstract:

Background: Primary care delivery in low- and middle-income countries is often framed through specific diseases or populations. Minimal attention has focused on how to improve the quality of primary care delivery in general ambulatory services for adults and adolescents.

Objective: We sought to measure the impact of implementing the WHO's Integrated Management of Adolescent and Adult Illness (IMAI) guidelines, combined with a program of sustained mentoring and supervision, on the quality of ambulatory primary care provided in rural Rwanda.

Methods: A plausibility design was used to collect data at eight health centre outpatient departments (OPDs) in one district in rural Rwanda using standardized observation of case management by nurses, pre-intervention (February and March 2011), and post-intervention (April 2011 to September 2012). Quality was defined as agreement between the nurse and a clinical mentor in diagnosis, treatment planning, and in measuring vital signs and screening. We applied means and t-tests for significance and conducted mixed effects regression to calculate the probability of agreement between the nurse and mentor.

Results: Four hundred and sixty four (464) patients were observed in the pre-intervention survey, and 506 in the post-intervention period, with consultations addressing a total of 1236 clinical complaints. Following IMAI training and mentoring, significant ($p<0.05$) improvements were seen in the taking of vital signs (increases in taking of temperature (+49%), pulse (+66%), and blood pressure

(+54%)) and in screening for TB and HIV. Frequency of agreement in diagnosis and treatment increased by +28% in the post-intervention period. After adjustment for effect modifiers the odds of agreement post-intervention doubled for diagnosis (OR,2.3; 95%CI,1.6-3.3) and treatment (OR,2.3; 95%CI,1.7-3.1). This measurable effect was observed in nurses who were not exposed to initial training but who did receive the mentoring intervention, but only for diagnosis agreement (OR,2.2; 95%CI,1.3-4.0).

Conclusions: When combined with a program of sustained clinical mentorship and supportive supervision, IMAI resulted in significant improvement in the quality of primary care delivery in Rwanda. IMAI is an important intervention to strengthen integrated primary care delivery in low- and middle-income settings.

Background

Historically, attention and investment in general primary care delivery in low- and middle-income countries (LMICs) has been much less than for disease- and population-specific health interventions (Kruk et al., 2010, Vasan et al., 2014b). However, this is now growing proportionally with overall global health investment (IHME, 2012). Despite this investment, primary care – or longitudinal, first contact health care delivered at the front lines of the health system - is often subsumed within efforts in 'health systems strengthening,'' which focuses closely on structural, bureaucratic, and administrative interventions to develop information systems, strengthen the health workforce and improve infrastructure (World Health Organization, Everybody's Business: Strengthening Health Systems to Improve Health Outcomes – WHO's Framework for Action., Jamison et al., 2006), amongst other areas. Typically, primary care in global health is not specifically addressed as a mode of care or as a service in itself. Investment into the clinical quality of primary care programs is usually rooted within maternal and child health (MCH) services, which are critically important, and yet an incomplete measure of population health and health systems performance in LMICs (Kruk and Freedman, 2008).

Interventions to reduce adult and adolescent mortality have been largely organized around specific diseases such as HIV, TB or malaria (Komatsu et al., 2010). Less attention has been given to other common acute conditions that typically present to basic primary care facilities, such as pneumonia or diarrhoeal disease, or to emerging chronic non-communicable diseases, though this trend is slowly shifting (Ebrahim et al., 2013). These conditions continue to be major contributors to mortality and years lost to disability in LMICs (Global Burden of Disease Study 2013

Collaborators, 2015). In addition, limited definitions of 'primary care' that focus on certain demographic groups and vulnerable populations, neglect the burden of general medical illness in the adult and adolescent populations in LMICs, and fail to recognize the important and wider systems benefits that could be gained from investing in the quality of general primary care services, as a foundation to complement and support disease and population-specific programs.

Integrated models of care that merge efforts to improve services for specific diseases and populations with those for general primary care could be mutually beneficial and reinforcing for health outcomes and quality of care (Frenk, 2009b, Kruk et al., 2015, Haregu et al., 2013). But limited data exist to support this hypothesis. A Cochrane systematic review of integrated care, for instance, failed to show clear benefit, and rather highlighted the paucity and poor quality of available data (Dudley and Garner, 2011). One notable randomized trial from South Africa integrated HIV services into rural outpatient departments (OPDs) staffed by nurses, but found no significant mortality benefit nor improvement in HIV-specific endpoints (Fairall et al., 2012).

Limited data exist describing the quality of services for basic primary care conditions. One of the few examples was The Practical Approach to Lung Health (PAL) developed by the World Health Organization (WHO) and partners, which was studied in South Africa (Bheekie et al., 2006, English et al., 2008) and Malawi (Schull et al., 2011). These studies measured the effect of integrating algorithms for lung health and HIV, respectively, into primary care services (Fairall et al., 2005, English et al., 2006) An improvement in TB case detection was observed, but the quantitative benefit on patient outcomes or other quality metrics have yet to be published. A baseline survey of primary care quality (Vasan et al., 2013b) in rural Rwanda found

that basic outpatient care provided for acute primary care conditions in adults and adolescents was of low quality and reported low rates of performance of basic clinical tasks.

The most comprehensive design of a program of integrated primary care service delivery at the point of care has been the WHO Integrated Management of Adolescent & Adult Illness (IMAI) (World Health Organization) described elsewhere in detail (Vasan et al., 2014c, Vasan et al., 2013d). IMAI is a protocol targeted at front-line health care workers (HCWs) to deliver integrated care within a single patient encounter. While much effort has gone into the design and adaptation of IMAI to different settings, little research has been done to assess its validity or its impact on quality of care and health worker performance. The few existing data are largely unpublished validations (Simoes et al., 1997) or are based on HIV-focused sub-protocols of IMAI (Seung et al., 2012, Woldie and Enquselassie, 2009). Limited funding and attention to the issue of general primary care for adults and adolescents could partially explain the lack of data on IMAI to-date, but it also reflects a series of practical operational challenges to implementing a comprehensive and integrated approach to the patient within weak health systems, where HCWs often lack adequate support and pre-service education, and face significant demands from vertical interventions.

The literature also suggests that while initial training is critical, it is insufficient to sustain improved health worker performance. Evidence from Uganda (Pariyo et al., 2005d), Benin (Rowe et al., 2010b, Rowe et al., 2009), Brazil (Amaral et al., 2004a), Bangladesh (Arifeen et al., 2009) and from the current project in Rwanda (Magge et al., 2015a) has shown that routine, sustained, and frequent supportive supervision and mentoring leads to improvements in quality and fidelity to the WHO

IMCI guidelines. This has also been demonstrated in general primary care services in the Philippines (Loevinsohn et al., 1995b), and for sexually transmitted infections in India (Mogasale et al., 2010) and a number of other settings.

In light of the evidence gaps for IMAI and primary care delivery, coupled with, our understanding of the role of post-training support and supervision in improving health worker performance and quality, this study investigates the impact of IMAI training in concert with a program of sustained mentorship and quality improvement (Anatole et al., 2013c), on the performance of front-line nurses and on the quality of care provided for adult and adolescent ambulatory primary care services in rural Rwanda. The objective of the present study was to investigate whether IMAI leads to improved decision making and routine behaviors and practices by nurses in the ambulatory primary care settings, when compared to the standard of the IMAI protocol implemented by a senior clinician-mentor.

Methods

Study setting

The study was conducted at eight Rwandan Ministry of Health (MoH) health centres. These are the front line facilities within the health system, led by nurses – in one district in Rwanda's Eastern Province bordering Tanzania and Burundi, which has an approximate population of 190,000 (2010 Rwanda National Census). Within these health centres, the study occurred in the OPDs, which are staffed by generalist nurses with the equivalent of secondary school training in nursing, human science, and health behavior. The study setting has been described in detail elsewhere (Vasan et al., 2013b).

Study population

The baseline pre-intervention survey occurred in February and March of 2011. The post-intervention survey occurred from April 2011 through September 2012. Consecutive patients 13 years or older presenting to any one of the health centre OPDs on a day of observation were eligible for inclusion in the study. The official start of adolescence in Rwanda is not clearly defined by law (Binagwaho et al., 2012), and thus age 13 was chosen for this study based on definitions used by the United States' Centres for Disease Control (CDC)(Centres for Disease Control and Prevention, 2008b). Other than currently working in the OPD service at the study health centre, there were no additional criteria set for nurses to be eligible to participate in the study, and no special incentives were given to them for their participation.

Study design

The study was designed as a pre- / post-intervention plausibility trial. The intervention was defined as nurse exposure to a one-week didactic training course in IMAI *Acute Care* (World Health Organization) followed by enhanced mentoring and supervision visits focused on clinical performance improvement and systems-based quality improvement. The structure of this mentoring intervention has been described elsewhere (Anatole et al., 2013c, Manzi et al., 2014), and is also detailed in Box 1 below. In brief, health centres were visited every four to six weeks by a district-based clinical mentor with the equivalent of bachelor's degree registered nurse (RN) education and at least five years of clinical experience, along with extensive training and experience in IMAI and OPD clinical care, mentoring techniques, data collection, and quality improvement methods. Mentoring visits

included clinical skills-based mentoring, coaching, and feedback in IMAI based on data gathered through direct case observation, as well as facility- and systems-based quality improvement, focusing on non-clinical and operational challenges. Quarterly review meetings were also held with the mentor at the district.

Box 1: Key features of the Mentoring and Enhanced Supervision at Health centres (MESH) program in southern Kayonza district, Rwanda

1. Health centre (HC) demographics
    - Range of catchment size per HC 20,000 to 24,900
    - Mean HC catchment area: 48 km^2
    - Distance from HC to district hospital: 22km (mean) / 21km (median)
    - Staffing: A2 nurses
2. HC clinical areas under MESH program
    - Child health (IMCI), **Adult & Adolescent care (IMAI),** Women's Health/MCH, NCDs, HIV/TB
3. Mentors
    - Post-graduate nurses with **secondary nursing degree** in an area of specialty and with multiple years of experience working clinically in this area
    - Selected per Rwandan regulations: **written exam** on specific clinical domain, **interviews** to assess technical skills, experience, competency and interpersonal skills and capacity for coaching/mentoring
    - Mentors received additional **clinical training** in their area of expertise (e.g. IMAI) as well as in clinical mentoring and quality improvement (QI) techniques, adult learning
    - Monthly mentor **support meetings** with clinical technical advisor (from PIH-IMB) to review mentoring activities, reinforce clinical and mentoring skills, review QI plans
    - **Mentoring of mentors** on-site on monthly basis; observation and feedback by clinical technical advisor during routine mentoring visit
4. Site visits
    - Frequency: approximately **every four to six weeks** at every district health center
    - Duration: **two to three days** per site visit with overnight stays
    - Activities:
        - **Side-by-side observation** of patient care with assigned health worker;
        - Focus on **clinical reasoning**, **physical exam skills, complex case management**
        - Trust building and **modeling** of professional behavior
        - Regular one-on-one **feedback sessions** at the end of each day
        - Limited group **didactic training** on specific clinical topics or priority knowledge gaps
        - **Skills demonstrations** on physical exam techniques, laboratory techniques, etc.
        - Data collection: **observation checklists** for clinical case management; **facility checklists** for systems assessment (drug supply, staffing, infrastructure).
5. Quality Improvement
    - Routine **data entry, aggregation, and analysis** from paper checklists
    - Quarterly summary reports on **health worker performance** and **facility systems assessment**
    - Quarterly clinical service-specific QI meetings; review performance from previous quarter, design tailored, health worker- and site-specific QI plan in response to gaps identified by data; meetings supervised by MESH team at PIH/IMB and MOH, including clinical technical advisor for the specific clinical service

Data collection

The baseline survey was conducted prior to the start of supervision activities; while the post-intervention survey was conducted during routine supervisory visits by the clinical mentor. Data were collected through direct observation of routine

care by health centre nurses, using a standard data collection tool developed to document critical components of the clinical encounter. This observation checklist was structured on the WHO-IMAI Case Management Observation Form, and included the standard triage checklist for emergency conditions contained within the IMAI Quick Check protocol (World Health Organization), part of the larger IMAI guideline (World Health Organization). The IMAI guideline was adapted to adhere to Rwandan national guidelines and to local epidemiology through consensus guideline review. Data collection procedures, including the origin and type of data collected has been described elsewhere (Vasan et al., 2013b) .

Outcomes

The primary outcomes of interest were agreement between the nurse and the clinical mentor in both the diagnosis and the treatment plan, with the clinical mentor considered the 'Gold Standard' for both diagnosis and treatment plan. Agreement was defined on a per complaint basis, with up to three complaints recorded for each patient, with the clinical mentor again considered the 'Gold Standard.' Treatment agreement was defined as full agreement in all elements of the treatment plan, including requests for laboratory or additional diagnostic testing, medications prescribed and referral or follow-up visits planned, as appropriate. Covariates included nurse-level factors such as years of experience in OPD care, time since initial training, baseline education and patient-level factors such as sex, age and reported signs and symptoms. Also reported were quality indicators such as frequency of vital signs collection and appropriate screening conducted.

Data analysis

Sample size was calculated to detect a 20% difference between the pre- and post intervention outcome (agreement) at the 5% significance level, with power (β) of 0.8, which set a target of 250 observations in each sample (pre- and post-intervention), allowing for the clustered study design. Frequencies and chi-squared tests were used for initial comparisons of categorical variables, while means and t-tests were used for continuous variables. For the primary outcome, a mixed effects binomial logistic regression was employed. We assumed the study nurses were a random selection from all nurses in Rwanda and that health centres represented national health centres. Therefore baseline heterogeneity in nurse and health centre performance was incorporated into the model using nested random intercepts, accounting for inherent nesting of observations within nurses and nurses within health centres. To minimize bias we estimated covariate effects using maximum likelihoods based on adaptive Gauss-Hermite Quadrature with the PROC GLIMMIX function in SAS v 9.2 (Cary NC, USA). A mixed random-effects model of the probability of agreement between nurse and mentor, per patient complaint, was reported (Breslowa and Clayton, 1993, Pinheiro and Chao, 2006). A conservative approach to missing data was used where missing values for the primary outcomes of interest were treated as errors in assessment, suggesting that failure to complete a diagnosis or treatment plan was also an indicator of poor performance and fidelity to the IMAI protocols.

Ethics

This study was approved by the Rwandan National Ethics Committee, and the Institutional Review Boards (IRB) at Partners Healthcare in Boston and the London School of Hygiene & Tropical Medicine. Data were collected as part of routine

program monitoring of an ongoing mentorship and quality improvement intervention in the study districts, previously described (Anatole et al., 2013c). No identifying nurse or patient information were collected. The IRB approved a waiver of informed consent for nurses and patients under the routine use of program monitoring data. The purpose of the data collection were explained to both patients and nurses, and both could opt-out of the study if desired, prior to the consultation.

RESULTS

Patient characteristics

Four hundred and sixty-four patients were observed pre-intervention while 506 were observed post-intervention. Patient and nurse demographics and presenting symptoms are presented in Table 8. Significantly more female patients were seen than males (p=0.05) both pre- and post-intervention, but patient age was not significantly different, at approximately 35 years. The most common presenting complaint in both the pre- and post- intervention surveys was cough and/or difficulty breathing (17.6 and 21.4 percent, respectively), followed by females presenting with pelvic pain or genitourinary complaints (16.3 and 20.3 percent, respectively). The presenting symptoms for the two surveys were otherwise similar (Table 8).

Nurse characteristics

Twenty-five nurses were observed during pre-intervention data collection at the eight study sites, none of whom had been previously trained in IMAI. A total of 16 nurses were trained in IMAI at the end of March 2011, prior to the start of mentoring and supervision activities, and a further 17 nurses were trained in October 2011. In

the post-intervention survey 33 nurses were observed, 15 (45%) of whom also contributed to the pre-intervention dataset. Eighteen of 33 nurses (55%) in the post-intervention survey received IMAI training, and the trained nurses managed 350 (69.2%) of the 506 patients seen and 70 percent of complaints assessed in the post-intervention survey. Comparison of nurse characteristics in the pre- and post-intervention surveys showed similar years of OPD experience and consultation times. Additional detail on nurse characteristics is shown in Table 8.

Quality of care indicators

The quality of care indicators in each survey, including measurement and recording of vital signs, conducting routine emergency triage, and performing routine screening and counseling activities during the patient encounter, are summarized in Table 9. Notable results include significant ($p<0.001$) increases in routine measurement of height (+17%), weight (+32%), pulse (+66%), temperature (+49%), and blood pressure (+54%) in the post-intervention survey compared to the pre-intervention survey. Routine screening for prevalent conditions, and the recording of key lifestyle behaviors and preventive strategies, increased in the post-intervention survey. Notable results include a +53% increase in screening patients for chronic cough, a +49% increase in screening for involuntary weight loss, a +52% increase in screening for insecticide-treated bed nets for malaria prevention, a +51% increase in screening for tobacco use, and a +52% increase in screening for alcohol abuse. Additionally, an increase of +26% was seen in patients referred for HIV testing, along with a 14% increase in patients counseled on safe sex practices, including condom use.

Agreement in diagnosis and treatment

During 970 total patient encounters observed, 1236 complaints were recorded. There were 207 (16.7%) women reporting genitourinary complaints or pelvic pain, 200 (16.2%) patients reporting cough or difficulty breathing, and 134 (10.8%) reporting fever (Table 10). In the pre-intervention survey the agreement between nurse and mentor was 22% for the diagnosis, and 23% for the treatment of cough and difficulty breathing, which increased to 49% and 62% in the post-intervention survey, respectively. Similar increases were seen for the treatment and diagnosis of other reported complaints. Overall there was an increase in agreement between nurse and mentor of 28% for diagnosis and 28% for the treatment plan after the intervention. Increases in diagnosis agreement were most pronounced for back/joint pain (+68%), fever (+58%), headache or neurological conditions (+47%), and cough/difficulty breathing (+28%). For agreement in treatment plan, the positive effect of the intervention was most notable for cough/difficulty breathing (+39%), headache/neurological conditions (+36%) and oral or throat problems (+36%) (Table 10).

Covariate analysis

The frequency of agreement between nurse and mentor in diagnosis and treatment in the pre- and post-intervention surveys is shown in Table 11. Significant differences were found between health centres in the magnitude of change in the frequency of correct diagnosis ($p=0.004$) and treatment ($p=0.039$). Significant differences were also found in the magnitude of change in frequency of correct diagnosis and treatment between nurses who were and were not trained in IMAI ($p<0.001$), as well as timing of their training (March vs. October). Years of OPD experience and patient sex were not significantly different in the two surveys, but

number of observations per nurse was associated with a significant change in both diagnosis and treatment agreement ($p<0.001$). Covariates were also tested for effect modification through univariate logistic regression. IMAI training was significantly associated with increased odds of agreement for diagnosis versus no training (March: OR,1.5; 95%CI,1.0-2.3; October: OR,3.3; 95%CI,2.2-5.1) as well as for treatment agreement. (March: OR,1.9; 95%CI,1.5-2.5; October: OR,6.8; 95%CI,3.6-12.7). For diagnosis agreement, patient sex, years of nurse OPD experience, and nurse workload (number of observations per nurse), were not found to be significant, whereas for treatment agreement, number of observations per nurse was significant.

Multivariate results

The results of multivariate mixed effects logistic regression for diagnosis and treatment agreement in the intervention period versus the baseline period is shown in Table 12. Overall results and stratified results by training cohort are shown, as this was highly correlated to the primary outcomes. Adjustment was made for significant effect modifiers as described above. Overall, both odds of diagnosis agreement and treatment agreement increased significantly and more than two-fold in the post-intervention period compared to pre-intervention for the entire nurse population under study (diagnosis: OR,2.3; 95%CI,1.6-3.3; treatment: OR,2.2; 95%CI,1.6-3.1). This effect was larger for nurses trained in October than in March, both when compared to themselves at baseline, and compared to all nurses. Notably, nurses who did not receive IMAI training, but were exposed to the mentoring intervention, also showed significant and greater than two-fold increase in the odds of diagnosis agreement compared to untrained nurses at baseline (OR, 2.2;

95%CI,1.3-4.0) and compared to all nurses at baseline (OR, 2.1; 95%CI,1.2-3.9), though no significant effect was seen in this cohort for treatment agreement. Also of note from the baseline data, nurses who were subsequently trained in March had a nearly 1.5 times increase in the odds of diagnosis agreement compared to baseline nurses who were never trained (OR,1.4; 95%CI,1.0-2.1), but nurses subsequently trained in October had 0.8 of the odds of diagnosis agreement, and this effect was not significant.

Effect of time on agreement

A line plot of diagnosis and treatment agreement per month, overall and stratified by IMAI training status, is shown in Figures 11 and 12. As expected, the effect of the intervention was greater for trained nurses than for untrained nurses, but both groups experienced gains over the course of the intervention and from baseline. IMAI trained nurses improved by 34% in diagnosis agreement from April 2011 until the end of the 18-month intervention period in October 2012, and they improved by 52% in treatment agreement over this period. Untrained nurses also improved by 27% in diagnosis agreement and 13% in treatment agreement. When time is modeled as a continuous variable rather than pre- and post-intervention, multivariate logistic regression resulted in a 5% average monthly increase in the odds of diagnosis agreement (adjusted OR=1.1; CI,1.0-1.1) and 3% monthly increase in odds of treatment agreement (adjusted OR=1.0; CI,1.0-1.1), though the latter effect was not significant.

Effect on nurses exposed to full intervention

Fifteen nurses were present in both the pre- and post-intervention surveys

and received the full training and mentoring intervention. These 15 nurses accounted for 285 of 574 (46.4%) complaints managed in the pre-intervention survey, and 343 of 662 (53.6%) in the follow-up period. A plot of the isolated effects of the intervention for these individual nurse pairs is shown in Figure 13. The majority of nurses (66.6%) showed improvement in their performance following the intervention, and mean improvement in frequency of agreement for these nurses was 32%. When stratified by timing of training, regression also showed that trained nurses improved significantly in diagnosis and treatment against themselves at baseline, with nurses trained in October driving the majority of improvement post-intervention (diagnosis: OR,4.2; 95%CI,1.8-9.7; treatment: OR,5.0: 95%CI,2.3-10.9) versus March (diagnosis: OR,1.3; 95%CI,1.0-1.8; treatment: OR, 1.7; 95%CI,1.4-2.2) (Table 12).

DISCUSSION

These results suggest that IMAI training coupled with routine and enhanced mentoring and supervision leads to significant improvement in the quality of ambulatory primary care provided to adults and adolescents. It also demonstrates that IMAI leads to significant improvements in routine primary care quality metrics, such as taking of vital signs, routine screening and preventive counseling.

The effect of the IMAI training and mentoring intervention on diagnosis agreement was significant, and remained similar for nurses who did not receive the initial IMAI training, but were exposed to sustained on-site mentoring and supervision. This reinforces the suggestion that training alone may be inadequate to ensure high quality care (Rowe et al., 2005e, Horwood et al., 2009, Ridde, 2010). However, for treatment agreement this did not hold true. This could be explained by

the fact that IMAI training was a pilot and not yet integrated into MoH guidelines for health centres, therefore it is likely that many nurses reverted to existing treatment guidelines when selecting therapies. In addition, OPDs were not simultaneously equipped with the additional drugs, diagnostics, and supplies suggested in the IMAI protocol, and thus nurses were forced to select amongst their limited existing formulary and tools. It is also possible that lack of effect of the mentoring intervention on treatment agreement for untrained nurses was limited by the stringent definition of treatment agreement used in the study, which required 100 percent agreement in all aspects of the treatment plan.

A notable issue from this study is the heterogeneity of exposure to the full intervention. Thirty percent of patients in the post-intervention survey were seen by a nurse that did not receive the initial IMAI didactic training, which reflects turnover in the nursing pool but is also a result of MoH regulations that require nurses to assume generalist roles and thereby have the capability to staff one of multiple services at the health centre. As a result, IMAI-trained nurses could have been staffing another clinical service at the health centre on the pre-determined day of observation, though this was not systematically documented. Another notable phenomenon from the data is that the bulk of the improvement in diagnosis and treatment agreement was driven by nurses trained in October versus March. This could be explained by the fact that these cohorts differed in their performance at baseline, with higher-performing nurses trained in March. This also could reflect start-up challenges for the intervention in the first few months, though this was not formally studied.

Despite heterogeneity of exposure to IMAI training, both trained and untrained nurses experienced gains in performance after exposure to the mentoring

and supervision intervention, which suggests that sustained, on-site, in-service training, and practice-based supervision and clinical mentoring is an important complement to traditional classroom-based training courses (Pariyo et al., 2005d, Workneh et al., 2013a, World Health Organization, 2005), and can produce benefits in quality and performance even in the absence of classroom training. The need for sustained mentoring and supervision is supported by qualitative research from the same project in Rwanda (Manzi et al., 2014). Strength or ''dose' of implementation is not a well-researched issue in the global health literature, but has been investigated in the context of community case management in Ethiopia (Miller et al., 2014) and to reduce maternal mortality in Uganda and Zambia (Kruk et al., 2014). We suggest that the heterogeneity of exposure to IMAI training in this study reflects the reality of implementing complex interventions in a poor setting like rural Rwanda, and is a strength rather than a limitation when considering the external validity of these results to similar challenging settings.

There were several limitations to this study. First, our definitions of quality of care are based entirely on process indicators and not from health outcomes, and thus only partially capture the spectrum of quality of care. It was beyond the scope of the study to follow patients through an illness episode, nor did we capture demographic data or systems impacts (e.g. cost) of the intervention. Fidelity to protocols and health worker performance (Osterholt et al., 2009, Rowe et al., 2012a, Rowe et al., 2005d) are widely used as measures of quality of care in global health programs. There is evidence that improving the quality of care through improved health worker performance can have an impact on health outcomes (Rakha et al., 2013, Arifeen et al., 2009, Bryce J et al., 2005), but often these performance improvement interventions are part of wider quality improvement efforts that include health

system supports in addition to training and supervision. Additionally, we must consider the potential observation bias introduced by the Hawthorne effect (Leonard and Masatu, 2006c), which could have resulted in improved nurse performance under observation. Another limitation involves IMAI itself, which has not been adequately validated as a clinical protocol.

This is the first study of its kind to assess the impact of IMAI with sustained and enhanced mentoring and supervision, on the quality of adult and adolescent primary care. Thus, the importance of this study is that it begins to fill the evidence gap for IMAI and for primary care delivery and quality improvement in poor settings. The study reinforces the importance of post-training supervision and mentoring as a critical part of quality improvement programs; as vital as the training itself. Integrated approaches to transforming primary care delivery in LMICs are much needed, particularly in light of attempts to complement programs targeted at specific diseases and populations with stronger health systems (Vasan et al., 2014b, Vasan et al., 2013d). Developing front line primary care systems that deliver integrated services to patients is a crucial step towards leveraging the success of vertical programs for systems-wide improvement. IMAI is an important attempt to integrate primary care services at the point-of care, and it is an approach worthy of further investigation and iteration. Future research is needed on the population health and systems impacts of IMAI training. With further improvement and research IMAI has the potential to improve the delivery of primary care in front-line health systems across the developing world.

Table 8: Patient and nurse characteristics in pre- and post-intervention surveys of outpatient department nurses in southern Kayonza, Rwanda between March 2011-September 2012

Patient (N= 970)	Pre (N=464)	Post (N=506)	Δ% Post - Pre	P-value
Sex				0.05
Male	146 (31.5)	189 (37.5)		
Female	318 (68.5)	315 (62.5)		
Age, years, mean +/- SD	35.4 +/- 15.8	35.3 +/- 15.5		0.98
Chief complaint				
Cough/difficulty breathing	81 (17.6)	118 (24.1)	+6.5	
Female with GU symptoms or pelvic pain	75 (16.3)	99 (20.3)	+4	
Epigastric pain	43 (9.4)	39 (8.0)	-1.4	
Fever	41 (8.9)	38 (7.8)	-1.1	
Headache or neurological condition	37 (8.0)	30 (6.1)	-1.9	
Mouth or throat problem	35 (7.6)	30 (6.1)	-1.5	
Skin problem or lump	32 (7.0)	21 (4.3)	-2.7	
Back or joint pain	32 (7.0)	55 (7.8)	+0.8	
Male with GU symptoms of lower abdominal pain	29 (6.3)	28 (5.7)	-0.6	
Diarrhoea	26 (5.7)	18 (3.7)	-2	
Other problem	20 (4.4)	8 (1.6)	-+2.8	
Genital or anal sore, ulcer, wart	5 (1.1)	3 (0.6)	-0.5	
Mental problem	4 (0.9)	0 (0)	-0.9	
Lower extremity oedema	0 (0)	2 (0.4)	+0.4	
Nurse characteristics				
Total number of nurses observed	25	33		
Nurses observed who were trained in IMAI	0	18		
Nurse characteristics by patient encounter				
Was nurse trained in IMAI?				<.0001
Yes	0 (0)	350 (69.2)	+69.2	
No	464 (100.0)	156 (30.8)		
Years' experience, mean +/- SD	5.2 +/- 4.1	6.0 +/- 7.7	+0.8	0.04
Consultation time in minutes, mean +/- SD	0:14 +/- 0:04	0:15 +/- 0:02	+0:01	0.86
Education level				<.0001
A1	0 (0)	43 (8.5)		
A2	461 (99.4)	461 (91.1)		
Missing	3 (0.7)	2 (0.4)		

Table 9: Quality of care indicators (per patient*) at pre- and post-intervention in outpatient departments in southern Kayonza, Rwanda between March 2011-September 2012

Vital signs	**Pre**	**Post**	Δ %	**p-value**
Taken by Registration clerk	258 (55.6)	415 (82.0)	+26.4	<.0001
Taken by Nurse	168 (36.2)	388 (76.7)	+40.5	<.0001
Taken by Other Health Centre staff	77 (16.7)	3 (0.6)	-16.1	<.0001
Recorded BP	77 (16.6)	357 (70.6)	+54	<.0001
Recorded height	0 (0)	84 (16.6)	+16.6	<.0001
Recorded weight	291 (62.7)	479 (94.7)	+32	<.0001
Recorded pulse	0 (0)	334 (66.0)	+66	<.0001
Recorded temperature	123 (26.5)	382 (75.5)	+49	<.0001
Quick check for Emergencies				<.0001
Yes	7 (1.5)	312 (61.7)	+60.2	
No	447 (96.3)	150 (29.6)	-66.7	
Missing	10 (2.2)	44 (8.7)	+6.5	
Screening performed				
Cough or difficulty breathing	45 (9.7)	319 (63.0)	+53.3	<.0001
Involuntary weight loss	2 (0.4)	249 (49.2)	+48.8	<.0001
Pallor	9 (1.9)	251 (49.6)	+47.7	<.0001
GU lesions	18 (3.9)	258 (51.0)	+47.1	<.0001
Urethral discharge (Male)	12 (2.6)	103 (20.4)	+17.8	<.0001
Scrotal pain or swelling (Male)	1 (0.2)	93 (18.4)	+18.2	<.0001
Mosquito net	3 (0.7)	268 (53.0)	+52.3	<.0001
Counseled on use of bed net	0 (0)	52 (10.3)	+10.3	
Reported having a bed net	2 (0.4)	179 (35.4)	+35	
Smoking/tobacco use	2 (0.4)	258 (51.0)	+50.6	<.0001
Counseled on cessation	0 (0)	39 (7.7)	+7.7	
Symptom present	1 (0.2)	41 (8.1)	+7.9	
Alcohol use	2 (0.4)	265 (52.4)	+52	<.0001
Counseled on cessation	0 (0)	117 (23.1)	+23.1	
Reported alcohol abuse	1 (0.2)	122 (24.1)	+23.9	
Sexually active	32 (6.9)	226 (44.7)	+37.8	<.0001
Counseled on safe sex practices	2 (0.4)	73 (14.4)	+14	
Reported sexually active	29 (6.3)	176 (34.8)	+28.5	
Pregnant	67 (14.4)	172 (34.0)	+19.6	<.0001
Reported to be pregnant	24 (5.2)	20 (4.0)	-1.2	
Family planning methods	10 (2.2)	46 (9.1)	+6.9	<.0001
Refer to family planning clinic	0 (0)	25 (4.9)	+4.9	
HIV test in the last 12 months	7 (1.5)	192 (37.9)	+36.4	<.0001
Confirmed HIV testing within last 12 months	2 (0.4)	102 (20.2)	+19.8	
Refer for HIV testing	1 (0.2)	133 (26.3)	+26.1	<.0001

*Note: percentages that do not add up to 100% are due to missing data within those categories

Table 10: Correct nurse diagnosis and treatment of patient illnesses, by patient complaint, in outpatient departments in southern Kayonza, Rwanda between March 2011-September 2012

Complaint	Total No. with complaint	Pre (n)	Post (n)	Diagnosis Pre (n%)	Diagnosis Post (n%)	Diagnosis Δ%	Treatment Pre (n%)	Treatment Post (n%)	Treatment Δ%
TOTAL	1236	574	662	173 (30.1)	386 (58.3)	+28.2	173 (30.1)	385 (58.2)	+28.1
Cough/difficulty breathing	200	82	118	18 (22.0)	58 (49.2)	+27.2	19 (23.2)	73 (61.9)	+38.7
Female with GU symptoms or pelvic pain	207	88	119	28 (31.8)	68 (57.1)	+25.3	23 (26.1)	60 (50.4)	+24.3
Epigastric pain	128	59	69	35 (59.3)	48 (69.6)	+10.3	10 (17.0)	29 (42.0)	+25
Fever	134	56	78	9 (16.1)	58 (74.4)	+58.3	37 (66.1)	58 (74.4)	+8.3
Headache or neurological condition	96	52	44	4 (7.7)	24 (54.6)	+46.9	26 (50.0)	38 (86.4)	+36.4
Mouth or throat problem	80	37	43	16 (43.2)	28 (65.1)	+21.9	10 (27.0)	27 (62.8)	+35.8
Skin problem or lump	60	32	28	21 (65.6)	14 (50.0)	-15.6	11 (34.4)	9 (32.1)	-2.3
Back or joint pain	126	42	84	5 (11.9)	67 (79.8)	+67.9	20 (47.6)	63 (75.0)	+27.4
Male with GU symptoms of lower abdominal pain	61	31	30	16 (51.6)	10 (33.3)	-18.6	6 (19.4)	16 (53.3)	+33.8
Diarrhoea	51	31	20	19 (61.3)	9 (45.0)	-16.3	10 (32.3)	9 (45.0)	+12.7
Hypertension	5	3	2	0 (0)	0 (0)		0 (0)	0 (0)	-
Genital or anal sore, ulcer, wart	8	5	3	1 (20.0)	2 (66.7)	+46.7	0 (0)	3 (100.0)	
Mental problem	6	6	0	0 (0)	0 (0)	-	1 (16.7)	0 (0)	-
Lower extremity oedema	11	5	6	1 (20.0)	0 (0)	-20	0 (0)	0 (0)	-
Other problem	63	45	18	0 (0)	0 (0)	-	0 (0)	0 (0)	-

Table 11: Covariate frequency pre- and post- intervention for observations with positive agreement between nurse and mentor, in outpatient departments in southern Kayonza, Rwanda between March 2011-September 2012

		Diagnosis Agreement = YES			Treatment Agreement = YES		
Total patient complaints	1236	Pre (N=173) N, % correct	Post (N=386) N, % correct	P-value	Pre (N=173) N, % correct	Post (N=385) N, % correct	P-value
Health centre	N, % total			<0.01			0.0395
Cyarubare	109 (8.8)	11 (6.3)	31 (8.0)		10 (5.8)	37 (9.6)	
Kabarondo	200 (16.1)	13 (7.5)	63 (16.3)		19 (11.0)	79 (20.5)	
Karama	133 (10.7)	33 (19.1)	45 (11.6)		25 (14.5)	41 (10.7)	
Ndego	127 (10.2)	30 (17.3)	33 (8.5)		21 (12.1)	32 (8.3)	
Nyamirama	199 (16.0)	34 (19.7)	71 (18.4)		35 (20.2)	59 (15.3)	
Rutare	144 (11.6)	15 (8.7)	38 (9.8)		15 (8.7)	40 (10.4)	
Ruramira	145 (11.7)	16 (9.3)	43 (11.1)		27 (15.6)	41 (10.7)	
Rwinkwavu	185 (14.9)	21 (12.1)	63 (16.3)		21 (12.1)	56 (14.5)	
Years of nurse experience		6.0 +/- 4.6	5.9 +/- 7.5	0.86	5.4 +/- 4.0	6.2 +/- 8.0	0.25
Nurse trained in IMAI				<.0001			<.0001
No	780 (62.8)	173 (100)	115 (29.8)		173 (100)	90 (23.4)	
Yes	462 (37.2)	0 (0)	271 (70.2)		0 (0)	295 (76.6)	
Patient sex				0.91			0.19
Male	413 (33.4)	58 (33.5)	131 (33.9)		58 (33.5)	147 (38.2)	
Female	823 (66.6)	115 (66.5)	255 (66.1)		115 (66.5)	238 (61.8)	
Observations per nurse (continous)		4.7 +/- 3.3	5.8 +/- 2.8	<.0001	4.2 +/- 2.9	6.1 +/- 3.0	<.0001
Observations per nurse (categorical)				<.0001			<.0001
1 - 3	201 (36.0)	106 (57.8)	115 (29.8)		106 (61.3)	95 (24.7)	
4 – 7	183 (33.8)	24 (13.9)	148 (38.3)		25 (14.5)	158 (41.0)	
8 – 10	174 (31.2)	49 (28.3)	123 (31.9)		42 (24.3)	132 (34.3)	

Table 12: Results of mixed effects logistic regression of odds of nurse and mentor agreement in diagnosis and treatment in outpatient departments in southern Kayonza, Rwanda between March 2011-September 2012

	Diagnosis											
	Effect vs. never trained at baseline				*Effect within strata of training cohorts*				*Effect vs. all nurses at baseline*			
	Pre-intervention		*Post-intervention*		*Pre-intervention*		*Post-intervention*		*Pre-intervention*		*Post-intervention*	
	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI
IMAI trained												
No	1	ref	**2.2****	1.3 – 4.0	1	ref	**2.2****	1.3 – 4.0			**2.2****	1.2 - 3.9
Yes (Mar. cohort)	**1.4***	1.0 - 2.1	**1.9****	1.2 - 3.1	1	ref	1.3	1.0 - 1.9	1	ref	**1.9****	1.2 - 2.9
Yes (Oct. cohort)	0.8	0.3 - 1.9	**3.2*****	2.0 - 5.1	1	ref	**4.2*****	1.8 - 9.7			**3.1*****	2.1 - 4.5
All Nurses (post vs. pre)	1	ref	**2.3*****	1.6 - 3.3								

Note: ORs are from binomial GLMMs estimated using maximum-likelihood from adaptive Gaussian-Quadrature and nested random effects by nurse and health centre. *$p \leq 0.05$; **$p \leq 0.01$; ***$p \leq 0.001$

	Treatment											
	Effect vs. never trained at baseline				*Effect within strata of training cohorts*				*Effect vs. all nurses at baseline*			
	Pre-intervention		*Post-intervention*		*Pre-intervention*		*Post-intervention*		*Pre-intervention*		*Post-intervention*	
	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI
IMAI trained												
No	1	ref	1.4	0.8 - 2.5	1	ref	1.4	0.8 - 2.5			1.5	0.8 - 2.7
Yes (Mar. cohort)	1.0	0.5 - 1.8	1.7	0.8 - 3.5	1	ref	**1.7*****	1.4 - 2.2	1	ref	**1.8****	1.2 - 2.7
Yes (Oct. cohort)	0.8	0.34 - 2.1	**4.2*****	2.1 - 8.3	1	ref	**5.0*****	2.3 - 10.9			**4.5*****	2.7 - 7.7
All Nurses (post vs. pre)	1	ref	**2.3*****	1.6 - 3.2								

Note: ORs are from binomial GLMMs estimated using maximum-likelihood from adaptive Gaussian-Quadrature and nested random effects by nurse and health centre. They are adjusted for the number of observations. *$p \leq 0.05$; **$p \leq 0.01$; ***$p \leq 0.001$

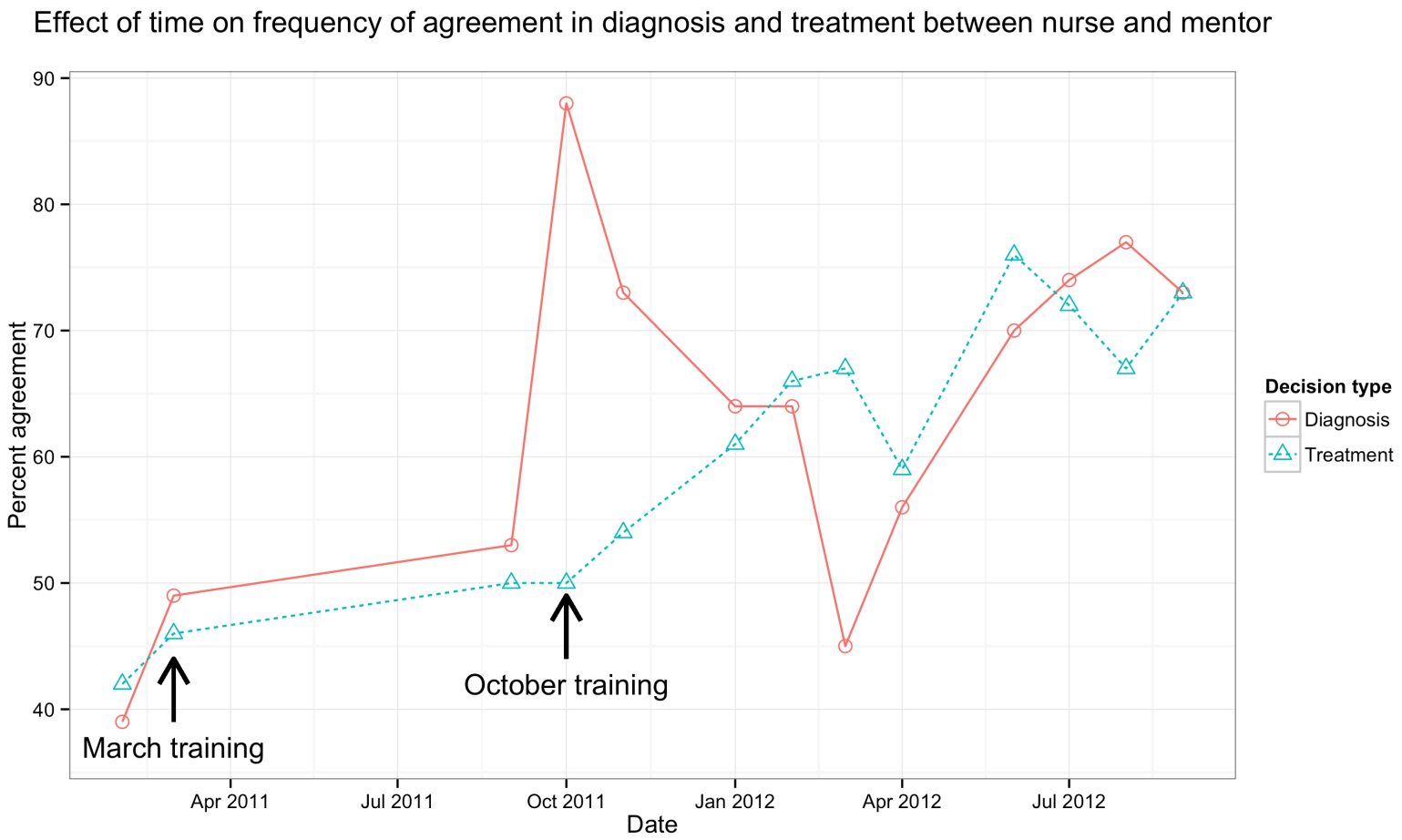

Figure 12: Frequency of agreement in diagnosis and treatment between nurse and mentor over time (months)

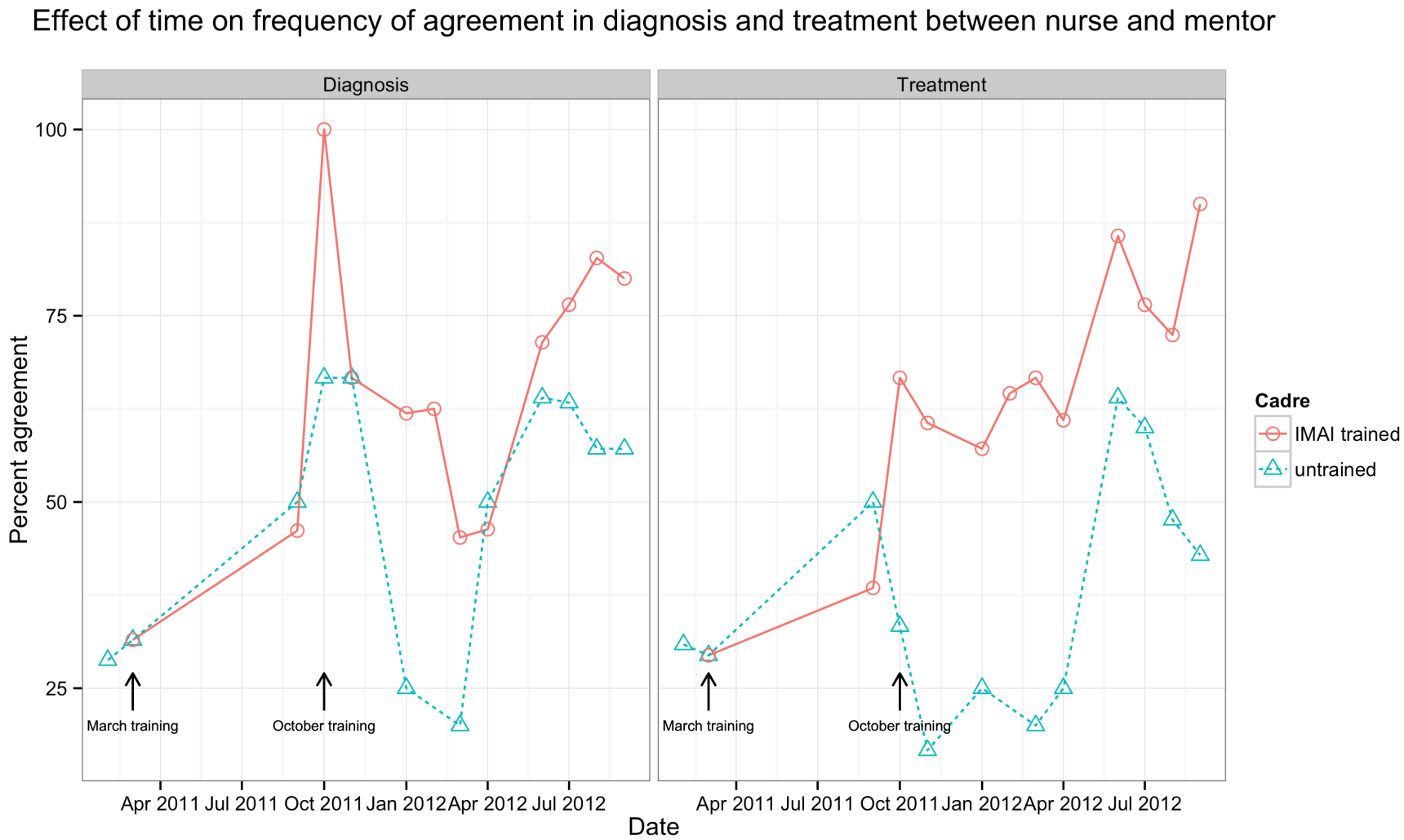

Figure 13: Frequency of agreement in diagnosis and treatment between nurse and mentor over time (months)

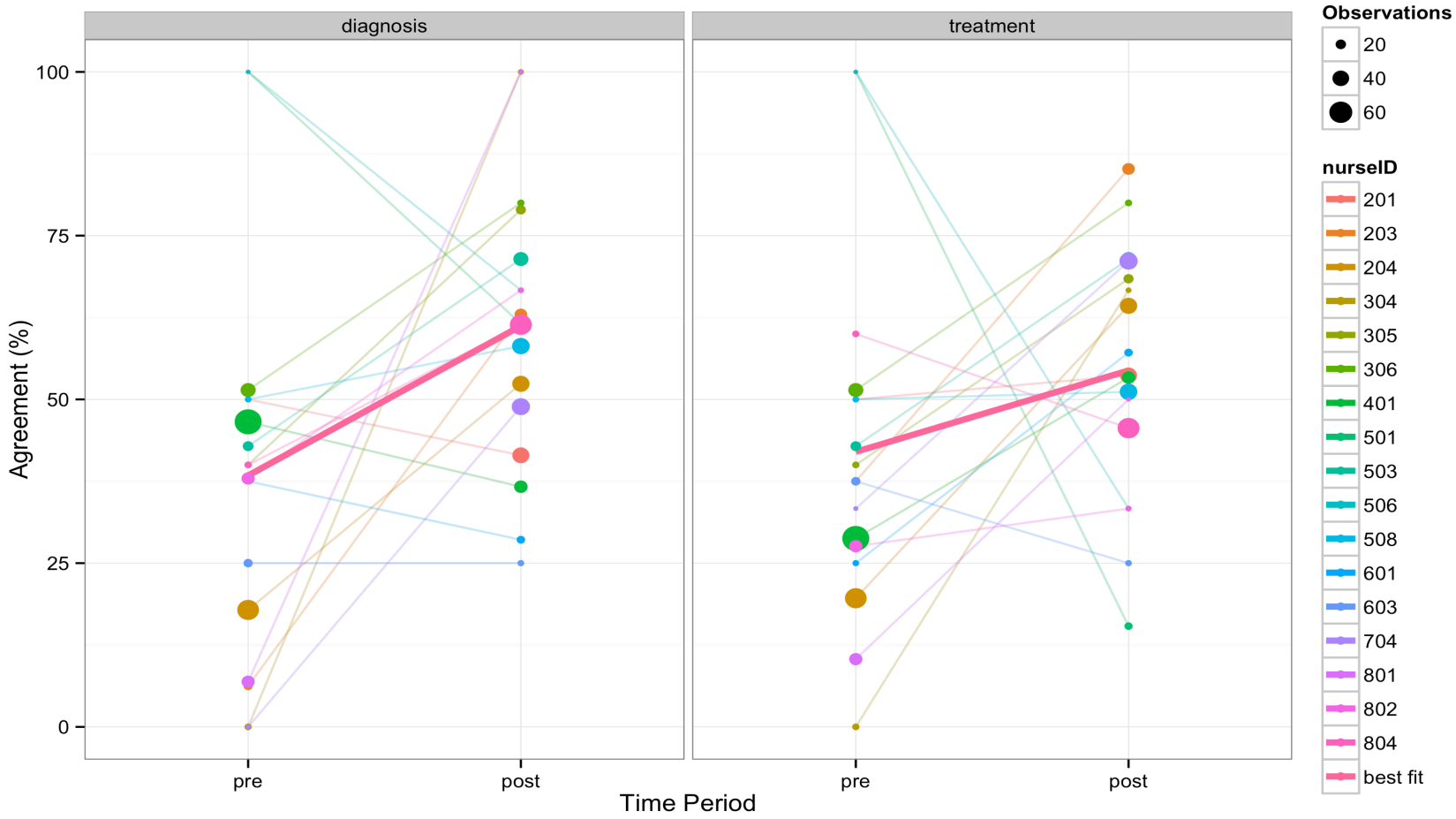

Figure 14: Isolated effect of intervention on frequency of diagnosis and treatment agreement by individual paired nurses

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Chapter 8

Conclusions

This thesis presents the results of an application of implementation research methods to the question of how to improve the quality of primary care delivery in a rural LMIC setting, thereby casting a pragmatic light on this under-researched topic. Specifically, this research has added to what is a limited body of evidence on effective strategies to improve the quality of care and of health worker performance in primary care settings in LMICs. This thesis does so by investigating the impact on quality and performance of a training and mentoring initiative based on the WHO-IMAI guidelines. The structure of this thesis outlines a common process by which programs are formulated, designed, tested, implemented, evaluated and researched in response to a known need or gap in quality or performance. The thesis illustrates the process of baseline quality assessment and survey, followed by field-testing and adaptation of protocols, and concluded with the findings of an implementation research trial. It is unique to have the entire process compiled in a single document that includes theoretical framing, pre-intervention surveys, and post-intervention analyses presented together as a distinct narrative of program development and piloting. In this way, the thesis illustrates the importance of rigorous application of research methodology to questions of programmatic relevance, while accounting for expected and unexpected variation in program fidelity and execution as a result of working under routine conditions in an under-resourced setting.

Aside from the general relevance of the thesis topic in addressing primary care delivery in LMICs, and the significance of the thesis structure itself in representing a complete description of an implementation research project, there are specific lessons that can be drawn from this work. First, the data show clearly that when implemented in conjunction with a program of sustained mentoring and supervision, IMAI training leads to significant performance and quality improvement at rural primary health centres in Rwanda. This is an important finding in that these are the first data to support the effectiveness of IMAI itself, which is relevant in light of its position as an important and untested WHO protocol, but also supports the concept of integrated primary care protocols and processes, more generally, to improve the quality of adult and adolescent ambulatory care in LMICs. This latter point is particularly important as the OPD is widely represented in primary care delivery throughout the developing world, and yet has infrequently been the recipient of quality improvement interventions to-date.

Second, the thesis provides important insight into the nature and effectiveness of health worker support and performance improvement interventions. Specifically, the data show that in spite of not receiving the classroom-based IMAI training course, the subsequent program of enhanced mentoring and supervision of OPD nurses was nevertheless significantly associated with improvements in performance and the quality of care with respect to diagnostic reasoning. In a global public health programming landscape that continues to be dominated by costly and time-intensive training workshops and didactic courses that draw human capacity away from the health sector, this is an important finding that suggests that post-training support is as important as the training itself, and perhaps even more critical to sustaining gains in quality and performance. As well this result suggests that the mechanism by which

training is delivered, particularly to health workers in rural, low-resource settings, may need to evolve beyond simple didactic courses and to strengthen its focus on side-by-side clinical mentorship and feedback, along with data-driven quality improvement derived from routine and sustained site-based engagement.

As with any research endeavor, and particularly with implementation research that is subject to socioeconomic, political, and cultural forces due to the fact it is conducted under routine conditions, there were several limitations to the research presented in this thesis. First, IMAI Acute Care is an untested guideline that has never been validated. This means that there is no evidence, despite the fact that they draw upon other evidence-based approaches (e.g. for HIV, STIs, TB, malaria), that the syndromic IMAI algorithms have diagnostic and treatment validity; whether they are sensitive and/or specific approximations of gold standard etiologic diagnosis and treatment. In general, and as was done for IMCI, it is first preferable to validate a clinical protocol, or test its efficacy, before assessing its impact, or effectiveness. Unfortunately these types of validation studies, either for individual algorithms within the integrated guideline, or for the entire guideline itself, were outside the scope of the funding for this thesis.

The definition of quality of care and health worker performance used in these studies, which included routine practices and behaviors as well as clinical decision-making, are not exhaustive with respect to defining quality of care. There are a number of other metrics, including health worker and patient satisfaction and perception of care, cost and cost-effectiveness of care, health care utilization, efficiency, and others, that together provide a comprehensive picture of quality, but were outside the scope of this thesis. In addition, ascertaining patients' clinical outcomes were also outside the scope of this research, as the ability to follow an illness episode to its conclusion in a

health system that remains structured upon acute, episodic ambulatory care, and which lacks a standard longitudinal patient record, is challenging and requires special resourcing to track patients and to address loss to follow-up. An important dimension of quality also involves provider perspectives of quality improvement and training interventions. While Chapter 4 provides some general insights into nurse providers' training needs and desires, specific information about nurse perception of IMAI, MESH, and quality improvement activities would strengthen the assessment of acceptability of the intervention described. In particular, it would be important to assess nurses' views on feasibility of IMAI and MESH in light of their other demands, and perceptions of how these interventions have improved the quality of their work and their overall satisfaction and motivation after receiving the intervention. Though outside the very specific scope of this thesis, this is an important and related research agenda for the future.

The reliance on observational data collection subjects the study to the influence of the Hawthorne Effect (Leonard and Masatu, 2006b), which suggests that any provider will perform better under observed conditions versus routine unobserved practice, simply by virtue of being observed and not due to any specific assistance provided by the observer. One way to combat this is to retrospectively examine charts or registers for the periods in between site visits, so as to gain insight into how clinical decisions were made when care was not observed. But given that our study was based on a pilot, and not yet a sanctioned MOH standard, we found that nurses did not routinely complete the IMAI Case Recording Form during the intervals between mentoring visits. The CRF was used as a decision support tool and job aid, as intended, but not as a record of the patient encounter that could be reviewed at a later time.

Additionally, the overall evaluation of IMAI (Chapter 7) is limited by the lack of

process evaluation of the MESH intervention itself. This is a separate research agenda underway elsewhere, with data not available to this researcher at the time of writing, but the research presented in this thesis on the impact of IMAI in addition to mentoring, would benefit from a rigorous understanding of the impact of specific MESH activities on quality of ambulatory adult and adolescent primary care. Specifically, it would be useful to study the possible impact or effect modification of the relative "dose" of mentoring received by each health centre and each health worker, on performance and quality, as measured by duration of mentoring visits, frequency of mentoring visits, and proportional mix of specific mentoring activities conducted during each visit.

An assessment of the limitations of this research must include questions about the nature of the gold standard used to judge agreement. Senior nurses were selected as the gold standard in this study, as their level of education, skill and performance was judged to be a realistic and attainable benchmark of clinical quality for a front-line nurse, rather than a physician. But because a gold standard was selected from within a similar health worker cadre, the research may have benefitted from inclusion of periodic assessments of quality and improvement of the IMAI mentor himself, based on data collected during mentoring-of-mentors activities. Another approach may have been to create an additional layer of MD-based evaluation of the mentor's assessment, either through review of a subset of charts and checklists, or through secondary evaluation of a subset of patients in real-time, subsequent to the initial nurse evaluation. Unfortunately, data from mentoring-of-mentors was not rigorously collected during the intervention period described in this research, and was thus not usable for the purposes of this evaluation. Additional secondary evaluation of charts or patients by an MD was cost and time-prohibitive in the context of this research.

Finally, our definition of 'primary care' is not exhaustive. Primary care is

certainly more comprehensive than adult and adolescent acute ambulatory care provided at front line facilities. It is reasonable to assert that services such as care for chronic NCDs, antenatal and maternal care, as well as basic pediatrics, also comprise primary care, in addition to immunization and sanitation programs, in some cases, or other epidemiologically-relevant vertical programs that address high-burden illnesses. Also it is clear that primary care is more than simply curative services, and includes important prevention and counseling interventions. While these were touched upon in this thesis through routine screening questions in IMAI, prevention and behavior change is certainly an important piece of primary care that has its own dedicated research agenda outside the scope of this thesis. Finally, it is clear that primary care includes more than just the care provided at first level facilities, and indeed involves the work of community-based and home-based care provided by CHWs and other mobile health workers. This thesis focuses on adult and adolescent acute ambulatory care as a proxy for general primary care, because it is a routine service provided in every health system in both the developed and developing worlds, but in general lacks innovation and rigorous research, both of which this thesis examines in Rwandan OPDs.

Despite its limitations, the implications of this research are several. First, one must consider the generalizability of these findings from Rwanda to similar low-income settings in the region that have not experienced such dramatic health sector reform and investment in the last 20 years, as described in Chapter 1. It is true that Rwanda is currently outpacing its peers in population health improvement as a result of these investments. But it also remains a low-income country that continues to struggle with basic measures of primary health care quality (e.g. high rates of maternal and child morbidity mortality, malaria, malnutrition, etc.), and that has a lower health worker density than its regional peers; Rwanda has 0.67 nurses for every 1000 people,

compared to 1.17 nurses per 1000 people in the WHO African Region (Africa Health Worker Observatory, 2015). As such, it is reasonable to suggest that IMAI and MESH, which emphasize simplified training approaches for primary health care supported by robust mentoring and quality improvement activities, would be appropriate interventions in a number of sub-Saharan African settings with similar epidemiology and workforce constraints.

One must also consider the implications of this intervention on dissemination and scale up. This operations research benefitted from implementation within a system that reflected a partnership between a well-resourced foreign NGO and the MOH health sector partner. As such, specific clinical and technical capacity was leveraged from the NGO to support implementation activities in the public sector. While this is a valuable model of partnership and accompaniment, it has implications for scalability, both for Rwanda and elsewhere where this partnership model may not be available. For example, while the MESH mentors, in particular, were well integrated into the district health workforce as clinicians and supervisors, the support activities around them (technical support, data analysis and reporting, quality improvement) were sourced largely from PIH-IMB. One could expect that in order for the MESH model to be scaled, that District Health Units (DHUs) would require additional resources, staffing, and support in order to administer such a program. As well there are implications on program integration, as introduced in Chapter 2. IMAI is based on a model of care that integrates clinical services at the point of service delivery. But upstream resources are largely divided by disease program or population risk group, and will remain so for the foreseeable future until donors and governments can agree on integrated approaches to financing for health systems strengthening. As such, in order to scale IMAI or OPD quality improvement, funds and administrative support must either come from a new,

separate vertical program dedicated to primary health care, or comprise an amalgam of resources taken from the dominant, well-funded vertical programs (e.g. immunization, maternal and child health, HIV, TB, malaria). This presents a complicated governance and administrative scenario to any DHU or upstream health sector leadership body that would be responsible for driving ambulatory primary care quality improvement.

The results presented in this thesis highlight the next steps of a future research agenda. First, and most clearly, this research reinforces the need to further study IMAI, both in Rwanda and in similar LMIC settings. As well as validation studies, there is scope for multi-country evaluation of IMAI, in the same manner that helped solidify IMCI as a core component of pediatric ambulatory care in LMICs. Additionally, there is a need for novel research on the gaps in IMAI and how to address them. For example, research is sorely needed to address the integration of acute and chronic care at the primary care level, and while IMAI Acute Care does offer a first attempt at integrating screening for chronic conditions within the routine patient encounter, more specific and dedicated innovation and research is needed to train front line health workers to address growing epidemics of diabetes, hypertension, cardiovascular disease, and other illnesses without creating further vertical program infrastructure that may compete with or detract from integrated primary care.

Additionally, there are a number of avenues of research into primary care delivery in its broader sense. Specifically, important questions arise about how to build on IMAI at the facility, by creating and testing guidelines for CHWs to follow up adolescent and adult care in the home and in communities, using an integrated approach. Integrated community case management (ICCM) (Hamer et al., 2012) is an important example of such a program that links to IMCI for under-five care. An analogous approach is needed for IMAI. Research is also needed to assess the impact of

primary care interventions on population health, in addition to patient care and quality. This is especially important as primary care is intended to be longitudinal and whole patient-centred, and as such involves more than just the clinical care provided in a single facility-based patient encounter. Rather, primary care sits at the intersection of patient care and behavior and lifestyle change, as well as population-based public health programs. Perhaps the best way to measure the intersection of these programs, then, is to combine demographic indicators with facility based patient metrics, and to advance research in population health management (Berwick et al., 2008) which involves the use of linked patient and demographic data to assess population-based control of health indicators or conditions such as obesity, blood pressure, blood sugar, etc. Efforts to define methods of triangulation of facility cohort and demographic data are already underway in Malawi, Tanzania, and Zambia, with the aim to apply these methods to longitudinal HIV cohorts (SEARCH, 2015). Further consideration of such approaches is needed, particularly as they apply to primary care delivery.

A number of recommendations and next steps arise from the results of this research, in addition to the research agenda above. First, these results highlight the need for further investment into primary health care delivery, including chronic care. In its current form, IMAI only emphasizes the role of ambulatory acute care in the delivery of front-line primary health care, but given the epidemiologic transition underway across the developing world, this research also highlights the need to invest in approaches to bolster systems for chronic care delivery at the front lines. Specifically, IMAI trains health workers to screen patients with new complaints or undifferentiated illness for a range of chronic illnesses, but there is currently little attention given to where these patients go to receive care subsequent to diagnosis or positive screen for risk factors (aside for HIV and its related risks). It is unrealistic and unsustainable to

expect that all chronic disease patients would receive care at district hospitals, and as such this research highlights the need to invest further in integrated ambulatory chronic care. Of note, WHO and partners are currently developing an IMAI Chronic Care Manual for Diabetes, Hypertension, and Chronic Respiratory Illness which will link to the Acute Care manual and offers a first attempt to operationalize this form of integration. More generally, these results highlight the need to create a foundation of care that can support high quality and complex vertical programs. This requires additional investment, commensurate to its importance within the front-line health system, and proportional to vertical programs that currently dominate the primary health care space.

The results also highlight the need for improvement of patient monitoring systems for ambulatory primary health care. Specifically, and in line with the recommendation above, current modes of acute, episodic of patient data recording are wholly inadequate to support high quality primary care delivery, and rather investment must be made into developing medical records that allow longitudinal patient tracking and syncing with multiple points of service delivery through the use of unique identifiers. This approach has already been used successfully to support TB programs that employ paper registers that allow for longitudinal data recording and simplified cohort analysis (WHO, 2006), and has also been introduced in HIV programs to support ART (WHO, 2013), and more recently in diabetes and hypertension programs in Middle East (Khader et al., 2012; Khader et al. 2012).

With respect to the research process itself, this thesis and its underlying institutional relationships highlight the complexity of conducting rigorous operations research in an environment focused primarily on service delivery and clinical care. Specific administrative systems and firewalls are needed to protect the integrity of

research from dissolution within routine clinical operations, while also maintaining the realistic focus and practicality that distinguishes operations research from classical experimental studies. The structure of the PHIT grant was such that the line between research and operations was opaque, and without strong accompanying research systems to manage competing demands and objectives, this research and projects like it remained under persistent threat of closure, and at risk of compromising quality and rigor. In future, it would be reasonable to suggest that specific operations research funding be separated from operations funding, but that joint planning and communication be maintained. Future studies such as this would benefit from this type of strategic alignment but financial and operational protection.

The results of this thesis provide an important contribution at a time when interest in primary care delivery as a means to strengthen health systems in LMICs is growing. As an example, the Bill and Melinda Gates Foundation, along with the World Bank, recently launched their 'Primary Health Care Performance Improvement Initiative' (IAPO, 2015), which aims to support LMIC governments to strengthen their primary care systems through better data and measurement of performance - a central topic addressed by this thesis. As such this research arrives at an opportune moment in the global public health discourse, at a time when primary care innovation and research in LMICs is needed.

To conclude, the work presented in this thesis advances our understanding of the design, implementation, and effectiveness of a specific strategy to improve primary health worker performance and quality of ambulatory primary care in LMICs. The investigation of IMAI, delivered with a novel approach to mentoring and supervision, represents an important guiding marker in what should be growing field of primary care research in the developing world.

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