

Case Management of Childhood Illness in the Private Health Sector

A review of models of care and their effectiveness in reducing childhood diarrhea, malaria, and pneumonia



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About SHOPS Plus: Sustaining Health Outcomes through the Private Sector (SHOPS) Plus is USAID's flagship initiative in private sector health. The project seeks to harness the full potential of the private sector and catalyze public-private engagement to improve health outcomes in family planning, HIV/AIDS, maternal and child health, and other health areas. SHOPS Plus supports the achievement of US government priorities, including ending preventable child and maternal deaths, an AIDS-free generation, and FP2020. The project improves the equity and quality of the total health system, accelerating progress toward universal health coverage.



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Acronyms

ACT	Artemisinin-based combination therapy
ADDO	Accredited drug dispensing outlet
AL	Artemether-lumefantrine
AMFm	Affordable Medicines Facility-malaria
AMT	Oral artemisinin monotherapies
AQ	Amodiaquine
BCC	Behavior change communication
BMGF	Bill and Melinda Gates Foundation
CBD	Community-based distributors
CHAI	Clinton Health Access Initiative
CHP	Community health promoter
CHW	Community health worker
DALY	Disability-adjusted Life Year
DAZT	Diarrhea Alleviation through Zinc and ORS Therapy
DFID	Department for International Development
DHS	Demographic and Health Survey
DTK	Diarrhea treatment kit
GDP	Gross domestic product
iCCM	Integrated community case management
iCCM2	New integrated community case management
IEC	Information education and communication
IMCI	Integrated management of childhood illness
ITN(s)	Insecticide-treated bed nets
IPC	Interpersonal communication
LCS	Licensed chemical sellers
MOH	Ministry of Health
mRDT	Malaria rapid diagnostic test
NGO	Nongovernmental organization
ORS	Oral rehydration salts

OTC	Over-the-counter
PA	Pharmacy assistant
PHSP	Private Health Sector Program
PMR	Private medicine retailer
PMV	Patent medicines vendors
POU	Point-of-use
POUZN	Point-of-Use Water Disinfection and Zinc Treatment Project
PPMV	Proprietary patent medicine vendors
PPP	Public-private partnership
PSI	Population Services International
QAACTs	Quality assured artemisinin-based combination therapy
RCT	Randomized controlled trial
SAM	Severe acute malnutrition
SHOPS Plus	Sustaining Health Outcomes through the Private Sector Plus
SUZY	Scaling Up Zinc for Young Children
TSHIP	Targeted States High Impact Project
UP	Uttar Pradesh
USAID	United States Agency for International Development
UNICEF	United Nations Children’s Fund
WHO	World Health Organization

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Executive Summary

Since 1990, the global under-five mortality rate has declined by more than half. However, in spite of this progress, 5.4 million children under five years of age died in 2017, 4.1 million within the first year of life. Diarrhea, acute respiratory infection (pneumonia) and malaria remain the primary causes of death in children under five. In addition, nearly half of all deaths in this age group are attributable to concomitant malnutrition, which increases frequency and severity of illness and delays recovery. Every day, millions of parents seek health services for their sick children, and the private sector is often the first point of consult. Across USAID's 24 maternal and child survival priority countries, 43% of care seekers go to private sector sources for their sick children. As such, there is increasing recognition that the private health sector has a key role to play in strengthening and scaling the delivery of child health interventions.

The Sustaining Health Outcomes through the Private Sector (SHOPS) Plus project conducted a review of peer-reviewed publications and grey literature in order to **summarize existing evidence of integrated approaches to the management of childhood illness (including diarrhea, pneumonia, and malaria) being implemented by the private commercial sector and other non-state entities**. These private sector health facilities include a wide range of community-based drug shops, pharmacies, nurses' and doctors' offices, health centers, and hospitals.

This document outlines findings from this literature review, including key definitions and concepts in Annex A and key search terms in Annexes B and C. A Project Management Index including information on the 126 papers reviewed accompanies this document. This review will be shared with global stakeholders to inform future implementation and will serve as the starting point for the private sector Integrated Management of Childhood Illnesses (IMCI) Child Health and Nutrition Research Initiative process led by USAID, SHOPS Plus, and Boston University. During this process, which will take place from November 2018 through March 2019, key thought leaders will generate, systematically evaluate, and rank research questions related to IMCI in the private sector. The end goal will be to have a set of priority research questions for the global health community to address in an effort to gather additional data on effective private sector childhood illness case management models.

Key Findings

- There remains a dearth of information on long-term sustainability or success of interventions after the initial implementation or donor focus. Additional evaluations of long-standing interventions, cost-effectiveness studies, process evaluations, and other such studies would significantly contribute to the evidence base. Few resources looked at cost-effectiveness as a formal measure and appropriately evaluated it as such.
- More information regarding non-donor reliant community-based private sector retail options is needed, as evidence exists about promising child health service models successfully scaled through community health workers and other community-based initiatives.
- There is a need to further explore mhealth and other digital interventions and their effectiveness in improving provider knowledge and patient outcomes.
- More information and evidence are needed regarding effective quality assurance and improvement measures in the private sector among clinical and nonclinical providers.

- Appropriately balancing resourcing and scale of interventions presents a challenge. In interventions that expanded malaria rapid diagnostic tests (mRDTs) to private sector locations, researchers observed that they may not be scalable, whereas less resource-intensive interventions often produced less effective outcomes.
- Private sector interventions can produce secondary or unintended effects. One study found that introducing mRDTs in the private sector increased the unnecessary use of antibiotics.
- While several papers in the review demonstrated successful efforts to implement integrated models via the private sector, there is a need for further research on the success of these models over time and novel approaches to financing and scaling private sector models that are sustainable without donor investment.

Global Context

Over the past two decades, thanks in large part to joint global efforts launched in pursuit of the Millennium Development Goals and other global health targets, there has been tremendous progress in reducing preventable child and maternal mortality. Since 1990, the global under-five mortality rate has declined by more than half—dropping from 90 to 43 deaths per 1,000 live births. Maternal mortality was also halved over the same period. Although this fell short of reducing child and maternal mortality by two-thirds by 2015 (Millennium Development Goals 4 and 5), the application of new medicines, technologies, and health service models has significantly improved child health worldwide. Despite this progress, 5.4 million children under age five died in 2017, 4.1 million within the first year of life. Childhood pneumonia still kills approximately 2,400 children per day across the globe,¹ the majority being children under age two. This trend is likely to continue without serious interventions, given that only an estimated 60% of children under age five presenting symptoms of pneumonia are taken to health services. Diarrheal disease, a preventable and treatable illness resulting from unsanitary environments, is the second leading infectious disease-related cause of death in children under age five, killing an estimated 525,000 children per year.² Young children remain the most vulnerable to malaria, resulting in roughly 285,000 malaria-related deaths in children under age five throughout Africa in 2016 alone.³ In addition, nearly half of all deaths in children under age five are attributable to concomitant malnutrition—where diminished nutritional status and stunting puts children at greater risk of common infection, increases frequency and severity of illness, and delays recovery.⁴

Since the 1990s—acknowledging that the factors related to providing quality care to sick children worldwide are interrelated and complex—the World Health Organization (WHO), the United Nations Children’s Fund (UNICEF), and the United States Agency for International Development (USAID) have advanced the development and widespread implementation of the Integrated Management of Childhood Illness (IMCI) and other integrated child health service delivery strategies. Although not uniformly applied across all country settings, IMCI and other integrated approaches generally recognize that the successful reduction of preventable childhood illness and death requires a focus on the well-being of the whole child and pursue this focus through clinical and nonclinical services implemented by families, communities, and health facilities. Every day, millions of parents seek health services for their sick children, and the private sector is often the first point of consult—across USAID’s 24 maternal and child survival priority countries, 43% of care seekers go to private sector sources for their sick children. Private sector health facilities include a broad range of community-based drug shops, pharmacies, nurses’ and doctors’ offices, health centers, and hospitals, which may often be easier to access than public facilities. Existing evidence, including a recent review of Demographic and Health Survey (DHS) data from 24 countries (see, Private Sector Counts <https://www.privatesectorcounts.org/>) reinforces that in many countries, private sector health service points are an important source of care for caregivers seeking sick child care outside the home. As such, there is increasing recognition that the private health sector (including a diverse range of commercial, nonprofit, and faith-based actors operating health services and distributing

¹ UNICEF (2018b).

² WHO (2017).

³ WHO (2018).

⁴ UNICEF (2018a).

health products outside state structures) have a key role to play in strengthening and scaling the delivery of child health interventions.

In this global context and despite substantial international investment to improve child health over the past several decades, there remains a distinct lack of summarized evidence about “what works” and what can be done to accelerate progress toward the new Sustainable Development Goals (SDGs) aimed at reducing child and maternal mortality. Particularly in terms of the private sector’s involvement, there is an urgent need to know more about what has been and is being done to support the private health sector’s participation in delivering child health services, what has worked and what has not, how it has worked or has not worked, which models might be most effective moving forward, and which interventions show promise in terms of high-quality service delivery and program sustainability.

To answer these questions, USAID requested that the Sustaining Health Outcomes through the Private Sector (SHOPS) Plus project conduct a broad review of peer-reviewed publications and grey literature in order to summarize existing evidence of integrated approaches to the management of childhood illness (including diarrhea, pneumonia, and malaria) being implemented by the private commercial sector and other non-state entities. In particular, the review sought to assess the structure and effectiveness of these models in order to provide an evidence base of what works to improve child health when delivered by the private health sector.

Methods

The literature review was conducted in an iterative fashion, where SHOPS Plus worked in close collaboration with USAID’s Child Health team to determine search parameters, inclusion and exclusion criteria, and to identify project reports and grey literature to ensure a robust body of global evidence for analysis.

Scoping Phase 1: May–September 2017

In late spring and summer 2017, in close consultation with USAID, SHOPS Plus embarked on a literature scoping review with the agreed purposes of 1) defining the scope of a private sector-focused literature review for child health case management; 2) performing a targeted search for published literature; 3) conducting a review and extracting lessons from available evidence; and 4) synthesizing findings in case studies and other useable formats to inform global child health stakeholders. The initial review included a search of Cochrane Library and PubMed and included search terms targeting “private,” “treatment,” or “management” of “child” or “infant” “malaria,” “diarrhea,” or “pneumonia.” This initial search yielded 162 papers for review (full search terms and database results are outlined in Annex B). An abstract review was performed on these papers and summarized in a short memo to USAID in the fall of 2017. Results of the initial search yielded two key findings: 1) formal evaluations of private sector case management approaches for common childhood illnesses appear to be extremely limited and 2) there is minimal data demonstrating if and how private sector child health programs can lead to sustained use of and positive effects on child health services among target populations—although some of these initial studies discussed trainings of private providers that led to increased child health knowledge.

Scoping Phase 2: October 2017–August 2018

Based on the findings of the initial literature scoping review, SHOPS Plus and USAID agreed that a broader scoping effort would be needed to ensure inclusion of all available global evidence. In particular, it was acknowledged that there were known models of private care not captured in the initial search and that a further emphasis on grey literature and project reports as well as a broadened search strategy was required. It was agreed that search terms would be expanded, additional databases and search engines would be utilized, and global experts would be engaged. In summer 2018, additional searches were carried out in grey literature databases, including the Children’s Investment Fund Foundation Grant Portfolio, the USAID Development Experience Clearinghouse power search, and the Department for International Development (DFID) development tracker. These searches generated an additional 359 pieces of grey literature for review, including project reports, case studies, and implementation work plans. Additional searches were conducted in PubMed using new and expanded search terms, such as “private management,” “pediatric,” “respiratory infection,” “drug seller,” “community health worker,” and “lower cadre provider” (see Annex C). This resulted in an additional 691 published sources of literature for review.

Analysis: September-November 2018

In total, the SHOPS Plus team sourced 853 pieces of published literature (162 in Phase 1 and 691 in Phase 2), plus an additional 359 pieces of grey literature for a total of 1,212 materials for full review. All abstracts were reviewed in their entirety, as were the abstracts or summaries for all grey literature. For materials without an abstract (in particular, project reports and other grey literature), the introduction and conclusion were reviewed. Per discussion with USAID, the SHOPS Plus team excluded papers that were not freely available in full text or that did not: (1) discuss an intervention deployed through the private sector; (2) involve case management of at least one of the following: diarrhea, malaria, pneumonia, or respiratory infection; or (3) focus on children under age five. This resulted in a total of 114 papers for further analysis. Given that the SHOPS Plus definition of private sector does not include community health worker (CHW) models implemented by the public sector, a large number of papers discussing publicly managed CHW models were excluded.

In September and October 2018, all 114 papers were reviewed in detail and summarized in a Project Management Index for stakeholder use. **Of note, utilizing the search criteria outlined for this review, there were no papers found that discussed private sector models to address pneumonia/acute respiratory infection in isolation.** Pneumonia interventions were, however, described in a number of documented, private sector approaches to IMCI.

In November 2018, following key expert interviews, review by external stakeholders and additional sourcing of citations found in key papers, additional documents were added to the Project Management Index. **This gave the authors a total of 126 published and grey materials for full analysis.** The disease areas covered, private providers involved, and emergent themes are summarized for all 126 papers in the Project Management Index.

Findings

Of the 126 published papers and grey materials reviewed, 55 focused on interventions dealing with malaria, 39 focused on interventions addressing diarrhea, and 32 discussed integrated approaches to childhood illness. These findings, including the lack of pneumonia-specific private sector models, are similar to findings from other systematic reviews sourced as part of this effort; there were no papers sourced that discussed treatment of childhood pneumonia as a stand-alone intervention. Two-thirds of the resources (84) focused on private medical vendors or other community-based drug dispensing outlets/shops. Thirty-two papers centered on the involvement of CHWs in private sector models of child health services, 23 focused on private physicians or hospitals, ten focused on private nursing facilities, and eight discussed interventions implemented by faith-based organizations operating outside state structures. In terms of emerging themes (explored further in the discussion section of this review), the papers covered a range of private health sector thematic areas including (but not limited to) private sector service provision and scale-up of child health interventions, provider trainings, approaches to quality assessment/quality improvement, private sector supply chain, potential for sustainability, and demand creation for privately delivered child health services. While all of the papers included some measure of effectiveness or impact, 19 robustly measured the effectiveness of specific private sector child health interventions.

Twenty-one project profiles were created in order to highlight and organize particular models and according to core themes and to expand on innovative and/or effective models. These profiles are presented by disease area, each summarizing the need, intervention, measures of effectiveness, and key lessons emerging from particular global experiences. Profiles M-1 through M-8 focus on malaria, Profiles D-1 through D-6 focus on diarrheal disease, and Profiles ICH-1 through ICH-7 focus on integrated approaches.

Malaria Case Management

Of the 55 papers covering malaria interventions, the vast majority profiled interventions or studies that involved private medical vendors or other community-based dispensing outlets. The majority focused on and/or included mention of East Africa, followed by West Africa. Of note, almost half of the interventions included some form of subsidization of antimalarial commodities with potential implications for sustainability. The project profiles presented were selected to present a range of key findings, including how large-scale training efforts can improve private provider knowledge and practice, how malaria rapid diagnostic tests (mRDTs) distributed via private sector outlets can improve the prescribing behavior of private drug dispensers, and how global mechanisms (such as the Affordable Medicines Facility-malaria) can impact the availability, price, uptake, and effectiveness of essential child health commodities (such as antimalarial drugs). Project profiles with negative findings were also included, highlighting for instance how further training may be needed to ensure private providers understand the dangers of under-dosing or non-adherence to antimalarial therapy and the challenges to scaling successful private sector malaria interventions. Below is a summary of key findings related to malaria case management.

The private sector is an important source of first resort consultation in the care of febrile children. Several studies and implementation experiences confirmed the fact that the private health sector (particularly at the community level) is a critical first source of consult for caregivers of children exhibiting malaria symptoms. As such, several papers conclude that

private medical vendors and other community-based drug dispensing outlets could serve as a critical source of care for febrile children.

There is a need for further evidence on improving the quality of privately delivered care and the inclusion of private providers in national malaria control strategies. Although several papers outlined how improving quality of care in private facilities could work to increase trust and collaboration between private health actors, none of the papers specifically addressed how private providers could be more systematically included in national malaria control strategies. More evidence is needed to document public-private collaboration efforts and the specific ways in which private providers can be integrated into national child health disease programs.

Large-scale provider training efforts can improve provider knowledge and practice related to childhood malaria. Although there is significant disparity across studies examined in the effectiveness of provider trainings to improve clinical performance, several implementation experiences involving training of private providers on childhood malaria protocols demonstrated that clinical tasks—such as stocking amodiaquine (AQ) medicines, asking questions about patient age, duration of illness, and previous treatments—were all improved with large-scale private provider trainings. Further, studies in this review demonstrated that district health initiatives focusing on training of private medicine vendors, when paired with traditional public health information campaigns and simple information, education, and communication (IEC) materials, can lead to measurable improvements in private provider performance on the treatment of childhood malaria at the community level. Of note, interventions utilizing text messaging and other electronic platforms of knowledge enhancement did appear to improve dispenser knowledge of childhood malaria treatment protocols, but did not demonstrate if or how that information was necessarily communicated or transferred to improve caregiver knowledge.

The use of mRDTs for diagnosis at private sector outlets can improve the prescribing behavior of private drug dispensers. The artemisinin-based combination therapy (ACT) consortium studies (and others in this review) demonstrated that mRDTs, when deployed with effective provider trainings, can improve dispenser prescribing behavior and reduce the overuse of antimalarial medications. In Ghana, delivering mRDTs via licensed chemical shops resulted in improved prescribing behavior for clients without malaria, while maintaining appropriate prescribing behavior for those with malaria.

Privately accessed mRDTs may be more likely to be used when they are provided free of charge to the client. Of note, although it was demonstrated that private sector outlets can increase the availability of mRDTs, evidence demonstrates that they are much more likely to be utilized or accessed when provided free of charge at the point of care. This is a concern when considering the sustainability of privately delivered models of care beyond donor commodity subsidization.

The Affordable Medicines Facility-malaria has positively impacted the availability and price of antimalarial drugs and the effectiveness of treatment. Several studies (such as those profiled above) demonstrated that the Affordable Medicines Facility-malaria (AMFm) has had a significant impact in increasing the availability of ACTs in the private health sector. These studies conclude by emphasizing the need for further exploration of quality of care among private providers benefitting from the AMFm program, including appropriate consultation practices and use of malaria commodities. **Where mRDTs were used, there was a reduction in antimalarials being dispensed to clients without malaria, while there was no increase**

or decrease in appropriate prescription of antimalarials to those with “true” and confirmed malaria.

Public-private partnerships are an essential avenue for achieving improvements. Several studies demonstrated that an appropriate mix of technical, management, and commodity-related solutions is needed to ensure appropriate introduction of malaria diagnostic and treatment options in the private health sector. Authors of these papers conclude that public-private partnerships (PPPs) are the essential pathway to deliver appropriate training, incentives, regulation, supervision, and communication with private providers.

Ensuring the quality of privately delivered care is an essential priority. Numerous studies demonstrated that although interventions with private sector providers can improve provider knowledge and prescribing behavior, significant quality gaps remain. Further training is needed to ensure private providers understand the dangers of overprescribing antimalarial medications, under-dosing, and/or non-adherence to therapy. For example, one study found that the introduction of mRDTs can reduce unnecessary use of antimalarials, and, in turn, create an increase in the unnecessary prescription of antibiotics.

Scale and sustainability are a challenge when projects rely on subsidized inputs. The large systematic review of malaria programs profiled in this report found that while mRDT access can improve case management of febrile illnesses, and that intensive interventions typically led to better outcomes, it is highly unclear if successful pilot interventions can be scaled or sustained at a national level. For example, in studies demonstrating success in one country, the factors of success did not hold in other settings. As outlined above, in Nigeria longer provider trainings did not appear to have any impact on patient uptake or adherence to antimalarials; however, we note here that adherence depends on several factors beyond provider recommendations (such as patient understanding). In Myanmar, shorter trainings had a more pronounced effect than longer ones, and in Tanzania, increasing mRDT subsidies to reduce the out of pocket cost to client had no impact on uptake despite all of these factors increasing positive outcomes in other settings. It was found that mRDTs were more likely to be used in chemical shops when they were provided free of charge to the client, **raising serious concerns about sustainability of programs beyond subsidies and donor investment.**

Malaria Case Management Profiles

Profile M-1: The effect of mobilizing chemical sellers to expand the reach of malaria rapid diagnostic tests and reduce child fever. Project: Ghana Health Service trial implementation, 2005

Though malaria remains endemic in Ghana, significant progress has been made in reducing malaria deaths and morbidity through the National Malaria Control Program. This progress has been attributed to an integrated approach to malaria control and scaling up of malaria case management and antimalarial availability.⁵ In children under age five, the national parasitemia prevalence dropped to roughly 20% in 2016, an almost 7% decrease from 2011.⁶ Licensed chemical shops are a common source of antimalarials in Ghana, especially among the rural poor. Licensed chemical shops are private sector drug shops licensed by the Pharmacy Council and managed by sellers who must meet a minimum educational threshold (secondary level).

⁵ United Nations in Ghana (n.d.).

⁶ President's Malaria Initiative (2018).

Licenses are renewed on an annual basis, and sellers are allowed to dispense over-the-counter (OTC) antimalarial medications. Over diagnosis and unnecessary or inappropriate treatment of fever is a serious issue—clients are often given antimalarials based on symptomatic presentation and without confirmatory diagnostic rapid testing or other diagnostic testing. This over-prescribing behavior can drive antimalarial drug resistance and often leaves other serious causes of fever and infection in children overlooked.

Intervention

Ansah et al. (2015) sought to measure the effect of mRDTs on correctly diagnosing causes of fever when provided via licensed chemical sellers (LCS) in an impoverished rural district of Ghana. Twenty-four communities, each with one to five licensed chemical shops, were eligible for inclusion. Clients presenting at a licensed chemical shop with a fever and/or requesting an antimalarial were eligible to be included. Pregnant clients, clients younger than six months, clients with severe illness, clients with a prescription from a health facility, or clients in the intervention district for less than a month were excluded.

Private licensed chemical shops in the intervention arm implemented the practice of conducting an mRDT prior to dispensing any antimalarial medication, while chemical shops in the control arm continued dispensing antimalarials without a diagnostic test result per their current practice. Additionally, focus group discussions were held with community members and private LCS to discuss the concept of mRDT utilization and how best mRDTs and improved prescribing practices could be introduced at chemical shops. This was a subsidized effort. Researchers provided mRDT test kits free of charge to the private chemical sellers, who in turn did not charge clients for either the product or the service. All chemical sellers (both in the control arm and the intervention arm) received a three-day training, where they were educated on various topics related to malaria diagnosis, treatment, and infection prevention and control. Chemical sellers in the intervention arm received an additional day of training, which covered the use of mRDTs, appropriate clinical management of clients who tested positive, and malaria-related record keeping. Chemical shops in the control arm were expected to dispense medicines without a test result as per current practice.

During the intervention from August 2011 to January 2013, services provided and record accuracy regarding medications dispensed were validated through random checks and mystery clients in both the control and intervention arms.

Measures of Effectiveness

A blood-based microscopy malaria test was conducted by the research team within three days of consult for all participants ($n = 4748$ adults and children) in the control and intervention arms. In the control arm, chemical sellers collected a blood sample in a “micro container” at the time of consult for study testing (but they did not perform an mRDT); in the intervention arm, a blood sample was collected for study testing and an mRDT was performed at the time of consult. Blood test slides were prepared and assessed by the study team and communicated back to the facilities after three days. If a client had tested positive for malaria (via the study slide) but had not received an antimalarial (from either the control arm or intervention arm), he or she was contacted and requested to present at a health facility for treatment. Researchers then assessed treatment and chemical-seller prescribing against what should have been the appropriate outcome. Of the roughly 4,600 clients included in the analysis, 70% in the intervention arm and 80% in the control arm tested negative for malaria. The proportion of clients who tested negative for malaria but still received an antimalarial (ACT or other) was significantly lower in the intervention arm (32%) than in the control arm (88%), suggesting that

the use of mRDTs reduced the number of malaria “negative” patients who received an unnecessary antimalarial treatment. Of clients in the intervention arm, 74% received appropriate treatment versus only 27% in the control arm, meaning that clients in the intervention arm were three times more likely to receive appropriate treatment than patients in the control arm, where mRDTs were not conducted. The differences in appropriate treatments between the intervention and control groups was attributed to a reduction in antimalarial provision among those without malaria. Notably, the use of mRDTs in the intervention arm did not lead to an increase or decrease in the number of clients with “true” malaria cases (as confirmed by the research team via microscopy) who received an effective antimalarial. Of those who were confirmed slide-positive for malaria, 690/787 (88%) in the intervention arm and 347/392 (89%) in the control arm received an ACT at the time of consult. Results were similar when the analysis was conducted separately for adults and children. Of note, the study did not achieve its planned sample size for children, which was attributed to difficulties in recruiting children under age five at the chemical shops. The study authors argued that the “large effect estimates, small P values, and moderately narrow 95% confidence intervals” provide evidence that the effect of the intervention was estimated with sound accuracy.

Key Lessons

This trial provides evidence that delivering mRDTs via LCS in Ghana resulted in improved prescribing practices for child and adult fever. In the intervention arm, **where mRDTs were used, there was a reduction in antimalarials being dispensed to clients without malaria, while there was no increase or decrease in appropriate prescription of antimalarials to those with “true” and confirmed malaria.** The extension of mRDTs via private retail locations in community-based settings can improve the targeting and clinically appropriate use of antimalarials among poor rural clients. However, the **study authors noted that the commodities and private services delivered in this intervention were subsidized and that they had difficulty recruiting children to the intervention arm. The findings hence suggest that although provider prescribing practices were improved via the use of mRDTs, this strategy may not be especially effective when considering under-fives in particular.** They note that mRDTs may be more likely to be used in chemical shop locations when they are provided free of charge to the client. **If the chemical seller is required to pay for mRDT procurement, it may limit availability and if clients are required to pay for the test it may limit utilization.** More information is required regarding community-based private sector retail options for mRDT expansion that are not reliant on donor subsidization.⁷

Profile M-2: Effect of the Affordable Medicines Facility-malaria financing mechanism in Ghana. Project: AMFm, Ghana, 2010–2012

Low levels of use or ineffective use of antimalarials and the use of mono-therapies that might accelerate resistance, all severely limit the effectiveness of malaria control efforts in endemic areas. Launched in 2010, the Affordable Medicines Facility-malaria financing mechanism (AMFm), hosted and managed by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), was a global financing mechanism focused on the provision of quality-assured ACTs in the public and private sector in malaria endemic countries. The aim of AMFm was to expand access to ACTs, improve malaria case detection and management, and in turn work to lower population drug resistance to antimalarials. AMFm was comprised of three key elements:

⁷ E. K. Ansah et al. (2015).

“price reductions through negotiations with ACT manufacturers; a buyer subsidy through a ‘co-payment’ for ACTs at the top of the global supply chain; and supporting interventions to promote appropriate use of ACTs including provider training and consumer education.” In Phase I of AMFm’s implementation, the four main aims were to: 1) make ACT more affordable; 2) increase the availability of ACTs; 3) increase use of ACTs, especially among vulnerable groups; and 4) “crowd out” oral artemisinin monotherapies (AMT), chloroquine, and sulfadoxine-pyrimethamine from the market by increasing ACT market share. AMFm’s initial pilot phase was conducted in eight countries: Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Republic of Tanzania (mainland and Zanzibar), and Uganda. In Ghana alone, between August 2010 and December 2012, almost 53 million doses of subsidized ACT were imported into the country via the AMFm mechanism.

Intervention

Adjei et al. (2016) carried out a study including cross-sectional mixed-methods design surveys, focus group discussions, and in-depth interviews in Ghana to evaluate the effectiveness of AMFm subsidies in relation to: 1) increased ACT access and 2) malaria case management practices at the household and community levels while AMFm subsidies were ongoing. The study was conducted in four hard-to-reach regions. Surveys of child caregivers assessed their knowledge of malaria symptoms, knowledge of malaria points of care, and their attitudes toward malaria prevention, control, and treatment. Surveys and interviews with LCS (who are often the first point of care for febrile illnesses in Ghana in remote and hard-to-reach areas) assessed their role in promoting treatment compliance, appropriate drug dispensing practices, and perceptions regarding ACT efficacy and availability as it related to children under age five. Health care providers, including community health nurses, disease control officers, physicians, and pharmacists, were also interviewed to ascertain their perceptions on the quality, reach, and availability of ACTs made available through the AMFm and their prescribing behavior for antimalarials. Finally, policy makers were interviewed to examine the high-level impact of the AMFm subsidies.

Measures of Effectiveness

The study found high ACT availability and sufficient provider knowledge for their dispensation, both believed to be a reflection of a high market share of AMFm-sourced ACT in these remote areas. Although ACT was made available via LCS for a fee to client, the study found that market forces in the private sector were “not necessarily problematic in relation to ACT availability.” The authors posit that, as demonstrated in previous studies, as a result of high market penetration, AMFm medications are generally less expensive than other ACTs. The survey found that the majority of caregivers surveyed believed that the AMFm ACTs were affordable. At LCS at the community level, ACTs were the most frequently purchased antimalarial with artemether-lumefantrine (AL) being the most popular choice. In LCS’ that had AMFm ACT stock available, the price charged was in line with the recommended selling price.

In terms of clinical competence, the study found that LCS attendants were able to recognize childhood malaria symptoms, which the researchers suggest indicates familiarity with other child health protocols such as the integrated management of newborn and childhood illnesses. Further, the study found that LCS attendants provided appropriate instruction regarding dosing and medicine storage, which may be due to instructions that accompany the AMFm program. A minority of LCS attendants did not appropriately identify childhood malaria symptoms, did not appropriately provide ACT to caregivers, or provided incomplete dosages. Caregivers of children under age five reported that they sought out antimalarials when children had a hot body (38%), vomiting (14%), loss of appetite (17%), or convulsions (2%). When asked why they

selected a drug shop to purchase antimalarials, caregivers reported concerns over the cost of care and medicines at health facilities, closer proximity, long wait times at health facilities, and lack of health insurance, which discouraged accessing private health facilities.

Key Lessons

While sustainability was not specifically addressed in this study, findings show that AMFm is working as intended in several regions in Ghana. AMFm positively impacted ACT availability and awareness and likely improved ACT affordability in poor, rural areas of Ghana. The sustainability argument for AMFm presented in a separate resource argues that without subsidies for ACTs, cheaper monotherapies will dominate the market and accelerate resistance to the only effective treatment for malaria, artemisinin.⁸ **Given that there was evidence of LCSs providing incomplete dosages, further training and supervision on malaria management practices, with a focus on the dangers and implications of under-dosing or incomplete treatment, may be necessary.** Per the researchers, the AMFm goal of “increasing access has not sufficiently extricated the concept of availability from affordability, both of which are viewed as critical to accessibility, the close overlap makes distinguishing between some of the associated variables problematic.”⁹ In 2012, the Global Fund Board modified the AMFm program by integrating lessons from Phase 1 into the Global Fund core grant management and financial processes, and the AMFm was transitioned into the Private Sector Co-payment Mechanism. This financing model aims to continue to expand access to quality assured artemisinin-based combination therapy (QAAC) through private sector distribution channels and is currently active in six countries.¹⁰

Profile M-3: Evaluating the Global AMFm Project Phase I. Project: AMFm, External Evaluation, Multiple Countries, 2012

In 2012, an external evaluation was conducted to assess the extent to which AMFm had achieved its Phase 1 objectives globally. The evaluation utilized baseline and endline secondary household survey data and nationally representative outlet surveys to identify key outcomes, as well as documenting the implementation process in each pilot country. Baseline and endline results were compared to the six established evaluation benchmarks to assess if any changes could be attributed to AMFm. Benchmark 4, for example, specifically sought “At least a 5-percentage point increase from baseline 2010 to endline 2011 in the percentage of children under age five years with fever in the last 2 weeks who received ACT treatment.” However, at the time of the evaluation, endline data for benchmark 4 were not available. To further assess impact, two complementary studies were also carried out. One study in a remote area conducted at endline in 2011 assessed price, market share, and availability of ACTs in hard to reach remote areas versus non-remote and urban locations. Another study assessed if ACTs with the AMFm logo had been successful in raising public awareness about ACT and whether this produced a marketing effect.

Measures of Effectiveness

Private sector “outlets” as reported here included a range of private sector entities across countries, including (in order of predominance) drug shops, general stores, private health

⁸ Institute of Medicine (2004).

⁹ A. A. Adjei et al. (2016).

¹⁰ The Global Fund to Fight AIDS, Tuberculosis, and Malaria (2018).

facilities, pharmacies, and itinerant vendors. The results of the multi-country evaluation(s) encompassed a wide variety of findings, including the following:

- Between baseline and endline there were large and significant increases in QAACT availability among all private sector outlets in Ghana, Kenya, Nigeria, Tanzania mainland, Uganda, and Zanzibar, with increases of 24–52 percentage points. Niger had a more modest increase of 10 percentage points.
- At endline, QAACT availability across all sectors ranged from 19% to 85%. QAACT availability was lowest in Niger (19%) and Madagascar (28%), ranged from 54% to 70% in Kenya, Nigeria, Tanzania mainland, and Uganda, and exceeded 80% in Ghana and Zanzibar.
- Availability of QAACTs with the AMFm logo was substantially higher than those without the logo everywhere except Madagascar and Niger. The availability of QAACTs without the logo varied from 6% to 21%.
- At endline, the availability of oral AMT was high in Ghana (41%) and Nigeria (34%). In all other intervention countries, oral AMT was stocked by less than 1% of outlets. There was little change between baseline and endline in all countries other than Zanzibar (Tanzania), where oral AMT availability fell from 17% at baseline to a negligible level at endline. In Ghana, oral AMT was primarily available in the private for-profit sector (47% of outlets at endline).
- Large and significant falls in median QAACT price per adult equivalent treatment dose were seen in the private for-profit sectors of six of the eight pilots, with the decline ranging from USD 1.28 to USD 4.82. No significant price change was observed overall in Uganda, but there was a significant fall of USD 2.68 in urban areas.¹¹ In Madagascar, there was a significant increase in the median price (USD 0.46), but the median price at baseline was only USD 0.14, reflecting the presence of an ACT subsidy program at baseline (brand name ACTipal), which included a very low recommended retail price (USD 0.10-0.20 for an adult equivalent treatment dose).
- QAACTs were slightly more expensive in urban than rural areas, except in Uganda, where the median prices were the same and in Nigeria, where the price was higher in rural areas.
- In the private for-profit sector at endline, QAACTs with the AMFm logo were generally much less expensive than those without the logo. In Ghana and Zanzibar, the price of QAACTs without the logo in the private for-profit sector was around seven times higher than those with the logo. In Kenya, Niger, and Nigeria, QAACTs without the logo were somewhat more expensive. In Uganda, the median price was the same for the two types of products, while in Tanzania mainland, QAACTs without the logo were less expensive in rural areas, but considerably more expensive in urban areas.
- Large and significant increases in QAACT market share were seen between baseline and endline in Ghana, Kenya, Nigeria, Tanzania mainland, Uganda, and Zanzibar, ranging from 16 percentage points in Tanzania mainland to 48 percentage points in Zanzibar. Madagascar saw a significant increase in QAACT share in urban areas of 23 percentage points. There was a large decrease in the market share of non-artemisinin

¹¹ Uganda was the only country that did not implement a recommended retail price during the pilot phase (recommended retail price on ACT was only implemented in Oct 2014). As a result, the significant cost savings achieved at the top of the supply chain thanks to the AMFm were not passed to the final consumers.

therapy in all countries, except Madagascar, where the decrease was small, and Niger, which saw an increase in the share of artemisinin therapy and a corresponding fall in the QAACT share.

- The vast majority of QAACTs sold in the private for-profit sector bore the AMFm logo in all countries except Niger, where both product types had a very low market share (each less than 5%).

Key Lessons

AMFm established six success benchmarks: 1) 20 percentage point increase in QAACT availability; 2) Median price of QAACTs with AMFm logo is <3 times the median price of the most popular antimalarial in tablet form that is not a QAACT (ratio); 3) Median price of QAACTs with AMFm logo is less than the median price of AMT tablets (difference, QAACT–AMT); 4) 5 percentage point increase in percentage of children with fever who received ACT treatment; 5) 10 percentage point increase in market share of QAACTs; and 6) Decrease in market share of oral AMTs (percentage point change). Five of the eight pilots met success benchmarks for QAACT availability and QAACT price relative to the most popular antimalarial that is not a QAACT. Four pilots met the success benchmark for QAACT market share. The success benchmarks related to AMT price and market share were met in all pilots with sufficient AMTs in the market to make these benchmarks relevant. The researchers concluded that possible facilitating factors for AMFm success in some countries included: 1) strong AMFm governance structures (including steering committees) and involvement of the private sector and technical assistance from the Clinton Health Access Initiative (CHAI); 2) generally smooth operation of the registration process for first-line buyers and ordering through the copayment mechanism; 3) strong, large-scale mass media campaigns, including promotion of the AMFm logo; 4) longer duration of implementation; 5) complementary regulatory changes, such as giving ACTs OCT status and implementation of the AMT ban; and 6) AMFm training in some countries (although only Ghana and Zanzibar had more than 20% training coverage).

Further, they concluded that possible hindering factors included: 1) delays in the public sector procurement process for copaid ACTs; 2) issues with Global Fund grants and delays in procurement of supporting interventions, meaning that implementation of most supporting interventions lagged behind the arrival of copaid ACTs by several months; 3) suspension of Global Fund disbursements or grants interrupting implementation of supporting interventions; 4) application of Global Fund demand levers to ration orders; 5) political and/or economic instability; and 6) an antimalarial provider market dominated by highly informal outlets operating outside of regulated distribution channels (in Madagascar and Niger).¹² Overall, the external evaluation concluded that AMFm has been a “game changer” in the private for-profit sector with the exception of those in Niger and Madagascar, with a material impact on the antimalarial market, through substantial increases in QAACT availability, decreased QAACT prices, and increased QAACT market share. These changes were substantial considering the short time frame, demonstrating the distributional capacity of the private sector.

¹² C. Goodman et al. (2012).

Profile M-4: The impact of Ministry of Health interventions on private medicine retailer knowledge and practices on improving antimalarial treatment in Kenya. Project: Kenya Division of Malaria Control trial implementation, 2002

Small-scale interventions to train private sector medicine retailers on malaria treatment have been shown to improve OTC medicine use, but there is little evidence on overall effectiveness to treat childhood malaria at scale. The 2001 Kenya National Malaria Strategy included home based management of malaria and specifically promoted programs to strengthen private medicine retailer (PMR) practices and community use of OTC antimalarial medicines.

Intervention

In 2002, with financial support from the Global Fund and UNICEF, the Division of Malaria Control in the Ministry of Health (MOH) adopted a policy to implement PMR training programs in malaria endemic districts of Kenya, beginning with five district “demonstration” programs. Generally, in the Kenyan context, private medicine shops vary in size and sell household goods alongside OTC medicines such as antimalarials, painkillers, and cough syrups. They are not allowed to sell prescription medicines.

Following the Division of Malaria Control guidelines, three districts implemented programs with two parts: 1) workshop-based training of all PMRs selling antimalarial medicines and 2) public information campaigns highlighting the use of OTC antimalarials. The intervention used the existing structure of the retail sector and did not interfere with existing antimalarial distribution channels. Centrally produced IEC materials included information booklets for PMRs to support training activities and posters. The implementing team was made up of the divisional public health officers (officers in charge of public health activities and sanitation in the local areas), undertaking the main management and training roles, and locally trained community resource persons who supported local coordination of training and public information campaigns. During two-day workshops, PMRs¹³ were trained on the signs of simple and severe malaria, malaria treatment and prevention, drug resistance, referral practices, storage and expiry of medicines, and communication skills. Public information activities were based on local public meetings and use of posters outside trained outlets and in public places.

Measures of Effectiveness

This study was conducted between July and October 2005 using a randomized controlled approach to evaluate the large-scale MOH programs in three of the five “demonstration” districts. Findings indicated that 30.7% of retailers in the intervention arm and 5.2% of retailers in the control arm sold MOH AQ to surrogate clients with the correct advice on administration. Similarly, 61.8% of retailers participating in the intervention and 6.3% of retailers in the control arm reported having the correct knowledge regarding dosing with AQ. There were no differences in the intervention and control arms in the proportion of PMRs that stocked antimalarial medicines across all sites. Of all outlets with any antimalarial in stock, 88.8% of PMRs in the intervention arm and 73.5% of PMRs in the control arm stocked AQ. Across all the districts, PMRs receiving the intervention more commonly asked questions about the age of the client, duration of the illness, and any previous treatments received. Among caregivers who were sold any antimalarial medicine, a higher proportion of those accessing a PMR in the

¹³ Private Medicine Retailers (PMRs) as defined in this study included sellers located in rural settings and described as relatively stable on the basis of local knowledge. The shops varied in size and scale of products available. There were no differences between the control arm and intervention arm in terms of sex, age, or level of education.

intervention arm (52.4%) received appropriate advice on their use, compared to 21.5% in the control arm.

Key Lessons

Kenya's large-scale approach to training PMRs and involving them in the national malaria control framework led to significant improvements in retailers' practices across the three districts. In particular, there were marked improvements in PMR practices. A significantly higher proportion of PMRs in the intervention arm stocked AQ medicines, asked questions about the age, duration of illness, previous treatment, and sold AQ with accurate information on its use. PMR personnel in the intervention arm were also more likely to know how to use AQ medicines than those from the control arm. In short, the large-scale MOH malaria control programs' targeting of PMRs in Kenya led to important improvements in PMR knowledge and practices. This study clearly demonstrates that **district health initiatives based on short trainings of PMRs and other private sector medicine retailers, paired with traditional public information campaigns with simple IEC materials, can improve private provider performance in the treatment of childhood malaria at the community level and have the potential to improve child survival in malaria-endemic settings.**¹⁴ Long-term evaluations of the impact of PMR programs on retailer practices and community drug use are important future areas of research.

Profile M-5: Introducing malaria rapid diagnostic tests in private medicine retail outlets. Project: Systematic literature review supported by multiple donors, 2017

Caregivers of children with symptoms of malaria often seek treatment from PMRs at the community level as their first point of care. Although many PMRs may dispense antimalarial medications, they do not always provide diagnostic services, which can lead to over-prescription of antimalarials when prescribing is based on symptomatic presentation alone. While the use of mRDTs has increased effectiveness of malaria diagnosis in the public sector in sub-Saharan Africa, in the private sector, mRDT access and use has remained low. Given that roughly one-third of febrile children being treated with antimalarial drugs will access them through private providers, ensuring that these providers have access to mRDTs is essential in improving effective diagnosis and appropriate treatment in malaria-endemic countries.

Intervention

Visser et al. (2017) carried out a systematic literature review to assess global experience with the introduction of mRDTs in PMRs, study outcomes, and factors to success that can inform scale-up. The review looked for outcomes relating to mRDT uptake, provider referrals, and adherence to protocols, cost, and safety. Additionally, the review examined the characteristics of interventions that were successful in introducing mRDTs. A total of 1,645 titles of studies or grey literature materials published prior to November 2016 were identified, and following title and abstract review, 136 publications were reviewed in full. A total of 12 studies were included for analysis, the majority of which profiled mRDT scale-up efforts in sub-Saharan Africa among drug shops or community pharmacies. Characteristic of the studies included the following:

- Many were trials of pilot inventions introducing mRDTs in PMRs, including a control arm without mRDTs and in the case of three studies, multiple mRDT intervention arms.

¹⁴ T. Abuya, et al. (2009).

- The number of private sector outlets included in the studies ranged from 29 to 600.
- In all of the studies, mRDTs were provided free of charge to patients or were heavily subsidized.
- Length and intensity of training delivered to providers varied from half a day to five days, and training content covered malaria symptoms, policies on antimalarial dispensing and safety, and adherence to test results in studies with an intervention arm.

Measures of Effectiveness

Appropriate diagnosis and treatment outcomes were assessed by looking at the studies' mention of uptake of mRDTs, RDT positivity and subsequent ACT provision, adherence to RDT results, referrals, safety and accuracy in performing RDTs, and the price patients paid for the mRDT. Findings included the following:

- All of the 12 studies¹⁵ included were small-scale trials or pilots of six to eight months, many of which were evaluated at a single point in time. The studies reported on mRDT uptake. However, five of the six formally published studies reported uptake under 50%, and uptake was as low as 8% in a study in Nigeria among the intervention arm, and as high as 100% in a study in Ghana.
- Eight of the 12 studies reported on the provision of ACTs, which ranged from 30% to 60% in the six published studies. Two studies from Uganda reported the highest and the lowest percentages of ACT use (81% and 29% respectively). When ACT provision between intervention and control arms was examined, fewer patients in the mRDT intervention arms received ACTs when compared to the control arms. In three of the included studies, "10 to 40 percentage points fewer patients in the mRDT intervention arms compared to the control arms obtained ACTs" (Visser et al. 2017). In one study in Uganda, patients in the intervention arm were more likely to receive ACT than those in the control arm by roughly 20%. In three studies, 50% to 60% of mRDTs used yielded a positive result.
- All of the included studies reported on provider adherence to RDT results, with **mRDT-negative patients less likely to receive antimalarials when diagnosed in an intervention arm**. In eight of the 12 studies, the percentage of mRDT-negative patients in an intervention arm who received an antimalarial was at or below 20%. In all 12 studies, the percentage of mRDT-positive patients in an intervention arm receiving antimalarials was above 65%, with six of the studies reporting percentages at or in excess of 85%.
- Five of the studies reported on patient referrals. Providers in these studies were trained to refer patients with malaria symptom presentation who were mRDT negative; however, **referral rates were low (10%) in four of the studies, which was attributed to a lack of formal referral systems and fear of losing clients**.
- Generally, most providers accurately performed mRDTs and were able to read results and follow protocol regarding the disposal of medical waste. In six studies, 85% or more of providers performed the test safely and appropriately. However, some studies found

¹⁵ The 12 included studies covered the countries of Liberia, Ghana, Myanmar, Uganda (x3), Tanzania, Nigeria (x2), Kenya, and Zambia.

issues with proper disposal of sharps, following infection and prevention protocols, and not waiting the appropriate amount of time to read mRDT results.

- Seven of the studies had a recommended retail price benchmark for purchase and clinical administration of the mRDT product. Retail prices ranged from USD 0.32 in Liberia and USD 1.02 in Nigeria.

Key Lessons

This systematic review found that while mRDT access can improve case management of febrile illnesses and intensive interventions usually displayed better outcomes, it is unclear whether interventions are sustainable or could be scaled to a national level. Three studies, one in Ghana and two in Uganda, displayed the highest uptake and adherence. These studies were characterized by longer trainings of four to five days, frequent supportive supervision, and low mRDT prices, meaning USD 0.20 or less. However, these studies included lower numbers of retail outlets, raising the question of whether larger interventions will demonstrate the same effectiveness.

Further, similar intervention characteristics did not produce similar outcomes across countries. In Nigeria, a study assessed the uptake of mRDTs and adherence to treatment guidelines in several interventions and found that **longer trainings did not significantly impact uptake or adherence**. In line with this finding, a study in Myanmar found that half-day trainings produced uptake and adherence that were an improvement over other interventions with longer trainings, **and a study in Tanzania found that increasing an mRDT subsidy by over 50% to reduce the direct cost-to-client did not increase client uptake of mRDTs**. Both public and private providers faced similar pressures to dispense antimalarials despite mRDT access or outcome, fearing that a client's condition would worsen and wanting to meet the demands of clients. The comparability of outcomes may be limited due to differing study settings and contexts, evaluation timing, method of data collection, number of outlets included in the study, and contamination of commodities (i.e., leakage from the public sector flooded the market with mRDTs).

In conclusion, the researchers carrying out this review believed that **none of the interventions assessed could be scaled up easily at the national level, as the inputs were too intensive. Interventions that required fewer resources were potentially more scalable, but also often produced poorer outcomes, including low RDT uptake and adherence, stock outs, and low engagement in behavior change communication (BCC) activities that could have led to increased uptake and adherence**. Findings from these studies suggest that introducing mRDTs through PMRs should be seen as part of introducing more comprehensive services. In order to achieve this, **the researchers suggest looking at approaching malaria from an integrated case management lens**, developing evidence around the training and coaching of PMR staff and introducing strategies to deal with hazardous waste at scale. Lastly, scale-up of mRDTs via the private sector will need to be appropriately addressed in the legal and regulatory frameworks of countries and broadly recognized by stakeholders.¹⁶

¹⁶ T. Visser, et al. (2017).

Profile M-6: Improved malaria case management in formal private sector through public private partnership in Ethiopia: Retrospective descriptive study. Project: USAID Private Health Sector Program, Ethiopia, 2012–2015

In 2013/2014 there were almost 60,000 public sector hospitalizations in Ethiopia due to malaria. Malaria-related services are provided free in the public sector; however, a significant number of Ethiopians still choose to seek malaria care from the private sector. In working toward malaria control and elimination, engaging Ethiopia's private health sector has been deemed crucial to malaria case reporting and widening the reach of malaria case management.

Intervention

Under the USAID Private Health Sector Program (PHSP) implemented by Abt Associates, a PPP for malaria care was introduced in six regional states in Ethiopia. The intervention was initiated in April 2012 and concluded in September 2015. During this period, 110 private health facilities were engaged to implement malaria services through partnerships with a team of malaria experts from the public sector. The PHSP followed a multistep implementation strategy. First, PPP approaches were developed in conjunction with government institutions, and approach validation workshops were held with public, private, and other relevant stakeholders. PHSP worked with government institutions to conduct facility readiness assessments in private sector locations, including service integration, malaria case load, human resources, and facility-owner engagement. The program subsidized training and commodity access at private facilities deemed ready for the introduction or scale-up of malaria services, with an emphasis on capacity building, service delivery, and quality assurance. Case managers, laboratory, and supply chain personnel received four days of malaria case management and malaria diagnosis methods trainings. The program sought to also build the business management capabilities of private health facility owners, linking them to the public sector supply chain, and preparing sites for participation in the national malaria control program. As part of this, PHSP produced and distributed a malaria register, reporting forms, job aids, and national malaria guidelines. Throughout implementation, facilities received supportive supervision visits on a quarterly basis from a team of public sector malaria experts. Demand creation activities, in the form of radio messages, brochures, and posters, were also launched.

Measures of Effectiveness

Argaw et al. (2016)¹⁷ sought to evaluate the contribution of the public-private mix approach to improving the quality of malaria case management in Ethiopia. Using retrospective data analysis, 42 months of private health facility quarterly reports on malaria were reviewed to assess malaria prevalence and providers' adherence to national standards. Laboratory and malaria morbidity registers were also reviewed.

Over the course of 2.5 years (April 2012–September 2015), 873,707 suspected malaria cases were identified in PHSP-affiliated private sites and approximately 25% of them were treated as malaria cases. In April–June 2012, when the PPP implementation began, health worker adherence to AL treatment stood at 48%. By July–September 2015, this had increased to more than 95%. Similarly, adherence to chloroquine treatment for *P. vivax* infections improved from 44% to 98% in the last quarter of the intervention. The majority (96%) of suspected malaria patients who received treatment in one of the 110 PPP facilities received parasitological

¹⁷ M. D. Argaw et al. (2016).

confirmation of infection, which stands in contrast to public facilities (84%) and other private facilities (60%).

From the start of the program through September 2015, 223,293 suspected patients were treated as malaria cases. Almost all of the suspected cases were confirmed through parasitological testing. Roughly 30% of the patients were ages 14 and under (15.2% ages five and under). The majority of the malaria-suspected cases were serviced in private for-profit facilities. Adherence to standards of *P. falciparum* infection treatment (AL) improved by nearly 48%, from 47.8% (April–June 2012) to 95.7% (July–September 2015).

Key Lessons

The study found that there was a significant improvement in adherence to nationally recommended standards from diagnosis and treatment of malaria through this PPP activity. **The recommendation was made to scale up PPPs for malaria care services through national malaria prevention and control programs and implementing partners—noting, however, that PHSP-provided subsidized training and commodity access to the private sector sites—and that future PPP efforts would benefit from a stronger attention to sustainability beyond donor support.**

Profile M-7: A cluster randomized trial of text message reminders to retail staff in Tanzanian drug shops dispensing Artemether-Lumefantrine: Effect on dispenser knowledge and patient adherence. Project: ACT Consortium, Tanzania, 2012

In Tanzania, accredited drug dispensing outlets (ADDOs) are a crucial source of malaria treatment. ADDOs are regulated drug shops that have undergone a process of formalization through training and certification and sell a limited number of approved prescription drugs, including ACTs. The availability of ACTs increased in the private sector after AMFm was implemented in 2010 (See Malaria Profile M-2 and M-3 for more information on AMFm). Though ACTs are often available in these private outlets, patient adherence can be compromised by dispensers who may not provide patients with the correct ACT dosage or advice on their use that is consistent with national guidelines. Inaccurate dosage and/or poor treatment adherence leads to an array of issues, ranging from poor clinical outcomes to contributing to the growth of drug-resistant malaria.

Intervention

Bruxvoort et al. (2014) carried out a cluster randomized controlled trial (RCT), funded by the ACT Consortium via a grant from the Bill and Melinda Gates Foundation (BMGF), to assess the effect of text messages on improving drug shop dispenser knowledge and their promotion of patient adherence to treatment. The study was conducted in a poor, rural region of Tanzania with a malaria prevalence of 17.4% among children ages 6–59 months. Prior to AMFm implementation in 2010, ACTs were not widely available in ADDOs in this region; however, at the time of the study in 2012, 88% of ADDOs reported stocking ACTs.

Among the selected drug shops, 42 of the 82 received text messages, which provided guidance on appropriate dispensing practices for AL. Most dispensers had a low-level qualification (i.e., nursing assistant). Dispensers in the intervention arm received messages once a day during the business week for four weeks, then every other business day for the next 10 weeks. Seven messages containing advice about AL dispensing practices were developed based on a government training booklet and recommended dispensing practices. ADDO dispensers were

asked to complete a registration form for all patients purchasing treatment for fever. Patients in both the intervention and control arm who purchased AL at drug shops were monitored, and questions were posed about their adherence roughly 72 hours after they had visited the ADDO. They were asked to share information about AL dosages and the advice they had received from the dispenser. Blood samples for a blood smear and mRDT were obtained and double read to confirm their malaria status. Patient adherence was defined as completing treatment (which was verified) and the time that each dose was taken.

Measures of Effectiveness

Knowledge of correct AL regimen for adults was higher among dispensers in the intervention arm (90%) versus those in the control arm (78%). However, dispensers in both arms displayed less knowledge of correct regimen prescription for children (75% versus 64%). Although dispensers in the intervention arm who received text messages displayed improvement in dispensing knowledge, there was a marginal difference between arms in terms of patient adherence measured as completion of all doses or completion of each dose at the correct time. Dispenser knowledge was assessed as higher in the intervention arm in terms of 1) providing correct advice to patients; 2) demonstrating knowledge of the correct regimen and dosing for children; 3) advising patients on when to return to a health facility (i.e., if condition worsened); 4) promoting completion of treatment; and 5) advising to take a second dose after eight hours. There was no difference in knowledge between the control and intervention arm in terms of knowledge among providers related to advising patients to take a replacement dose if vomiting occurred within half an hour.

There was only a slight difference in patient adherence between arms, where completion of treatment was measured at 70% in the control arm and 68% in the intervention arm; 60% of patients in both arms reported that they were given guidance on how to take AL correctly, and timely completion stood at 33% for patients in both the control and intervention arm.

Key Lessons

The intervention successfully increased dispenser knowledge of appropriate AL guidance for patients; however, knowledge was already relatively high among these dispensers. **Although it appears that text messages did improve dispenser knowledge among the intervention arm, improvements in knowledge did not lead to an increase in patients reporting that they received additional information.** Patients in the intervention arm did not have higher levels of adherence than those in the control arm, which suggests the need to further evaluate interventions that aim to improve adherence to ACTs delivered via private sector points of care.¹⁸

Profile M-8: Impact of introduction of rapid diagnostic tests for malaria on antibiotic prescribing: Analysis of observational and randomized studies in public and private healthcare settings. Project: ACT Consortium, Multiple Countries, 2007–2013

Unnecessary and over-prescribed use of antimicrobials is seen as a driving force in the development of bacterial resistance. Diagnostic facilities for non-malaria febrile illnesses are limited in many malaria-endemic countries, leading health workers to prescribe treatments

¹⁸ K. Bruxvoort et al. (2014).

based on the symptomatic presentation of febrile patients without a confirmation that they had malaria.

Intervention

Researchers from the ACT Consortium, funded through a grant from the BMGF to the London School of Hygiene and Tropical Medicine, hypothesized that improving malaria diagnoses would reduce the overuse of antibiotics. As such, they sought to evaluate the impact of mRDTs on the appropriate diagnosis of malaria and prescription of antimicrobials (antibiotics) for febrile illness in Africa and Asia. Several linked and co-designed formative research studies were carried out between 2007 and 2013 in six countries (Afghanistan, Cameroon, Ghana, Nigeria, Tanzania, and Uganda) in both rural and urban settings to evaluate the impacts of introducing mRDTs on healthcare in various epidemiological settings and health service sectors (community, public, private retail). The studies evaluated interventions to implement mRDT where participating providers could prescribe antibiotics and antimalarials. Sites with and without the intervention were compared. Prescriber behavior was assessed and documented as a primary outcome. Individual patient data on diagnostic test results and treatments prescribed including antibiotics were analyzed.

Three separate analyses of the studies were performed to assess different clinical and policy perspectives. The first analysis looked at the risk ratio of being prescribed at least one oral or injectable antibiotic, the second analysis was restricted to patients in intervention settings with a positive test result compared with those with negative results (for the purpose of showing the effect of test results on the prescription of antibiotics), and the third analysis categorized prescribed antibiotics by drug class to investigate the use of different antibiotic classes in different settings.

Measures of Effectiveness

Across the three analyses, antibiotics were prescribed to 59% of patients in intervention groups and 53% in control groups. This included 40% of patients who received a positive malaria test, and 69% of those with a negative result. The study authors suggest that this is the effect of over prescription resulting from inadequate provider knowledge or pressure from the client for a prescription. The proportion of patients given at least one oral or injectable antibiotic fluctuated from 15% to 78.5% in settings where an mRDT intervention was conducted and 18% to almost 73% in control settings. Where mRDTs were introduced, relative to control settings (in all but one of study in Nigeria), the proportion of patients receiving an “antibiotic prescription was higher or had a trend towards being higher with risk ratios ranging from 0.65 to 2.98.” The likelihood of appropriate antibiotic prescription was 21% higher where mRDTs were introduced, although there was heterogeneity between studies. Analysis found that the prescription of antibiotics was higher among patients who tested negative for malaria. Antibiotics were prescribed to 53% of patients in control groups and 59% in intervention groups. Trimethoprim-sulfamethoxazole (TMP-SMX, or cotrimoxazole) and penicillin were the antibiotics most commonly prescribed, with metronidazole ranking third. However, some of the studies showed that up to 52.1% of cases (Cameroon) did not know the type of antibiotic being prescribed because of coding issues or a weak data collection approach.

Key Lessons

The ACT consortium studies demonstrate that mRDTs, when deployed in conjunction with effective training, can decrease the overuse of antimalarials. However, in this analysis, which included over half a million children and adults with acute febrile illness in Asia and Africa, **researchers found that introduction of mRDTs to reduce unnecessary use of**

antimalarials could contribute to an unintended increase in the use of antibiotics; this unintended effect was highest among those who tested negative for malaria but was also found among approximately 40% of those testing positive for malaria.¹⁹

Diarrhea Case Management

Of the 39 papers describing diarrhea-focused interventions, nearly 70% focused on programs in Asia, a quarter focused on programs in West Africa, and several discussed interventions in East Africa. As in the case of malaria, the majority of these interventions focused on private medicine vendors or other community-based drug dispensers; however, several papers also discussed interventions targeting diarrhea treatment among private physicians and hospitals, community-based organizations, CHWs, and nursing facilities. The project profiles outlined below were selected to demonstrate the range of themes and key lessons emerging from global implementation experience, including (but not limited to) the importance of public-private collaboration for oral rehydration salts (ORS)/zinc scale-up, the key role of demand creation and mass media efforts, the effect of co-packing ORS/zinc for private sector retail, and the cost-effectiveness of private sector approaches to diarrhea management. Negative findings were included that discussed the risk of increased, inappropriate antibiotic use among private providers trained to administer ORS/zinc, the need to integrate diarrhea management with other child health interventions, and the urgent need for improved private health sector regulation. Below is a summary of key findings related to diarrhea case management.

ORS/zinc projects relying on subsidized products may not be scalable or sustainable.

Many of the projects reviewed as part of this report utilized subsidized ORS/zinc commodities. Where successful, such as in Population Services International (PSI) Myanmar's project, the results may not be generalizable because of the degree of subsidization and/or the fact that private provider networks may be receiving additional donor support that will not be sustained long term. Evidence has further demonstrated that highly subsidized or free commodities can create low-price expectations among consumers, who may not be willing to pay the full market price after the end of the social marketing program.²⁰ More practical information is needed regarding the relative merits and challenges to sustainability various levels of product subsidization create.

The links between provider knowledge, caregiver awareness, and treatment use are very complex. Several papers reported improvements in caregiver awareness after the implementation of provider-focused trainings and knowledge improvement. However, experts consulted as part of creating this brief highlight how DHS data show little correlation between caregiver awareness and actual use of ORS or zinc products. In Tanzania for example, knowledge about ORS progressed by 16 points between 1992 and 2015, but ORS use declined by 12 points over the same period. **More information is needed regarding the complex process of translating caregiver awareness to actual product use.**

There is mixed evidence regarding the importance of mass media and interpersonal communication (IPC) in creating demand, increasing awareness, and encouraging correct, consistent use of ORS/zinc products. In Indonesia, the Point-of-Use Water Disinfection and Zinc Treatment Project (POUZN) found that a sustainable marketplace for a new product can be quickly generated under the right conditions and when matched to local context. Once producers recognize the value that a new product offers them, they will contribute

¹⁹ H. Hopkins et al. (2017).

²⁰ G. Fisher et al. (2013).

their own resources, as long as appropriate public policy components are in place. In Benin, the program found that using mass media was essential to creating awareness and generating demand for previously unknown zinc products. This was especially true in urban areas. However, experts consulted as part of creating this brief highlight how there are also several examples of mass media and IPC campaigns that failed to achieve their objectives. For example, in Tanzania, the POUZN project's BCC campaign, which targeted caregivers using community-level activations, road shows, and radio spots between 2007–2010 appears to have had limited impact, and in Ethiopia, improved care seeking for diarrhea between 2010 and 2016 may have been more closely linked to health infrastructure and health workforce improvements rather than parallel mass media efforts.²¹ Demand creation activities and mass media efforts may therefore be an important component of a comprehensive ORS/zinc project, but more evidence is needed regarding their efficacy in reaching intended targets, triggering expected behavior change, and overcoming additional barriers such as cost to action.

Additional provider training and knowledge transfer activities (such as supportive supervision and/or pharmaceutical detailing) are needed to curb the over-prescription of antibiotics and antidiarrheal agents and to increase the confidence of private providers in advising on ORS/zinc use. Ensuring that private providers are adequately trained to participate in collaborative efforts to target and meaningfully engage on childhood diarrhea are essential to promoting the short- and long-term impact of interventions. Further, once providers are trained and active at their worksite, they require some form of ongoing support and continuing education. Several papers demonstrate that supportive supervision from public, private, or donor sources can enhance pharmaceutical practices and reduce unnecessary or over-prescription of antibiotics. Further, models borrowed from the pharmaceutical industry adapted to the realities of private providers has also demonstrated success.^{22,23}

In addition to provider level activities, incorporating community-level BCC to circulate messages regarding appropriate sources of diarrhea treatment and to maximize the impact of those messages on care-seeking practices. In addition to increasing awareness activities targeting caregivers, interventions should include generating demand for ORS/zinc.

More efforts are needed to discourage the use of zinc as a stand-alone product. Several studies reported that provider-prescribing behavior for childhood diarrhea improved with access to training and subsidized commodities. However, more incentives are needed to encourage the use of ORS/zinc together, such as in a co-pack/diarrhea treatment kit (DTK).

Partnership is critical to success. As demonstrated in the Scaling Up Zinc for Young Children (SUZY) project, partnerships between government, NGOs, and the private sector are critical to ensuring the success, scale, and sustainability of private sector initiatives. Partnerships can effectively align incentives, promote improved knowledge acquisition and exchange between actors, and help guide long-term strategic planning.

There are challenges when informal private providers are operating illegally. The Diarrhea Alleviation through Zinc and ORS Therapy (DAZT) model and other implementation experiences highlight how identifying and working with informal private providers can be a challenge when those providers are operating underground and/or are reluctant to be identified by the public sector. Efforts that involve informal providers or those otherwise wary of the public sector must

²¹ Academy for Educational Development (2011).

²² Y. Tao et al. (2017).

²³ CHAI (2011).

work to support formalization of private facilities through licensing or accreditation, for example, and ensure collaborative efforts do not lead to negative consequences for private providers.

Future programs must make private providers aware of the dangers of incorrect or unnecessary treatments. There remains a risk that private providers capacitated to provide ORS/zinc will not demonstrate improved prescribing behavior. Program efforts that seek to increase the supply of these interventions must also work to ensure providers understand the dangers of mistreatment with antidiarrheals and antibiotics, including the risks of drug resistance or negative patient outcomes. For example, in one study, practitioners maintained the belief that children with mild dehydration should not drink ORS because of the salty taste. Similarly, some providers were unable to adequately inform caregivers that ORS can increase the frequency of stool. Given that there is no simple assessment tool or clinical technique to differentiate between bacterial and non-bacterial causes of child diarrhea, private providers are often faced with significant uncertainty in recommending treatment. Experts consulted as part of preparing this brief posited that many providers simply prescribe an antibiotic as the safe option. Provider training programs must take this into account, emphasizing the correct use of antibiotics, the risks of antimicrobial resistance, and, most importantly, the routine use of ORS/zinc.

Diarrhea Case Management Profiles

Profile D-1: The effectiveness of the Point-of-Use Water Disinfection and Zinc Treatment Project. Project: USAID POUZN, Multiple Countries, 2005–2010

Diarrhea remains one of the biggest threats to child health. At the time of this study, globally, approximately 1.5 million childhood deaths per year were attributed to diarrhea, an estimated 17% of all child mortality at the time (UNICEF/WHO 2009). According to data from 2005–2008, only one third of children with diarrhea in the developing world were given ORS. The lowest rates of ORS use were found in South Asia and Africa. Starting in 2004, the WHO and UNICEF recommended that national guidelines for treatment of diarrhea include zinc therapy and a new low-osmolarity formulation of ORS.

Intervention

In 2005, USAID launched the five-year POUZN project in order to increase the availability and use of ORS/zinc. POUZN was a multinational project led by the Academy for Educational Development, Abt Associates, and PSI. Implementers partnered with local pharmaceutical industry leaders in countries of implementation to build provider demand and increase uptake of zinc among young children with diarrhea. The project had several aims, including: 1) building a nationwide supply of zinc; 2) creating an enabling environment for adoption of the new treatment; and 3) influencing the prescribing behaviors of providers and creating demand among caregivers. In order to increase access to diarrhea prevention and treatment products for caregivers of children under age five, POUZN used both commercial and social marketing approaches. Approaches deployed included expanding the provision of affordable water disinfection products targeted at the household level and marketing zinc products as an addition to ORS that could decrease the severity, duration, and recurrence of diarrhea in children.

To create a sustainable supply of both ORS/zinc products, POUZN partnered with commercial manufacturers and private sector distributors who could produce high-quality products. In countries where commercial approaches were not realistic or consumers' ability to pay was more limited, subsidized and socially marketed brands were introduced. The project's strategy

was to eventually jump-start the commercial market for ORS/zinc, which in turn would demonstrate to commercial firms that these products were commercially viable. Each partnership was coupled with an accompanying behavior change strategy, supported by POUZN, which aimed to increase knowledge about the prevention and treatment of diarrhea, instill certainty about the benefits of point-of-use (POU) water and zinc products, and overcome behavioral barriers to appropriate use.²⁴

Measures of Effectiveness

The POUZN project conducted impact evaluations in seven of its countries (Benin, Kenya, DR Congo, Madagascar, Nepal, Pakistan, and Rwanda). Household surveys were conducted in all of the countries and were supplemented by (in selected countries) qualitative surveys and mystery client surveys to complement program evaluations. Impact evaluations were conducted for four of the POU programs. Evaluations found that many caregivers do not seek advice or treatment outside of the home. For example, in Benin and Madagascar, almost 20% of respondents reported that they did not treat diarrhea at all. In three of the programs, ORS/zinc use was high, including when products were not co-packaged. However, adherence to the recommended 10-day regimen was mixed; accordingly, researchers recommended that adherence receive focused attention in ensuing programs.

In Benin, one in three children sick with diarrhea were given zinc in 2009. In 2011, this increased to over half of children with diarrhea receiving zinc. ORS use also increased by 18% (40%–58%). Almost all zinc users correctly administered ORS/zinc in 2009 and 2011 (97% and 100%, respectively).

In Nepal, from 2006 to 2008, zinc use increased from 4% to 15.4%. An independent study drawing on POUZN data from a population-based household survey further found that the project successfully promoted zinc use. Per the survey, 15% of children with diarrhea surveyed two weeks prior to the survey were treated with zinc (irrespective of having received ORS), a significant increase compared to use as reported in the Nepal 2006 DHS. The objective of the communication campaign was to improve knowledge and perceptions of zinc and, accordingly, was successful in increasing use. Over half of survey respondents had heard of zinc and almost 70% held the perception that zinc is effective for treating diarrhea.²⁵

Key Lessons

By increasing access to zinc (and POU) and increasing exposure to key messages, significant uptake diarrhea treatment products is possible. Deploying mass media and IPC is essential to creating awareness and encouraging correct, consistent use of health products. A key lesson learned was that program design must be adapted to local contexts. For example, in Indonesia, POUZN found that a sustainable marketplace for a new product can be quickly generated under the right conditions.²⁶ **Once producers recognize the value that a new product offers them, they will contribute their own resources, as long as the appropriate public policy components are in place.**²⁷ Producers learned that by establishing common messages, both sectors could benefit from amplified promotion and help assure quality outreach.²⁸ In Benin, the program found that using mass media was essential to creating awareness and generating demand for previously unknown zinc products. This was especially

²⁴ A. Stene et al. (2011).

²⁵ W. Wang and V. MacDonald (2009).

²⁶ Academy for Educational Development (2011).

²⁷ Stene et al. (2011).

²⁸ POUZN Project(b) (2010).

true in urban areas. Additional findings showed that building on brand name recognition can be a successful marketing approach.²⁹

Profile D-2: The effect of drug detailing and trainings among private providers on the uptake of ORS/zinc. Program: Diarrhea Alleviation through Zinc and ORS Therapy (DAZT), Uttar Pradesh, India, 2011–2014

At the time of this study in 2011, diarrhea was the third-leading cause of childhood mortality in India and responsible for 13% of all deaths per year in children under age five.³⁰ Most diarrheal deaths can be prevented by a simple and effective treatment regimen of ORS/zinc. Despite being widely available in India since the 1980s, ORS is used only to treat one quarter of diarrheal episodes. Similarly, zinc was first endorsed by the Indian Academy of Pediatrics in 2004 but was not widely available in Uttar Pradesh (UP) until 2011.

Intervention

The BMGF's four-year DAZT program, which built on the POUZN/India project, was launched in 2011 and sought to improve diarrhea treatment for children under five by encouraging uptake of ORS/zinc among private sector clients in UP, India. In UP, caregivers of children with diarrhea often seek care from private providers versus public sector providers. The goal of the private sector interventions, led by FHI360, was to increase ORS/zinc prescribing among both formal and informal private sector providers. The DAZT program deployed a two pronged "push–pull" strategy to engage the private sector. The "push" worked to change diarrhea prescription practices through routine drug detailing for informal providers and formal training sessions for practicing and registered private sector physicians. For the "pull" component of the strategy, FHI360 recruited and trained staff from NGOs and private pharmaceutical companies in the treatment of childhood diarrhea with ORS/zinc. Rural, informal private sector providers received visits from trained staff to promote and sell ORS/zinc.³¹

Measures of Effectiveness

To evaluate the effectiveness of DAZT, Walker et al. (2016)³² conducted an independent descriptive study of the project activities in 2012, one year after program roll-out in June 2011. Evaluators conducted interviews and direct observations among a randomly selected group of both formally registered and informal (unregistered) private sector providers in 12 districts in UP. The evaluation found that 67% of providers reported receiving a diarrhea treatment training or drug detailing visit. However, during the interviews, only 14% of providers reported prescribing zinc to all children with diarrhea and 36% reported prescribing zinc to more than half of diarrhea cases. Direct observation showed 77.3% of providers prescribing ORS and 29.9% prescribing zinc independent of ORS. Treatments other than zinc and ORS were commonly prescribed, including antidiarrheals (17.5%) and antibiotics (61.9%). Providers reported their intention to prescribe ORS/zinc during the interviews, but were less likely to do so in the observation portion of the study. While this study suggests some improvement in provider knowledge and prescribing behavior, it is a descriptive study at a fixed point in time.

²⁹ USAID and Abt Associates (2010).

³⁰ S. Lakshminarayanan and R. Jayalakshmy, (2015).

³¹ Informal private providers refers to any health professional or cadre operating or working at health facilities that are not officially certified or legally registered with the national health authorities. A formal private provider would be any health provider or cadre that is officially certified or legally registered with the relevant national health professional council or registration board.

³² Walker (2016).

In other global contexts, separate studies have more rigorously measured the effectiveness of drug detailing and training among private providers. In Nigeria, Tao et al. (2017) found that peer detailing among proprietary patent medicine vendors (PPMV) providers increased overall knowledge of the most effective treatment for diarrhea, and logistic regression analysis suggested that PPMVs had higher odds of having both zinc and ORS in stock as compared with PPMVs that were not detailed in the previous month.³³

Key Lessons

Informal private providers who play a major role in childhood diarrhea treatment in hard-to-reach areas and are the most sought source of care for childhood diarrhea in UP. Understanding private providers' knowledge and willingness to provide appropriate diarrhea treatment, including ORS/zinc, is crucial. The DAZT private sector model mirrors how drug information is delivered to private providers through drug detailing visits. **The authors argue that the expansion of drug detailing to include zinc and ORS represents a sustainable approach, especially for reaching the informal sector with critical information and products for adequately treating childhood diarrhea.** However, communication to USAID by POUZN-implementing partners suggested that sustainability was a major challenge, as most companies would not pay for detailers to visit rural medical providers where prescribing volumes were low. Building on this knowledge, CHAI implemented a follow-on ORS/zinc program in UP and two other Indian states that sought to address sustainability through different partnership, including partnering with the pharmaceutical sector. Findings from that program are expected in early 2019.

Informal private providers often operate underground to avoid government penalties for practicing medicine without recognized credentials, accordingly, the DAZT model also highlighted the challenges in identifying and working with informal private providers. In spite of the Indian Academy of Pediatrics guidelines which do not recommend antibiotics for the treatment of acute diarrhea, antibiotics remain the first line treatment for most private providers. In spite of **these challenges, informal private providers continue to be the first choice of caregivers and should continue to be targeted for diarrhea management programming. Additional training and knowledge transfer activities are needed to curb the potential misuse and over-prescription of antibiotics and antidiarrheals and to increase the confidence of private providers in advising clients to utilize ORS/zinc treatments.** Policy makers and program implementers must ensure collaborative efforts to target and meaningfully engage informal private providers.

Profile D-3: An external evaluation of the Diarrhea Alleviation through Zinc and ORS Treatment. Project: DAZT, Gujarat and Uttar Pradesh, India, 2011–2014

As outlined in profile D-2, the DAZT program was implemented from 2011 to 2013 in Gujarat and from 2011 to 2014 in UP, India, in order to measure scale-up in the availability and uptake of ORS/zinc for the treatment of diarrhea among children under age five. This profile (D-3) relates to an external evaluation conducted in 2015 to assess the efficacy of the DAZT program.

Intervention

The main objective of the DAZT program was to scale-up adequate treatment of diarrhea among children under age five through both public and private sector channels in selected rural

³³ Tao and al. (2017).

districts of India. Nutrition International³⁴ and FHI360 were tasked with carrying out project activities in the public and private sectors, respectively. As profile D-2 above described, Walker et al. (2016) conducted a descriptive study of drug detailing interventions within DAZT in UP, profile D-3 here describes an external evaluation of the effectiveness of DAZT program as a whole in Gujarat and UP. Key project components included building the capacity of health providers and frontline health workers (in both the public and private sectors) and ensuring a donated ORS/zinc supply so that delivery could be extended to communities through frontline workers and at health facilities by trained service providers free of charge.³⁵ The overall goal of the private sector activities was to increase ORS/zinc prescribing by both formal and informal private sector providers. Formal providers included those who had completed government-recognized medical degrees. Informal providers included those with no medical training or certificates in traditional *Ayush* (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy) medicine. To target both groups, FHI360 used a “push–pull” strategy as outlined in profile D-2.

Measures of Effectiveness

This evaluation aimed to assess changes in ORS/zinc treatment during the program period through cross-sectional household surveys in program districts at baseline and end line. State-specific logistic regression models were constructed with generalized estimating equations to assess changes in ORS/zinc treatment. Findings reflect that over the course of the DAZT project, zinc coverage increased significantly in Gujarat (2.5% at baseline to 22.4% at endline) and modestly in UP (3.1% to 7.0%); however ORS coverage was significant in Gujarat (15.3% to 39.6%) but almost negligible in UP. In both states, the probability of adequate treatment was higher among those who sought care outside the home, but the effect was greater in the public sector, as compared to the private sector. Between baseline and endline, recognition of public sector providers as appropriate sources of diarrhea care and zinc awareness increased in both Gujarat and UP, and ORS awareness increased in Gujarat. Among caregivers of children with diarrhea in the preceding two weeks, public sector care seeking was higher at endline, private sector care seeking remained high in UP and experienced a slight decrease in Gujarat. Diarrhea prevalence decreased from baseline to end line, however, this was likely attributable to the surveys timing (different diarrhea seasons). The proportion of children treated with antidiarrheals from baseline to endline experienced a statistically significant increase in both regions. The proportion of children who received antibiotics was higher at endline in Gujarat but not in UP. Unlike the trend in antidiarrheals, the increase in antibiotics observed in Gujarat was primarily driven by a rise in the proportion of children obtaining antibiotics in the private sector, as antibiotics obtained via the public sector did not change between baseline and endline.

Key Lessons

The stark difference in ORS/zinc coverage levels between Gujarat and UP highlights **how contextual factors in the implementation setting are central to understanding the success or failure of an intervention**. Per the authors suggestion, since the odds of receiving ORS/zinc were higher in the public sector, it is possible that less robust ORS/zinc coverage in UP was due, potentially in part, to the relatively smaller increase in public sector health-seeking behavior. Experts consulted during this review drew attention to how additional programmatic differences or contextual factors like the scale of intervention, intensity, and quality of implementation may also have played a central role in differences between the two states.

³⁴ Formerly Micronutrient Initiative (MI).

³⁵ Nutrition International (n.d.).

Increases in ORS/zinc awareness and greater recognition and utilization of public sector channels for diarrhea care seeking occurred in spite of the lack of caregiver demand generation activities. **Given the program's sole focus on provider-level activities, changes in caregiver knowledge and practices could only have resulted through word-of-mouth.**

In order to maximize the impact of community-level BCC, future programs should incorporate messages regarding appropriate sources of diarrhea treatment and care-seeking practices. In addition to increasing awareness, activities targeting caregivers should also focus on generating demand for ORS/zinc. Future programmatic investment in the private sector is both crucial and worthwhile. **While altering the diarrhea treatment practices of private providers was challenging, only a gradual shift was observed toward public sector care seeking with the majority of caregivers continuing to seek care through private sources.** This finding emphasizes the importance of total market approaches in the treatment of childhood illness, ensuring that treatments are available from both public and private sources.

The increasing trend in antidiarrheals and antibiotics from baseline to endline may be related to the fact that through greater awareness to diarrhea management, providers were more likely to provide advice on ORS/zinc treatment but also additional, inappropriate treatments. **Future programs should be aware of this risk and focus efforts on warning providers of the dangers of misuse or over-reliance on antibiotics and antidiarrheals.** Future evaluations should seek to address these nuances, as well as diarrhea treatment preferences and expectations of both providers and caregivers. Finally, **the results suggest that provision of ORS/zinc are complementary in that the odds of receiving ORS increased when the provider recommended zinc and vice versa.** This finding highlights the importance of emphasizing both ORS/zinc in training providers in either sector. Future programs should continue to build upon prior investments in public and private sector provider training and supply chain sustainability in addition to targeted caregiver demand-generation activities.³⁶

Profile D-4: Social marketing zinc to improve diarrhea treatment practices. Project: POUZN, Cambodia, 2007

Data from the 2005 Cambodia DHS indicated that 20% of children under age five had experienced an episode of diarrhea in the two weeks preceding the survey. In response to these findings, the Cambodian MOH and PSI introduced new, low-osmolarity ORS/zinc through the private sector. The private, for-profit health sector is an important source of healthcare in Cambodia. Data indicate that many Cambodians first seek care from for-profit providers or treat illness at home. However, the for-profit private sector is not adequately regulated, resulting in health products and services that are not to standard. In 2006, the majority of pharmacies and drug sellers were not licensed. In March 2006, the Cambodian MOH and PSI, in coordination with WHO and with financial support from USAID, introduced a demonstration project to launch a DTK, branded as OraselKIT, through the private sector. The launch occurred in two provinces: Pursat and Siem Reap.

Intervention

The DTK contained two sachets of WHO/UNICEF-recommended reduced osmolarity ORS, and a blister pack of ten, 20-mg tablets of dispersible zinc and an instructional leaflet providing guidance on the treatment of simple diarrhea. DTKs were distributed through commercial retail outlets. PSI's approach worked to ensure that low-income people were able to access high-

³⁶ L. M. Lamberti et al. (2015).

quality ORS and zinc products at affordable prices which were subsidized by POUZN through private sector distribution networks. The product price was set at a price-point that was affordable for the target audience. BCC outreach was implemented through mass media and IPC was designed to encourage healthy behaviors among individuals. The product was distributed through traditional commercial retail outlets such as pharmacies and drug shops, and PSI also partnered with two local NGOs implementing rural child survival programs.

Measures of Effectiveness

A rapid assessment of this pilot program was conducted by USAID, WHO, and Abt Associates in order to measure the impact and effectiveness of the intervention on increasing the availability of zinc. The assessment was comprised of stakeholder interviews, field visits, a secondary literature review, and focus group discussions. Interviews were held at the central, provincial, and district levels with stakeholders, such as MOH authorities, retail outlet clerks, pharmacies and village shops, and caregivers at health facilities. Evaluators traveled to Siem Reap and Pursat to conduct field visits, to observe refresher trainings for local partners, visit retail outlets, village shops, and Sun Quality Health Network providers, a PSI partner. Evaluators held four focus group sessions (two with users and two with nonusers) in Kralanh district (two sessions held with 25 and 19 women respectively) and in peri-urban Siem Reap (two sessions with 14 and 19 women respectively).

Key Lessons

ORS use in Cambodia is relatively low and consumers held a negative perception of the quality of ORS previously available. By combining ORS and zinc and offering a new formulation of ORS in the DTK, the project succeeded in ensuring that caregivers did not use zinc alone and encouraged trial of the new low-osmolarity ORS. Village shops proved to be vital to improving caregiver access to appropriate treatment. Unlike clinicians or pharmacists, village shopkeepers were relatively easily persuaded to recommend the DTK. This in part was due to the lack of large variety of alternatives to recommend. Practitioners maintained the belief that children with mild dehydration would not drink the standard ORS formulation because of the salty taste. **Additionally, they observed that it increases stools, which in turn makes mothers more anxious about the lack of diarrhea cessation.** At the time of this study, the authors concluded that more efforts were needed to discourage the use of zinc as a stand-alone product and that more incentives were needed to encourage the sole use of the DTK or ORS alone. This conclusion remains relevant now. **Reinforcement of key messages on the appropriate treatment of diarrhea and training of providers is needed.** One major issue highlighted was the inadequate regulation of the for-profit private sector, resulting in inconsistent and often poor-quality health products and services.³⁷

Profile D-5: Scaling Up of Zinc in Early Childhood Project. Project: SUZY, Bangladesh, 2003–2006

The International Centre for Diarrheal Disease Research developed SUZY, a project performance framework that was developed in partnership with key stakeholders. The project was implemented in Bangladesh from 2003 to 2006, aiming to implement zinc treatment promotion and delivery strategies that would set Bangladesh on the path to reaching all children with diarrhea, regardless of gender, income, or where they live.³⁸

³⁷ M. Boggs et al. (2007).

³⁸ C. P. Larson et al. (2012).

Intervention

As a first step, a partnership comprised of a broad range of public leaders, private sector stakeholders, NGOs, and multinational sector agencies was created. Private sector participants were drawn from national associations representing licensed and unlicensed health care providers, a local pharmaceutical laboratory, and a marketing agency, and a technology transfer from the European patent holder of the dispersible zinc tablet formulation promoted in the scale-up campaign. National scale-up activities included product registration and technology transfer, formative and operational research, orientation of health professionals, and preparation of mass media messages. In late 2006, a national mass media campaign was launched to promote *Baby Zinc* for the treatment of childhood diarrhea. All messages in the media campaign linked ORS and zinc treatment together.³⁹

Measures of Effectiveness

Following the launch of the zinc scale-up campaign in 2006, a number of evaluations took place. In order to monitor intended and unintended consequences, repeat impact surveys were conducted. Household surveys monitored three primary outcomes: 1) the actual use of zinc to treat child diarrhea; 2) changes over time in caretaker awareness of zinc as a treatment; and 3) the use of ORS. By the third year of the launch, almost 90% of urban caregiver and over 70% of rural caregivers knew about zinc treatment. During the scale-up campaign, the disparity in zinc coverage favoring urban, upper income populations was reduced by 50%.

A follow-up evaluation monitored results through survey sites from the first two years of the SUZY campaign. Households in each survey site were selected randomly and seven surveys were conducted at each site between September 2006 and October 2008. Of parents surveyed, over 90% of them used private sector providers for drug treatment; accordingly, the campaign focused on zinc tablet distribution in the private sector. Prior to the launch of the campaign, awareness of ORS/zinc was less than 10% in all communities. This percentage peaked 10 months later at 90%, 74%, 66%, and 50% in urban, non-slum, municipal, urban slum, and rural sites respectively. **Use of zinc was shown to be safe, with few side effects, and did not affect the use of traditional treatments for diarrhea.⁸ As a result of this intervention, Bangladesh has the world's highest coverage rates of ORS (77%) and zinc (44%).**

Key Lessons

Partnerships with the government, NGOs, and the private sector were critical factors to the SUZY project's success. In order to address barriers to scale-up in both public and private sectors, activities were implemented to help accelerate progress on zinc scale-up.⁴⁰ The project performance framework developed for the scale-up of zinc in Bangladesh can be applied to a diverse range of health interventions in low-resource settings. The framework was generated by identifying important gaps in knowledge. **These gaps in knowledge helped to guide strategic decisions and also reassured stakeholders that scale-up could be conducted safely and would not adversely affect other beneficial practices.**

The Bangladeshi government exhibited a strong political will and a long-term commitment to promote ORS and child health. **The project conducted extensive formative research, which identified knowledge gaps and provided ample understanding of consumer attitudes and behavior. Large-scale and long-term awareness campaigns helped to entrench public knowledge of ORS, and engaging the private sector provided an opportunity to embed**

³⁹ C. P. Larson et al. (2009).

⁴⁰ N. Goh and K. Pollak (2016).

sustainable practices.⁴¹ While important achievements were made throughout SUZY implementation, an extension of the program and additional time for roll out could have aided in achieving long-term goals.^{42,43,44}

Profile D-6: The cost-effectiveness of using a social franchise network to increase uptake of oral rehydration salts and zinc for childhood diarrhea in rural Myanmar. Project: PSI, Myanmar, 2010

Care seeking for diarrhea treatment is limited in Myanmar.⁴⁵ In rural areas, where 70% of Myanmar's population reside, 40% of individuals who do seek care for diarrhea seek care first from private providers.

Intervention

The initiative was implemented by PSI in Myanmar three townships in 2010 to promote an ORS/zinc co-packed product called ORASEL in PSI's existing social franchise program.

Measures of Effectiveness

The study examined the cost-effectiveness of achieving increased use of ORS/zinc co-packed for the management of acute diarrhea in children under age five through social franchising, compared to standard government and private sector practices. Costing included program, provider, and household costs for the 2010 calendar year. Program costs were obtained through a review of financial records and key informant interviews. Household out-of-pocket payments for diarrheal episodes were obtained from a household survey conducted in the study area. Additional estimates of household income lost due to parental caregiving time for a sick child were estimated. Incremental cost-effectiveness relative to status quo conditions was calculated per child death and disability-adjusted life year (DALY)⁴⁶ averted in 2010. According to the thresholds for cost effectiveness set forth by the Commission for Macroeconomics and Health, the cost per DALY of an intervention needs to be below the gross domestic product (GDP) per capita of a country to be considered highly cost effective. The Myanmar GDP per capita in 2010 was USD 876.2 (2010 estimate).⁴⁷ PSI's franchising-based distribution of ORASEL kits produced an incremental cost per DALY averted of USD 214 (societal perspective) and USD 339 (medical perspective). These results indicate that delivery of ORASEL through a social franchise may be cost-effective.⁴⁸

Key Lessons

Investing in developing a network of private sector providers and keeping them stocked with ORS/zinc as was done in PSI's social franchise in Myanmar can be cost-effective in terms of dollars per DALY averted. The perceived advantage of the franchise network is that the health care providers are community members, supported by the fees they charged patients for services. They received a highly subsidized product and were given the incentive to distribute it in the form of a USD 0.12 markup per packet. Note that this analysis may not be widely

⁴¹ Larson et al. (2009).

⁴² Larson et al. (2012).

⁴³ Goh and Pollak (2016).

⁴⁴ Supplementary resource (2010).

⁴⁵ T. Aung et al. (2011).

⁴⁶ Disability Adjusted Life Years (DALYs) – a summary measure of disease inclusive of both morbidity and mortality.

⁴⁷ United Nations Statistics Division (2012).

⁴⁸ WHO (2001).

generalizable because PSI Myanmar's provider network was already established and ORASEL was subsidized by donor support.⁴⁹

Integrated Child Health Service Models

Of the 32 papers discussing integrated disease management approaches for child health, the vast majority focused on interventions carried out in East and West Africa, four focused on programs Southeast Asia, and three discussed interventions in Southern Africa. As with malaria and diarrhea interventions, **the vast majority of integrated approaches focused on private medicine vendors or other community-based approaches to private sector service provision**, while four papers focused on integrated approaches implemented across multiple private provider types (including physicians, nurses, and drug dispensers). The project profiles presented below were selected to highlight a range of key findings from integrated interventions, including the importance of community-based private medical vendors as a first resort consult, the priority of integrating child health interventions in packages such as integrated community case management (iCCM) and IMCI, private sector success in scaling access to integrated services and commodity access, and options for sustainably mobilizing CHWs as part of private sector approaches. Several profiles also demonstrate that given that iCCM and integrated strategies have primarily been implemented via public sector-managed CHWs, there is a need for additional evidence and experience to translate integrated approaches to private sector providers. Below is a summary of key findings related to integrated child health service delivery models in the private sector.

Integrated approaches to child health services can improve private provider case management. Integrated approaches such as iCCM and IMCI can arm private providers with expanded clinical knowledge related to the presentation of diarrhea, malaria, and pneumonia in children. Expanded provider knowledge across disease areas can in turn improve appropriate symptomatic assessment, reduce symptomatic dispensation of antimalarials, and improve provider case management and referral. Furthermore, as malnutrition is often a concomitant health issue exacerbating the intensity and frequency of other childhood illnesses, it is critical that iCCM strategies include attention to nutritional status, particularly to under-nutrition and stunting.

Social franchising may be key to organizing multiple private providers toward integrated approaches. As demonstrated in numerous private sector mobilization projects implemented by SHOPS Plus, leveraging social franchises, provider networks, and other umbrella organizations can be a rapid and effective way of mobilizing multiple providers toward specific disease interventions. In the case of iCCM, networks or franchises can allow independent providers to access trainings, commodities, and other supports they would not otherwise receive without network access. Franchise or network-led organizations can also support providers as a coordinating and oversight agency to ensure private providers are accountable. Such approaches have demonstrated that PPMVs and other community-based medicine vendors can be successfully integrated into community case management strategies.

Public-private partnerships are powerful tools in advancing integrated approaches. Several studies demonstrated the power of PPPs to reduce the incidence of common childhood illnesses. As with stand-alone disease projects, PPPs can help private providers be successfully integrated into community case management strategies, facilitate access to trainings and

⁴⁹ D. Bishai et al. (2015).

commodities, and improve private provider quality by linking them to public sector and donor-supported supervision processes. Given that integrated approaches involve various government bodies, disease management agents, and funding streams, PPPs can assist in clarifying and coordinating various public and private actors in moving toward shared goals.

Private community distribution efforts can be successful in insecure and unstable environments. As demonstrated in South Sudan, where private providers are brought into iCCM strategies or other integrated child disease approaches, there is an important emphasis on integrated training. However, perhaps more important than training are the associated health system efforts to strengthen oversight, align private programs with other national health initiatives, reduce parallel systems, integrate service delivery, simplify supervision, and help providers adapt to ever-changing contexts.

Donors must continue to innovate to ensure integrated approaches utilizing CHWs are sustainable. Several papers assessed as part of this review discussed the fact that successful iCCM and IMCI strategies mobilized among CHWs remain largely public sector and/or donor funded. There is a need to assess more sustainable models of care, in particular how the private sector can mobilize CHWs for iCCM. Although the Living Goods initiative relied and still relies on a significant amount of donor funding, the model has demonstrated how innovative hybrid business models for last-mile distribution of essential medicines, with sufficient support from technical assistance partners, can help CHWs integrate siloed disease areas, reduce duplicative community programs, and incorporate the latest technology to support advancing quality of care.

There is a need to intensively focus on quality of care when applying integrated approaches. In Uganda, although iCCM was successfully scaled up through private medicine vendors, only 10% of febrile children were correctly managed in the study. The authors argue that these findings demonstrate a missed opportunity for children to quickly access appropriate and timely treatment of common childhood illnesses, and there is an urgent need to improve the standard of integrated care provided at drug shops.

Integrated Child Health Service Profiles

Profile ICH-1: Integrated community case management and the private sector in Africa. Project: Makerere University and PSI, Systematic Literature Review, 2014

Integrated community case management of malaria, pneumonia, and diarrhea has been an effective strategy to improve sick children's timely access to treatment in resource-limited settings. To date, iCCM has been widely scaled across Africa, through public sector services, and widely rolled out via various cadres of CHWs. However, there is significant evidence that in many low-income countries the first source of care for most children with fever is the private sector (i.e., drug shops or small medicine vendors). The quality of services provided by these cadres is largely unknown in many countries. To address this knowledge gap, researchers from Makerere University and PSI carried out a systematic review of global literature, seeking to determine the extent to which the private sector has been used in providing integrated care for children under age five with community-acquired malaria, pneumonia, or diarrhea.

Intervention

The systematic review focused on published literature for iCCM experiences in both the public and private sector. PubMed and Google Scholar were searched up to and including July 2014. Search terms included “malaria,” “pneumonia,” “diarrhea,” “private sector,” and “community case management.” Grey literature was also sourced by searching the websites of organizations involved in private sector child health work. The number and characteristics of studies reporting iCCM interventions are described below.

Measures of Effectiveness

The review found 385 papers mentioning private sector experiences with iCCM. Following rigorous screening, 13 papers were included for analysis. The vast majority of private iCCM experiences were malaria focused—86% evaluated only the introduction of malaria drugs and/or diagnostics in the private sector. No articles reported private sector community-level interventions for pneumonia treatment or diagnosis, and only one study evaluated diarrhea management in a public and private setting. Overall, there was a demonstrated lack of iCCM-related experiences in the private sector reported in the published literature. Of note, PSI reports outlined their experiences implementing iCCM in several countries (although not exclusively private sector focused), and one paper in preparation at the time of the systematic review (Larsen et al.) was looking at improving quality of private sector case management of diarrhea, pneumonia, and malaria in Uganda using a social franchising approach.

Key Lessons

Integrated management of childhood illness is becoming an increasingly important priority at the community level. The iCCM strategy is one vehicle to accomplish this. **To date, iCCM interventions in the private sector have focused on malaria alone**, suggesting that many private sector approaches are better described as community case management rather than true iCCM. Although there have been many efforts to improve quality of care in the private sector, there is still a significant lack of global evidence outlining the process and effect of employing iCCM in the private sector. In terms of improving iCCM in the private sector, the authors conclude that **social franchising may be a key tool in organizing multiple health providers for iCCM, allowing an independent network of health outlets to provide services and commodities with the support of an oversight coordinating agency and providing incentives for service scale-up and accountability**. To date, there has been little done to harness the potential of the private sector to improve access to “non-malaria” fever treatment among children under age five. **More research is needed on how to mobilize for iCCM and how to build sustainable iCCM models in the private sector.**⁵⁰

Profile ICH-2: The impact of incorporating patent medicines vendors in integrated community case management of childhood diseases. Project: USAID Targeted States High Impact Project, Nigeria, 2009–2015

Although Nigeria represents only 2% of the world’s population, it accounts for more than 10% of global infant, child, and maternal mortality. Malaria claims over 300,000 children under age five each year, accounting for ~30% of Nigeria’s annual child mortality. The situation was most pronounced in the northern regions of Bauchi and Sokoto, where under-five mortality was 260/1000 and 269/1000 respectively. To address this, the USAID-funded Targeted States High Impact Project (TSHIP) was implemented to increase the use of high-impact integrated

⁵⁰ P. Awor et al. (2014).

maternal, newborn and child health, and family planning and reproductive health services. Under the TSHIP project, a cross-sectional interventional study was implemented 2013–2015 to assess the impact of TSHIP interventions.

Intervention

From 2013–2015, a cross-sectional case-control study of a pilot intervention was carried out with 3,077 and 2,737 under-fives respectively in the pre- and post-intervention periods. The study assessed the impact of TSHIP's support to the Bauchi State Agency for Tuberculosis and Malaria control to incorporate patent medicines vendors (PMVs) into the community case management of childhood diseases, including improved access to ACT and distribution of insecticide-treated bed nets (ITNs) to households. Between May and August 2014, 188 PMVs received training based on an iCCM modular toolkit and implementation guide for community case management of childhood illnesses. The study then further explored whether household socioeconomic characteristics had any positive or negative influence on the impact of the intervention on malaria-related fever in the under-five-year olds in Bauchi State, Nigeria.

Measures of Effectiveness

This intervention was effective in reducing the prevalence and likelihood of childhood malaria fever. Households with ITNs increased from 73.1% in the pre-intervention period to 87.1% post-intervention and measured as high as 96.2% in intervention households. The estimated two-week occurrence of fever among under-fives declined from 56.6% at pre-intervention to 42.5% in the post-intervention period. The fever prevention attributable to possession of ITNs in the household was statistically significant and the likelihood of fever in children post-intervention was also significantly less than in the pre-intervention period. The authors argue that the PMV intervention strategy significantly protected against malaria fever. The results indicate that the odds of fever in under-fives in households with ITNs was significantly lower than those without ITNs and that bed nets distributed by PMVs (and public sector providers) offered 27.8% protection against malaria fever.

Key Lessons

The interventions implemented in this study (ITN distribution and the integration of PMVs into integrated management of childhood malaria) significantly decreased the odds of and protected against childhood fever. **Increased ITN coverage alone provided 21.7% protection against fever, whereas the collective intervention provided as much as 58.1% protection.** The authors argue that the impact recorded in this study demonstrates the potential to use innovative PPPs for the reduction of common childhood diseases. The results underscore evidence that **PMVs and other community-based medicine vendors can be successfully integrated into community case management strategies, particularly in malaria endemic communities where poor health systems and access to appropriate treatment are limited.**^{51,52}

Profile ICH-3: Improving integrated community case management of childhood illness among Nigeria's patent proprietary medicine vendors, 2015–2016

⁵¹ USAID (2015).

⁵² John Snow, Inc (n.d.).

Nigeria historically has one of the highest child mortality rates in the world, with 109 deaths out of 100,000 live births reported in the latest DHS as being related to malaria, diarrhea, pneumonia, and concomitant malnutrition. Per the 2013 Nigeria DHS, only 37% of children with pneumonia were treated with antibiotics, only 34% of children with diarrhea were treated with ORS and only 18% of children diagnosed with malaria received an ACT. Additionally, the DHS found that 34% of households prefer to seek treatment from community-based PPMVs versus all other sources of healthcare.⁵³

Intervention

From March 2015 to November 2016, a pilot intervention, implemented by an array of partners, including PATH, the Expanded Social Marketing Project in Nigeria, Society for Family Health, in collaboration with the Federal MOH, the National Malaria Elimination Program, and the Ebonyi State MOH, was launched to assess whether improving the competency of PPMV staff to deliver quality case management services through training and routine supervision could lead to improved health outcomes at a population level. The pilot consisted of training PPMV personnel in case management of febrile illness, utilizing the Federal MOH's national iCCM curriculum which covers malaria, diarrhea, and pneumonia. Although this training curriculum had been utilized for iCCM elsewhere in Nigeria, the training approach in Nigeria was novel in that it also trained PPMV personnel on the use of mRDTs and on the protocols for prescribing amoxicillin dispersible tablets to treat pneumonia. For many PPMVs, these were the first trainings received for mRDTs. Following their iCCM training, PPMVs received further mentorship on effective case management during regular site visits where case management competency was assessed. Additionally, systematic issues such as stock-outs and price surges were monitored to ensure market conditions did not affect the outcome of the study.

As part of monitoring the intervention, 1) baseline and endline evaluations were conducted, including household surveys, outlet surveys, and focus group discussions; 2) technical assistance was provided to strengthen quality assurance systems to monitor program implementation; and 3) a cost analysis was conducted. A quasi-experimental design was used to gather outcomes in two intervention and two control communities. The study team recruited 325 PPMVs from the two intervention local government areas. Only PPMVs who were registered with the Pharmaceutical Council of Nigeria, the regulatory body for PPMVs, were selected. Of these 325, 295 (91%) met the remaining eligibility criteria of literacy, attending to sick children at their respective shops, and were able to complete the training.

Measures of Effectiveness

Of the PPMVs in the intervention arm that received at least two assessment visits during the nine-month implementation period, performance improved for all five competency areas (clinical inquiry, physical examination, performance of an mRDT, effective diagnosis and treatment, and appropriate workplace environment). This is encouraging given the relatively short period of intervention and assessment. Overall competency indicators for care revealed large improvements in correctly diagnosing illnesses (16% at baseline versus 89% at endline) and in giving the correct treatment or referring for danger signs (16% at baseline versus 88% at endline). At endline nearly 99.7% of presenting fever cases were tested with an RDT, of which 85% tested positive. One-hundred percent of positive RDT cases were treated with an ACT. Similarly, 99% of cases provided with an ACT by a PPMV had a positive RDT. For diarrhea

⁵³ A PPMV is defined as "a person without formal training in pharmacy who sells orthodox pharmaceutical products on a retail basis for profit." PPMVs not only sell pharmaceutical products including ACTs, ORS, zinc, and amoxicillin, but also perform client consultations and recommend treatments.

management, 96% of diarrhea cases were appropriately treated with ORS/zinc, 3% were treated with ORS alone, and only 1% received zinc alone. Regarding pneumonia, there were similar improvements. Ninety-eight percent of suspected pneumonia cases were further assessed by counting breathing (per national protocol), 48% of cases were confirmed, and over 100% (119%) of confirmed pneumonia cases were treated with amoxicillin.

In terms of diagnostic abilities, at endline, nearly all PPMVs in the intervention arm (96%) identified a blood test as the best way to treat malaria, as compared to 55% of PPMVs in the control arm at endline. All PPMVs in the intervention arm at endline had either seen or heard of an RDT. This represents an increase from the proportion reported at baseline (34%) and is higher than the proportion of PPMVs in the control arm who had either seen or heard of an RDT (76%). Of those PPMVs who had ever tested for malaria using an RDT, similar proportions of both the control arm and intervention arm correctly identified a positive test at endline, 91% and 95%, respectively. Similarly, 80% of PPMVs in the intervention arm correctly identified a respiratory timer as the best method for diagnosing probable pneumonia, as compared to 13% in the control arm. Further, a greater proportion of PPMVs from the intervention arm at endline could correctly identify at least one danger sign of severe illness in children under five (70%) than the control arm at endline (53%).

Key Lessons

This implementation experience demonstrates significant success in improving the capacity of community-based PPMV providers to provide comprehensive and integrated treatment of childhood illnesses. Recommendations emerging from the pilot encourage greater PPMV involvement in national planning, scaling up training of PPMVs to improve iCCM, the creation of a certificate program for iCCM-trained PPMVs, and the strengthening of supervision structures that operate within and are financed by national health systems rather than external donor support. It was hypothesized that costs could be lowered by targeting PPMVs with higher caseloads and lower baseline performance. Additionally, as evidenced by a lack of reliable mRDT supply for many facilities, it was suggested that future efforts should work to strengthen the supply of quality commodities to PPMVs. Overall, this pilot demonstrated significant positive outcomes among the intervention arm, suggesting that a targeted iCCM training and technical assistance approach can greatly enhance iCCM among private providers.⁵⁴

Profile ICH-4: Testing the effectiveness of introducing iCCM via informal drug shops in Uganda. Project: Makerere University Implementation Study, Uganda, (n.d.)

Early and accurate treatment of pneumonia, malaria, and diarrhea is essential to preventing child mortality and irrational use of medications. The iCCM strategy, in addition to integrating the treatment of childhood illnesses, aims to advance task-shifting approaches that extend the management of common childhood illnesses beyond health facilities to where children are in the community. As already mentioned, iCCM approaches have largely been implemented by CHWs in public sector models. However, in Uganda, informal drug shops at the community level are routinely the first point of consultation when a child becomes ill.

⁵⁴ MalariaCare (2017).

WHO studies have estimated that between 30% and 70% of febrile children are treated in Uganda's private sector, including informal drug shops. Other studies have reported that between 39% and 53% of people who seek treatment for an illness consult the private sector first, including general merchants, pharmacies, for-profit health providers, and informal drug sellers. Many of these private sector outlets are unlicensed and unsupervised, meaning that there is an urgent need to assess and improve the quality of care provided by private sector health providers who are currently serving as a critical first point of community-based consult. At present, there is evidence that subsidizing ACT through private sector drug shops in rural areas can greatly increase ACT coverage for reported fevers; however, there is a lack of similar evidence on iCCM strategies that include treatment of pneumonia and diarrhea.

Researchers at the Department of Community Health and Behavioral Sciences at Makerere University implemented a study to determine the role of and appropriateness of care provided by private sector drug shops treating childhood fever, respiratory symptoms, and diarrhea. The researchers proposed that engaging private drug sellers to diagnose and treat common childhood diseases might be a sustainable method of iCCM delivery to reduce child mortality in Uganda.

Intervention

A snowball-mapping technique was utilized to map licensed and unlicensed drug shops in four rural sub-districts of Kamuli district in Eastern Uganda. The resulting GPS data map was further analyzed to determine the geographic distribution of drug sellers and distances from public health facilities. The study supported unlicensed drug sellers to license their drug shops, subsidizing half of the licensing fee (approximately 60,000 Ugandan shillings) and providing technical assistance to help them navigate the licensing process. At each drug shop location, the research intervention team trained up to two drug sellers in iCCM and assisted with the procurement of subsidized, prepackaged medicines for distribution to children under age five diagnosed with malaria, pneumonia, and/or diarrhea. To assess the intervention, the team carried out surveys and focus group discussions with drug shop sellers, conducted exit interviews with clients, and supplemented the information with key informant interviews.

Measures of Effectiveness

For households presenting for care at the drug sellers, the study found that the decision to seek treatment for an ill child was often made by the mother (854/53% of households), whereas the father or husband authorized any expenditure for treatment in (1,173/73% of households). The main reasons for seeking care at drug shops, as described by caregivers included: perceived good customer service (62%), distance and proximity (21%), competent staff (20%), regular supply of drugs (14%), and the drug seller being a friend (13%).

Among children with fever for whom treatment was sought at a drug shop, only 15% received appropriate treatment according to current national guidelines (i.e., an ACT for three days within 24 hours of onset of illness). For children presenting with cough and fast breathing (defined as pneumonia according to iCCM guidelines), 71.9% received an antibiotic, although it was mainly cotrimoxazole (56.3% of cases) and only 15.6% of children were treated with the recommended first-line drug of amoxicillin. Zero children presenting with cough and fast breathing received amoxicillin for the recommended full duration of 5–7 days. Similarly, only 14.3% of children presenting with diarrhea were treated with ORS, and none of them received zinc tablets. These findings suggest poor quality of care and a need for further data to determine whether medicines were offered, whether clients accepted them or refused available treatments, or other secondary factors that led to negative intervention findings beyond drug shop quality of care.

Of concern, up to 108 caretakers (66%) bought a drug from the drug shop without a prescription. Of those that purchased drugs, 113 (69%) reported that the price was within their financial reach, although in 78 (48%) of those cases, the type or amount of drugs purchased were determined by what was affordable to the care seeker.

Key Lessons

The study confirms earlier findings that the private sector is an important first consult in the care of febrile children, where more than one-half of all care for children under age five was first sought in the private drug shop or clinic. The study further documents **that the quality of care received at private drug shops in Uganda was poor. According to current iCCM guidelines for management of fever, cough, and diarrhea, only 10% of febrile children in the study were correctly managed in the study.** The authors argue that these findings demonstrate a missed opportunity for children to quickly access appropriate and timely treatment, and there is an urgent need to improve the standard of care provided at drug shops. The authors further suggest that **an appropriate mix of technical solutions are needed that incorporate training, incentives, regulation, supervision, and communication, including demand creation.**⁵⁵ In conclusion, this paper argues that PPPs are an essential path for achieving these improvements.

Profile ICH-5: The impact of training and deploying pharmacy assistants to increase access to essential medicines for children under five in Malawi. Project: VillageReach, Malawi, 2017

Persistently low access to essential medicines in lower-middle income countries can be attributed to inadequate financing, regulatory issues, lengthy procurement processes, poor logistics management, and a lack of qualified health workers to manage the medicines' supply chain. As sub-Saharan Africa faces severe shortages in the healthcare workforce, task-shifting pharmacy supply and dispensing tasks has the potential to increase the effect of the health workforce and the cost-effectiveness of health service delivery strategies. However, a lack of training on medicines logistics management among lower-level health cadres has resulted in inefficiencies in the supply chain, negatively impacted the quality of clinical care which in turn has severe health consequences for patients.

Intervention

To address the shortage of well-trained pharmacy workers in Malawi, VillageReach, a Seattle-based international NGO with expertise in supply chain management, initiated an innovative pharmacy assistant (PA) training program in conjunction with the Malawi College of Health Sciences and the Malawi MOH. Initiated in 2013, the training program provided a select group of health workers with two years of training toward a Certificate in Pharmacy (i.e., PA). A prospective evaluation was designed to measure the impact of pharmacy worker training and deployment on access to essential medicines for malaria, pneumonia, and diarrhea. Researchers hypothesized that PA training and deployment, as implemented by VillageReach and partners, would improve access to essential medicines such as ACTs, antibiotics, and ORS, through improved management, logistics information flow for essential medicines, and supply chain functions at the primary health center level.

The study utilized a quasi-experimental design that drew data from three population-based cluster household surveys: one pre-implementation sample conducted in 2014 and two post-

⁵⁵ D. L. Buchner and P. Awor (2015).

implementation samples conducted in 2015 and 2016. The primary outcome, as measured in the survey was access to ACTs, antibiotics, and ORS, where “access to medicines” was defined as the percentage of children with non-severe malaria, pneumonia, or diarrhea in the last two weeks who obtained a full course of ACT, antibiotics, or ORS, respectively. The sample was drawn from four districts in Malawi: Ntchisi and Machinga (intervention) and Dedza and Chikwawa (comparison matched to region; high burden of malaria, pneumonia, and diarrhea; access to basic services; and socioeconomic status). The PA training program was composed of both didactic training and an extended practicum. For the first year, students received ten weeks of class-based instruction at the Malawi College of Health Sciences. In year two, half of the students received five-months of field training, where they were supervised by a pharmacy technician at a district hospital, while the other half underwent additional didactic training.

In the data collection phase, the researchers identified households (using self-report by parent or caregiver) with at least one child under age five with symptoms of nonsevere malaria, pneumonia, or diarrhea in the previous two weeks. The questionnaire, adapted from the 2010 Malawi DHS questionnaires, included details about household characteristics, care-seeking behaviors, and medicine use. Approximately 4,000 children were included in the study across the three rounds of annual surveys, 1,840 (46%) in the districts to which PAs were deployed (intervention) and 2,096 (53%) in the districts to which no PAs were deployed (comparison).

Measures of Effectiveness

VillageReach reported that the intervention (via the training program) expanded the health workforce in Malawi and the deployment of PAs appeared to increase community access to antimalarials in the short term. Monitoring data collected by VillageReach during supervision visits also showed that the PA students increased data quality (from 55% to 73% report accuracy) and improved adherence to storeroom management (from 72% to 79% adherence) and dispensing standards (from 41% to 60% adherence). However, the intervention did not produce a sustained impact on access to antimalarials over two years, nor did it appear to have an impact on access to other medicines evaluated in this study. In terms of the impact of training PAs, three separate data analyses were run to measure impact. Analysis of Model 1 showed a significant effect of the program on the odds of access to any antimalarial and to ACT specifically, while their analysis of Model 3 showed that the effect of PA training and deployment on access to any antimalarial was restricted to the first year post-intervention. The analysis showed no effect of PA training and deployment on access to antibiotics or ORS.

Overall, study’s results were mixed. An increase in access to antimalarials over the first year that was attenuated during the second year, additionally, there was no impact on access to antibiotics for pneumonia and ORS for diarrhea. The hypothesis that PA training would increase access to iCCM interventions was accurate for antimalarials (over the first year); however, that was not the case for antibiotics and ORS. The researchers argue that this may be explained in part by the difference in funding structures and supply chain dynamics for malaria, antibiotics, and ORS in Malawi during the study period.

Key Lessons

Privately deployed PAs are engaging in task sharing and are viewed as valuable additions to the health workforce in Malawi, however, their short-term impact on access to child health essential medicines for children was limited. Of note, the study authors mentioned that antimalarials are frequently donor-supported and channeled to tertiary health facilities through an informed “push” system, where commodities are then distributed from tertiary locations to lower level health facilities. **Other essential medicines, including antibiotics and ORS, are**

more often supplied through the government central medical stores with limited donor support and channeled through a traditional “pull” system. While the reasons for the weakening in the effect of pharmacy worker training and deployment on access to antimalarials in the second year were unclear, it is not uncommon for low-income countries such as Malawi to experience supply chain issues which interrupt the supply of medicines, including donor-funded or donor-supplied medicines. Retention of task-shifted health workers is a major problem in Malawi because CHWs and other health workers are asked to work in challenging environments, are often poorly paid, and can be under-motivated. For instance, at the time of the conclusion of this impact evaluation, 100% of the graduates of the PA training program were employed by the MOH. **Some of these disappointing results may reflect a broader challenge related to donor-facilitated barriers to providers’ access to the full package of commodities needed to deliver a comprehensive iCCM package of services.**⁵⁶

Profile ICH-6: Making a business case for advancing Integrated Case Management Phase 2 in South Sudan. Project: DFID-funded iCCM2/Sudan, £25 million in 2017–2018

South Sudan is one of the poorest countries in the world, where half of the population lives on less than USD 1 per day. Years of conflict have eroded South Sudan’s infrastructure and caused the death and displacement of millions of people. Of the estimated 11.4 million population, over 80% live in rural areas. South Sudan’s health needs are vast and largely unmet by the government, which allocates less than 3% of their budget for the whole health sector, compared to over 60% on security (2015/2016). Conflict in December 2013 affected millions of people, causing widespread displacement, human rights violations, deaths, disease and injuries, severe food insecurity, and a major malnutrition crisis. Since December 2013, 2.4 million people have been displaced: 1.7 million internally, and over 725,000 have fled to the region, becoming refugees. Approximately 40,000 children under age five die every year: 21% of these deaths are attributable to pneumonia (including neonatal), 7% to malaria, and 8% to diarrhea. Responding to this, since 2012 DFID has supported two critical health care interventions in South Sudan: 1) Health Pooled Fund and 2) iCCM. The £200 million Health Pooled Fund program is also supported by other donors: Canada, Sweden, the EU and the United States, and the World Bank supports a similar program in two Northeast states (Jonglei and Upper Nile).

Intervention

The goal of Health Pooled Fund is to increase access to quality health services, but its activities do not include treatment and case management of diseases at the community level. It will take many years for South Sudan to build a primary health care system that reaches the majority of women and children in rural communities.

The DFID iCCM was initiated by DFID and PSI in South Sudan in April 2013 to complement the Global Fund home management of malaria for children under age five. The initiative aimed to integrate community-based household-level treatment of pneumonia, diarrhea, and severe acute malnutrition (SAM) in 26 counties across 9 out of the 10 states in South Sudan. Community volunteers in villages outside walking distance of a health facility provide treatment to children under age five for malaria, diarrhea, pneumonia and SAM—as well as increasing the quality, demand, and utilization of nutrition services. In addition, the program focused on strengthening health systems coordination with the MOH by establishing linkages between

⁵⁶ J. B. Babigumira et al. (2017).

iCCM and the formal health system, (especially the Boma Health Initiative aimed at linking community-based health workers with primary healthcare centers); building tighter coordination with the multi-donor Health Pooled Fund; scaling the number of iCCM-trained community-based distributors, community nutrition volunteers, and supervisors.⁵⁷

Measures of Effectiveness

In a midpoint review for the original iCCM program (March 2015), the program noted reducing the percentage of reported stock out events (April 2014–December 2014) for ACTs by more than 6% (110% against midpoint target); for amoxicillin by more than 13% (108% against target); ORS by 6% (118% against target); and zinc by 7% (117% against target). By March 2015, the project had also screened 203,492 children for acute malnutrition and reduced stock outs of Plumpy’Nut by 36%. Further, the project was credited with increasing the percentage of CBDs that were supervised at least once per quarter and the number of CBDs (12,520) trained to properly identify and treat fever, pneumonia, and diarrhea in children under age five. This was all achieved despite reported fighting in Juba in December 2013, a tense security situation and unstable environment throughout Year 2, and other challenges throughout the program, including migration, flooding, and severe logistic challenges.

Aiming to build on the success of the original iCCM program, DFID developed a business case for a new Integrated Community Case Management (iCCM2) South Sudan program—a £25 million project over two years (2017–2018) aimed at scaling the delivery of critical care to reduce under-five child mortality in South Sudan. iCCM2 activities will capitalize on the experience of iCCM by continuing to ensure essential medicines are available to CBDs in 24 counties across nine states in South Sudan. iCCM2 will seek to continue supporting the network of 8,000 CBDs, 200 community nutrition volunteers and 1,100 supervisors trained under iCCM, and providing an additional 1.3 million treatments for malaria with ACT, 1.1 million treatments for pneumonia with antibiotics, 900,000 treatments for diarrhea with ORS/zinc, and 100,000 children treated for SAM with ready-to-use therapeutic foods such as Plumpy’nut.

Key Lessons

The DFID iCCM project (and resultant iCCM2 business case) demonstrate how community distribution efforts can be implemented in insecure and unstable environments. Despite consistent logistic, security, and supply challenges, the iCCM project demonstrates the importance of focusing iCCM efforts on integrated training on child illness, but perhaps more importantly the parallel efforts to strengthen oversight, aligning private programs with other national health initiatives, reducing parallel systems,⁵⁸ integrating service delivery, simplifying supervision, and adapting to ever-changing contexts.⁵⁹

Profile ICH-7: Extending life-saving products via sustainable community health entrepreneurs. Project: Living Goods, Kenya, Myanmar, Uganda, Zambia, 2015–2018

Per UNICEF, more than 7 million children die every year needlessly from preventable causes for want of simple health products. This is due in part to the lack of effective systems to deliver

⁵⁷ Department for International Development [DFID] (2017).

⁵⁸ The iCCM programme in South Sudan has been a parallel system since inception in 2010. In 2018, the iCCM implementing partners in South Sudan (IRC, Save, and MC) have successfully advocated for iCCM integration within stronger PHC systems. This will be the case going forward and HPF3 will include iCCM3 with the aim of streamlining iCCM service delivery through CHD systems.

⁵⁹ Integrated Community Case Management (iCCM) South Sudan (2015).

simple health interventions and life-saving products. In addition, CHWs have been widely recognized as one of the most effective methods of preventing deaths in children under age five. However, as outlined in other case studies above, they have been predominantly managed in the public sector and have yet to reach full potential due to weak oversight and lack of incentive for performance and remuneration. In practice, many of these CHWs are actually operating as volunteers, and are poorly supported in their role as the first and only link to health care for millions of children worldwide.

Living Goods, partnering with PSI, the ELMA Growth Foundation, the Republic of Kenya, BRAC, CARE, the Children's Investment Fund Foundation, and the Republic of Uganda, implemented a three year, USD 52.3 million CHW-focused project seeking to fundamentally change how CHW programs are designed in Uganda and to offer governments and donors an alternative to existing CHW models.

Intervention

Living Goods is based on the idea that CHWs, when trained, motivated, and equipped with health information, tools, and products, can be a key resource in reducing child mortality. The Living Goods program operates via networks of independent entrepreneurs called CHPs, who sell low-cost subsidized health and health related products door-to-door and motivate households to adopt healthy behaviors. CHPs distribute life-saving products for malaria and diarrhea, as well as safe delivery kits, fortified foods, clean cook stoves, water filters, and solar lights. The model “generates revenue that pays for the products, a retail margin that provides motivating incomes for the CHP, and a wholesale margin that covers much of the field distribution costs.” Per Living Goods, the model “solves two of the most vexing problems in community health: how to keep vital products in stock, and how to pay the millions of CHWs who distribute them where clients are.” In addition to the revenue generation model, Living Goods provides CHPs with health and business training, low-cost financing, a “business in a bag” package, health commodities and products via the Living Good’s branch warehouses, and a smartphone with mHealth applications. The mHealth applications help CHPs track and support pregnant women and newborns, diagnose and treat common childhood illnesses, send reminders to clients, flag high-risk cases, and provide timely referral or follow-up. Living Goods and its partners also set targets, track indicators and performance, and provide real-time support to CHPs via the Living Goods analytics platform.

Measures of Effectiveness

Living Goods and BRAC recently completed an independent RCT in Uganda, which showed the CHP model is reducing under five mortality by 27% where the networks are operational.⁶⁰ **Children in Living Goods villages were 3.3 times more likely to have interacted with a CHW compared to control group, were 12% more likely to sleep under an ITN, and were 33% more likely to receive a follow-up visit after falling ill with diarrhea, malaria, or pneumonia.** In addition, the **cost effectiveness of the hybrid business model was assessed to be generating revenues** via customer purchase of products, generating motivating incomes for the CHPs, and covering most of the distribution costs. As a result, **Living Goods reports that they are reducing deaths of the most vulnerable for a net yearly cost per capita of less than USD 2.**

Key Lessons

⁶⁰ Children's Investment Fund Foundation (2017).

The Living Goods program demonstrates how donors can utilize business models to improve the sustainability and efficiency of current CHW programs. Living Goods has asserted that the model helped to build networks of high-impact, low-cost community health entrepreneurs, lower child and maternal mortality, and improve nutrition.⁶¹ **Critically, the model provided a last-mile distribution platform for essential medicines that adequately compensated and motivated the CHWs delivering the services.** The model demonstrates how, **with sufficient support from technical assistance and partners, hybrid business model approaches can help CHWs integrate siloed disease areas, reduce duplicative community programs, and incorporate the latest technology to support advancing quality of care.** Efforts that pair CHWs with high-quality products and training can positively impact healthcare quality by removing dangerous products at the community level.⁶² Bjorkman M, Svensson J, Yanagizawa-Drott D. (2012) found that the Living Goods and BRAC models of community engagement can have positive externalities, such as reducing the number of substandard and counterfeit malaria drugs by almost half. To date, Living Goods has trained 1,200 CHPs in Uganda and is actively working to scale to 6,645 in 2018. There are also plans to launch a Kenya network of 1,800 health promoters and to advance partnerships with PSI in Myanmar and CARE in Zambia to test and replicate the model. There also plans for future replication in Ghana, Nigeria, and India.

⁶¹ Clinton Global Initiative (n.d.).

⁶² M. Bjorkman et al. (2012).

Future Challenges

The sections above have outlined several successes and key lessons that can be drawn from diverse private sector efforts to treat childhood illnesses worldwide. As country context was mentioned as a crucial factor, donors and global implementing partners (IPs) must also be aware of reported negative findings in particular, and of potential challenges facing future efforts to scale and sustain private sector delivery of child health services.

The reported success of private sector-focused interventions surveyed as part of this literature review varied widely depending on the clinical intervention, type of private sector outlet, and cadre of attending personnel. In the case of malaria, for example, several studies reviewed highlighted the fact that a principal barrier to utilization of mRDTs in community-based malaria care is the lack of a sustainable purchase price or product supply. Hawkes et al. (2009) highlight how, given the relatively high cost of mRDTs compared to the cost of a single ACT treatment course, the average health service payer paying for an mRDT product and its' application by a community health worker or accessing via a private dispensing agent or pharmaceutical outlet at the community level, would need to value the cost of using an mRDT to confirm their diagnosis as worth the benefit of helping them avoid the cost of a potentially unnecessary ACT treatment. In the DRC, for example, this equates to USD 8.79, which is eight times the cost of an ACT treatment course and 60% of the annual *per capita* public expenditure on health care (USD 15/pp/py). This raises questions about where, and in what type of prevalence settings, the use of mRDTs might be most cost-effective and practical to scale rapid diagnosis of malaria. Reports have highlighted, for example, that the probability of mRDTs being cost-effective is less than 50% beyond a malaria prevalence of 80%, and mRDTs are likewise only cost-saving below a prevalence of 52-55%.⁶³

In Nigeria, interventions that improved private provider and community knowledge of the treatment of uncomplicated malaria (interventions that have worked in other global settings), did not lead to a significant proportion of patients being treated in accordance with malaria treatment guidelines. Less than half of all febrile patients attending private clinical facilities were tested for malaria, across facilities in the intervention arm who had received training on the treatment of uncomplicated malaria as well as facilities in the control arm who had received no training. Of those who were tested, the proportion of patients who tested positive and received or were prescribed an ACT was actually lower in the intervention arm. Despite most private providers reporting to have charged the recommended price of 100 Naira (USD 0.60), there was also considerable variation in ACT price, with some providers and patients reporting paying up to ten times the recommended price. Ultimately, the authors concluded that a full cost-effectiveness analysis of the program was not even considered necessary given the higher costs and minimal effect in the intervention arm.⁶⁴

Negative findings from private sector programs focused on diarrhea management were present as well. In the global POUZN project, success and failure varied widely by context. As reported, when the right conditions existed, scale-up of private sector ORS/zinc delivery was achieved in a relatively short period of time, but there was wide differentiation across countries. In India, POUZN offered a stipend to the newly trained NGO "detailers" and the project's pharmaceutical partners received free samples of zinc and ORS as would typically be provided to regular drug representatives. Although this approach facilitated program start-up, the project was not

⁶³ C. Zikusooka et al. (2008); E. Rolland et al. (2006).

⁶⁴ O. Onwujekwe et al. (2015).

sustainable at scale and was streamlined to reduce the overall costs of intended detailer facility visits from four detailer visits to only one over a five month period. POUZN India sought to create and prime a rural market for ORS/zinc that would stimulate pharmaceutical company engagement and lead to the removal of subsidies, but the model was not sustainable at scale over time. Similarly, the POUZN Tanzania project reported that although providers (in both dukkas/shops and ADDOs) who were trained in diarrhea management and provided with a subsidized supply of ORS and zinc successfully prescribed zinc to 27% of clients and ORS to 16% of clients – nearly 57% of child clients with symptoms of diarrhea did not receive either ORS or zinc. In licensed pharmacies, zinc prescribing rose from zero to 34%, but ORS/zinc (the gold standard) only rose to 23%.⁶⁵ Across the POUZN countries, it was argued that until the use of ORS/zinc is streamlined into private sector health services at the community level, it is unlikely that such products will receive substantial financial and marketing support to promote a truly sustainable private sector commercial market. Results such as these suggest that no amount of investment in strengthening provider knowledge or promoting mass-media campaigns will be effective without addressing the significant challenge of changing provider and consumer behavior towards new treatments at the community level.⁶⁶

In Kenya, Tavrow et al. (2003) reported that whether clients accessing antimalarials were told the correct dose varied significantly by both drug (chloroquine (CQ), sulfadoxine-pyrimethamine (SP), or amodiaquine (AQ)), and private provider type (shops/kiosks, pharmacies, and private clinics of various size), and the price recommended by private outlet attendants fluctuated from USD 0.03 to USD 2.29 for the same medication. The authors concluded that, due to this variation in dosing and pricing, improving the quality of low performing private outlets at a cost low enough for the activity to be scaled nationally would be significantly challenging. In Uganda, an inventory of private health providers reported by Tawfik et al. (2006)⁶⁷ included a range of formal practitioners (physicians, nurses and midwives, medical officers, and pharmacists) and informal practitioners (nurse assistants, traditional birth attendants, health aides, drug sellers, and shop keepers). Although many facilities were appropriately registered, there were a large number of private practices that were not registered with district health authorities, and numerous facilities were offering services they were not authorized to provide. As donors and global IPs look to scale successful private sector efforts, it is critical that the total universe of private health facilities, providers, and practices is taken into consideration.

⁶⁵ POUZN Project(a), 2010.

⁶⁶ Stene et al. (2010).

Advancing the Research Agenda

Several papers we reviewed highlighted areas where more research is needed in order to advance understanding of child health case management through the private sector:

Long-term evaluations are needed to understand the full impact of private sector-focused interventions. Several interventions presented in this literature review provided details on initial program outcomes; however, few looked at long-term implementation experiences (longer than 2–3 years) and there remains a dearth of information on long-term sustainability or success of interventions after the initial implementation or donor focus. There is a need to follow up on recent interventions to more fully understand long-term impact and to design longer term evaluations as models are brought to scale. The above profile ICH-3, for example, highlights evidence indicating that working with informal providers who are not formally registered with national health authorities (in at least some states in Nigeria) can produce effective results over time. **Additional evaluations of longer term interventions, effectiveness studies, and other such studies could significantly build on this evidence base with more rigorous and robust evidence.** A current RCT being carried out in Uganda (results expected in 2020) seeks to provide such evidence, looking at the replication of the Living Goods and BRAC model at scale and over time.

New models of private sector community-based service delivery are needed that are sustainable by design and not reliant on long-term donor subsidization are needed. Several papers presented child health service models successfully scaled through CHWs and other community-based initiatives. However, as the majority of CHWs remain public sector managed and/or donor funded, there is a need for additional research on financially and logistically sustainable models to mobilize CHWs through the private sector, **including supervision and oversight mechanisms.**

There is a need to more rigorously evaluate interventions that aim to improve provider knowledge and customer adherence to private sector-delivered products. Given that text message applications had mixed effectiveness in improving provider knowledge and patient outcomes, there is a need to further explore mHealth or other technological innovations that can improve private sector provider knowledge and assist patients to adhere to prescribed therapies.

Additional evidence on effective quality assurance and improvement measures is needed. Regardless of the child health disease area or private sector model used, there is a need to emphasize quality assurance and improvement in all interventions. Similarly, more information is needed regarding successful quality assurance/quality improvement interventions in the private sector and specifically, models of quality assurance/quality improvement that will work for child health interventions in the private health sector among both clinical and nonclinical providers.

There is a need for research that sheds light on appropriately balancing resourcing and scale of interventions. In experiences that expanded mRDTs to private sector locations, it was observed that well-resourced and broad interventions may not be scalable, while interventions that require fewer resources that were more scalable often produced poorer outcomes. More information is needed to understand the scalability of private sector mRDT options and how resource utilization and scalability can be balanced and rationalized for greatest impact.

More research is needed on secondary or unintended effects of private sector interventions. The introduction of mRDTs in the private sector can reduce the unnecessary use of antimalarials, but can in turn spurn the unnecessary use of antibiotics. More research is needed to understand this phenomenon and to better understand how providers can be better informed regarding the risks of overusing antibiotics. Further, there is a need for researchers and implementers to look for such secondary or unintended effects of private sector implementation.

There remain a number of informal and unlicensed private health providers (such as PPMVs) that require interventions to improve quality. Almuzaini (2013) found that there is a higher prevalence of substandard and counterfeit drugs in private unlicensed outlets.⁶⁸ As implementers approach the private health sector, it is important to focus on both registered and formal health facilities but also on informal private providers delivering services and products of unknown quality.

More research is needed on how to mobilize iCCM in the private sector and how to build sustainable iCCM models. To date, there has been little done to harness the potential of the private sector to improve access to non-malaria fever treatment among children under age five. Further, although several papers in this review demonstrated successful efforts to implement integrated models via the private sector, there is a need for further research on the success of these models over time and novel approaches to financing and scaling private sector models that are sustainable without donor investment.

There are additional private sector interventions that warrant inclusion in a similar literature review. Upon review of these findings by members of the global Child Health Task Force, areas that also warrant a review include childhood vaccinations through the private sector and gender empowerment. Considering most of the CHWs in many countries are women, it would be useful to determine if/how private sector projects have been gender sensitive and/or empowered women in low-income settings.

This literature review sought to serve as a first step in assessing the gaps in global literature on private sector implementation approaches to addressing childhood malaria, diarrhea, and pneumonia. As noted above, beyond broadly sharing this review with global stakeholders to inform future programming, **the findings will also be used during a Child Health and Nutrition Research Initiative process that will more fully explore these evidence gaps and produce a prioritized research agenda on private sector-driven models for case management of childhood illness.**

⁶⁸ T. Almuzaini et al. (2013).

Annex A. Key Definitions and Concepts

Assessments – analyzing the private health sector landscape to better understand the role the private sector plays in a country and identify ways to maximize its potential.

Expanding access – increasing access to products and services in underserved areas.

Formal private providers – any health provider or cadre that is officially certified or legally registered with the relevant national health professional council or registration board.

Health financing and universal health coverage – expanding access to health services and enhancing financial risk protection for the poor through a variety of financing options, including vouchers, insurance, and contracting.

Informal private providers – any health professional or cadre operating or working at health facilities that are not officially certified or legally registered with the national health authorities.

Integrated approaches – any approach that seeks to address more than one child health disease area via the same intervention, including but not limited to iCCM or IMCI.

Networks and franchising – strengthening and scaling private provider networks and franchises.

Pharmaceutical partnerships and social marketing – expanding access and use of priority health products through social marketing and partnerships with manufacturers.

Policy and stewardship – promoting policy and regulatory change to enhance the climate for the private health sector and helping governments maximize the sector's contributions.

Private sector – SHOPS Plus broadly defines the private sector to include all non-state actors, including commercial, nonprofit, and faith-based health providers and facilities, as well as the numerous corporate and commercial entities engaged in health.

Provider access to finance – working with financial institutions to increase lending to private providers.

Provider quality – improving the quality of care in the private sector through training, supportive supervision, and support to associations.

Public-private engagement (PPE) – building the public sector's capacity to better steward the private sector while giving the private health sector a voice in health system decisions.

Public-private partnership (PPP) – any formal arrangement between government and a private entity established for the purpose of providing health services and commodities.

Subsidized versus commercial approaches – Subsidized versus commercial approaches affect costs borne by clients. Subsidies are funds from a government or other source that enables suppliers to provide goods/services to clients at costs below what they would normally incur in the absence of the subsidy. In contrast, a commercial approach does not include subsidies.

Universal health coverage – access to health care for all without financial hardship.

Annex B. Year 1 Search Terms, Source Databases, and Results Generated

Database	Search Terms	Search Date	Filters Applied	# Results Generated
Cochrane Library	private AND ("treatment" OR "management") AND ("children" OR "infants") AND ("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia")	18-May-17	Published between 2000 to 2017; search terms must appear in title, abstract or keywords	2
PubMed	("private") AND (("treatment" OR "management")) AND (("children" OR "infants")) AND (("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia"))	18-May-17	Published between January 1, 2000 and May 18, 2017, English language only, full text freely available	139
PubMed	("private") AND (("strengthening")) AND (("children" OR "infants")) AND (("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia"))	18-May-17	Published between January 1, 2000 and May 18, 2017, English language only, full text freely available	7
PubMed	"(proprietary patent medicine vendor)" and "Nigeria"	18-May-17	Published between January 1, 2000 and May 18, 2017, English language only, full text freely available	5
PubMed	"(TSHIP)"	18-May-17	Published between January 1, 2000 and May 18, 2017, English language only, full text freely available	8
PubMed	"(POUZN)"	18-May-17	Published between January 1, 2000 and May 18, 2017, English language only, full text freely available	1

Annex C. Year 2 Search Terms, Source Databases, and Results Generated

Database	Search Terms	Search Date	Filters Applied	# Results Generated
WHO Global Index Medicus	private AND ("treatment" OR "management") AND ("children" OR "infants") AND ("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia")	3-Jul-18	None	250
CHIFF Grant Portfolio	"malaria"	3-Jul-18	None	14
CHIFF Grant Portfolio	"diarrhea"	3-Jul-18	None	6
CHIFF Grant Portfolio	"diarrhoea"	3-Jul-18	None	11
CHIFF Grant Portfolio	"pneumonia"	3-Jul-18	None	7
USAID DEC Power Search	private NOT public AND ("treatment" OR "management") AND ("children" OR "infants") AND ("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia")	3-Jul-18	2000 to present, English language only	22
Gates Foundation's Grant Portfolio	private AND (treatment OR "management") AND (children OR infants) AND (malaria OR diarrhea OR diarrhoea OR pneumonia)	3-Jul-18	None (note that GFGP only indexes back to 2010)	25
DFID Development Tracker	private management malaria children	3-Jul-18	None	1
DFID Development Tracker	private management diarrhea children	3-Jul-18	None	0
DFID Development Tracker	diarrhea management	3-Jul-18	None	5
DFID Development Tracker	malaria management	3-Jul-18	None	16
DFID Development Tracker	pneumonia management	3-Jul-18	None	2
PubMed	("private") AND (("treatment" OR "management" or "strengthening")) AND (("children" OR "infant")) AND ("acute respiratory infection"))	5-Jul-18	Published between January 1, 2000 and July 5, 2018, English language only, full text freely available	4
PubMed	("private") AND (("treatment" OR "management" or "strengthening")) AND (("pediatric" OR "paediatric"))	5-Jul-18	Published between January 1, 2000 and July 5, 2018, English language only, full text freely available	21

	AND (("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia" OR "acute respiratory infection"))			
PubMed	("OTCM") AND (("treatment" OR "management" or "strengthening")) AND (("pediatric" OR "paediatric" OR "children" OR "infant")) AND (("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia" or "acute respiratory infection"))	5-Jul-18	Published between January 1, 2000 and July 5, 2018, English language only, full text freely available	0
PubMed	("ADDO") AND (("treatment" OR "management" or "strengthening")) AND (("pediatric" OR "paediatric" OR "children" OR "infant")) AND (("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia" or "acute respiratory infection"))	5-Jul-18	Published between January 1, 2000 and July 5, 2018, English language only, full text freely available	9
PubMed	("pharmacy" or "pharmacies") AND (("treatment" OR "management" or "strengthening")) AND (("pediatric" OR "paediatric" OR "children" OR "infant")) AND (("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia" or "acute respiratory infection"))	5-Jul-18	Published between January 1, 2000 and July 5, 2018, English language only, full text freely available	218
PubMed	("drug seller") AND (("treatment" OR "management" or "strengthening")) AND (("pediatric" OR "paediatric" OR "children" OR "infant")) AND (("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia" or "acute respiratory infection"))	5-Jul-18	Published between January 1, 2000 and July 5, 2018, English language only, full text freely available	4
PubMed	("informal providers") AND (("treatment" OR "management" or "strengthening")) AND (("pediatric" OR "paediatric" OR "children" OR "infant")) AND (("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia" or "acute respiratory infection"))	5-Jul-18	Published between January 1, 2000 and July 5, 2018, English language only, full text freely available	6
PubMed	("lower cadre providers") AND (("treatment" OR "management" or "strengthening")) AND (("pediatric" OR "paediatric" OR "children" OR "infant")) AND (("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia" or "acute respiratory infection"))	5-Jul-18	Published between January 1, 2000 and July 5, 2018, English language only, full text freely available	1
PubMed	("community health worker" OR "community health workers") AND (("treatment" OR "management" or "strengthening")) AND (("pediatric" OR "paediatric" OR "children" OR "infant")) AND (("malaria" OR "diarrhea" OR	5-Jul-18	Published between January 1, 2000 and July 5, 2018, English language only, full text freely available	214

	"diarrhoea" OR "pneumonia" or "acute respiratory infection"))			
PubMed	("private" OR "OTCM" OR "ADDO" OR "pharmacy" OR "pharmacies" OR "drug seller" OR "informal providers" OR "lower cadre providers" OR "community health worker" OR "community health workers") AND (("oral rehydration salts" OR "ORS" OR "zinc" OR "rotavirus vaccine" or "ACT" or "artemisinin-based combination therapy" OR "cotrimoxizole" OR "amoxicillin")) AND (("pediatric" OR "paediatric" OR "children" OR "infant")) AND (("malaria" OR "diarrhea" OR "diarrhoea" OR "pneumonia" or "acute respiratory infection"))	5-Jul-18	Published between January 1, 2000 and July 5, 2018, English language only, full text freely available	178
DefeatDD	"private"	17-Aug-18	2008 to present; Content type: Reports	6
DefeatDD	"private"	17-Aug-18	2008 to present; Content type: Published Research	1
DefeatDD	"informal providers"	17-Aug-18	2008 to present; Content type: Any	1
DefeatDD	"community health worker" or "community health workers"	17-Aug-18	2008 to present; Content type: Any	21
DefeatDD	"pharmacy" or "pharmacies"	17-Aug-18	2008 to present; Content type: Any	6
DefeatDD	"drug seller" or "drug sellers"	17-Aug-18	2008 to present; Content type: Any	1
DefeatDD	"lower cadre provider" OR "lower cadre providers"	17-Aug-18	2008 to present; Content type: Any	0

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