



DRUG SHOP INTEGRATED MANAGEMENT OF CHILDHOOD ILLNESS



CONTINENT

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DRUG SHOP INTEGRATED MANAGEMENT OF CHILDHOOD ILLNESS, UGANDA

A pilot programme to assess the feasibility and effectiveness of engaging private sector drug shop owners in the provision of care to children under five.

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ABBREVIATIONS

ACT	Artemisinin-Combination Therapy
DSO	Drug shop operators
iCCM	Integrated Community Case Management
LiST	Lives Saved Tool
MOH	Ministry of Health
NDA	National Drug Authority
ORS	Oral rehydration solution
RDT	Rapid diagnostic test
UGX	Ugandan shilling
US\$	United States dollar

CASE INTRODUCTION

The Drug Shop Integrated Management of Childhood Illness project is a collaborative research initiative undertaken by Makerere University, the Karolinska Institute, Uppsala University and the University of Bergen. Structured as a pilot programme, it aims to assess the feasibility and effectiveness of engaging private sector drug shop owners in the provision of care to children under five, living in low-income areas in Uganda, particularly for treatment of malaria, diarrhoea and pneumonia. Prior studies have found that timely and appropriate management of these diseases can reduce mortality by 60-90% (Sirima et al., 2003; Munos, Walker & Black, 2010; Sazawal & Black, 2003). In Uganda, up to 63% of parents seek care for their febrile children primarily from private clinics and drug shops (Rutebembera et al., 2009; Awor et al., 2012). The project selected a group of drug shop owners and provided them with integrated community case management (iCCM) training, appropriate diagnostics equipment, and subsidised medication supplies. Quality assurance and referral systems were put in place to link private drug shops to the public health care system. A campaign was also run to increase the awareness and knowledge of the local community around the type and cost of services

they could expect from accredited health facilities. Research was initially conducted using information from 7 667 children visits occurring across 40 drug shops, and is currently ongoing.

This case study illustrates that activities intended to strengthen the technical capacity and quality delivered by the health care system need to extend beyond the public sector to include private sector providers. This is particularly appropriate in countries like Uganda, with high out-of-pocket health expenditure, and where low-income patients regularly first seek care from private facilities. This case also highlights the opportunity for more collaboration between academics, policy makers, regulators and entrepreneurs in the design of implementation strategies. More comprehensive and holistic strategies help ensure that an effective innovation is financially sustainable and amenable to widespread adoption.

“It excites us a lot that we’ve shown a way to engage with this group of drug shops and actually harness their potential for improving outcomes in child health.” (Dr Phyllis Awor, Primary Researcher)

1. INNOVATION PROFILE AT A GLANCE

Project Details

Project name	Drug Shop Integrated Management of Childhood Illness in Uganda
Founding year	2011
Founder name	Dr Phyllis Awor (Primary Researcher)
Founder nationality	Ugandan
Organisations involved	Makerere University College of Health Sciences, School of Public Health, Uganda; Centre for International Health, University of Bergen, Norway; Division of Global Health, Karolinska Institute, Sweden; International Maternal and Child Health Unit, Department of Women's and Children's Health, Uppsala University, Sweden.
Organisational structure	Inter-university collaboration
Team size	7 researchers and 3 full-time field managers

Innovation Value

Value proposition	Reducing under-five mortality by extending the reach of integrated community case management (iCCM), as opposed to the formerly prevalent and less effective single-disease management approach, beyond the public sector providers into privately owned drug shops
Beneficiaries	Children under five, living in low-income areas in Kaliro District, Eastern Uganda
Key components	<ul style="list-style-type: none"> • Engagement of private drug shop owners • iCCM training of all drug shop owners • Subsidised drug supplies • Community awareness campaigns

Operational Details

Main income streams	Grant funding: Einhorn Family Foundation, Swedish Research Council, Medicines for Malaria Venture, WHO - Alliance for Health Policy and Systems Research, Grand Challenges Canada - Stars in Global Health
Cost considerations	This project's biggest cost components were iCCM training costs and the costs associated with providing drugs at a subsidised price.

Scale and Transferability

Scope of operations	Implemented in Kaliro district in Eastern Uganda in 2011; scaled to Mbarara district in Western Uganda in 2013. Kaliro district population 237 000* Mbarara district population 474 000* * Uganda National Population Census 2014
Local engagement	Engagement with Ugandan Ministry of Health, district health departments and the Ugandan National Drug Authority
Scalability	Scaling may be considered in countries that have: <ul style="list-style-type: none"> • high childhood mortality associated with malaria, pneumonia and diarrhoea; • regulatory frameworks permitting the dispensing of medication by private drug shop owners; • capacity for ongoing supervision of drug shop owners.
Sustainability	Suggested considerations for sustainability: <ul style="list-style-type: none"> • conducting a full financial analysis of implementation costs for project team and drug shop owners; • improving financial sustainability through integrating certain processes into existing national systems and structures e.g. supply chain management; • assessing community willingness to pay for medicines as a means of determining appropriate drug subsidies.

2. CHALLENGES

Globally, there has been a focussed effort to reduce under-five mortality. Despite remarkable progress made during the Millennium Development Goals period, it is estimated that in 2015, 5.9 million children under the age of five died (UNICEF, 2015). Children in low and middle-income countries remain at risk of mortality attributable to preventable diseases. Pneumonia, malaria and diarrhoea are responsible for three quarters of deaths in children under five (Liu et al., 2012). The lack of access to prompt and effective health care services remains an important contributor to this burden. Studies have found that timely community case management of malaria can reduce mortality by 60%; early treatment with oral rehydration salts can prevent 90% of deaths caused by acute watery diarrhoea; and providing antibiotic treatment in the case of pneumonia can result in a 70% reduction in mortality (Sirima et al., 2003; Munos, Walker & Black, 2010; Sazawal & Black, 2003).

The integrated community case management (iCCM) strategy has been shown to increase access to life-saving diagnostics and treatment for children under five at the community level in developing countries. Its adoption has rapidly increased since early 2000. In 2005, only ten countries in sub-Saharan Africa had adopted iCCM, but by 2013, 28 countries had adopted this approach (UNICEF, 2005; Rasanathan et al., 2014). The adoption of iCCM was further promoted by the release of a World Health Organization-UNICEF Joint Statement for iCCM in 2012. The utilization of community health workers was proposed as the backbone of this strategy, aiming to enhance equity and access to essential treatment services for children (WHO/UNICEF, 2012). The implementation of iCCM has shown varied results depending on a number of factors. Firstly, factors influencing country adoption of the iCCM strategy at a policy level include its alignment with existing health system structures; the extent to which country ownership and leadership for the strategy has been achieved; and access to sustainable sources of funding (Bennett et al., 2014). Secondly, countries are seeing mixed results in terms of the rate of mortality decline in areas where iCCM is implemented compared to areas where it has not

been implemented. Factors influencing the impact of iCCM include community health worker motivation, deployment and retention; demand-side barriers to utilisation; unreliable pharmaceutical supply chains; and weak supervisory and monitoring systems (Amouzou et al., 2014; Oliver et al., 2014).

Uganda achieved a reduction in its under-five mortality rate from 179 per 1000 live births in 1990 to 66 per 1000 live births in 2013 (Awor, 2016). In addition to various public sector intervention programmes aimed at reducing under-five mortality beginning in 2002, the Ugandan Ministry of Health (MOH) adopted a policy supporting iCCM in 2010, which gave village health teams the ability to treat pneumonia with amoxicillin, malaria with artemisinin-combination therapy (ACT), and diarrhoea with oral rehydration solution (ORS) and zinc (Mubiru et al., 2015). The national pilot was initially launched in eight districts in mid-western Uganda, home to 1.8 million people, 20% of whom are children under five. More than 5000 village health team members were trained in iCCM. The results of the study conducted in the intervention districts were encouraging. Care seeking behaviour for all three diseases improved, there was an increase in treatment coverage for diarrhoea, and enhanced timeliness of treatment for malaria and pneumonia. More recently, the programme was expanded to include newborn care, making Uganda one of the first countries globally to do so (Nalwadda Kayemba et al., 2012). Looking ahead, Uganda has proposed scaling up iCCM to an additional 33 districts between 2015 and 2016 (Wambua & Morgan, 2015).

Despite the success that iCCM implementation has achieved in Uganda through its implementation in the public sector, up to 63% of parents continue to seek care for their febrile children primarily from private clinics and drug shops (Rutebemberwa et al., 2009; Awor et al., 2012). Drug shops are small private outlets that offer over-the-counter medicines and supplies for common illnesses, particularly in rural and hard-to-reach areas. In 2010, Uganda had 6 636 registered drug shops and many more unregistered ones primarily serving the

population residing in rural areas (Uganda Bureau of Statistics (UBOS) & ICF International Inc., 2012). The Ugandan National Drug Authority (NDA) regulates drug shops. Along with over-the-counter medicines, drug shops have been given permission to dispense family planning (pills, condoms and injectables) as well as anti-malarial drugs (Akol et al., 2014; Mbonye et al., 2015). Drug shops are primarily run as private commercial businesses with staff that include a nursing attendant. Community members' preference for seeking care

from these providers is based, inter alia, on ease of access, frustration with drug stock-outs at public health centres, non-fruitful referrals and distrust of village health team members (Rutebemberwa et al., 2009; Nanyonjo et al., 2012; Awor et al., 2012). While care provided within drug shops has been of poor quality traditionally, the sizeable role of drug shops within the Ugandan health context cannot be ignored. Incorporating private providers into the broader iCCM model provides an opportunity for innovation (Awor et al., 2012).

3. INTERVENTION AND IMPLEMENTATION

3.1. ENGAGING THE PRIVATE SECTOR IN REDUCING UNDER-FIVE CHILD MORTALITY

Dr Phyllis Awor, a Ugandan senior research fellow at Makerere University's School of Public Health, started the Drug Shop Integrated Care Management of Childhood Illness Project with colleagues in 2011. This project was an inter-institutional collaborative research project between Makerere University, the Karolinska Institute, Uppsala University and the University of Bergen.

Based on high rates of patient preference and utilisation, Dr Awor and her team identified an opportunity to engage registered private sector drug shops in the Integrated Community Case Management Strategy.

[The] biggest lessons are that solutions are available all around us and we can work with what is on the ground ... Particularly if we are able to do this at the grassroot [level], we should be able to see the solutions. (Dr Phyllis Awor, Primary Researcher)

3.2. EQUIPPING DRUG SHOP OPERATORS (DSOs) IN APPROPRIATE CARE PROVISION

In August 2011, the project was launched in Kaliro and Kamuli, two high-malaria prevalence rural districts in eastern Uganda province, approximately 150 km north-east of Kampala. The intervention was implemented in Kaliro district

within 40 drug shops, and Kamuli district served as the comparison.

The project team set out to equip DSOs and the surrounding community in three ways, which are described below.

iCCM training

All participating DSOs received five days of training in iCCM and received their practical experience at local public health facilities. Accredited district health officials provided all training, and at regular intervals a supervisor and the district drug inspector would conduct visits to the shops to assess treatment provision. Referral systems were put in place to facilitate DSOs referring children with severe conditions to the local public health facility.

Equipment and subsidised drugs

All drug shops were provided with diagnostic equipment for iCCM - respiratory timers and malaria rapid diagnostic tests. Drugs were pre-packed as unit doses which included: ACT, oral rehydration solution, zinc sulphate and amoxicillin. Amoxicillin, an antibiotic, was the only drug that initially had to be procured from outside the country, but since the initiation of the project a local pharmaceutical company started producing amoxicillin in Uganda. All drugs were subsidised during the project period and distribution occurred through registered pharmacies in the vicinity of the drug shops.

Community awareness

A campaign was run to increase awareness and knowledge amongst the local community. Different channels were used, including radio announcements, spreading messages through the local village health team members, and accreditation signage at each participating drug shop.

3.1. COST CONSIDERATIONS

The project was made possible through research grant funding from the Einhorn Family Foundation, the Swedish Research Council and the Medicines for Malaria Venture and WHO Alliance for Health Policy and Systems Research.

Project-associated costs totalled approximately US\$ 500 000. The biggest project related expense, outside of research and data collection, was the cost of iCCM training sessions for DSOs. In addition, the project team decided to subsidise drugs, at 20% of the original price, to DSOs. Retail prices were recommended to DSOs and all pre-packaged medicines received clear price labels (for example ACT at UGX 1000 and Amoxicillin at UGX 1000). DSOs were able to generate a profit margin of 50–80% on drugs. All diagnostic tests were provided free of charge to participating DSOs. The only costs incurred by beneficiaries were the drug purchases. Diagnostic procedures and health advice were provided free of charge.

4. OUTPUTS AND OUTCOMES

4.1. IMPACT ON HEALTHCARE DELIVERY

It excites us a lot that we've shown a way to engage with this group of drug shops and actually harness their potential for improving outcomes in child health. (Dr Phyllis Awor, Primary Researcher)

Utilising a quasi-experimental approach, Dr Awor and her team embarked on a rigorous multi-method data gathering exercise to evaluate whether DSOs who were equipped with iCCM were able to deliver appropriate and high quality of care to children with fever. The intervention was implemented in Kaliro district and Kamuli district was used as the control in order to assess the project's impact. A total of 7 667 children visits occurred across 40 drug shops in Kaliro during the study period. Children had a mean age of 21 months and 80% of children who were seen were recorded as having fever.

Across all drug shops, 98% of children were tested for malaria using a rapid diagnostic test (RDT) and 78% of these tested positive. Prior to the project, no children received a diagnostic test for malaria. Further, 94% of children with a positive RDT result received the recommended malaria treatment. Fast breathing was assessed in 67.9% of children who visited drug shops during the intervention, of

whom 45% were classified as having pneumonia according to iCCM guidelines. Amoxicillin antibiotic treatment was administered to 91% of the children diagnosed with pneumonia. Diarrhoea affected 31% of children, of whom 89% received treatment of oral rehydration solution and zinc. A joint diagnosis of malaria and pneumonia was applicable in 31% of the children visits and in 9% of cases, all three diseases were diagnosed (Awor et al., 2015).

The intervention supported the replacement of cotrimoxazole - the antibiotic that was previously incorrectly used by drug shop owners to treat symptoms of fast breathing - with amoxicillin. There was also a marked improvement in appropriate amoxicillin and ACT utilization. In the intervention district, there was 13 times better access to ORS and zinc for the management of diarrhoea. Overall, it was found that 88% of sick children presenting at drug shops with fever, cough and diarrhoea were appropriately managed according to iCCM guidelines. Lastly, Dr Awor and her team found an increase in the utilization of registered trained drug shops as parents shifted away from unregistered drug shops and other informal health care providers (Awor et al., 2014).

4.2. COMMUNITY AND BENEFICIARY EXPERIENCES

Beyond the results from the rigorous research conducted, the community and beneficiary experiences from this project were positive. Drug shop operators (DSOs) were pleased and thankful for the opportunity to improve their skills. They perceived the benefits of the training to be twofold: it increased their ability to deliver a better service to their clients; and it also increased their clientele, and strengthened their business. Furthermore, mothers of ill children expressed their satisfaction with the accessibility and cost of the service, in comparison to public health facilities where waiting times are long and it is expensive to

reach. *“The mother is saying... ‘You have helped us for a cheap price, which is good’.”* (Drug Shop Operator)

The district health department officials who participated also expressed their satisfaction with the project and emphasised that they had observed an improvement of care and increased happiness from their community. *“[M]others, especially those who have sick children, have been very happy because they were being treated by just self-medication, but now after being trained [drug shop operators] ...give them the proper treatment.”* (Senior Health Educator, District Health Office)

5. SUSTAINABILITY AND SCALABILITY

The results from this project have left the implementation team feeling encouraged and excited about their work. Since starting in eastern Uganda, they have expanded to the west of Kampala and the project is being implemented in Mbarara district. Financial sustainability and integration into the health system are two areas of focus for them. Several elements may assist in achieving greater financial sustainability of the project. Training of DSOs has been integrated within the public structures operating at district level through the utilisation of district health trainers. In terms of the associated supply chain and drug costs, the project team was responsible for importing amoxicillin into Uganda and then utilising existing pharmacies as dispensing agents from which DSOs could purchase drugs. Since the project started, a pharmaceutical company has begun producing amoxicillin in the country.

The team has also identified the opportunity to utilise the national or district medical stores as an alternative distribution channel for medicines. The subsidisation percentage of the iCCM medicines is a further area, which could potentially contribute to sustainability. A market analysis of customer willingness to pay would be valuable as there are currently no standard recommended drug prices in Uganda. In other similar contexts in Uganda, drug

costs are higher and unsubsidised yet remain in demand.

In 2014 and 2015, Dr Awor and her team were able to publish five peer-reviewed journal articles on the research findings of the project. A key question for the team is how to utilise this evidence to influence policy that could support other DSOs who are also adopting the iCCM strategy and dispensing the required medications. Policy change in Uganda, as in many other countries, is a slow process but there are several opportunities or channels that could facilitate adoption. The main change would need to occur at the level of the Ugandan National Drug Authority, the agency responsible for the regulation of medicines and dispensing practices. The provision of antibiotics by DSOs would require a regulatory change since there is currently no recognition of DSOs as official health providers. One option would be for DSOs to be classified as complementary health support staff, for which guidelines do currently exist. A second option would be to leverage an intermediary organisation, such as a non-governmental organisation or social franchise specialising in pharmaceuticals, as an umbrella legal entity to supervise and provide quality assurance of drug shops. One organisation, as an example of this, is the Uganda Health Marketing

Group which takes products, including antibiotics, and services to communities through health camps. Integrating DSOs more closely with implementing governmental priorities, such as

childhood immunization and family planning, would provide authorities with an even more compelling argument for engaging drug shops.

6. KEY LESSONS

6.1 IMPLEMENTATION LESSONS

Getting started

The idea for this project arose from previous work conducted by the team members on care seeking behaviour of communities, especially from private sector providers (Rutebemberwa et al., 2009). A natural next step was to explore whether these providers, who receive a high demand for patient care, especially children with febrile illness, would be able to provide an appropriate level and quality of service.

Framed primarily as a research study, this work had to gain clearance from the ethical review boards of Makerere University as well as the Ugandan National Council of Science and Technology. Establishing a strong relationship with the National Drug Authority was vital to ensuring that DSOs would have the legal authority to dispense antibiotics such as amoxicillin.

Maintaining efforts

The project team started recruiting and training DSOs in the Mbarara district in western Uganda in 2014. One of the factors for the project's success in eastern Uganda was the high prevalence of malaria in that area. This allowed DSOs to increase their clientele base and also achieve positive outputs of malaria diagnosis and treatment. The next step for the team would be to assess the feasibility and success of this approach in a lower prevalence malaria area. Further studies are also being conducted: firstly, to understand the perceptions of participating DSOs and community members, and secondly, to understand the financial implications of implementation to both the project team and the DSOs.

The project team has been active in trying to engage the donor community in its work. The

Global Fund is a key supporter of iCCM in Uganda and through a new co-funding mechanism with other donor agencies, they are supporting the scale up of the programme to 33 districts in Uganda. To date, only community health care workers are recognised for support through this funding, not private sector providers such as DSOs (The Global Fund, 2015).

Overcoming challenges

We turned many stones and we tried to turn every stone and we were patient and we have just kept going and growing better. (Dr Phyllis Awor, Primary Researcher)

Dr Awor and her team had to work hard to overcome several challenges during the course of pioneering this project. The greatest challenge was to align all of the relevant project stakeholders to the overall vision of working together to improve healthcare services for children under five. Other challenges in the implementation process included the need for ongoing training for DSOs due to staff turnover in the shops. Further, time and funding was required to support several drug shops in gaining official registration from the NDA ahead of enrolment in the project.

6.2. PERSONAL LESSONS

It has been a five-year journey for Dr Awor and her team, from conceptualisation of the project to publication of the results. As the senior research fellow on the project, it was a significant personal time investment for Dr Awor, especially as a mother of a young family. The visible changes in people who were engaged in the project and having the opportunity to contribute to giving children a healthy future, motivated and inspired her.

What brought me the most joy... when you see a sick child getting better or a mother actually telling you, 'Thank you' ... You listened to this drug seller actually thanking me four times. That's the joy that it brings to us. ... Changing some people's lives -

the business life and also particularly improving the health of the community - that's what brings the biggest joy. (Dr Phyllis Awor, Primary Researcher)

CASE INSIGHTS

1. Activities to strengthen the technical capacity and quality delivered by the health system need to extend beyond the public sector to also include private providers. This may be particularly appropriate in countries with high out-of-pocket health expenditure and where low-income patients first seek care from private outlets or facilities.
2. Raising community awareness is an important complementary strategy to improving the quality of care provision. Increasing community knowledge on the type and cost of services they can expect, along with clear branding of accredited health facilities could reduce unwarranted private out of pocket expenditure.
3. There is an opportunity for broader collaboration between academics, policy makers, regulators and entrepreneurs in the design of implementation strategies. More comprehensive and holistic strategies help ensure that an effective innovation is financially sustainable and amenable to widespread adoption.

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