Our thanks to the following organizations that provided funding and/or editorial support to produce this supplement:

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Volume 87 | Number 5 | Supplement

The American Journal of Tropical Medicine and Hygiene

Advancing global health since 1903

THE AMERICAN JOURNAL OF TROPICAL MEDICINE AND HYGIENE

official Journal of the American Society of Tropical Medicine and Hygiene

VOLUME 87 NOVEMBER 2012 NUMBER 5 SUPPLEMENT

Special Supplement on integrated Community Case Management

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THE AMERICAN JOURNAL OF TROPICAL MEDICINE AND HYGIENE

(ISSN 0002-9637)

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American Society of Tropical Medicine and Hygiene

The American Journal of Tropical Medicine and Hygiene (ISSN 0002-9637) is a peer-reviewed journal published twelve times a year, in two volumes, by the American Society of Tropical Medicine and Hygiene, 111 Deer Lake Road, Suite 100, Deerfield, IL 60015. The journal is the leading international journal in tropical medicine. Content includes original scientific articles and *cutting-edge* science covering new research with an emphasis on laboratory science and the application of technology in the fields of tropical medicine, parasitology, immunology, infectious diseases, epidemiology, basic and molecular biology, virology, and international medicine. The journal publishes unsolicited peer-reviewed manuscripts, invited review articles, short reports, case studies, reports on the efficacy of new drugs and methods of treatment, prevention and control methodologies, new testing methods and equipment, and letters to the editor. Topics range from applied epidemiology in such relevant areas as AIDS to the molecular biology of vaccine development.

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The American Journal of Tropical Medicine and Hygiene is abstracted or indexed in the *Index Medicus, Biological Abstracts, Protozoological Abstracts, Helminthological Abstracts, Review of Applied Entomology, Tropical Disease Bulletin,* and *EMBASE/Excerpta Medica.*

The American Journal of Tropical Medicine and Hygiene is printed on acid-free paper that meets the requirements of ANSI/NISO Z39.48-1992 (Permanence of Paper).

Postmaster
Periodicals postage is paid at Deerfield, IL, with an additional office at Hanover, PA. POSTMASTER: Send address changes to the American Society of Tropical Medicine and Hygiene, 111 Deer Lake Road, Suite 100, Deerfield, IL 60015.

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ACKNOWLEDGMENTS

This supplement was made possible by the generous support of the United Nations Children's Fund in collaboration with Save the Children Federation, Inc. and the American people through the United States Agency for International Development (USAID) Maternal and Child Health Integrated Program (MCHIP). Any opinions expressed in this supplement do not necessarily reflect the views of USAID or the United States Government.

COVER PHOTO ATTRIBUTIONS

Top left, top center, and bottom: Franco Pagnoni, WHO/TDR and Global Malaria Program, Geneva, Switzerland

Top right: Karin Källander, Malaria Consortium, Kampala, Uganda

Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, p. 1
doi:10.4269/ajtmh.2012.12-0546

Preface

Special CCM Supplement in the *American Journal of Tropical Medicine and Hygiene*

Although substantial progress has been made over the past two decades in reducing child mortality, the fact remains that far too many children continue to die before their fifth birthday. A large proportion of these deaths—more than one-third—occur as a result of pneumonia, diarrhea, and malaria. Addressing these child killers in the communities where they occur is, therefore, critical for achieving our child survival goals.

In June of this year the Governments of Ethiopia, India, and the United States, in collaboration with UNICEF, brought together over 700 government, civil society, and private sector participants from more than 80 countries to renew the global commitment to end preventable child deaths. The evidence presented at the Call to Action summit demonstrated that it is feasible for the world to greatly decrease that most outrageous of inequities—the huge gap in child mortality between the poorest and richest nations—by focusing on reaching the most disadvantaged and hardest to reach children in every country.

The program strategy addressed by the papers in this supplement, integrated community case management (iCCM), is one of the novel approaches that will help us do just that. In 2010 UNICEF released "Narrowing the Gaps to Meet the Goals," a special report on a new study, which showed that an equity-focused approach could move us more quickly and cost-effectively toward MDG 4 & 5, with the potential of averting millions of child deaths by 2015. Training and deploying community health workers to deliver basic health services in hard to reach areas is one of the main equity-focused strategies that must be used.

However, we need more evidence on the most effective ways to implement iCCM and information on how to overcome the main barriers that impede the success of this strategy. We need to understand better the best ways to support frontline health workers and the systems they need to effectively deliver iCCM to populations without easy access to facility-based services, and to address demand-side barriers to care. There is a need for well-designed applied research to optimize delivery of these interventions at the community level and to help make these interventions more cost-effective and sustainable.

These are exactly the issues and questions that the papers in this important supplement on iCCM address. We hope that the new evidence contained in this supplement will help to inform policymakers, program managers, and all partners who are supporting scale up of community treatment programs aimed at reaching poor and disadvantaged children. It is important to note that, in addition to appropriate treatment, there is recognition that a broad inter-sectoral approach focused on effective prevention—breastfeeding, clean water, good sanitation and hygiene, immunization, insecticide-treated nets, and appropriate behavior change communication—is required for maximum impact on pneumonia, diarrhea, and malaria.

We at UNICEF recognize the importance of strong partnerships and will continue to work closely with key partners as part of the global CCM Task Force to put this evidence into action. This includes the World Health Organization (WHO), Special Program for Research and Training in Tropical Diseases (TDR), United States Agency for International Development (USAID), Save the Children, Boston University, Karolinska Institutet, and others, many of whom have made important contributions to this special supplement.

UNICEF is committed to working with governments to achieve universal coverage of effective interventions and support iCCM as an essential strategy, which will foster equity and contribute to sustained reduction in child mortality. The evidence presented here will help us do just that.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 2–5
doi:10.4269/ajtmh.2012.12-0504

Introduction to a Special Supplement: Evidence for the Implementation, Effects, and Impact of the Integrated Community Case Management Strategy to Treat Childhood Infection

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In 2010, 7.6 million children died before the age of five,[1] two-thirds unnecessarily.[2] A concise list of evidence-based, life-saving interventions guides health policy makers, planners, and program implementers to decrease child mortality in low and middle income countries.[2,3] Adding to the list, through discovery science, is challenging and exciting. Bringing existing interventions to families who need them, through delivery science, is at the same time more challenging, perhaps a bit less exciting, but more life-saving. The greatest gains to be made in intervention coverage across the continuum of care are for newly introduced interventions, as expected, and for existing curative interventions.[4] Similarly, modeling exercises have repeatedly shown that the greatest reductions in mortality for children less than five years of age are to be achieved through increasing the coverage of treatment interventions for the three major causes of childhood mortality: pneumonia, malaria, and diarrhea.[5]

Because millions live at or beyond the periphery of the health system, there is a need to improve access to care for common childhood infectious diseases by bringing treatment closer to the community, especially in rural settings where distance, cost, and limited availability of primary health centers exist. Integrated community case management (iCCM) is a strategy to train, support, and supply community health workers (CHWs) to provide diagnostics and treatments for pneumonia, diarrhea, and malaria for sick children of families with difficult access to case management at health facilities. A pro-equity strategy, iCCM is not easy to implement.[6] Health systems tend to be the most challenged in those high mortality settings in which iCCM is most needed. Moreover, iCCM has many steps that must be performed sequentially and completely for care to be successful. Deviations can result in bad outcomes for the sick child, the community (i.e., increased drug resistance), and the program. In addition, CHWs delivering iCCM must master ancillary skills, such as documentation and supply management, among others. The global health community needs guidance for implementing iCCM.

In response, a World Health Organization–Tropical Disease Research/United Nations Children's Fund (WHO-TDR/UNICEF) Joint Meeting for Community Case Management of Fever (Geneva, June 2008) produced a CCM research agenda.[7] The global CCM Operations Research Group (ccm.org) further refined the agenda at a UNICEF meeting in New York (October 2008) and at a Program for Global Pediatric Research workshop on CCM for pneumonia in Vancouver (May 2010).[8] This agenda remains in place today (Table 1).[9] In Stockholm (May 2009), ccm.org proposed a generic evaluation framework for iCCM (Figure 1).[9] On the basis of a results framework,[10] the schema includes outcomes (boxes in top three rows) and processes (partitioned box at the bottom) to implement the strategy.

The World Health Organization and UNICEF have just released a Joint Statement for iCCM as an equity-focused strategy to improve access to case management.[11] This supplement commences with a re-publication of this document,[12] which summarizes much of the global evidence base until now. The purpose of these papers is to augment the experience base and evidence base for iCCM, and then chart the way forward for future research. We have mapped the included contributions against the research questions (Table 1) and results and/or processes (Figure 2). This large collection of CCM research informs 16 research questions. The country reports are almost exclusively from sub-Saharan Africa, with analyses from the Democratic Republic of the Congo, Ethiopia, Ghana, Côte d'Ivoire, Malawi, Mali, Rwanda, Sierra Leone, Uganda, Zambia, and Pakistan. Other papers address global issues, such as methods to measure access to case management[13] and indicators to monitor iCCM programs.[14]

This supplement informs nearly all results and processes in the evaluation framework (Figure 2). Chinbuah and others[15] evaluated the impact on all-cause mortality of children 2–59 months of age, adding an antibiotic for pneumonia to an existing home-based antimalarial for fever strategy in Ghana. Mukanga and others[16] reported the effect of implementing the iCCM package on the clinical outcome of febrile disease and on the quality of drug use in Uganda, Ghana, and Burkina Faso. Regarding use of CCM in eastern Uganda, Rutebemberwa and others[17] measured care-seeking from community medicine distributors in urban and rural settings, and Kalyango and others[18] compared the effect of iCCM and home-based management of fever strategies on care-seeking from community medicine distributors and on community drug use. Kayemba and others.[19] reported health system implications for adding newborn care to iCCM in Uganda. In Malawi, Nsona and others[20] described the

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TABLE 1
Global CCM operations research agenda with contributions from this supplement*

Topic	Question	Supplement contribution
Front-line health workers	1. What is the effect on the performance of CHW when management of one or more disease is added to the existing responsibility?	Chinbuah and others,[15] Kayemba and others[19]
	2. Are CHWs able to assess, classify, and treat various illnesses under integrated CCM?	Mukanga and others[16]
	3. What are the best ways to improve and sustain performance of CHWs?	
	4. What are the cost and performance of different training methods for (illiterate/literate) CHWs?	
	5. What are the best methods for evaluating the quality of service provided by CHW?	Cardemil and others[28]
	6. What is the optimal number of CHWs to give near universal coverage to a given geographic area?	Guenther and others[13]
	7. What are the best ways of supervising CHWs?	
	8. Which factors increase recruitment and reduce attrition?	Strachan and others[26]
	9. Which methods of remuneration/incentivization are effective and sustainable?	
Implementation	10. What are the cost and cost-effectiveness of CCM?	Sadruddin and others[29]
	11. What are appropriate methods for cost recovery and financing?	
	12. How can effective coverage be achieved by CCM (equity, community effectiveness, etc.)?	Guenther and others,[13] Kalyango and others[18]
	13. How can the private sector become involved in delivering integrated CCM?	Awor and others[23]
	14. How acceptable are CHWs to the health system, and how can CCM requirements for drugs, supplies, supervision, etc. be met?	Callaghan-Koru and others,[21] Chandani and others[27]
	15. What are health system effects of CCM on referral and caseload and mix?	Nsona and others,[20] Lainez and others,[30] Seidenberg and others[25]
	16. What is the effect of CCM on antibiotic resistance?	
	17. What is the impact of CCM on drug use and therapeutic outcomes in the community?	Kalyango and others,[18] Mukanga and others[16]
Management of illness	18. How can available tools (RDTs, clinical signs, timers, drugs, pulse oximeters, etc.) be combined into clinical algorithms?	
	19. What is the algorithm performance in different epidemiologic scenarios?	
	20. What is the appropriate duration of antibiotic treatment of WHO-defined non-severe pneumonia in African settings?	
	21. Can CHWs treat WHO-defined severe pneumonia in the community?	Sadruddin and others[29]
	22. How can age-dose regimens for different drugs be harmonized, and what are the effects on treatment of different packaging techniques?	
	23. What is the impact of pre-referral drugs on clinical outcomes of children with severe disease?	
	24. What is the most appropriate antibiotic for treatment of pneumonia?	
	25. What is the most appropriate formulation of antibiotics?	
Families and caregivers	26. Do family members recognize the disease and promptly seek care?	Seidenberg and others,[25] Nanyongo and others,[24] Awor and others[23]
	27. What are the elements that facilitate family members to use CCM services?	Rutebemberwa and others[17]
	28. Do family members follow treatment recommendations properly?	
	29. How does prescription of multiple medicines for multiple diseases (e.g., malaria and pneumonia) impact adherence?	
Impact	30. What is the impact of integrated CCM on health and survival of children?	Chinbuah and others,[15] Mukanga and others[16]
	31. Does CCM lead to increased penetration in terms of reaching the poor? (effective coverage)	Guenther and others,[13] George and others[22]

*CCM = community case management; CHW = community health worker; RDT = rapid diagnostic test; WHO = World Health Organization.

national scale-up of iCCM, and Callaghan-Koru and others[21] studied health workers' and managers' perceptions of the iCCM strategy and the CHWs delivering it. McGorman and others[14] proposed, through a health systems lens, benchmarks and indicators for planning, introducing, and scaling up iCCM. Guenther and others[13] measured and modeled access to case management with and without iCCM in Malawi, Mali, and Zambia. George and others[22] characterized the CHWs relied upon to increase access to case management across sub-Saharan Africa. Regarding demand for iCCM in Uganda, Awor and others[23] studied care-seeking for sick children, noting the potential role for and the uneven quality of care in the private sector; and Nanyongo and others[24] reported community acceptability of iCCM. In Zambia, Seidenberg and others[25] reported the effect of iCCM on care-seeking practices for sick children. Regarding policy, the joint statement of Young and others[12] endorses iCCM globally, to encourage countries and donors alike.

Regarding processes to ensure access, Strachan and others[26] reported stakeholder perceptions of approaches to improve CHW retention and motivation. Chandani and others[27] studied determinants of medicine supply for CCM in three countries, and Cardemil and others[28] compared methods to assess case management performance; both papers highlighted processes to ensure service quality. Sadruddin and others[29] reported the household cost savings afforded by CCM for severe pneumonia in Pakistan, an important process to enable the policy environment. Lainez and others[30] report practical applications of routine CCM service statistics, a cross-cutting process informing several intermediate results. The 19 reports in this supplement make important additions to a growing evidence base, which must still grow further.[31]

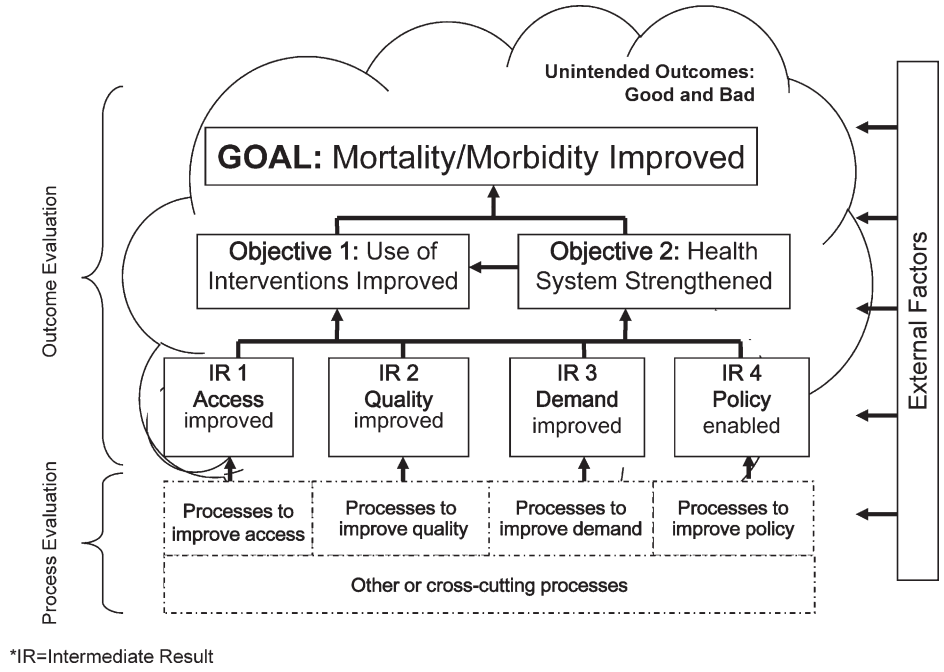

FIGURE 1. Evaluation framework.

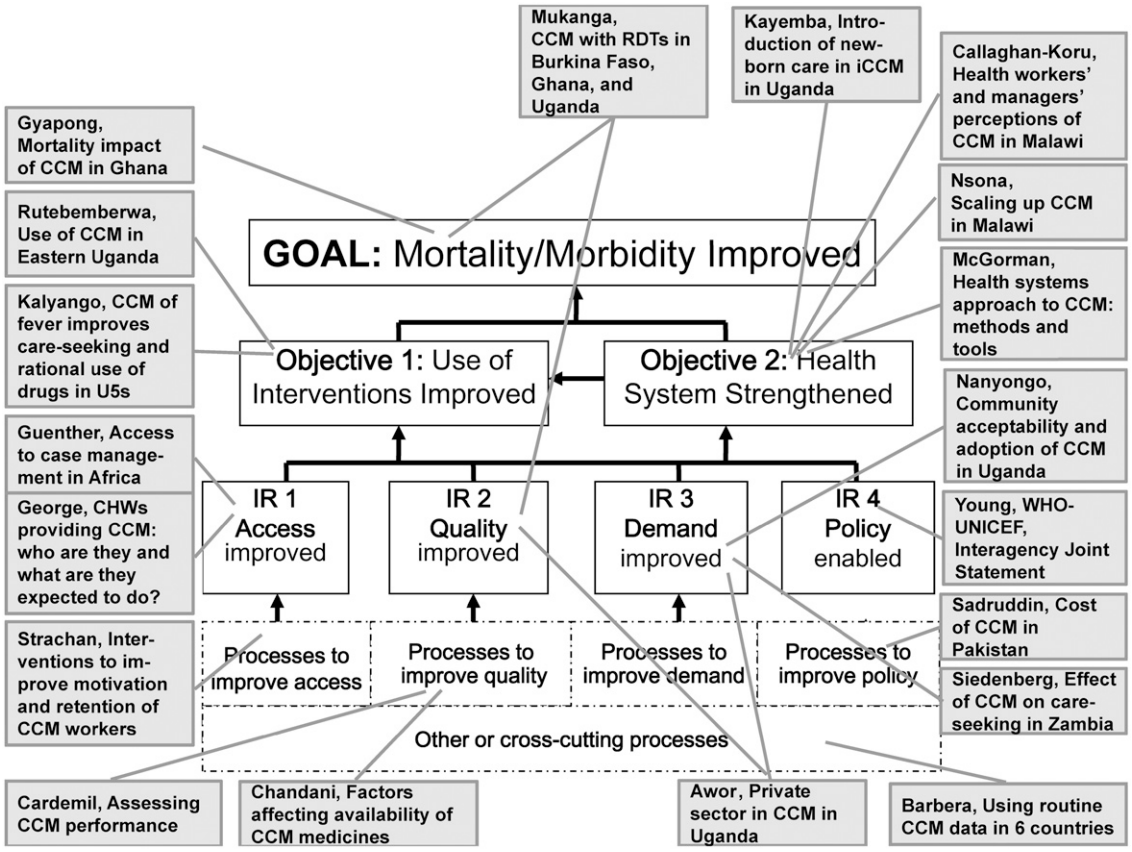

FIGURE 2. Evaluation framework with Supplement contributions. iCCM = integrated community case management; CHW = community health worker; WHO-UNICEF = World Health Organization–United Nations Children's Fund.

Received August 11, 2012. Accepted for publication August 17, 2012.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 6–10
doi:10.4269/ajtmh.2012.12-0221

World Health Organization/United Nations Children's Fund Joint Statement on Integrated Community Case Management: An Equity-Focused Strategy to Improve Access to Essential Treatment Services for Children

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Abstract. This statement presents the latest evidence for integrated community case management of childhood illness, describes the necessary program elements and support tools for effective implementation, and lays out actions that countries and partners can take to support the implementation of integrated community case management at scale.

BRINGING TREATMENT CLOSER TO HOME

Despite the progress made in reducing mortality in children less than five years of age, 75% of the deaths are still caused by a handful of conditions, specifically pneumonia, diarrhea, malaria, and newborn conditions. Malnutrition is associated with approximately one-third of the deaths.

The correct treatment of childhood pneumonia, diarrhea, and malaria is one of the most powerful interventions for reducing mortality.[1] However, in most countries with high mortality rates, facility-based services alone do not provide adequate access to treatment,[2,3] and most importantly not within the crucial window of 24 hours after onset of symptoms. If child mortality is to be adequately addressed, the challenge of access must be undertaken.

Community health workers, appropriately trained, supervised, and supported with an uninterrupted supply of medicines and equipment, can identify and correctly treat most children who have the conditions mentioned above.[4,5] In 2004, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) issued joint statements on the management of pneumonia in community settings[6] and the clinical management of acute diarrhea,[7] both of which highlighted the important role of community-based treatment. A recent review by the Child Health Epidemiology Reference Group estimated that community management of all cases of childhood pneumonia could result in a 70% reduction in mortality from pneumonia in children less than five years of age.[8] Community case management (CCM) of malaria can reduce overall and malaria-specific mortality in children less than five years of age by 40% and 60%, respectively, and severe malaria morbidity by 53%.[9,10] Oral rehydration salts (ORS) and zinc are effective against diarrhea mortality in home and community settings, and ORS is estimated to prevent 70–90% of deaths caused by acute watery diarrhea,[11] and zinc is estimated to decrease diarrhea mortality by 11.5%.[12]

For these reasons, UNICEF, WHO, and partners working in an increasing number of countries are supporting the integrated CCM (iCCM) strategy to train, supply, and supervise front-line workers to treat children for diarrhea and pneumonia, and for malaria in malaria-affected countries, using ORS and zinc, oral antibiotics, and artemisinin-based combination therapy. In addition, the availability of high-quality rapid diagnostic tests for malaria has made it possible to test for malaria at the community level. Use of these tests will make the need for high quality integrated treatment, including iCCM, even more pressing, to ensure adequate health worker response to febrile children with or without malaria. Finally, iCCM also enables community health workers to identify children with severe acute malnutrition through the assessment of mid-upper-arm circumference.

CURRENT CONTEXT

The number of children dying worldwide continues to decrease, and although this is encouraging, the decrease has been slow, stagnating or even reversing in many countries, particularly in sub-Saharan Africa. Although new preventive interventions, especially pneumococcal conjugate and rotavirus vaccines, will also help reduce mortality, prompt and effective treatment of pneumonia, diarrhea, and malaria remains essential.

The delivery of health services is often weakest where the needs are greatest, and low coverage of the most needed interventions results in a significant unmet need for treatment of these major child killers. In developing countries, current treatment levels are unacceptably low: only 39% of children receive correct treatment of diarrhea,[13] only 30% of children with suspected pneumonia receive an antibiotic,[13] and less than 20% of children with fever in sub-Saharan Africa received a finger/heel stick for malaria testing, in 11 of 13 countries with available data in the region.[14]

Poor and disadvantaged children without access to facility-based case management are at even greater risk, as shown in Figure 1. The role of community health workers in improving access to treatment in underserved areas is shown in Figure 2.

JUSTIFICATION FOR INTEGRATED CCM

Programmatic experience shows that an integrated strategy can be effective in achieving high treatment coverage and delivering high quality of care to sick children in the community. In Nepal, which has more than 20 years of experience in community-based management of child illness, 69% of children less than five years of age have access to treatment,[15] and the case-fatality rate for acute diarrhea and the proportion of severe pneumonia among acute respiratory infection cases across the country have significantly decreased.[16] In

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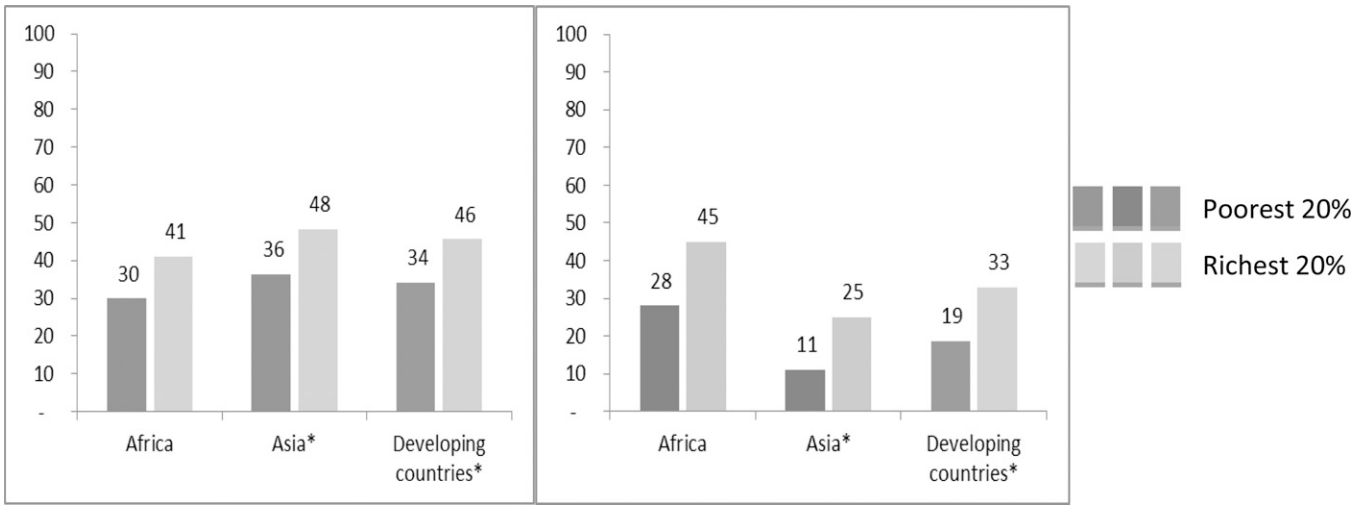

FIGURE 1. Proportion of children < 1–59 months of age with diarrhea receiving oral rehydration salts (ORS) therapy with continued feeding (CF) and those with suspected pneumonia receiving antibiotic, 2006–2011. UNICEF = United Nations Children's Fund.
Notes: Estimates are based on a subset of 59 countries for ORT+CF and 34 countries for the antibiotics indicator, with wealth data for the period 2006-2011 covering 65 per cent and 50 per cent, respectively, of the total under-five population in developing countries (excluding China, for which comparable data are not available).
Oral rehydartion therapy refers to ORS packets, recommended home-made fluids or increased fluids.
*Excludes China
Source: UNICEF global databases, 2012

Ghana, 92% of caregivers of sick children sought treatment from community-based agents trained to manage pneumonia and malaria. Most sought care for their children with fever within 24 hours of onset of fever.[17] In Zambia, a CCM study on pneumonia and malaria found that 68% of children with pneumonia received early and appropriate treatment from community health workers, and that overtreatment of malaria significantly decreased.[5] In Ethiopia, workers deployed in remote communities delivered two and a half times as many treatments for the three diseases than all the facility-based providers in the same district.[18] The proportion of children receiving artemisinin-based combination therapy globally is also increasing, although significant gaps remain.[14]

With adequate training and supervision, community health workers can retain the skills and knowledge necessary to provide appropriate care. In Malawi, 68% of classifications of

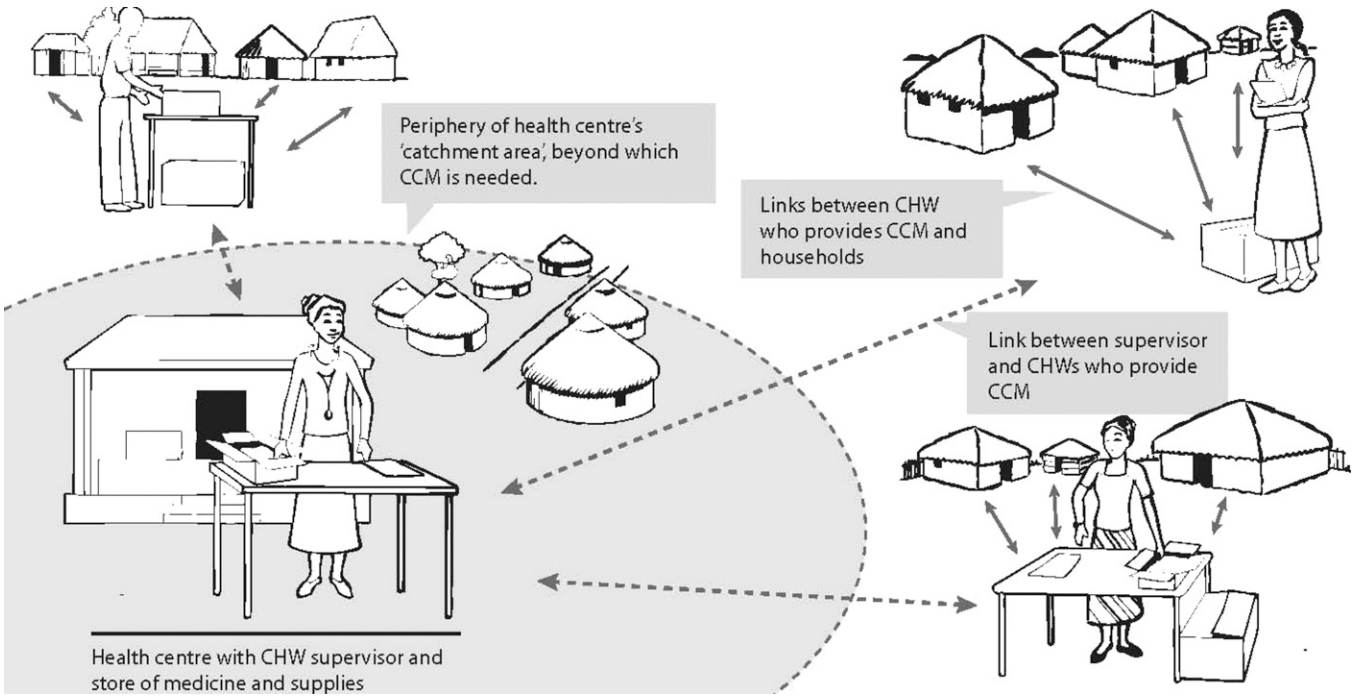

FIGURE 2. Role of community health workers in improving access to treatment in underserved areas. CHW = community health worker; CCM = community case management.

common illnesses by health surveillance assistants were in agreement with assessments done by physicians, and 63% of children were prescribed appropriate medication.[19]

DEPLOYING COMMUNITY HEALTH WORKERS CAN INCREASE COVERAGE AND ACCESS TO TREATMENT

Community health workers are an effective option for investment as part of a comprehensive primary health care system. However, CCM should not be viewed as an inexpensive or low-cost measure. Effective implementation requires policy support, training, supervision, performance maintenance, and regular supplies. In addition, community health workers are increasingly responsible for many health and development tasks, and expansion of their duties needs to be carefully considered in this light.

RESPONSIBILTIES OF COUNTRIES THAT DECIDE TO DEPLOY COMMUNITY HEALTH WORKERS TO INCREASE COVERAGE OF ICCM

Examine the policy options. Existing policies may need to be modified, or new policies put in place, to enable non-medical community health workers to administer antibiotics.

TABLE 1

Eight benchmarks for implementation

Country-level planning, implementation, monitoring, and assessment of integrated community case management (iCCM) activities can be facilitated using a set of benchmarks (www.CCMCentral.com) that were developed by an interagency team.* These benchmarks are organized according to eight system components, each of which key activities and milestones to guide the process:

1. **Coordination and policymaking:** Needs assessment and situation analysis for community-based treatment services, including geographical mapping of communities suitable for iCCM; national policies and guidelines in place to allow treatment at the community level; mapping of current CCM activities and partners; and a national coordination mechanism for iCCM.
2. **Costing and financing:** Costing exercise to ensure that necessary financing is secured.
3. **Human resources:** Clear and well-articulated roles and expectations for community health workers and communities; comprehensive basic and refresher training plan for community health workers; and strategies for retention and motivation.
4. **Supply chain management:** Appropriate child-friendly medicines and supplies for iCCM included in the national essential medicines list; and procurement plan, inventory control, resupply logistics system and logistics management and information system for iCCM with standard operating procedures.
5. **Service delivery and referral:** Appropriate guidelines for clinical assessment, diagnosis, management and referral, including plans for rational use of medicines (and rapid diagnostic tests where applicable); and referral and counter-referral system for iCCM.
6. **Communication and social mobilization:** Communication and social mobilization plan and strategy; and materials and messages for iCCM.
7. **Supervision and performance quality assurance:** Plan and appropriate tools to support effective supervision; trained supervisors; and resources (e.g., vehicles, fuel) to conduct supervision and provide skills coaching to community health workers.
8. **Monitoring and evaluation and health information systems:** Comprehensive monitoring framework and system for all CCM components, integrated within the national health sector plan and health information system; and operational research agenda for iCCM.

* McGorman L and others.[20]

Build on existing programs and initiatives. In many countries, community-based programs for single diseases, such as malaria, have been institutionalized and even scaled up. In these cases, the experience gained from malaria management can serve as a foundation to which case management of pneumonia and diarrhea can be added.

Ensure quality of care. Community health workers need support to maintain and enhance their skills in assessing and managing child illness. Refresher training should be undertaken at periodic intervals, and supportive supervision needs to be planned and carried out on a regular basis. New approaches, such as peer supervision, clinical mentoring, and the use of electronic devices (e.g., cell phones and DVDs), are being used or tried out in some situations.

Ensure adequate and uninterrupted supplies and medicines. It is critical that medicines for iCCM meet the particular needs of young children and their families, and that appropriate formulations, dosages, and packaging designed to improve adherence are used. Coordinated efforts to consolidate systems and support the supply chain management function can be aided by a functioning logistics management information system.

Monitor and assess. A systematic approach to gathering, aggregating, analyzing and reporting data will serve to map and identify key gaps in treatment coverage. Analysis of national and sub-national data related to causes of death, patterns of care-seeking, coverage of interventions, quality of care, and other key indicators can help identify where deployment of community health workers for iCCM may be most effective.

One potential model for such an approach is the Expanded Program of Immunization's Reaching Every District strategy. Through this approach, data on the number of children receiving appropriate treatment for pneumonia, diarrhea, and malaria could be made available to respond to surges in

TABLE 2

Implementation support tools

Training in clinical skills: The World Health Organization and the United Nations Children's Fund have developed an integrated package to train community health workers to manage illness in children 2–59 months of age. Caring for the Sick Child in the Community is the gold standard training package for integrated community case management (iCCM). The interventions require the use of four low-cost medicines and one test: an antibiotic, an antimalarial drug, oral rehydration salts, zinc treatment, and rapid diagnostic test (see treatment recommendations in Table 3). In addition, the guidelines support an assessment using the mid-upper arm circumference strip. The sequence to be followed by the community health worker is based on the principle that one observation leads to one action, and does not depend on individual judgment.

Program management: The CORE Group of non-governmental organizations, with support of the U.S. Agency for International Development, published Introduction to Community Case Management Essentials: A Guide for Program Managers, which contains guidance for iCCM. WHO produced a five-day training course, Managing Programs to Improve Child Health, which includes CCM as a crucial ingredient in national child health programming.

These and other tools are available at www.CCMCentral.com. This website, set up by the global CCM Task Force, is a virtual resource center for iCCM tools and information, including relevant publications and case studies.

TABLE 3

Current treatment recommendations*

☐ If **diarrhea** (< 14 days AND no blood in stool)	☐ **Give oral rehydration salts (ORS).** Help the caregiver give the child ORS solution in front of you until the child is no longer thirsty. ☐ **Give the caregiver 2 ORS packets to take home.** Advise to give as much as the child wants, but **at least** 1/2 cup of ORS solution after each loose stool. ☐ **Give a zinc supplement.** Give 1 dose daily for 10 days: ☐ Age 2–6 months: 1/2 tablet (total = 5 tablets) ☐ Age 6 months–5 years: 1 tablet (total = 10 tablets)
☐ If **fever** (< 7 days) in a malaria-endemic area	☐ **Do a rapid diagnostic test (RDT).** __Positive __Negative ☐ **If RDT result is positive, give the oral antimalarial** artemether-lumefantrine. **Give twice a day for 3 days:** ☐ Age 2 months–3 years: 1 tablet (total = 6 tablets) ☐ Age 3–5 years: 2 tablets (total = 12 tablets)
☐ If **fast breathing**	☐ **Give an oral antibiotic** (250 mg amoxicillin tablet). Give twice a day for 5 days: ☐ Age 2–12 months: 1 tablet (total = 10 tablets) ☐ Age 12 months–5 years: 2 tablets (total = 20 tablets)

* Adapted from World Health Organization, Integrated Management of Childhood Illness: Caring for Newborns and Children in the Community, 2011. Geneva: World Health Organization.

the number of cases and to assess performance, adjust strategies, and monitor supplies.

SUPPORT OF MINISTRIES OF HEALTH IN THESE STEPS BY WHO, UNICEF, AND PARTNERS

A systematic set of benchmarks is shown in Table 1. These will, among other things, help identify research priorities, determine the support needed for operational and implementation research activities, and document and disseminate good practices from current and emerging iCCM implementation. Implementation support tools are shown in Table 2. Current treatment recommendations are shown in Table 3.

CONCLUSIONS

Accelerated action against the main child killers is imperative as countries work to reduce mortality rates in children less than five years of age by two-thirds to achieve the fourth Millennium Development Goal by 2015. Action includes reaching out to underserved populations to provide them with the essential health services they need. Appropriately trained and equipped community health workers, provided with the necessary system supports, can deliver iCCM for malaria, pneumonia, and diarrhea as an effective intervention that increases access to and availability of treatment services for children. WHO and UNICEF support iCCM as an essential strategy that can both foster equity and contribute to sustained reduction in child mortality.

Received April 5, 2012. Accepted for publication April 12, 2012.

Acknowledgments: We thank Liliana Carvajal, Theresa Diaz, and Renee Van de Weerdt (UNICEF); Elizabeth Mason, Jose Martinez, and Franco Pagnoni (WHO); Salim Sadruddin (Save the Children USA); and Troy Jacobs and Lawrence Barat (U.S. Agency for International Development) for providing valuable support in the development of this document through review and comments on various drafts.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 11–20
doi:10.4269/ajtmh.2012.12-0078

Impact of Community Management of Fever (Using Antimalarials With or Without Antibiotics) on Childhood Mortality: A Cluster-Randomized Controlled Trial in Ghana

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Abstract. Malaria and pneumonia are leading causes of childhood mortality. Home Management of fever as Malaria (HMM) enables presumptive treatment with antimalarial drugs but excludes pneumonia. We aimed to evaluate the impact of adding an antibiotic, amoxicillin (AMX) to an antimalarial, artesunate amodiaquine (AAQ+AMX) for treating fever among children 2–59 months of age within the HMM strategy on all-cause mortality. In a stepped-wedge cluster-randomized, open trial, children 2–59 months of age with fever treated with AAQ or AAQ+AMX within HMM were compared with standard care. Mortality reduced significantly by 30% (rate ratio [RR] = 0.70, 95% confidence interval [CI] = 0.53–0.92, $P = 0.011$) in AAQ clusters and by 44% (RR = 0.56, 95% CI = 0.41–0.76, $P = 0.011$) in AAQ+AMX clusters compared with control clusters. The 21% mortality reduction between AAQ and AAQ+AMX (RR = 0.79, 95% CI = 0.56–1.12, $P = 0.195$) was however not statistically significant. Community fever management with antimalarials significantly reduces under-five mortality. Given the lower mortality trend, adding an antibiotic is more beneficial.

INTRODUCTION

Mortality in under-five children remains a major concern. It is one of the key millennium development goals.[1] Although some countries have seen reductions in under-five mortality rates, rates of decline have been slower and almost stagnant in Africa and Asia.[2–4] In Ghana, under-five mortality increased from 108 of 1,000 live births in 1999 to 111 of 1,000 live births in 2003 and remained at that level in 2006.[5] Globally, most post-neonatal deaths in under-five children are caused by only a handful of conditions: pneumonia, malaria, diarrhea, malnutrition, and acquired immunodeficiency syndrome (AIDs).[1,6] Globally, pneumonia is the commonest cause of childhood death, but in developing countries, especially most of sub-Saharan Africa (sSA), malaria is often the commonest cause of death in under-five children.[7,8] Malaria and pneumonia are responsible for 16% and 15% of under-five mortality, respectively, in sSA.[9] In Ghana, malaria and pneumonia are the next most important causes of under-five mortality after early neonatal mortality, contributing 25% and 20% of under-five mortality, respectively.[5] Early treatment has been shown to reduce morbidity and mortality for both diseases.[10–12]

In malaria-endemic Africa, children with pneumonia could easily be misdiagnosed and treated as having malaria. Similarities between symptoms have been well described and in their severe forms, they both present with fever, rapid breathing, and chest in-drawing, with a rapid decline to death, and co-morbidity is not uncommon.[13–16]

Given that these similarities provide opportunities for missed diagnosis, over-treatment and or under-treatment, appropriate diagnostic tools and effective medication are essential to enable health workers determine if a child has malaria, pneumonia or both in order to treat the child quickly and appropriately.[15] Where resources are constrained this becomes even more complicated. Although many forms of health care exist in all societies, most of the African populace has access to orthodox health care mainly through public health centers. These provide primary health care but often lack the requisite equipment and trained staff to provide laboratory-assisted diagnosis of either condition. Indeed, for the majority of rural Africa, even this level of care may be unavailable and not always affordable. Children are thus often first treated at home or within communities.[17,18] Health centers are a second or last resort and children often die at home or within the community.[19]

To address this issue of access to affordable and effective health care, the concept of using laypersons referred to as community health workers (CHWs), previously untrained in health to manage and report on simple ailments has been advocated.[20] The home management for malaria (HMM) strategy is one such strategy that enables fever to be managed presumptively as malaria. Although the concept of home and community management of malaria is well established in Africa, unlike Asia, this is not so for pneumonia despite the co-morbidity reported by others.[15] Community programs managing uncomplicated pneumonia reduced mortality of children in Nepal.[8] In Ghana, earlier attempts to introduce community management of pneumonia where CHWs had to distinguish malaria from pneumonia were abandoned after CHWs consistently found it difficult to distinguish and manage these two illnesses separately.[21] Following the call by the United Nations Children's Fund (UNICEF) and World Health Organization (WHO) in 2002 for pneumonia to be managed at the community level and integrated with ongoing community programs, and given the difficulty in distinguishing malaria from pneumonia, the problems of access, and the importance of reducing the current mortality rates in under-five children, we explored through a cluster-randomized open trial, the added survival benefit of including an antibiotic to the routine management of fever with an anti malarial drug in children under-five. We report on this trial using guidelines from the extension of the consort statement of pragmatic trials.[22–25]

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METHODS

Study site. The trial was conducted between January 2006 and December 2009 in Dangme-West district in southern Ghana, a district with a population of about 110,000 people. Malaria transmission occurs throughout the year with peaks during the rainy seasons in April and October. *Plasmodium falciparum* constitutes 97–99% of parasitemia. Peak parasite rates occur in children 5–9 years of age but morbidity and mortality are highest in children younger than 5 years of age.[26,27] At the time of the trial, caregivers could take their sick children to either of the four health centers or six community clinics in the district. Only one health center had a functioning laboratory microscopic testing for malaria parasites. Elsewhere, malaria was treated presumptively using artesunate amodiaquine. None of them had x-ray facilities. Pneumonia was treated with amoxicillin in line with the national drug guidelines. There was no district hospital and severely ill children were referred to hospitals of neighboring districts. There were two private clinics, two private maternity homes, two pharmacies, and 42 registered drug retail shops in the district from which caregivers were likely to seek care.[28] Drugs used to treat children with fever and or fast breathing within communities was often inappropriate and included chloroquine and various antibiotics such as co-trimoxazole and metronidazole. Baseline data indicated that more than a third of caregivers treated their children themselves with left over drugs or stored drugs. (Results of care seeking and treatment received before the intervention was introduced will be presented elsewhere.) Dodowa Health Research Center (DHRC), a research site of the Ghana Health Service (GHS) is situated in the district, and collects information on vital events during biannual censuses (Health and Demographic Surveillance System [HDSS]).

Hypothesis. The hypothesis for this trial was that early and appropriate management of fever in children under 5 years of age with an antimalarial and an antibiotic within the HMM strategy by CHWs would significantly reduce mortality when compared with only using an antimalarial. The primary outcome was all-cause mortality in the intervention arms (two-arm design), and the control arm (three-arm design). Secondary outcomes were to determine the impact of the intervention on some morbidity indicators (results to be presented elsewhere).

Trial design. This was a cluster-randomized controlled open trial of an antimalarial versus an antimalarial plus an antibiotic for the treatment of fever among children 2–59 (inclusive) months of age in which the interventions were introduced in a stepped wedge manner. The cluster design was chosen over the individual randomized controlled design to reduce contamination that would be difficult to control, to improve supervision of CHWs, and to reduce the overall cost of implementing the trial. The stepped wedge design was chosen for pragmatic reasons, because it was impossible to introduce the interventions into all clusters simultaneously[29]; this also enabled the team to ensure that all children in the study area would eventually receive the intervention, avoiding the ethical issue of leaving children in a study area without the intervention (efficacious drugs) that work.

Randomization. There were 376 communities scattered all over the district with populations of under-five children ranging between 0 and 153. Each community had their own local name and many had their own clan head or leader. Using HDSS data on the community populations, communities were grouped into clusters of ~100 children under 5 years of age. In all, 114 clusters of about 100 children under 5 years of age were formed. Stratified randomization and cluster allocation were performed using computer generated randomization in "Microsoft Excel" 2007 (Microsoft, Redmond, WA) by an independent (visiting) statistician. Briefly, communities belonging to a cluster averaging 100 children were assigned a unique number. Clusters were then assigned random numbers using the Excel random function into the three arms, namely the control arm in which the standard care (usual care available for a sick child through a combination of orthodox and unorthodox drug providers and health facilities) available in the district before the intervention remained unchanged, the artesunate amodiaquine arm (AAQ) and the artesunate amodiaquine and amoxicillin (AAQ+AMX) arm. Because of the stepped wedge design, clusters randomized to the control arm were then subjected to another level of randomization and reassigned random numbers into AAQ and AAQ+AMX arms. No restriction, minimization or allocation sequences were applied.

The intervention. The CHWs dispensed an antimalarial drug alone (artesunate amodiaquine [AAQ]), or together with an antibiotic (artesunate amodiaquine plus amoxicillin [AAQ+AMX]) to children with a fever. Communities were sensitized using various information, education, and communication (IEC) media including community meetings, audio messages, and drama.

Eligibility criteria. Children, 2–59 months of age with fever as reported by the caregiver, born to mothers' resident at least 3 months in the district were eligible. Children as they turned 2 months and children 2–59 months of age who moved into the district during the study were included.

Exclusion criteria. Severely ill children with danger signs (vomiting everything, unable to breastfeed or drink water, lethargy or coma, convulsions) were excluded and referred. Children > 59 months of age and children who turned 60 months of age during the trial were excluded.

Selection of CHWs. The details of the selection process of CHWs are the same as those described in a related trial in which the feasibility of using CHWs in Ghana was explored.[30] Briefly, lay persons resident in their various communities were selected through an interactive process based on criteria set by community members during an open community meeting or by their community leaders. Nominated CHWs were informed that their participation would be voluntary and without any financial remuneration.

Training of CHWs. A CHW manual, relevant data capture tools such as data capture of the sick child consultation, referral forms, and drug recording forms were designed. Various IEC messages and an IEC video were developed. The CHWs were trained over 3 days using modified Integrated Management of Childhood Illnesses (IMCI) modules and video that had been developed with the Ministry of Health/Ghana Health Service for health workers.[31] Training was conducted by experienced Ghana Health Service national IMCI trainers together with some study team members. Training was held separately for CHWs from different arms and was identical apart from one aspect: CHWs from AAQ+AMX clusters received additional training on how to administer amoxicillin and on how to teach caregivers from those clusters to administer amoxicillin at home.

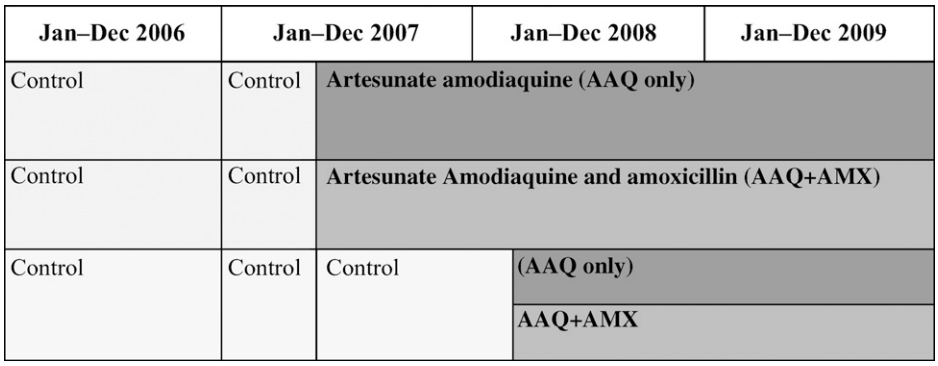

FIGURE 1. Overall timeline of the trial with a stepped wedge introduction of the interventions.

Assessment of child by CHWs. All CHWs were trained to receive clients and to enquire about fever. Fever was not assessed with a thermometer. The CHWs were trained to assess for signs of severe illness defined as difficulty in breastfeeding or drinking water, excessive vomiting, convulsions, lethargy, and coma and such children were referred. The CHWs were also trained to assess the child's respiration for fast breathing (respiratory rates were counted for one minute using a watch), chest in-drawing and stridor as well as other symptoms/signs such as palmer pallor, severe weight loss, diarrhea lasting more than 5 days, bloody diarrhea, and pedal edema. However, no criteria for pneumonia were applied; thus, the presence of any of these symptoms was not used to determine the type of treatment a sick child would receive within their cluster in line with our study design. These caregivers were provided the study drugs for their child's fever, counseled, and referred to the health center with a written referral form where they were told these other symptoms would be treated. Attempts were made to follow-up all referred children (results to be presented elsewhere). The CHWs were provided a list of children within their communities however treatment was not denied any non-resident sick child if they were taken to a CHW by their caregivers with a complaint of fever.

Drugs and dosage. All drugs were produced in different strengths and color-coded for age. Drugs were provided at no cost to caregivers. Artesunate and amodiaquine were prescribed as follows: 25 mg artesunate plus 75 mg amodiaquine for children 2–11 months of age and 50 mg artesunate plus 150 mg amodiaquine for those 12–59 months of age, all once per day for 3 days. Dispersible amoxicillin tablets were prescribed as follows: 300 mg to children aged 2–11 months, 500 mg to those aged 12–35 months, and 650 mg to those 36–59 months of age, twice per day for 3 days[32–34]: the first dose was given under CHW supervision. The CHWs did not follow-up the children at home but caregivers were asked to return with their children after 2 days. Caregivers were also counseled to return if their child's condition worsened, if the child convulsed, developed a skin rash or began itching, became pale, weak, were unable to breastfeed or drink, began vomiting, or had diarrhea or bloody diarrhea after they took the study drug. Generally, caregivers were encouraged to return immediately if their child's condition changed or did not seem to improve. Adverse drug reactions were followed up passively through reports to CHWs by caregivers. These caregivers were followed up by field supervisors and interviewed.

Introduction of the intervention. Over a 3-month period, the intervention was introduced into two-thirds of the 114 clusters (randomized to receive AAQ [37 clusters] and AAQ+AMX [39 clusters] and the remaining third of the clusters were left as control clusters (38 clusters) without any intervention. All three arms ran concurrently allowing the three-arm design to run for 6 months, after which the intervention was introduced into the remaining control clusters leading to a two-arm design (55 clusters in the AAQ arm and 59 clusters in the AAQ+AMX arm), which was maintained until the end of the trial resulting in the stepped wedge design (Figure 1).

Quality assurance. The CHWs were visited fortnightly by field supervisors who checked drug supplies and forms using a standard checklist. Two CHW review trainings were held during the period of the study. The drugs were tested to ensure drug quality during the trial period. The drugs met the minimum standards with a mean disintegration time of 2 min, a dissolution time ranging between 91.5% and 94.6%, and the percentage active ingredients ranging between 94.35% and 95.1%. Field workers who collected data during surveys were different from field supervisors who supervised CHWs and those who collected and validated mortality data.

Sample size for determining mortality rates. The under-five mortality rate within the region was 80 of 1,000 live births at the time the study was initiated.[35] To measure the difference in all-cause mortality between the two intervention arms, using a coefficient of variation of 0.25, a design effect factor of 1.68, an alpha of 0.05% and 80% power, and targeting an effect size of 20% 100 clusters (50 per intervention arm) of 100 children had to be followed up over 18 months. Sixty clusters (30 in each arm) were required to detect an effect size of 25% in all-cause mortality between the AAQ and control arms, and for AAQ+AMX and control arm, the number of clusters was 20 clusters/arm.

Data collection. During the first year baseline information was collected. Mortality was assessed through bi-annual censuses conducted routinely by the HDSS team complimented by a Community Key Informant system (CKI). All selected CHWs were also trained to record any deaths, births, and pregnancies that occurred within their communities. Such information was collated monthly by the study team and reported to the HDSS team for verification.

Other surveys. Twice per year 10 clusters were selected randomly for cross-sectional surveys to collect information on demography, height, weight, hemoglobin level, parasitemia, fever during the preceding 14 days, vitamin A and immunization

status, and presence and use of insecticide-treated bed nets. This was to enable us to determine the impact of the trial on morbidity (results will be presented elsewhere).

Analysis. The data set constituted all deaths collated by the HDSS and the CKI. Because of the stepped wedge nature of the trial, person-years of follow-up were used to calculate each child's contribution to the denominator. Person-time of follow-up for the control period was calculated using either January 1, 2006 (the start of the trial), date child attained 2 months, or date of entry if the child was born or moved in after the start of the trial but before the intervention began for that cluster. Person-time contributing to the intervention phase was calculated from the date that the last community in a cluster began its drug intervention. For most clusters, these dates did not vary much as CHWs were trained in clusters. Follow-up ended when children died, turned 60 months of age, exited the district, or at the end of the trial. Migration between clusters was reduced in the design by providing CHWs with a list of children in their communities and caregivers were requested to visit their own CHWs during sensitization meetings. Migration of children in and out of the district was taken into account during analysis in the following manner: All children each provided with unique identification numbers, were followed up by the HDSS as part of the household census carried out biannually. During a visit to a household, all household members are enumerated. If an eligible child had left the district, the date they left the district was noted; the child designated as "exited" on that date and no longer contributed person-years of follow-up. If the child was found to have come back during the next enumeration census, the dates of return were noted and that child would begin to contribute person-years of follow-up again. If the child had not returned, the event remained noted as "exited from the district," not contributing any more person-years of follow-up. Using this method, multiple periods of follow-up were calculated for children where necessary, thus excluding from the follow-up period, any period for which they had been absent from the district. Migration between clusters could not be totally controlled, however our analysis was by intention to treat. The estimated effects of the intervention are presented as relative risks together with 95% confidence intervals (CI). Crude mortality rates were compared using the χ^2 test for significance. Crude age-specific mortality rates were calculated. Adjusted analysis took into account gender,

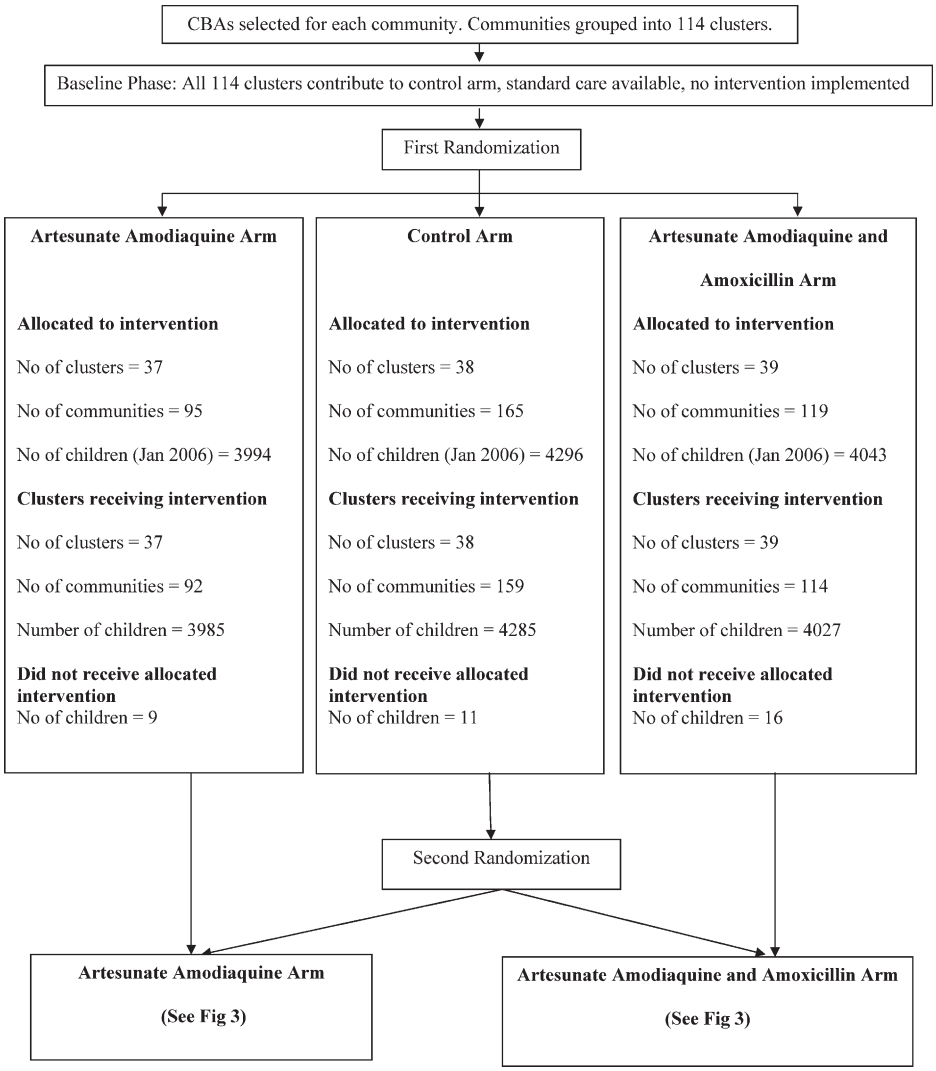

FIGURE 2. Cluster and participant flow after first randomization.

age groups, seasonality, and the cluster-randomized design using the random effects in a Poisson regression model.

Ethics. The trial was approved by the ethics committees of the Ghana Health Services and WHO, through the Special Program for Research and Training in Tropical Diseases (TDR). District health and local government authorities provided approval for the study. Group consent was obtained from community leaders and members during community meetings that were held in the first year before the intervention begun. Written individual informed consent was obtained from all caregivers in the first year to determine their willingness to participate in the entire trial, but written informed consent was also obtained from parents or guardians for all subsequent surveys or interview(s).

RESULTS

In January 2006, there were 12,333 children under 5 years of age resident in the district, a number that increased to 12,454 by December 2009. Almost all caregivers agreed to the general participation of their eligible children under 5 years of age in the trial. The decline rate was 0.2%. All 114 clusters contributed to the control arm until April 2007, when the 37 clusters with 3,994 children were randomized to receive AAQ, 39 clusters with 4,043 children to receive AAQ+AMX received the intervention and 38 clusters with 4,296 children continued to receive standard care (control arm). The control clusters randomized to either of the two interventions received their intervention 6 months later, resulting in two arms of 55 (AAQ) with 6,121 children and 59 (AAQ+AMX) clusters with 6,212 (Figure 1). Initiation of the intervention was delayed because of costs and logistical challenges causing the three-arm design to last for only 6 months instead of 1 year to allow sufficient time for follow-up of the two-arm design. Data on clusters, children included per arm, and deaths are shown in the participant flow charts (Figures 2 and 3). Details on almost 13,000 consultations by CHWs will be published elsewhere however, correct drugs per age group were provided in over 90% of consultations.

Table 1 provides the baseline characteristics of children 2–59 months of age collected during cross-sectional surveys from a total of 30 randomly selected clusters between April 2006 and April 2007 before the interventions were introduced. These surveys established that randomization of clusters to the three arms were similar for almost all relevant variables. The mean age of the children was 29.1 months,

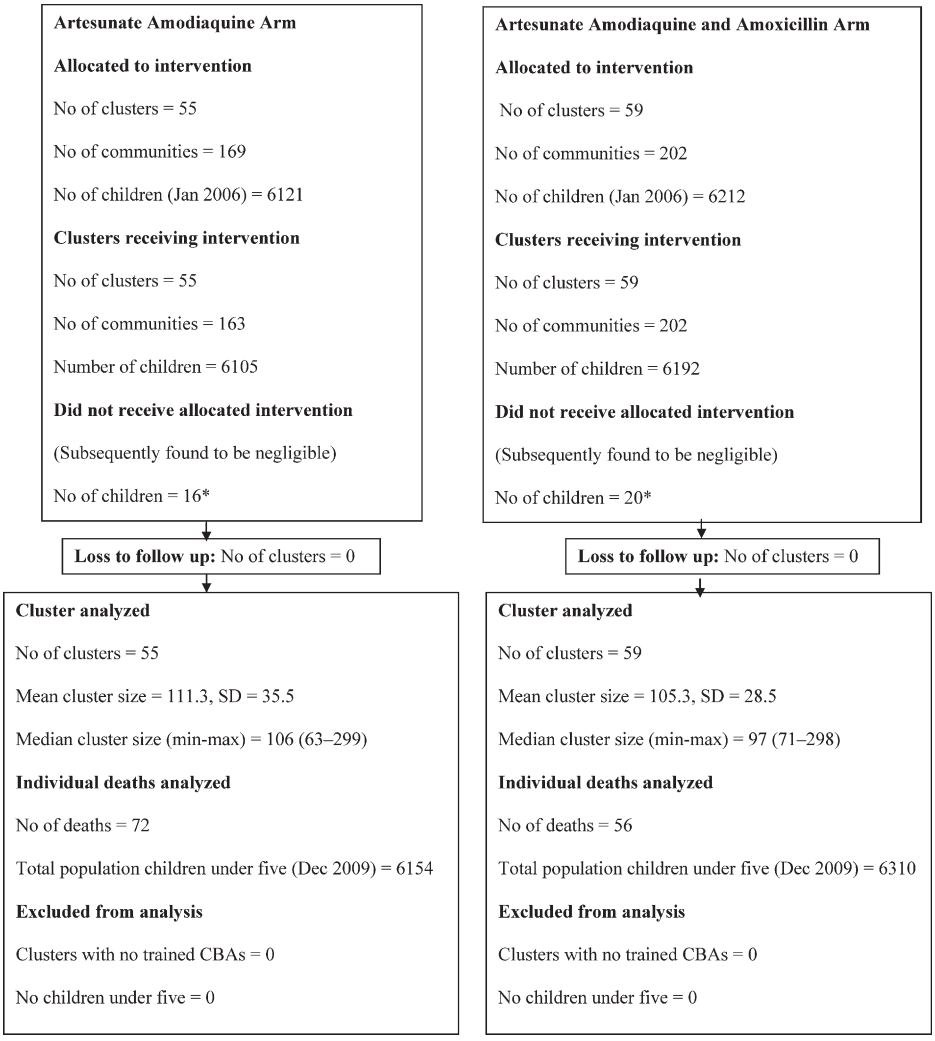

FIGURE 3. Cluster and participant flow after second randomization.

TABLE 1

Baseline variables established during 2-week morbidity recall surveys conducted in randomly selected clusters allocated to specific interventions in the pre-intervention phase of the trial*

Variable	AAQ n/*N* (%)	AAQ+AMX n/*N* (%)	Control n/*N* (%)	Total n/*N* (%)
Children	863 (32.0)	826 (30.6)	1012 (37.5)	2701 (100.0)
Male/Female ratio	49.4:50.6	52.3:47.7	51.6:48.4	51.1:48.9
Mean age months (SD)	29.4 (15.15)	28.9 (16.60)	29.7 (15.85)	29.4 (15.86)
Treated nets*	269/863 (31.2)	302/826 (36.6)	386/1012 (38.1)	957/2701 (35.4)
Parasite count/μL < 5000†	87/863 (10.1)	73/826 (8.9)	148/1012 (14.7)	308/2701 (11.4)
Parasite count/μL ≥ 5000	6/863 (0.7)	3/826 (0.4)	6/1012 (0.6)	15/2701 (0.6%)
Mean hemoglobin g/dL (SD)	9.8 (1.65)	9.9 (1.71)	9.9 (1.57)	9.9 (1.64)
Febrile episodes	80/863 (9.3)	96/826 (11.7)	96/1012 (9.5)	272/2701 (10.1)
Wt for age-underweight < 2 SD	160/854 (18.7)	132/817 (16.2)	191/1008 (18.9)	483/2679 (18.0)
Height for age-stunting < 2 SD	156/850 (18.4)	164/807 (20.3)	197/998 (19.7)	517/2655 (19.5)
Weight for height-wasted < 2SD	61/850 (7.1)	54/807 (6.7)	57/998 (5.7)	182/2637 (6.9)
Children 12–23 months fully immunized∞	144/198 (72.7)	137/176 (77.8)	158/215 (73.5)	439/589 (74.5)
Vitamin A coverage*	723/863 (87.3)	694/826 (90.2)	849/1012 (88.8)	2266/2701 (88.8)

*AAQ = clusters randomized to AAQ artesunate amodiaquine arm; AAQ+AMX = clusters randomized to AAQ+AMX artesunate amodiaquine with amoxicillin arm. Control = clusters randomized to remain without any intervention in the first phase of randomization.

†Statistically significant difference at $P < 0.05$; SD = Standard Deviation. ∞ one dose BCG, three doses DPT/HIPHEP, one dose measles and yellow fever.

SD = 15.86, the male/female ratio was 51.1:48.9. Clusters randomized to the different arms were similar in all but two aspects: in the prevalence's of household ownership treated nets and parasitemia in the children. Clusters randomized to the AAQ arm had a significantly lower prevalence of the use of household ownership of treated nets (31.2%) compared with the clusters randomized to the AAQ+AMX arm (36.6%), and clusters randomized to remain the control arm (38.1%) ($P = 0.005$). The prevalence of parasitemia was also significantly lower in clusters randomized to both the AAQ arm (10.1%) and the AAQ+AMX arm (8.9%) compared with the control arm (14.7%) ($P = 0.000$).

There were 310 deaths during the trial, including 181 that occurred during the control period. During the intervention, 72 children died in AAQ clusters and 57 in AAQ+AMX clusters (Table 2). The number of deaths, person-years of follow-up, crude mortality rates within each arm, as well as mortality rates for the control period in the year 2006 and 2007 remained the same, although a decline in mortality was observed in the intervention arms from 2008 to 2009 (Table 2). Mortality rates in the two intervention arms declined significantly in comparison to the control arm but the difference between the two intervention arms was not statistically significant. The attributable risk indicates a difference between AAQ and AAQ+AMX of < 1/1,000. After adjusting for gender, age group, wet and dry seasons, and clustering, there was still a statistically significant reduction in all cause mortality between both intervention arms and the control arm (AAQ: reduction 30%, RR = 0.70, 95% CI = 0.53–0.92, $P = 0.011$ and AAQ+AMX: reduction 44%, RR = 0.56, 95% CI = 0.41–0.76, $P = 0.011$). However, the difference in the mortality reduction between the AAQ and AAQ+AMX arms of 21% was not significant (RR = 0.79, 95% CI = 0.56–1.12, $P = 0.195$) (Tables 3 and 4) Gender and seasonality had no effect on mortality rates. The mortality reduction was highest in the 36–47- and 48–59-month age groups compared with the 2–11 months age group (Tables 3 and 4). Reduction in all cause mortality between each intervention and the control arm was statistically significant for children in the 36–47 months and 48–59 months age groups (Table 3).

In total 5,818 and 6,601 eligible children were treated in the AAQ and the AAQ+AMX clusters respectively. The numbers of deaths averted were 109 and 124, respectively. The number of children that need to be treated to prevent one child death in both arms was 53. Seven adverse drug reactions were reported by caregivers however only one was assessed by the research team to be so. This child experienced itching after receiving the combination treatment.

TABLE 2

Crude mortality rates by intervention arm and year*

	Intervention arm	Deaths	Person years	Mortality rate/1,000 py	95% confidence intervals
	Control	181	26,760	6.76	5.85–7.82
	AAQ	72	15,109	4.77	3.78–6.00
	AAQ+AMX	57	14,968	3.81	2.94–4.94
Year	Intervention arm	Deaths	Person years	Mortality rate/1,000 py	95% confidence intervals
2006	Control	98	12,8504	7.64	6.27–9.31
2007	Control	64	10.1678	6.30	4.93–8.04
	AAQ	8	1,7714	4.52	2.26–9.03
	AAQ+AMX	11	1.7614	6.24	3.46–11.28
2008	Control	19	3.0324	6.27	3.00–9.82
	AAQ	25	5.6979	4.39	2.97–6.49
	AAQ+AMX	20	5.5894	3.58	2.31–5.55
2009	Control	NA	NA	NA	NA
	AAQ	39	7.2293	5.40	3.94–7.38
	AAQ+AMX	26	7.2079	3.61	2.46–5.30

*AAQ = artesunate amodiaquine only; AAQ+AMX = artesunate amodiaquine with amoxicillin; NA = not applicable.

TABLE 3
Adjusted mortality rate ratios

Indicators	Initial three-arm design		Final two-arm design	
	Rate ratio (95% confidence interval)	*P* value	Rate ratio (95% confidence interval)	*P* value
Arm				
Control*	1		N/A	
AAQ	0.70 (0.53–0.92)	0.011	1	
AAQ+AMX*	0.56 (0.41–0.76)	< 0.001	0.79 (0.56–1.12)	0.195
Age group*				
2–11	1		1	
12–23	0.85 (0.62–1.15)	0.282	0.67 (0.41–1.11)	0.119
24–35	0.67 (0.49–0.93)	0.016	0.79 (0.49–1.27)	0.326
36–47	0.36 (0.24–0.53)	< 0.001	0.41 (0.23–0.73)	0.003
48–59	0.35 (0.24–0.52)	< 0.001	0.34 (0.19–0.63)	0.001
Gender				
Male	1		1	
Female	1 (0.80–1.25)	0.979	0.95 (0.67–1.34)	0.758
Dry season	1		1	
	1.06 (0.84–1.33)	0.627	0.99 (0.70–1.40)	0.952

Three arm: Likelihood-ratio test of alpha = 0: $\chi^2(01) = 1.04$; probability > = $\chi^2 = 0.153$; Two arm: Likelihood-ratio test of alpha = 0:χ^2 (01) = 0.00; probability > = $\chi^2 = 1.000$. AAQ = artesunate amodiaquine only; AAQ+AMX = artesunate amodiaquine with amoxicillin.
*Adjusted for age group, gender, season, clustering, and random effect.

DISCUSSION

Treatment of uncomplicated fever episodes among children 2–59 months of age with the antimalarial (AAQ), or in combination with the antibiotic (AAQ+AMX) at community level by trained CHWs resulted in reduction of all-cause mortality in comparison to those treated with standard care that includes treatment at home, by traditional healers, care from drug retail shops, or from the formal health sector. The AAQ reduced mortality by 30% and AAQ+AMX by 44%, both significantly different in comparison to standard care but without significant difference between the two interventions. We aimed at assessing if adding an antibiotic to the antimalarial treatment as proposed by Home-based Management of Malaria would reduce mortality. Within HMM strategy, children in malaria-endemic areas with fever are considered to suffer from malaria and treated as such if diagnostic means are not available. This approach neglects other causes of fever, in particular respiratory infections, the next important cause of fever in children in Africa. Considerable overlap of symptoms between malaria and pneumonia has been reported such that clinical diagnosis was considered unreliable.[13,15,16] A combination of very high respiratory rate in relation to age and chest in drawing indicates severe pneumonia, but also severe malaria, and is reason for referral. In line with the HMM program, our approach was practical; fever was noted by a caregiver, generally the mother, the CHW examined the child, assessed the need for referral and gave treatment. For examination and assessment a checklist was used. Information on symptoms and signs at baseline among sick children with a fever is being used to study overlap between malaria and pneumonia in our study population. This practical approach is likely to be common practice in many areas in the countryside of sSA.

We, like others before us, have shown that community management of fever by trained CWHs using antimalarials and antibiotics is feasible, even with artemisinin combination treatment with or without an antibiotic.[36] Studies on community case management of pneumonia among 0–5-year-old children showed a 50–70% reduction of deaths.[8,37] The 21% reduction between our intervention arms is likely caused by reduction of deaths because of bacterial infections, notably

TABLE 4
Adjusted mortality rate ratios between the two intervention arms and the control arm

Indicators	AAQ vs. control		AAQ+AMX vs. control	
	Rate ratio (95% confidence interval)	*P* value	Rate ratio (95% confidence interval)	*P* value
Arm				
Control*	1		1	
AAQ	0.70 (0.53–0.92)	0.011	NA	
AAQ+AMX*	NA		0.56 (0.41–0.76)	< 0.001
Age group*				
2–11	1		1	
12–23	0.96 (0.68–1.34)	0.800	0.83 (0.59–1.17)	0.281
24–35	0.70 (0.49–1.00)	0.052	0.59 (0.41–0.85)	0.005
36–47	0.37 (0.24–0.58)	< 0.001	0.31 (0.20–0.49)	< 0.001
48–59	0.37 (0.24–0.57)	< 0.001	0.34 (0.22–0.53)	< 0.001
Gender				
Male	1		1	
Female	0.99 (0.77–1.27)	0.940	1.03 (0.80–1.33)	0.813
Dry season	1		1	
	1.10 (0.85–1.40)	0.459	1.05 (0.81–1.37)	0.702

Three arm: Likelihood-ratio test of alpha = 0: $\chi^2(01) = 1.04$; probability > = $\chi^2 = 0.153$;
AAQ = artesunate amodiaquine only; AAQ+AMX = artesunate amodiaquine with amoxicillin.
*Adjusted for age group, gender, season, clustering, and random effect.

pneumonia. Pneumonia is a significant cause of childhood mortality in Ghana consistently ranking second or third as top causes of childhood mortality after malaria.

Several factors probably contributed to the lack of statistical significance for the difference between the two intervention arms. Only mortality rates for children 0–59 months of age in the study district were available and formed the basis for our calculations, however our intervention was limited to children aged 2–59 months. Neonatal and post-neonatal mortality have since been shown to contribute considerably to overall under-five mortality in Ghana.[5] The mortality rate in our study population was probably lower, reducing the power of the study. By not targeting pneumonia specifically for treatment in the second arm, we incur a dilution effect, thereby reducing our ability to achieve significant differences. A *post hoc* calculation based on the actual prevailing mortality rate for this age group during the control period shows a power of 64%. Mortality declined in general (Table 2), which may be a reflection of the socio-economic development in the country and general improvements in health and health care, but major shifts in child health care within our study district and the country did not occur during the study period. Since the end of our study the Ghana Child Health policy supports management of malaria and pneumonia at community level by trained CHWs.

At the time of conceptualization of our study and during the study (2006–2010) RDTs had not yet been evaluated on large scale in the countryside let alone if used by CHWs in community projects. We acknowledge this as a limitation. Recent field trials have proved that RDT use by CHWs is feasible and improves the ability of these workers to distinguish between malaria and pneumonia.[38–41] The use of RDTs in identifying children with fever not caused by malaria, may lead to better case management of other diseases and to further mortality reduction. However, RDTs have not always led to rational use of antimalarial drugs. Health workers have been reluctant to decline antimalarial treatment of RDT negative patients leading to over-prescription of ACTs.[38–40,42,43] Current WHO malaria treatment guidelines (2010) recommend parasitological confirmation of malaria before treatment in all age groups and settings, including at the community level.[44] Some authors have cautioned against a policy that abandons presumptive treatment for RDT use at all levels, however others insist the change must be made.[45,46] In 2011, Ghana was unable to implement the use of RDTs even at health facility level. In its most current guidelines for case management of malaria, although the GHS recognized RDTs as being beneficial, health care workers were encouraged to consider laboratory confirmation of malaria in under-five children on a case-by-case basis, if their practice settings were favorable."[47]

We acknowledge other limitations of our study. Children were assessed for criteria for referral (high respiration rate and chest in-drawing). Fever was not actually measured. The basis of our study was the HMM approach: fever was treated as malaria unless another cause is obvious. The WHO RDT-based policy at the time was restricted to adults and older children.[48] Children under 5 years of age were still treated presumptively. This approach did not include respiratory infections, inclusive of pneumonia and other treatable bacterial infections. Furthermore, a previous trial in Ghana in which CHWs had to be trained to distinguish malaria from pneumonia using respiratory rates had faced major challenges resulting in that part of the trial being abandoned.[5] With the well-described symptom overlap between malaria and pneumonia, our aim was not to distinguish malaria from pneumonia but to determine if there would be a reduction in under-five mortality sufficient enough for Ghana to review its HMM policy at the community level where diagnostic facilities are not available. Fever was used because it is the entry point for HMM. The caregiver's report of fever as a proxy for malaria has been found to be a reliable indicator of malaria in children in the same district, although fairly unreliable elsewhere.[49] Differences in the reliability of fever as malaria may be caused by the differences in malaria transmission and general disease epidemiology of those countries. We also realized that large-scale use of antibiotics may have negative consequences. However, in a controlled community trial like this, compliance with antibiotic regimen and rational antibiotic use has been shown to improve rather than deteriorate (data not shown). In Ghana, access to antibiotics although regulated, is poorly controlled and caregivers can buy antibiotics over the counter from several sources. During baseline surveys, a third of caregivers reported storage of antibiotics including amoxicillin and co-trimoxazole at home (data not shown). Access to antibiotics in the AAQ arm could also have contributed to further reducing our effect size, however this cannot be confirmed. Caregiver compliance with treatment regimen was high (data to be presented elsewhere). A significant reduction in mortality between the two intervention arms could have helped in the discussion on the balance of positive and negative effects of this approach, however we were unable to show statistical significance. The cost-benefit analysis of this approach was investigated and found to be cost-effective both for the antimalarial arm and the antimalarial and antibiotic arm.[50]

The stepped wedge design has been described in Hussey and Huges as "particularly useful for evaluating the population-level impact of an intervention that has been shown to be effective in an individually randomized trial."[51] Introducing the intervention and disseminating information to a population of 110,000 could only be performed gradually, hence a phased design. The period of randomization into three arms was actually too short for a concurrent comparison. The two interventions are in fact compared without a concurrent control group, thus with a historical control group, which is not ideal. However, withholding treatment from children was considered unethical. A concurrent design would have meant implementing a HDSS in another district that would have required funds far beyond the funding for this trial. The alternative would have been to use panel surveys to access mortality in a neighboring district but the limitations of that, given our financial and logistic constraints made this unfeasible. Lack of a concurrent control group for the full duration of the study meant we compared mortality rates overlapping different years and this does not account for other factors that might have influenced mortality in one year but not another. Fortunately, there were no major epidemics or changes in health or economic policies over the study period that could have directly impacted child mortality in the district.

Mortality rates in the district were found to be lower than estimated by the DHS report for mortality among under-five children within the region and was not anticipated because the Dangme-West district is rural and mortality rates in rural districts tend to be higher than the reported regional average mortality rates in Ghana.[35]

The study findings are unlikely to be the same in areas with different malaria transmission patterns. If ARI are caused by viral infections, antibiotics are then unnecessary, however, if bacterial pneumonias contribute significantly to under-five mortality tthen the trend toward lower mortality is biologically plausible.

In conclusion, our study clearly shows that home management of fevers, a strategy in which lay persons are trained to assess and treat children 2–59 months of age reported to have fever with antimalarials with or without an antibiotic significantly reduces mortality. The trend toward lower mortality in the group receiving an antimalarial and an antibiotic, and evidence from other studies that show the benefits of treating pneumonia at the community level, suggests that integrated management of both malaria and pneumonia is preferable to therapy of malaria alone.

Received February 2, 2012. Accepted for publication July 10, 2012.

Acknowledgments: The authors thank the caregivers, their children, and community members of the Dangme-West District who participated in this trial. We acknowledge the contribution of Dodowa Health Research Centre staff, especially the HDSS team, the malaria pneumonia team, and staff of the health centers who received our referrals. We are grateful for technical input from K. Koram of Noguchi Memorial Institute for Medical Research, Evelyn Ansah-The District Director of Health Services, Dangme West District, Ghana. Frank Cobelens from the Academic Medical Center Netherlands and Simon Cousens of the London School of Hygiene and Tropical Medicine who reviewed our analysis.

ICMJE criteria for authorship met: M. A. Chinbuah, P. A. Kager, M. Gyapong, J. O. Gyapong made primary contributions to the design and undertaking of the trial, analysis, interpretation of results and writing the manuscript. M. Abbey and J. Nonvignon contributed to the undertaking of the trial and edited written drafts. E. Awini contributed to the HDSS field work, analysis and edited written drafts. M. Adjuik conducted the randomization of clusters, contributed to analysis and edited written drafts. M. Aikins contributed to the overall design of the study and edited written drafts. F. Pagnoni contributed to the interpretation of the results and writing of the manuscript.

Financial support: This was provided by UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases and the Knowledge Enriches Programme of the Netherlands Organization for the Advancement of Tropical Research, WOTRO (NWO) in the Netherlands.

Disclosure: TDR/UNDP Trial registration. A: 20189: The trial protocol can be accessed from the WHO (Ethics Committee).

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 21–29
doi:10.4269/ajtmh.2012.11-0816

Integrated Community Case Management of Fever in Children under Five Using Rapid Diagnostic Tests and Respiratory Rate Counting: A Multi-Country Cluster Randomized Trial

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Abstract. Evidence on the impact of using diagnostic tests in community case management of febrile children is limited. This effectiveness trial conducted in Burkina Faso, Ghana, and Uganda, compared a diagnostic and treatment package for malaria and pneumonia with presumptive treatment with anti-malarial drugs; artemisinin combination therapy (ACT). We enrolled 4,216 febrile children between 4 and 59 months of age in 2009–2010. Compliance with the malaria rapid diagnostic test (RDT) results was high in the intervention arm across the three countries, with only 4.9% (17 of 344) of RDT-negative children prescribed an ACT. Antibiotic overuse was more common: 0.9% (4 of 446) in Uganda, 38.5% (114 of 296) in Burkina Faso, and 44.6% (197 of 442) in Ghana. Fever clearance was high in both intervention and control arms at both Day 3 (97.8% versus 96.9%, $P = 0.17$) and Day 7 (99.2% versus 98.8%, $P = 0.17$). The use of diagnostic tests limits overuse of ACTs. Its impact on antibiotic overuse and on fever clearance is uncertain.

INTRODUCTION

Malaria and pneumonia are leading causes of morbidity and mortality among under-fives in sub-Saharan Africa,[1–3] despite the availability of cost-effective interventions for both conditions. Community case management of malaria and pneumonia have both been shown to reduce under-five mortality,[4,5] and both strategies are recommended by the World Health Organization (WHO).[6–8]

Parasitological confirmation before administration of anti-malarial treatment has recently been recommended by WHO for everyone presenting with symptoms compatible with malaria at all levels of the health system.[9] Such confirmation is increasingly important in the context of declining malaria transmission, when a decreasing proportion of fever cases is likely to be caused by malaria.[10] Furthermore, given the overlap in symptoms between malaria and pneumonia,[11] the WHO and the United Nations Children Fund (UNICEF) now recommend integrated community case management (iCCM) of malaria and pneumonia in endemic areas in low- and middle-income countries.[8]

Rapid diagnostic tests (RDTs) for malaria are now available with sensitivities comparable to routine microscopy in detecting malaria[12–14] and offer a practical means[15,16] to improve diagnosis and quality of care of febrile children in malarious areas. Several studies have shown that community health workers (CHWs) can use RDTs safely and effectively.[14,17–20]

Increased respiratory rate is one of the most specific symptoms of pneumonia[21–23] and respiratory rate timers (RRTs)[24] have been recommended by WHO and UNICEF as a diagnostic tool for pneumonia, with studies[19,25,26] showing that CHWs can be successfully trained to use them.

We designed an integrated diagnostic and treatment package for malaria and pneumonia, which involves trained CHWs, equipped with RDTs and RRTs and supplied with anti-malarial drugs (artemisinin based combination therapy (ACTs)) and antibiotics, administering treatments based on the results of the two tests. We report here an effectiveness trial conducted in three African countries, Burkina Faso, Ghana, and Uganda, with differing national health systems. We evaluated the effect of the package on the clinical outcome of febrile episodes in children and on the use of anti-malarial and antibiotic drugs.

MATERIALS AND METHODS

Study areas and populations. We report this evaluation using the CONSORT statement extension to cluster randomized trials.[27] The evaluation was conducted in Burkina Faso, Ghana, and Uganda, in the districts of Saponé, Kassena Nankana, and Iganga, respectively. Saponé and Kassena Nankana are situated in the Sudan-Sahelian eco-climatic zone, with a seasonal malaria transmission pattern. Iganga is situated in South Eastern Uganda with an equatorial climate and minimal seasonal variation in malaria transmission.[28] In Saponé, malaria transmission is markedly seasonal, with most transmission occurring during the rainy season, and with an entomological inoculation rate (EIR) ranging from 50 to 200 infective bites/person/year. *Plasmodium falciparum* is the predominant malaria parasite accounting for more than 95% of infections in children < 5 years of age. The malaria burden is heaviest among children < 5 years of age, who experience an average of two clinical malaria episodes every transmission season. Iganga district has year-round malaria transmission, and over 90% of malaria cases are caused by *P. falciparum* infection.[28] Transmission peaks are seen following the rains: i.e., April to June and September to December.[29] The annual EIR is not known, but is reported to be > 500 infective bites/person/year in the neighboring district of Tororo.[30] In Kassena Nankana, malaria transmission occurs during most months of the year; however, there is a distinct seasonal pattern with the peak of transmission coinciding with the period of the major rains (May–October) and the dry season (November–April) seeing very low rates of malaria infection. Transmission has been estimated to be 418 infective bites/person/year.[31–33]

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Data were collected in Burkina Faso from August 2009 to June 2010, in Ghana from April 2009 to February 2010, and in Uganda from October 2009 to October 2010. The sites were selected by an advisory committee from those who responded to a call by TDR in 2006. Some variations in the methodology were unavoidable, because in each case the specific national health framework was followed. Because of varying sample size per country, and the ease of access to nationally available supplies, the studies started and ended at different times.

Twelve villages participated in the study in Burkina Faso, 16 in Ghana, and 14 in Uganda. In Burkina Faso, the 12 villages were selected from two community clinic catchment areas within the Saponé Health District with an estimated total population of 9,000. The 16 villages selected in the Kassena-Nankana districts were drawn from 47 villages with a total population of 150,000 under continuous demographic surveillance. The 14 villages in Iganga were all drawn from Namungalwe sub-county, which has a population of ~38,100 in 19 villages. Malaria, pneumonia, and diarrheal diseases are the leading causes of ill-health among children 1–59 months of age in the three study areas.[34–36]

We included children 6–59 months of age (with the exception of Uganda where the lower limit was 4 months in line with national guidelines on the use of ACTs in children[37,38]) with measured fever or history of fever (last 24 hours), who presented to a CHW. Exclusion criteria included severe illness (according to Integrated Management of Childhood Illness [IMCI] guidelines), known chronic disease, reported anti-malarial or antibiotic treatment in the previous 2 weeks, or known sensitivity to the study medications.

Study design. The study was designed to assess the effect of the use of a diagnostic and treatment package for iCCM, comprising RDTs and ACTs for malaria, RRTs and antibiotics for pneumonia, on recovery from fever, and the rational use of medicines.

We performed an open, cluster randomized two-arm trial in the three countries. Clusters were the villages (catchment populations) of individual CHWs. Within the study areas we excluded, for ethical reasons, clusters that were more than 5 km from a designated health facility where CHWs referred cases for special care to minimize non-completion of referral because of distance. A cluster randomized design was chosen over an individually randomized design to reduce contamination, facilitate supervision, reduce costs, and to ensure that the CHWs maintained the correct treatments based on the tests in the intervention arm and the presumptive treatment in the control arm.

In the intervention arm, CHWs assessed children with acute febrile illness for malaria using RDTs, and for pneumonia by counting their respiratory rate with RRTs. Treatment was then provided on the basis of the test results. Children with a positive RDT received artemether-lumefantrine in Burkina Faso and Uganda, and artesunate-amodiaquine in Ghana. Children with a high respiratory rate received amoxicillin in Ghana and Uganda, and cotrimoxazole in Burkina Faso. The criterion for antibiotic administration was the presence of a high respiratory rate, regardless of the presence of cough or difficult breathing, in contrast to WHO guidelines.[39] Additionally, paracetamol (PCT) was provided to all children in whom both RDT and RRT were negative, and to children with an axillary temperature > 38.5°C.

In the control arm, all febrile children received ACTs based on a presumptive diagnosis of malaria as provided for in the current IMCI guidelines. In line with the protocol, CHWs in Burkina Faso and Uganda were not provided with antibiotics. In Ghana, in line with existing practice, CHWs in the control clusters were also supplied with amoxicillin that they could provide to children based on clinical judgment. Antibiotics and anti-malarial drugs were provided as 3-day treatment courses, whereas PCT was provided for 2 days, so that it did not interfere with the fever assessment on Day 3. The first dose of all treatments was administered under the supervision of the CHW, and if the child vomited within 30 minutes they were given another dose. The dosing schedule was explained to caregivers who then administered the remaining treatments at home.

Malaria RDTs used. First Sign Malaria Pf Card Test (Unimed International, Inc., Santa Clara, CA), Paracheck Pf Rapid test for *P. falciparum* Malaria (Device) (Orchid Biomedical System, Goa, India), and ICT Malaria Pf Cassette test (ICT Diagnostics South Africa) were used in Burkina Faso, Ghana, and Uganda, respectively. First Sign, Paracheck, and ICT have panel detection scores (PDS) at parasite densities from 2,000 parasites/μL of 86.1%, 97.5%, and 97.5%, respectively, and PDSs at parasites densities of 200 parasites/μL of 31.7%, 54.4%, and 82.3%, respectively.[40]

Drugs used in the study. The ACTs used in the study were Coartem manufactured by Novartis Pharma in Burkina Faso, Acumal (artesunate-amodiaquine) manufactured by JCPL Pharma PVT Ltd., India in Ghana, and Coartem manufactured by Novartis Pharmaceuticals Corporation Suffern, New York in Uganda. Antibiotics used in the study were cotrimoxazole in Burkina Faso manufactured by Medicamen Biotech Ltd., India, Kinamox (amoxicillin) in Ghana manufactured by Kinapharma Ltd., and in Uganda amoxicillin manufactured by Zhangjiakou Shengda Pharmaceutical Co. Ltd., China (re-packed by Kampala Pharmaceutical Industries, 1996 Ltd.).

Paracetamol used in the study was manufactured by Laborate Pharmaceutical (India) for Burkina Faso, Kinapharma Ltd. for Ghana, and Kampala Pharmaceutical Industries (1996) Ltd. for Uganda.

Community health workers. A total of 57 CHWs were recruited (13 in Burkina Faso, 16 in Ghana, and 28 in Uganda), half of whom were randomized to the intervention arm. The CHWs were selected by their respective community, based on minimum criteria that included the ability to read and write clearly so that they would be able to complete the study Case Report form (CRF). In Burkina Faso new CHWs were selected, whereas in Uganda existing CHWs previously trained to provide anti-malarial drugs in the community as part of the community case management were used. In Ghana, existing community health nurses (living within the community and hired and trained by the Ghana Health Service to provide basic services) were used.

Sample size. The estimated sample size for the study was 4,360 febrile children between 4 and 59 months of age, with Burkina Faso and Ghana contributing 1,200 each, and Uganda 1,960. The sample size was estimated using the simplified formula by Hayes and Bennett[41] for cluster randomized trials, with a power of 80% to detect an absolute difference in fever clearance 72 hours after initiation of treatment of 10% (85% against 75%) between the two arms with a two-sided alpha of 0.05. The estimation took seasonality into account, and accounted for loss to follow-up. We assumed a coefficient of variation between clusters of 0.12.

Training. The CHWs were taught how to take a history, recognize clinical features of uncomplicated malaria, and signs of severe illness requiring referral; preparation of thick blood films for malaria microscopy; the use of classification and treatment algorithms for malaria and pneumonia (intervention arm only); use of simple dosing guidelines based on age for ACTs and PCT; managing drug supplies; obtaining informed consent; and completing CRFs including documentation of reported signs and symptoms, physical examination results, and medications administered to the child. In cases where informed consent was declined, the child received standard presumptive management of fever with an ACT.

In addition, CHWs in the intervention arm were taught the clinical features of non-severe pneumonia; use of malaria RDTs; infection control measures; how to count respiratory rate; and the use of simple dosing guidelines based on age for antibiotics.

There was interactive training consisting of oral presentations, discussions, role play, and supervised hands-on practice for all the study CHWs. At the end of the training, facilitators assessed the competency of the CHWs to follow the algorithm, complete study forms, and for CHWs in the intervention arm the appropriate use of RDTs and RRTs, as reported elsewhere.[19]

At the health facility level, health personnel were oriented on the treatment strategies in the two arms, and received refresher training on IMCI. These staff provided care to children referred from the study and provided supportive supervision to the CHWs.

Quality assurance plan. The CHWs were supervised weekly by field supervisors to detect and correct any deviations from the protocol. During these visits, the following were monitored: completeness of data captured in the CRFs, respect of inclusion/exclusion criteria, drug administration, drug and RDT storage conditions, and assessment and follow-up of enrolled children.

At each supervisory visit three samples of RDTs were collected from the batch in use. The RDT samples were tested against a sample of blood confirmed positive by microscopy to ensure the RDTs were still functioning with adequate sensitivity.[42]

At the end of each month all CHWs attended a review meeting at the health center at which the assessment, treatment, and follow-up algorithms were reviewed, and problem areas were identified and discussed. The CHWs brought their registers and CRFs. The CHWs identified as having problems with a particular part of the algorithm were followed up and were provided with support and retraining by the study team. The accuracy of CHWs in performing the RDTs was assessed as part of each supervisory visit. When there were no patients at the time of the visit, CHWs were asked to demonstrate how they perform the procedure, including how they do the finger prick and how they read the RDT result. The CHWs were observed and reminded to perform the RDT in a well-lighted place.

Refresher training was provided to the health facility microscopists on malaria microscopy before enrollment started. Ten slides per month were selected for quality control (5 low density and 5 negative slides) using a random number system recommended by WHO[43] and sent to a reference laboratory for rereading on a "blinded" basis.

Data collection methods. All children who were tested for malaria on Day 0 also had a thick blood film prepared by the CHWs. The blood films were collected within 24 hours in all three sites by a fieldwork supervisor with a motorbike. Blood films were stained with 10% Giemsa stain for 10–15 minutes and screened microscopically under a $\times 100$ oil immersion lens using a light microscope by a microscopist trained by the study teams and based at the referral center. A blood slide was taken at Day 0 in the control arm to enable a comparison of the prevalence of malaria in the two arms (in Uganda this was only done in a sub-sample of enrolled children across both dry and rainy seasons).

The number of parasites present per white blood cell was counted, and the figure multiplied by 8,000 (an average white blood cell count per μL) to give the parasite density.[44] Slides were double read, and when there was a discrepancy between the two readings the slide was read again by an experienced/senior microscopist who was independent of this study and whose reading was considered final. The microscopy results were used to establish the accuracy of the RDTs when used in the communities. Children with a negative RDT, but with a positive slide reading were traced at home and treated with ACTs. All patient data were recorded on CRFs at all three sites.

Patient management and follow-up. The CHWs reviewed children and completed the CRF on Days 0, 3, 7, and on unscheduled visit days. A review on Day 3 determined if a child had recovered from fever (temperature below 37.5°C as measured by a digital thermometer). Children in either arm who had not recovered were referred to a designated health center. All children not referred at Day 3 (clinically recovered) were reviewed on Day 7, and any fever relapse cases

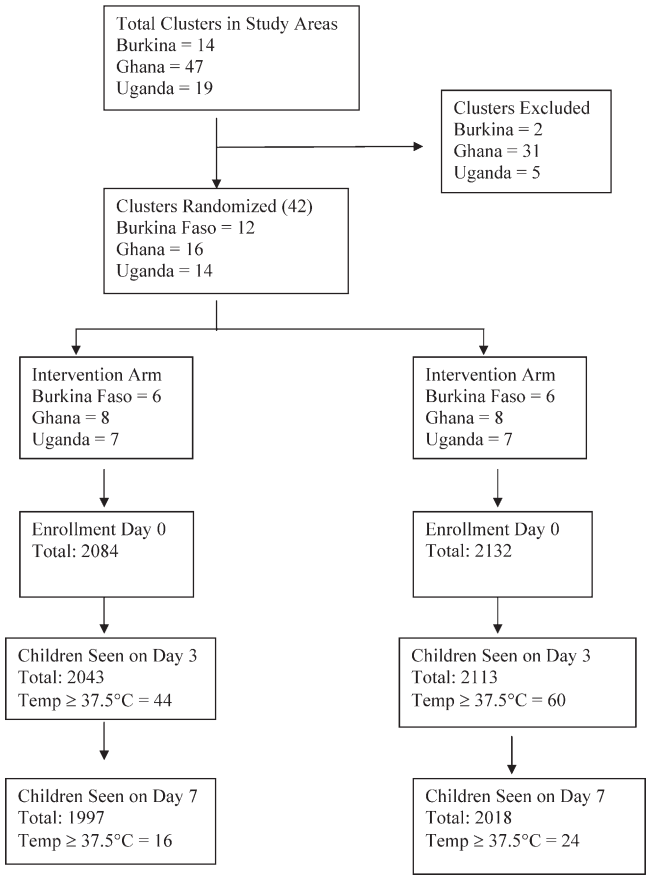

FIGURE 1. Study profile.

TABLE 1
Baseline characteristics of children at enrollment

	Burkina Faso		Ghana		Uganda	
	Intervention	Control	Intervention	Control	Intervention	Control
Number of children enrolled	525	576	584	591	975	965
Number (%) with measured temperature ≥ 37.5	436 (83.0%)	457 (79.3%)	351 (60.1%)	372 (62.9%)	563 (57.7%)	512 (53.1%)
Mean age (in months)	28.7	30.3	24.6	26.0	27.8	27.3
Number (%) of females	277 (52.8%)	276 (47.9%)	277 (47.4%)	317 (53.6%)	451 (46.3%)	478 (49.5%)
P. f. asexual parasitemia prevalence (by microscopy)	284 (54.1%)	313 (54.3%)	439 (75.2%)	435 (73.6%)	783 (80.3%)	475/674* (70.5%)
Geometric mean parasite density in positives	11,841	10,505	15,320	12,350	7,663	7,318
Number (%) of children with cough	252 (48.0%)	241 (41.8%)	123 (21.1%)	226 (38.2%)	555 (56.9%)	–
Number (%) of children with diarrhea	134 (25.5%)	154 (26.7%)	208 (35.6%)	208 (35.2%)	–	–

*Blood smear for microscopy done in only a sub-sample of children in the control arm in Uganda.

were referred to the health center. All children referred (Day 3 or 7) were examined by a trained project nurse, and managed according to IMCI guidelines. Children who did not come for scheduled visits were traced and assessed at home.

Study outcomes. The primary outcome was resolution of fever at Day 3, whereas resolution of fever at Day 7, and the use of anti-malarial and antibiotic drugs were secondary outcomes. Outcomes were measured and analyzed at the individual level.

Data analyses. Data were entered into microcomputers and analyzed using Epi-Info 6.0 (CDC, Atlanta, GA) and STATA 9.0 (College Station, TX). We compared proportions of the study outcomes between the two groups. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated using random effects logistic regression analysis with the treatment arm and country as fixed effects, and cluster as a random effect. Analysis was by intention-to-treat.

Ethical approval. Ethical approval for these studies was granted by the WHO Ethics Review Committee and by the appropriate national and Institutional Ethical Review Boards of each participating country. Approval was obtained from district, local, and community leaders as well as household heads. Informed consent was obtained from caregivers of children who participated in the studies. The WHO TDR project numbers are A60486 for Burkina Faso, A60490 for Ghana, and A60487 for Uganda. The trial was registered online at http://register.clinicaltrials.gov with the registration number NCT00720811.

RESULTS

Baseline characteristics. Overall, 4,216 children between 4 and 59 months of age were enrolled in Burkina Faso, Ghana, and Uganda. The number of children enrolled in intervention and control arms respectively were 525 and 576 in Burkina Faso, 584 and 591 in Ghana, and 975 and 965 in Uganda (Figure 1). With the exception of reported cough, baseline characteristics were comparable across the two arms (Table 1). In total, 64.5% (2,691 of 4,216) had temperatures ≥ 37.5°C at enrollment and 69.5% (2,729 of 3,925) had microscopically confirmed malaria.† The RDT positivity rate was 74.5% (391 of 525) in Burkina Faso (Table 2A), 84.2% (492 of 584) in Ghana (Table 2B), and 87.9% (857 of 975) in Uganda (Table 2C).

†Blood smear for microscopy done in only a sub-sample of children in the control arm in Uganda.

Use of medicines. Use of medicines by assessment classification is summarized by country in Table 2A–C. In the intervention clusters, there was good compliance with RDT results by CHWs across the three countries with minimal overuse of ACTs. Only 1 case out of 1,740 RDT-positive children did not receive an ACT, whereas only 4.9% (17 of 344) of RDT-negative children were prescribed an ACT.

With regard to antibiotics, there were varying degrees of overuse (prescription to a child with a normal respiratory rate) in Burkina Faso, Ghana, and Uganda, with 38.5% (114 of 296), 44.6% (197 of 442), and 0.9% (4 of 446) of children with a normal respiratory rate receiving an antibiotic, respectively. Conversely, some children with high respiratory rates did not receive an antibiotic: 13.5% (31 of 29) in Burkina Faso, 27.5% (39 of 142) in Ghana, and 1.7% (9 of 529) in Uganda. Among children with high respiratory rates, we analyzed data within the subgroup that also had a cough; 16% (20 of 125) in Burkina Faso, 17.9% (7 of 39) in Ghana, and 0.9% (3 of 337) in Uganda of these children did not receive an antibiotic. The overall rate of antibiotic underuse in this subgroup was 6.0% (30 of 501).

In the control clusters, ACTs were given to all children in all countries, leading to a potential unnecessary prescription of ACTs in 25.6%, 15.8%, and 12.1% of cases in Burkina Faso, Ghana, and Uganda, respectively (assuming a similar proportion of RDT negative cases in the control and intervention clusters). In Ghana (where antibiotics were available in control clusters as well) 51.4% (300 of 584) of all children were prescribed antibiotics in the intervention clusters compared with 64.3% (380 of 591) in the control clusters (OR 1.7, 1.34–2.17; $P < 0.001$), suggesting less overprescription of antibiotics in the intervention arm.

Impact on fever clearance. Fever clearance results are summarized in Table 3. There were high fever clearance rates across the countries and arms. Fever clearance rates at Day 3 and Day 7 were 97.8% (95% CI 97.0, 98.7) and 99.2% (95% CI 98.7, 99.8) in intervention clusters, and 96.9% (95% CI 96.1, 97.6) and 98.8% (95% CI 98.3, 99.3) in control clusters. The estimated ORs for failure to clear fever (intervention versus control) were 0.69 (95% CI 0.41, 1.16; $P = 0.17$) at Day 3 and 0.62 (95% CI 0.32, 1.22; $P = 0.17$) at Day 7.

A subgroup analysis was done to explore if the use of antibiotics in the control arm in Ghana may have diluted the effect of the intervention, with Ghana data excluded. Fever clearance was marginally better in the intervention arm at 97.7% (95% CI 96.8, 98.6: 1,431 of 1,465) compared with

TABLE 2A
Assessment classification and treatment in Burkina Faso

	Number (%) of children by assessment classification	Number (%) of children treated with ACT+; AB+; PCT± (A)	ACT+; AB–; PCT± (B)	ACT–; AB+; PCT± (C)	ACT–; AB–; PCT+ (D)
Intervention clusters					
Children with positive RDT and high RR (1)	173* (32.9)	141 (81.5)	31 (17.9)	0 (0.0)	0 (0.0)
Children with positive RDT, high RR, and coughφ (2)	90 (17.1)	70 (77.8)	20 (22.2)	0 (0.0)	0 (0.0)
Children*with positive RDT and normal RR (3)	218* (41.5)	75 (34.4)	141 (64.7)	0 (0.0)	0 (0.0)
Children with negative RDT and high RR (4)	56* (10.7)	3 (5.4)	0 (0.0)	37 (66)	0 (0.0)
Children with negative RDT, high RR and coughφ (5)	35 (6.7)	2 (5.7)	0 (0.0)	33 (94.3)	0 (0.0)
Children with negative RDT and normal RR (6)	78* (14.9)	2 (2.6)	0 (0.0)	37 (56.4)	26 (33.3)
Total	525	221 (42.1)	172 (32.8)	74 (14.1)	26 (5.0)
Control clusters					
Total	576	0	575 (99.8)	0	0

*Row data has missing records on treatment given.
N.B: Cells shaded gray represent correct treatment of the row.
The rows with the symbol φ at the end of the row title are a subset of the row just above them. The numbers in the row cells do not count in the respective column totals.
ACT = artemisinin based combination therapy; AB = antibiotic; PCT = paracetamol; RDT = rapid diagnostic test; RR = respiratory rate.

TABLE 2B
Assessment classification and treatment in Ghana

	Number (%) of children by assessment classification	Number (%) of children treated with ACT+; AB+; PCT± (A)	ACT+; AB–; PCT± (B)	ACT–; AB+; PCT± (C)	ACT–; AB–; PCT+ (D)
Intervention clusters					
Children with positive RDT and high RR (1)	130 (22.3)	92 (70.8)	38 (29.2)	0 (0.0)	0 (0.0)
Children with positive RDT, high RR and coughφ (2)	32 (5.5)	25 (78.1)	7 (21.9)	0 (0.0)	0 (0.0)
Children with positive RDT and normal RR (3)	362 (62)	144 (39.8)	218 (60.2)	0 (0.0)	0 (0.0)
Children with negative RDT and high RR (4)	12 (2.1)	0 (0.0)	1 (8.3)	11 (91.7)	0 (0.0)
Children with negative RDT, high RR and coughφ (5)	7 (1.2)	0 (0.0)	0 (0.0)	7 (100)	0 (0.0)
Children with negative RDT and normal RR (6)	80 (13.4)	0 (0.0)	2 (2.5)	53 (66.3)	25 (31.3)
Total	584	236 (40.4)	259 (44.3)	64 (11)	25 (4.3)
Control clusters					
Total	591	360 (60.9)	203 (34.4)	20 (3.4)	8 (1.4)

N.B: Cells shaded gray represent correct treatment of the row.
The rows with the symbol φ at the end of the row title are a subset of the row just above them. The numbers in the row cells do not count in the respective column totals.
ACT = artemisinin based combination therapy; AB = antibiotic; PCT = paracetamol; RDT = rapid diagnostic test; RR = respiratory rate.

TABLE 2C
Assessment classification and treatment in Uganda

	Number (%) of children by assessment classification	Number (%) of children treated with ACT+; AB+; PCT± (A)	ACT+; AB–; PCT± (B)	ACT–; AB+; PCT± (C)	ACT–; AB–; PCT+ (D)
Intervention clusters					
Children with positive RDT and high RR (1)	459 (47.1)	449 (97.8)	9 (2.0)	1 (0.2)	0 (0.0)
Children with positive RDT, high RR and coughφ (2)	286 (29.3)	282 (98.6)	3 (1.0)	1 (0.3)	0 (0.0)
Children with positive RDT and normal RR (3)	398 (40.9)	4 (1.0)	394 (99.0)	0 (0.0)	0 (0.0)
Children with negative RDT and high RR (4)	70 (7.2)	2 (2.9)	0 (0.0)	68 (97.1)	0 (0.0)
Children with negative RDT, high RR and coughφ (5)	51 (5.2)	2 (3.9)	0 (0.0)	49 (96.1)	0 (0.0)
Children with negative RDT and normal RR (6)	48 (4.9)	0 (0.0)	7 (14.6)	0 (0.0)	41 (85.4)
Total	975	455 (46.7)	410 (42.1)	69 (7.1)	41 (4.2)
Control clusters					
Total	965	0 (0.0)	965 (100.0)	0 (0.0)	0 (0.0)

N.B: Cells shaded gray represent correct treatment of the row.
The rows with the symbol φ at the end of the row title are a subset of the row just above them. The numbers in the row cells do not count in the respective column totals.
ACT = artemisinin based combination therapy; AB = antibiotic; PCT = paracetamol; RDT = rapid diagnostic test; RR = respiratory rate.

96.2% (95% CI 95.0, 97.3: 1,464 of 1,522) in the control arm at Day 3, with a 41% reduction in odds of having fever at Day 3 (OR = 0.59, 95% CI 0.38–0.93). At Day 7, fever clearance was 99.4% in the intervention arm (95% CI 98.8, 99.99) compared with 99.0% (95% CI 98.7, 99.4) in the control arm (OR = 0.64, 95% CI 0.28, 1.49).

Although no formal pharmacovigilance system had been put into place, there were no passive reports of severe adverse events or deaths at any of the three sites.

DISCUSSION

We performed an effectiveness trial in three countries, examining the effects on fever clearance and rational use of medicines of a diagnostic and treatment package, comprising RDTs and ACTs for malaria, respiratory rate (RR) timers, and antibiotics for pneumonia, implemented at the community level to treat children < 5 years of age with fever episodes. In each country, we adopted a pragmatic approach, following existing

TABLE 3
Fever persistence on study Days 3 and 7 after the onset of treatment

Cluster	# of ch. with Temp ≥ 37.5 and/or reported hot body at D0	# of ch. seen at D3	# of ch. with Temp ≥ 37.5 at D3 (% of ch. Seen at D3)	#. of ch. seen at D7	# of ch. with Temp ≥ 37.5 at D7 (% of ch. Seen at D7)
Intervention clusters					
Burkina Faso	525 (436)	507	11 (2.2)	485	2 (0.4)
Ghana	584 (351)	578	10 (1.7)	561	6 (1.1)
Uganda	975 (563)	958	23 (2.4)	951	8 (0.8)
Total	2084	2043	44 (2.2)	1997	16 (0.8)
Control clusters					
Burkina Faso	576 (457)	563	21 (3.7)	527	5 (0.9)
Ghana	591 (372)	591	8 (1.4)	573	10 (1.7)
Uganda	965 (512)	959	37 (3.9)	918	9 (1.0)
Total	2132	2113	66 (3.1)	2018	24 (1.2)

national policies. This resulted in some variations in what was actually done in each country. The package led to a clear improvement in the appropriate use of ACTs, and in Ghana, the only site in which antibiotics were available in the control arm, to fewer prescriptions of antibiotics. The vast majority of children recovered from fever in both the intervention and control groups, and no effect of the intervention on the clinical outcome (recovery from fever) were detected. The microscopy positivity rates reported from the three sites (54–80%) are not for the general population, but for children who had been sick and were taken to CHWs for care. These rates are much higher than what would have been expected in a population-based sample.[28,32]

Inappropriate use of ACTs is a major concern, because it may lead to the development of resistance to these highly effective drugs.[45] The potential for misuse of ACTs could be particularly high at the community level, where ACTs are distributed by non-professional staff.[46,47] The latest WHO malaria treatment guidelines[9] recommend parasitological confirmation before administering anti-malarial drugs to a patient presenting with fever in all areas, including highly malaria-endemic settings. The shift from symptom-based to RDT-based treatment with ACTs has major implications. It limits the over-diagnosis of malaria and thus the inappropriate use of ACTs and expenditure,[48] and reduces missed diagnosis of other causes of fever[49,50] at a time when a declining proportion of fevers in Africa are attributable to malaria.[10] Administering ACTs only to patients with a positive RDT has led to dramatic reductions in the use of ACTs in Cambodia,[18] mainlandTanzania,[51] and Zanzibar.[52] Nevertheless, in some health facility settings substantial proportions of patients with negative test results were reported to receive ACTs,[53–56] although improvements in adherence to treatment guidelines were achieved after intensive training in some cases.[51,57]

Poor adherence to RDT results has also been reported when febrile episodes are managed at the community level by CHWs, with up to 58% of patients with a negative RDT result being treated with an antimalarial.[58] Poor compliance with referral advice by patients with fever but with a negative RDT result has also been reported.[59] It is noteworthy that in both these studies there was no alternative diagnostic test, nor treatment of RDT-negative patients. However, very high levels of appropriate prescription of ACTs after rapid malaria testing were achieved in Chikankata, Zambia in a program in which febrile children were assessed for pneumonia, and antibiotic treatment was provided as appropriate[25]; similar findings were reported more recently in another study in Zambia that used an intensive training and supervision model.[60]

The results of our study in three sub-Saharan African countries, conducted with a similar design to the one in Chikankata, confirm that inappropriate use of ACTs is extremely rare (< 5% of cases) when alternative diagnostic tests and treatment of other conditions are provided to patients with negative RDT results (in our study children with fever and a negative RDT were prescribed antibiotic treatment if there were signs of pneumonia, and PCT if there were none). On the contrary, when anti-malarial treatment is administered to all febrile children, without prior parasitological confirmation, as in the control clusters of our study, an important proportion of cases are treated with ACTs unnecessarily. This study was conducted in areas of high malaria prevalence, confirmed both by microscopic examination and RDT (Tables 1 and 2). It is important to note that the use of RDTs to guide treatment decisions in these high transmission settings resulted in substantial overprescription of ACTs, compared with treatment based on the results of blood slide microscopy. Nonetheless, based on the proportion of negative RDT results in the intervention clusters of the study sites, the proportion of unnecessary use of ACTs was estimated to vary between 12% and 26% across the three sites. This finding has public health implications, suggesting that a disease management approach based on a diagnostic and treatment package improves the appropriate use of ACTs, and provides alternative treatment of other causes of febrile illness.

Inappropriate use (non-compliance with study guidelines) of antibiotics was high in two study sites. More than a third of children with a normal RR received antibiotic treatment in Ghana and Burkina Faso, whereas 27% and 14% of children with a high RR did not receive any antibiotics in the two countries, respectively. In Ghana, however, where CHWs could prescribe antibiotics in control clusters based on their clinical judgment, 64.3% of children were treated with antibiotics in control clusters compared with 51.4% in intervention clusters. In this study, we used only a high respiratory rate as the criterion for antibiotic use, whereas the WHO[39] recommends the presence of cough or difficulty breathing together with high respiratory rate as the criteria. This is a limitation of this study, and fewer children would have been treated with antibiotics under WHO guidelines than were treated using a criterion of rapid breathing alone. Overuse of antibiotics is a well-known phenomenon at all levels of the health system in low-, middle-, and high-income countries, as reported by the WHO,[61] and has been recently reported to be aggravated by the introduction of RDT in the decision algorithm.[51] In Uganda, over- or under-prescription of antibiotics was rare, accounting for only 0.9% and 1.7% of cases. This difference between Uganda and the other sites may be explained by the more intensive supervision program of the CHWs, and

by local treatment practices. It is possible that local antibiotic prescription practices influenced behavior in the intervention clusters. Vialle-Valentin and colleagues[62] have reported higher antibiotic use among under-five children in Ghana compared with other countries including Uganda.

The study was conducted in areas with microscopic malaria prevalence ranging between 54% and 80%. Cost-effectiveness of the integrated package compared with presumptive malaria treatment may be lower in areas with high rather than low malaria transmission, if judged only by savings in anti-malarial treatments. However, the WHO now recommends that all suspected cases of malaria be confirmed with a diagnostic test before treatment[9] in all settings; furthermore, the development of an integrated package fitting all epidemiologic settings, regardless of the relative prevalence of malaria and pneumonia, has obvious advantages in terms of translation into policy. It is also possible that the overuse of medicines may be higher in settings with lower malaria prevalence, in which many of the RDTs would be negative. It will be important to explore this issue further in these lower transmission settings.

The primary endpoint of our study was fever clearance 3 days from initiation of treatment. One might expect a higher proportion of children with fever to be afebrile after a few days if treated more rationally, with different drugs based on the results of diagnostic tests. Consistently across the study sites, over 96% of the children were afebrile at the follow-up visits in both intervention and control arms. Although a smaller proportion of children in the intervention arm remained febrile at Days 3 and 7 compared with the control arm, the numbers of such children were small and the difference observed could be caused by chance. This result is not easy to interpret. One possibility is that the frequency of minor, self-limiting viral infections as the cause of fevers was high, and diluted the effect of specific anti-malarial and antibacterial treatment. Furthermore, in a context of high parasitemia, it is possible that antibiotics might not have a measurable effect on fever clearance. Our findings are consistent with those from a study in Zambia[25] that found no evidence that the risk of persistence of fever differed in intervention and control clusters after 5 and 7 days of treatment. Adding cough/difficulty breathing to our treatment algorithm would not have altered this because most under-five children who needed an antibiotic received one in the intervention arm.

The subgroup analysis that was conducted suggests that the use of antibiotics in the control arm in Ghana may have diluted the effect of the intervention, as there was some evidence of an effect of the intervention on fever clearance when data from only Burkina Faso and Uganda were used. However, visual inspection of the data from these two countries does not suggest a large difference in fever clearance rates at Day 3 in the intervention compared with the control arm.

Other aspects of feasibility, and acceptability of the approach based on the diagnostic and treatment package was assessed in all sites and will be reported in detail elsewhere. Overall, the CHWs were found to be able to perform their tasks satisfactorily, including RDTs for malaria and respiratory rate counting. A study in Uganda found that when RDT results and RR were double-checked by laboratory technicians and pediatricians there was a concordance rate of 100% for RDTs and 93% for RR.[19] The acceptability of CHWs performing RDTs and RR counting was also high among communities, CHWs, and health staff. The majority of interviewed community members were satisfied with CHWs treating children according to the package.[19]

Though the study was not designed to evaluate RDT performance, the positivity rates for microscopy were consistently lower than those for RDTs across the three sites. This may be explained by the fact that all three RDTs used HRP2 as the target antigen, which can persist in the blood stream after parasite clearance,[63–67] suggesting that some positive RDTs were indicative of past rather than current infection. The choice of which RDT to use was made for one of the following reasons: availability, resistance to high storage temperature (40°C), delivery time, and national policy. Burkina Faso received their supply from TDR as their original supplier failed to deliver. The RDTs used were FirstSign in Burkina Faso, Paracheck pf in Ghana, and ICT in Uganda. It should also be noted that the RDTs were selected before the publication of "Malaria Rapid Diagnostic Test Performance – Results of WHO product testing of malaria RDTs Round 2"[40] in which RDT performance was recorded for 67 RDTs. The ranking of the PDS for the RDTs was 28 for ICT, 49 for Paracheck, and 59 for First Sign,[40] indicating that none really achieved a high combined measure positivity rate, along with inter-test and inter-lot consistency, although their PDSs were above 70/100.

The study shows that an iCCM approach based on the use of diagnostics and medicines for malaria and pneumonia by CHWs improves the rational use of anti-malarial drugs, and may reduce the inappropriate use of antibiotics at the community level in settings where they are already available. Fever clearance was very high in both intervention and control arms at both Day 3 and Day 7 and when all three countries were included in the analysis there was no clear evidence of a clinical benefit of the intervention. These findings add to the evidence base for iCCM as a public health strategy.

Received December 31, 2011. Accepted for publication July 14, 2012.

Acknowledgments: We thank the community members, opinion leaders, CHOs, the health workers, research assistants, field supervisors, and workers in the districts of Sapone in Burkina Faso, Kassena Nankana in Ghana, and Iganga in Uganda; this study would not have been possible without their co-operation. We also acknowledge the technical and financial support from the UNICEF/UNDP/World Bank/WHO Special Program for Research and Training in Tropical Diseases.

Financial support: This study was funded by UNICEF/UNDP/World Bank/WHO Special Program for Research and Training in Tropical Diseases (TDR) through project numbers A60486 for Burkina Faso, A60490 for Ghana, and A60487 for Uganda.

Disclaimer: The authors declare that they have no competing interests.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 30–35
doi:10.4269/ajtmh.2012.11-0732

Use of Community Health Workers for Management of Malaria and Pneumonia in Urban and Rural Areas in Eastern Uganda

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Abstract. Use of community health workers (CHWs) has been implemented the same way in urban and rural areas despite differences in availability of health providers and sociodemographic characteristics. A household survey was conducted in rural and urban areas in eastern Uganda, and all children who were febrile in the previous two weeks were assessed for their symptoms, treatment received at home, and when and where they first went for treatment. Rural children were more likely to use CHWs than urban children. Urban children received outside treatment more promptly, and used herbs at home less. Symptoms and proportion of children being taken out for treatment were similar. Children from the poorest households used CHWs less and private providers more than the middle quintiles. Drug shops and private clinics should be included in the community case management to cater for the poorest in rural areas and persons in urban areas.

INTRODUCTION

Malaria and pneumonia are among the main killers of children less than five years of age in low-income countries.[1,2] One of the interventions to reduce child mortality that has been effective is the community management of malaria and pneumonia by using community health workers (CHWs).[3,4] The World Health Organization recommended use CHWs at the community level for the management of malaria and pneumonia through community case management.[5] The availability of alternative sources of quality care and medicines in nearby health facilities contribute to the care-seeking patterns of mothers of febrile children,[6,7] and these are different between urban and rural areas. There are also underlying socioeconomic differences between rural and urban areas that make urban mothers behave differently towards febrile illnesses in children than rural mothers.[8,9]

Few studies have evaluated differences in use of CHWs between urban and rural areas. It is important that as community case management is implemented, an assessment is conducted on who is actually benefiting from the program in rural or urban areas and how CHWs are being used alongside other partners in health care provision. Therefore, we conducted a study that assessed these potential differences.

MATERIALS AND METHODS

Study area. A survey was conducted in the Iganga-Mayuge Demographic Surveillance Site (DSS) in eastern Uganda located approximately 115 km east of the capital Kampala. The DSS covered approximately 70,000 persons in 65 villages by the end of 2009. There were approximately 11,000 children less than five years of age. Within the geographic boundaries of the DSS is Iganga Hospital, a 100-bed general hospital located in the town of Iganga; six lower level government facilities, one of which is in Iganga; four non-governmental organization lower level health facilities, one of which is in Iganga; approximately 120 drug shops and private clinics mostly in the trading centers and Iganga; traditional healers; and 132 CHWs with at least two CHWs per village. Two large villages were allocated three CHWs. Twenty eight CHWs were in the urban area and 104 were in the rural area. The CHWs had been involved in community-based distribution of antimalarial drugs (arthemether–lumefantrine) and antibiotics (amoxicillin) in the DSS since December 2009. All CHWs were involved in distribution of antimalarial drugs but 58 of them also distributed amoxicillin. The health facilities, drug shops, and clinics in the DSS are shown in Figure 1.

Data collection. Data were collected during the DSS round during February–June 2010. This was conducted by field assistants who work in the DSS during the regular update round. The field assistants collect the routine demographic data and data for studies that need information from all the households in the DSS. Field assistants had a minimum of secondary school education and were trained in data collection techniques and confidentiality. For the purpose of this study, they were trained on the purpose of the study and the research tool. The tool was translated into Lusoga, the local language, and pretested in the neighboring area just outside the DSS.

All children in the DSS who had become ill with a fever in the previous two weeks were asked about their symptoms, the treatment they received at home, whether they went out for treatment, whether they went out the same day they noticed the symptoms or later, and where they sought treatment first. Those who went out on the same day were considered to have gone for treatment within 24 hours, and those who went out later were considered to have gone out later than 24 hours. This assumption was made because the general population does not use watches, and this was an attempt to estimate those children who received treatment within 24 hours, which is the recommended time for early treatment of acute illness.

The options they went out for treatment first were CHW, health facility, drug shop, or private clinic. A drug shop was defined as a place where they went to purchase drugs such as tablets or syrup but the attendant did not examine the child. A private clinic was defined as a place where they went for

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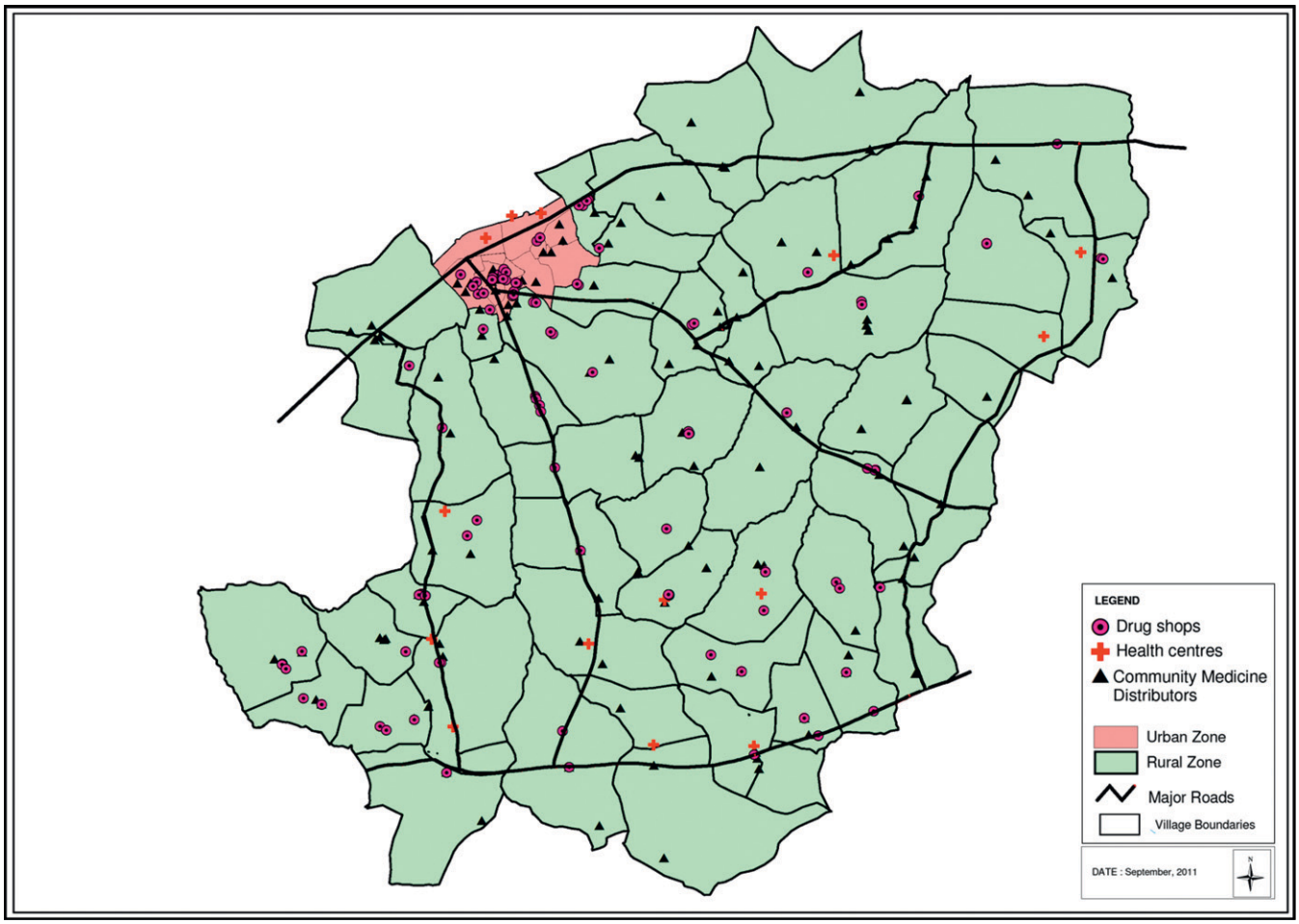

FIGURE 1. Iganga-Mayuge demographic surveillance site in Uganda, showing health centers, drug shops and clinics, and community health workers in rural and urban areas.

treatment and the child was examined. Data were collected by using paper questionnaires.

Data management and analysis. Data was transferred to the DSS headquarters on a daily basis and checked for consistency and completeness. Data was then entered using FoxPro software (Custom Computer Services, Danbury, CT) and cleaned. To obtain sociodemographic variables such as mother's age, mother's education level, and household socioeconomic status, data were linked with the DSS database. Data were then exported into STATA version 10 (StataCorp LP, College Station, TX) for bivariate and multinomial analysis. Calculation of socioeconomic status has been described by Rutebemberwa and others.[10]

To establish whether there were differences between the urban and rural sick children, the two groups were compared with respect to age, sex, presenting symptoms, socioeconomic status of their households, and mothers' age and education. The two groups were also assessed on what treatment caretakers gave the child immediately they noticed the child was sick, whether they went to seek treatment outside the home, whether they did it on the same day or after one or two days, and which provider they visited: CHW, health facility, drug shop, or private clinic. The association between the household socioeconomic status and age and education of the mother with the choice of provider was assessed by using multinomial regression for choice of provider, using those who went to CHWs as the referent group. Because some households had more than one child less than five years of age who had been sick and care-seeking habits are associated with household socioeconomic status, adjustment for clustering was performed by using the svy feature in STATA. The unit of analysis was the sick child episode.

Ethical clearance. The study was approved by the Makerere University School of Public Health Higher Degrees Research and Ethics Committee and the Uganda National Council for Science and Technology. Permission to conduct the study was granted by the DSS Management, the District Health Office, and the village local council leaders. In addition to the consent that respondents gave in the routine data collection of the DSS rounds, verbal consent was sought and received specifically for this tool, which was assessing care-seeking practices for febrile illness within urban and rural areas.

RESULTS

Of 10,181 children less than five years of age visited during the survey, 3,234 (30.8%) reported having fever in the previous two weeks. Of those who had fever, 254 (7.9%) lived in urban areas and 2,980 (92.1%) lived in rural areas. The children's age, sex, and presenting symptoms are shown in Table 1. There were no significant differences between febrile

TABLE 1
Characteristics of children and their symptoms, Uganda*

Characteristic	Urban, n = 254, no. (%)	Rural, n = 2,980, no. (%)	OR	*P*	95% CI
Age, months					
0–12	61 (24.0)	657 (22.1)	1		
13–24	52 (20.5)	695 (23.3)	1.24	0.3	0.84–1.82
25–36	70 (27.6)	681 (22.8)	0.90	0.6	0.63–1.29
37–48	42 (16.5)	587 (19.7)	1.30	0.2	0.86–1.95
49–60	29 (11.4)	360 (12.1)	1.15	0.5	0.72–1.82
Sex					
F	119 (46.9)	1,520 (51.0)	1		
M	135 (53.1)	1,460 (49.0)	0.85	0.2	0.66–1.10
Symptoms					
Fever					
Yes	249 (98.0)	2,875 (96.5)	1		
No	5 (2.0)	105 (3.5)	1.82	0.189	0.73–4.50
Vomiting					
Yes	86 (33.9)	796 (26.6)	1		
No	168 (66.1)	2,184 (73.4)	1.41	0.01	1.07–1.85
Fast breathing					
Yes	58 (22.8)	667 (22.4)	1		
No	196 (77.2)	2,313 (77.6)	1.02	0.87	0.75–1.39
Runny nose					
Yes	220 (86.6)	2,580 (86.5)	1		
No	34 (13.4)	400 (13.5)	1	0.1	0.70–1.47
Cough					
Yes	189 (74.4)	2,334 (78.4)	1		
No	65 (25.6)	646 (21.6)	0.80	0.14	0.60–1.08
Difficulty in breathing					
Yes	63 (24.8)	860 (28.8)	1		
No	191 (71.2)	2,120 (71.2)	0.81	0.17	0.61–1.10
Diarrhea					
Yes	89 (35.0)	1,041 (35.9)	1		
No	165 (65.0)	1,939 (65.1)	1	0.98	0.77–1.31
Convulsions					
Yes	17 (6.7)	151 (5.1)	1		
No	237 (93.3)	2,828 (94.9)	1.34	0.26	0.80–2.26

*OR = odds ratio; CI = confidence interval.

children from urban and rural areas with respect to sex, age, and presenting symptoms, except for vomiting, which was more frequent in urban areas than in rural areas.

Comparison of urban and rural febrile children. Results of comparison of urban and rural febrile children is shown in Table 2. Compared with urban areas, households with febrile children in rural areas were poorer, more likely to have mothers who were older, and more likely to have fewer mothers who had finished a post-primary level of education. For example, in urban areas, 32.8% (83 of 254) of the households of febrile children were classified as being least poor compared with 9.5% (248 of 2,980) of those in rural areas. In urban areas, 28.9% (62 of 254) of the mothers were less than 25 years of age compared with 19.8% (510 of 2,980) in rural areas. In urban areas, 54.4% (136 of 254) of children had mothers who had finished a post-primary level of education compared with 17.8% (511 of 2,980) in rural areas.

There was no significant difference between urban and rural areas with respect to the proportion of febrile children who sought treatment outside the home (odds ratio [OR] = 1.27, 95% confidence interval [CI] = 0.89–1.80). When providers where children went to first were assessed, children from urban areas more likely went to health facilities than those from the rural areas. Febrile children in rural areas used more CHWs (OR = 1.74, 95% CI = 1.07–2.83), drug shops (OR = 1.48, 95% CI = 1.04–2.12),and private clinics (OR = 66, 95% CI = 1.13–2.46) than those in urban areas. However, children in urban areas were more likely to be taken outside for treatment within 24 hours than children from rural areas (OR = 1.93, 95% CI = 1.44–2.58). A total of 11.4% (29 of 254) of caregivers from urban areas and 19.6% (585 of 2,980) of caregivers from rural areas used herbs as first treatment of febrile illness before they sought care from outside the home. Caregivers who treated their children with herbs were less likely to be in urban areas than in rural areas (OR = 0.53, 95% CI = 0.35–0.79). Other treatments offered at home were tepid sponging, chloroquine, pain killers, arthemether–lumefantrine, and cotrimoxazole. There was no significant difference in the use of other treatments at home between urban and rural areas.

Choice of provider for febrile children according to sociodemographic characteristics. The association between the household wealth quintiles of febrile children, the mother's age and education, treatment received at home, promptness of seeking outside treatment, and eventual choice of provider were assessed. It was not possible to separate the urban from rural areas because of the small numbers in the urban areas. Pooled results are shown in Table 3. Household socioeconomic status was not associated with any choice of provider except for the less poor, who were less likely to choose private clinics than CHWs (adjusted OR [aOR] = 0.52, 95% CI = 0.31–0.86) and the least poor, who were more likely to choose health facilities than CHWs (aOR = 2.03, 95% CI = 1.02–4.04). Care givers whose education level was post-primary were more likely to choose a health facility than CHWs (aOR = 1.86, 95% CI = 1.01–3.44), and those who had finished primary school chose drug shops more often than CHWs (aOR = 1.77, 95% CI = 1.16–2.88). The mother's age did not affect the choice of provider. Those who went to CHWs were more likely to go there within 24 hours than those who went to health facilities (aOR = 2.28, 95% CI = 1.62–3.19) drug shops (aOR = 1.66, 95% CI = 1.23–2.22), and clinics (aOR = 2.40, 95% CI = 1.74–3.30). Those who had given herbs at home were less likely to go to CHWs than to private clinics (aOR = 0.35, 95% CI = 0.20–0.61) and drug shops (aOR = 0.38, 95% CI = 0.22–0.61).

DISCUSSION

The CHWs were more likely to be used by rural children than urban children. Urban febrile children came from less poor households, had younger and more educated mothers, and were taken outside for treatment more promptly than their rural counterparts. They were less likely to be given herbs for treatment at home. The more educated and least poor were less likely to use CHWs than health facilities and drugs shops. Children who went to CHWs were more likely to have been taken within 24 hours than those who went to other health providers.

Findings from the study indicate that CHWs were used more by children in rural areas than those in urban areas. Other studies have also demonstrated less use of CHWs in urban areas than that reported in rural areas.[11] The CHWs provide free treatment to all children less than five years of age who have a febrile illness. To caretakers in rural areas, introduction of community case management for malaria and pneumonia through CHWs was a relief. Previously, the major providers in rural areas in the absence of government health facilities were the drugs shops and clinics.[12,13] Before implementation of community case management through CHWs in

TABLE 2
Socioeconomic status, mother's characteristics, and care seeking for urban and rural febrile children, Uganda*

Characteristic	Urban, n = 254, no. (%)	Rural n = 2,980, no. (%)	OR	*P*	95% CI
HH wealth quintiles					
Poorest	3 (1.8)	439 (16.8)	1		
Poorer	15 (9.1)	653 (25.1)	0.30	0.04	0.09–1.04
Poor	16 (9.8)	722 (27.8)	0.31	0.04	0.10–1.07
Less poor	47 (28.7)	538 (20.7)	0.09	< 0.001	0.012–0.26
Least poor	83 (50.6)	248 (9.5)	0.02	< 0.001	0.00–0.07
Mother's age, years					
< 25	62 (28.9)	510 (19.8)	1		
25–35	113 (52.8)	1,486 (57.7)	1.6	< 0.001	1.15–2.22
≥ 36	39 (18.2)	580 (22.5)	1.81	< 0.001	1.19–2.75
Mother's education					
None	13 (5.2)	298 (10.3)	1		
Primary	101 (40.4)	2,062 (71.9)	0.89	0.71	0.50–1.61
Post-primary	136 (54.4)	511 (17.8)	0.16	< 0.001	0.09–0.30
Treatment outside home					
Yes	213 (83.9)	2,389 (80.3)	1		
No	41 (16.1)	587(19.7)	1.27	0.17	0.89–1.80
Promptness in getting treatment outside					
≤ 24 hours	96 (47.8)	748 (32.1)	1		
> 24 hours	105 (52.2)	1,580 (67.9)	1.93	< 0.001	1.44–2.58
Facility					
Health facility	61 (28.8)	481 (20.3)	1		
CHW	25 (11.8)	343 (14.5)	1.74	0.02	1.07–2.83
Drug shop	75 (35.4)	876 (36.9)	1.48	0.03	1.04–2.12
Clinic	51 (24.1)	670 (28.3)	1.66	0.01	1.13–2.46
Treatment given at home					
Tepid sponging					
Yes	27 (10.6)	297 (10.0)	1		
No	227 (89.4)	2,682 (90.0)	1.07	0.11	0.71–1.63
Herbs					
Yes	29 (11.4)	585 (19.6)	1		
No	225 (88.6)	2,394 (80.4)	0.53	< 0.001	0.35–0.79
Pain relief					
Yes	90 (35.4)	918 (30.8)	1		
No	164 (64.6)	2,060 (69.2)	1.23	0.13	094–1.61
Arthemether–lumefantrine					
Yes	10 (3.9)	90 (3.0)	1		
No	244 (96.1)	2,890 (97.0)	1.32	0.42	0.68–2.56

*OR = odds ratio; CI = confidence interval; HH = household; CHW = health care worker.

the Iganga-Mayuge DSS, studies highlighted more use of drug shops and private clinics in the rural areas compared with health facilities.[7] The health facilities are not easily accessed geographically in rural areas and in most cases the poor people in the villages are left with drug shops and clinics where they have to pay for treatment.[14] Therefore, introduction of CHWs provided a safety net for caretakers in rural areas to receive free treatment that they would not have previously received. In rural areas, caretakers are also poorer and lack money and transportation to take sick children to fairly distant health facilities, most of which are in urban areas. Therefore, it is important to recognize that CHWs address a need, especially in rural areas, where there are higher proportions of poor, elderly, and less educated persons.

Herbs were more likely to be used for treating rural children before seeking treatment outside the home than for urban children. Those who used herbs were less likely to visit CHWs than the drug shops and private clinics. This finding is a challenge because children who are given herbs, which might or might not be curative, might eventually not be taken to CHWs, to whom the government was providing efficacious drugs. Giving herbs also delayed sick children being taken to CHWs or health facilities. Studies have highlighted the likelihood of using herbs for the treatment of fever, especially among the elderly.[15,16] Although studies have indicated that communities had started shifting from giving traditional medicine as a first-line treatment for fever to offering modern medicines,[8,17] giving traditional medicines could still be a delaying factor when one considers rural areas. A possibility of including other health providers such as using registered drug shops and private clinics in community case management could be considered because they are more likely to take care of a category of children that would have been given herbs. This activity further delays access of children to adequate and appropriate treatment.

Findings from this study indicated that febrile children in rural areas came from poorer households than those from urban areas. However, use of CHWs was not significantly associated with the poorest quintile, even when the rural sick children were considered alone. Community case management of fever was intended to address the challenges the poorest people experience in accessing care. In this case, middle quintiles were accessing CHWs more than the poorest quintile. Previous studies have demonstrated that the poor have less access to health care than the rich.[18] Households that had a higher economic status have been associated with completing treatment of fever compared with poorer households.[19] In this case, middle quintiles accessed

TABLE 3
Use of health providers in relation to CHWs, Uganda*

Characteristic	CHW (referent), no. (%)	Health facility			Drug shop			Clinic		
		No. (%)	AOR	95% CI	No. (%)	AOR	95% CI	No. (%)	AOR	95% CI
Wealth quintiles										
Poorest	46 (14.4)	62 (13.5)	1		135 (16.5)	1		115 (18.9)	1	
Poorer	77 (24.1)	97 (21.2)	1.08	0.62–1.89	207 (25.4)	0.96	0.60–1.54	154 (25.3)	0.91	0.56–1.49
Poor	89 (27.8)	132 (28.8)	1.25	0.74–2.11	195 (23.9)	0.76	0.45–1.20	165 (27.1)	0.82	0.51–1.32
Less poor	83 (25.9)	112 (24.5)	1.19	0.69–2.05	182 (22.3)	0.82	0.51–1.33	93 (15.3)	0.52	0.31–0.86
Least poor	25 (7.8)	55 (12.0)	2.03	1.02–4.04	97 (11.9)	1.41	0.75–2.63	83 (13.6)	1.75	0.93–2.81
Mother's age, years										
< 25	66 (20.8)	92 (19.7)	1		116 (20.5)	1		154 (24.7)	1	
25–35	176 (55.4)	259 (55.6)	1.24	0.81–1.90	468 (57.8)	1.17	0.80–1.72	358 (57.5)	0.86	0.61–1.27
≥ 36	76 (23.9)	115 (24.7)	1.41	0.85–2.34	176 (21.7)	1.14	0.72–1.81	111 (17.8)	0.70	0.44–1.14
Mother's education										
None	45 (12.7)	40 (7.6)	1		81 (8.9)	1		82 (11.7)	1	
Primary	246 (69.5)	353 (67.0)	1.42	0.85–2.37	642 (70.8)	1.77	1.16–2.88	472 (67.1)	1.18	0.58–1.87
Post-primary	63 (17.8)	134 (25.4)	1.86	1.01–3.44	184 (20.3)	1.60	0.91–2.81	149 (21.2)	1.06	0.60–1.89
Prompt care seeking										
≤ 24 hours	166 (46.8)	144 (27.5)	1		319 (34.4)	1		208 (29.7)	1	
> 24 hours	189 (53.2)	379 (72.5)	2.28	1.62–3.19	608 (65.6)	1.66	1.23–2.22	492 (70.3)	2.40	1.74–3.30
Tepid sponging										
Yes	35 (9.5)	59 (10.9)	1		116 (12.2)	1		50 (6.9)	1	
No	333 (90.5)	483 (89.1)	1.15	0.69–1.95	834 (87.8)	1.05	0.65–1.71	671 (93.1)	1,685	0.98–2.85
Herbs										
Yes	33 (9.0)	79 (15.5)	1		231 (24.3)	1		146 (20.3)	1	
No	335 (91.0)	463 (85.5)	0.73	0.41–1.27	719 (75.7)	0.38	0.22–0.61	575 (79.7)	0.35	0.20–0.61
Pain killer										
Yes	84 (22.8)	137 (25.3)	1		185 (19.5)	1		144 (20.0)	1	
No	284 (77.2)	404 (74.7)	1.10	0.65–1.86	765 (80.5)	1.38	0.85–2.24	577 (80.0)	1.03	0.60–1.78
Arthemether–lumefantrine										
Yes	5 (1.4)	12 (2.2)	1		14 (1.5)	1		11 (1.5)	1	
No	530 (97.8)	363 (98.6)	0.73	0.24–2.22	937 (98.5)	0.90	0.30–2.66	710 (98.5)	0.76	0.25–2.36

*CHWs = health care workers; AOR = adjusted odds ratio; CI = confidence interval.

CHWs more than poorest quintiles. This finding agrees with the inverse equity hypothesis, which Victora and others highlighted in public health programs to improve child health in Brazil, where the poor benefit from programs much later in the intervention.[20] This finding calls for two actions: first, that interventions need to be sustained for a longer time so that the poorest persons can also benefit from them; and second, to have more focused interventions targeting where the poorest go for treatment (in this case drug shops and private clinics).

Children in urban areas were more likely to seek care within 24 hours than the children from rural areas. One of the aims of integrated community case management is to provide timely care to sick children.[21] Previous studies have indicated that children who went to CHWs were more likely to have got treatment within 24 hours.[10] The presence of CHWs could have contributed to more prompt treatment of febrile children especially in rural areas. Caretakers might be delaying to get treatment from the drug shops and clinics because they have to get funds first to pay for the drugs they receive but with subsidized treatment, the promptness may increase. It is important to note that drug shops and private clinics still take care of a considerable number of children. Studies that have been conducted to assess use of private and public providers have highlighted that some children derive their care solely from private providers[22] or when they need ambulatory care.[23] Inclusion of private providers in community case management of malaria and pneumonia may provide another avenue to reach the febrile children promptly. Using drug shops has been shown to improve prompt treatment of febrile children in Kenya.[24]

The socioeconomic status that was used for households in this study was the one calculated from the data collected in the DSS during January–June 2008 and was in effect for two years. Thus, new households that were included in the DSS within the previous two years did not have a socioeconomic status ascribed to them. This finding could have affected estimates for use according to socioeconomic status because of missing values. However, for those that were available, values were two years old. Because the wealth quintiles estimate wealth that is long term,[25] it is possible that there would not have been significant changes within household socioeconomic status in the two years and if they took place, they were minimal. The strength of the study was that it was a census of all children who became sick in the previous two weeks. Therefore, results represent closely use of CHWs by care takers of children less than five years of age at that time.

The CHWs are used proportionately more in rural areas than in urban areas. Rural areas have more of elderly mothers and less educated mothers. The CHWs are therefore supporting a specific category of the poor (less educated and elderly mothers). The use of herbs for the treatment of fever in children was more likely to be used in rural areas than in urban areas. Because those who use herbs are more likely to see other providers rather than CHWs, a possibility of incorporating other providers in the community case management could be explored. The poorest households use the CHWs less than the middle quintiles. It is critical that CHWs should focus in rural areas, where most of the poorest persons live, and include drug shops and private clinics, where most of the poorest persons seek care. In addition, drugs shops and private

clinics should be used in community case management in towns because these facilities are highly used by urban dwellers.

Received November 25, 2011. Accepted for publication April 12, 2012.

Acknowledgments: We thank the study participants, research assistants, the Iganga/Mayuge Demographic Surveillance Site, and the Iganga and Mayuge Districts for their support and contributions.

Financial support: This study was supported by the United Nations Children's Fund/United Nations Development Program/World Bank/World Health Organization Special Programme for Research and Training in Tropical Diseases.

Disclaimer: The contents of this study are solely the responsibility of the authors and do not reflect the views of United Nations Children's Fund/United Nations Development Program/World Bank/World Health Organization Special Programme for Research and Training in Tropical Diseases or the authors' institutions of affiliation.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 36–45
doi:10.4269/ajtmh.2012.11-0733

Increased Use of Community Medicine Distributors and Rational Use of Drugs in Children Less than Five Years of Age in Uganda Caused by Integrated Community Case Management of Fever

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Abstract. We compared use of community medicine distributors (CMDs) and drug use under integrated community case management and home-based management strategies in children 6–59 months of age in eastern Uganda. A cross-sectional study with 1,095 children was nested in a cluster randomized trial with integrated community case management (CMDs treating malaria and pneumonia) as the intervention and home-based management (CMDs treating only malaria) as the control. Care-seeking from CMDs was higher in intervention areas (31%) than in control areas (22%; $P = 0.01$). Prompt and appropriate treatment of malaria was higher in intervention areas (18%) than in control areas (12%; $P = 0.03$) and among CMD users (37%) than other health providers (9%). The mean number of drugs among CMD users compared with other health providers was 1.6 versus 2.4 in intervention areas and 1.4 versus 2.3 in control areas. Use of CMDs was low. However, integrated community case management of childhood illnesses increased use of CMDs and rational drug use.

INTRODUCTION

Approximately 1.4 million children in Africa die of malaria and pneumonia each year.[1] Effective drugs for treatment of these two illnesses are available, but they should be administered promptly, i.e., within 24 hours, to minimize the adverse outcomes of the illnesses.[2,3] However, caregivers experience several barriers and children do not always receive timely and effective treatment.[4–9]

Efforts to overcome some of these barriers were made through the introduction of the so called home-based management of fever strategy (HBMF) in regions with endemic malaria. Uganda was one of the first countries to implement this strategy in 2002. In this strategy, community medicine distributors (CMDs), also known as community drug distributors or community health workers, treat children with fever in the community with antimalarial drugs.[10–12] The CMDs lacked formal medical training but were trained for at least five days in management of fever as a symptom of malaria. The proportion of children receiving prompt and appropriate treatment increased with this strategy, but was nevertheless below the 2000 Abuja targets of 60%[13] and its use was low.[7,9,14,15] Furthermore, some children with other illnesses (e.g., pneumonia) were treated with antimalarial drugs[16] because of symptom overlap or co-infection.[17]

Integrated community case management of childhood illnesses (ICCM) was recommended in 2004 and has been adopted by some countries, including Uganda. In ICCM, CMDs use an evidence-based algorithm to treat children at the community level with antimalarial drugs, antibiotics, and oral rehydration salts. More drugs are accessible to the community under ICCM than under HBMF and this increased acccessibility may improve treatment patterns of children. However, easy access to drugs could also promote drug misuse, leading to wasting of resources and development of resistance to antibiotics. In Zambia, ICCM improved pneumonia treatment of children treated by CHWs.[18] However, it remains unclear whether this new strategy will improve use and appropriateness of treatment compared with what has been achieved with the HBMF strategy in other settings with different care-seeking and treatment practices. Therefore, the aim of this study was to compare the effect of ICCM and HBMF strategies on use of CMDs and community drug use patterns in children 6–59 months of age.

METHODS

Study design and setting. A cross-sectional study was conducted during January–February 2011 in Iganga-Mayuge Health and Demographic Surveillance Site in eastern Uganda. The population in the area is approximately 70,000 persons living in 13,000 households in 65 villages, where approximately 90% live in rural areas. Malaria is endemic to the area, and there are two main transmission seasons (March and September). The population of children less than five years is approximately 11,000 and the mortality rate in children less than five years of age is 128 per 1,000 live births.[19] The study area has 10 government and 3 non-governmental organization health facilities, 122 drug shops and private clinics, and 132 CMDs. A cluster randomized trial to evaluate the impact of integrated presumptive management of malaria and pneumonia with antimalarial drugs and antibiotics on mortality in children less than five years of age has been ongoing in the area since 2009 (trial registration no. ISRCTN52966230).

Description of cluster randomized trial. The 65 villages in the area were aggregated into 8 urban and 18 rural clusters, which were then randomized to either intervention arm or control arm. Each village has two CMDs that treat children less than five years of age. The basic criteria for working as a CMD are that one is able to read and write, is chosen by the community, and has received short-term training in treatment of children. The CMDs were all trained initially for one week in the management of malaria. In the intervention arm, the CMDs received additional training in the management of pneumonia for one week. Finally, CMDs in both arms receive monthly refresher training. In the intervention arm,

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CMDs treat children with fever using antimalarial drugs (artemether–lumefantrine [AL]). Children with non-severe respiratory symptoms according to Integrated Management of Childhood Illnesses guidelines[20] are also treated with antibiotics (amoxicillin). In the control arm, CMDs treat children with fever using antimalarial drugs (AL), and those with respiratory symptoms of any severity are referred to health facilities. In both arms, children with severe respiratory or severe malaria symptoms[20] are referred to health facilities (Figure 1). The medicines used by the CMDs were pre-packaged in age-specific doses. Health workers from the nearest health center or hospital conduct monthly support supervision of CMDs in both arms to assess drug storage, treatment practices, and record keeping. Before the start of the study, community sensitization seminars about the intervention, recognition of illness in children, and prompt care seeking were conducted.

Participants and sampling. We sampled 1,400 children 6–59 months of age from the health and demographic surveillance site database by using random sampling stratified by intervention and control villages to obtain equal numbers from each arm of the cluster randomized trial. We assumed that with expected non-response rate of 25% based on a previous study in the area,[21] this would give us 1,094 children (547 in each arm) that we needed to answer the objectives. The sample size was estimated by using the formula for comparison of two proportions with adjustment for clustering.[22] Assumptions used were 5% level of significance, 80% power, design effect of 1.9, 54% of children ill in previous 2 weeks,[23] and a change in proportion of children receiving prompt and appropriate treatment of malaria equivalent to what was observed under HBMF (i.e., 7.4–13.5%),[9] giving a change rate of 13.5–24.3%. This sample size was also adequate to detect a 30% difference in use of CMDs in the intervention and control areas. All children whose caregivers were available at home and consented to participate in the study were enrolled.

Data collection. Eight experienced and trained interviewers used a pre-tested questionnaire to interview the caregivers. The interviewers were supervised by a pharmacist (Joan N. Kalyango) and a pediatrician (Ann Lindstrand). Data were collected on knowledge about fever, malaria, and pneumonia; perceptions of quality of care; availability of health providers; illness in the previous two weeks; care-seeking patterns; and treatment received including the dose, frequency, duration, timeliness, and source.

Medicine posters showing drugs commonly used in the area for treatment of children were used to help the caregivers to identify which treatment children had received. Medicine packages, when available, were also checked to confirm the drug and dose prescribed. Data on child and caregiver demographics, distances of the households from the nearest CMD (using global positioning system coordinates), and the wealth index of the household were extracted from the health and demographic surveillance site data base. The wealth index was computed by using principal components analysis on the basis of household characteristics and assets similar to those used by the Uganda Bureau of Statistics,[19] and categorized into five quintiles of relative wealth (poorest to least poor) as described elsewhere.[24]

Variable definitions. A child was considered as having had malaria if the caregiver reported fever in the previous two weeks.[25] Self-reported pneumonia symptoms were defined as caregiver report of cough and fast breathing with or without fever; cough and difficult breathing with or without fever; difficult and fast breathing with or without fever; and fever and difficult breathing.[2]

We categorized treatment as appropriate if the child used the recommended drug, dose, frequency, and duration. In addition, if the child used appropriate treatment promptly, i.e., if it was administered on the day of onset of symptoms or the next day,[14,23] it was categorized as prompt and appropriate.[9] Assessment for appropriateness of treatment was conducted for the first treatment given to the child (i.e., first treatment action) and for the second treatment given to the child if they needed further treatment (i.e., second treatment action).

We based assessment of appropriateness of medicines used on national[26] and CMD treatment guidelines,[27] and treatment recommendations of the British National Formulary,[28] which is widely used in Uganda. The medicines considered

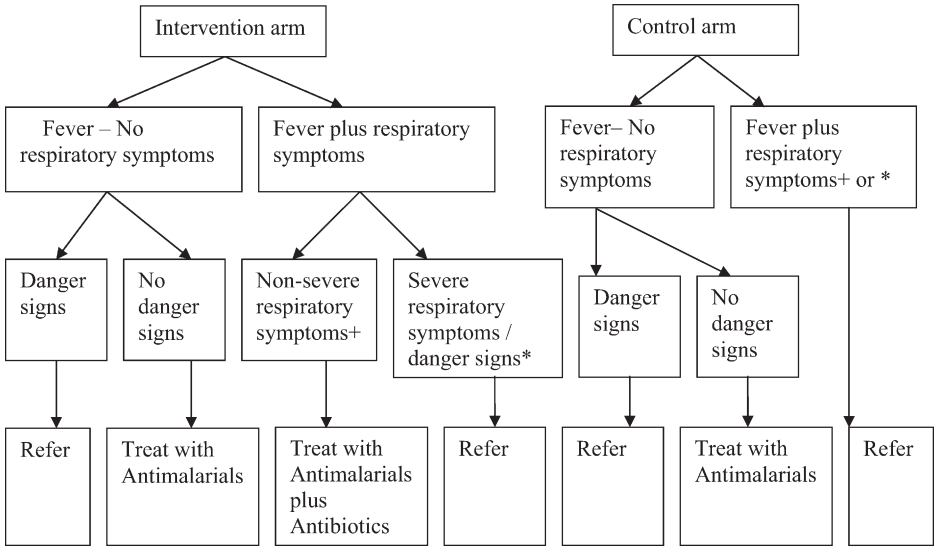

FIGURE 1. Algorithm for treatment of children by Community Medicines Distributors in Iganga-Mayuge health and demographic surveillance site. + Cough or difficult breathing with fast breathing (i.e. ≥ 50 breaths per minute for child aged 4-12 months; ≥ 40 breaths per minute for child aged 12–59 months). * Cough or difficult breathing with chest indrawing or noisy breathing.

appropriate for treatment of malaria and pneumonia are shown in Appendix 1.

Use of CMDs was defined as care seeking from a CMD for the first or second treatment action for illness in the previous two weeks.

We classified a respondent as having knowledge of transmission of malaria if they could identify mosquito bites as the method by which malaria is transmitted from person to person. A score was generated for each of the other knowledge dimensions, i.e., knowledge of malaria and pneumonia prevention, symptoms, and danger signs of illness in children. The respondent obtained one mark on knowledge for each correct answer they gave.[29]

Data management and analysis. Data were double-entered in a FoxPro computer package and exported to STATA version 10 (StataCorp LP, College Station, TX) for analysis. Descriptive statistics were used for description of participants, estimation of the proportions of persons receiving appropriate treatment, and CMD use. Chi-square or Fisher's exact tests were used for comparison of proportions. Logistic regression was used to assess the relationship between various independent variables and prompt and appropriate treatment and CMD use. Unadjusted analysis was performed and on the basis of this analysis, factors that had P values < 0.2 were carried forward for multivariate analysis. Interaction was assessed by comparing log likelihoods of reduced and full models. All analyses were adjusted for the loss in variation because of use of stratified sampling with svy commands in STATA. A P value of 5% was considered statistically significant.

Ethical issues. Ethical clearance was obtained from the Makerere University School of Public Health Higher Degrees Research and Ethics Committee, the Uganda National Council of Science and Technology and the Regional Ethics Committee of Karolinska Institutet, Sweden. Permission to conduct the study in the area was also obtained from the local administration of Iganga and Mayuge Districts and the demographic surveillance site. Written informed consent was obtained from the participants.

RESULTS

Demographic and illness characteristics of participants. We enrolled 1,095 (78%) of the 1,400 sampled children in the study (547 in the control arm and 548 in the intervention arm). Households where either the child or caregiver was not available at the first visit were visited a second time. Approximately half (49.3%) of the children were females and the mean (SD) age was 34.9 (20.3) months (Table 1). Households were mostly within the poorer to less poor wealth quintiles. The median distance to the nearest CMD was 422 meters

TABLE 1
Demographic and illness characteristics of 1,095 children in Iganga-Mayuge demographic surveillance site, Uganda*

Characteristic	Overall	Intervention	Control	P
No. children	1,095	548	547	
Female children, no. (%)	540 (49.3)	263 (48.0)	277 (50.6)	0.38
Mean age of children, months (SD)	34.9 (20.3)	35.5 (24.4)	34.4 (15.1)	0.47
Female respondent, no. (%)	870 (80.1)	444 (81.6)	426 (78.6)	0.21
Mean age of respondents, years (SD)	33.2 (10.8)	32.9 (11.0)	33.5 (10.8)	0.22
Male household heads, no. (%)	941 (89.2)	466 (88.4)	475 (90.0)	0.42
Mean age of household head, years (SD)	41.5 (12.3)	41.4 (12.5)	41.6 (12.3)	0.85
Wealth Index of household				
Poorest	164 (17.5)	86 (18.3)	78 (16.8)	0.48
Poorer	207 (22.1)	106 (22.5)	101 (21.7)	
Poor	238 (25.4)	108 (22.9)	130 (28.0)	
Less poor	212 (22.7)	104 (22.1)	108 (23.2)	
Least poor	115 (12.3)	67 (14.2)	48 (10.3)	
Median distance from CMD, meters (range)	422 (5.6–1,635)	415 (12.0–1,466.9)	425.3 (5.6–1,635.4)	0.48
Children ill, no. (%)	811 (74.1)	419 (76.5)	392 (71.7)	0.07
Treated for illness, no. (%)	780 (96.2)	406 (96.9)	374 (95.4)	0.27
Sought care outside home, no. (%)	703 (86.7)	358 (85.4)	345 (88.0)	0.09
Malaria symptoms among the ill, no. (%)	754 (93.0)	381 (90.9)	373 (95.2)	0.02
Pneumonia symptoms among the ill, no. (%)	236 (29.1)	134 (32.0)	102 (26.0)	0.06
Mean knowledge score of malaria (SD)	4.1 (1.8)	4.1 (1.9)	4.1 (1.9)	0.66
Mean knowledge score of pneumonia (SD)	1.0 (1.3)	1.0 (1.3)	1.0 (1.3)	0.70
Mean knowledge score of danger signs (SD)	2.3 (1.0)	2.4 (1.2)	2.3 (1.1)	0.18
Symptoms of children, no. (%) (n = 811)				
Runny nose	755 (93.1)	383 (91.4)	372 (94.9)	0.05
Fever	754 (93.0)	381 (90.9)	373 (95.2)	0.02
Cough	652 (80.4)	333 (79.5)	319 (81.4)	0.50
Loss of appetite	380 (46.9)	192 (45.9)	188 (48.0)	0.55
Headache	302 (37.2)	142 (33.9)	160 (40.8)	0.05
Diarrhea	244 (30.1)	132 (31.5)	112 (28.6)	0.37
Chills	243 (30.0)	118 (28.2)	125 (31.9)	0.26
Vomiting	211 (26.0)	108 (25.8)	103 (26.3)	0.87
Difficult breathing	157 (19.4)	86 (20.5)	71 (18.1)	0.39
Fast breathing	145 (17.9)	83 (19.5)	62 (15.8)	0.15
Convulsions	32 (4.0)	19 (4.5)	13 (3.3)	0.27
Stomach pain	22 (2.7)	13 (2.4)	9 (1.6)	0.34
Rash	21 (2.6)	6 (1.1)	15 (2.7)	0.23
Other†	32 (3.9)	23 (4.2)	9 (1.6)	0.44

*CMD = community medicine distributor.
†Includes nose bleeding, weakness, yellowing of eyes, pallor, mouth sores, loss of consciousness, mumps, measles, painful eyes, chicken pox, itching, and excessive crying.

TABLE 2
Treatment-seeking characteristics for 734 children that sought care in Iganga-Mayuge demographic surveillance site, Uganda*

Characteristic	Overall	Intervention	Control	*P*
Source of first treatment				
Private clinic	231 (31.5)	120 (31.4)	111 (31.5)	0.97
CMDs	187 (25.5)	112 (29.3)	75 (21.3)	0.01
Drug shop	180 (24.5)	87 (22.8)	93 (26.4)	0.26
Government unit	126 (17.2)	56 (14.7)	70 (19.9)	0.07
NGO unit	5 (0.7)	4 (1.1)	1 (0.3)	0.21
General shop	3 (0.4)	2 (0.5)	1 (0.3)	0.61
Traditional healer	2 (0.3)	1 (0.3)	1 (0.3)	0.95
CMD use				
Sought treatment from CMD as first or second action	195 (26.6)	117 (30.6)	78 (22.2)	0.01
Ever used services of CMD (n = 1,095)	765 (70.0)	392 (71.7)	373 (68.3)	0.23
Mention CMDs as one of the providers where can take child (n = 1,095)	797 (73.0)	415 (75.9)	382 (70.1)	0.04
Willing to take child to CMD again (n = 700)	678 (96.9)	342 (96.3)	336 (97.4)	0.45
CMD use among children with pneumonia symptoms (n = 213)†	61 (28.6)	43 (35.5)	18 (19.6)	0.01
CMD use among children with malaria symptoms (n = 687)†	175 (25.5)	103 (29.5)	72 (21.3)	0.01

*Values are no. (%). CMD = community medicine distributor; NGO = non-government organization.
†Children with specific symptoms who sought care.

(range = 5.6–1,635 meters). There was no difference in demographic characteristics of the children, respondents and household heads in the two arms of the cluster randomized trial. There was also no difference in their knowledge of malaria, pneumonia, and danger signs.

Approximately 74% of the children were reported to have been ill in the two weeks before the study. Of these children, 96% were treated with some type of medication and 87% sought care outside the home. More children in the control arm reported malaria symptoms (i.e., fever) than in the intervention arm (95% vs. 91%), and more children in the intervention arm reported pneumonia symptoms (32% vs. 26%). Runny nose and fever were the most common symptoms (both reported by 93%), followed by cough (80%) (Table 1).

Use of CMDs. Of the children that sought care outside home 27% (95% confidence interval [CI] = 23–30%) sought care from a CMD, and there was a higher proportion in the intervention arm than in the control arm (31% vs. 22%; $P = 0.01$). Approximately 70% had used the services of CMDs, and 97% of these persons were willing to take their children to CMDs again. The most common source of initial treatment was private clinics (32%), followed by CMDs (Table 2). The most common reasons for seeking care from CMDs were not having to pay for treatment (60%), services were nearby (60%), and services were good (10%).

TABLE 3
Medicines received among 811 children that were ill in Iganga-Mayuge demographic surveillance site, Uganda

Drug class	Overall	Intervention	Control	*P*
Drugs used in home treatment, no. (mean)	n = 77	n = 48	n = 29	
Antipyretics*	48 (0.62)	29 (0.60)	19 (0.66)	0.65
Antimalarial drugs†	22 (0.29)	16 (0.55)	6 (0.21)	0.003
Antibiotics‡	16 (0.21)	10 (0.21)	6 (0.21)	0.99
Antihistamines§	5 (0.06)	4 (0.08)	1 (0.03)	0.40
Other¶	9 (0.11)	4 (0.08)	5 (0.17)	0.24
Drugs given by health providers, no. (mean)	n = 734	n = 381	n = 353	
Antimalarial drugs#	471 (0.64)	249 (0.65)	222 (0.63)	0.83
Antipyretics**	459 (0.63)	222 (0.58)	237 (0.67)	0.44
Antibiotics††	359 (0.49)	207 (0.54)	152 (0.43)	0.34
Antihistamines§	80 (0.11)	39 (0.10)	41 (0.12)	0.85
Steroids‡‡	56 (0.08)	28 (0.07)	28 (0.08)	0.92
Hematinics	15 (0.02)	8 (0.02)	7 (0.02)	0.98
Vitamins	14 (0.02)	6 (0.02)	8 (0.02)	0.83
Other§§	14 (0.02)	9 (0.02)	5 (0.01)	0.76
Combination drugs for flu¶¶	13 (0.02)	8 (0.02)	5 (0.01)	0.82
Dewormers	9 (0.01)	4 (0.01)	5 (0.01)	0.87
Anticonvulsant (diazepam)	8 (0.01)	4 (0.01)	4 (0.01)	0.97
Received at least one drug	733 (90.4)	387 (92.4)	346 (88.3)	0.05
Received at least one antibiotic	132 (33.7)	187 (44.6)	319 (39.3)	0.007
Overall mean number of medicines (SD)	2.2 (1.1)	2.3 (1.0)	2.2 (1.1)	0.94
Unidentified crushed tablets,## no. (%)	34 (4.6)	12 (3.1)	22 (6.2)	0.05

*Paracetamol, aspirin, and ibuprofen.
†Artemether–lumefantrine and quinine.
‡Amoxicillin, metronidazole, and cotrimoxazole.
§Chlorphenramine and cetirizine.
¶Combination drugs for influenza, vitamins, hematinics, diazepam, bronchodilators, steroids, and dewormers.
#Artemether–lumefantrine, quinine, amodiaquin, sulfadoxine–pyrimethamine, chloroquine, and artemether.
**Paracetamol, aspirin, ibuprofen, and diclofenac.
††Amoxicillin, cotrimoxazole, metronidazole, erythromycin, azithromycin, benzyl penicillin, penicillin V tablets, chloramphenicol, ampicillin, ampicillin plus cloxacillin, and cloxacillin.
‡‡Dexamethasone and prednisolone.
§§Metoclopramide, antacids, bronchodilators, oral rehydration salts, nystatin oral suspension.
¶¶Combinations of antihistamines, antipyretics, and systemic nasal decongestants.
##Medicines mixed and crushed by health worker and given to caregiver in powder form.

Factors associated with use of CMDs by multivariate analysis were being in the intervention arm of the cluster randomized trial (odds ratio [OR] = 1.60, 95% CI = 1.09–2.35), being in the poorest to less poor wealth quintiles compared with the least poor quintiles (OR = 1.92, 95% CI = 0.99–3.71), increased knowledge of malaria prevention strategies (OR = 1.39, 95% CI = 1.12–1.73), increased knowledge of danger signs of illness (OR = 1.22, 95% CI = 1.03–1.43), and not having fever (OR = 2.55, 95% CI = 1.26–5.16). Distance of the household from the nearest CMD of more than 500 meters was negatively associated with use of CMDs by unadjusted analysis (OR = 0.68, 95% CI = 0.47–0.96) but not by multivariate analysis.

Approximately 80% of caregivers that sought care from CMDs rated the service as good and 20% rated it as fair. None of them rated the quality of care received as poor. Respondents whose children sought care from the government health unit, private clinics, and drug shops rated the care received as poor in 4.8%, 1.3%, and 0.6%, respectively.

Treatment practices. *Medicines used.* Antipyretics were the most commonly used drugs in self (home) treatment, and antimalarial drugs were the most commonly used by those who sought care outside the home. More children in the intervention arm (92%) who were ill received at least one drug than children in the control arm (88%). The proportion of children that received any antibiotic was higher in the intervention arm than in the control arm (45% versus 34%; $P = 0.007$). The mean (SD) number of medicines per child was 2 (1.1), and there were no difference between arms. Overall, 5% of the children used unidentified crushed medicines (medicines mixed and crushed by the health worker and given to the caregiver in powder form with directions on how to estimate the dose), and 2% were treated with herbs (Table 3).

Antibiotic use was lower among children that sought care from CMDs than in those that sought care from elsewhere in the intervention arm (44% versus 49%; $P = 0.003$) (CMDs in the control arm did not have antibiotics). The mean number of drugs was lower among children that had sought care from CMDs than in those that sought care from elsewhere in the control arm (1.4 versus 2.3; $P < 0.001$) and in the intervention arm (1.6 versus 2.4; $P < 0.001$).

Treatment of malaria symptoms. More than 90% of the children with malaria symptoms (i.e., fever) received prompt treatment. However, only 61% received an antimalarial drug and 51% received a recommended antimalarial drug. Overall, only 15% received prompt and appropriate treatment of malaria symptoms, and this proportion was higher in the intervention arm than in the control arm (18% versus 12%; $P = 0.03$) (Figure 2).

A higher proportion of children received prompt and appropriate treatment for malaria among CMD users than among other health providers (37% versus 9%; $P < 0.001$). All children who received care from CMDs were treated with the recommended drug, compared with only 38% among the children who received care from other health care providers. There were also significant differences in children receiving recommended dose, frequency, and duration (Figure 3).

Multivariate analysis showed that the factors associated with prompt and appropriate treatment of malaria were CMD use (OR = 7.27, 95% CI = 4.47–11.82), age of the household head (OR = 1.02, 95% CI = 1.00–1.04), younger children (OR = 0.98, 95% CI = 0.96–0.99), knowledge of malaria transmission (OR = 2.05, 95% CI = 1.23–3.41), and increasing knowledge of signs of pneumonia (OR = 1.40, 95% CI = 1.14–1.72). Being in the intervention arm of the

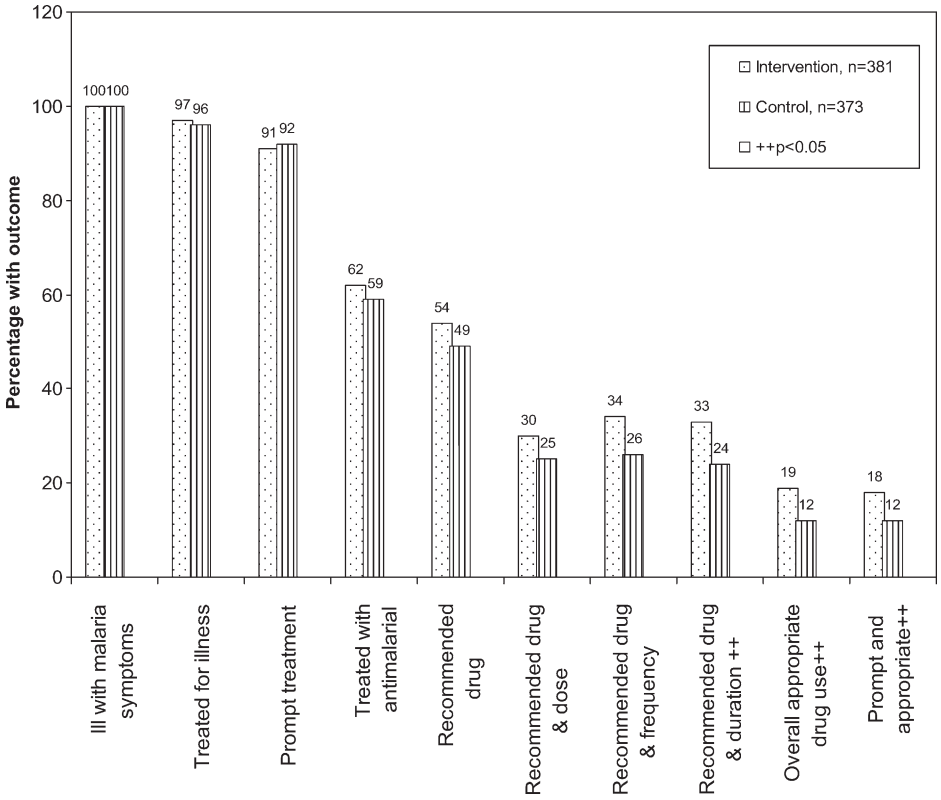

FIGURE 2. Malaria symptoms treatment practices in intervention and control arms in Iganga-Mayuge demographic surveillance site, Uganda.

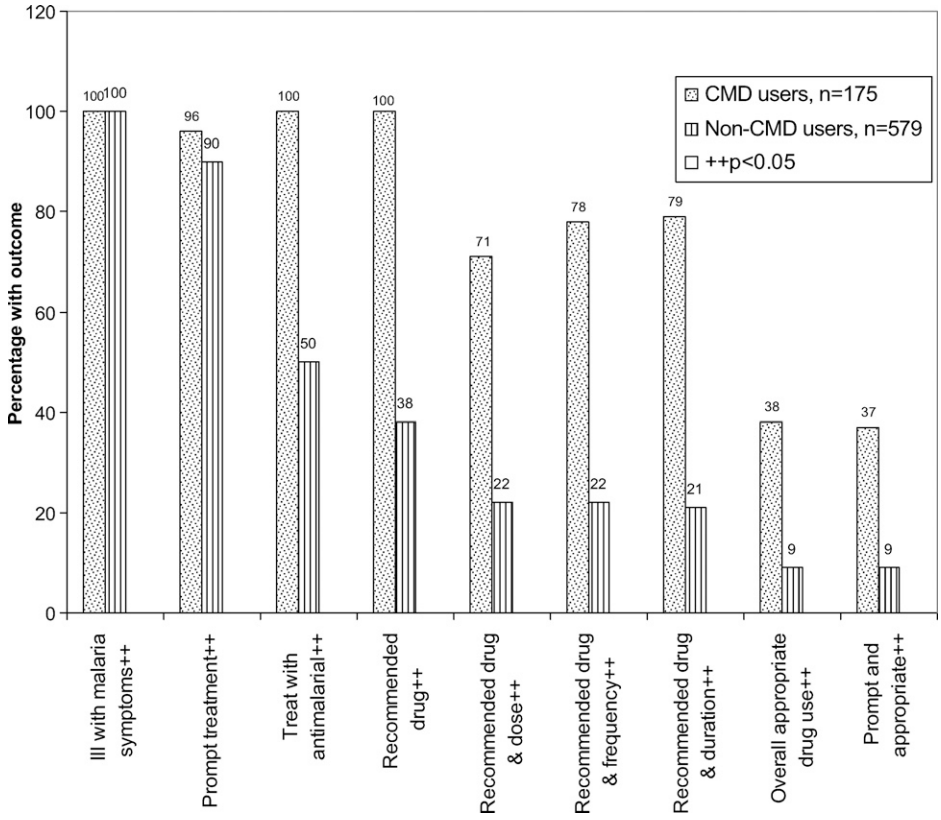

FIGURE 3. Malaria symptoms and treatment practices among community medicine distributor (CMD) and non-CMD users in Iganga-Mayuge demographic surveillance site, Uganda.

cluster randomized trial was significantly associated with prompt and appropriate treatment of malaria symptoms by unadjusted analysis (OR = 1.52, 95% CI = 1.01–2.28) but not by multivariate analysis.

Treatment of pneumonia symptoms. Approximately 42% of children with self-reported pneumonia symptoms received a correct antibiotic, but with no significant difference observed between the intervention and control arms (45% versus 37%; $P = 0.44$). However, only 9% received prompt and appropriate antibiotics, but there was no significant difference between the intervention and control arms (11% versus 5%; $P = 0.10$) (Figure 4).

Approximately 48% of children treated with antibiotics received cotrimoxazole, and only 39% were treated with amoxicillin. A higher proportion of children treated with antibiotics for self-reported pneumonia symptoms in the intervention arm received amoxicillin than those in the control arm (49% versus 21%; $P = 0.007$). Approximately 47% of those treated with amoxicillin received it from CMDs. The proportion of children who received antibiotics for pneumonia symptoms did not differ between CMDs users and non-CMD users in the intervention arm (42% versus 45%; $P = 0.39$). There were also no differences in proportions of children that received the correct dose, frequency, and duration of antibiotics (Figure 5).

DISCUSSION

Care-seeking from CMDs for sick children was higher in the intervention arm (31%) than in the control arm (22%), although it was quite low overall (27%). The CMDs were the second most preferred source of treatment after private clinics. Most caregivers highly rated the quality of care received from CMDs. The CMDs improved rational use of medicines through reduction of polypharmacy, better malaria treatment practices, and improved promptness of treatment.

The level of use of CMDs in our study is within the range of 2–59%, which has been reported in other studies.[9,14,21,30] Unlike in our study in which most CMDs were newly enrolled, Ajayi and others enrolled pre-existing CMDs, and this may have resulted in the much higher use rate of CMDs (59%).[14] In contrast, Rutebemberwa and others reported a low level of use of CMDs (2%), which was probably caused by a recent change in the Uganda malaria policy to artemisinin-based combination therapy as first-line antimalarial drug, which had not been accompanied by provision of artemisinin-based combination therapy to CMDs.[21]

The level of use of CMDs in Iganga-Mayuge was lower than could be expected given that the CMDs have been operational for approximately two years, and that the treatment was free and easily accessible. This finding may have been caused by caregiver preference for private clinics, which are perceived to have skilled health professionals and a wider range of services. Second, although there was community sensitization about the CMDs at the start of the program, there was no continued sensitization. Third, CMDs were affected by periodic drug shortages.

Having CMDs who can only treat malaria has been cited as one of the possible reasons for low use of their services because many children have multiple illnesses.[9] Our study

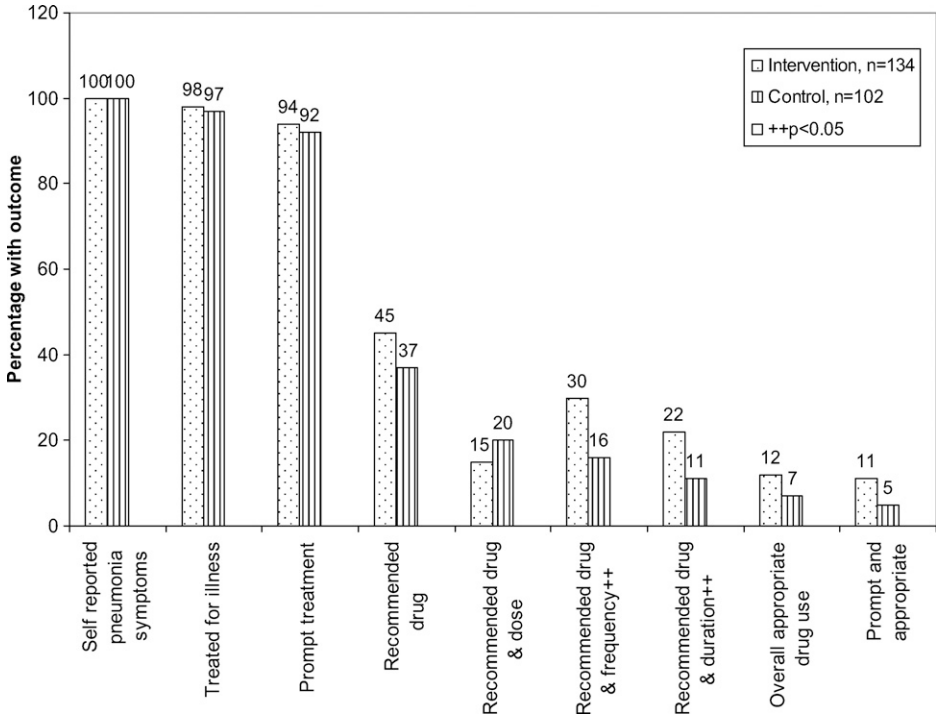

FIGURE 4. Self-reported pneumonia symptoms and treatment practices in intervention and control arms in Iganga-Mayuge demographic surveillance site, Uganda.

suggests that CMDs with broader options, such as in the intervention arm of this study, have more clients. In our study, caregivers in the intervention arm were 1.6 times more likely to seek treatment for their children from CMDs than caregivers in the control arm.

Caregivers with lower socioeconomic status were more likely to seek care for their children from CMDs compared with caregivers with higher socioeconomic status. This finding confirms the findings of a qualitative study from Uganda, which showed that persons from the poorest quintile were more likely to use free public health facilities.[31] However, our findings contrast with those of a study in western Uganda in which children in the least poor quintile were more likely to receive medicines from CMDs.[9] The differences in the

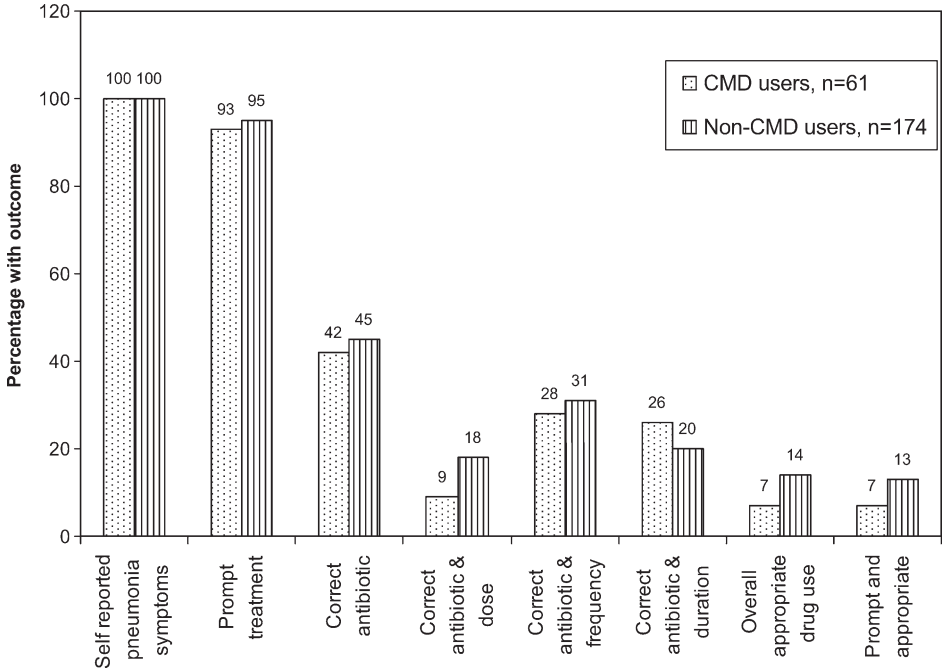

FIGURE 5. Self reported pneumonia symptoms and treatment practices among community medicine distributor (CMD) and non-CMD users in the intervention arm in Iganga-Mayuge demographic surveillance site, Uganda.

study findings may be caused by differences in availability of other sources of health care, e.g., private clinics that the caregivers of higher socioeconomic status are more able to afford.

Caregivers with more knowledge of malaria preventive strategies and danger signs of illness were more likely to seek care for their children from CMDs than those with less knowledge. This finding may reflect transmission of knowledge from CMDs to caregivers when the caregivers seek care for their children from CMDs. It could also be explained by caregivers having more knowledge about illness being more aware that they can get effective drugs for the illness from CMDs and therefore seek care from them. Knowledge has been shown to influence treatment practices in other studies.[9,32,33]

The findings of rational use of medicines among CMDs in our study are similar to those of studies in western Uganda, rural Senegal, and Zambia.[9,18,34] All children treated for malaria symptoms by CMDs received the recommended drug. However, only 37% of them received prompt and appropriate treatment. The children treated for malaria by CMDs had much better results than those treated by other health providers, for which only 38% received the correct drug and 9% received prompt and appropriate treatment. The main challenges of treatment for CMDs and other health providers were in dosing schedules and treatment duration. These challenges might be caused by dosing errors or inadequate information on drug administration given to caregivers by health providers, or misinterpretation of instructions by caregivers. In children treated by other health providers, there was an additional problem of prescription of ineffective medicines, which calls for stronger drug regulation to avoid having these drugs on the market. The proportion of children receiving prompt and appropriate treatment in our study was slightly higher than that found in a previous study in western Uganda under the HBMF strategy[9] and in rural Senegal.[34]

It is more difficult to interpret the results for the treatment of pneumonia symptoms from our study. We could only get self-reported pneumonia symptoms, and it is well known that not all children with self-reported pneumonia symptoms have objective signs of pneumonia and therefore should be treated with antibiotics. The CMDs have been trained to promote rational use of antibiotics through respiratory rate assessment before prescription. The proportion of children treated with recommended antibiotics did not differ between CMD users and non-CMD users in the intervention arm, which suggested that CMDs may perform as well in provision of appropriate medicines for pneumonia as other health care providers. Furthermore, the concern that CMDs may increase overuse of antibiotics does not seem to be correct. However, there is a need to ensure that their skills in respiratory assessment are adequate and that they are not failing to diagnose pneumonia in children. This finding is supported by findings from a study among CMDs in Uganda where classification of pneumonia was inadequate.[35] Further studies of pneumonia treatment by CMDs are needed in which objective measurements of pneumonia are included.

Surprisingly, the use of pre-packed antibiotics did not result in better dosing among children treated by CMDs for self-reported pneumonia symptoms. Pre-packaged drugs have been reported to result in better drug use.[36] These findings may result from caregiver's non-adherence to dosing instructions either because of misunderstanding of the instructions or of wrong perceptions about how the medicines should be administered to children. The dosing range for the amoxicillin used by CMDs is 1–3 tablets. This number of tablets is quite high compared with what caregivers are used to for treatment of common conditions in these age groups. This finding may explain why many of the children not treated with recommended doses had used does that were too low. This hypothesis may need to be explored with further studies. However, we also cannot not rule out incorrect dosing by CMDs, or misreporting of how medicines were administered because of problems in recall because we used caregiver reports of medicines used for illness in the past two weeks.

Having CMDs that provide amoxicillin increases the use of a more effective oral drug against pneumonia instead of cotrimoxazole, which most other health providers are prescribing but to which high levels of resistance have been demonstrated elsewhere.[37] Approximately half of the children who were treated with antibiotics received cotrimoxazole. However, approximately half of those that received amoxicillin received it from CMDs.

We had hypothesized that ICCM would improve drug use patterns for pneumonia because of the improved access to medicines, having pre-packaged medicines delivered by trained CMDs, and general improvement in practices especially of health workers that supervise the CMDs. However, our study did not find a significant difference in the proportions of children that received prompt and appropriate treatment for self-reported pneumonia symptoms in the intervention and control arms. Nevertheless, there were higher proportions of children in the intervention arm that received drugs in the correct frequency and duration. The non-significant difference in overall practices in the intervention and control arms may have been caused by insufficient power to detect differences because of the low numbers that were ill with pneumonia and subsequently the low numbers receiving appropriate treatment. It is likely that the influence of ICCM on the community drug use patterns may have been small, therefore requiring large sample sizes to detect it.

We used caregivers reports of illness in children in the two weeks before the interview, which may have led to inclusion of illness that occurred earlier than the two weeks. This finding may explain the high illness rate (74%) reported in our study. In addition, we did not have sufficient power to detect differences in pneumonia treatment practices between study arms because of the small number of children with pneumonia symptoms who received prompt and appropriate treatment. Measurement bias may have occurred because of misreporting of symptoms or treatments in children by caregivers, and misinterpretation of fast breathing. However, we showed caregivers posters of commonly used drugs in the area to aid recall and also examined prescriptions and dispensed drugs when these were available.

Use of CMDs increased in the intervention arm, suggesting that CMDs who can treat pneumonia, in addition to malaria, increase uptake of their services. However, overall CMD use is still quite low and private clinics and drug shops are still preferred. Nevertheless, CMDs may have greater effect in districts where private clinics and drug shops are less numerous. Because most children in our study sought care from other sources, especially private clinics, interventions to improve the management of malaria and pneumonia should

be introduced in the private sector. Malaria treatment was much better among CMD users than non-CMD-users, whereas no difference could be seen in the treatment of self reported pneumonia symptoms. However, prompt and appropriate treatment of malaria and pneumonia is poor and mainly caused by inappropriate drug use. The CMDs are championing the use of effective antimalarial drugs and antibiotics in a situation in which children continue to receive ineffective medicines.

Received November 25, 2011. Accepted for publication January 22, 2012.

Acknowledgments: We thank the study participants and Iganga-Mayuge Health and Demographic Surveillance Site administration and staff, most notably Edward Galiwango, Judith Kaija, Jane Mirembe, and James Kalungi for making this study possible; and the research assistants and data entrants for their hard work during this research.

Financial support: This study was supported by the Swedish International Development Cooperation Agency and the United Nations Children's Fund/ United Nations Development Program/World Bank/World Health Organization Special Program for Research and Training in Tropical Diseases.

Disclaimer: The findings and conclusions in this article are those of the authors and do not necessarily represent the views of Swedish International Development Cooperation Agency or the United Nations Children's Fund/ United Nations Development Program/ World Bank/World Health Organization Special Program for Research and Training in Tropical Diseases.

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APPENDIX 1: APPROPRIATE MEDICINES FOR MALARIA AND PNEUMONIA TREATMENT

Medicines were considered appropriate for malaria treatment if the child was treated with artemether–lumefantrine, 1 tablet twice a day for children less than 3 years of age or 2 tablets twice a day for children 3–5 years of age for 3 days; artesunate plus amodiaquine, 4 mg/kg and 10 mg/kg of body weight, respectively, per day for 3 days; dihydroartemisinin plus piperaquine, 2–4 mg/kg/day plus 16–18 mg/kg/day, respectively, for 3 days; quinine, 10 mg/kg, 3 times a day for 7–10 days.[26] The weights of children used for evaluation of the doses were estimated according to age by using the Ugandan standard growth chart.[26]

Medicines were considered appropriate for pneumonia treatment if the child received amoxicillin, 125 mg twice a day for children less than 12 months of age, 250 mg twice a day for children 12–35 months of age, 375 mg twice a day for children 36–59 months of age for 3 days if the treatment was from community medicine disteributors[27] or 15–25 mg/kg every 8 hours for 5days if treatment was given by other health providers; erythromycin, 10–15 mg/kg every 6 hours for 5 days; azithromycin, 10 mg/kg/day for 3 days; ampicillin, 25–50 mg/kg plus cloxacillin, 25–50 mg/kg every 6 hours for at least 5 days; gentamicin at a dose of 2.5 mg/kg every 12 hours plus ampicillin at a dose of 25–50 mg/kg every 6 hours for at least 5 days; benzyl penicillin, 50,000 IU/kg every 6 hours, which could be changed to oral amoxicillin to complete 5 days of treatment with antibiotics; procaine penicillin fortified for at least 3 days plus amoxicillin to complete at least 5 days of treatment with antibiotics; chloramphenicol, 25 mg/kg every 6 hours for 5–10 days and cotrimoxazole, 24 mg/kg twice a day for 5 days;[26] cefuroxime, 125–250 mg twice a day for 5 days; amoxicillin plus clavulanate, 15–25 mg/kg based on amoxicillin 2–3 times a day.[28]

Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 46–53
doi:10.4269/ajtmh.2012.12-0133

Introduction of Newborn Care within Integrated Community Case Management in Uganda

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Abstract. Uganda's Ministry of Health, together with partners, has introduced integrated community case management (iCCM) for children under 5 years. We assessed how the iCCM program addresses newborn care in three midwestern districts through document reviews, structured interviews, and focus group discussions with village health team (VHT) members trained in iCCM, caregivers, and other stakeholders. Almost all VHT members reported that they refer sick newborns to facilities and could identify at least three newborn danger signs. However, they did not identify the most important clinical indicators of severe illness. The extent of compliance with newborn referral and quality of care for newborns at facilities is not clear. Overall iCCM is perceived as beneficial, but caregivers, VHTs, and health workers want to do more for sick babies at facilities and in communities. Additional research is needed to assess the ability of VHTs to identify newborn danger signs, referral compliance, and quality of newborn treatment at facilities.

INTRODUCTION

Uganda is accelerating efforts to achieve Millennium Development Goal (MDG) 4 to reduce under 5 years mortality by two-thirds from the 1990 level by 2015.[1] Each year, 141,000 Ugandan children under the age of 5 years die. Of these deaths, 28% occur during the neonatal period.[1] Three additional causes account for another one-half of all child deaths in Uganda: malaria (22%), diarrhea (16%), and pneumonia (12%).[2] Meaningful progress to MDG 4 will require controlling deaths caused by these preventable and treatable conditions. Integrated community case management (iCCM)[3] is a widely adopted strategy to deliver treatment of pneumonia, diarrhea, and malaria through community-based health workers.[4] Given the current and likely future importance of newborns to under 5 years mortality, community-based strategies to address newborn mortality within the context of iCCM are also needed.[5]

In 2008, Uganda's Ministry of Health revitalized and expanded the dormant village health team (VHT) program. A VHT consists of five to six community members who collectively deliver maternal, newborn, and child health and sanitation interventions.[6] The VHT post is volunteer-based, with incentives of training and supervision occasionally supplemented with *ad hoc* donor support. The VHT program includes community case management for treating childhood pneumonia, diarrhea, and malaria in children aged 2–59 months.[7,8] Of the five to six VHT members, two to three member receive additional training in iCCM. The standard iCCM training consists of 6 days of modular, classroom-based sessions using workbook review, discussion, role plays, and practical sessions at a health facility, where trainees learn to assess, classify, and treat sick children.

In recognition of the importance of newborn mortality to overall child mortality and the growing evidence base for community-based newborn interventions, a newborn preventive care component was included as part of Uganda's iCCM program. To develop the package of care for babies 0–59 days, architects of the current VHT and iCCM strategy drew on findings from the Uganda Newborn Survival Study (UNEST) and global evidence.[9–12] Because up to three-quarters of neonatal deaths take place during the first week of life, the VHTs are trained to make home visits on days 1, 3, and 7 after birth and refer sick newborns to health facilities with extra supportive care at home for small babies (Panel 1).[13,14]

The Ugandan Ministry of Health is scaling-up iCCM with support from partners like Malaria Consortium and United Nations Children's Fund (UNICEF). The iCCM strategy in Uganda is among the first globally to include preventive care from birth; however, how successfully the strategy has delivered newborn care is not known. The aim of this paper is to describe how newborn care is addressed within iCCM implementation in Uganda and the perceptions of VHT members, facility-based health workers, and family members relating to newborn care in the context of community-based treatment of illness for older children. The paper identifies what is lacking for newborn care in the current strategy, describes stakeholder perceptions of the larger iCCM context in which newborn care is nested, and provides recommendations to address gaps.

MATERIAL AND METHODS

Study design. In this cross-sectional survey, we used qualitative and quantitative methods in three midwestern districts of Uganda, Kiboga (population 109,000), Kyankwanzi (population 121,000), and Hoima (population 344,000), where Malaria Consortium is implementing and evaluating iCCM (Figure 1).[15] These districts were selected, because they had sufficient numbers of trained VHT members who had been implementing iCCM for at least 5 months.

Ethics. The study was part of the formative research of the inSCALE project, which aims to understand community health worker (CHW) performance and motivation, community uptake and use of CHWs, and challenges to ICCM implementation in Uganda and Mozambique. The study protocol was approved by the Institutional Review Board of Makerere University School of Public Health and the Uganda National

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PANEL 1. Newborn care within VHT and iCCM training.

Newborn care covered in basic VHT training.

- Emphasize the importance of facility deliveries.
- Record births that take place at home.
- Identify and record newborn danger signs (difficulty breathing, weakness, fever, difficulty feeding, umbilical cord is red or discharging pus, convulsions, and vomiting).
- Encourage routine postnatal checks at the health facility at 6 hours, 6 days, and 6 weeks after birth.
- For babies born at home, practice immediate essential newborn care (dry the baby, wrap the baby, ensure that breastfeeding is initiated, check for danger signs every 1 hour, and refer if needed).
- Make home visits to the newborn after delivery: first visit within the first day after delivery, second visit on the third day after delivery, and third visit on the seventh day after delivery.
- Advise the mother and the family on healthy newborn and maternal practices, including early and exclusive breastfeeding, thermal care, clean and dry cord care, immunizations, skin to skin care, and extra breastfeeding support for small babies.

Newborn care instruction provided during iCCM training.

- Initiate breastfeeding soon after delivery within 1 hour and breastfeed exclusively.
- Delay the first bath, and wrap baby in warm clothing to prevent low body temperature.
- Recognize very small babies and give extra care.
- Mothers and other caregivers should always wash hands before breastfeeding or handling the baby.
- Check on the cord regularly and ensure that it is clean and dry.
- Follow-up of the newborn in the community by the VHT member.
- Make home visits to the newborn after delivery: first visit within the first day after delivery second visit on the third day after delivery, and third visit on the seventh day after delivery.
- VHT should take opportunities such as child health days to actively look for sick newborns.

Council of Science and Technology (HS 875). All participants were informed of the study purpose and objectives and that participation was purely voluntary with no penalties to the respondent in case s/he declined to participate or dropped out at any time. After this discussion, each respondent was individually asked to sign a consent form authorizing their participation in the study.

Individual interviews and focus group discussions with VHTs. The total number of VHT members trained in iCCM in the three study districts was 1,992. Using the Kish formula and a prevalence of 50% for our primary indicator, which is the proportion of trained VHT members who show knowledge of newborn care messages for well and sick babies, we estimated a sample size of 384.[16] We added 10% (38) for nonresponse to reach a total of 422 as our target sample size for individual VHT interviews. We distributed the sample of VHT members proportional to the number trained in each district (215 VHT members from Hoima, 113 VHT members from Kiboga, and 94 VHT members from Kyankwanzi). We randomly selected one-half of the subcounties in Hoima (five), Kiboga (three), and Kyankwanzi (three). Within each selected subcounty, we randomly selected 9–11 parishes and interviewed all the iCCM-trained VHT members in those parishes. We used a structured questionnaire translated into the local language (Lunyoro) and back-translated to English to inquire about the training the VHT members received and their knowledge of newborn care.

In addition to the individual VHT interviews, one focus group discussion (FGD) per district was conducted with VHT members. We randomly selected one subcounty and one health facility and invited seven to nine VHT members supervised by the selected facility to participate. Health assistants at the facilities recruited the VHT members for the FGDs. The themes discussed included the role of VHTs within iCCM; newborn care offered by VHT members to sick and well newborns; key messages related to newborn care; record keeping; supervision; motivation; challenges faced within the iCCM program; and perceptions about the overall iCCM program.

Health worker (in-charges) in-depth interviews. In-depth interviews (IDIs) of health facility in charges were conducted in four health facilities in each district to represent all levels of the health system: hospital and health center IV, III, and II. The in-charges in the selected facilities were recruited to participate, with the exception of one health center IV where a midwife participated for an in-charge who was not available. All IDIs were one on one with the exception of one hospital, where two health workers in charge of the community health department were interviewed together. Themes explored in the health worker interviews included awareness about iCCM generally and newborn activities specifically; supervision activities; newborn referral within iCCM; record keeping; and perceptions about VHTs and their role in newborn care.

Key informant interviews. We interviewed three district personnel in charge of iCCM activities in the districts and one staff of the implementing partner (Malaria Consortium). The issues explored were the same as those issues examined with the facility-based health workers.

Caregiver focus group discussions. All health facilities in each district were listed on a piece of paper, and two facilities were randomly selected from each district, one to recruit female caregivers and the second to recruit male caregivers for a total of six FGDs of seven to nine participants each. This sampling was done so that the caregivers were not from the same households. To be eligible, the caregiver had to live in the district and have a living child less than 3 months of age. The health assistants at the health facilities mobilized participants from the catchment area of each health facility. Themes explored in the FGD included knowledge about available community programs for children and newborns; roles of community members in health activities; general knowledge about newborn care and danger signs; actions taken when newborns are sick; and perceptions about VHT members and their role in newborn care.

Document review. We reviewed the national iCCM implementation guidelines, training manuals, registers, supervision checklists, and job aids used by VHTs and health workers to understand how the newborn care was designed to be implemented within the VHT and iCCM context.

Data collection and management. Study tools were pretested in the Kawempe division of Kampala district and adjusted accordingly. A total of seven local research assistants were recruited and trained for 2 days on the study objectives and use of study tools. Quantitative data were coded and entered electronically, and they were analyzed using STATA version 10. Qualitative data from in-depth interviews and FGDs were tape-recorded, transcribed, and translated into English. The findings were reviewed daily, and probes were

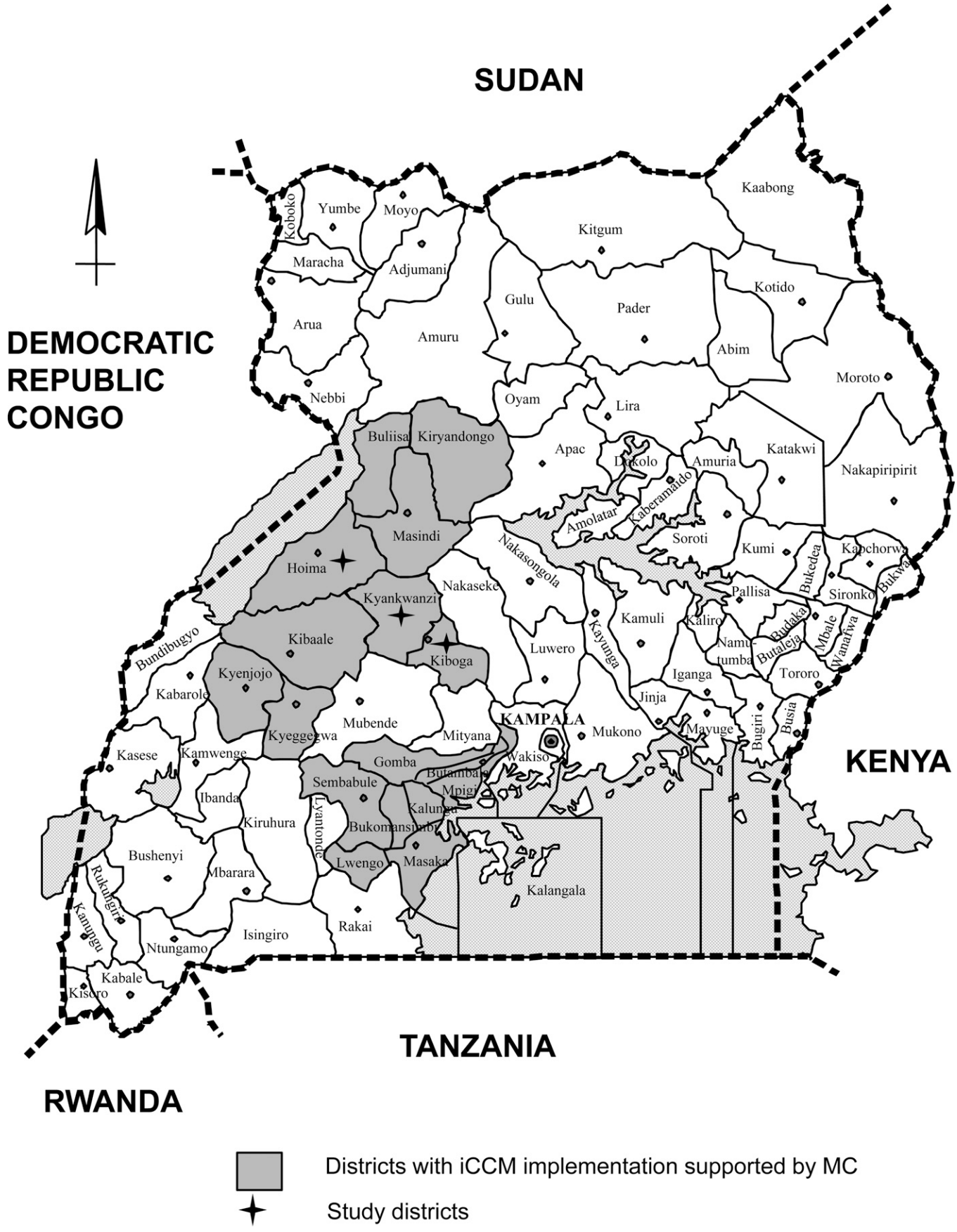

FIGURE 1. Map of Uganda identifying districts covered by iCCM.

slightly modified to follow up and clarify newly emerging or anticipated findings. Analysis was done using conventional qualitative content analysis.

RESULTS

Characteristics of VHTs. Individual interviews were completed with a total of 436 VHT members (196 from Hoima, 101 from Kiboga, and 139 from Kyankwanzi). In the study setting, men and women serve as VHT members in almost equal numbers (53% male). Nearly 60% of VHT members had completed at least some secondary education, and 81% of VHT members were married. The majority of VHT members (61%) reported holding a position of leadership in their communities as members of the local executive councils, leaders in schools or churches, or workers in other health programs such as mobilization for family planning.

All of the VHTs received 6 days of training in the basic VHT package of health promotion before commencing service as VHT members and an additional 6-day training in iCCM. VHT parish coordinators (peer supervisors) and VHT members with additional responsibilities received a 14-day training. After the training, the VHT members were equipped with medications, including artemisinin combination therapy for malaria and rectal artesunate for severe malaria, amoxicillin tablets for pneumonia, and oral rehydration solution and zinc for treating diarrhea. Additionally, they were equipped with rapid diagnostic tests for malaria, gloves, a respiratory timer, a sick child job aid, and a register.

Newborn care concepts and skills in VHT and iCCM training. Preventive newborn care is covered in iCCM and basic VHT training (Panel 1). The newborn danger signs listed in the VHT sick child job aid include fever, infected cord, lethargy, convulsions, failure to breastfeed, chest in-drawing, and skin pustules (Supplemental Figure 1).[17] The VHT members are trained to immediately refer to the nearest health facility any newborns with the danger signs specified in their job aid. The time allocated to cover newborn care is 2 hours on the last day of the 6-day iCCM training, and it focuses on newborns 0–7 days old. Clinical practice sessions do not include a newborn case, and newborn content is not covered in the post-test.

All the VHT members trained in iCCM reported that their training covered preventive care and how and when to refer sick babies for additional care. Despite the limited training time for the newborn, three-quarters (76%) of VHT members reported that the training was long enough to gain knowledge and skills. Of those VHT members who reported that the period of training was not adequate, 60% suggested that the training period should be up to 14 days. Although the length of training was deemed sufficient by most VHT memners, there were concerns expressed about the need to upgrade skills periodically.

Early preventive and promotive care for newborns. The VHT strategy in Uganda includes preventive visits at specific time points during pregnancy and in the first week after birth, necessitating active surveillance by VHT members with support from community members and health facility staff.[6] VHT members identified pregnant women through various means (Table 1), most commonly (78%) by observing women's physical and behavioral changes. Most VHT members (67%) learned of deliveries by notification from community members. Only 10.9% reported receiving information on births directly from health facilities.

TABLE 1

Methods used by VHTs to identify pregnant and newly delivered women and babies

Methods	Frequency (%)
Methods used by VHTs to identify pregnant women*	
Seeing pregnancy	224 (51.6)
Home/follow-up visits	143 (33.0)
Body and behavioral changes	116 (26.7)
Mother comes for consultation about ANC	73 (16.8)
Health educational meetings in villages	61 (14.0)
Information from other community members	41 (9.5)
Through health facility maternity unit	19 (4.4)
Methods used by VHTs to identify newly delivered women and babies*	
Notification by community members	274 (63.4)
Close monitoring of pregnant women	164 (38.0)
Home visits	143 (33.1)
Visiting health facilities to get list of newly delivered women	47 (10.9)
Through friends and relatives	16 (3.7)

*Multiple responses elicited.

Most VHT members (73%) reported that, during home visits in the first week of life, they congratulate the mother and ask to assess the baby. The most common aspect of preventive care cited was promotion of exclusive breastfeeding (67%). Less than one-half of VHT members mentioned counseling on the importance of keeping the baby warm (45%) and hygienic practices (38%) or asking the birth weight (32%) or date/time of delivery (14%). Few (4%) VHT members reported repeat home visits for newborn care.

Identification and referral of sick newborns. Two-thirds (65%) of VHT members reported checking the baby's skin and cord and assessing for danger signs during routine home visits, but fewer than 1 in 10 (9%) VHT members reported advising mothers about prompt care-seeking for danger signs. The majority of VHT members (87%) could name three or more newborn danger signs, but they were not necessarily the signs that best predict severe illness. Infected umbilical cord (81%) and skin rash (69%) were the two most frequent responses. Fewer than one-half (43%) of VHT members mentioned failure to breastfeed, one of the most important newborn danger signs.

Nearly all VHT members (99.8%) mentioned that they would refer a sick newborn to the nearest health facility, which is in line with iCCM program guidelines. Participants in FGDs emphasized that, as VHT members, they were not supposed to treat sick newborns but only refer them to health facilities:

> "During the training, we were told not to treat the newborns at all; we just refer them to the health workers in the health units."—VHT FGD (Kyankwazi).

Caregivers also knew that VHTs do not treat newborns but rather assess them and refer to the nearest health facility if the baby is sick.

> "When you take the newborn to the VHT, she checks the baby and registers it, but she does not give drugs. She gives you a referral to take to the health unit."—caregiver FGD (Kiboga).

Almost all VHT members (96%) believed that caregivers comply with referrals and that newborns receive treatment at

health facilities when referred. Some caregivers' VHTs were an extra step along the way to receiving care for their sick babies:

> "VHTs do not have drugs for newborns. We take them [to the VHT], but they just tell us to go the health facility, because they do not have the drugs for newborns . . . We know VHTs do not have drugs for newborns so we just take our babies wherever is convenient for us."—caregiver FGD (Kyankwanzi).

Health workers also believed that caregivers complied with VHT referrals. A referral note issued was perceived to facilitate compliance to referral.

> "Yes, they do [comply], because those that come bring with them the referral notes or if not, a referral is written on a piece of paper."—health worker IDI (Kiboga).

However, some health workers mentioned that some referrals were not complied with because of barriers such as transport, cultural beliefs, and misconceptions about the services provided.

Similarly, some VHT members also mentioned several reasons why caregivers may not comply with referrals for their newborns: failure to obtain money for transport (32%), lack of medicines at the health facility (24%), long distances to the health facility (20%), and cultural barriers (9%). Caregivers reported being frustrated after complying with a referral only to find that the necessary medicines were not available at the health facility.

> "It is like we do not have a program for the newborns here in Kyankwanzi. Even if we go to the health facility, there are no drugs."—caregiver FGD (Kyankwanzi).

Two-thirds of VHT members (68%) reported receiving direct feedback from health workers concerning referred newborns, and only one-third (34%) reported following up the newborns at home after recommending referral to check on the status of the mother and baby.

Supportive supervision and program documentation. Facility-based health workers are responsible for training and supervising the VHT members in their catchment areas, distributing drugs to them, and checking their registers. Three-quarters of VHT members reported receiving a monthly supervision visit, usually by the Parish Coordinator (a VHT who received additional training), the in-charge at health facilities, and/or the Malaria Consortium staff. This supervision visit focused on observation of a sick child with no specific provision for a routine newborn care visit, which is in line with the iCCM supervision checklist (it does not include any newborn-specific content). One in six (17%) VHT members reported no supervision at all and during the FGDs, and some health workers noted that supervision had become irregular.

Over 98% of the VHT members reported keeping household registers that captured information on pregnant women and newborns including the expected delivery date, antenatal care attended, danger signs observed, outcome of mother at delivery, place of delivery, and postnatal checks received at a health facility. VHTs trained in iCCM also fill out the sick child form, identifying the date of visit, name of the child, period of illness, presence of a danger sign, respiratory rate, and referral notes for the sick newborn, which indicate the date and time of referral and the danger sign as well as home visits on day 1, 3, and 7 after birth. The outcome of the newborn referral is not captured, although it is for children 2–59 months (Supplemental Figure 2).[18] The majority of the VHT members (97%) mentioned that they give the records to the Parish Coordinator on a monthly basis.

Motivation of VHT members and overall perceptions of the program. In the IDIs, VHT members mainly reported satisfaction with their current role and responsibilities. Motivators included allowances for meeting attendance (32%), ability to help community members (30%), transport (26%), and availability of drugs (17%). When asked what would make them stop working as VHT members, 43% said that nothing would convince them to quit. Others mentioned unreliable drug supply (15%) and lack of allowance (14%). However, some VHT members expressed concern about the inability to treat sick newborns.

> "The program is not good concerning newborns, because we cannot treat them." —FGD VHT (Kyankwanzi).

Similarly, VHT members prioritized the challenges that they face as delays in receiving drugs and other supplies (59%), lack of transport (47%), interference with personal work (30%), and lack of lighting at night (25%) (Table 2).

Overall, health workers perceived the iCCM program positively. In addition to saving lives and reducing illness, the program was felt to have strengthened the relation between health workers and the VHT members, and it increased childhood immunization rates. They felt that the program could be used to fill other gaps, such as distributing treated mosquito nets to women who may not attend antenatal clinics.

Similarly, both male and female caregivers gave positive feedback about the iCCM program, particularly the routine VHT visits to newborns, especially those babies born at home.

> "If you give birth in the village, VHT come and see your baby and advise you to take the baby to the hospital."—caregiver FGD (Kyankwanzi).

Community members also described how community members support VHT members in different ways.

> "They [VHT members] are not paid; they don't ask us for money, so we give them lifts on our motorcycles and even bicycles or some money; in such a way, we are helping them to do their work."—caretaker FGD (Hoima).

TABLE 2
Most critical challenges faced by VHTs as they perform their work

Challenges faced by VHTs*	Frequency (%)
Delayed supply of drugs/supplies	255 (59.0)
Lack of transport	203 (46.7)
Interference with personal work	129 (29.8)
Lack of lighting source at night	110 (25.4)
Lack of allowances/low facilitation	73 (16.9)
Community members demand treatment of children who test negative for malaria	59 (13.6)
Caretaker not complying to dose given to children	58 (13.4)
Long distances	38 (8.8)
People think VHTs are paid	22 (5.1)
Language barriers	10 (2.8)
Lack of supervision	8 (1.9)
Lack of feedback from health facilities	8 (1.9)
Lack of recognition from supervising health facility	4 (0.9)
Absence of health workers at heath facilities	2 (0.5)

*Multiple responses elicited.

However, the community members also had concern regarding drug supply, inadequate numbers of trained VHT members per village, and difficulty identifying VHT members in the village. They also pointed out that, because the VHTs are not paid, they should be motivated with transport such as bicycles, especially to undertake routine home visits for newborn care.

DISCUSSION

The iCCM program in Uganda, one of the first to include a newborn component, presents an important learning opportunity. Our study used a mix of qualitative and quantitative methods to assess the early implementation experience in three districts of Uganda. The integration of newborn care and CCM for older children provides an opportunity for harmonized service delivery and greater impact in terms of lives saved, but it is not without challenges. These challenges, which are outlined below, include some specific to the addition of the newborn to iCCM and some more general to iCCM.

Limited newborn care within iCCM training and supervision. Although VHT members were knowledgeable in preventive newborn care messaging, home visit schedule, and guidelines for referral, their knowledge of newborn danger signs and messages around care-seeking for newborn care was lacking. Seven danger signs are associated with severe illness in infants less than 2 months of age: history of difficulty feeding, history of convulsions, movement only when stimulated, respiratory rate of 60 breaths per minute or more, chest in-drawing, temperature of 37.5°C or more, or temperature below 35.5°C.[19] These signs are covered in the training and VHT job aid with the exception of low/high body temperature, which is difficult for community workers to recognize without a thermometer. However, the training for newborn care is brief; it is at the end of a 6-day training, it is not assessed during training, and it is not reinforced through clinical practice sessions or supervision. In addition, the focus is on newborns aged 0–7 days, and it does not cover the entire newborn period. During interviews, few VHT members mentioned all of these evidence-based signs, and very few (less than 1 in 10) reported emphasizing to caregivers the importance of care-seeking if they encounter these signs. Because the routine home visits are conducted during the first week after delivery, promotion of family-initiated care-seeking is also important. Most VHT members acknowledged the importance of the early home visit, but few mentioned critical aspects such as assessing the baby's birth weight and breastfeeding.

These findings indicate a need to further strengthen the newborn care component within the iCCM training, implementation, and supervision. Integrating newborn content throughout the training, including newborn cases in the clinical sessions, and covering the full newborn period would help prioritize the newborn and should more reliably impart knowledge and skills to VHT members. VHT members expressed a clear need for consistent supervision as well as opportunities to refresh their newborn care skills. Newborn-specific content should be added to the existing iCCM supervision checklist, and facility staff should be trained to provide supervisory support to the newborn component of iCCM. We found a cadre of VHT peers (Parish Coordinators) not mentioned in the national iCCM implementation guidelines. This cadre of supervisor was useful in coordinating VHT activity at the parish level and improving linkages with health workers, and their role could be further explored.

Timely identification of newborns. In low-income countries, a postnatal home visit within the first 2 days of life by trained CHWs can reduce neonatal mortality.[20] To achieve this early home visit, VHTs require a system for identifying pregnant and newly delivered women. A 2009 assessment of the basic VHT preventive care package (not including iCCM) found that home visits for pregnancy and newborn care were rarely carried out, and specific newborn care training and counseling materials were lacking.[8] Even in research settings with routine home visits, trained enumerators may only capture up to two-thirds of the estimated live births.[21] Waiting to observe bodily changes in women to identify pregnancies and relying on community members to notify VHT members about newly delivered mothers and babies may be even less reliable, and it risks missing the poorest, hardest to reach, and most vulnerable community members. Innovative solutions, such as cell phone notifications from health facility or family members to the appropriate VHT member, are needed to reduce the delay in identifying newly delivered women and babies.

Referral follow-up and quality of care for newborns. Compliance with referral for sick newborns was perceived as high by VHT members and health facility staff. Even if referral compliance is as high as perceived, there is still a need for trained service providers, essential medicines, and equipment at receiving facilities. Previous studies show that families face difficulties in seeking care for their sick children and receiving quality care at health facilities.[22,23] Uganda's national standards and implementation framework for newborn care services stipulate that antibiotics to treat newborn infection should be available at the first-level health facilities (i.e., HCII), but this stipulation has not been operationalized.[24,25] Ill newborns deteriorate faster than older children, and quick action is needed when critical danger signs are present. It is not clear from the results whether there is a sense of urgency around newborn referral by either caregivers or health providers. The lack of essential drugs and health providers competent in newborn case management at the lowest level may result in delays in reaching a higher-level facility equipped to care for newborn illness.[26] This lack has the potential to undermine the VHT member who referred the family at the outset.

A potential concern with implementing different care guidelines for various age groups in iCCM (i.e., treatment or referral) is that VHTs may feel pressure to treat sick newborns instead of referring them for similar problems that they are able to treat in older children. However, virtually no (1%) VHT members reported actually treating sick newborns. This positive finding should be validated through routine supervision that ensures that current referral guidelines are followed.[26]

The lack of follow-up for referred newborns by VHT members is also an important gap that may contribute to a false sense of security about referral compliance as well as the quality of care provided at the health facility. The iCCM training guideline states that "after referral of a child, it is important to follow-up this child the next day."[7] However, this guidance is geared to older children and should specify a follow-up visit for referred newborns as well. Although the routine home visits are scheduled to take place during the first week of life, which is the period of highest risk, families also need to be counseled on how to identify and seek care throughout the neonatal period, because the majority of sepsis cases occurs after this first week.

Balancing treatment of older children with preventive home visits for newborn care. The newborn protocol calls for

VHT members to visit all newborns several times within the first week of life, which is in contrast to the protocol for older children, where families are expected to seek care from the VHT members when a child is sick. These preventative home visits may be viewed by volunteer VHTs as extra work that takes them away from their other responsibilities to provide curative services for older children. Difficulties identifying births and frustration at being unable to provide treatment of sick newborns may also drive VHT members to focus on the curative component. More research is needed to better understand how to balance these often competing demands.

Collection and use of newborn care indicators. Relevant newborn indicators are captured through the VHT registers and the supervision checklists, and one core indicator specific to newborn care is captured at the national level (proportion of newborns visited at home on day 1, 3, and 7). At the time of data collection, the Malaria Consortium was in the process of installing a data collection system to use data more effectively during supervision to improve VHT services and at the district level, to link community- and facility-based care for sick children as well as newborns. One simple addition to the register would be to include the outcome of referral of the sick newborn, similar to how it is captured for older children. This addition will identify whether families comply with referral and whether the newborns recovered. Linking the identification of pregnant women (through antenatal care [ANC] registers or active surveillance) to VHT members responsible for iCCM could enable reaching mothers and babies early during the first week after birth.

Our study also identified challenges to the iCCM program as a whole, including difficulties in providing regular supervision, ensuring a regular supply of drugs at community and health facility level, maintaining motivation of VHT members, and improving training tools and methods so that CHWs provide correct advice and identify most important danger signs. Although newborns are not treated by the VHTs, at the time of the study, there were stock outs of drugs and supplies needed by VHT members to treat older child illnesses because of much higher consumption than anticipated, especially for antibiotics. Supply chain management and the commitment to procure and distribute medicines for iCCM are important to maintain program credibility and motivate VHT members. Despite these challenges, the newborn component can be considered well-positioned within the iCCM program in Uganda. The positive reputation and branding of the iCCM program seems to be beneficial; although young, iCCM is well-known and respected as evidenced by positive feedback from community members.

There are some limitations to this study. Our assessment relied on knowledge, attitudes, and perceptions of VHTs, caregivers, health workers, and key stakeholders pertaining to the iCCM program. The VHTs were not administered a competency assessment of sick and normal babies using a case scenario or observation of a home visit, which limits assessing true clinical knowledge and skills. Additionally, referral compliance was not verified, and the caregivers interviewed were limited to those caregivers with live children because of the additional sensitivity involved in talking to parents with children who had died. Despite these limitations, this study examined the implementation experience of the often-overlooked aspect of newborn care within fast-growing iCCM programs and identified areas for strengthening that can be applied in Uganda and similar settings (Panel 2).

PANEL 2. Recommendations for improving newborn care within iCCM.

Training recommendations.

- Specify the national schedule for visits during pregnancy as well as the first week of life and clearly delineate roles where other VHT members are providing the pregnancy home visits.
- Emphasize the importance of identifying pregnant women and newborns to successfully adhere to the postnatal home visit schedule.
- Highlight the most important preventive messages (e.g., early and exclusive breastfeeding, thermal care, and dry cord care) and critical danger signs for newborn care (e.g., history of difficulty feeding, history of convulsions, movement only when stimulated, fast breathing, chest in-drawing, baby too hot, and baby too cold).
- Provide a short refresher during iCCM training on newborn care, including extra care for small babies.
- Highlight the need for follow-up of referred newborns by the VHTs.
- Include the parish coordinator cadre in the policy document and introduce the supervisor in training to improve accountability of supervision.

Policy and programmatic recommendations.

- Consider use of small incentives (allowance, support for transport, and supplementary materials) to VHTs, especially those VHTs tied to routine care, to incentivize home visits.
- Consider updating the routine home visit recommendations to include a weekly routine preventive home visit between days 7 and 59 when babies are particularly at risk of infection but out1of the age range for first week home visits and treatment through iCCM.
- Consider innovative strategies to reach distant VHTs for supervision.
- Improve newborn care aspects of supervision visits, specifically reviewing documentation and counseling messages.
- Continue to improve communication between implementing partners, health workers, and VHTs.

Future research agenda. There is a need for further study to assess VHT skills in preventive newborn care, danger sign messaging, and correctly identifying newborn danger signs. Additionally, more research is needed to determine the effectiveness of VHTs in identifying pregnant and newly delivered women; compliance by VHT members with the home visit schedule and factors that can enhance coverage; compliance of families with newborn referrals; and appropriateness of treatment received at the facility for those individuals who do seek care.

Conclusion. As one of the first national adaptations of iCCM to include newborn care, Uganda's experience is important for other settings considering service integration across the continuum of care. The national iCCM program is highly appreciated by stakeholders, including caregivers, VHTs, facility-based health workers, and district personnel. The program is perceived to have improved the health outcomes of sick newborns and older children. The distinction between care provided for newborns and the care provided to older children by the VHT members through iCCM is understood by the majority of stakeholders, although it may pose some logistical and policy challenges. Challenges remain at

each step. VHTs need to know (1) whom to visit, (2) how to deliver the content of the routine visit, (3) how to assess all danger signs, (4) when to refer and how to facilitate and follow-up recommended referral. Additionally, staff must be (5) trained and (6) equipped and supplied to deliver newborn case management. The health information system must be (7) able to capture reliable, timely data on service delivery and availability of essential supplies and equipment. Maintaining motivation of VHTs will be important to continue addressing as the program matures. In addition to known benefits for older children, iCCM has potential to improve newborn survival in communities where it is being implemented.

Received February 27, 2012. Accepted for publication April 7, 2012.

Note: Supplemental figures and data appear at www.ajtmh.org.

Acknowledgments: The authors thank the Mid-Western Region Malaria Consortium office and district health officers in the study districts who helped facilitate this research. We also extend our sincere appreciation to the families, community members, Village Health Team members, and health workers who participated in the study.

Financial support: This study was funded by the Saving Newborn Lives program of Save the Children with funding through The Bill & Melinda Gates Foundation.

Disclaimer: The opinions expressed are the opinions of the authors and do not necessarily reflect the views of The Bill & Melinda Gates Foundation.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 54–60
doi:10.4269/ajtmh.2012.11-0759

Scaling Up Integrated Community Case Management of Childhood Illness: Update from Malawi

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Abstract. The Government of Malawi (GoM) initiated activities to deliver treatment of common childhood illnesses (suspected pneumonia, fever/suspected malaria, and diarrhea) in the community in 2008. The service providers are Health Surveillance Assistants (HSAs), and they are posted nationwide to serve communities at a ratio of 1 to 1,000 population. The GoM targeted the establishment of 3,452 village health clinics (VHCs) in hard-to-reach areas by 2011. By September of 2011, 3,296 HSAs had received training in integrated case management of childhood illness, and 2,709 VHCs were functional. An assessment has shown that HSAs are able to treat sick children with quality similar to the quality provided in fixed facilities. Monitoring data also suggest that communities are using the sick child services. We summarize factors that have facilitated the scale up of integrated community case management of children in Malawi and address challenges, such as ensuring a steady supply of medicines and supportive supervision.

INTRODUCTION

The United Nations (UN) Interagency Group for Child Mortality Estimation (IGME) recently reported that, in 2011, 7.6 million children died worldwide before the age of 5 years, a reduction from 8.1 million deaths in 2008.[1] Despite global progress in reducing child mortality rates, the average annual rate of reduction is low in many countries. Too few children are reached with effective interventions to treat common causes of death, such as pneumonia, malaria, and diarrhea.[2] Training and deploying skilled community-based health workers (CBHWs) to provide quality childcare services can improve access to life-saving interventions, and the use of CBHWs is recommended by global policies.[3,4] According to the World Health Organization (WHO), 39 of 74 countries with high maternal and child mortality had adopted a policy allowing CBHWs to treat pneumonia in the community by the end of 2012, 24 of which were located in sub-Saharan Africa.[5] Countries that allow community management of pneumonia often also support the management of malaria and diarrhea in the community. A UNICEF survey conducted in the African region in 2010 found that, among 40 countries, 18 countries had established policies allowing CBHWs to treat pneumonia, diarrhea, and malaria.[6] However, important questions have arisen about the quality, use, and impact of community child services.[7,8]

In 2008, the Government of Malawi (GoM) started a program to train an existing cadre of CBHWs, known as Health Surveillance Assistants (HSAs), to provide integrated community case management of childhood illness (iCCM). In this paper, we document progress in the scale up of iCCM between 2008 and 2011, describe some critical challenges that affect the effectiveness and sustainability of the program, and propose solutions. Because Malawi is one of the first sub-Saharan African countries to scale up iCCM for common child illnesses, we describe the experiences to contribute to the global understanding and learn about scaling up effective community child health services.

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CONTEXT

Malawi is considered on track to achieve the Millennium Development Goal 4. Mortality among children less than 5 years of age decreased from 225 deaths per 1,000 live births in 1990 to 92 per 1,000 live births in 2010.[1] Nevertheless, 53% of children under 5 years are stunted, and 4% are wasted.[9] In 2006, only 27% of children with diarrhea received oral rehydration therapy, only 30% of children with suspected pneumonia received an antibiotic, and only 25% of children with fever received an appropriate antimalarial.[10] Additionally, the percentage of infants born to human immunodeficiency virus (HIV)-positive mothers who are infected is estimated at 14%, although there is a steady increase in the proportion of pregnant women who are reached by prevention of mother-to-child transmission (PMTCT) interventions.[11] Thus, a large proportion of children in Malawi are still at increased risk of mortality because of common childhood infections, such as malaria, pneumonia, and diarrhea.

In Malawi, access to health services is an important barrier to intervention coverage. An estimated 30–35% of the population lives more than 8 km from a health center, particularly in rural areas. In 2004, the GoM adopted a Plan of Action to strengthen health services that was centered around the delivery of an Essential Health Package (EHP).[12] The EHP specifies community-based treatment of common childhood illnesses to be delivered free of charge.

METHODS

This paper provides an overview of the implementation of CCM in Malawi, summarizing information from multiple data sources. The main sources of data were program records and Health Management Information System (HMIS) reports from the Integrated Management of Childhood Illness (IMCI) unit in the Ministry of Health (MOH), and they included statistics on the number of HSAs trained, the number of village health clinics (VHCs) established, the proportion of target areas reached, and the number of treatments provided by month. These data are compiled by the MOH from monthly reports provided by trained HSAs and reported through health facilities and the district health office on a monthly

basis. The density of HSAs per 1,000 population (based on the Malawi 2009 census estimates of district population)[13] and the ratio of functional VHCs per hard-to-reach area (as identified by the MOH) were calculated in Microsoft Excel.

We also include the results of additional assessments conducted for an external evaluation of maternal and child health programming in Malawi led by the Institute for International Programs at Johns Hopkins University (IIP-JHU) and the Malawi National Statistics Office (NSO), here referred to as the Independent Evaluation Team (IET). In 2009, the IET conducted an assessment of the quality of care provided by HSAs through direct observation and reexamination by a gold-standard clinician.[14] The assessment also included measurement of caregiver satisfaction with CCM services through a client exit interview and qualitative investigation of health workers perceptions of the CCM program.[14,15] The assessment was conducted in six districts that were strong in early implementation, and results are not representative of all districts during that period, which had variable implementation. The IET collected follow-up data on implementation strength in 2011 through a telephone survey of a random sample of CCM-trained HSAs in one district.[16]

HSAs program. HSAs are community-based health workers recruited and salaried by the Malawi MOH. This cadre of worker was established for smallpox vaccination in the 1960s and continued to serve evolving needs of the health system, including response to cholera outbreaks during the 1970s and 1980s and environmental health education and population surveillance in the 1990s. With a grant from the Global Fund in 2008, the government doubled the size of the HSA workforce to over 10,000 HSAs, each serving approximately 1,000 people, for the delivery of community-based interventions. The minimum education level for HSAs is a junior certificate (grade 10), and all HSAs follow a 10-week basic training to learn the core set of tasks for which they are responsible (not including iCCM). Their remuneration is based on the government's civil service salary scale and equivalent to the remuneration of a first-level clerical staff. The current job description includes (1) promotion of hygiene and sanitation, (2) provision of health education, (3) home visitation and maintenance of community registers, (4) conducting community assessments, including public facility inspection, (5) disease surveillance, (6) conducting outreach clinics, including immunization, and (7) conducting VHCs to provide iCCM services. Additionally, selected HSAs are also involved in diverse activities, such as distribution and administration of contraception, treatment of tuberculosis, and voluntary counseling and testing for HIV. Many HSAs are young and male. They do not always originate from the communities that they serve and may not reside in their catchment area.

Introduction of iCCM in Malawi. *Caring for the sick child in the community.* The WHO/UNICEF training materials on caring for the sick child in the community are a simplified version of the IMCI guidelines for first-level health workers and focus on the major causes of death among children under age 5 years.[17] CBHWs learn to identify and treat uncomplicated cases of suspected pneumonia, fever (presumed malaria), and diarrhea and identify and refer children with danger signs, severe malnutrition, or other problems that they have not been trained to treat. A job aid, known as the Sick Child Recording Form (SCRF), specifies the algorithms for assessment and classification of the sick child's signs and symptoms, and it guides CBHWs on selection of treatment with an antibiotic, antimalarial, and/or oral rehydration salt (ORS) and zinc tablet (Panel 1). The SCRF serves as the basis for training and can serve as a main reference tool when providing services in the community.

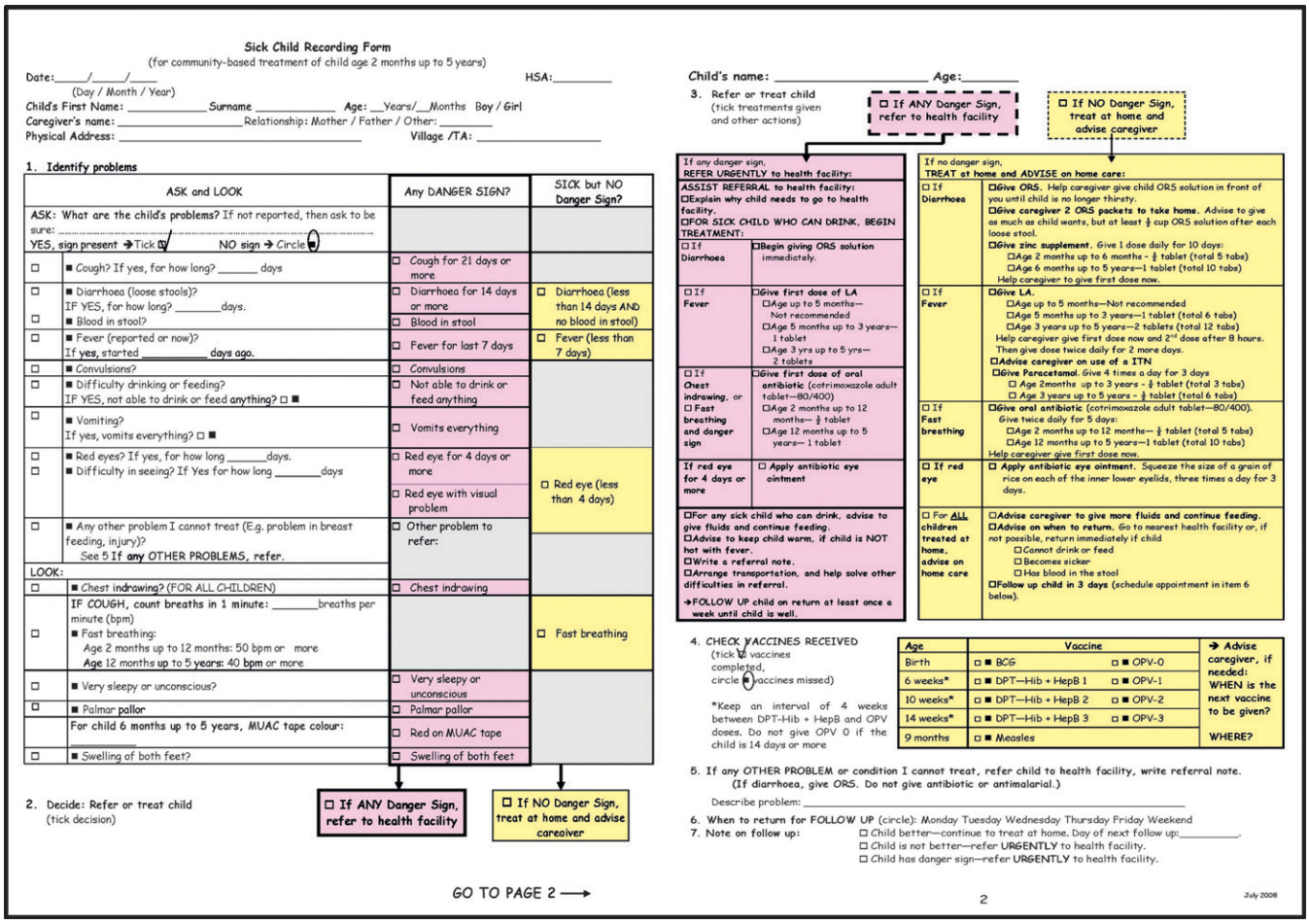
Provision of iCCM requires minimal medicines and equipment. In addition to the four essential medicines listed, CBHWs also learn to use a rapid diagnostic test (RDT) to assess for malaria and a mid-upper arm circumference (MUAC) strap to assess for severe acute malnutrition. A timer to count respiratory rate is desirable but not mandatory.

The initial iCCM training is 6 days and includes seven clinical practice sessions, two sessions in inpatient facilities to practice recognition of danger signs and five sessions in outpatient facilities to practice the entire process of assessment and treatment or referral. A follow-up visit to the CBHW by an experienced facilitator within 4–6 weeks of training is strongly recommended for additional skills reinforcement; also, regular supervision that includes observation of clinical practice is recommended.

Adoption and early introduction. The Malawi MOH IMCI unit adopted the materials included in caring for the sick child in the community in June of 2008 after a demonstration course. Minimal adaptations were made to the clinical content (i.e., the inclusion of palmar pallor as a danger sign and management of eye infections). Use of RDT to assess for malaria was not part of the initial version of the WHO/UNICEF generic materials and hence, was not included in the adaptation. It was decided that the implementation strategy would target HSAs in hard-to-reach areas based on (1) distance to the nearest health facility of 8 km or more or (2) difficult access because of geographical terrain or natural barriers. Using these criteria, district management teams (DHMTs) identified 3,452 hard-to-reach areas.

Targeting the hard-to reach areas, DHMTs, under the guidance of the district IMCI coordinator, became responsible for establishing community-based child health services. Establishment involved conducting community orientation and HSA training, providing medicines and supplies, supervision, and monitoring. HSAs are provided a drug box after training, and they replenish medicines from the nearest health center. They use a register based on the SCRF to record the care provided to children that they see. They send standard reporting forms to the health facility monthly, from which summary reports are sent to the DHMT and the national IMCI unit. Village health committees support and safeguard the work of an HSA. For example, the committee contributes to managing the medicine supply by holding a key for the HSA's drug box; the drug box has double locks, and a committee member must assist the HSA in opening the box on the day of the VHC. HSAs, in principle, conduct VHCs to provide curative care on scheduled days of the week, taking into consideration their other responsibilities and tasks.

Early implementation of iCCM in Malawi. *Current implementation status.* By the end of 2010, all districts in Malawi had adopted the policy of iCCM, focusing on the establishment of VHCs by iCCM-trained HSAs in hard-to reach areas. As of September of 2011, 3,296 HSAs had received iCCM training, and 2,709 (or 79%) were providing services, hence managing functional VHCs. The iCCM approach was being implemented in all districts, with 13 of 28 districts



PANEL 1. Sick child recording form job aid with iCCM guidelines.

having coverage of more than two HSAs per 10,000 total population (Figure 1A). All but 2 districts had reached 50% coverage of the targeted hard-to-reach areas, and 17 districts had reached coverage of 76% or more (Figure 1B).

Use of iCCM services and children treated for common illnesses. A quality of care assessment undertaken in 2009 (described below) included a review of HSA registers to assess routine use of iCCM services in six districts with early implementation.[14] Of 131 HSAs surveyed, 102 HSAs had complete registers for the month of September of 2009 and had documented seeing a median number of 41 sick children per month (interquartile range of 19–73 visits per month). The central IMCI unit established a system to monitor use of iCCM services in 2009. For the period of October of 2010 to September of 2011, on average, 68% of functional VHCs submitted monthly reports. Figure 2 summarizes the numbers of treatments given and referrals made at those VHCs per 1,000 children ages 0–4 years in all districts. To reflect the national policy of VHCs in hard-to-reach areas, an analysis of the average monthly number of treatments by VHCs was also done for one district with a high level of monthly reporting by HSAs. Figure 3 shows the average monthly number of treatments and referrals at VHCs in Phalombe district in the period of January to December of 2011. Each VHC treated an average of 41.3 children for fever (presumed malaria), an average of 20.6 children for presumptive pneumonia, and an average of 11.6 children for diarrhea each month. On average, two children were referred every month. The predominance of fever treatments may be partially explained by the national policy of presumptive treatment of fever for malaria.

Selected quality of care findings. In late 2009, IIP-JHU, MOH, and WHO conducted an early assessment of the quality of iCCM services provided in the community by HSAs; the full methodology and results are described elsewhere. Briefly, the assessment was carried out in six districts that had made progress in implementation as of September of 2009. Table 1 presents selected results from directly observed consultations with sick children for common illnesses (signs of pneumonia, fever/malaria, and diarrhea) and danger signs compared with a clinician trained as a master iCCM trainer. The proportion of sick children receiving correct assessment, classification, and treatment of common illnesses was similar to the proportion observed in previous studies.[18,19] Just over one-half of children requiring referral were referred appropriately. An analysis of common errors in clinical steps reported elsewhere provides additional insight into the factors affecting the performance. For example, only 37% of children were assessed correctly for all four physical danger signs. The survey also assessed caregiver satisfaction through an exit interview, in which 97% of caregivers reported to have found the

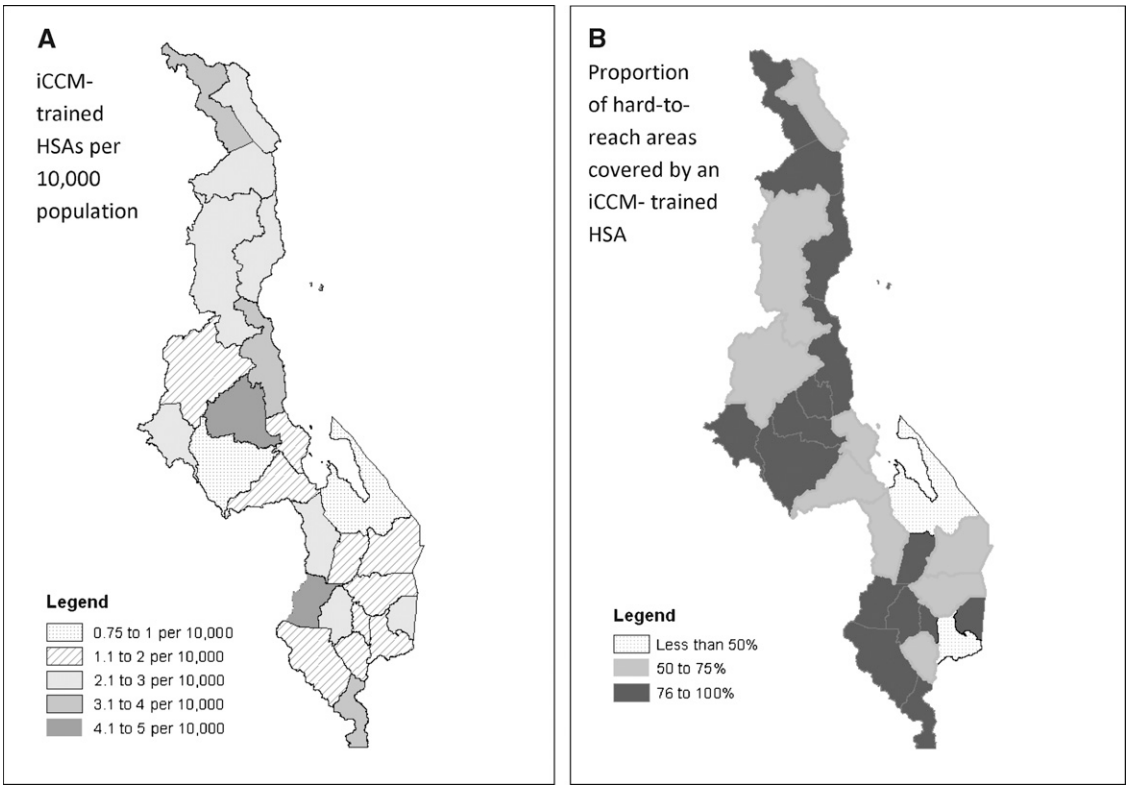


FIGURE 1. District coverage of iCCM-trained HSAs (**A**) by population and (**B**) in hard-to-reach areas.

services excellent (34%) or good (63%) and 99% reported that they would visit the HSA again for a child's illness. Qualitative interviews indicated that both program managers and HSAs positively received the program.[15] HSAs reported increased feelings of usefulness and respect in the community, although they also perceived their workload to have increased with iCCM.[15]

The assessment found that supervision and drug supply in the first year were less than optimal. Less than 40% of HSAs included in the sample had received an iCCM-specific supervisory visit in the previous 3 months, and only 16% received a visit that included clinical observation of case management. Although the sample was drawn only from HSAs having received initial drug stocks, only 69% of VHCs manned by HSAs had all three primary treatments (cotrimoxizole, antimalarials like lumefantrine-artemether [LA], and ORS) on the day of the visit.[14]

A telephone survey conducted by the Malawi NSO and IIP-JHU in coordination with the MOH between March and April of 2011 in the Balaka district found that, among 49 iCCM-trained HSAs, 74% had received a medicine box, 71% had treated sick children in the previous 3 months, and 67% had treated sick children in the previous 7 days. The proportion of HSAs with an uninterrupted stock in the previous 3 months was 11% for ORS, 40% for LA, and 82% for cotrimoxazole[16]; 53% of HSAs had received supervision in the previous 3 months, 29% of HSAs had supervision at their VHC, and 40% of HSAs reported receiving

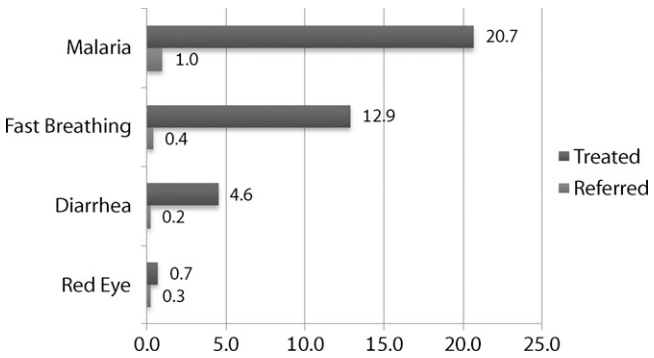


FIGURE 2. Monthly average number of treatments given and referrals made at VHCs per 1,000 population ages 0–4 years in all districts from October of 2010 to September of 2011.

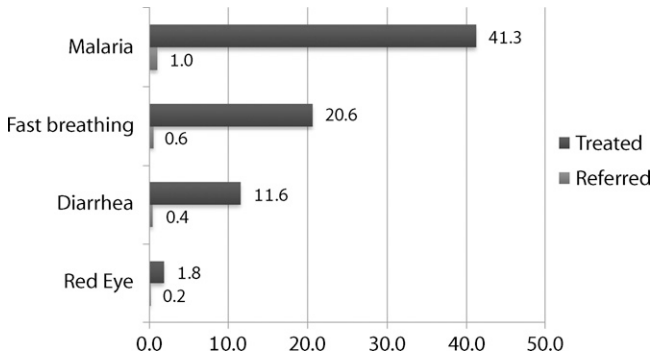


FIGURE 3. Monthly average number of treatments given and referrals made at VHCs in Phalombe district per health clinic from January to December of 2011.

TABLE 1

Selected results from the quality of care assessment of HSAs providing community case management services for common child illnesses in Malawi in October and November of 2009

	N (sick children)	In six districts (95% CI)*
Sick child consultation for common illnesses		
Proportion of children assessed for cough, fever, and diarrhea	382	77% (71–82%)
Proportion of children with classifications matching fever, cough and fast breathing (pneumonia), and diarrhea	382	68% (62–73%)
Proportion of children receiving correct treatment of fever, pneumonia,† and/or diarrhea	242	62% (56–68%)
Sick child consultation for danger signs		
Proportion of children assessed for four physical danger signs‡	382	37% (30–45%)
Proportion of children with danger signs requiring referral who were referred	69	55% (42–68%)

*95% Confidence limit adjusted for sick children seen by the same HSA (within HSA correlation).
†Defined as cough and fast breathing.
‡Chest indrawing, palmar pallor, red on MUAC tape, and swelling of both feet.

iCCM-specific supervision with reinforcement of clinical practices in the health center or at their VHC.[16] Although this survey was restricted to one district in Malawi's central region, the high levels of CCM activity among trained HSAs who received their drug boxes are consistent with the use reports of Phalombe district included in Figure 2.

DISCUSSION

After the first 3 years of implementation, the iCCM approach is showing signs of success in Malawi. First and foremost, there is strong MOH support for both the policy and practice of iCCM. The HSA cadre is quite stable and well-respected in the communities, both likely a result of the cadre being salaried and formally recognized by the MOH. Routine monitoring and survey data, albeit incomplete, show stable monthly use rates of HSAs' iCCM services and relatively high measured quality of care. Data from the most recent Demographic and Health Survey (DHS) show that care seeking for pneumonia and fever in a health facility or from a skilled provider were reported at 65.7%, and 59.4%, respectively. Care seeking for diarrhea and treatment with ORS were reported at 57.3% and 69%, respectively.[20] These data suggest progress since 2006, when care seeking for pneumonia was reported at 51% and treatment of diarrhea was reported at 26%.

Although factors that have facilitated the scale up of the iCCM services to date can be identified (Table 2), there are also important challenges that affect the availability and quality of the community-based services. Several areas stand out.

The first area relates to the frequent stock outs of medicines. Limited district budgets and stock outs at health centers, where

TABLE 2

Meeting the challenges of scaling up iCCM in Malawi

Program component	What has been shown to work
National orientation and capacity building	Clear leadership of the MOH and an understanding of partners about their roles and responsibilities
	Demonstration course for district and national managers to create awareness among relevant stakeholders
	National planning and adaptation workshop to reach consensus moving forward
	Minimal adaptation to the generic WHO/UNICEF guidelines
	Orientation of DHMTs, mapping of hard-to-reach areas, and joint planning
	Engagement of the national IMCI technical working group in the process
	Proper coordination of available support and collaboration of partners to roll out activities in assigned districts
Community ownership and participation	Community dialogue before introduction of the services
	Formation of village health committees under each functional VHC
	Engagement of community leaders to manage the VHC
Skills building	Devolution of HSAs training to district level
	Leadership of district IMCI coordinators and engagement of DHMT members
	Appropriate case load in district hospitals for inpatient and outpatient clinical practice during training
Supervision	Assignment of specified responsibilities to various cadres of staff (senior HSA, environmental officer, and community nurse)
	Training supervisors in iCCM and supervisory skills
	Development of integrated checklists incorporating key elements of the sick child recording form
	Creation of a mentorship program for periodic skills reinforcement of trained HSAs
Medicines and supplies	Provision of medicines to HSAs during their monthly visits to the designated health center
	Supervisors carrying medicines and supplies to alleviate stock outs
	Guidance on quantification of medicines to DHMTs
	Rollout of standard operating procedures for logistics management information systems to strengthen use and management of medicines and other supplies
Referral	Designation of health centers where HSA should refer
	Use of referral note and feedback on the same
	Engagement of VHC in finding solutions to facilitate referral, such as bicycles or ox cart as transport, and escorts at night
Monitoring	Recruitment of a national monitoring and evaluation officer in the IMCI unit
	Development of the iCCM register based on the sick child recording form
	Quality of care assessment of HSAs performance
	District-based village clinic review meetings to strengthen implementation
Motivation	Recognition of HSAs as formal members of the health work force
	Provision of adequate housing to HSAs in hard-to-reach areas through village health committees
Innovations	Provision of mobile phones to HSAs to facilitate contact and SMS-based reporting and ordering of medicines and supplies

HSAs are supposed to restock their supplies, combined with limited capacity for forecasting needs have led to important breakdowns in service provision in the community. There are serious concerns that these disruptions will, in the long run, undermine the credibility of the HSAs and the likelihood that families will seek care promptly when children show signs of illness. To overcome this barrier, partners, such as Management Sciences for Health (MSH) and John Snow International (JSI), have been working with the MOH to strengthen logistics management, including forecasting and medicine quantification, to improve the consistency of drug supply to VHCs. The MOH is also piloting the introduction of RDTs for assessing children with fever, which will contribute to further rationalizing of the use of antimalarials. An initiative currently implemented in six districts is the Supply Chain Management for iCCM (SC4CCM) approach, which uses frontline Short Message Service (SMS) for monthly reporting and ordering of stocks by HSAs. The system connects each HSA with the supply manager in the DHMT who receives the SMS information, prepares the new supply, and notifies the HSA when it is ready for pick up in the health facility. The system is to be fully evaluated, but preliminary experiences suggest fewer stock outs among participating HSAs.

A second main challenge is that VHCs are scheduled in light of other responsibilities that the HSAs have to fulfill, and in some instances, they are conducted only one or two times per week. Hence, services may not be available when a child needs them. This concern seems to be less of an issue when the iCCM-trained HSA resides in the community, but it is a seriously limiting factor to service availability in communities that are served by HSAs who do not live in their catchment area. Although a stronger articulation of national policy on the provision of services in VHCs will be required, planning and management at the district level has proven to be an important factor in addressing this challenge. Verbal reports from IMCI coordinators and district health officers have indicated that community dialogue and engagement of the village health committees in planning and managing the community service have been critical for the initiation and sustainability of the services. Where communities were involved from the start, they took responsibility to establish housing for the HSAs, identified the location of the VHC, constructed the building, and assisted in managing the service, including monitoring of the drug box. In districts with little efforts to community involvement, DHMTs experienced difficulties in finding housing for trained HSAs in the targeted communities and initiating the VHC services. Anecdotal evidence suggests that, where HSAs reside in their community, access to iCCM extends beyond the VHC hours, and community members can consult the HSAs more frequently or on need.

A third challenge relates to the linkages between the HSAs and the health center level for timely referral, improved monitoring, and supervision. Although the results of the quality of care assessment of HSAs were encouraging, they also illustrated a clear need for skills reinforcement and sustained support. The fact almost one-half of children requiring referral were not appropriately referred is of particular concern, and this information calls for continued education and practice of assessment and decision-making skills, including through direct observation, vignettes, and photo and video exercises. Designated supervisors are senior HSAs and environmental health officers who traditionally do not have clinical responsibilities. They are trained in iCCM but do not treat sick children. To bridge the gap in their skills to provide effective supervision, the MOH, in collaboration with Save the Children, has developed a 2.5-day competency-based supervisory skills training course that targets the senior HSAs and environmental health officers. In addition, the MOH is promoting other skills reinforcement activities, such as mentoring of HSAs by clinical staff in health facilities. The fact that HSAs visit the health facility regularly provides a clear opportunity for organizing a program of work to strengthen the knowledge and skills of HSAs. However, it requires that the staff in health facilities is well-versed with the iCCM approach and can act as a gold standard for iCCM management. Results from a health facility survey among IMCI-trained health professionals also conducted in 2009 showed that quality of sick childcare in health facilities had important limitations and was not markedly better than the care in VHCs.[21] Hence, the approach for quality improvement has to address HSAs and health facility-based staff in concert.

The MOH, in collaboration with the independent evaluation team at IIP-JHU and Malawi NSO, has embraced a national platform approach to evaluation of the iCCM program.[22] In this approach, monitoring program implementation and outputs is an essential pre-requisite to attribute any changes in coverage and/or mortality to the CCM program. The MOH and partners are working to strengthen the availability and reliability of CCM indicators, many analogous to the proposed CCM Benchmark indicators,[23] at the district level. An emphasis on better information at the district level through routine monitoring and special exercises, such as telephone surveys among iCCM-trained HSAs to assess drug supplies, frequency and content of supervision, and use of services,[16] will provide additional information about the strength of CCM implementation and allow program managers to identify ongoing weaknesses for improvements.

In conclusion, although it is too early to determine the effects of introducing iCCM in Malawi on treatment coverage and under 5 years child mortality, the strategy has the potential to achieve the government's goal of universal coverage of key child health interventions. Moving curative services closer to communities can help to overcome important geographical barriers to accessing care for sick children. The MOH and its partners are researching and developing strategies to ensure ongoing quality of services and availability of drugs and commodities. Among other developments, the MOH may adapt the iCCM recording form to include RDTs of all children with fever to ascertain the likelihood of malaria. A policy discussion on the need for daily service delivery has also been initiated with a view on revision of this aspect in the job description of iCCM-trained HSAs. An ongoing prospective evaluation of MNCH rapid scale up in Malawi, which strongly focuses on the iCCM approach, will provide evidence if the rollout is related to increases in treatment coverage and decreases in mortality among children less than 5 years of age.

Received December 5, 2011. Accepted for publication May 12, 2012.

Acknowledgments: The authors thank all individuals and partners who contributed to the introduction and scale up of the iCCM approach in Malawi, especially Dr. S. B. Kabuluzi, Edward Nkhono (MOH), Susan Kambale (WHO), Ketema Bizuneh (UNICEF), Rudi Thetard (USAID/BASICS), Robert Mahala (JSI), Tiyese Chimuna (Save the Children), Dyson Likomwa (Population Services International), and the staff responsible for scale up of MNCH interventions in the districts.

Grants made available by the Bill and Melinda Gates Foundation (BMGF) through the WHO and JSI, the Canadian International Development Agency (CIDA) through UNICEF, PSI, and Save the Children, and USAID through MSH/BASICS and JSI greatly facilitated the implementation. The external evaluation activities are funded by the BMGF and CIDA. We would also like to thank IIP-JHU and the Malawi NSO for sharing their results related to iCCM implementation; this study was led by Elizabeth Hazel at IIP-JHU and Willie Kachaka at Malawi NSO, with funding support from CIDA through the Real-Time Tracking of Results Grant and BMGF through a grant to the Partnership for Maternal, Neonatal and Child Health. H.N., B.D., J.A.C.-K., and K.G. conceptualized the paper. H.N., B.D., and L.M. prepared the first draft of the manuscript. A.M., J.A.C.-K., and K.G. prepared the coverage data and contributed to the writing and interpretation of the findings. T.K. reviewed the paper and provided suggestions.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 61–68
doi:10.4269/ajtmh.2012.11-0665

Health Workers' and Managers' Perceptions of the Integrated Community Case Management Program for Childhood Illness in Malawi: The Importance of Expanding Access to Child Health Services

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Abstract. Community case management (CCM) is a promising task-shifting strategy for expanding treatment of childhood illness that is increasingly adopted by low-income countries. Its success depends in part on how the strategy is perceived by those responsible for its implementation. This study uses qualitative methods to explore health workers' and managers' perceptions about CCM provided by health surveillance assistants (HSAs) during the program's first year in Malawi. Managers and HSAs agreed that CCM contributed beneficially by expanding access to the underserved and reducing caseloads at health facilities. Managers differed among themselves in their endorsements of CCM, most offered constrained endorsement, and a few had stronger justifications for CCM. In addition, HSAs uniformly wanted continued expansion of their clinical role, while managers preferred to view CCM as a limited mandate. The HSAs also reported motivating factors and frustrations related to system constraints and community pressures related to CCM. The impact of CCM on motivation and workload of HSAs is noted and deserves further attention.

INTRODUCTION

Community case management (CCM) of childhood illnesses by community-based health workers is a strategy supported by the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF)[1,2] that holds great potential for increasing coverage of child survival interventions and reducing child mortality.[3] Many countries are starting to implement CCM on a large scale. However, there is insufficient attention in the literature to implementation factors that lead to successful scale-up of CCM programs.[4] This study addresses one key factor in the implementation of CCM, namely perceptions about the program among community-based health workers, their supervisors, and senior district managers.

Previous research has demonstrated that policy implementation rarely follows a hierarchy from policy makers to implementers and then end users. Rather, it involves a process of negotiations between stakeholders.[5,6] In cases where program managers and health workers hold positive perceptions about a new program, they can be instrumental in facilitating its uptake. In contrast, when they hold negative perceptions about a program or have competing priorities, they may resist or undermine the program, leading to implementation failure.[6] The importance of stakeholder perceptions is amplified in decentralized health systems where district managers have greater autonomy in making decisions about allocating resources to a new strategy or intervention.[7–9]

Task shifting programs such as CCM redraw the boundaries between different cadres of health workers, which can further complicate negotiations involved in implementing health policy.[10] Clinicians and professional medical associations have objected to the delegation of clinical tasks to lay health workers in several program areas, including human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS).[4,11–14] In addition, there is a history of resistance to programs using community-based health workers (CBHWs), and the public health community has debated the role of CBHW cadres for decades, particularly whether these workers should provide curative services.[13,15] When governments implement task shifting, there is the risk that they will assign additional responsibilities to lower level health workers without increasing their compensation, leading to reductions in motivation.[12] Conversely, studies have shown that in some settings, the addition of responsibility for curative services has increased CBHWs' motivation and the community's respect for CBHWs, leading to better performance.[16–18] Task shifting strategies that are able to establish a sense of self-efficacy and legitimacy for CBHWs, and an assurance of support from supervisors, have been shown to achieve better results.[17] Although health systems researchers have identified operational research on the perceptions held by health staff regarding task shifting as a priority,[12] few studies have examined health workers' reactions to large-scale CCM programs.

This paper reports data collected during the first year of the national CCM implementation in Malawi. Malawi is a country that is on-track to meet Millennium Development Goal (MDG) 4, but must still reduce the current under-five mortality rate from 127 to 75 deaths per 1,000 to reach its MDG target.[19] In an effort to improve child mortality indicators, Malawi's Ministry of Health (MOH) added CCM to the activities of an existing national cadre of CBHWs known as health surveillance assistants (HSAs). The rollout of CCM began in 2008 with the training of HSAs posted in hard-to-reach areas, those furthest from a health center. The overall goal of this study was to explore perceptions of health workers in Malawi regarding the introduction of CCM. The specific objectives were to describe 1) program managers' attitudes about the CCM program and their perceptions of the quality of care provided by HSAs, and 2) HSAs' perceptions about the CCM program and the potential impact of CCM on HSAs' motivation.

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METHODS

Research setting. Malawi is a land-locked country with 13 million persons in eastern Africa, and is ranked as one of the 10 poorest countries in the world. The major causes of under-five death in Malawi are malaria (17%), HIV/AIDS (14%), pneumonia (11%), and diarrhea (11%).[20] Coverage of treatment of childhood illnesses is low; 2006 estimates suggested that only 30% of children with suspected pneumonia in Malawi were treated with antibiotics, and treatment rates for fever cases was even lower.[19] Malawi's MOH faces many challenges in the delivery of health services, including limited geographic access to health facilities for rural populations.[21] and a severe shortage of human resources for health.[22,23] In 2007 the MOH adopted a policy supporting integrated CCM by HSAs for children 2–59 months of age, to be provided free similar to all government health services in Malawi and to compliment services provided with fees by private facilities managed the Christian Health Association of Malawi.[24]

Malawi's HSAs were first recruited into the country's health system to serve as vaccinators in the 1950s and later participated in the smallpox eradication campaign.[25] Newly recruited HSAs are required to have 12 years of education, and older HSAs may have only some secondary schooling. The HSAs receive 10 weeks of basic training and are assigned to serve a community of approximately 1,000 persons. Survey data from a random sample of HSAs providing CCM in the six districts in this study showed that 81% were male and 43% had been recruited after 2006.[26]

Currently, HSAs' primary responsibilities include health surveillance and environmental health promotion.[27] In addition, HSAs in some areas support various other services, including family planning, tuberculosis (TB) treatment, and voluntary counseling and testing for HIV/AIDS. The direct supervisors of the HSAs are area environmental health officers, who are attached to health centers, and senior HSAs. The Malawi MOH increased the size of the HSA cadre during 2002–2008 with grants from the Global Fund to Fight AIDS, TB, and Malaria, to reach an estimated ratio of 1 HSA per 1,000 population.[28]

Implementation of CCM in Malawi began in 10 districts selected by the MOH with the poorest child health indicators in each of Malawi's three geographical regions (northern, central, and southern).[29] The World Health Organization and UNICEF supported the MOH Unit for Integrated Management of Childhood Illness (IMCI) in roll out of CCM in the 10 districts with a grant from the Catalytic Initiative to Save a Million Lives. The program was introduced to district health management team members through visits from WHO and IMCI Unit representatives. District IMCI coordinators and other clinicians from each district were subsequently trained as CCM training facilitators in June 2008. After training of the HSAs, the respective communities were to receive a sensitization visit by district managers to introduce and explain the new service, although limited availability of transport and other challenges sometimes prevented these visits.

The CCM training is a six-day in-service training that uses classroom sessions and clinical practice to prepare HSAs to follow an adapted IMCI algorithm for treatment of children with uncomplicated cases of pneumonia, fever (presumed malaria), and diarrhea, and to assess children for danger signs requiring referral to the nearest health facility.[30] The HSAs are instructed to hold CCM clinics at scheduled days of the week in a central location in the village (such as in a church building or under a tree) and during the first year of implementation received CCM supervision primarily from the district IMCI coordinator, rather than their routine supervisors, environmental health officers and senior HSAs.

Research methods. This study is an exploration of the perceptions held by health workers regarding Malawi's CCM program. It was conducted as a sub-study of a larger assessment of the implementation strength and quality of CCM in six districts participating in the early CCM rollout supported by WHO and UNICEF. Districts were selected for the study on the basis of adequate levels of implementation for a quality of care assessment, including 1) at least 10% of HSAs trained in CCM, and 2) at least 50% of CCM-trained HSAs had received initial drug stocks of antibiotics, antimalarial drugs, antipyretic drugs, and oral rehydration salts.[26]

Qualitative data collection activities consisted of in-depth interviews and focus groups conducted during four weeks in November and December 2009. District IMCI coordinators, the managers with the primary responsibility for the CCM program, were interviewed in all six districts. Four districts were further chosen for interviews with members of the district health management team and focus groups with HSAs conducting village health clinics. These four districts were selected to represent high- and low-performing districts in terms of supervision and drug supply, on the basis of preliminary results from the quality of care assessment, to satisfy a separate objective to assess health system support delivery strategies for CCM. A pilot exercise was held in a separate district to identify the range of suitable respondents and refine interview guides and protocols.

This research was conducted in partnership with the Malawi Ministry of Health as a part of an independent evaluation of the Catalytic Initiative, led by the Institute for International Programs at Johns Hopkins University and the Malawi National Statistics Office. All interviews and focus groups were conducted by two independent Malawian qualitative researchers and one researcher from Johns Hopkins after permission from the Malawi Ministry of Health. Interviews with program managers and clinicians were in English, as all respondents received education in English and are fluent speakers. Focus groups were conducted with HSAs because pilot testing showed that HSAs were more responsive to questions through group discussion rather than individual interviews. The group discussions were conducted in a mixture of English and the local language, Chichewa, to ensure that participants could contribute comfortably. All district managers involved in CCM implementation were asked to participate and were interviewed in private in their offices. District IMCI coordinators facilitated the research team's visit to a convenient health center to interview clinicians and HSA supervisors. In advance of the team's visit, health center staff called all CCM-trained HSAs within each chosen health center's catchment area to invite them to participate in a focus group discussion at an appointed time. Health center-based interviews and focus groups took place in available private settings, such as meeting rooms.

Interview and discussion guides covered a variety of health systems issues involved in CCM implementation, including informants' overall perceptions about the CCM program. Regarding perceptions, respondents were asked their general

opinions about the CCM program towards the end of the interviews by using open-ended questions to elicit spontaneous, unprompted responses. The HSAs were asked to discuss aspects of CCM work that they liked and did not like in the same open-ended manner. Interviewers often probed respondents to elaborate on and explain their responses.

All interviews and focus group discussions were recorded and transcribed, with translation into English where necessary. Inductive analysis was conducted according to the framework approach, a process for coding, categorizing, and explaining qualitative data in a grounded manner.[32] All transcripts were read and open coding was used to develop coding indices, organized by thematic category, for focus groups and in-depth interviews separately. Each transcript was subsequently coded according to the corresponding index in ATLAS.ti, a qualitative data analysis software package (http://www.atlasti.com). The frequencies of codes and corresponding comments were assessed to detect major categories of perceptions. Short memos and word tables were used to summarize the overall perspectives expressed by each informant, define major categories of comments, and organize descriptive categories into themes. Charting of data was used to assess differences in stakeholder perceptions of the CCM program between low-performing and high-performing districts.[32] Feedback from managers and other MOH personnel was received when initial results were shared in a national analysis and dissemination meeting. This study was approved by the Institutional Review Board at Johns Hopkins Bloomberg School of Public Health and the Malawi National Health Sciences Research Committee, and all respondents provided verbal consent.

RESULTS

Fifty-seven participants from six districts were included in the qualitative data set for this study, including in-depth interviews with 28 supervising and senior managers and four focus groups with 5–9 HSAs per group (Table 1). Managers interviewed for the study represented a range of positions within the district health management team and frontline supervisors, from district health officers to medical assistants serving as health center in-charges. All HSAs included in the study had received CCM training and were operating CCM clinics in the communities where they were posted and were representative of HSAs in the district. The following sections describe the themes that emerged from analysis of informants' perceptions about the CCM program, and contrast the perspectives held by program managers and HSAs (Table 2 and Table 3, respectively). The themes included community and health facility benefits of CCM; qualified endorsement of CCM by program managers; diverging perspectives on HSAs' roles as village doctors; and motivating factors for HSAs. No systematic differences in perceptions were found between high-performing and low-performing districts.

TABLE 1
Description of respondents in the study, Malawi*

Position	No. districts	No. participants
Manager		
Administrators	4	4
Assistant environmental health officer	3	4
District environmental health officer	2	2
District health officer	3	3
Medical assistant	3	3
IMCI coordinator and deputy	7	6
Pharmacy technician	4	4
Senior environmental health officer	2	2
Community-based health worker		
Health surveillance assistant	4	29

*ICMI = integrated management of childhood illness.

Community benefits of CCM. Managers and HSAs agreed that the CCM program is helpful to the communities that it serves. The most commonly cited benefit for communities was increased geographic access to health services for children, discussed in 3 of 4 HSA focus groups and in 17 of the 29 manager interviews. As described earlier, the HSAs selected for CCM training were those stationed in areas designated as hard-to-reach, generally defined as being located ≥ 7 km from a health center. Informants reported that having a CCM clinic improved health care access for these communities:

> *"I like [the] village clinic because the community receives drugs near, and children, when they are sick, are treated quickly. So I like it because the community is not suffering."* (HSA) *"I know that [HSAs operating CCM clinics] are coming from remote areas where medical treatment is a problem and I have supported the idea of giving them the drugs so that they can help the people in those areas"* (medical assistant).

In addition to geographic access, managers believed that communities benefited from CCM because HSAs living in the communities were available to provide health services at all times (24 hours). Two managers stated that they expected that increased access to health counseling and curative services in the community through CCM would result in reduced use of traditional healers by community members. Informants also cited improved health outcomes and/or mortality reduction as a key benefit of the CCM program in 11 interviews and all focus groups. The HSAs believed that CCM benefited the community by creating more opportunities for community members to have contact with HSAs and receive health counseling.

Health facility benefits of CCM. Aside from benefits to the community, managers reported that CCM had (or would have) benefits for health facilities, including reduced caseloads, improved work hours for medical assistants, and reduced operating costs for health facilities as a result of less use. Some managers noted a visible reduction in cases at the health center with the introduction of CCM:

> *"When I was coming [to this health center] three years ago, there wasn't this program and I was having much workload. Most of the patients who were coming were under-fives. After introducing this program, the workload has been reduced and you can find that children who come here are those from within the health center [vicinity] and not people from far places"* (medical assistant).

Similar to managers, HSAs also believed that CCM reduced facility caseloads and eased the strain on facility-based clinicians. One HSA suggested that by reducing the number of facility cases, the CCM program has led to improved treatment of patients by medical assistants at the health facility, who were previously harsh to patients when busy.

Qualified endorsement of CCM by managers. Although all managers included in this study made positive comments about the concept of the CCM program, these positive comments did not always indicate whole-hearted endorsement of the program. Several managers expressed concerns about

TABLE 2
Managers perceptions about the CCM program, Malawi*

Benefits of CCM program	Concerns about CCM program
Community benefits	**Policy concerns**
Increased geographic access for underserved areas	CCM program should have limited scope (e.g., only minor illnesses)
Expanded (24-hour) service hours for childhood illness	CCM should ideally be provided by more qualified health workers
Increased contact and opportunities for HSAs to provide health education to community members	CCM's age restrictions cause conflict with the community members who want treatment of adults
Improved, earlier care seeking for childhood illness	HSAs may misuse drug stocks
Reduced cases of severe illness	
Reduced use of traditional healers	**Implementation concerns**
Reduced mortality and morbidity in children less than five years of age	Program data should be collected and analyzed to assess whether the CCM program is providing benefits (e.g., improved child health, reduced facility use, high quality of care)
Improved long-term social and economic development caused by a healthier population	HSAs are overburdened with activities
	Health center staff should be included in implementation of CCM (communications, supervision)
Health facility benefits	HSAs need frequent supervision to ensure quality and work ethic
Reduced caseload at health facilities	Training period for CCM should be lengthened
Cost savings through shifting use to the community	
Reduced strain on health facility staff	

*CCM = community case management; HSAs = health surveillance assistants.

CCM that qualified their positive assessment of the program. The most commonly stated concern was that HSAs needed support to provide a high quality of care, an idea discussed by 15 managers. The type of support that managers considered critical was primarily supervision, but also included drugs, equipment, and shelters for holding CCM clinics. The following comment from an IMCI coordinator reflects the common concern that HSAs must be supported.

"The quality of care that HSAs can provide will also depend on supervision or support that you are providing to them. These are not medically oriented personnel. We are making them to be medically oriented hence we need to provide them with the necessary support that they might require" (IMCI coordinator).

Similar comments made by other managers also tended to emphasize the low level of education or lack of clinical background among HSAs.

In addition to asserting the need for the CCM program to support HSAs, 11 informants qualified their support of the program by emphasizing the limited scope of CCM. The limitations described by informants included that CCM only addressed minor illnesses and specific conditions, and that HSAs were only allowed to treat children within a certain age range. The comment by one area environmental health officer that *"[HSAs] are given a limit and they are performing within that range, which is good,"* illustrates the beliefs of several managers that the CCM program should be circumscribed by clear boundaries.

The third manner in which informants qualified their positive assessment of CCM was by reserving their final judgment of the program, especially with regards to the question of whether HSAs are providing a high quality of care. Five respondents indicated that they felt it was too early for them to judge the impact or quality of the CCM program, or that they wished to see data to make a judgment.

Village doctors or stopgap measures? During focus group discussions, HSAs strongly indicated that their new role of operating village health clinics changed how they view their own position in the health system. HSAs explained that, with CCM, the community recognized them as village doctors, and that they viewed themselves as being on more equal footing with Medical Assistants, the primary clinicians at Malawi's health centers. One HSA described the CCM training as having provided him with a new career, indicating a sense of significant change in his role, and a higher status within the health system and the community.

"In the past people [in the villages] used to call us doctors, but with this program, we are real doctors because [we are] giving them medicines and I feel happy that I am a doctor" (HSA).

TABLE 3
Motivating and demotivating factors associated with CCM work, as reported by HSAs, Malawi*

Motivating factors	Demotivating factors
Opportunity to develop new skills	Increased workload and irregular hours
Satisfaction from helping the community caused by curative role	Inadequate drug supply, equipment, and supervision
Increased recognition/appreciation from the community caused by curative role	Lack of assistance in solving problems
Assistance from the community when operating village clinics	Spending personal funds for running the CCM clinic
Allowances received during CCM training and review meetings	Anxiety over community perceptions relating to the CCM clinics (e.g., inadequate drugs, HSAs' inability to treat complicated illnesses and older children)
Perception of higher status for HSAs with a curative role	

*CCM = community case management; HSAs = health surveillance assistants.

Although HSAs expressed satisfaction at the prospect of a more important role in the health system and community, they were frustrated that this perceived change had not been more formally recognized by the health system. A common complaint voiced by HSAs was that their workload and responsibilities had increased but they had not received an increase in salary or incentives. Caregivers could bring sick children to the HSA at any time, and HSAs would have liked to receive allowances for working during the night and on weekends. Some HSAs also expressed a desire for non-monetary recognition of their perceived new role, such as inclusion in meetings with clinicians and new uniforms.

"We expected that after being trained, since we are now part of the curative part, there will be change in our monthly salaries but there is no change. Also we thought we will be given uniforms for our identification that these people are part of the health center of sub medical assistants (laughter from the group), but no change" (HSA).

The HSAs also expressed a wish to go further with the village clinics by treating more illnesses and different age groups, including older children and elders. For some HSAs, these wishes stemmed from a desire to be useful to the community, and other HSAs expressed an interest in receiving more training and skills that they hoped would lead to promotion.

Managers were aware that community members perceived HSAs as doctors, sometimes making little distinction between an HSA and a clinician at a health center. However, managers tended to regard HSAs as non-clinical workers with limited qualifications. Several managers described HSAs as not medically oriented, not clinicians, and not health workers. The manager's view of HSAs as non-clinical workers did not seem to have changed fundamentally with the addition of CCM to the HSAs' responsibilities. When asked his opinion about the CCM training course, one district environmental health officer said, *"It is not complicated as if we are making them become doctors."* As mentioned previously, managers emphasized the limited scope of the CCM program, and some expressed a worry that with CCM, HSAs would become too confident and try to go beyond what the CCM program allows them to treat.

It may appear contradictory that most managers supported the provision of some curative services by HSAs despite believing that HSAs are not clinical providers. This seeming contradiction may be explained by the comments of several managers who justified the CCM program as a stopgap measure that addressed the human resource constraints in Malawi's health system. One IMCI coordinator said, *"HSAs are not clinical providers, they are being used to provide CCM because of the problems we have at hand."* A district health officer described CCM as a good initiative but a less-than-ideal use of low-level health workers.

"This program is there because we want to deal with the crisis that we have in terms of human resources. If we had for example enough nurses who are purely trained community nurses, they could [be the] responsible people to run these clinics and not HSAs . . . To me I think the best way is to make sure that human resources are available and they should be [the] right human resources. I think the community health nurses are the lowest that we can try and do" (district health officer).

This district health officer supported the CCM program, given the deficit of human resources in Malawi's health system, but he would have preferred to have community health nurses provide community-level curative services. Other less frequent justifications that managers cited for HSAs providing clinical services were: 1) that the government has an ethical obligation to provide community-based services such as CCM, which was described by one DEHO as being *"a program which deserves to be supported, because it addresses the poorest of the poor . . . so it's a human rights intervention;"* and, 2) that HSAs were providing medications that community members could have purchased themselves in local shops.

Although many managers did not regard HSAs as clinical workers, most manager-level informants expressed a belief that most HSAs are meeting performance expectations for CCM. Most managers also made positive comments about the CCM training course, and a few indicated that they believed that HSAs might have been providing better care than patients would otherwise receive at the health center. These managers were impressed by the amount of time HSAs spent with each patient, and their thoroughness. A pharmacy technician assessed CCM quality as follows.

"There is quality of care [at CCM clinics] because they [HSAs] do not see many patients . . . they have time to examine the patient unlike at a district hospital where there is a long queue" (pharmacy technician).

Many managers also expressed a desire to see the CCM program grow. Eleven managers stated that more HSAs should be trained to provide CCM, and two managers believed that HSAs should treat patients of older ages, and one administrator believed that HSAs should provide a broader range of clinical services.

Motivating and demotivating factors for HSAs. Comments made by HSAs during focus group discussions indicate that CCM work provides unique motivational factors beyond those that HSAs find in their traditional prevention work (Table 3). The HSAs expressed satisfaction at learning new skills and being useful to the community. In particular, HSAs reported receiving more appreciation from the community as a result of their CCM work.

"I am always happy when I hear from the caregiver that the child is now OK since I gave the child medicine. And [I] am so popular in that village because I am treating under-five children who have uncomplicated illnesses; those that are serious we refer and they come [to the health center] to get treatment. When the child is healed we are praised because we wrote a referral letter for them" (HSA).

Other HSAs described their pride at helping others, including their friends in the community, and their belief that they were contributing to the social and economic development of the country by operating village health clinics. Finally, the opportunity to receive allowances during training and review meetings was cited as a motivating factor by HSAs.

The HSAs also experienced new frustrations and burdens associated with their village clinic work. By far the most frequently mentioned demotivating factor for the HSAs was the perception that they were given a large responsibility without receiving the support needed to help them meet expectations. The specific issues involved in this type of complaint were many and varied; for example, different HSAs believed that they needed shelters for holding village clinics, materials for infection prevention, and more feedback and corrections from supervisors. Several HSAs described their frustration

as resulting from broken "promises" and/or neglect by CCM program managers.

> *"We are human beings and we need to be corrected or appreciated on what we are doing because this helps us to change or know that we are doing better. As of now we are just working but we don't know whether we are doing better or not because they don't come to supervise"* (HSA).

Several HSAs complained that supervisors do not respond to their complaints, and that despite making supervisors aware of their needs, their needs went unaddressed.

The second most frequent challenge reported by HSAs operating village health clinics was a conflict between CCM policies and community expectations. The HSAs reported that they received pressure from community members to treat children more than five years of age and even adults. The HSAs worried about the damage that may occur to their relationship with the community by refusing to treat patients that are outside of the CCM age limits. One focus group participant said that if an HSA turns people away, *"they think you are a tough person and as a result people hate you."* Insufficient supplies, especially drugs, were also said to strain the HSAs' reputation with the community. Several HSAs expressed a desire for program managers to provide them with more assistance in communicating CCM policies to the community and in managing community expectations.

Additional burdens of CCM reported by HSAs related to time, finances, and safety risks. Most HSAs reported that the CCM program had increased their workload. During CCM training, HSAs were advised to select specific days during the week for holding village clinics. However, HSAs report that due to pressure from patients, they are not able to restrict the days and times when they do village clinic work. Having to attend to patients late at night and on the weekend was one of the most common complaints from HSAs. However, managers cited 24-hour access to care as a benefit and expectation of the CCM program. The HSAs also complained about the time burdens associated with completing multiple patient records and traveling long distances to the health centers to restock drugs. Aside from time burdens, HSAs reported paying out-of-pocket for transport to collect drugs and lamp oil and candles to see patients at night. Considering personal safety, some HSAs reported fears that they may contract infections from patients, or that attackers may try to steal their drug supplies.

Reports of resistance. Although the informants in this study all indicated positive responses to CCM, managers from three districts and HSAs from two districts did report incidents of resistance to the program. Each reported incident involved medical assistants at the health center, who either refused to support the program or to provide drugs to HSAs. Some HSAs also accused medical assistants of being selfish by withholding adequate supplies of drugs even when they had sufficient stock to fully supply HSAs. Most managers who reported medical assistants' resistance to the program attributed this behavior to insufficient orientation of medical assistants at the start of the program or to staff turnover. Only one manager, a district environmental health officer, stated that medical assistants felt threatened by CCM, which could be considered an erosion of their influence. In all reported cases, the resistance was overcome by the district managers' efforts to convince skeptical medical assistants to support the program. These interventions included an informational meeting for all medical assistants in one district and individual contacts with resisting medical assistants in two districts.

DISCUSSION

This study developed an initial understanding of health workers' perceptions about the CCM program in Malawi through qualitative interviews and focus groups with a broad range of district health workers involved in early CCM implementation. Most participating health workers, both managers and HSAs, responded positively to the introduction of the CCM program in Malawi, regardless of whether the district was high-performing or low-performing in terms of supervision and drug supply for CCM. Managers and HSAs agreed that CCM addressed health system needs by expanding access to the underserved and reducing caseloads at health facilities. The HSAs reported an increase in feelings of usefulness, self-esteem, and prestige when operating CCM clinics. These positive perceptions are consistent with those reported in a small number of studies on CCM implementation,[18,33,34] and are likely to have contributed to the strong early implementation in the six districts included in this study. The positive perceptions of CCM among health workers in these districts contrasts with the stance of some managers in districts not actively implementing CCM and with professional bodies such as the Medical Council of Malawi. Medical Council representatives considered the CCM program to be illegal as late as December 2009, when they voiced their objections to HSAs performing clinical services at a national CCM stakeholders meeting.

Although informants included in this study supported the implementation of CCM, their comments also showed varied and nuanced opinions about the benefits, drawbacks, and success factors for the program. Although HSAs wanted continued expansion of their clinical role, managers preferred to view CCM as a limited mandate, with some characterizing CCM as a stopgap measure. These findings highlight the complex negotiations associated with implementing interventions that imply health systems reforms, particularly with regard to task shifting.

The results of this study provide important lessons for the scale-up of CCM programs. The experience in Malawi shows that clinicians and other health managers can be supportive of the provision of limited clinical services by lower-level health workers. In addition, existing community health workers can benefit from increased motivation and an enhanced relationship with the community when curative services are added to their activities. These findings are positive for the current movements to expand the provision of CCM in sub-Saharan Africa and elsewhere.[35] However, policy makers and advocates should take note of the concerns expressed by informants when planning and implementing CCM programs. Managers may be unlikely to support a CCM program if they feel that the scope of curative services is too broad. In addition, CBHWs and managers will have more positive perceptions of CCM programs that ensure a high level of support for CBHWs. When CBHWs perceive that they are given greater responsibility without the necessary support, it is damaging to their motivation and trust in their supervisors.[12] It is therefore important that Malawi's CCM program work to ensure the consistency of drug supply and frequency of supervision; a survey of CCM clinics in September and October 2009 found that only 69% of HSAs had all the necessary drugs in stock and only 38% of

HSAs had a CCM supervision visit in the three months before the survey.[31] If advocates adequately address the concerns of stakeholders, CCM programs hold great promise for improving child health in low-income settings.

The data presented here were collected as a part of a larger study on health systems factors involved in the successful implementation of CCM in Malawi. Our effort to be comprehensive limited the interviewers' ability to extensively probe any one topic. However, through this study we were able to collect data from a broad range of health workers, all of whom played important roles in CCM implementation. In addition, our involvement in larger studies on quality of CCM services and health systems implementation factors provided important contextualizing information. Therefore, this report can be considered an initial exploration of the subject critical for informing further in-depth research in Malawi and other settings. The extent to which these findings are generalizable outside Malawi is not known, and further work is needed to compare CCM perceptions across settings and to assess how these perceptions change over time. Additional research is also needed to understand the perceptions that community members have about CCM services provided by HSAs, their demand for these services, and compliance with referral to health centers.

On a broader scale, these findings demonstrate the need to place more research and policy attention on the social aspects of implementing task shifting policies such as CCM and assessing their health system effects. Although CCM has proven effective at reducing child mortality rates in controlled intervention trials and programs with limited scope,[36–39] more health systems research is needed to understand the implication of implementing these interventions at scale in the context of current health systems. Despite the importance of health workers' perceptions in implementing task shifting, this area is inadequately addressed by the current research, which provides more anecdotes than data on stakeholder perceptions.[14] Given the important role that task shifting is expected to play in addressing the human resources for health crisis in Africa, the social and organizational culture implications of task shifting deserves urgent research attention.[12]

Received October 25, 2011. Accepted for publication April 17, 2012.

Acknowledgments: We thank the Malawi Ministry of Health and the World Health Organization for administration and management support; Bernie Zakeyo and Josiah Mayani for their assistance in conducting the interviews and transcribing the data; Dr. Caitlin Kennedy for providing input on analysis methods; Dr. David Bishai, Dr. Caitlin Kennedy and Dr. Catherine Klegg-Smith for comments on early drafts of the paper; Dr. Agbessi Amouzou for management of the Catalytic Initiative evaluation in Malawi and support of this study; senior faculty at the Institute of International Programs for guidance related the study design, methods, and analysis; and Dr. Storn Kabuluzi for his support and assistance as Malawi MOH Director of Preventative Health.

Financial support: This study was supported by the Canadian International Development Agency and the Bill and Melinda Gates Foundation through the Catalytic Initiative to Save One Million Lives in Malawi and its evaluation.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 69–76
doi:10.4269/ajtmh.2012.11-0758

A Health Systems Approach to Integrated Community Case Management of Childhood Illness: Methods and Tools

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Abstract. Integrated community case management (iCCM) of childhood illness is an increasingly popular strategy to expand life-saving health services to underserved communities. However, community health approaches vary widely across countries and do not always distribute resources evenly across local health systems. We present a harmonized framework, developed through interagency consultation and review, which supports the design of CCM by using a systems approach. To verify that the framework produces results, we also suggest a list of complementary indicators, including nine global metrics, and a menu of 39 country-specific measures. When used by program managers and evaluators, we propose that the framework and indicators can facilitate the design, implementation, and evaluation of community case management.

BACKGROUND

Integrated community case management (iCCM) enjoys broad-based policy support at the global level from a range of development partners and donor agencies. Across the developing world, countries are increasingly scaling up this strategy in efforts to meet the fourth Millennium Development Goal. Joint policy documents released by the World Health Organization (WHO) and United Nations' Children's Fund (UNICEF) support home-based management of fever, as well as community management of pneumonia, diarrhea, severe and acute malnutrition.[1–4] The U.S. Government supports iCCM through the Global Health Initiative and the President's Malaria Initiative (PMI)[5], the Bill and Melinda Gates Foundation (BMGF) and the Canadian International Development Agency[6] support iCCM research and scale-up, and many Ministries of Health (MOHs) and non-governmental organizations directly implement iCCM.

Although published evaluations of iCCM operating at scale are forthcoming, a body of peer-reviewed literature from CCM pilots documents a number of factors that contribute to programmatic success. Key studies by Kidane and Morrow,[7] Winch and others,[8] and Barat and Schubert[9] reference the importance of robust quality assurance schemes, appropriate training, and retention of human resources, and uninterrupted drug supply. Conversely, studies by Kelly and others[10] and Nsungwa-Sabiti and others[11] refer to the challenges associated with timely and quality supervision and insufficient community sensitization and dialogue, which have undermined the impact of some programs. Recent systematic literature reviews also show that community health worker (CHW) programs may face political obstacles in environments where CHWs are still seen as a second rate option for service delivery or where mechanisms for their remuneration may cause controversy.[12,13] At the same time, the factors that have facilitated iCCM policy change and scale-up have not been well documented.[14] The evidence suggests that with appropriate support and training, CCM can improve child health outcomes, but that program planners require support to design iCCM programs that are scalable and politically supportable.[15]

In light of existing evidence, we propose that community case management must be designed from a health systems perspective to be successful. Without careful attention to financing, human resources, supply chain management, quality assurance, and other inputs, iCCM programs risk uneven roll out and disappointing results. Creating a new or revitalizing an existing cadre of CHWs, who may or may not become routine health system expenditures, also exposes iCCM to political vulnerability, and program planners require frameworks that justify designing iCCM from an evidence-based perspective.[16] Alternatively, where iCCM is built on top of an existing CHW network, a health systems approach to community-case management can offer insights on how to develop comprehensive service delivery. Given the proliferation of MOHs and development partners implementing iCCM, a shared framework can also improve coordination, communication, and roll out.

To assist in effective design and implementation, we present an interagency framework, in the form of a benchmarks matrix, to ensure key components are addressed throughout the life of an iCCM program. To verify that the achievement of benchmarks produces positive child health outcomes, we also propose a two-tiered set of indicators, including nine global indicators, and 39 country-specific measures to assist in monitoring and evaluation of iCCM.

METHODS

Development of a programmatic tool: iCCM benchmarks. In mid-2008, the United States Agency for International Development (USAID) initiated a consultative process to review policies surrounding and support of iCCM programs. USAID hosted stakeholder meetings to discuss implementation of iCCM and evidence that had been gathered to date on this strategy, at which participants recommended that a group of experts codify and share a list of key components

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TABLE 1

Integrated community case management benchmarks matrix*

Component	Advocacy and Planning	Pilot and Early Implementation	Expansion/Scale-up
1. Coordination and Policy Setting	Mapping of CCM partners conducted	MOH leadership to manage unified CCM established	MOH leadership institutionalized to ensure sustainability
	Technical advisory group established including community leaders, CCM champion, and CHW representation		
	Needs assessment and situation analysis for package of services conducted		
	Stakeholder meetings to define roles and discuss current policies held	Discussions regarding ongoing policy change (where necessary) completed	Routine stakeholders meetings held to ensure coordination of CCM partners
	National policies and guidelines reviewed		
2. Costing and Financing	CCM costing estimates based on all service delivery requirements undertaken	Financing gap analysis completed	Long-term strategy for sustainability and financial viability developed
	Finances for CCM medicines, supplies, and all program costs secured	MOH funding in CCM program invested	MOH investment in CCM sustained
3. Human Resources	Roles of CHWs, communities and referral service providers defined by communities and the MOH	Role and expectations of CHW made clear to community and referral service providers	Process for update and discussion of role/ expectations for CHW in place
	Criteria for CHW recruitment defined by communities and the MOH	Training of CHWs with community and facility participation	Ongoing training provided to update CHW on new skills, reinforce initial training
	Training plan for comprehensive CHW training and refresher training developed including modules, training of trainers, and monitoring and evaluation plan		
	CHW retention strategies, incentive/motivation plan developed	CHW retention strategies, incentive/motivation plan implemented and made clear to CHW; community plays a role in providing rewards, MOH provides support	CHW retention strategies reviewed and revised as necessary. Advancement, promotion, and retirement offered to CHWs who express desire
4. Supply Chain Management	Appropriate CCM medicines and supplies are consistent with national policies and included in the essential drug list	CCM medicines and supplies procured consistent with national policies and plan	Stocks of medicines and supplies at all levels of the system monitored (through routine information system and/or supervision)
	Quantifications for CCM medicines and supplies completed		
	Procurement plan for medicines and supplies developed		
	Inventory control and resupply logistic system for CCM and standard operating procedures developed	Logistics system to maintain quantity and quality of products for CCM implemented	Inventory control and resupply logistics system for CCM implemented and adapted based on results of pilot with no substantial stockout periods
5. Service Delivery and Referral	Plan for rational use of medicines (and RDTs where appropriate) by CHWs and patients developed	Assessment, diagnosis and treatment of sick children by CHWs with rational use of medicines and diagnostics	Timely receipt of appropriate diagnosis and treatment by CHWs made routine
	Guidelines for clinical assessment, diagnosis, management, and referral developed	Review and modify guidelines based on pilot	Regular review of guidelines and modifications as needed
	Referral and counter referral system developed	Referral and counter referral system implemented: community information on where referral facility is made clear, health personnel also clear on their referral roles	CHWs routinely referring and counter referring with patient compliance, information flow from referral facility back to CHW with returned referral slips

(Continued)

Table 1
Continued

Component	Advocacy and Planning	Pilot and Early Implementation	Expansion/Scale-up
6. Communication and Social Mobilization	Communication strategies developed, including prevention and management of community illness for policy makers, local leaders, CHWs, communities, and other target groups	Communication and social mobilization plan implemented	Communication and social mobilization plan and implementation reviewed and refined based on monitoring and evaluation
	Development of CSM content for CHWs on CCM and other messages (training materials, job aids)	Materials and messages to aide CHWs in place	
	Materials and messages for CCM defined, targeting the community and other groups	CHWs dialogue with parents and community members about CCM and other messages	
7. Supervision and Performance Quality Assurance	Appropriate supervision checklists and other tools developed, including those for the use of diagnostics	Supervision visit every 1–3 months, includes reviewing of reports, monitoring of data	CHWs routinely supervised for quality assurance and performance
	Supervision plan, including number of visits, supportive supervision roles, self-supervision established	Supervisor visits community, makes home visits, provides skills coaching to CHWs	Data from reports and community feed-back used for problem solving and coaching
	Supervisors trained in supervision and provided access to appropriate supervision tools.	CCM supervision included as part of the CHW supervisor's performance review	Yearly evaluation that includes individual performance and evaluation of coverage or monitoring data
8. M and E and Health Information Systems	Monitoring framework for all components of CCM developed and sources of information identified	Monitoring framework tested and modified accordingly	Monitoring and evaluation through HMIS data performed to sustain program impact
	Standardized registers and reporting documents developed	Registers and reporting documents reviewed	OR and external evaluations of CCM performed as necessary to inform scale-up and sustainability
	Indicators and standards for HMIS and CCM surveys defined		
	Research agenda for CCM documented and circulated	CHWs, supervisors and M&E staff trained on the new framework, its components, and use of data	

*CCM; community case management; MOH = Ministry of Health; CHW = community health worker; RDTs = rapid diagnostic tests; CSM = communication and social mobilization; M and E; monitoring and evaluation; HMIS = health management information system; OR = operations research.

of successful programs. USAID led the initial effort to specify the components, which resulted in a matrix of iCCM benchmarks. Colleagues from UNICEF, Save the Children, and other members of the iCCM Interagency Task Force[17] finalized the framework's contents and shared them for review with in-country partners.

Proposed benchmarks, grouped into three phases of program evolution: advocacy/planning, pilot/early implementation, and expansion/scale-up are shown in Table 1. We identify eight health systems components: coordination and policy setting; costing and financing; human resources; supply chain management; service delivery and referral; communication and social mobilization; supervision and performance quality assurance; and monitoring and evaluation. These components mirror those of the WHO health systems' building blocks[18] (leadership and governance; health financing; health workforce, quality health services; and drugs, vaccines, and technologies), with the addition of communication/social mobilization and supervision/performance quality assurance. Within each component, we define key activities for each phase of implementation.

In principle, all benchmarks in each phase should be completed before initiating activities in the next column (i.e. the development of a functional logistics and resupply system, which falls under advocacy/planning, should take place before CHWs are actually trained, which falls under pilot/early implementation). In cases where curative interventions are being proposed within the context of existing CHWs, benchmarks in the advocacy/planning phase stress that iCCM costing estimates be based on all service delivery requirements and that CHW training be performed comprehensively. These pre-implementation planning exercises, especially in the context of existing community-based activities, provide the information necessary to decide whether a given setting is appropriate for iCCM implementation.

In addition to recommending a phased approach, the framework aims to mitigate the potential imbalance of budgetary and managerial resources across iCCM. Several aspects of integrated CCM, such as the training and deployment of human resources, typically receive substantial attention from program managers and Ministries of Health, and others, such as supply chain management and supervision, reflect areas where we believe partners should place greater prioritization. In the case of supply chain management, we advocate that iCCM products be included in the national essential medicines list, but also emphasize the establishment of a functional system for the resupply of CHW commodities. Recent research projects, such as the Bill and Melinda Gates Foundation–funded Improving Supply Chains for Community Case Management of Pneumonia and Other Common Diseases of Childhood, have documented limited availability of essential iCCM products at the community level, and only 35–50% of CHWs surveyed having all key drugs in stock on the day of the visit in Malawi, Rwanda, and Ethiopia.[19–21] The benchmarks stress that there is no program without a product, and advocate for investing the resources needed to establish a functional supply chain.

Similarly, in the case of supervision and performance quality assurance, we emphasize that CHWs must be linked to higher levels of the health system by means of designated supervisors. Our framework recommends that CHWs receive clinical supervision once every 1–3 months by a trained supervisor and that supervisory visits be used as mechanisms for quality improvement through coaching, clinical observation and on-the-spot-training. We stress that programs include training in supervision, given that some CCM pilots have found that low competence among CHWs is associated with poor supervisors.[22] Where iCCM has been added to a package of existing community health services, the greatest efforts possible should be made to streamline both training and supervision processes across CHW responsibilities.

Taken together, the benchmarks matrix and its components offer a systematic framework for designing and monitoring CCM. When used as a tool by managers and stakeholders, the benchmarks may improve and simplify the design and roll out of iCCM, offering a globally vetted framework that distributes attention appropriately across community-based health systems.

Development of iCCM benchmarks indicators. A framework may improve planning and implementation, but to verify the effects and impact of iCCM across countries, harmonized indicators are required. The need for a collaborative process to develop CCM indicators based on program experience was first identified in a country exchange meeting in the Democratic Republic of Congo in 2009. Subsequently, the iCCM Task Force supported an interagency effort to develop an accompanying list of benchmark indicators, building upon the work of the CCM Operations Research Group and Save the Children's CCM results framework.[23] The Task Force also used the interagency countdown to 2015 indicators, which provide a measurement approach for benchmarks as achieved on a yes, no, or partial scale.[24] In November 2010, indicators pertaining to the quality of care were refined in a meeting convened by WHO and in June 2012 the full list of indicators was reviewed and finalized. The resulting compendium has nine global indicators for cross-national comparisons, and a list of 39 country-level indicators. The indicators list incorporates input, process, and output and outcome measures, applicable across the life of a program.

In this report, we present and discuss the nine global indicators listed in Table 2, of which there is one or two per benchmark component. A web annex presents a complete list of indicators, including the 39 country-specific measures.[25] Some proposed indicators are currently being used by CCM programs, and other aspects of the framework have required the establishment of new metrics, for which field testing is ongoing. New indicators have been included to draw attention to particular aspects of programs believed to be important. However, if incorporated into national plans, countries will need to invest in systems through which they can be tracked. Country-specific indicators are intended to be incorporated into routine monitoring on an as needed basis, depending on the scale and location of the program. Global indicators are intended to be used by all countries implementing CCM, such that progress can be tracked internationally.

The proposed global metrics used several data collection methods. Medicine and diagnostic availability, routine supervision coverage, and the inclusion of iCCM indicators in the health management information system can be gathered through supervision records, CHW surveys or review of HMIS documents. Other global indicators, such as caregiver knowledge of illness signs and treatment coverage, necessitate household surveys. Given that CCM-specific questions are just beginning to be integrated into the Demographic and Health Surveys and Multiple-Indicator Cluster Surveys, we propose that evaluators work with partners to devise an appropriate mixture

TABLE 2

Integrated community case management benchmarks global indicators list*

Component	Indicator	Definition	Metric
Coordination and Policy Setting	CCM policy	CCM is incorporated into national MNCH policy/guideline(s) to allow CHWs to give: • low osmolarity ORS and zinc supplements for diarrhea; • antibiotics for pneumonia • ACTs (and RDTs, where appropriate) for fever/malaria in malaria-endemic countries	**Yes:** National policy guidelines allow CHWs to provide treatment in line with WHO recommendations for all relevant conditions **Partial:** National policy guidelines allow CHWs to provide treatment in line with WHO recommendations for at least one but not all relevant conditions **No:** No national policy guidelines exist that support CCM in line with WHO recommendations
Costing and Financing	Annual CCM costed operational plan	A costed operational plan for CCM exists and is updated annually	**Yes:** A costed operational plan/work plan for CCM for all relevant conditions† exists (or is part of a broader health operational plan) and is updated annually **Partial:** a) A costed CCM plan exists including at least one relevant health condition OR b) A costed CCM work plan exists but is not updated on an annual basis **No:** No costed plans for CCM are available for any relevant health condition
Human Resources	Targeted CHWs providing CCM	Proportion of CHWs targeted for CCM that are trained and providing CCM	**Numerator:** Number of CHWs targeted for CCM‡ that are trained and can provide evidence of providing CCM services in the last three months **Denominator:** Total number of CHWs targeted for CCM
Supply Chain Management	Medicine and diagnostic availability	Proportion of CCM sites with all key CCM medicines/diagnostics in stock§	**Numerator:** Number of CCM sites with all key CCM medicines/diagnostics in stock **Denominator:** Total number of CCM sites either visited or reporting on their stocks
Service Delivery and Referral Service Delivery and Referral	Treatment coverage	Proportion of sick children who receive timely and appropriate treatment¶	**Numerator:** Number of children under five with a CCM condition‖ that received timely and appropriate treatment **Denominator:** Number of children under five with a CCM condition
Communication and Social Mobilization	Caregiver knowledge of illness signs	Proportion of caregivers who know two or more signs of childhood illness that require immediate assessment/treatment	**Numerator:** Number of caregivers who can correctly state two or more signs of childhood illness that require immediate assessment/treatment **Denominator:** Total number of caregivers interviewed
Supervision and Performance QA	Routine supervision coverage	Proportion of CHWs who received at least one administrative supervisory contact** in the last three months	**Numerator:** Number of CHWs who received at least one supervisory contact in the last three months **Denominator:** Total number of CHWs trained in and deployed for CCM††
	Correct case management (knowledge)	Proportion of CHWs who demonstrate correct case management knowledge‡‡	**Numerator:** Number of CHWs who correctly manage sick child case scenarios **Denominator:** Total number of CHWs assessed

(Continued)

Table 2
Continued

Component	Indicator	Definition	Metric
Monitoring & Evaluation and Health Information Systems	National monitoring and evaluation plan for CCM	Existence of a comprehensive, integrated monitoring and evaluation (M&E) plan for CCM	**Yes:** An M&E plan for CCM has all critical components and covers all relevant CCM conditions. Critical components of an M&E plan include: program goals and objectives, indicators to be measured, data collection methodologies and frequency, and mechanisms for dissemination/use of information **Partial:** M&E plan exists but has only some critical components or does not cover all CCM conditions **No:** Either a CCM M&E plan exits, but has no critical components, or no written M&E plan that covers CCM exists

*CCM = community case management; MNCH = maternal, newborn, and child survival; CHW = community health worker; ORS = oral rehydration salts; ACTs = artemisinin-based combination therapies; RDTs = rapid diagnostic test; WHO = World Health Organization; QA = quality assurance; HMIS = health management information system.
†Relevant conditions specified by country policy or implementation status.
‡The number of targeted CHWs should be specified in the country's national CCM plan.
§Key products defined by country policy; this indicator can be measured as on the day of assessment visit or on the last day of the reporting period.
¶This indicator is measured through maternal recall in household surveys and usually specifies a time period in the last two weeks.
‖CCM conditions include diarrhea, suspected pneumonia, or malaria in malaria-endemic areas.
**An administrative supervisory contact should include registers and/or reports being reviewed.
††If this indicator is measured through a survey rather than administrative records, the denominator should be amended to represent the total number of CHWs interviewed.
‡‡This can be measured by either individual CHWs or by CHW service delivery point.

of data collection methods that work best on a country-by-country basis. As the level of community-based data available increases, the iCCM Task Force will refine data collection methodologies and revise the list accordingly.

RESULTS

Beta versions of the benchmarks and indicators have been piloted in a variety of countries as part of both the design and monitoring and evaluation of iCCM. Thus far, these tools have accompanied the presence of external technical assistance, although we believe that both could be translated and used locally as part of routine program management. The benchmarks have been used in development of the USAID/President's Malaria Initiative-supported iCCM program in Mali, as well as the framework for USAID/President's Malaria Initiative iCCM documentations in Senegal, the Democratic Republic of Congo, and Malawi. A select number of benchmarks indicators have also been used in a study of the quality of care of iCCM in Malawi by Johns Hopkins University, the Malawian Ministry of Health, WHO, and UNICEF, as well as in Save the Children projects in Ethiopia and Zambia.

In the USAID Senegal documentation, a review of iCCM benchmarks performance highlighted many success factors, but also showed the need to stress routine supervision and improve functionality of the community-based supply chain. In the case of Malawi, a review guided by the framework indicated a need for action to be taken in the areas of financing and human resources. The USAID-funded Child Survival and Health Grants Program is also undertaking a review of 17 CCM projects in 12 countries (Sudan, Benin, Niger, Nepal, Uganda, Zambia, Burundi, Liberia, Afghanistan, India, Ethiopia, and Rwanda), which is likely to produce a significant amount of data on benchmark performance across countries and provide useful feedback on the framework itself.

The iCCM indicators are also now being used across agencies and implementing partners. In a Save the Children program in Ethiopia, many indicators are being tracked at the project level and have received high ratings; however, indicator performance in service delivery has shown room for improvement. Similarly, in the case of the Senegal, high marks were received in government commitment to iCCM and financing from donor agencies, but weaknesses in quality and service delivery were observed, particularly in CHWs' knowledge regarding the correct management of diarrheal disease.[26] Indicators included in the Johns Hopkins University quality of care evaluation showed that CHWs in Malawi also showed relatively low levels of correct counseling on the treatment of diarrheal disease. However, other skills in Malawi were better developed, such as the correct prescription of artemisinin-based combination therapies for the treatment of malaria.[27]

Results of implementation of benchmarks and indicators have been consistent with our *ex ante* predictions; namely, that there has been a great deal of progress made in the financial and political commitments to CCM, but there is room for improvement in supervision and quality assurance, as well as supply chain management. These asymmetrical outcomes highlight the importance of examining iCCM from a systems perspective, and caution against evaluations that examine only one or two program components, which may miss the broader context and fail to offer comprehensive recommendations.

DISCUSSION

Because of the relatively recent phenomenon of iCCM operating at a national scale, benchmarks and indicators will continue to be tested and refined on an ongoing basis. The full list of iCCM indicators are being formally assessed in Mali and Malawi as part of the USAID Translating Research into Action Project, which should offer additional information on the extent to which they can be integrated into national monitoring plans. In the meantime, we propose that these tools and metrics be incorporated into the planning and evaluation of CCM in a manner that is financially feasible and context-specific, while providing room for flexibility, adjustment, and continuous feedback from the field.

Despite the need for ongoing research, we propose that a systems approach is an effective method for designing and evaluating iCCM. Evaluations of CCM pilots have documented the importance of various health systems inputs in facilitating success, and recent evaluations of iCCM operating at scale emphasize the need to review programs holistically.[28] The iCCM benchmarks framework provides such an approach, outlining components that span the health system, and codifying various steps that managers should follow throughout the course of design and implementation. In addition, the iCCM indicators offer a mechanism for verifying that the achievement of benchmarks results in positive health outcomes.

In a global environment in which CCM programs are proliferating within and across countries, a coordinated approach to iCCM and how to measure it has the potential to facilitate global implementation. Designed with input from a wide variety of donor agencies and implementing partners, we believe that the iCCM benchmarks and indicators can assist in the effective design, implementation, and monitoring and evaluation of CCM. As more data from evaluations of CCM becomes available, we plan to revise the framework and indicators as necessary, with the goal of providing state of the art guidance to program managers and evaluators alike.

Received December 4, 2011. Accepted for publication February 18, 2012.

Note: Web Annex (Supplementary Table 3) appears online at www.ajtmh.org.

Acknowledgments: Development of the iCCM benchmarks and indicators has been an interagency process, and we thank the following persons for their contributions to this effort (in alphabetical order by affiliation). Tim Williams (John Snow International); Theresa Diaz, Ngashi Ngongo, Nicholas Oliphant, and Mark Young (United Nations Children's Fund); Kamden Hoffmann (United States Agency for International Development/University of Pittsburgh); Mary Hamel and Alex Rowe (Centers for Disease Control and Prevention); Heather Casciato and Katherine Farnsworth (United States Agency for International Development Maternal and Child Health Integrated Project); and Samira Aboubaker, Bernadette Daelmans, Franco Pagnoni, and Cathy Wolfheim (World Health Organization).

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 77–84
doi:10.4269/ajtmh.2012.11-0747

Beyond Distance: An Approach to Measure Effective Access to Case Management for Sick Children in Africa

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Abstract. Health planners commonly use geographic proximity to define access to health services. However, effective access to case management requires reliable access to a trained, supplied provider. We defined effective access as the proportion of the study population with geographic access, corrected for other barriers, staffing patterns, and medicine availability. We measured effective access through a cross-sectional survey of 32 health facilities in Malawi, Mali, and Zambia and modeled the potential contribution of community case management (CCM). The population living within Ministry of Health (MOH)–defined geographic access was 43% overall (range = 18–52%), but effective access was only 14% overall (range = 9–17%). Implementing CCM as per MOH plans increased geographic access to 63–90% and effective access to 30–57%. Access to case management is much worse than typically estimated by distance. The CCM increases access dramatically, again if providers are available and supplied, and should be considered even for those within MOH-defined access areas.

INTRODUCTION

Malaria, pneumonia, and diarrhea remain the leading causes of death in children less than five years of age globally, despite the availability of effective and affordable treatments.[1–5] Children need reliable access to case management for these illnesses because they can become ill at any time and die quickly. Access is often defined and measured by Ministries of Health (MOHs) and program planners in geographic terms, namely distance to a health facility.[6,7] However, even families with geographic access can face other barriers such as those that are physical (mountains, rivers), temporary (flooding, rains), security, cultural, social and economic.[8,9] The normative definition of access better suits preventive than curative interventions because under-staffed and under-supplied facilities can serve as staging points for outreach teams that bring their own personnel to deliver interventions. However, to provide case management, a health facility must be open daily and for sufficient duration; staffed with persons trained to treat sick children; and supplied with essential frontline treatments.

There is no single agreed framework or even definition for access to health care.[8–11] Terms such as access, accessibility, and availability are used commonly but inconsistently.[11] Many theories and frameworks have been developed to better define and standardize what is meant by access to care, but none have been fully adopted.[9,11] A point of consistency across these various theories and framework is the notion that access to health care is multi-dimensional and requires interplay of demand and supply side factors.[8–11] In this study, we focused on the supply side, exploring factors that influence travel to a health facility and receiving treatment services once there.

We coined the term effective access to case management of child illness to mean access to a trained provider and to appropriate medicines. The primary purpose of our study was to measure levels of effective access to case management of child illness at health facilities in Malawi, Zambia, and Mali and to describe the influence of selected factors on effective access. A secondary purpose was to explore the potential contribution of community case management (CCM), in which community-based health workers (CBHWs) are trained and equipped to provide case management for common child illnesses closer to the home.

MATERIALS AND METHODS

Study site and context. The study was conducted in three districts, one each in Malawi, Mali, and Zambia, where Save the Children (SC) supports the MOH to improve integrated case management services at the community level (Table 1). All study areas are rural and under-served and have limited roads, public transportation, and electricity. Our study focused on public health facilities that provided case management services for children less than five years of age. The MOH definition of access to health care varied: ≤ 5 km (Zambia) versus ≤ 8 km (Malawi) versus ≤ 10 km (Mali). In Zambia and Malawi, facility-based health services were managed at the district level and provided free. In Mali, health facilities were managed by local health committees who charged user fees to deliver and maintain services. All three districts lacked private sources of standard case management. Data collection for the study was completed as part of routine programmatic activities and did not involve the collection of any individual identifiable data.

The design and implementation stage of CCM programs varied by country. In Malawi, the MOH was scaling up CCM through a cadre of paid, centrally recruited health surveillance assistants (HSAs) and targeting hard-to-reach areas (> 8 km from a health facility). In Zambia, CCM was delivered through unpaid community health workers selected by their communities, although the policy was under review. In Mali, the MOH recently created a new cadre of paid, CBHWs, Agents de Santé Communautaire, to deliver CCM supported through local health committees.

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TABLE 1
Characteristics of the study districts*

Parameter	Malawi	Mali	Zambia
District	Mulanje, Southern Region	Bougouni, Sikasso Region	Lufwanyama, Copperbelt Province
Population (source year)	525,429 (2008 census)	459,509 (2009 census)	87,592 (2010 census)
Size (population density/km^2)	2,056 km^2 (256)	20,028 km^2 (23)	8,774 km^2 (10)
Ministry of Health definition of access	≤ 8 km	≤ 10 km	≤ 5 km
Health facility infrastructure	23 facilities (1 district hospital, 1 mission hospital, 18 health centers, 2 dispensaries, and 1 maternity center)	140 facilities (1 district hospital, 34 health centers, and 105 maternity centers)	15 facilities (11 health centers and 4 health posts)
CBHW cadre for CCM	Health surveillance assistants (HSAs) centrally recruited and assigned to hard-to- reach areas (> 8 km from HF); Each HSA serves approximately 1,000–1,500 population	Newly introduced cadre Agent de Santé Communautaire recruited by local government/health committees to serve areas > 5 km from health facility and with a population of at least 1,500	CHWs and/or TBAs, both which are identified by communities, trained centrally for 6 weeks to serve hard to reach communities in clinic catchment areas. A CHW is expected to cater for a population of 1,000, and a TBA serves 500
Age group and conditions covered by CCM	Treat children 2–59 months of age for malaria (ACTs), pneumonia (cotrimoxazole) and diarrhea (ORS and zinc)	Treat children 2–59 months of age for malaria (ACTs), pneumonia (amoxicillin) and diarrhea (ORS and zinc)	Treat children 2–59 months of age for malaria (ACTs), pneumonia (amoxicillin) and diarrhea (ORS and zinc)
No. CBHWs trained in CCM at time of study	81	35	59

*CBHW = community-based health worker; CCM = community case management; HF = health facility; CHW = community health worker; TBAs, traditional birth attendants; ACT = artemisinin-based combination therapy; ORS = oral rehydration salts.

Study design and sampling. We conducted a cross-sectional assessment of health services in study areas, including all 15 health facilities in Lufwanyama, Zambia; all 10 health centers in the SC intervention areas of Mulanje, Malawi (representing approximately half the district population and health facilities); and all seven health centers in the health zones of Bougouni, Mali, where SC was implementing CCM (representing nearly one-third of the district's population).

Study tools and data collection. Save the Children staff collected data through structured interviews with the health facility in-charge and other staff during July–October of 2010 as part of baseline assessments and program planning. Relevant district authorities granted permission, and all respondents provided consent upon being informed of the study purpose.

We designed survey tools to collect the following information at each facility: number of staff trained in case management of childhood illness; number of hours during the previous week the trained staff was available (either on-site or on-call) to provide case management; and availability of first-line antimalarial drugs (artemesinin-based combination therapy), antibiotics (amoxicillin or cotrimoxazole) and oral rehydration salts. In Malawi and Mali, we determined the number of stockout days for each medicine in the last month. In Zambia, we observed availability on the day of the survey. Respondents also listed all villages in their catchment area, specifying for each total population, distance to health facility in kilometers, and presence of CBHWs providing CCM either then or in the near future. For villages with MOH-defined geographic access, we assessed other barriers that would affect reaching a health facility: permanent physical (mountains, rivers), temporary physical (flooding), and security (check-points, insecure areas). Permanent physical barriers referred to features such as mountains or rivers that increased travel time by foot (carrying a sick child) beyond the times implied by the MOH distance definitions (e.g. > 1 hour for 5 km, > 1.5 hours for 8 km, or > 2 hours for 10 km). For temporary physical or security barriers, respondents estimated the number of months per year that travel to the facility was affected.

Data analysis. Data were entered in Microsoft (Redmond, WA) Excel (Malawi/Zambia) and Microsoft Access (Mali) and analyzed by using Microsoft Excel. We defined geographic access as the proportion of the total study population living within the MOH-defined distance to a health facility. We then calculated an annualized adjustment factor to account for other barriers to reaching a health facility for this population. This factor was the proportion of annual person-months the population with official access actually had access to the facility after accounting for permanent and temporary physical barriers or security barriers. The denominator of annual person-months was the study population living within MOH-defined access areas multiplied by 12 months.

The numerator was the denominator minus the number of person-months over a 12 month period during which access was affected by any of the barriers. We then multiplied geographic access by the annualized adjustment factor to obtain adjusted geographic access.

We defined effective access as adjusted geographic access to a facility plus available trained staff, with available essential frontline medicines. Thus, effective access was the product of (adjusted geographic access) × (staff availability) × (medicine availability). Staff availability was the proportion of time one or more staff trained in case management was available. The numerator was the total number of hours a trained provider was available, within the denominator of the 84 hours defined by 8:00 AM to 8:00 PM seven days per week. The definition of medicine availability varied by setting. In Malawi and Mali, medicine availability was calculated as100% less the sum of reported stockout days in the past month for three essential case management medicines (artemisinin-based combination therapy, antibiotic, and oral rehydration salts) divided by a total of 90 potential stock-out days (three medicines × 30 potential stock-out days/medicine) expressed in percentage. In Zambia,

TABLE 2
Geographic and adjusted geographic access by study area

Parameter	Mulanje, Malawi	Bougouni, Mali	Lufwanyama, Zambia
Health facilities sampled	10	7	15
Study population*	269,305	147,095	119,799†
Population within Ministry of Health–defined access limits (access limit)	133,657 (≤ 8 km)	76,573 (≤ 10 km)	22,148 (≤ 5 km)
Geographic access	50%	52%	18%
Population affected by permanent physical barriers (no. months affected)	2,735 (12 months)	0	2,756 (12 months)
Additional population affected by temporary physical barriers (no. months affected)	802 (5 months)	1,498 (3 months) 1,363 (2 months)	0
Population affected by security barriers	0	0	0
Total no. person-months affected over one year	36,830	7,220	33,072
Annualized adjustment factor‡	98%	99%	88%
Adjusted geographic access	48%	52%	16%

*Based on facility estimates of their catchment population.
†Lufwanyama facilities use headcount figures for population estimates that tend to be higher than official census figures.
‡Calculated among the proportion of the population with geographic access. Denominator = population within Ministry of Health–defined access limits × 12 months; numerator = denominator – number of person-months affected by physical, cultural, or security barriers.

medicine availability was 100% less the sum of the number of health facilities with stockouts for each type of medicine divided by the total number of health facilities times the number of medicines (15 health facilities × same three medicines) expressed as a percentage. All access variables were calculated for each health facility and then for each study area by weighting each health facility's value according to its population size.

To explore the potential contribution of CCM, we calculated the proportion of the study population with potential geographic access and with potential effective access to case management once CBHWs trained in case management were deployed. In each study area, we used MOH data on the number and location of CBHWs already trained or scheduled for training in CCM. We ran two scenarios. The first assumed that deployed CBHWs would be available continuously and fully stocked with necessary medicines (ideal), and the second applied levels of likely availability of CBHWs (75%) and medicines (60%) based on data from separate monitoring studies conducted around the same time (U.S. Agency for International Development/Malawi Community Case Management Evaluation).

RESULTS

The catchment areas of the 32 surveyed health facilities included 541 villages with a population of 536,199. Our sample represents approximately half of the combined population of the three study districts. The impact of geographic and other factors that influence reaching a health facility is shown in Table 2. More than half (57%) of the total study population lived beyond MOH-defined access limits, which varied from ≤ 5 km in Zambia to ≤ 10 km in Mali. Among those with geographic access, other barriers such as mountains or rivers and temporary factors like flooding had little additional effect on access. Only 4% (range = 3–12% by district) of those living within MOH-defined access areas across study districts were affected by year-round or temporary physical barriers. Security barriers were not reported for any village in the study.

Although nearly all health facilities were mandated to provide case management, availability of trained staff was uneven (Table 3). In Mulanje, trained staff was available an average of 30 hours per week across facilities, and only 36% were available the desired 84 hours/week. In Bougouni, staff availability varied highly across facilities (range = 6–99%). In Lufwanyama, four facilities had no staff trained in case management, and one facility reported a single trained staff member who was absent the entire week before data collection; staff availability in the remaining 10 facilities ranged from 36% to 88%.

Frontline medicines for case management of malaria, pneumonia, and diarrhea were available in most facilities in Mulanje and Lufwanyama. In Mulanje, five health centers had stockouts in the previous 30 days, mostly for oral rehydration

TABLE 3
Staff availability and medicine availability at health facilities by study area*

Parameter	Mulanje, Malawi	Bougouni, Mali	Lufwanyama, Zambia
Health facilities sampled	10	7	15
No. HFs with ≥ 1 staff trained in case management	9	7	12
Total no. staff trained in case management available across HFs	18	8	16
Average hours per week CM services available	30	36	45
Staff availability†	36%	42%	47%
No. HFs with stockouts (total no. stockout days)			
ACTs	1 (3)	7 (185)	0 (NA)
Antibiotics	1 (5)	0	2 (NA)
ORS	4 (62)	1 (30)	0 (NA)
Medicine availability‡	91%	66%	93%

*HF = health facility; CM = case management; ACT = artemisinin-based combination therapy; ORS = oral rehydration salts.
†Denominator = 7 days × 12 hours = 84 hours/week.
‡Malawi and Mali calculation: (Total no. stockout days for all medicines/total no. potential stockout days, where total no. stockout days = 30 days × 3 medicines); Zambia calculation: (Total no. health facilities with stockout × no. medicines with stockouts/no. health facilities × no. medicines).

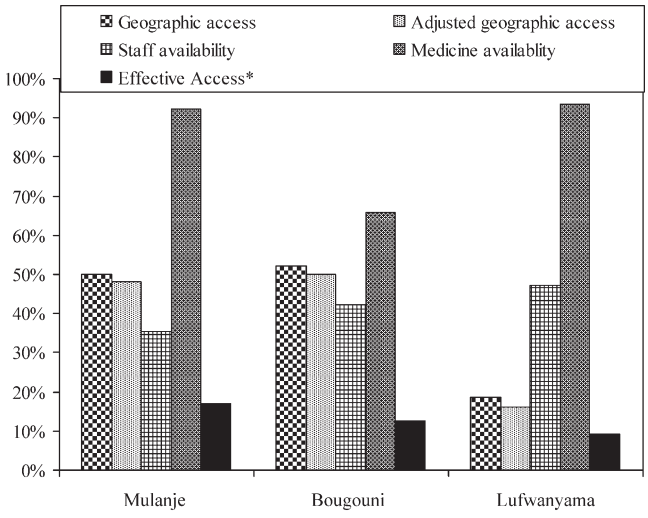

FIGURE 1. Effective access to case management for childhood illness at facility level by study area.

salts and ranging from 14 to 21 days. In Lufwanyama, two facilities lacked amoxicillin on the day of the survey. Stockouts for antimalarial drugs were pervasive in health facilities in Bougouni, where all seven facilities reported stockouts of antimalarial drugs in the past 30 days (average = 26 days).

Effective access. Effective access was low (< 20%) in all settings (Figure 1). Full details by facility are shown in Table 4. In Mulanje, half of the study population had geographic access, but case management was only available at the facilities 34% of the time, mainly because of shortages of trained staff; medicines for case management were generally available. As a result, effective access was only 17%, just one-third of geographic access.

Similar patterns were observed in Bougouni. Effective access was only 13%, just 25% of geographic access. Among the population within 10 km of a health facility with no additional barriers, access to a trained provider equipped with all necessary medicines to treat malaria, pneumonia, and diarrhea was available only 24% of the desired time. In Lufwanyama, the overall pattern of access was also similar, but a greater proportion of the population did not have geographic access, partly because of the stricter MOH definition of access. Among those living within 5 km of a health facility, access to trained staff averaged approximately 47%, which was higher

TABLE 4
Access indicators and effective access by study district and health facility

District and health facility	Total population	Geographic access	Annualized adjustment factor	Adjusted geographic access	Staff availability	Medicine availability	Effective access
Mulanje, Malawi							
Mulomba	51,067	23%	100%	23%	33%	100%	8%
Thuchira	34,072	65%	93%	60%	36%	97%	21%
Bondo	21,670	28%	82%	23%	42%	79%	8%
Mimosa	22,655	71%	100%	71%	37%	78%	21%
Mpala	25,494	82%	98%	80%	50%	100%	40%
Chambe	45,968	40%	100%	40%	42%	77%	13%
Dzenje	8,583	86%	100%	86%	0%	0%	0%
Kambenje	21,854	46%	100%	46%	42%	92%	18%
Milonde	14,833	28%	100%	28%	33%	100%	9%
Chinyama	23,109	72%	100%	72%	41%	100%	30%
Total	269,305	50%	98%	48%	36%	92%	17%
Bougouni, Mali							
Keleya	25,515	56%	98%	55%	99%	67%	36%
Domba	11,773	34%	100%	34%	19%	67%	4%
Koumantou	28,542	44%	100%	44%	6%	67%	2%
Faragouaran	15,086	54%	97%	52%	40%	83%	18%
Bougouni-ouest	28,367	61%	100%	61%	32%	67%	13%
Garalo	18,457	42%	100%	42%	93%	33%	13%
Kologo	19,355	66%	99%	65%	7%	78%	4%
Total	147,095	52%	99%	52%	42%	66%	13%
Lufwanyama, Zambia							
Bulaya	4,503	14%	100%	14%	88%	100%	13%
Chikabuke	3,416	30%	100%	28%	36%	100%	11%
Chinemu	11,585	21%	100%	18%	76%	100%	16%
Fungulwe	5,345	23%	81%	23%	88%	100%	17%
Kapilamikwa	5,800	14%	0%	14%	0%	100%	0%
Lumpuma	6,107	26%	100%	26%	88%	100%	23%
Mibenge	4,142	34%	100%	34%	0%	100%	0%
Mibila	10,500	7%	100%	7%	0%	100%	0%
Mukumbo	10,859	20%	89%	20%	88%	100%	16%
Mukutuma	5,752	7%	100%	7%	0%	67%	0%
Mushingashi	13,382	11%	34%	11%	52%	100%	2%
Nkana	4,917	65%	100%	0%	48%	100%	31%
Shimukunami	9,272	33%	84%	32%	67%	100%	18%
St. Joseph's	10,353	11%	100%	11%	76%	100%	8%
St. Mary's	13,866	5%	100%	5%	0%	67%	0%
Total	119,799	18%	88%	16%	47%	93%	9%

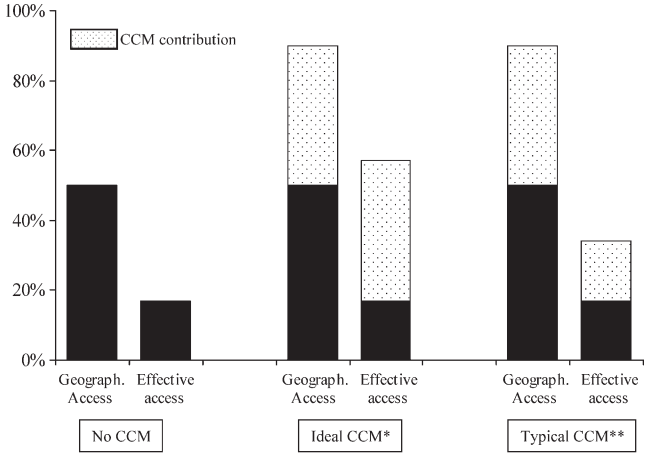

FIGURE 2. Model of geographic (geograph.) and effective access to integrated case management for childhood illness with community case management (CCM) implemented according to Ministry of Health (MOH) plans in Mulanje study area. CBWWs = community-based health workers.

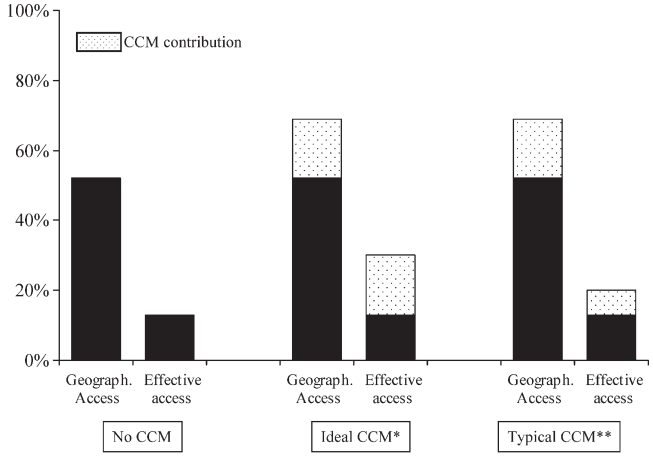

FIGURE 3. Model of geographic (geograph.) and effective access to integrated case management for childhood illness with community case management (CCM) implemented according to Ministry of Health (MOH) plans in Bougouni study area. CBWWs = community-based health workers.

than the other study areas. In total, effective access was only 50% of MOH-defined access.

Potential contribution of CCM. Results for Mulanje are shown in Figure 2. The addition of the 81 CBHWs trained in CCM increased the proportion of the population with potential geographic access to case management in Mulanje from 50% to 90%. The ideal CCM scenario where CBHWs are always available and fully stocked showed that potential effective access overall tripled from 17% to 57%. However, the addition of CCM in the hard-to-reach areas alone did not address the limited availability of trained staff and supplies at the health facility. As a consequence, there was a facility service gap for the 50% of the population who had MOH-defined access, constraining potential effective access for the total population. Potential effective access under typical CCM conditions in Mulanje (75% availability of CBHWs and 60% availability of medicines) reached 35%, barely half of the ideal CCM scenario, but twice the level without CCM. The addition of CCM as per MOH plans in Bougouni and Lufwanyama increased potential geographic access to 69% and 63% and potential effective access under ideal CCM conditions to 30% and 58%, respectively; full details are shown in Figures 3 and 4 and Table 5.

DISCUSSION

This study showed that official measures of access based on distance overestimate the proportion of the population with access to integrated case management by between two- and three-fold. The distinction between access to a service site and access to life-saving case management cannot be overstated. Access to a trained provider supplied to treat malaria, pneumonia, and diarrhea was less than one-third among those who lived within MOH-defined access areas.

Effective access is the product of several factors, low levels of most will yield a low overall value. In our study, limited availability of trained staff at health facilities in particular translated into low effective access. Even if all necessary medicines were available at the health facilities studied, effective access would remain less than 20% for the total population and range between 28% and 48% for those living within the MOH-defined access across the study areas. A simultaneous household survey in Lufwanyama District showed that the proportion of children receiving antibiotics for likely pneumonia (13%) and fever/malaria (12%) was nearly equal the level of effective access (9%) and was much lower than the proportion who reported seeking care for these illnesses, highlighting the gaps at facility level (Yeboah-Antwi K and others, unpublished data). Families may consider what care may or may not be available at a health facility before committing their time and resources to care-seeking. The poor human resource availability at health facilities in developing countries is well documented.[7,12–14] A recent study in Malawi reported that only 49% of the expected clinical staff was available in

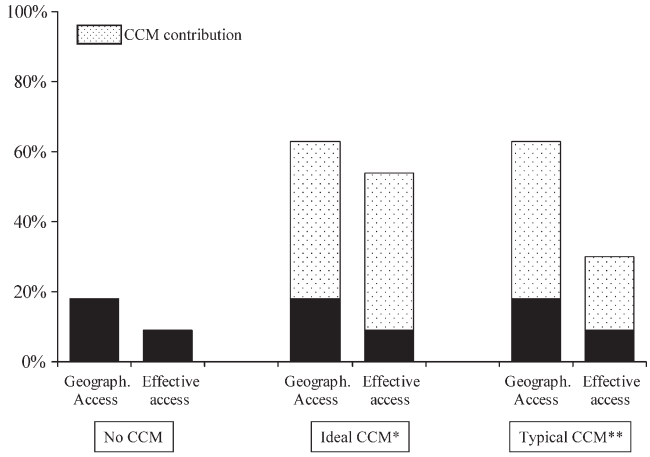

FIGURE 4. Model of geographic (geograph.) and effective access to case management for childhood illness with community case management (CCM) implemented according to Ministry of Health (MOH) plans in Lufwanyama study area. CBWWs = community-based health workers.

TABLE 5
Geographic access and effective access with addition of CBHWs trained in CCM by study district and health facility*

District and health facility	Total population	Geographic access, no CCM	Effective access, no CCM	CBHWs trained in CCM	Potential geographic access	Potential effective access, ideal†	Potential effective access, typical‡
Mulanje, Malawi							
Mulomba	51,067	23%	8%	16	80%	65%	33%
Thuchira	34,072	65%	21%	11	99%	54%	36%
Bondo	21,670	28%	8%	9	100%	79%	40%
Mimosa	22,655	71%	21%	2	80%	29%	24%
Mpala	25,494	82%	40%	4	100%	58%	48%
Chambe	45,968	40%	13%	18	88%	61%	34%
Dzenje	8,583	86%	0%	1	100%	14%	6%
Kambenje	21,854	46%	18%	10	99%	70%	41%
Milonde	14,833	28%	9%	5	81%	62%	33%
Chinyama	23,109	72%	30%	5	87%	45%	36%
Total	269,305	50%	17%	81	90%	57%	35%
Bougouni, Mali							
Keleya	25,515	56%	36%	6	73%	53%	44%
Domba	11,773	34%	4%	4	47%	17%	10%
Koumantou	28,542	44%	2%	5	61%	19%	9%
Faragouaran	15,086	54%	18%	3	60%	24%	20%
Bougouni-ouest	28,367	61%	13%	5	75%	27%	20%
Garalo	18,457	42%	13%	6	63%	34%	22%
Kologo	19,355	66%	4%	6	94%	31%	16%
Total	147,095	52%	13%	35	69%	30%	21%
Lufwanyama, Zambia							
Bulaya	4,503	14%	13%	4	59%	58%	33%
Chikabuke	3,416	30%	11%	1	48%	29%	19%
Chinemu	11,585	21%	16%	2	79%	74%	42%
Fungulwe	5,345	23%	17%	2	70%	63%	38%
Kapilamikwa	5,800	14%	0%	2	74%	60%	27%
Lumpuma	6,107	26%	23%	6	70%	67%	43%
Mibenge	4,142	34%	0%	4	100%	66%	30%
Mibila	10,500	7%	0%	4	100%	93%	42%
Mukumbo	10,859	20%	16%	2	39%	35%	25%
Mukutuma	5,752	7%	0%	1	11%	4%	2%
Mushingashi	13,382	11%	2%	6	19%	10%	6%
Nkana	4,917	65%	31%	0	65%	31%	31%
Shimukunami	9,272	33%	18%	5	52%	38%	27%
St. Joseph's	10,353	11%	8%	10	70%	67%	35%
St. Mary's	13,866	5%	0%	10	91%	86%	39%
Total	119,799	18%	9%	59	63%	54%	30%

*CBHW = community-based health worker; CCM = community case management.
†CBHWs are always available and have all three drugs in stock 100% of the time.
‡CBHWs are available 75% of the time and have all three drugs in stock 60% of the time.

health centers because of unfilled positions and to staff absences related to trainings and leave time.[14]

At the time of the study, medicine availability on the whole was quite good at the health facilities we assessed. However, medicine stocks fluctuated and lengthy stockouts were common, as shown by antimalarial drug stockouts in Bougouni and other studies in Malawi and Zambia.[14,15] In Lufwanyama, we measured availability of medicines on the day of the survey and did not capture reports of stockouts; and in Mulanje and Bougouni, a stockout of one of the three medicines only contributed one-third of a stockout day. Thus, we may have overestimated the availability of medicines.

We did not commonly identify permanent or temporary physical barriers or security barriers to reaching the facilities in these study districts. In other settings, such as South Sudan where rainy seasons are lengthy and disruptive or Somalia where insecurity is rife, these barriers would be more important. In the few study areas that did report additional year-round or temporary physical barriers, they often affected most of a given facility's catchment area, highlighting the importance of identifying such areas so that solutions can be tailored.

This study showed that even those living near health facilities often lacked access to trained staff and medicines. These observations can help explain the often contradictory findings regarding influence of distance on access to health care and shed light on why those living nearby facilities still face poor health outcomes.[8,16–18] These findings reinforce the need to consider options to mitigate access barriers for those living within MOH-defined access areas. In instances where staffing problems are caused by lack of training in case management (as opposed to staffing shortages and operational hours), training of existing staff in IMCI is sensible. However, addressing staff shortages at health facilities will take more time and resources. The CBHWs can be trained to treat common childhood illness in as little as six days, but CCM involves similar if not greater inputs for supply chain management and supervision. Typically, CCM programs target communities beyond the MOH-defined access areas, but MOHs could consider redefining the catchment areas so that more CBHWs could be deployed, even in areas traditionally considered to have access as a complementary strategy to help ensure reliable access to case management. Families living at the margins of these MOH-defined access areas often have

limited alternatives for care and venturing on foot even 4 or 5 km to seek care is a significant time and resource gamble.

Our exploration of the potential contribution of CCM showed that training CBHWs to provide case management nearer to the home can reduce the geographic barriers for those living beyond the traditional access areas. However, the modeled results depended on the MOH implementation plan, underscoring the need to ensure that CCM policy makers, planners, and managers consider how to optimize distribution and availability of CBHWs within defined target areas. Furthermore, our study showed that under typical conditions of CCM programming at scale CBHWs are not always available because of other responsibilities or turnover and stockouts can be common. Thus, the potential increase in effective access from CCM is not fully realized. In Malawi for example, CBHWs (HSAs) are encouraged by the MOH to operate their village health clinics for at least two days per week, in recognition of the other tasks HSAs are expected to perform. In addition, although HSA basic training guidelines request HSAs to reside in their catchment areas, this requirement is not consistently enforced, and hard-to-reach areas targeted for integrated CCM (iCCM) tend to be the most difficult to staff. The competing demands on HSAs' time, combined with the reality that many do not reside in their catchment areas, limit the availability of case management at the community level in Malawi. Policies that support availability of CBHWs to deliver CCM on a routine basis, including for emergencies after hours and on weekends, are needed to help protect against erosion of services.

Another challenge concerns medicine availability. At present, iCCM programs in most settings are supported by partners who provide additional inputs, such as medicines and support to the government supply chain to improve medicine availability at the community level. As a result, availability of medicines for iCCM in areas wholly dependent on government supply chain would in some settings likely be even lower than the 60% we modeled. Strategies for supply chain management and effective human resources management for CCM programs operating at scale are essential to optimize the returns on investments in CCM.

We designed a simple, rapid method to measure effective access to iCCM that can be conducted by program planners with limited time and financial resources. Although more sophisticated methods exist to precisely measure distance to a health facility and to quantify other access barriers, they require additional human and financial resources and may be more difficult to communicate to decision-makers.[19,20] Our experience in Malawi demonstrated that the process of systematically considering access barriers for each village within a facility catchment area was valued by district health officials and led to areas not previously considered hard-to-reach being so identified and targeted for CCM (Chimuna T, unpublished data).

The study has limitations. The study settings were underserviced, rural districts of three countries in Africa where availability of facilities, trained staff, and supplies were probably lower than typical. Governments often ask implementing partners to program in under-served areas. The study was cross-sectional and captured effective access at a single point in time and from a supply perspective only. Collection of data at multiple time points would strengthen the reliability of an annualized estimate. Estimates of distance and whether villages faced physical or security barriers were based on reports by facility staff, which may have underestimated the communities' perspective. Furthermore, the quality of case management and availability of essential supplies, such as timers, to provide case management were not assessed. Other documented barriers to effective access from the demand side, such as cultural, economic, and social constraints, were not captured. Likewise, we did not measure clients' expectations. Experiencing an understaffed facility or a stockout of even one essential medicine could discourage future care seeking for sick children, not only by the family in question, but also by neighbors. In light of the off-setting biases (relatively under-served districts versus overestimations of access), the findings probably do represent much of rural Africa.

This study demonstrates that access to case management is much worse than officially estimated once the contribution of physical barriers, staff availability and stockouts are accounted. We also proposed a method to account for intermittent barriers. In study areas, less than 50% of the population had geographic access (i.e., lived within 5, 8, or 10 km of a facility), and less than 20% had effective access. Our findings highlight the important distinction between access to a health facility and access to case management. Poorly staffed and supplied facilities cannot save the lives of sick children, and planning for curative services should look at how to improve effective access for the total population, including those who live within MOH-defined access areas. Although CCM typically targets areas that do not have geographic access, CCM can also be considered even in those areas near to facilities to overcome other access barriers such as physical barriers and limited staff availability. However, CCM will only improve effective access if CBHWs are adequately distributed and supported.

Received December 1, 2011. Accepted for publication February 24, 2012.

Acknowledgments: We thank the SC staff for participating in data collection; the health facility staff for giving time and input into the study; and Deborah Sitrin, Janani Vijayaraghavan, Davidson H. Hamer, and Stefan Peterson for reviewing the manuscripts and comments.

Financial support: This study was supported by the Canadian International Development Agency in Malawi and the U.S. Agency for International Development in Mali and Zambia.

Disclaimer: The opinions expressed are those of the authors and do not necessarily reflect the views of the Canadian International Development Agency or the U.S. Agency for International Development.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 85–91
doi:10.4269/ajtmh.2012.11-0757

Community Health Workers Providing Government Community Case Management for Child Survival in Sub-Saharan Africa: Who Are They and What Are They Expected to Do?

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Abstract. We describe community health workers (CHWs) in government community case management (CCM) programs for child survival across sub-Saharan Africa. In sub-Saharan Africa, 91% of 44 United Nations Children's Fund (UNICEF) offices responded to a cross-sectional survey in 2010. Frequencies describe CHW profiles and activities in government CCM programs ($N = 29$). Although a few programs paid CHWs a salary or conversely, rewarded CHWs purely on a non-financial basis, most programs combined financial and non-financial incentives and had training for 1 week. Not all programs allowed CHWs to provide zinc, use timers, dispense antibiotics, or use rapid diagnostic tests. Many CHWs undertake health promotion, but fewer CHWs provide soap, water treatment products, indoor residual spraying, or ready-to-use therapeutic foods. For newborn care, very few promote kangaroo care, and they do not provide antibiotics or resuscitation. Even if CHWs are as varied as the health systems in which they work, more work must be done in terms of the design and implementation of the CHW programs for them to realize their potential.

INTRODUCTION

In sub-Saharan Africa, diarrhea, pneumonia, malaria, severe and acute malnutrition, and newborn conditions are the leading causes of child mortality.[1] Many child deaths can be avoided with appropriate and timely care, but access to treatment remains inadequate, especially for those children who are marginalized the most.[2–4] Based on treatment algorithms refined under integrated management of child illness (IMCI), community case management (CCM) broadens access to treatment by training and supporting community health workers (CHWs) to assess, classify, treat, and refer sick children in the communities where they live,[5–9] and therefore, this program should increase access to care for those children who are most marginalized.

Because of the potential to reach marginalized children most in need of treatment, governments are scaling up CCM of child diarrhea, pneumonia, and malaria throughout sub-Saharan Africa[10]; however, little is known about the profile of CHWs carrying out this intervention. Recent reviews[11–13] reinforce a long-standing body of work[14,15] on the general role of CHWs in primary healthcare, with a few reviews reaching consensus on the effectiveness of CHWs for child survival in particular.[16] Although information about the demographic characteristics, roles, and responsibilities of CHWs is needed to inform operational models for CCM,[17,18] findings from two cross-national surveys on CCM disclose some details regarding CHW profiles.[19,20] To support the scaling up of CCM, additional information about the educational level, sex, ethnicity, level of training, population covered, and range of activities undertaken by CHWs is essential for refining supervision and operational guidance for CCM. This article updates and expands previous work done on CHWs delivering CCM[18,19] by detailing the profile (education level, training, and sex), inputs (incentives and supplies), and activities (curative and preventive) of CHWs across a broader range of CCM conditions (namely diarrhea, malaria, pneumonia, nutrition, and newborn care) within government CCM programs in sub-Saharan Africa.

METHODS

A cross-sectional survey was initiated in 2010 to all 44 UNICEF country offices in the sub-Saharan African region through questionnaires administered separately by the West and Central Africa Regional Office (WCARO) and the Eastern and Southern Africa Regional Office (ESARO). The questionnaires included closed-ended questions on forms of remuneration/motivation, duration of CCM training, and range of activities expected of CHWs working in government CCM programs. Data were also collected on availability of CCM drugs and diagnostics at primary healthcare facilities. In addition, ESARO collected information on the population covered by CHWs as well as their educational level, duration of general health training, and sex. Data entry and analysis were undertaken using Epi Info 7.[21] During analysis, country and regional offices were followed up to ensure accuracy of data, specifically to complete missing information and clarify qualitative comments made by country offices in response to the survey. These clarifications were logged in Word documents and used to help explain non-responses or outlier responses.

In the survey, we defined a CHW as any health worker who carries out functions related to healthcare delivery, is trained in some way to deliver an intervention, and has no formal professional or tertiary education degree. Because some countries have more than one kind of CHW undertaking child survival activities, we focused data collection on the most numerous government CHW cadre that provides curative treatment of child illness at the community level. Various forms of remuneration/motivation given to CHWs in government programs were considered: regular payments in the form of salaries, financial incentives (mark up on drugs, user fees, or other partial financial incentives), and non-financial incentives (clothing, equipment, job aides, training, etc.). The survey measured what CHWs were expected to be doing according to their

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roles in national programs as per the understanding of UNICEF country officers; it did not measure actual performance.

Because we are interested in implementation at the national scale in routine programs, we focused our research on government implementation defined as having CHWs trained and deployed to provide curative services for CCM conditions supported by the Ministry of Health (MoH). Governments that had begun training CHWs for CCM but had not yet deployed them to provide curative services in 2010 were not considered as implementing CCM. Governments that were implementing CCM as pilot projects or operations research were not considered to be implementing CCM in routine programs and thus, were not included. Geographic scale of implementation was measured as being either (1) less than one-half of the districts in the country or (2) greater than or equal to one-half of the districts in the country. Details regarding extent of MoH implementation in terms of CCM conditions and scale in sub-Saharan Africa are reported elsewhere.[10]

RESULTS

Respondents. Forty of forty-four (91%) country offices covered by UNICEF's sub-Saharan African regional offices responded. The four UNICEF country offices that did not respond included Cape Verde, Gabon, Guinea-Bissau, and Sao Tome and Principe. Of these 40 country offices, 29 (16 WCAROs and 13 ESAROs) offices reported that governments were implementing CCM, and these programs are the focus of our analysis regarding remuneration/motivation and range of activities undertaken (Supplemental Tables 1–5). After follow-up with country offices, 22 offices provided information on the duration of CCM training, and 19 offices provided information on the general health training of CHWs in their programs.

Government CCM CHW profiles. Country offices reported governments using a combination of incentives for CHWs, with financial and non-financial partial incentives being the most common. Only a few governments paid CHWs monthly salaries (Ethiopia, Guinea, Lesotho, Malawi, Niger, and Nigeria); at the other extreme, only a few countries had volunteers who exclusively received non-financial incentives in recognition of their contributions (Central African Republic, Côte d'Ivoire, Democratic Republic of the Congo, Eritrea, and Liberia). Among the kinds of financial incentives reported, three governments allowed CHWs to collect user fees (Mali, Senegal, and Togo), whereas a few countries, mostly in West Africa, allowed CHWs to collect a mark up on drugs (Benin, Burkina Faso, Ghana, Madagascar, Mali, Mauritania, Senegal, and Uganda). Although there was no association between the number of CCM conditions addressed by government programs and the forms of incentives or remuneration provided, governments that paid CHWs monthly salaries or financial incentives of some kind were more likely to have CCM in one-half or more of the districts in the country (Figure 1).

Two country offices reported additional information regarding the financing for CHW programs. In South Africa, the government subcontracts non-governmental organizations (NGOs) to manage CHWs that deliver government service packages at the home/community level. Funding is channeled through the Department of Health and comes from various sources, including the Expanded Public Works program, which is a job creation and poverty alleviation program. In Rwanda, the government allocates funds collectively for CHWs based on measured outputs. Money is paid to CHW cooperatives rather than individual CHWs. The cooperatives invest the funds and use the profits for the welfare of their CHW members.

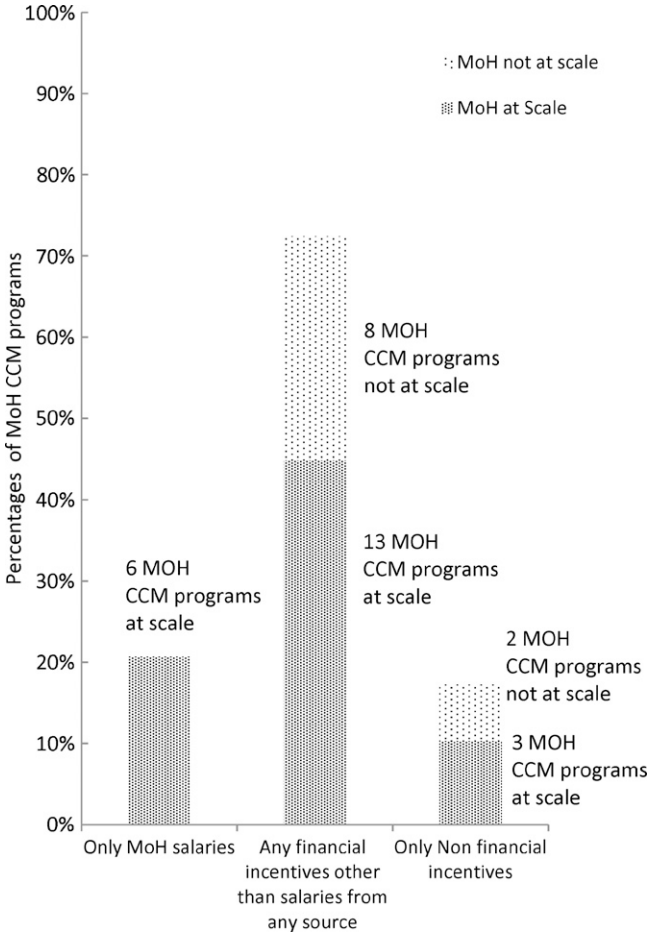

FIGURE 1. UNICEF country offices reporting forms of motivation received by CHWs working in MoH CCM programs by scale (greater than 49% of all districts in the country) for diarrhea, malaria, and/or pneumonia programs in sub-Saharan Africa in 2010 ($N = 29$).

Twelve country offices from Eastern and Southern Africa answered questions regarding educational level, sex, and population covered. In Ethiopia and Malawi, CHWs had completed at least secondary school, whereas other country offices reported to have CHWs with less than secondary school education. With regard to information on the sex of CHWs, four countries were mixed (Eritrea, Madagascar, Mozambique, and Rwanda), two countries were mostly male (Malawi and Zambia), and six countries were primarily female (Ethiopia, Kenya, Lesotho, Swaziland, Uganda, and Zimbabwe). In terms of households assigned to each CHW, government CCM programs varied from less than or equal to 100 households (Lesotho, Rwanda, Swaziland, and Uganda) to greater than 100 but less than or equal to 500 households (Eritrea, Ethiopia, Kenya, Mozambique, and Zimbabwe) to greater than 500 but under 1,000 households (Malawi and Zambia).

Although most government CCM programs (64%; 14 of 22) offered training for up to 1 week, some (23%; 5 of 22) programs

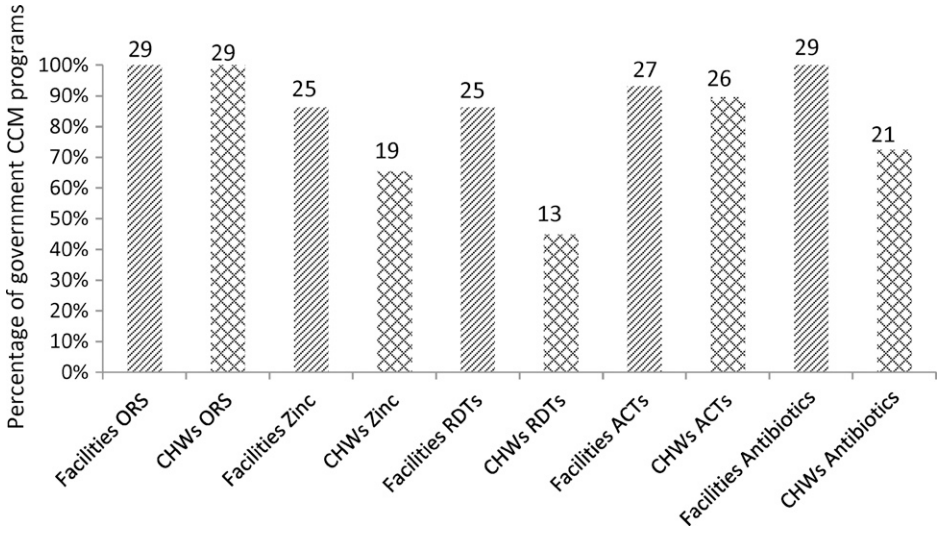

FIGURE 2. UNICEF country offices reporting facility and CHW diagnostics and treatments in government implementation of CCM diarrhea, malaria, and/or pneumonia programs in sub-Saharan Africa in 2010 ($N = 29$, $N = 28$ for malaria).

offered up to 2 weeks of training, and a few (14%; 3 of 22) programs offered training for up to 3 months. Duration of CCM training was not associated with the type of motivation, number of CCM conditions, or whether the government program was operating in one-half or more of the districts. Almost one-half (47%; 9 of 19) of government CCM programs had general health training that lasted between 2 weeks and 3 months, whereas CCM programs with salaried workers tended to have training of up to 1 year or more.

Government CCM CHW activities. With regard to curative activities related to diarrhea, country offices reported that all government programs were expected to have oral rehydration salts at the facility and CHW levels and that all CHWs were expected to promote the increase of fluids and continued feeding for children sick with diarrhea (Figure 2). Fewer government programs (86%; 25 of 29) expected primary healthcare facilities to dispense zinc, and even fewer programs (66%; 19 of 29) expected CHWs to dispense zinc. With regard to malaria, government primary healthcare facilities expected to have rapid diagnostic tests (RDTs) were almost double (89%; 25 of 28) the number of government CHWs expected to have RDTs (46%; 13 of 28), whereas almost all government primary healthcare facilities (96%; 26 of 28) and CHWs (93%; 26 of 28) were expected to have artemisinin-based combination therapy (ACTs). Although all government primary healthcare facilities were expected to have antibiotics for pneumonia, fewer programs expected government CHWs to either have timers (76%; 22 of 29) or antibiotics (72%; 21 of 29).

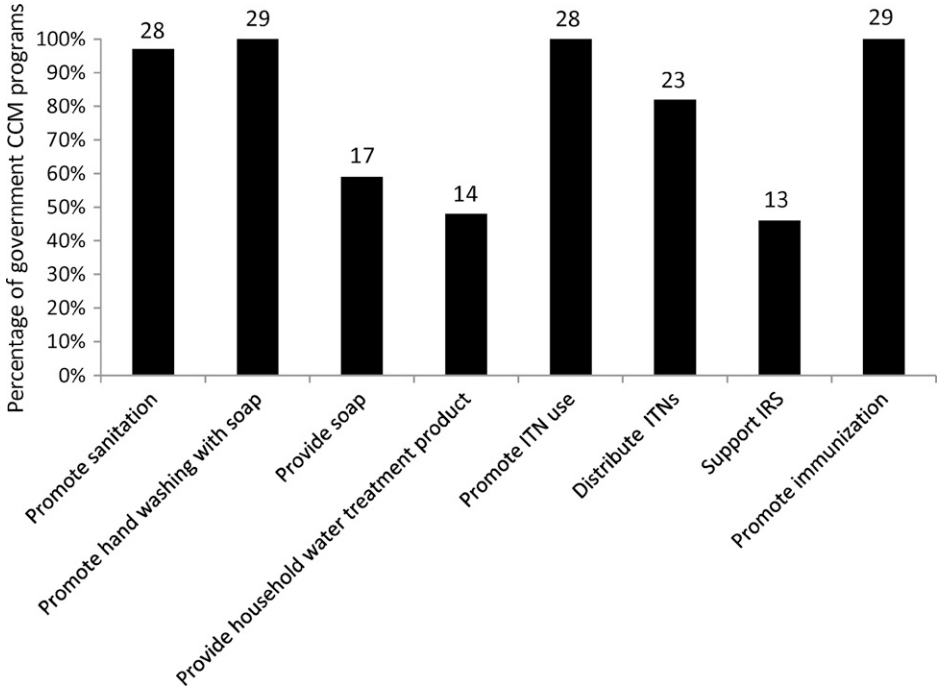

FIGURE 3. UNICEF country offices reporting CHW health promotion and preventive activities in government implementation of CCM diarrhea, malaria, and/or pneumonia programs in sub-Saharan Africa in 2010 ($N = 29$, $N = 28$ for malaria).

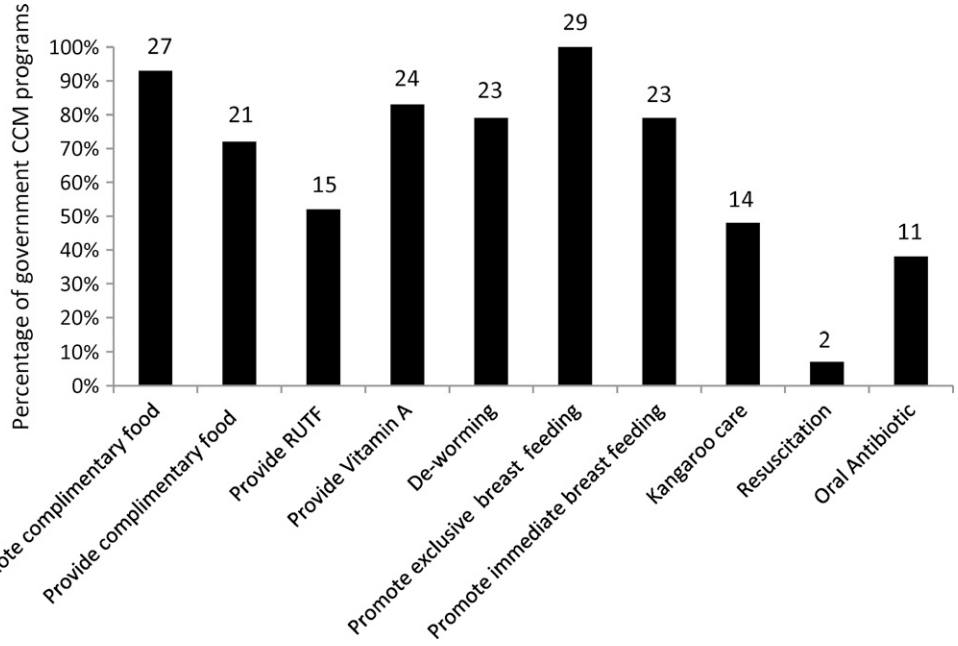

FIGURE 4. UNICEF country offices reporting activities related to nutrition and newborn care undertaken by CHWs involved in government implementation of CCM diarrhea, malaria, and/or pneumonia programs in sub-Saharan Africa in 2010 ($N = 29$).

With regard to health promotion directly related to CCM diarrhea, malaria, and pneumonia programs, all or nearly all government programs expected CHWs to promote sanitation, handwashing with soap, use of insecticide-treated nets (ITNs), and immunization. Fewer programs provided soap (59%; 17 of 29) or household water treatment products (48%; 14 of 29). Although a large proportion of government programs expected CHWs to distribute ITNs, fewer programs expected them to support indoor residual spraying (IRS; 46%; 13 of 28) (Figure 3).

For nutrition, high proportions of government programs expect CHWs to provide vitamin A (83%; 24 of 29) as well as deworming (79%; 23 of 29). All government programs expect CHWs to promote exclusive breastfeeding, and almost all programs promote complementary feeding (93%; 27 of 29). Fewer programs expect CHWs to provide complementary food (72%; 21 of 29), and even fewer programs expect them to distribute ready-to-use therapeutic food (RUTF; 52%; 15 of 29). With regard to newborn care, fewer government programs expect CHWs to promote immediate breastfeeding (79%; 23 of 29) than exclusive breastfeeding (100%). Very few governments expect CHWs involved in CCM of diarrhea, malaria, or pneumonia programs to promote kangaroo mother care (48%; 14 of 29) and even fewer programs expect CHWs to undertake resuscitation (7%; Niger and Senegal) or provide oral antibiotics (38%; 11 of 29) for newborns (Figure 4). Ethiopia does permit CHWs to undertake resuscitation and provide oral antibiotics for newborns but only in a limited research setting, which for the purposes of this survey, was not considered as routine government implementation.

DISCUSSION

In summary, our findings show that most CHWs working for government CCM programs in sub-Saharan Africa receive a combination of incentives for their work. Many CHWs receive financial and/or non-financial partial incentives, and only a small number of CHWs are salaried workers or at the other extreme, volunteers who are not financially rewarded in any manner. Government programs seem to use CHWs with less than secondary schooling and either female CHWs or a mix of male and female CHWs. The number of households each government program expects a CHW to cover varies substantially. Despite these differences across CCM programs, most CHWs working in government CCM programs receive up to 1 week of CCM training. In terms of curative tasks, although all government CHWs are expected to provide oral rehydration salts (ORS), fewer CHWs are expected to provide zinc, dispense antibiotics, or use timers or RDTs. Many government CHWs are tasked with general health promotion activities, but they are not expected to be provide soap, water treatment products, IRS, or provision of RUTF. With regard to newborn care, very few CHWs implementing CCM for the sick child are expected to be involved in promoting kangaroo care or providing antibiotics or resuscitation for newborns.

This survey is desk-based, with UNICEF country offices reporting their perceptions of who CHWs working in government CCM programs are and what they are expected to do. Despite follow-up enquiries, it proved difficult at times to collect data in a standardized form for such a large number of countries with programs that vary distinctly. These data are not meant to replace improved human resource information systems that include CHWs or more in-depth but more time- and resource-intensive research based on interviews with CHWs and observations of their actual performance. It, nonetheless, provides an overview across a continent that confirms previous research[19,20] and points to important patterns that need to be considered for policy and programs.

Other studies have found that incentives used to reward CHWs working in government CCM programs vary substantially across countries in low and middle income countries.[18]

The few countries that rely on user fees and mark up on drugs are largely West African, most likely because of the legacy of the Bamako Initiative. The question as to whether CHWs should be paid remains controversial.[13] The issue may not be easily resolved given the variance that exists among CHW types and their expected roles in the health systems. Financial incentives are effective when linked to improving staff motivation and quality, but they are less effective when focused on cost recovery alone because of how it skews incentives to irrational care.[22] Financial incentives also do not have a universal value across national contexts. In Nepal, volunteers did not want to be paid, because payment was seen to equate them with unresponsive government workers. Work that they undertook at their discretion was seen as helping the community and improving their social status. At the same time, they did expect to be compensated for scheduled activities, which may take away from their livelihood activities.[23] Even with such a positive finding about the importance of volunteerism in a CHW program, evidence that volunteerism can be sustained for long periods is contested.[13] Although CHWs may originally be expected to spend only a small amount of time on health-related activities, community demands and task-shifting measures may increasingly require full-time performance.[12,13] Our data show that, as government CCM programs move to scale, they are more likely to financially reward CHWs working for them.

The question of how best to motivate CHWs is much broader than how to reward them for their time,[24] and the answer is not based solely on extrinsic factors. "The motivation and retention of CHWs is influenced by who they are in the community context. The inherent characteristics of CHWs, such as their age, sex, ethnicity and even economic status will affect how they are perceived by community members as well as their ability to work effectively."[24] Credibility in terms of their skills, their role in competing health markets, and their standing in the health system—as well as their role in the community—is important.[25] Sex is one element of the social status of CHWs that influences their intrinsic and extrinsic motivation. Many articles do not disclose whether CHWs are male or female. In one review,[13] 70% of articles with information of this kind reported female CHWs. Although assumptions are sometimes made that female CHWs are more effective than male CHWs, there is insufficient research or evidence to verify this assumption.[26] Some articles document how sex colors both the professional and personal elements of being a CHW.[27–29]

The most worrying aspect of this information is that most CHWs seem to receive the same kind of CCM training regardless of their occupational status (whether paid) or the complexity of the CCM program being implemented (number of health conditions addressed). Although much effort has gone to standardizing training for literate CHWs, more work needs to be done to adapt training to targeted CHWs whether literate or not and ensure that competency is gained from training and ensured in practice. Volunteers may be unable to spare long periods of time for training and may require more frequent refresher training and specialized supervision models that emphasize clinical supervision on site. Supportive supervision that defines objectives and expectations, monitors performance, helps interpret data, provides focused education, helps with planning and problem solving, and enhances community participation is critical.[30] In practice, supervision of CHWs can be non-existent,[31] or when available, it faces its own challenges, which limits its constructive purpose.[32–34]

Although competencies regarding CHW's curative CCM role have been clarified, similar competencies with regard to their roles in health promotion and prevention are being developed as part of the World Health Organization (WHO) –UNICEF training materials for CHWs looking after children's health growth and development. This material includes guidance on the range of promotion messages and the forms of promotion (counseling, cards, etc.) and follow-up needed. Overall, government programs expected CHWs involved in CCM to be engaged in various health promotion activities but less involved when it came to providing products (bednets, soap, or water treatment products) or supporting activities outside of the health sector (IRS). More research is required to understand the balance between the preventive and curative roles that CHWs undertake. Although CHWs report that CCM increases their status,[35,36] making their health prevention and promotion roles more credible, this finding has not been corroborated by households. Research is also required to see whether preventative commodities can as effectively boost CHW credibility and demand for CCM services as curative commodities.

As previously found by in other work,[19,20] there is large variation in terms of the number of households that each CHW is expected to cover. Little is known about the appropriate population ratio for CCM CHWs or the settlement patterns involved (high to low population density). Although a small population ratio is required for counseling and behavioral interventions, larger population ratios are required to ensure adequate caseloads of sick children to maintain curative skills. In addition, there is a limit to how many different activities a CCM worker is able to effectively undertake. CHWs play a vital role in the assessment of malnutrition and promotion of various nutrition messages, but they are not expected to provide complementary feeding or RUTF.[8] Although CCM of sick children entails family members seeking out the CHW when a child falls ill, implementation of CCM for newborns entails the CHWs seeking out pregnant women, mothers, and newborns for early and repeated home visits. The full integration of curative roles for CHWs across all these conditions entails a different kind of workload and more intensive counseling skills, which may not be feasible in every context.

In general, more work needs to be done to support CHWs to reach their potential in saving children's lives from conditions for which effective interventions exist. As the work by Lehmann and Sanders[13] concludes, "CHW programs are not cheap or easy, but remain a good investment, since the alternative in reality is no care at all for the poor living in geographically peripheral areas." More work needs to be done in terms of supporting the design of CHW programs (CHW role definition, selection, community recognition, health service integration, advancement, and geographic distribution) and their implementation (training and refresher training, supervision, supply systems, and incentives/remuneration). With regard to CCM particularly, standardization of competencies gained from CCM training is essential, with the format and duration of such training adapted to the different types of CHW cadres involved. With regard to the curative roles of CHWs, more work must be done to support the role of CHWs in quality integrated CCM by ensuring their access to diagnostics and

newer products, such as zinc. More attention needs to be paid to the health promotion and counseling roles of CHWs, including their involvement in newborn care, taking into consideration the support that they are provided and their roles in the health systems and the communities in which they work.

Received December 4, 2011. Accepted for publication June 6, 2012.

Note: Supplemental tables appear at www.ajtmh.org.

Acknowledgments: We thank UNICEF country offices for responding to the survey and validating survey responses. In addition, UNICEF colleagues who provided valuable support include Ahmet Afsar, Mandana Arabi, Erin Boyd, Paul Edwards, Sandra Fonki, Gabriele Fontana, Susan John, Julia Kim, Yolande Kouame, Marie-Reine Jibidar, Binod Mahanty, Camielle Noordam, Nicholas Oliphant, Christiane Rudert, Alyssa Sharkey, Tesfaye Shiferaw, and Judith Tiedje. This study was based on UNICEF staff time, with no external funding for the study.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 92–96
doi:10.4269/ajtmh.2012.11-0791

Private Sector Drug Shops in Integrated Community Case Management of Malaria, Pneumonia, and Diarrhea in Children in Uganda

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Abstract. We conducted a survey involving 1,604 households to determine community care-seeking patterns and 163 exit interviews to determine appropriateness of treatment of common childhood illnesses at private sector drug shops in two rural districts of Uganda. Of children sick within the last 2 weeks, 496 (53.1%) children first sought treatment in the private sector versus 154 (16.5%) children first sought treatment in a government health facility. Only 15 (10.3%) febrile children treated at drug shops received appropriate treatment for malaria. Five (15.6%) children with both cough and fast breathing received amoxicillin, although no children received treatment for 5–7 days. Similarly, only 8 (14.3%) children with diarrhea received oral rehydration salts, but none received zinc tablets. Management of common childhood illness at private sector drug shops in rural Uganda is largely inappropriate. There is urgent need to improve the standard of care at drug shops for common childhood illness through public–private partnerships.

INTRODUCTION

Fever-related conditions, including malaria, pneumonia, and diarrhea, are the major causes of mortality among children less than 5 years old in low-income countries.[1] In Uganda, the Home-Based Management of Fever (HBMF) strategy was initiated in 2002 to treat all febrile children with antimalarials. The HBMF strategy was promoted through public and community health worker systems. As a result, the community health workers' mandate has been broadened to use diagnostics such as rapid diagnostic tests (RDTs) for malaria and respiratory timers for pneumonia and treat febrile children with antimalarials, antibiotics, and oral rehydration salt with zinc tablets (ORS/Zinc) accordingly. This new approach is called the integrated community case management (iCCM) of malaria, pneumonia, and diarrhea in children, which is now national policy in Uganda.[2]

Whereas the iCCM strategy is implemented through volunteer community health workers, the majority of parents in Uganda seek care for their febrile children from private clinics and drug shops.[3,4] Unfortunately, the standard of care in private health facilities, including drug shops, is not well-documented, although it is known to be wanting. There is need to study interventions aimed at improving the standard of care provided by the private sector in the management of common childhood illnesses.[4,5]

In 2011, the Global Fund, through the Affordable Medicines Facility—Malaria (AMFm), began to subsidize and promote artemisinin combination therapy (ACT) for the treatment of fever through the private sector in eight low-income countries, including Uganda.[6] Studies have shown that subsidizing ACT through private drug shops in rural areas can greatly increase ACT coverage for reported fevers.[7,8] Unfortunately, there is no similar strategy to improve treatment of pneumonia and diarrhea in the private sector, where many sick children are first seen.

In addition, studies are exploring the feasibility of introducing malaria RDT in the private sector. However, there is extremely limited understanding of how to offer appropriate alternative treatment to those children with RDT-negative fever with or without signs of other illnesses.[9] This lack of understanding limits the adherence to RDT results and leads to continued inappropriate use of ACT, with adverse consequences for cost, resistance development, and children suffering from other illnesses than malaria.[10,11] Furthermore, there is also indication of increased likely inappropriate use of antibiotics to treat RDT negative fever.[9]

The private sector plays an important role for care of febrile children in Uganda. Through the AMFm, the role of the private sector may further be expanded for care of malaria. The objective of this study was to determine the role and appropriateness of care provided by private sector drug shops in treating childhood fever, respiratory symptoms, and diarrhea in Uganda.

METHODS

The study was conducted in two rural districts of Kaliro and Kamuli in eastern Uganda as part of a baseline assessment for a larger study determining the effectiveness of introducing and promoting pre-packaged drugs and diagnostics for treatment of childhood fever and diarrhea within drug shops in Uganda.

The two districts were purposively selected as representative of a typical rural setting with a high burden of febrile illness and diarrhea in children. The research strategy included a community household survey and exit interviews at drug shops to determine care-seeking patterns and the appropriateness of treatment provided at drug shops for febrile children less than 5 years of age in Uganda. All data were collected in May of 2011.

Household survey. A two-stage cluster sampling using probability proportional to population size was used to select 1,604 households with children less than 5 years of age in both study districts. At the first stage, a probability sample of 30 villages/clusters was sampled. At the second stage, 26 target households were sampled from each cluster. Because of

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the lack of an updated village list of households, it was not possible to have a random sample within a cluster. The study team, therefore, randomly identified a starting point from a list of households obtained from the local leaders and thereafter, sampled every fifth household with children less than 5 years of age. The main caretaker (usually the mother) aged 15 years and above was interviewed face to face using a semistructured questionnaire. If a sampled house was empty or the caregiver was absent, it was replaced by the neighboring house. The questionnaire was designed to elicit care-seeking practice for the most recent illness (less than 2 weeks before the interview).

Five-day training was conducted for data collectors, and it included a pilot within a cluster that was not included in the survey. Five field teams collected the data, and a team was comprised of four data collectors and one supervisor.

Exit interviews at drug shops. One-half of all the licensed/registered drug shops in the two study districts were randomly selected for exit interviews ($N = 40$). All clients exiting the drug shops were approached and requested to be interviewed if they had come to the drug shop seeking treatment of a child less than 5 years of age. Data collectors were at the drug shop all day (from 8:30 AM to 7:00 PM) during the study period, and 163 interviews were conducted.

A semistructured questionnaire was used. The questions asked included what the child's symptoms were, when the current illness was noticed, and any care sought before coming to the drug shop. We asked for all the medicines purchased and noted down information, including drug name, dosage, duration of treatment, and whether instructions were given on how to use the purchased medicines.

The data were entered separately for the household and exit interviews in Epi data software, and they were analyzed using SPSS. Ethical approval was obtained from the Makerere University School of Public Health Higher Degrees Research and Ethics Committee as well as the Uganda National Council of Science and Technology. Informed consent was obtained from all the study participants.

TABLE 1

Baseline characteristics of the study population ($N = 1,604$)

Median age (years) of primary caregiver/respondent (IQR)	28 (23, 35)
Median age (months) of child (IQR)	14 (7, 24)
Median household size (IQR)	6 (4, 8)
Median number of children less than 5 years old in the household (IQR)	2 (1, 2)
Educational background of caretaker/respondent	
No education	308 (19.2%)
Primary level	908 (56.6%)
Secondary level	362 (22.6%)
Higher education	26 (1.6%)
Household head	
Self (caretaker/respondent)	212 (13.2%)
Partner/husband	1,323 (82.5%)
Other male adult	52 (3.2%)
Other female adult	17 (1.1%)
Educational background of partner/husband ($N = 1,568$; some have no partner)	
No education	138 (8.8%)
Primary level	809 (51.6%)
Secondary level	422 (26.9)
Higher education	72 (4.6%)
Do not know	127 (8.1%)
Occupation of partner/husband ($N = 1,568$)	
Farmer	896 (57.1%)
Trader	91 (5.8%)
Civil servant	94 (6.0%)
Other office work	54 (3.4%)
Business man/self-used	346 (22.1%)
Unemployed	26 (1.7%)
Do not know	61 (3.9%)
Who makes the decision to seek medical treatment when a child is sick?	
Mother	854 (53.2%)
Husband	312 (19.5%)
Mother and husband together	402 (25.1%)
Relatives/others	36 (2.2%)
Who authorizes expenditure for treatment of sick children in household?	
Mother	163 (10.2%)
Husband	1,173 (73.1%)
Mother and husband together	220 (13.7%)
Relatives/others	48 (3%)
Ownership of house	
Self-owned	1,394 (86.9%)
Rented	123 (7.7%)
Relative (pays no rent)	85 (5.3%)
Other	2 (0.1%)

RESULTS

The median (interquartile range [IQR]) age of the primary caregiver, number of children less than 5 years old, and household size were 28 (23, 35) years, 2 (1, 2) children, and 6 (4, 8), respectively (Table 1). The decision to seek treatment of the ill child was usually made by the mother in 854 (53.2%) households, whereas the father/husband mainly authorized expenditure for treatment of sick children in 1,173 (73.1%) households.

Up to 934 (58%) children had been sick within the previous 2 weeks of the study (Table 2). The number of children with an illness within the last 2 weeks who first sought treatment in the private sector (private clinics and drug shops) was 496 (53.1%) versus 154 (16.5%) in a government health facility. Caregivers who first managed the sick child at home were 228 (24.4%), whereas 31 (3.3%) caregivers first visited a community health worker, 13 (1.4%) caregivers first visited a traditional healer, and 12 (1.3%) caregivers first visited a spiritual healer or the church.

The median (IQR) age of children for whom treatment was sought at the drug shop was 15 (9, 36) months; 65% of the caretakers who bought drugs for sick children at the drug shops were female, and their education level was primary in 75 (52.8%) and ordinary level in 53 (37.3%) women. The main presenting complaint/symptoms for which treatment was sought at the drug shop was fever in 145 (89%), cough in 100 (61.3%), and diarrhea in 56 (34.4%) children. Both cough

TABLE 2

First point where care was sought for illness within the last 2 weeks in a child less than 5 years of age ($N = 934$)

Healthcare service provider	Number (%)
Private health provider	496 (53.1)
Drug shop	279 (29.9)
Private clinic	217 (23.2)
Managed at home	228 (24.4)
Government health facility	154 (16.5)
Rural health center	120 (12.8)
Hospital	34 (3.6)
Community health worker	31 (3.3)
Traditional healer	13 (1.4)
Spiritual healer/church	12 (1.3)

TABLE 3
Symptoms of the child for whom treatment was sought at the drug shop

Symptom/complaint ($N = 163$)	Number (%)*
Fever	145 (89)
Cough	100 (61.3)
Rapid/difficult breathing	40 (24.5)
Cough and rapid/difficult breathing	32 (19.6)
Diarrhea	56 (34.4)
Vomiting	20 (12.3)
Others	37 (22.7)

*The total is more than 100%, because more than one complaint is possible.

and rapid/difficult breathing were the presenting complaint in 32 (19.6%) children (Table 3).

Of all children with fever for whom treatment was sought at a drug shop, only 15 (10.3%) children received appropriate treatment according to current national guidelines with an ACT for 3 days and within 24 hours of onset of illness (Table 4). For children who presented with cough and fast breathing—defined as pneumonia according to the iCCM guidelines—23 (71.9%) children received an antibiotic, although it was mainly cotrimoxazole (56.3%). Only 5 (15.6%) children were treated with the recommended first-line drug of amoxicillin. However, zero children with cough and fast breathing received amoxicillin for the recommended duration of 5–7 days. Similarly, only 8 (14.3%) children with diarrhea were treated with ORS, and none of the children with diarrhea received zinc tablets.

TABLE 4
Appropriateness of treatment obtained from drug shops

Appropriateness of treatment of fever, cough with rapid/fast breathing and diarrhoea	Number (%)
Treatment of fever ($N = 145$)	
Proportion of children with fever receiving any ACT drug	37 (25.5)
Proportion of children with fever receiving any ACT for 3 days	27 (18.6)
Proportion of children with fever receiving any ACT within 24 hours	22 (15.2)
Proportion of children with fever receiving any ACT within 24 hours of onset of fever and for 3 days	15 (10.3)
Proportion of children with fever receiving any ACT within 24 hours of onset of fever and for less than 3 days	1 (0.7)
Proportion of children with fever receiving any ACT within 24 hours of onset of fever and for more than 3 days	6 (4.1)
Treatment of cough with rapid/fast breathing ($N = 32$)	
Proportion of children with both cough and fast breathing treated with any antibiotic (amoxicillin, cotrimoxazole, or any other antibiotic)	23 (71.9)
Proportion of children with both cough and fast breathing treated with cotrimoxazole only	18 (56.3)
Proportion of children with both cough and fast breathing treated with amoxicillin	5 (15.6)
Proportion of children with both cough and fast breathing treated with amoxicillin for 5–7 days	0
Treatment of diarrhea ($N = 56$)	
Proportion of children with diarrhea treated with ORS	8 (14.3)
Proportion of children with diarrhea treated with ORS and zinc	0

TABLE 5
Accessibility and affordability of drugs from the drug shop ($N = 163$)

Bought drugs without a prescription	108 (66.3%)
Reason for choosing the drug shop	
Good service/customer care	101 (62%)
Distance (proximity)	34 (20.9%)
Good/trained staff	32 (19.6%)
Regular supply of drugs	23 (14.1%)
Drug seller is my friend	22 (13.5%)
How long does it take to walk from home to this drug shop?	
Less than 15 minutes	51 (31.3%)
15–30 minutes	42 (25.8%)
30–60 minutes	39 (23.9%)
1–2 hours	19 (11.7%)
Spent money to get to drug shop?	60 (36.8%)
Median amount spent (range)	1,000 Ugshs (200–7,500)
Walking distance to the nearest public health facility	
Less than 15 minutes	34 (20.9%)
15–30 minutes	39 (23.9%)
30–60 minutes	35 (21.5%)
1–2 hours	28 (17.2%)
Was not able to afford all drugs prescribed/advised	47 (28.8%)
Why not able to buy all drugs? ($N = 47$)	
I did not have enough money	42 (89.4%)
When buying drugs, what determines the amount that you buy?	
The dosage prescribed	65 (39.9%)
The amount of money that I have	78 (47.8%)
Other	20 (12.3%)
How do you rate prices in the drug shop with respect to your ability to buy them?	
Too expensive	50 (30.7%)
Prices within my reach	113 (69.3%)

Up to 108 (66.3%) caretakers bought drugs from the drug shops without a prescription (Table 5). Although the amount of money available to a care-seeker determined the amount of drugs bought in 78 (47.8%) cases, the prices of drugs were reported to be within reach of the majority (113; 69.3%). The main reasons for seeking care at the drug shop included perceived good service/customer care in 101 (62%) cases, distance/proximity in 34 (20.9%) cases, good/trained staff in 32 (19.6%) cases, regular supply of drugs in 23 (14.1%) cases, and the drug seller being a friend in 22 (13.5%) cases (Table 5).

DISCUSSION

In this study, we have documented that the majority of parents/caretakers in two districts in rural Uganda take their febrile children to the private sector and that the care that they receive at drug shops for treatment of the main diseases causing pediatric death is inadequate. The significant role of the private sector in healthcare delivery has been previously described. The work by Rutebemberwa and others[3] showed that 62.7% of care for febrile children sought outside the home was first obtained from drug shops/private clinics. Our study confirms this finding, with more than one-half of all care for children less than 5 years of age being first sought in private drug shops and clinics. This finding is also in agreement with the finding in the work by Konde-Lule and others[4] that private providers play a major role in healthcare delivery in rural Uganda.

However, we document that the care received at private drug shops is poor. According to the current Ugandan iCCM guidelines for management of fever, cough, and diarrhea, only 10% of febrile children were correctly managed in our study (that is, correct treatment with ACT for the correct duration and within 24 hours of onset of illness). Management of cough with fast breathing at the drug shops was even worse, with no children receiving the recommended drug—amoxicillin—for the correct duration of time. Also, no child with diarrhea received ORS with zinc tablets according to current treatment guidelines. This more comprehensive assessment of correct management for a range of symptoms shows similar results to previous studies of the appropriateness of care provided by the private sector to sick children less than 5 years of age.[5,12,13]

Although drug shops in Uganda are commonly owned and registered by middle-level health workers, they are usually manned by either lower-level nurses (nursing assistants who have some level of medical training that allows them to manage simple health problems like treatment of fever) or people with no previous medical training.[14] Generally, most drug shop attendants have some secondary school education. Given the poor management of childhood malaria, pneumonia, and diarrhea by drug shop attendants and their limited medical training, there is urgent need for more effective training and supervision in this part of the private sector.[5,14]

Although both drug shops and government facilities were a similar distance from their homes, 62% of the caretakers interviewed reported that the reason that they chose to seek care at a drug shop was because of good service/customer care. Poor interpersonal handling of patients and longer waiting time at government facilities as well as lack of trust in staff at public health facilities have been reported as reasons for preferred use of private drug shops for acute febrile illness.[15] Improving customer experience at public health facilities could, thus, contribute to increased use of these facilities.

The Global Fund now supports the AMFm with subsidized ACT through the private sector in eight countries. It has ambitions to increase prompt access to effective antimalarials, particularly to increase ACT affordability, availability, and use and crowd out artemisinin monotherapies, chloroquine, and sulfadoxine-pyrimethamine by gaining market share. Challenges for the AMFm include ensuring that the subsidy is passed on to consumers, increasing access to diagnostic confirmation, reaching the poor and remote, and identifying appropriate benchmarks to evaluate the AMFm pilots.[16] Although increasing prompt access to ACT through the private sector through subsidies has been shown to be feasible,[7] this access may well come at the expense of rational use when ACT is used to treat fever presumptively. The experience of introducing ACT and malaria RDT in the private sector in Cambodia over the last 10 years has shown challenges in maintaining constant supply and determining effective incentives for private providers and consumers to use the RDT and adhere to their results.[17] There may also be inadvertent effects on the use of antibiotics. Studies from Zanzibar[18] and mainland Tanzania[9] have shown dramatically increased prescription rates for antibiotics when RDTs were introduced, particularly in RDT-negative cases.

We hypothesize that adherence to test results, adequate management of the febrile child, and rational use of ACT as well as antibiotics may be dependent on diagnostics for malaria as well as pneumonia (respiratory timers) and alternative appropriate treatment being provided, including paracetamol, to the likely majority of patients who do not fulfill the criteria for antimalarial or antibiotic treatment. With changing epidemiology of malaria and pneumonia, this group will be a higher and higher proportion of children.[19]

To realize the full potential of ACT and RDT to treat malaria and adequately cater to the febrile child, it may, therefore, be important to extend the logic and policy recommendation of integrated community case management of febrile illness to the private sector. This extension will be in support of the World Health Organization (WHO)/United Nations Children's Fund (UNICEF) recommendations for managing childhood febrile illnesses[20] and further explore opportunities to enhance public–private partnerships. We are now undertaking a proof-of-concept study of iCCM in registered drug shops in Uganda and encourage others to do the same in other settings.

Methodological considerations. Part of the data presented was based on caretaker's report of child's illness. This method is prone to both recall and reporting bias, where a respondent may not remember relevant details of the illness and may report what they think is expected of them, respectively. The use of exit interviews minimized recall bias, because we asked about a child's current illness and which drugs were bought at a drug shop. We also minimized recall bias by considering only illness that occurred within 2 weeks of the household interviews, which is a standard and acceptable method applied in similar cross-sectional surveys. The results obtained are comparable with other studies. However, selection bias remains relevant when exit interviews are used, because people who seek care from private drug shops may be different from the general population.

Conclusion. The majority of parents in Uganda first seek care for febrile children in the private sector, notably drug shops and private clinics. However, febrile children mostly receive inappropriate treatment at the private sector drug shops. This finding means that there is a missed opportunity for them to access appropriate and timely treatment of fever, cough, and diarrhea at this level. There is urgent need to improve the standard of care provided at drug shops through a mix of appropriate technical solutions (drugs and diagnostics), training, incentives, regulation, supervision and information, education, and communication. Public–private partnerships would provide an adequate avenue for such improvements.

Received December 20, 2011. Accepted for publication February 24, 2012.

Acknowledgments: We are grateful to the Einhorn Family Foundation—Sweden for funding this study and the Medicines for Malaria Venture for field support.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 97–104
doi:10.4269/ajtmh.2012.11-0763

Community Acceptability and Adoption of Integrated Community Case Management in Uganda

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Abstract. Integrated community case management (iCCM) is a recommended strategy to curb child mortality. Drawing on diffusion of innovations (DOIs), the acceptability and adoption of iCCM were qualitatively explored. Data from focus group discussions and interviews with community members, community health workers (CHWs), and supervisors conducted in seven communities were analyzed using content analysis. Perceived relative advantage and compatibility of the program with sociocultural beliefs and healthcare expectations of the communities positively affected acceptability and adoption of iCCM. The degree of stringency, quality, and cost of access to healthcare were crucial to adoption. Failure of the health system to secure regular drug supplies, monetary support, and safe referrals globally hindered adoption. Individual CHW characteristics like undesired behavior, demotivation, and lack of reciprocated trust deterred adoption in some areas. Optimal functioning of iCCM programs will require community sensitization and targeted health systems strengthening to enhance observable program benefits like reduced child mortality.

INTRODUCTION

Integrated community case management (iCCM) of childhood illnesses has been proposed as a strategy to reduce child mortality by improving access to healthcare for sick children in resource-poor settings.[1] It involves the use of community health workers (CHWs) in the treatment of uncomplicated childhood illnesses, including malaria, pneumonia, and diarrhea, as well as referral of complicated cases.[1,2] Although the strategy was officially recommended by the World Health Organization (WHO) as early as 2004,[1] its implementation has been slow, especially with regards to pneumonia and diarrhea in high-child mortality countries.[3,4]

Slow progress in intervention implementation has been attributed to the fact that health interventions are often introduced as complex sets of innovations consisting of technologies and processes into an adopting social system of stakeholders with competing interests.[5] The stakeholders are normally a mix of people at different levels of the system, including health workers, policy makers, and community members. The level of integration and the number of stakeholders involved in the intervention determine its level of complexity.[5,6] The iCCM strategy integrates approaches for three different diseases that all have different sets of case management tools at community and health facility levels, making it a relatively complex strategy.

Various theories explain the process of adoption of interventions.[7–9] The theory of diffusion of innovations (DOIs), which relates to how conditions increase or decrease the possibility that members of social system will adopt an innovation,[7,10] has been one of the most widely used theories in disciplines such as medicine and public health sciences.[10]

Drawing from the theory of DOI in the work by Rogers,[7] an innovation is more likely to be accepted by the adopting system and thus, would be scalable if it has attributes of perceived relative advantage in relation to other options, compatibility with existing values and practices, trialability (which is the degree to which an innovation can be experimented with on a limited basis), perceived simplicity or ease of use, and observability (which is the degree to which the results can be visualized) (Table 1).[7,11,12]

Although the importance of community participation in any health intervention is well-known,[13,14] few studies have identified the community processes and social factors that affect people's acceptability and adoption of community-based programs. Earlier diffusion studies have been criticized for making individuals the unit of analysis, assuming that new innovations are better than old ones and that adoption is more worthy of study than rejection, and using the invariable assumption that research can be transferred to new contexts without adaptation.[15] Despite the existence of a known association between social factors that hinder people from accessing healthcare and program outcomes, most studies report on the factors that lead to failure of community-based systems but not why these factors occur.[16] To improve iCCM program success, it is important to explore how the attributes of the program interact with the social system to either enhance or hinder its adoption by the community.

This study sought to explore the acceptability and adoption of iCCM by Ugandan communities using the theory of DOI. The data were collected as part of the inSCALE project (innovations at scale for community access and lasting effects), which aims to test strategies to improve CHW motivation, retention, and performance in Uganda and Mozambique.

METHODS

Setting. Implementation of iCCM in Uganda commenced in July of 2010 when the national strategy was launched by the Vice President. The study was conducted in eight districts in midwestern Uganda (Buliisa, Masindi, Kibaale, Kyegegwa, Kyankwazi, Kiryandongo, Kiboga, and Hoima), where iCCM implementation has been supported by the Malaria Consortium since August of 2010. The districts have an estimated 1.8 million

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TABLE 1
Diffusion of innovation model and examples of how it was used in data collection

Program attribute	Definition (Rogers[7])	Examples of questions
Relative advantage	The degree to which an innovation is perceived as being better than preceding ideas.[7]	Where do you take your children when they suffer from (name disease) and why? Thinking about the VHT services, could you tell me what you like or dislike about them? If you were to choose between going to a VHT and (a) a health center or (b) alternative healthcare, tell me which one you would choose and why?
Compatibility	The degree to which an innovation is perceived as being consistent with values, needs, and experiences of an adopting society.[7]	What are the healthcare needs of children in your community, and how are they normally obtained? Of all the ways of obtaining healthcare that you have mentioned, which ones do you consider most valuable and why?
Complexity	The degree to which an innovation is perceived as being difficult to use and understand.[7]	Thinking about any of the occasions you took your child to a VHT, please describe what you thought about the process of taking your child to the VHT, the information given to you by the VHT, the way that your child was handled by the VHT, and anything else you would like to discuss.
Trialability	The degree to which an innovation may be experimented with on a limited basis.[7]	Why would you be happy or unhappy to visit a VHT from another community or village? What would you gain or lose by visiting a VHT? Why would you consider it important or not to visit a VHT before you can decide to always take your children to the VHT whenever they get (name disease)?
Observability	The degree to which the results of the innovation are visible to others.[7]	What makes you think that children get effective treatment or not when they visit a VHT? What differences, if any, have you noticed in the health of children since the iCCM program was started? Describe what would make you go back to a VHT if your child fell sick. Could you tell me why you would or would not recommend this program to other caregivers?

people, with 20% being children under 5 years of age. The districts each contain 160 to 1,000 villages, approximately totaling to 4,000 villages in the study area. They constitute people of different tribes and cultural practices, including nomadic cattle herders, fishing community members, and peasant farmers. In the area, approximately 13,500 CHWs—locally known as village health team members (VHTs)—are operating, where 5,700 have been trained to deliver iCCM. They diagnose, refer, and treat children between 2 months and 5 years for malaria, pneumonia, and diarrhea using rapid diagnostic tests for malaria (RDTs, Standard Diagnostics Inc., Hagal-dong Giheung-Ku, Yongin-si Kyonggi-do, Korea), simple respiratory timers for pneumonia, artemether/lumefantrine (Coartem, Norvatis Pharma Services Inc., Basel Switzerland), amoxicillin (Imrs b.v Larsserpoortweg, Lelystad, The Netherlands), oral rehydration therapy (ORS, Medipharm Industries Ltd., Kampala, Uganda), and zinc (Nutriset S.A.S., Malaunay, France). They also carry out regular home visits for health promotion and disease prevention, and they do active case detection and referral of sick newborns. Children with severe malaria are given pre-referral rectal artesunate (Mepha AG, Aesch BI, Switzerland) or Coartem, whereas children with severe pneumonia are given amoxicillin before referral. Each village has an average of two iCCM-trained VHTs who, on average, see 20 children every 1 month when drugs are available. The VHTs are supervised by staff from the health facilities (VHT supervisors). Each village is governed by a local council chairperson (LC1).

Study design and data collection. A qualitative study design with an explanatory approach was used to identify factors that influence uptake of iCCM.[17] During July of 2011, A.N. and three experienced research assistants conducted homogenous focus group discussions (FGDs) with female caregivers ($N = 6$) and male caregivers ($N = 1$) of children under 5 years residing in seven communities. Interviews were held with female ($N = 1$) and male ($N = 6$) resident primary caregivers of children. Female FGDs consisted of 8–10 participants who were principally mothers, aunties, or grandmothers responsible for the children. The FGD with males consisted of only fathers. Key informant interviews were held with VHTs ($N = 7$), VHT supervisors ($N = 7$), and LC1s ($N = 6$). Interviews and FGDs were conducted in a convenient and private place within the village. Key informant interviews were held at the respondent's home for VHTs and LC1s and in a private setting at the health facility premises for VHT supervisors.

Sample selection and recruitment of participants. During sampling, a community was operationally defined as a village served by one or more VHTs trained on iCCM. Participants were purposively sampled from seven communities in mid-western Uganda that were believed to possess rich information on barriers and facilitators for iCCM adoption. Only resident primary caregivers of children under 5 years of age were identified with the help of the LC1 chairpersons of the selected villages. The study team contacted the VHTs as well as the supervisors responsible for the selected communities. The sampling method sought to achieve maximum variation within the sample[18] in terms of attributes theoretically known to influence use of health services, such as age and geographical location.[19,20] Participants with varied age and gender from different geographical areas believed to have low or high uptake of iCCM were recruited into the study. Given the close relationship between adoption and uptake,[21] it was deemed appropriate to sample participants from communities with varying uptake levels as defined by the VHT supervisor and confirmed by VHT activity records. During the study period, communities were classified as high-uptake areas if the VHT supervisor reported high VHT attendance and if VHT records confirmed that at least 10 sick children had been seen in the previous 2 weeks (on average, 10–20 cases are treated in each village). Communities were presumed to be low-uptake areas if the supervisor reported low VHT

attendance levels and if the VHT records showed less than five sick children seen by the VHT in last 2 weeks, despite high case attendance at the affiliated health facility. Table 2 shows the sampling matrix for the participants.

The FGDs and interviews. An exploratory research strategy probing for attributes of iCCM that could either foster or hinder its uptake within communities was used during FGDs and interviews. The FGDs sought to explore the general trends in the communities with respect to iCCM, whereas the interviews explored individual experiences. The concept of DOI was used to frame thematic semistructured FGD and interview guides. The guide themes broadly captured attributes of iCCM (Table 1), with probes on how the attributes could affect acceptability and use of services. The guides were pre-tested and modified. Interviews and FGDs were digitally recorded with the informed consent of each participant and ranged from 60 to 120 minutes. Group and individual interviews were conducted in native languages among community members, VHTs, and LC1s. Interviews with VHT supervisors were conducted in English.

Analysis. The audio recordings from all interviews were transcribed into English by the research team and cross-checked by A.N. In the analysis, acceptability was defined as the degree to which a service is sufficiently tolerable to its users as reflected not only in uptake but also in perceived quality. Adoption was characterized as use of health services provided by VHTs. The software Nvivo version 9 (QSR International Pty Ltd., Doncaster, Victoria, Australia) was used to aid the process of coding, organization, and searching for descriptive sections from each interview. It also allowed for sections about themes across a range of interviews to be compared and linked for a logical analysis. Two independent raters, including A.N., read the text and identified meaning units; the meaning units were labeled to make codes, and the codes were grouped into subcategories and pre-defined categories within the theory of DOI using a directed content analysis approach (Table 1).[22] The analysis was cyclical (i.e., moving among literature review, data collection, transcription, preliminary analysis, and scrutiny by the authors). The analysis sought explanations for health-seeking behavior for malaria, pneumonia, and diarrhea, initial choice of healthcare provider, and factors affecting program adoption in communities.

Ethical considerations. Written informed consent was obtained from all study participants. Approval was obtained from the Institutional Review Board at Makerere University School of Public Health and the Uganda National Council of Science and Technology (HS 958) (Table 2).

TABLE 2
Summary of the sampling framework

District	Rural	Periurban	Hard to reach	Low uptake	High uptake
Buliisa	x		x	x	
Hoima	x		x		x
Kiboga		x			x
Kibaale	x			x	
Kyankwanzi	x		x	x	
Kyegegwa	x			x	
Masindi		x			x

Low-uptake area is an area listed as one with low attendance by the supervisor and fewer than five children were recorded to have seen a VHT in the past two weeks. High-uptake area is an area listed as one with high attendance by the supervisor and more than 10 children were recorded to have seen a VHT in the past two weeks.

RESULTS

The informants. Characteristics of interviewees and FGD participants are summarized in Table 3. Of the key informants, six were male LC1s with at least primary level education; seven were VHTs, and seven were VHT supervisors. Of the supervisors, three of seven were female, four of seven were in charge of the health facility, two of seven were health assistants, and one of seven was a health educator.

Program compatibility with social-cultural beliefs and healthcare expectations. In the area of compatibility, two subcategories emerged describing the programs compatibility with community expectations, cultural beliefs, and lived experiences. The subcategory "cultural construction of disease" described the influence of local perception of illness on treatment-seeking behavior, whereas "program compatibility with healthcare expectations" described how met or unmet expectations of healthcare affected health provider choice. Overall, treatment options varied from care at home with local herbs and drug leftovers to care outside the home from traditional healers, VHTs, and the health facility.

Cultural construction of disease. *Local perception of disease severity.* This perception varied among communities and shaped treatment choices. In two of the selected villages, diarrhea and pneumonia were believed to be very severe diseases from the start with rapid progression to death, requiring immediate attention at a health facility (Table 4).

Local perception of disease cause. In some communities, it was often believed that pneumonia was caused by non-biomedical causes; thus, it required non-Western medical treatment options (Table 4).

TABLE 3
Summary of characteristics of respondents

Characteristics of interviewees	Focus group discussions (%)	Interviews with community members (%)	Interviews with VHTs (%)
Sex	$N = 60$	$N = 7$	$N = 7$
Female	90	14	29
Male	10	86	71
Age (years)	$N = 60$	$N = 7$	$N = 7$
18–27	47	0	0
28–37	35	29	14
38–47	17	29	29
47+	2	44	57
Education level	$N = 60$	$N = 7$	$N = 7$
None	23	14	0
Primary 1–7	62	57	29
Senior 1–4	15	29	57
Senior 4–6			14
Employment status	$N = 60$	$N = 7$	$N = 7$
Petty business	8	0	0
Housewife	12	0	0
Bar attendant	2	0	0
Farmer or pastoralist	70	14	43
Fish trading	7	85	14
Teacher	2	0	14
Tailor	0	0	14
Church leader	0	0	14
District	$N = 60$	$N = 7$	$N = 7$
Buliisa	18	14	14
Hoima	17	14	14
Kibaale	20	14	14
Kyegegwa	13	14	14
Kyankwanzi	8	14	14
Kiboga	10	14	14
Masindi	13	14	14

TABLE 4
Categories, subcategories, and examples of citations

Core category	Subcategories	Examples of codes	Citations showing category
Compatibility	Cultural construction of disease	–Disease is severe	"The caregivers rush (pneumonia cases) to health workers, because it is a feared disease. It is a serious disease. No one tampers with it; 10 out of 10 caregivers rush to the health worker, because pneumonia previously killed many children. Caregivers don't go for local herbs to cure pneumonia."—male VHT
Compatibility	Cultural construction of disease	–Disease is caused by non-biomedical causes	"Caretakers also have false beliefs of millet extraction obulo, and when a child develops pneumonia, they relate it to false millet in the chest that is stopping the child from breathing well, so they put cuts on the child's chest to extract it. . ."—male supervisor
Compatibility	Compatibility with expectations of healthcare	–Services are easily accessible –Adequate supply of the right drugs –Good quality of services –Training of CHW	"I expect VHTs to check and test children before giving them drugs so that they know exactly what they are treating and to advise on how and when to administer these drugs . . . For pneumonia, I expect her to give me drugs that suit my child's age."—participant, female FGD
Relative advantage	Financial benefits and non-financial benefits	–Services are free –Waiting time is shorter –Facility is nearer	"She makes follow-ups on the children she has treated yet she does all that free of charge. Some caregivers use a motorcycle to get to her place but sometimes we call her and she comes to our homes if we can't make it to her place."—female caregiver
Simplicity		–Services are easy to access –VHTs give information in simple terms	
Trialability		–If the services are free –If a significant other recommends it	
Observability		–Reduced morbidity –Reduced mortality –Quick treatment –Quick recovery –Health facility decongestion	"Before the VHTs were selected and trained, it was very difficult to have young children treated as sometimes, one had no money, and once a child fell sick, we could resort to the use of traditional herbs as we look for the money to go to the health facility or drug shop, and this delay led to the death of many children. So with the coming of the VHT during the time when they had the drugs, all that had changed, as we could quickly run to the VHT in case of an illness."—male caregiver
Complexity		–Program is not always functional –VHT possesses bad characteristics	"I didn't have drugs, so I referred her to the health center. After 4 days, she came back with another child, and I told her the same story. Now last week, she came back, and I still didn't have drugs; this time she asked me a question. What are you people doing if all the time you don't have drugs; then we shouldn't bother coming here, because you just hold titles of musawo, yet in the actual sense, you are not helping us."—female VHT

Malaria was widely treated at both the community (by VHTs) and health facility levels. However, local herbs such as mululuza and mukungulanya were often used as initial therapy in a number of areas. Fevers manifesting with severe symptoms were at times attributed to witchcraft and therefore, were not treated with Western medicines.

"Those who are perceived to be having awola (witchcraft) are taken to a traditional healer . . . Witchcraft in children comes like fever, and for children who are suspected to be bewitched, they are taken to traditional healers who remove some black things from the child's stomach, and it is believed that if such a child is treated with Western medicine, he/she will die instantly."—male VHT.

Program compatibility with healthcare expectations. In all communities, caregivers would normally opt for health services that meet their usual expectations of healthcare. Services were likely to be perceived as compatible if they were easily accessible in terms of distance from the home, if the facility had an adequate supply of the right drugs and diagnostic tools, if the services were perceived as prompt and good quality, and if professionalism or good customer care was observed. Participants also mentioned community sensitization, sanitation and hygiene, net distribution, school education, and coverage of a wide range of diseases in both adults and children as key components of what they perceive as a normal community healthcare package. Members of the VHT were well-accepted if they were perceived to give easily accessible healthcare with good quality, examining children tenderly and prescribing free drugs only after conducting investigations (Table 4).

Community members also expected VHTs to be equipped with a minimum level of training, diagnostic tools, and experience in managing children. In some communities, VHTs were at times criticized by caregivers who felt that VHTs had been trained for too short a time to have enough knowledge for treating children (Table 4).

Some communities had defined what should be an ideal service from an ideal VHT. When this expectation was not met, aggression to the VHTs often arose. This aggression was fueled by the assumption that VHTs are salaried workers; the

refusal of drugs after negative malaria tests; the refusal to treat children older than 5 years; and the refusal of more drugs that are demanded by community members. Community members were also likely to shun VHTs who they did not trust because of undesired behaviors like heavy drinking and suspected practicing of witchcraft.

"Most community members think that VHTs are paid and want to hold them accountable; like when caregivers go to the VHT's home and they don't find them there, they confront the VHTs and accuse them of wanting to behave like other government employees who don't want to offer services for which they are employed; this annoys the VHTs a lot."—male supervisor.

Conversely, in all communities, healthcare at the health facilities, although perceived to be driven by health workers with high technical expertise, was often disappointing for many of the respondents. They often expressed unmet healthcare expectations and opted for drug shops and private clinics with regular drug supplies, despite high drug cost and fee for service.

"I don't want to go to the health facility and line up or when I am asked by the health worker from the government facility to go and look for some of the drugs which he has prescribed for me that are out of stock. So, I will not have anywhere to buy such drugs other than the drug shop."—male caregiver.

Two villages had established a policy where community members were first required to visit VHTs before progressing to the health facility. In such areas, caregivers were more likely to go to the VHTs before going to the health center.

"The fact that health workers at the health centre ask for a referral form from the VHT is a clear indication that health workers trust what VHTs do, which means that the program is effective."—female FGD.

Relative advantages of the program. The perceived relative advantages of services offered by VHTs included both financial and non-financial benefits. Financial benefits included reduced expenditure on transportation to the health facility and drugs. Non-financial benefits included improved proximity and convenient access to services, because there were less official procedures in obtaining healthcare, with shorter waiting times and convenient opening hours.

"There are so many people at the health centre, yet at the VHT's home, they are few or none. There is no queue; you don't waste time, as it can take approximately only 20 minutes to be seen."—male caregiver.

The program was flexible, allowing for the possibility of making appointments with VHTs over the phone and treatment at home. It also provided for follow-up visits, counseling services, and routine health promotion visits, which were believed to have reduced disease prevalence. Caregivers with children who were referred by VHTs were prioritized at the health facility.

Program simplicity and complexity and access to healthcare. In communities where the iCCM program was well-accepted, it was perceived as difficult to neither understand nor use by community members. Caregivers often mentioned that, when fully functional, the program provided quick and easily accessible services with minimal inconvenience. The process of approaching VHTs was easy, and there was room for fixing quick appointments. The VHT members also provided useful information with simple explanations and practical demonstrations.

"I was content with the information she gave me, because she even mixed for me the drugs using boiled water and gave the child the first dose while I was watching and even educated me on how to mix the drugs. I learnt a lot during that process. "—male caregiver.

Complexity in communities where iCCM attendance is low was related to weaknesses within the program, such as frequent and frustrating drug stock outs, inappropriate selection of VHT candidates, and inadequate performance of VHTs. It was characterized by limitation in access to healthcare because of periodic migration of VHTs without prior notice to the supervisor or community and distrust and personal wrangles between VHTs and community members. Distrust aggravated program rejection if individual VHTs were believed to practice witchcraft and could, thus, pass on negative energies to community members.

"People in this community have complained about one VHT whose home is characterized by witchcraft, and caregivers sometimes fear to take their children for treatment."—female supervisor.

Trialability. Overall, trialability was not a problematic attribute of the program. Caregivers were often open to trying out iCCM services even within new communities and were attracted by the free access to effective drugs and the fact that the program was officially recommended by health workers. The caregivers who had tried the services were even willing to recommend them to others. Trialability was more likely to be influenced by recommendation of a significant other and was limited to only disease conditions perceived as nonsevere to avoid delay in accessing care from professional health workers.

"When you visit the VHT, because the child might be very ill, and the caregiver wastes time going to the VHT, yet he/she would use that time to get to the hospital on time. But because of that delay, sometimes children die along the way."—LC1 chairman.

There was a common belief in the communities that drips, injections, and syrups were stronger than tablets. The few medicine formulations provided by VHTs under iCCM limited trialability in some communities.

Observability. The iCCM program, when fully functional, was associated with highly visible or quick tangible rewards that were observable at the community and health facility levels of the healthcare system in all communities. Key observed results mentioned by the caregivers included quick treatment of children by VHTs, quick recovery, reduced frequency of disease episodes, reduced child mortality, and reduced health expenditure (Table 4). Health workers observed reduced patient traffic and workload at the health facility.

Perceived program use barriers. Despite tangible observed results, participants often cited a number of obstacles to program adoption. From the caregivers' point of view, key program challenges included frequent stock outs of drugs and diagnostic tools, the guilt of keeping VHTs away from their regular income-generating activities, and work overload for the VHTs. Occasional absence of VHTs from their work posts and lack of community sensitization after VHTs received new stocks of drugs were also mentioned as program constraining factors.

"Many people because of that [drug stock-out] have started saying that the VHT problems are like those at the health facility, because when you visit the VHT and there are no

drugs, she just refers you to the health facility and while at the health facility, a medical prescription is just written down for you and then you are sent to the drug shops and clinics to buy; hence, the last point is the clinic and that is where some people resort to go directly instead of wasting time and getting only referrals."—LC1 chairman.

The existing community constitution and beliefs were cited as potential barriers to service use by one LC1 chairperson. Migratory communities and sociocultural beliefs were believed to affect program adoption.

"The program is being hindered by the nature of the people on the landing sites [at the lake] . . . there are many tribes and foreigners in the area who have different practices and beliefs that they spread to other people. That is why some people have still failed to embrace the program."—LC1 chairman.

At the VHT level, program impediments included lack of supervision and feedback; lack of monetary facilitation, transport refunds, fuel for lighting, soap for hand washing, and clean water; frequent drug stock outs; and hostility from the communities. Lack of drugs, supervision, and feedback often resulted in lack of continuous practice, forgetfulness, and hence, poor performance and demotivation.

"Sometimes caregivers bring sick children requiring administration of the first dose of tablets from my place, yet sometimes I don't have boiled water. I would want to provide the water, but it is scarce in our area and I have to boil it. All this is costly yet important." —female VHT.

From the supervisors' perspective, major obstacles to program use were inherently associated with lack of facilitation, and they included demotivation, lack of financial support for supervision and communication, work overload, and considerable attrition among VHTs, which necessitates fresh and costly training.

"[We] supervisors have no air time to communicate with the VHTs, yet they keep beeping us. I have a motorcycle, but I have no fuel, so I can't visit all the VHTs. Some supervisors have lost morale. Only three of the six are active. Personally, I am not as active as I was before." —male supervisor.

DISCUSSION

Despite the existence of a mounting body of literature on the association between prevailing conditions and adoption of innovation, there is limited evidence on how complex innovations can successfully be implemented.[5,7,15] The findings from this study qualitatively confirm an association between the attributes of iCCM and its adoption in the communities, and they describe why variation occurs in uptake of the program among communities. Although iCCM is seen as an effective intervention, its acceptability and adoption are driven by context-specific factors. At the community level, disease construction and illness classification together with expectations of standard healthcare determine health provider choice. There was disconnection between the community's classification of the cause and severity of disease and the biomedical classification, which poses a challenge for program adoption. In some communities, the disease etiology for potentially severe pneumonia and malaria cases was witchcraft. Such phenomena have been described by earlier studies that have highlighted the importance of understanding perceived etiological factors as well as non-biomedical perceptions of disease symptoms and illness in African settings.[23–25]

The purpose of iCCM is to ensure that life-saving interventions, such as pre-referral rectal artesunate, are brought closer to the children who need them[1–3]; caregivers who perceived their children as having severe disease were more likely to take the children directly to the health facility. In terms of tailored interventions, such a move could deprive and cause a delay in access to life-saving treatment of children with severe malaria and pneumonia who require pre-referral treatment. This information should be scrutinized in the light of a Tanzanian study, which showed caregivers' reluctance in referral completion after improvement in the child's status after administration of rectal artesunate.[26,27] In relation to program simplicity, caregivers often found the health services provided by the program easy to use. Health system-related factors such as drug stock outs and non-fruitful referrals affected adoption in all areas. Conversely, societal and individual CHW factors, such as reciprocated trust between the communities and the CHWs, interpersonal relationships, demotivation, and undesired CHW's behavior predominantly affected acceptability in specific areas. Trialability was generally good, and participants believed that the iCCM package was attractive. However, the community's perception of what constitutes strong and effective medicine was negatively associated with iCCM medicines. Such patterns of hierarchical classifications (medicine formulations with drips being perceived as better than injections and injections being perceived as better than syrups) have been described elsewhere.[28]

It is known from previous studies on community case management of malaria that, although an intervention may be acceptable to communities, its acceptability is only as good as against what it is competing.[29] Although iCCM was generally well received in most communities based on its relative advantage and highly observable results compared with the status quo, the study shows that more is needed to make it the best alternative for healthcare at the community level. Given its sole dependence on voluntary CHWs, the program must further be scrutinized within the light of the problems that CHWs face in their day to day life as lay people in healthcare.[30,31] The problems do not only stem from the community but also from the health system, which sometimes fails to supervise and deliver the drugs and supplies to VHTs on a timely basis, thus exposing VHTs to similar solutions of referring patients to drug shops as is the practice at the health facility when drugs are out of stock.

The study was conducted within the framework of DOI model. The model has been commended for its substantial contribution to understanding behavioral change and thus, facilitating adaption of innovations to cultural needs and norms.[15,32] Identifying strengths and weaknesses of innovations using the attributes of the theory of DOI is central to effective health education and promotion in public health interventions.[32] Limitations of the theory include individual rather than system blame, recall bias because of dependency of the diffusion process on time, and a proinnovation bias.[15,32] Nonetheless, the study highlights important system challenges as well as positive and negative attitudes to iCCM.

Other study limitations included participant inhibition in FGDs, inability of interviews to produce data on how people act outside the interview context, and inability of the study to establish patterns in adoption overtime. However, the triangulation of participants, interviews, and FGDs as well as the

use of maximum variation sampling ensured that varied experiences were examined.

Although the aim of the iCCM strategy is to target the poorest families and efforts to scale it up are underway,[1,33] there is a need for holistic health systems strengthening to improve barriers for access to healthcare.[34,35] This strengthening will require operational drug supply chains, facilitation and reward (not exclusively monetary), operating supervision systems, and establishment of functional referral systems.[36–38] It is crucial to carry out systematic program sensitization using behavioral change communication (BCC) strategies adapted to the local context and local belief systems to improve adoption.[5,39,40] The BCC messages should clearly define what causes disease and what constitutes severe illness, and they should discourage irrational beliefs surrounding hierarchical classifications of medicines. This information will limit unnecessary self-referrals to the health facilities, while giving communities guidelines on when to seek healthcare from a VHT. At the community level, systems to ensure that selected CHWs are people who have the right mix of characteristics acceptable to both individual society groups and health workers in the formal sector will be required. Interventions ensuring CHW motivation, realistic remuneration, and performance will also be required.[30,31]

Received December 7, 2011. Accepted for publication February 18, 2012.

Acknowledgments: We wish to extend our thanks to the research assistants who collected the data and the inSCALE team Uganda, particularly Stella Settumba and Edmound Kertho.

Financial support: Funding for this research was provided by The Bill and Melinda Gates Foundation through a grant to Malaria Consortium for the inSCALE project (http://www.malariaconsortium.org/inscale/).

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 105–110
doi:10.4269/ajtmh.2012.11-0799

Impact of Integrated Community Case Management on Health-Seeking Behavior in Rural Zambia

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Abstract. Provision of integrated community case management (iCCM) for common childhood illnesses by community health workers (CHWs) represents an increasingly common strategy for reducing childhood morbidity and mortality. We sought to assess how iCCM availability influenced care-seeking behavior. In areas where two different iCCM approaches were implemented, we conducted baseline and post-study household surveys on healthcare-seeking practices among women who were caring for children ≤ 5 years in their homes. For children presenting with fever, there was an increase in care sought from CHWs and a decrease in care sought at formal health centers between baseline and post-study periods. For children with fast/difficulty breathing, an increase in care sought from CHWs was only noted in areas where CHWs were trained and supplied with amoxicillin to treat non-severe pneumonia. These findings suggest that iCCM access influences local care-seeking practices and reduces workload at primary health centers.

INTRODUCTION

Pneumonia, malaria, and diarrhea are three of the leading causes of mortality in children under 5 years old worldwide, accounting for approximately 3.6 million deaths annually.[1] Integrated community case management (iCCM) of these common childhood illnesses is a strategy that is increasingly being adopted to help reduce the burden of deaths of children under 5 years old in resource-poor countries in Asia and sub-Saharan Africa. This approach allows the provision of care closer to home and thus obviates the need for transportation or a long walk to a health center and the associated loss of productive time for the child's care provider. It may possibly halt progression to more severe disease. In addition, it has potential to reduce the volume of patients seen at primary health facilities. Given the human resource constraints in many countries,[2,3] there is a need for task shifting from primary healthcare centers to the community.

There are a number of factors that influence care-seeking behavior, including perceptions of cause of illness, distance, cost, and quality of available care.[4–6] Several studies have evaluated the impact of community-based management of malaria with artemisinin-based combination therapy (ACT) on care-seeking behaviors. A before and after survey of communities where volunteer Malaria Control Assistants in Sudan provided treatment of malaria for children guided by rapid diagnostic tests (RDTs) found a significant increase in treatment-seeking for fever at the community level after introduction of this program.[7] Similarly, a study that evaluated the home management of malaria in Burkina Faso found that this approach resulted in significant reductions in health center attendance.[8] A cross-sectional survey in Malawi found that consulting a community health worker for evaluation of febrile illness might decrease health center attendance.[5] The delivery of ACT by community medicine distributors was well-accepted by community members in five urban sites in sub-Saharan Africa, and the community-based agents were often the first point of care when a child was ill with fever.[9] Although all of these studies suggest that the availability of malaria diagnostics and quality treatments at the community level are well-accepted and likely to reduce the workload of health workers at primary health centers, none have evaluated the impact of iCCM on care-seeking behaviors or healthcare center attendance.

The Zambia Integrated Management of Malaria and Pneumonia Study (ZIMMAPS) was a cluster randomized controlled trial that compared two approaches to iCCM of malaria and/or non-severe pneumonia in children provided by trained community health workers (CHWs) in two rural districts of Southern Province, Zambia.[10] This study provided a context to evaluate the impact of the availability of iCCM services in the community on healthcare-seeking behaviors and the use of CHWs relative to rural health centers as a first point of care for young children with possible malaria and/or pneumonia. Our primary objective was to determine the impact of two different models of iCCM on health-seeking behaviors, and we also sought to determine whether there were differences in health-seeking practices as a function of the types of services offered by CHWs.

METHODS

Study population and design. Cross-sectional household surveys on healthcare-seeking practices were performed before and immediately after ZIMMAPS. The study was conducted within the catchment area of Chikankata Mission Hospital (CMH), which has a population of about 70,000 covering parts of Mazabuka and Siavonga Districts in Southern Province, Zambia between December of 2007 and November of 2008. Healthcare in the study area is provided by the mission hospital, five rural health centers (RHCs), of which only one has a full complement of staff (clinical officer, environmental health technician, and midwife), and CHWs who work in a fixed location called the community health post (CHP), which serves several villages. There are no private clinics or drug shops in the study area.

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Before the study, CHWs treated children suspected to have malaria with sulfadoxine-pyrimethamine and referred those children with suspected pneumonia cases to the nearest health facility. They were also responsible for managing other minor illnesses, including diarrhea, with oral rehydration therapy. All children with signs of severe disease were referred to the RHC for management. The CHWs were supposed to receive kits (containing essential drugs and supplies) from CMS or the RHCs every one month, but the supply of the kits was very irregular. The CHWs were also supposed to engage in community mobilization and sensitization for outreach services and health education, but these activities were rarely performed. The study team did not perform community sensitization to raise awareness of the new iCCM models that were being evaluated in the CMS catchment area before study initiation.

ZIMMAPS was a cluster randomized controlled trial that compared two approaches to the iCCM of malaria and/or non-severe pneumonia in children by trained CHWs in the two rural districts. CHWs in iCCM model A clusters were taught to perform and interpret RDTs for malaria, administer artemether-lumefantrine (AL) to children who tested positive for malaria, and administer amoxicillin for treatment of children diagnosed with non-severe pneumonia. CHWs in iCCM model B clusters were supplied with AL for treatment of suspected malaria cases and were taught to refer all non-severe pneumonia cases to the nearest rural health center for treatment as per the standard of care. Both groups of CHWs were given antipyretics for treatment of children with fever (including RDT-negative fever) and were taught to immediately refer all children with signs and symptoms of severe illness to the nearest RHCs. The detailed study design and results have been described elsewhere.[10]

Household surveys and data collection. Household surveys were designed to measure baseline and post-study healthcare-seeking behavior among the targeted population of households with children under 5 years. The surveys collected information on demographics, care-seeking behaviors, childhood morbidity and mortality, preventive health measures, and knowledge of danger signs for childhood illnesses plus acceptability and use of CHWs, RHCs, and other informal healthcare sector services. Women were also asked specific questions surrounding the most recent illnesses of their under 5 years of age children, including disease-specific signs and symptoms, where they sought care, what kind of care they sought, what kind of care they received, and adherence to the treatment regimens provided. They were also queried about their knowledge of signs of severe illness.

We recruited women aged 15–45 years old who had at least one child under the age of 5 years and resided within the study area. Two villages per CHP cluster were randomly selected for recruiting women, and the same villages were used for selecting women for both the baseline and post-study data surveys. However, we did not make any conscious effort to recruit the same women for both the baseline and post-study surveys, and therefore, it is most likely that different women were interviewed in the surveys. In each village, 14 households with mothers with young children were selected systematically. The center of the village was identified with the help of the village headman, and the first house with the door nearest to the center was selected. The next house selected was the one with the door nearest to the previous one, and this process continued until the number of survey participants for the village was attained. Only one woman per household was allowed to participate, and if more than one woman resided in a household, the oldest woman was selected. If the woman had more than one child under 5 years, the child with the most recent illness was selected. For these surveys, women were not required to have had their children enrolled in the randomized trial to participate.

For both baseline and post-study surveys, trained data collectors administered the questionnaires. Data collectors underwent training in study procedures, use of study instruments, research ethics, and informed consent protocols.

Informed consent and ethical clearance. Written informed consent was obtained from all women participating in the household surveys before surveys were conducted. Ethical approval for the study was obtained from the University of Zambia Research Ethics Committee and the Boston University Institutional Review Board. We also received approval from the Zambian Ministry of Health, the two District Health Management Teams (Mazabuka and Siavonga) where the studies were conducted in Southern Province, and local community leaders.

Statistical analysis. Data were double entered into CS Pro 3.3 (US Census Bureau, Washington, DC); consistency and validation checks were conducted. Analyses were performed with SAS v 9.1.3 (SAS Institute, Cary, NC). With respect to questions on first action taken by mothers when the child was sick, those women who reported visiting a RHC and those women who visited a hospital were classified as having sought care at a health facility. We also combined mothers who reported visiting a traditional healer with those mothers who visited spiritual leaders. Regarding signs of infection, we combined mothers who reported seeking care if their child had either fast or difficult breathing. With respect to medications, we combined mothers who reported using amoxicillin with those mothers who used other antibiotics. We compared crude proportions of source of first care in response to different illnesses in the iCCM model A and B groups at baseline and post-study using the Mantel–Haenszel χ^2 or Fisher exact test as appropriate. Data for changes in health-seeking behavior are presented as relative risks (RRs) adjusted for sampling cluster effect (adjusted RR [aRR]). We included both groups in the model and included a group $\times$ time interaction to determine whether there were significant differences in healthcare-seeking behaviors between the two iCCM models. We used a significance level of 0.05 to report *P* values.

RESULTS

A total of 440 women (210 from iCCM model A and 230 from iCCM model B communities) was interviewed during the baseline survey conducted in August of 2007, and 441 women (213 from model A and 228 from model B communities) were interviewed during the post-study household surveys conducted in December of 2008. In both surveys, the women were recruited from 62 villages (2 villages per each of the 31 study clusters).

Study population characteristics. There were no major differences in demographic characteristics (age, household size, marital status, and education) in the model A and B communities at both the baseline and post-study periods (Table 1). Most women reported being married, having obtained a primary school level of education, and working as farmers or housewives within the study area, although there were more

TABLE 1
Demographic and household characteristics of survey respondents

Characteristic	iCCM model A*		iCCM model B**	
	Baseline ($N = 210$)	Post ($N = 213$)	Baseline ($N = 230$)	Post ($N = 228$)
Mean age in years (range)	27.5 (16–46)	28.7 (15–48)	27.5 (15–68)	29 (16–66)
Mean household size (range)	5.8 (1–14)	5.7 (3–15)	5.8 (2–14)	5.9 (2–12)
Mean number of children under 5 years old in the household (range)	1.5 (0–4)	1.5 (1–3)	1.5 (1–5)	1.5 (1–3)
Education (highest level attained)				
No formal education	28.7%	32.2%	36.7%	34.2%
Primary	65.1%	59.1%	57.7%	59.9%
Marital status				
Married	88.0%	86.2%	90.9%	86.6%
Single/divorced	11.5%	12.8%	9.1%	13.4%
Occupation				
Housewife	33.0%	36.2%	51.3%	45.5%
Farmer	61.2%	61.4%	43.5%	51.1%
Reported household cell phone ownership	8.6%	19.3%	11.3%	20.6%
Reported use of ITN for malaria prevention	68.4%	94.4%	60.4%	92.5%
Reported that a < 5-year-old child slept under ITN last night	57.9%	85.0%	53.5%	83.3%

*Model A CHWs performed and interpreted malaria RDTs, administered AL to children who tested positive for malaria, and administered amoxicillin for treatment of children diagnosed with non-severe pneumonia.
**CHWs in iCCM model B communities treated suspected malaria cases with AL and referred all non-severe pneumonia cases to the nearest rural health center.

farmers and fewer housewives in the model A communities than the model B communities. During the course of the study, household ownership of cell phones and the use of insecticide-treated bednets (ITNs) increased in both model A and B groups. In addition, more households in both the models A and B communities reported that a child under 5 years had slept under an ITN the previous night during the post-study period.

Maternal knowledge of serious illness. When mothers were asked to tell the interviewer (without prompting) the signs of illness that would indicate that their child was very sick and in need of urgent attention or treatment, most mentioned high fever and not playing (Table 2). Other common signs that were mentioned included vomiting, not eating or drinking, difficulty in waking, difficult breathing, and having convulsions. At baseline, mothers in the model B communities described several potential danger signs less frequently than mothers in model A communities. Notably, the survey that was done after study completion revealed significant decreases in maternal knowledge of danger signs of illness for several specific signs in model A and to a lesser extent, model B.

Care-seeking behaviors. In both the model A and model B groups, more than 80% of mothers reportedly sought care on the day that their child first showed signs of illness or the next day, and there was no significant difference between baseline and pre-and post-study in both groups. In the pre-study baseline period, the mothers of children in both iCCM models A and B communities used CHWs about one-half the time and health facilities a little over 40% of the time as the first source of care for any reported illness (fever, cough, fast/difficult breathing, or diarrhea), whereas a small proportion managed their child at home or sought assistance from traditional healers (Table 3). There were no differences in treatment-seeking behaviors at baseline between the model A and B communities. There was a significant increase in the proportion of mothers who sought care from CHWs between baseline and post-study in both groups for all types of illness, whereas there was a decrease in use of health facilities and traditional healers (Table 3).

First health-seeking action for children with fever. At baseline, about one-half of mothers in both communities used CHWs as their first source of care if their child was febrile, with health facilities serving as the next most common source of care (Table 3). Comparing care-seeking for fever between groups (iCCM models A and B) as well as changes over time (baseline and post-study surveys), similar patterns to the patterns of all illnesses were observed. There was a significant increase in the proportion of mothers who sought care from a CHW between the baseline and post-study surveys in both

TABLE 2
Maternal knowledge of signs of severe childhood illness

Signs of illness*	iCCM model A communities		iCCM model B communities	
	Baseline ($N = 209$)	Post ($N = 212$)	Baseline ($N = 230$)	Post ($N = 228$)
Not playing	167 (79.9)	168 (79.2)	196 (85.2)	179 (78.5)**
Not eating or drinking	133 (63.6)	102 (48.1)†	113 (49.1)	103 (45.2)
Difficult to wake	104 (49.8)	76 (35.8)‡	66 (28.7)	84 (36.8)**
High fever	193 (92.3)	187 (88.2)	205 (89.1)	195 (85.5)
Vomits everything	140 (67.0)	84 (39.6)†	133 (57.8)	86 (37.7)†
Difficult breathing	97 (46.4)	53 (25.0)†	51 (22.2)	50 (21.9)
Convulsions	82 (39.2)	49 (23.1)‡	40 (17.4)	42 (18.4)

*More than one response possible.
**Comparison of baseline and post-study survey results ($P = 0.06$).
†Comparison of baseline and post-study survey results ($P < 0.001$).
‡Comparison of baseline and post-study survey results ($P < 0.01$).

TABLE 3
First source of care for illness stratified by iCCM model

	iCCM model A communities				iCCM model B communities			
	Baseline	Post-study	RR (95% CI)	Adjusted RR (95% CI)	Baseline	Post-study	RR (95% CI)	Adjusted RR (95% CI)
Any illness	*N* = 174	*N* = 191			*N* = 163	*N* = 203		
Managed at home	9.2%	2.6%	0.47 (0.16–1.39)	0.55 (0.18–1.64)	5.5%	4.0%	0.43 (0.19–0.98)	0.41 (0.12–1.38)
CHW	47.1%	79.1%	1.55 (1.31–1.84)	1.39 (1.11–1.74)	50.9%	77.3%	1.64 (1.38–1.95)	1.55 (1.20–2.01)
Health facility	40.2%	18.3%	0.44 (0.31–0.62)	0.49 (0.28–0.86)	41.7%	17.7%	0.44 (0.31–0.62)	0.49 (0.29–0.82)
Traditional/spiritual healer	3.4%	0			1.9%	1.0%	0.29 (0.06–1.40)	
Fever	*N* = 149	*N* = 179			*N* = 154	*N* = 190		
Managed at home	10.1%	2.2%	0.43 (0.13–1.40)	0.48 (0.14–1.60)	5.2%	3.7%	0.37 (0.15–0.88)	0.37 (0.10–1.30)
CHW	48.3%	81.0%	1.58 (1.33–1.87)	1.42 (1.14–1.78)	51.3%	77.9%	1.61 (1.34–1.94)	1.55 (1.18–2.02)
Health facility	39.6%	16.8%	0.40 (0.28–0.59)	0.45 (0.25–0.81)	41.6%	17.4%	0.44 (0.31–0.63)	0.48 (0.28–0.81)
Traditional/spiritual healer	2.0%	0			5.9%	1.1%	0.52 (0.09–3.09)	
Cough	*N* = 140	*N* = 142			*N* = 133	*N* = 156		
Managed at home	7.9%	2.1%	0.40 (0.11–1.5)	0.42 (0.11–1.63)	5.3%	3.8%	0.48 (0.19–1.29)	0.52 (0.15–1.83)
CHW	52.9%	79.6%	1.51 (1.26–1.81)	1.45 (1.15–1.81)	52.6%	78.8%	1.49 (1.25–1.78)	1.39 (1.07–1.79)
Health facility	37.9%	18.3%	0.45 (0.30–0.68)	0.42 (0.23–0.79)	40.6%	16.7%	0.44 (0.29–0.66)	0.54 (0.31–0.94)
Traditional/spiritual leader	1.4%	0%			1.5%	0.6%	0.45 (0.04–4.90)	
Difficult or fast breathing	*N* = 61	*N* = 35			*N* = 59	*N* = 25		
Managed at home	6.6%	2.9%	0.56 (0.06–5.20)	0.49 (0.05–4.82)	5.1%	12.0%	1.83 (0.44–7.59)	1.79 (0.31–10.18)
CHW	50.8%	74.3%	1.37 (1.01–1.86)	1.39 (0.98–1.98)	54.2%	52.0%	1.02 (0.65–1.61)	1.10 (0.68–1.77)
Health facility	42.6%	22.9%	0.59 (0.30–1.17)	0.56 (0.23–1.32)	39.0%	36.0%	0.85 (0.46–1.54)	0.78 (0.42–1.47)
Traditional/spiritual healer	0	0			1.7%	0		
Diarrhea	*N* = 105	*N* = 52			*N* = 103	*N* = 59		
Managed at home	7.6%	1.9%	0.33 (0.04–2.67)	0.33 (0.04–1.10)	5.8%	5.1%	0.67 (0.18–2.42)	0.65 (0.14–3.01)
CHW	54.3%	78.9%	1.62 (1.27–2.07)	1.48 (1.10–1.99)	48.6%	76.3%	1.41 (1.12–1.76)	1.39 (1.02–1.89)
Health facility	34.3%	19.2%	0.44 (0.24–0.80)	0.49 (0.23–1.01)	43.7%	16.9%	0.49 (0.27–0.92)	0.55 (0.27–1.24)
Traditional/spiritual healer	3.8%	0			1.9%	1.7%	0.44 (0.05–3.89)	

model A (48.3% versus 81.0%, aRR = 1.42, confidence interval [CI] = 1.14–1.78) and model B (51.3% versus 77.9%, aRR = 1.55, CI = 1.10–2.02) groups. There was a corresponding decrease in the proportion of mothers who sought care from health facilities between baseline and post-study in both model A (39.6% versus 16.8%, aRR = 0.45, CI = 0.25–0.81) and model B (41.6% versus 17.4%, aRR = 0.48, CI = 0.28–0.81) groups. Mothers in both groups used traditional healers less after the study period, but this difference was not significant. There were no significant between-group differences in the use of CHWs or health facilities over time.

First health-seeking action for cough. In the pre-study period, mothers in both groups used CHWs as the first source of care for cough about one-half the time, with the health facility serving as the next most common source of care (Table 3). Mothers in the post-study survey used the CHWs significantly more than at baseline in both groups (model A: 52.9% versus 79.6%, aRR = 1.51, CI = 1.26–1.81; model B: 52.6% versus 78.8%, aRR = 1.49, CI = 1.25–1.78). There was a concurrent significant decrease in the use of health facilities in both groups. There were no significant between-group differences in the use of CHWs or health facilities over time.

First health-seeking action for children with fast or difficulty breathing. For children with difficulty or fast breathing, there was an increase of 23.5% in the proportion of women who sought care from CHWs between the baseline and post-study in the model A communities that was significant on unadjusted analysis but became non-significant after adjustment for clustering (Table 3). There was also a decrease in the proportion of women who sought care from health facilities between baseline and post-study surveys in the model A group; this finding was significant when unadjusted but then became non-significant after adjustment for clustering. In contrast, there were no differences in care-seeking in the model B communities. Despite an increase in the use of CHWs as the first source of care for fast/difficult breathing in model A relative to model B communities, the between-group difference was not significant.

First health-seeking action for diarrhea. In the pre-study period, mothers in both groups used CHWs as the first source of care for diarrhea about one-half of the time, with the health facility serving as the next most common source of care (Table 3). Mothers in the post-study survey used the CHWs significantly more than at baseline in both groups (model A: 54.3% versus 78.9%, aRR = 1.48, CI = 1.10–1.99; model B: 48.6% versus 76.3%, aRR = 1.39, CI = 1.02–1.89). There was a concurrent significant decrease in the use of health facilities in both groups, especially in the model B communities.

Medication use. For the most recent illness in children under 5 years, mothers reported significant increases in the proportion of febrile children receiving antipyretics (paracetamol) between time periods in the model A communities (84.1% versus 96.7%, $P < 0.001$) and a trend to an increase in the model B areas (90.3% versus 95.7%, $P = 0.06$).

Mothers in both groups reported increases in the use of AL for their children's most recent illnesses between pre- and post-study periods, although there was a larger increase in the proportion receiving AL in the model B communities (14.0–72.2%, $P < 0.001$) where CHWs had been taught to treat all children presenting with fever with AL without confirmatory testing with RDTs. The proportion of mothers who reported receiving antibiotics for their child's most recent illness increased between pre- and post-study time periods in model A areas, where the CHWs were able to treat non-severe pneumonia with amoxicillin (16.0% versus 25.0%, $P = 0.04$) but decreased in model B areas, where the CHWs referred children with pneumonia to the health facility for evaluation (21.1% versus 10.7%, $P = 0.01$).

Maternal satisfaction with CHWs. Maternal satisfaction with the care provided by CHWs was high at both baseline (312/327, 95.4%) and post-study surveys (415/417, 99.5%) in

both model A and B communities. When asked in the pre-study period whether they would go to a CHW the next time that their child was sick, the vast majority of mothers in both communities would see a CHW again (96.1%, 199/207; 97.8%, 224/229, respectively). During the post-study survey, all (100%, 213/213, $P = 0.003$ compared with baseline survey) of the mothers in the model A group would see a CHW again, and nearly all model B mothers would see a CHW again (223/228, 97.8%).

DISCUSSION

Two approaches for iCCM of malaria and non-severe pneumonia in children under 5 years old in rural Zambia led to significant changes in health-seeking behavior by mothers living in these areas with access to these programs. More mothers in both areas (models A and B communities) reported visiting CHWs as their first source of care for any illness after the introduction of iCCM in their villages, and both groups of mothers reported similar increases in the use of CHWs for febrile illnesses. At the same time, mothers reported decreases in care sought for all illnesses and fever from formal health facilities as well as care provided at home or from traditional healers after the introduction of enhanced care delivery by CHWs through the ZIMMAPS iCCM programs. The increase in the use of the services of the CHWs was most likely because of the confidence that the community had in the improved CHW services as a result of the availability of drugs, supplies, and up-to-date skills and knowledge. Before ZIMMAPS, the CHWs did not have drugs and had not received any refresher training for years. Mothers reported increased use of AL for management of malaria and antibiotics for pneumonia (the latter in the model A clusters only). These findings corroborate the findings of the main study, which showed significant increases in the prescription of AL for malaria and amoxicillin for pneumonia by CHWs based on review of their logbooks.[10]

In model A areas, where the CHWs were trained to provide amoxicillin to children presenting with signs/symptoms of non-severe pneumonia and perform RDTs to diagnose malaria, mothers of children with difficult or fast breathing reported increases in first care sought by CHWs with concomitant decreases in care sought at health facilities and home management. The same changes were not recorded in model B communities, where CHWs were trained to provide AL to all children with fever and refer children with signs/symptoms of non-severe pneumonia to the nearest formal health facility. Because the two surveys were carried out during different seasons (baseline in August, which is the cold, dry season; post-study in December, which is early rainy season), there were fewer children with recent episodes of fast/difficulty breathing (suggestive of pneumonia) in the post-study survey period. Although there was a more than 20% increase in visits to CHWs in model A and no change in model B, the lack of significance might be because of the small numbers reporting fast/difficulty breathing during the post-study period. It is encouraging to note that the inclusion of skills, training, supplies, and an additional clinical algorithm for CHWs to evaluate and treat non-severe pneumonia in the community led to shifts in health-seeking behaviors by mothers in communities with these services and a greater percentage of children having recently been treated with antibiotics. As more iCCM programs are being designed and implemented, these findings suggest that there is potential for successful uptake of iCCM in settings similar to rural Zambia.

Interestingly, we found that mothers' first care-seeking behavior for children with diarrhea was also significantly affected by the introduction of the iCCM approaches in both models A and B communities. Larger proportions of mothers in both communities reported seeking care for children with diarrhea from CHWs after introduction of two iCCM models and a concomitant decrease in care sought from health facilities. Although ZIMMAPS did not train CHWs to manage and treat diarrheal diseases in children and it did not assure increased availability of oral rehydration solutions through its enhanced CHP supply chain system, the surrounding communities might have developed more confidence in the care provided for all illnesses by CHWs after the introduction of iCCM and witnessing enhanced services for malaria and non-severe pneumonia. The CHWs also may have helped to educate community members about the risk of complications of diarrhea and the need for early oral rehydration therapy. The implementation of a routine referral system (CHP to RHC or mission hospital) by ZIMMAPS-trained CHWs may have also led to more children with diarrheal disease being evaluated and managed at the first point of care by CHWs at CHPs. Regardless of possible causes, if implementation of iCCM for specific illnesses (like malaria and non-severe pneumonia in ZIMMAPS) leads to increased community demand for the care of other illnesses by the same cadre of healthcare providers, this change has public health implications for the scope of iCCM programs. This finding may be an argument in favor of designing iCCM programs that integrate commonly presenting diseases and illnesses, like diarrhea, malaria, pneumonia, and potentially, identification of malnutrition, to account for these care-seeking behavior changes and avoid vertical disease programs. At the same time, caution must be entertained that community-based health workers are not being asked to provide care for which they are neither trained nor equipped to manage or to perform too many duties, which may limit their ability to provide quality care.

Overall satisfaction with CHWs both pre- and post-iCCM implementation was extremely high in both iCCM model areas, with most mothers reporting that they would continue to use CHWs for future care. Although the survey did not probe deeper for reasons for such high satisfaction, this finding may partly be a reflection on the austere setting in rural Zambia where ZIMMAPS was conducted and both the limited access and great distances that people need to travel for more formal healthcare delivery through Zambia clinics and hospitals. In any case, such high community acceptance for programs like ZIMMAPS portends well for the design, implementation, and overall scale-up of future iCCM programs in similar settings with limited access to healthcare.

Although ZIMMAPS focused on sensitizing communities to the iCCM programs before their introduction, we did not provide any ongoing health education for the mothers and caregivers of under 5 years children. This lack of education might explain why maternal knowledge of signs of severe childhood illnesses (Table 2) did not improve over time and in fact, seemed to have worsened during the post-study survey. In addition, mothers may have changed their perceptions of disease severity in their children knowing that convenient, immediate care was available.

Although several past studies have shown that the capacity of CHWs to treat malaria was associated with increased use of community-based providers for initial care and reduced visits to primary health centers,[5,7–9] our study is one of the first to show changes in health-seeking behavior for multiple diseases based on the local availability of iCCM. Two recent qualitative studies in Malawi and Uganda found that local health workers noted reductions in patients presenting to their health facilities after the introduction of iCCM in their communities.[11,12] In contrast to our findings, another study in Uganda that evaluated the impact of community medicine distributors trained to treat febrile children with AL and children with non-severe pneumonia with amoxicillin found only marginally increased use of this cadre of health worker by mothers in the community.[13] The context in this rural area of Uganda was substantially different from our study site in rural Zambia, because in Uganda, there were many other options available for local treatment, including private clinics, drugs shops, and government health centers.

There are several limitations to this study, including the use of different survey participants at baseline and post-study, potential recall bias for mothers completing the survey, absence of data from RHCs on the volume of sick children seen during the pre-/post-study periods, and lack of survey questions investigating why mothers changed their health-seeking behaviors over time.

The recently released WHO and UNICEF Inter-Agency joint statement advocates for the more widespread use of iCCM of common childhood illnesses by trained community-based healthcare providers in resource-limited environments as a strategy to address the burden of morbidity and mortality in children less than 5 years old.[14] Although many factors influence successful introduction and scale-up of iCCM programs, such as stakeholder perceptions, community-based reporting systems, government policy, training, supervision, and supply chain management, their effectiveness as child survival interventions is dependent on changes in care-seeking behavior and practices in the communities where iCCM programs are being introduced.

Received December 23, 2011. Accepted for publication April 13, 2012.

Acknowledgments: We would like to recognize the excellent support from the Siavonga and Mazabuka District Health Management Teams and the Chikankata Mission Hospital. The study was funded by the Child and Family Applied Research project at Boston University by means of Cooperative Agreement GHS-A-00-03-00020-00 with the US Agency for International Development (USAID) and the President's Malaria Initiative.

Disclaimer: The opinions expressed herein are the opinions of the authors and do not necessarily reflect the views of USAID.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 111–119
doi:10.4269/ajtmh.2012.12-0030

Interventions to Improve Motivation and Retention of Community Health Workers Delivering Integrated Community Case Management (iCCM): Stakeholder Perceptions and Priorities

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Abstract. Despite resurgence in the use of community health workers (CHWs) in the delivery of community case management of childhood illnesses, a paucity of evidence for effective strategies to address key constraints of worker motivation and retention endures. This work reports the results of semi-structured interviews with 15 international stakeholders, selected because of their experiences in CHW program implementation, to elicit their views on strategies that could increase CHW motivation and retention. Data were collected to identify potential interventions that could be tested through a randomized control trial. Suggested interventions were organized into thematic areas; cross-cutting approaches, recruitment, training, supervision, incentives, community involvement and ownership, information and data management, and mHealth. The priority interventions of stakeholders correspond to key areas of the work motivation and CHW literature. Combined, they potentially provide useful insight for programmers engaging in further enquiry into the most locally relevant, acceptable, and evidence-based interventions.

INTRODUCTION

It has been estimated that Millennium Development Goal (MDG) 4 of reducing under-five child mortality by two-thirds from base levels of 1990 may not be attained in sub-Saharan Africa until 2165[1] unless efforts are made to increase the coverage of key interventions. Integrated community case management (iCCM) of childhood illnesses could potentially prevent more than 60% of the annual deaths of under-five children due to malaria, pneumonia and diarrhoea in sub-Saharan Africa[2] and is being adopted in several countries. To counter human resources and skill shortages, bring health service delivery closer to the community, and in response to the recent World Health Organization (WHO) emphasis on health worker task shifting to lay personnel, many countries are using volunteer community health workers (CHWs) to deliver iCCM.[3–9]

CHWs were used by national health ministries as key agents in the delivery of primary health care after the 1978 Alma Ata Conference[1,5]; however, by the early 1990s enthusiasm for CHW programs had diminished in part caused by the challenge of sustainability linked to poor retention and motivation of workers.[5,7] Interest in CHWs has resurged in recent years; however, there remains a lack of available information related to CHW retention and motivation. Proven strategies are needed[10–12]; as despite a large volume of programmatic experience relating to CHW motivation, there has been little documentation.

This work reports the findings of interviews with stakeholders with a range of program and research experience in diverse settings. Interviews were designed to elicit stakeholder perceptions and priorities related to strategies for improving the retention and motivation of CHWs in low income settings. The data were collected as the first stage of a process of implementation design for the inSCALE project (innovations at scale for community access and lasting effects), which aims to test strategies to improve CHW motivation, retention, and performance in Uganda and Mozambique using a randomized controlled trial design. The aim was to establish an overview of intervention ideas and approaches that program implementers and researchers felt had the potential for impact. The perceptions and priorities of stakeholders are presented in the Results section before being discussed in light of key directions from the work motivation and CHW literature.

MATERIALS

Data were collected using a semi-structured interview guide (Appendix 1: Web Annex) that covered: participants' experiences working with CHWs, including successful and challenging aspects of their work and recommendations for other CHW programs, perceptions of the most effective approaches for increasing motivation and retention levels, and any innovations and novel ideas they had or had heard of relating to motivation and retention. Participants were asked to provide an indication of priority for their recommendations based on potential for impact and to explain their rationale.

The interview guide contained probes based on previous work in the context of CHW motivation and retention including in the areas of training, supervision, incentives, community involvement and ownership, information and data management, and mHealth, which have been included as sections in the Results.[5,9–12]

METHODS

Semi-structured key informant interviews were conducted with 15 stakeholders selected because of their experience in the design, implementation, and evaluation of both small-scale and national level CHW programs in a range of low-income settings. Recruited stakeholders were academics and non-governmental organization (NGO) workers based in Europe, North and South America, Africa, and Central Asia. Further details relating to each stakeholder are provided in Table 1. Six participants were identified by the inSCALE project team and a further nine were identified through snowball sampling where each participant recommended people they considered influential in the CHW field. Ten participants

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TABLE 1
International stakeholder research participants: professional profiles

Role	Location and reference
Technical roles with international non-governmental organizations (NGOs) delivering health services	East Africa (participants 6,14,15) and Central Asia (participant 1)
Senior roles with international NGOs focused on delivering health services through CHWs in Africa, Asia, and South America	USA (8–11)
Senior roles with an NGO that facilitates knowledge sharing and collaborative action between NGOs in the context of public health for underserved populations	USA (2,4)
International consultant with extensive experience working with CHW programs in sub-Saharan Africa	USA (3)
University-based researchers with experience in the research and dissemination of data relating to the motivation and retention of CHWs and providing key support to the development of strategy and policy for bilateral organizations and governments	USA (5,12)
Recently graduated PhD student whose work focused on the retention of CHWs in Southern Africa	USA (7)
Advocate for a Central Asian community health program successfully using CHWs in the delivery of health services	USA (13)

were interviewed in person at an international conference focusing on community health,[13] one interview was conducted in person at the participant's workplace and four were conducted remotely over the internet.

Each stakeholder was assigned a number at random, which appears in the 'location and reference' column in Table 1 and alongside their priorities and perceptions in Tables 2–9. Ethical approval was given by the London School of Hygiene and Tropical Medicine (reference 5762) and signed informed consent was obtained for all in person interviews and emailed informed consent for interviews conducted over the internet.

Interviews were conducted by one trained researcher using a semi-structured guide and took between 60 and 90 minutes. Notes were taken during the interview and all interviews were audio recorded; after each interview expanded notes were written up in full.

The data were analyzed thematically for potential interventions and practices through multiple readings of the notes and listening to the audio recordings.[14,15] In line with a process of analytic induction that used an iterative approach to data analysis based on both predetermined categories and the data generated, sections relating to cross-cutting approaches and recruitment were added to the probes which generated the richest data to complete the thematic sections presented in the results.[14–16] Interventions that stakeholders considered most likely to be effective or of contemporary relevance are highlighted within these sections.

RESULTS

Cross-cutting approaches. A number of participants made suggestions related to the general approach to be taken when designing interventions aiming to increase motivation and retention. These are termed here *cross-cutting approaches*. Major themes to emerge were the need for tailoring interventions to context, adopting a multi-faceted approach, and paying adequate attention to CHW workload and expectations if interventions are to be effective. It was also suggested that promoting program success and having consistent branding could increase motivation and retention. Table 2 contains details of the specific rationale for each of the main themes of response.

Recruitment. The manner in which CHWs are recruited was recognized as a critical influence on their retention and motivation. A broad recommendation was that in order for the role to be filled productively over time strategies must focus on recruiting those who have the drive to both provide a service to their community and share their knowledge. Suggested approaches for achieving this were to encourage community involvement in selection and support for CHWs and address the need for succession planning through CHWs identifying and mentoring their successors. Although ensuring specific CHW capacities through the adoption of criteria-based recruitment was a suggested approach, the possibly negative impact on gender equity and retention was noted especially when adopting education-based criteria. Table 3

TABLE 2
Suggested cross-cutting approaches

Theme	Rationale
Interventions tailored to context	• Interventions based on formative research designed to understand CHW experiences and motivations and their variations across the population will improve acceptability, uptake, and the possibility of potential success (2,3,7,11,14).
Multifaceted intervention design	• Packages of interventions that address different facets of motivation at community, CHW, and implementer level are more likely to be successful (1,4). • Based on experience in central Asia a phased implementation approach will avoid loss of quality and increase effective community engagement (1).
CHW expectations and workload	• Programs need to understand CHW expectations and adequately meet or manage them to ensure trust is maintained and retention and motivation are likely (1,5,6,8–11,14). • Formal volunteer contracts established collaboratively (6), regular feedback, (5,7), and the management of workload (12) are important for worker satisfaction.
Communicating success of programs	• Highlighting programmatic success through evidence as early as possible to the Ministry of Health and key stakeholders is important for program sustainability (1,6,8,14). • Conveying the impression of a reliable and united program worthy of respect through consistent branding promotes volunteer understanding of the value of their role (1,5).

TABLE 3
Suggested strategies related to recruitment

Theme	Rationale
Community selection and support of CHWs	• Participatory community selection increases community acceptability and demand for CHW services and encourages community support for CHWs. In doing so it contributes to the sustainability of programs and CHW motivation and retention. It also increases the likelihood of selecting those both motivated to work and representative of the community (1,2,8,13).
CHWs mentoring successors	• Functional CHWs identifying and mentoring their successor ensures continuity in the delivery of CHW services and enhances the prospect of recruiting individuals willing and able to perform the role. It also serves to manage new CHWs' expectations through supplying a clear and experience-based role description and increases the likelihood of establishing community support for the new CHW through familiarization (1,9,12,14).
Using criteria for CHW recruitment	• Adopting criteria for selection may ensure CHWs have desirable skills but if based on education and/or literacy may influence both gender balance and retention. In areas of low female educational opportunity a strategy based on education/literacy criteria may result in increased selection of males (2). There may also be a negative correlation between education and retention caused by greater alternative employment opportunities for educated workers (1).

contains details of the specific rationale for each of the main themes of response.

Training. Technically strong and relevant training that is valued by CHWs and respected by the community was reported as important for retention and motivation. Providing credible training certification and pathways for strong performers to become peer trainers were also proposed. Several participants identified the development of skills as a key incentive for both attracting and retaining CHWs. It was suggested skills development could focus on both developing core CHW skills required through exchange visits with health facility based supervisors and non-core skills such as training in agricultural techniques that may assist in generating revenue. Initial CHW and supervisor input into the content and form of skills development approaches, and indeed any refresher training, was also suggested to increase credibility. Both non-core function and refresher training were considered more likely to have a positive impact when their implementation was phased. Table 4 contains details of the specific rationale for each of the main themes of response.

Supervision. Many participants considered supervision to be the most important factor for maintaining a functional cadre of motivated CHWs stressing its potential for conveying a sense of belonging and connectedness to the program. Issues around cost and feasibility were however noted. Supervision strategies proposed for increasing motivation and retention were made in themed areas of supportive supervision, group and peer supervision approaches, effective selection and training of supervisors, and supervision frequency and regularity. Table 5 contains details of the specific rationale for each of these themes of response.

Incentives. Participants spent more time talking about incentives than any of the other thematic areas. A range of financial and non-financial incentives—including those designed to promote CHW credibility and status—were proposed. With regard to financial incentives, the manner in which they are introduced and maintained, and that they are both equitable and reliable was a key concern. When contemplating a move from a voluntary to remunerated system it was recommended that the first step be to conduct an assessment, including a community consultation, to gauge CHW and community expectations, identify the most appropriate, context-based CHW motivators and establish the feasibility of sustaining funding. The potential for altering the status of formerly unpaid workers with both negative and positive consequences was emphasized. Systems for generating payments to CHWs such as flat fee for service, revolving funds, collective funds, and micro credit schemes were flagged.

A broad range of non-financial incentives were proposed falling into the following thematic areas: creating professional pathways and skills development through exchange visits (see Table 4: training), providing CHWs with the tools to perform the job with a particular emphasis on ensuring a reliable supply of drugs, reimbursing expenses and travel costs, supplying mobile phones and airtime in lieu of a salary, and possibly food and other commodities as an incentive for meeting attendance, inspiring the community to take the lead in establishing and maintaining CHW performance incentives, and seeking to

TABLE 4
Suggested strategies related to training

Theme	Rationale
Credible certification	• Symbolic recognition of the CHW role is an incentive to become and remain a CHW (6,13).
Pathways for peer training	• The perceived importance of performing CHW tasks appropriately and the credibility of the approach are enhanced when explained by a peer (5). • The opportunity to progress to peer trainer level increases CHW motivation (5,8).
Skills development	• Exchange visits between health facility-based supervisors and CHWs where understanding and respect for each other's role is promoted, skills are developed and connections between the community and health facility are strengthened will motivate CHWs (10,14). • Providing training in areas not directly relevant to iCCM but identified by CHWs as beneficial in generating supplementary income (e.g., in agriculture or livelihoods) will motivate CHWs, reduce their need to pursue alternative, revenue generating opportunities, and enhance retention rates (5). • Keeping skills up to date with refresher training delivered in the context of supportive supervision and where CHWs select content is a cost-effective incentive for motivating CHWs (8,9,13). Supervisor involvement in training will lend credibility to the content for CHWs (9).

Table 5
Suggested strategies related to supervision

Theme	Rationale
Supportive supervision approaches	• Supportive supervision where CHWs are provided with feedback on technical and interpersonal skills and refresher training in response to their needs is motivating for CHWs (1,4,6,8,12).
Group supervision	• A group supervision approach that highlights the benefits of working as and feeling part of a team and creates a less intimidating learning environment is motivating for CHWs (8,9,13).
Peer supervision	Supervision by previous or current CHWs is motivating for CHWs as: • Peers more readily empathize with the perspective of CHWs and often make the best supervisors (8). • "Career pathways" for CHWs to a paid role within the health system may be an incentive (2). • Greater levels of community trust and confidence may result as supervisors are locally known and more likely to be "in tune" with local issues (2). Sensitivity to the management of expectations of those not selected for a peer supervision role was advised (1).
Effective selection and training of supervisors	• Selection and training of supervisors was recognized as important, but there were few tangible suggestions related to approach (8,12). Adult learning approaches were proposed but only after understanding supervisor perspectives as approaches perceived as unconventional may be counterproductive (8).
Supervision frequency and regularity	• Regular (monthly was the preferred interval), maintained and reliable supervision is important for CHW motivation (6,8,12). • Community- and facility-based supervision was viewed favorably depending on logistical feasibility (8,13).

elevate the status and credibility of CHWs by promoting their successes, maintaining their supplies, linking them to the health system in a manner convincing to both CHWs and their community, and providing CHWs with visual signifiers of this standing. Table 6 contains details of the specific rationale for each of these themes of response.

Community involvement and ownership. Increasing levels of community involvement and the perception of ownership of CHW programs was considered critical to the retention and motivation of CHWs by participants. Suggested approaches for achieving this were shifting program emphasis from "community based" to "community owned" where decisions and

Table 6
Suggested strategies relating to incentives

Theme	Rationale
Financial incentives	
Introduced equitably and reliably in a manner sensitive to expectations	• Payments should be locally benchmarked to ensure equity and acceptability (7). • If payments are introduced but not reliably maintained CHW retention rates will decline (6).
Altering status of formerly unpaid workers	• Strategies need to be implemented to counter the perception, and potentially detrimental impact on demand for services, of previously unpaid workers being seen as "agents of the government" as opposed to community members (5). • Providing CHWs with the opportunity to benefit from paid roles, such as assisting with mass vaccination programs or developing side businesses, is an incentive that will motivate and does not require large program outlay (5,9).
Remuneration schemes proposed	• Various financial incentive models were put forward as potentially motivating and sustainable. These were: • Revolving funds, where a pre-determined amount of money is provided in a one—off startup payment by the program for CHW acquisition of drugs that are then sold at a small profit (8). • Flat fee per service where demand for services is sufficient to warrant the CHW replenishing drug stocks (11). • Self-managed, collective funds for groups of CHWs with the purpose of providing financial support in times of need (9). • Micro credit strategies for CHWs and access to competitively priced goods (12).
Non-financial incentives	
Equipping CHWs with the tools necessary to perform their role	Provide CHWs with the resources they require to perform the role–especially drugs but also: • Equipment such as rain jackets and torches (1,14). • Travel expenses (10) and direct cost support (9). • Mobile phone airtime (9).
Providing useful and valued commodities	• Provide incentives for meeting attendance in the form of food and consumable products (2).
Generating increased CHW status and community credibility and recognition	Community recognition and CHW status and credibility are critical planks of programmatic success (1,3,5–12,14). Key components are: • Both maintaining drug supply and promoting the CHW role beyond supplying drugs to sustain demand for services (e.g., referral) when stock outs occur (1,6). • Encouraging the community to identify and maintain incentives for CHWs to perform and remain in role (3,5,7). • CHW credibility often relies on community perception of CHW effectiveness and the functional link between CHWs and health facilities and the national health system. Promoting successes and health system links are therefore important (1,8,12). • CHWs being visible as agents of a respected system by wearing program branded t-shirts and badges and/or receiving accreditation certificates and recognition letters that afford status are important for generating community esteem for CHWs (6,10).

TABLE 7
Suggested strategies related to community involvement and ownership

Theme	Rationale
Shift in program emphasis	• The enduring success of a CHW program will occur only when the community worker is truly the representative of the community and is obliged to report back on all the information and training they receive, and where the community take ownership for the direction of the program, what they want to achieve, and how they want to achieve it. This represents a shift in ideology from community "based" to community "owned" programming (1,13).
Approaches to stimulate community involvement and ownership	• Establishing local health committees who provide some form of management support to CHWs to engage with the community, address issues locally, and encourage local ownership of the program will increase CHW motivation (8,10,11). • Community-level meetings, chaired and facilitated by health facility staff at program commencement and annually and designed to promote community understanding and ownership of the program, explore opportunities for community support and contribution, promote CHW successes, and generate demand for services will increase CHW motivation (1,6,9,13).
Retaining program flexibility to respond to community-generated ideas	• Adopting an approach that retains the flexibility to respond to ideas and solutions that come from the community and specifically the CHW is critical to retaining local relevance and the perception in the community of program value (1,14).
Partnership defined quality[17]	• The participatory methodology of *Partnership Defined Quality* allows for a greater understanding of the perspectives of different arms of the health system, e.g., community members (consumers) and health facilities and CHWs (providers). It can be time-consuming and needs to be seen through to completion if positive benefits are to be realized despite having the potential to break down barriers, unite the community, and motivate CHWs (10).[17]

directions are at least in part determined by participants and there is sufficient program flexibility to respond to community generated ideas, establishing local health committees and community meetings to generate interest and support, and adopting participatory methodologies such as "partnership defined quality."[17] Table 7 contains details of the specific rationale for each of the main themes of response.

Information and data management. The retention and motivation of CHWs could potentially improve if they more meaningfully engaged with the data they are asked to collect according to participants. Suggested approaches for achieving this were to encourage CHW data analysis, promote the appreciation of CHW data collection by supervisors, and to potentially adopt a community stakeholder approach to data collection such as the "Community Based Health Information System."[18] Table 8 contains details of the specific rationale for each of the main themes of response.

mHealth. Despite a growing perspective that the designers of health development programs should avail themselves of the latest advances in technology, and especially mobile phones (hence "mHealth") to maximize impact, few participants emphasized this area for the retention and motivation of CHWs. They did however highlight the need to focus on the person rather than the technology and understand user acceptability; cautioned that phones needed to be kept securely and identified the motivating and functional potential of communication between CHWs as well as CHWs and supervisors. Table 9 contains details of the specific rationale for each of the main themes of response.

DISCUSSION

The volume and diversity of suggestions that emerged from discussions with stakeholders indicate the breadth of activities considered feasible for implementation by programs seeking to influence the motivation and retention of CHWs. Stakeholder participants proposed a range of specific interventions related to recruitment, training, supervision, incentives, community involvement and ownership, information and data management, and mHealth. They also suggested key cross-cutting themes such as packaging interventions that are relevant to the context of implementation. Approaches to tailoring packages of interventions to motivate and retain CHWs have commonly been proposed based on models of motivation.[10,12,19,20] These models emphasize several key areas for program focus, three of which are used here to show that

TABLE 8
Suggested strategies related to information and data management

Theme	Rationale
Meaningful CHW data interaction	Data collection approaches must be coherent, simple, and consistent with a strong emphasis on the data collector appreciating the value of the task if any motivational benefits from improved CHW data collection is to be seen (1,10,13). Proposed means for achieving this were: • CHWs become active in the analysis of the data and find it applicable to their working context (9). • Supervisors appreciate the value of the data collected and as a result increase their level of support and encouragement for CHW data collection (8, 10).
Community stakeholder approach to data collection	• If health facility workers, CHWs, and community members discuss and understand the data that has been collected and see the impact of what is happening in their community over time the influence of CHWs in the community will become increasingly evident resulting in increased CHW motivation. The Community-Based Health Information System (CBHIS) initiated by an international NGO in an East African country feeds back to the community aggregates and analyses performed at the health facility of data that CHWs have collected. Over time CHWs have come to demand this information. The need for champions of the effectiveness of this initiative in the community to promote acceptance and sustainability was emphasized for successful implementation (10).

TABLE 9
Suggested strategies related to mHealth

Theme	Rationale
Focus on the person rather than the technology	• It is the person handling the technology that is the key to success. User acceptability of any tools and training in the necessary skills in their use is critical lest the means of communication become a disproportionate focus (4,14,15). • When introducing new technologies it is important to consult CHWs on the most appropriate ways in which to implement them as they will be in the best position to adapt technology to the local community (2,14).
Importance of security of valued commodities such as mobile phones	• Although the risk of theft is legitimate, seeking to prevent it can be turned into a positive by branding phones with the program name or purpose. This is likely to provide a deterrent by limiting their potential post theft usability as well as promote the perception of community/collective ownership of the CHW's work (14).
Mobile phones as means of reaching the community (motivational)	Opportunities for using mobile technology to motivate CHWs through increased engagement with the community—conceptualized both as the geographic community serviced by the CHW and the community of CHWs themselves—and stimulate their acceptance and ownership of the program were raised. Proposed means of achieving this were: • Communicating program and health messages directly and simultaneously by SMS with large numbers of community members (though the suggestion was made that radio may be just as effective in some cases) (1). • CHWs communicating directly with each other and to provide peer support from a distance. If every CHW has a mobile phone the perception of connectedness to the program may be fostered through such initiatives as sending an SMS to CHWs on their birthday (3). • If the community can see the value added they may be more receptive to undertaking local fundraising to support the associated airtime costs (1).
Mobile phones as a CHW job aid (functional)	Being more effective in work tasks by virtue of mHealth solutions is motivating for CHWs (1,8). Suggested strategies were: • The CHW calling the health facility in the presence of the patient to show that there is someone there to receive them and to reassure them that they will be expected (1,8). • Two-way communication between the health facility-based supervisor and the CHW to alert about rissues and/or upcoming events (1). • Mobile phones used for data collection and submission (1).

many stakeholder perceptions and priorities have a firm foundation in the work motivation theory and contemporary reviews of CHW motivation and incentives.[10,12] These are needs satisfaction, CHW identity and context, motivation and incentives, and CHWs and their community.

Needs satisfaction, CHW identity, and context. The satisfaction of needs occurring in a hierarchy influenced by context is a well-established concept in the work motivation literature.[21] The degree to which a worker's needs are either satisfied or dissatisfied is a factor commonly linked to the likelihood of their retention.[10,11,21,22] Meeting lower level needs alone is unlikely to lead to motivation though it is also unlikely dissatisfied workers can be motivated. Absence of dissatisfaction (termed "satisfaction" in much of the literature) has therefore been proposed as a key indicator for the retention of workers.[11]

The human resources implications of the decentralization of health services have been acknowledged.[23] In Uganda there is evidence to suggest that decentralization has led to a lack of faith in the health system to provide adequately for the basic needs of workers leading to the adoption of alternative "survival strategies" or money generating enterprises.[24] What is most salient to these workers is the need to provide for themselves and their families. The pursuit of this need negates to some degree the possibility of them performing their role (unless of course this is compatible with generating sufficient income). The pursuit of "survival strategies" decreases retention levels and highlights the necessity of interventions designed to "satisfy" workers' basic needs and increase retention rates before or while seeking to motivate them. One suggestion from stakeholders to counter the need for such "survival strategies" was the provision of training designed to provide alternative earning opportunities complementary to an ongoing CHW role in areas additional to the core iCCM skill set. In addition, identifying the need to reliably supply the tools for the job (including drugs) demonstrates an understanding of the minimal conditions required to satisfy workers and provide a platform for motivating them.

A useful theory for understanding the relationship between needs prioritization and work motivation is the Social Identity Approach.[25] From this perspective, when thinking about needs prioritization one must look at the aspirations workers have for themselves as both individuals and group members. When identifying less as a group member and more as an individual needs tend to focus on individual advancement and actualization. When group or collective identity is more salient, that is when the social context results in greater identification with a collective, needs focus more on enhancing group-based self-esteem through the pursuit of group goals and a sense of relatedness, respect, and belonging.[22,25] The needs and goals of a CHW program are therefore more likely to be pursued when their attainment is compatible with the collective identity of CHWs.[25] If the collective identity of CHWs is viewed positively by CHWs and reinforced in the community it follows that taking actions considered likely to maintain this positive identity will become a priority for CHWs. The emphasis stakeholders continually placed on connecting CHWs to each other (e.g., through peer support mechanisms, mHealth) and the health system (e.g., supervision approaches, use of data, mHealth) indicate that they understand the value of seeking compatibility between program goals and CHW needs through building a shared and positive identity.

Stakeholders also stressed the need to understand the broader community context of CHW operation, to seek community support for CHWs, and for the program to engage and consult on key decisions relating to recruitment if CHWs are to

be motivated and retained. In terms of satisfaction and motivation it seems that the most important aspect for programs is to understand how the local context influences CHW needs and priorities and how these needs and priorities are formed and acted upon as a function of a positive CHW identity. Pursuing such enquiry through formative research was emphasized by stakeholders. It is likely that an understanding of the degree to which CHWs accept and embrace the wider perception of their role (its identity) and its functions, and the degree to which they feel it meets their needs will yield useful information relating to what satisfies (or dissatisfies) and motivates these CHWs in their areas of operation.

Motivation and incentives. The concepts of "expectancy" and "equity" have been proposed as most useful in understanding the complex interplay of factors that influence outcomes stemming from the use of incentives.[21]

"Expectancy" refers to the process where the degree to which a given incentive leads to the outcome intended by the program is contingent upon both the value placed on the incentive by the CHW (based on need) and a reasonable expectation that their actions may lead to its attainment.[21] "Equity" refers to the theory that over time workers develop beliefs about their input and the resultant output they receive through comparison with others, and that acceptance of program aims and outcomes are enhanced by the perception of fairness and equality of these outputs and the workplace in general.[22] Although historically theories of workplace equity (and indeed the broad area of incentives) have focused on parity of financial incentives and remuneration, more recently equity has been considered from an organizational standpoint.[21] This has led to more transparent and participatory approaches such as collaboration between workers and supervisors when setting goals and emphasizing worker roles as a functional part of a larger, effective mechanism.[26]

International stakeholders proposed a range of financial and non-financial incentives for retaining and motivating CHWs. They stressed the importance of understanding CHW expectations and warned of the durability of perceptions that specific rewards will follow effort even in the face of contrary information. They highlighted that failure of programs to deliver on CHW expectations (expectancy) would be viewed as a breach of trust (equity) and almost certainly result in drastic consequences for the retention of workers. It was recommended that a package of incentives be tailored to match CHW expectations and program priorities and that once established they be reliably delivered.

In concert with the principles of workplace equity as described, international stakeholders also emphasized the importance of promoting connectedness of CHWs to the health system. They suggested linking CHWs to supervisors and peers through mHealth applications and providing CHWs with symbolic signifiers of their role and connection to a respected program. They also advocated for greater community collaboration in the recruitment of CHWs, suggesting it would increase the perception of representativeness and a broader understanding of the value of the role. Also proposed were the creation of career pathways and ongoing skills development opportunities and the provision of appropriate tools for the job. A range of financial incentives were also explored however, as with all incentives described, stakeholders warned that if introduced programs must be sure to consistently and reliably deliver them, and highlight the link between CHW performance and any contingent rewards, if they are to have an ongoing impact on retention and motivation.

CHWs and their community. International stakeholders emphasized the factor commonly considered to be most critical to the success of CHW programs—the relationship between the CHW and their community.[5,10,27,28] When advocating for a change in ideology away from community-based to community-owned programming, international stakeholders echoed the suggestion that the WHO's task-shifting agenda insufficiently emphasizes the need for CHWs to be "embedded" in their communities of operation.[5] Campbell and Scott[5] point to a recent trend of moving away from the Alma Ata conference's emphasis on the importance of community participation in all aspects of CHW performance, which they attribute to it being too difficult. They argue for a return to greater levels of input from local communities in the design and operations of health-focused CHW programs and, in common with a section of international stakeholders, suggest that the perceived interests and needs of communities will be more closely met as a result.

A number of suggestions were made to enhance community awareness of, and participation in, CHW programs. The establishment of committees and discussion forums as well as promoting the use and understanding of CHW collected data were put forward as a means of improving local understanding and credibility of CHW programs. These suggestions were supported in the CHW motivation literature, which repeatedly highlights the potential for such strategies to improve CHW support, status, and standing leading to greater levels of retention and motivation.[5,10,27] The key challenge for programs would appear to be retaining the flexibility, especially at national scale, to engage with local issues and adopt local solutions.

There were some study limitations. Although recruiting stakeholder participants who the authors were aware had extensive experience of both national level and small-scale CHW programs generated diverse and valuable data, it is likely additional stakeholders not known to the authors could also have provided data of value. For this reason a larger number of participants recruited through the snowball method would have been desirable. Although three stakeholders who currently work with CHWs were recruited, a greater number of participants with direct, day-to-day interaction with CHWs and indeed engaging CHWs themselves would undoubtedly have added a valuable perspective. In addition, participants from the Ministry of Health in countries implementing CHW programs would certainly have provided key insights. Because of the importance of their views, key Ministry of Health personnel have since been engaged regarding the design and feasibility of interventions in inSCALE's countries of operation, although they were not included in the current study because the aim was to sample figures with experience in multiple settings. More than half of the participants were either based in the United States or worked for American institutions (universities and NGOs); greater diversity of national affiliation among participants would have been preferable.

Although the perceptions and priorities of stakeholders provide a rich description of the range of possibilities for influencing CHW motivation and retention, it is important to note that they do not constitute recommendations for implementers. Rather they are intended as a first step toward the

development of appropriate interventions. During this development an assessment needs to be made as to the applicability of stakeholder suggestions in context, and consideration given to the implementation scale of a given program, before interventions are adopted to ensure feasibility when implementing large public sector CHW programs based on the lessons of smaller scale programs. The second step, as undertaken by the inSCALE project, is to review the existing evidence in each suggested intervention area to establish which activities and approaches should be adopted as currently the most promising and which represent an opportunity for demonstrating the impact of new, innovative practice. Such an approach followed by context-specific formative research, including, critically, engagement with CHWs and the supporters and recipients of the services they provide, and appropriate piloting of chosen interventions with users, is most likely to produce interventions that have a sustained and positive impact on the motivation and retention of CHWs delivering iCCM.

CONCLUSION

This work has explored interventions identified by international stakeholders as having the greatest potential for impact on CHW motivation and retention. Their suggestions resonate with key areas of the work motivation and CHW literature; namely, needs satisfaction, CHW identity and context; motivation and incentives; and, CHWs and their community. It has been suggested that programs seeking to positively influence CHW motivation and retention need to adopt a multi-level approach. Although there are a range of specific individual interventions that have stakeholder support, tailoring an appropriate package, which is feasible in context and balances the needs of the program with the needs of CHWs while achieving community support for the program is considered the approach most likely to result in a positive and enduring impact on the motivation and retention of CHWs.

Received January 13, 2012. Accepted for publication July 24, 2012.

Note: Supplemental appendix appears at www.ajtmh.org.

Acknowledgments: We thank those who gave their time to share their perceptions and priorities related to CHW motivation and retention with us.

Financial support: Funding for this research was provided by the Bill & Melinda Gates Foundation through a grant to Malaria Consortium, The London School of Hygiene and Tropical Medicine, and The Centre for International Health and Development, University College London for the inSCALE project (http://www.malariaconsortium.org/inscale/).

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 120–126
doi:10.4269/ajtmh.2012.11-0781

Factors Affecting Availability of Essential Medicines among Community Health Workers in Ethiopia, Malawi, and Rwanda: Solving the Last Mile Puzzle

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Abstract. To understand how supply chain factors affect product availability at the community level, the Improving Supply Chains for Community Case Management of Pneumonia and Other Common Diseases of Childhood Project developed a theory of change (TOC) framework for gathering, organizing, and interpreting evidence about supply constraints to community case management (CCM). Baseline assessments in Ethiopia, Malawi, and Rwanda conducted in 2010 provided information on the strengths and weaknesses of existing CCM supply chains for five main products: antibiotics for pneumonia, oral rehydration solution, ready to use therapeutic food, zinc, and artemether/lumefantrine. The assessments tested the strength and validity of causal pathways identified in the TOC that were believed to influence availability of CCM products among community health workers (CHWs) for treating common childhood illnesses. Results of the assessments showed product availability to be weak in each country, with more than half of CHWs stocked out of at least one tracer product on the day of the assessment. This report will focus on the findings related to three key preconditions of the TOC and how these were used to inform the design of the CCM supply chain improvement strategy in each country. The three key preconditions include product availability at CHW resupply points, supply chain knowledge and capacity among CHWs and their supervisors, and availability of appropriate transportation.

INTRODUCTION

To treat common diseases of childhood, national programs must ensure that supply chains effectively reach community health workers with affordable, quality medicines for treating pneumonia, malaria, diarrhea and malnutrition. Yet there is little understanding of the factors that enhance or constrain product availability at the community level, the last mile of community case management (CCM) supply chains. Understanding and identifying solutions to address these supply constraints to CCM provision may yield substantial improvements in programs' effectiveness, scale, and impact in reducing child mortality.[1,2]

Although there is limited evidence defining the supply constraints on CCM approaches, some studies have shown that child health programs often suffer shortages of key products, which suggests that supply chain factors may be adversely affecting outcomes of those programs. Robertson and others studied the availability of essential medicines for child health in the private and public sectors in 14 countries in central Africa.[3] Their findings from a sub-analysis of ten medicines, which included medicines used in CCM for child health, showed poor availability across different levels of the health system and across both the public and private sectors. Not surprisingly, they found that at lower levels of the system, such as in primary health clinics, there were fewer medicines available than in either teaching or district hospitals. Using a drug availability index, the study of Pagnoni and others on community-based treatment of presumptive malaria in children showed a decrease in severe malaria in areas with good drug availability at health center level.[4] More researchers and program managers are developing an increased awareness of and appreciation for the importance of effective logistics in their programs. For example, Bhandari and others, who looked at zinc supplementation in India, concluded that "Diarrhea is more effectively treated when caregivers receive education on zinc supplementation and have ready access to supplies of ORS and zinc."[5] These findings accentuate the need for CCM programs to ensure that their supply management systems are effective at ensuring availability of essential child health products.[6]

The Improving Supply Chains for Community Case Management of Pneumonia and Other Common Diseases of Childhood Project (SC4CCM) was created to identify supply chain factors that affect product availability in sub-Saharan Africa, develop strategies to address these factors, and demonstrate that product availability can be substantially improved at the lowest levels of the supply chain. The ultimate goal is to address the gap in evidence about how supply chains work at the community level so that implementers are better able to improve child health outcomes. As a learning project, SC4CCM is implemented in three countries (Ethiopia, Malawi, and Rwanda) in three stages: 1) conceptualization of the theory of change (TOC), baseline assessment of CCM supply chains, and use of results to design strategies; 2) implementation and monitoring of performance improvement strategies; and 3) evaluation of strategies to identify simple, affordable, sustainable solutions and advocacy to catalyze their adoption and scale-up. This paper reports the findings of the first stage of the project and how they relate to and validate the TOC of the project.

MATERIALS AND METHODS

Theory of change. The primary unit of interest of the SC4CCM is community health workers (CHWs) and their health product supply chain. Country specific names for community health workers include health extension workers in Ethiopia, health surveillance assistants in Malawi, and community health workers (CHWs) in Rwanda. All are referred to as CHWs in this report. To map out all factors that could affect availability of essential health commodities for CCM of childhood illness at this level and hypothesize the causal pathways to improve it, the first step the project took was to design a TOC.[7] The TOC, which was used to guide technical activity planning and evaluation, was created through iterative rounds

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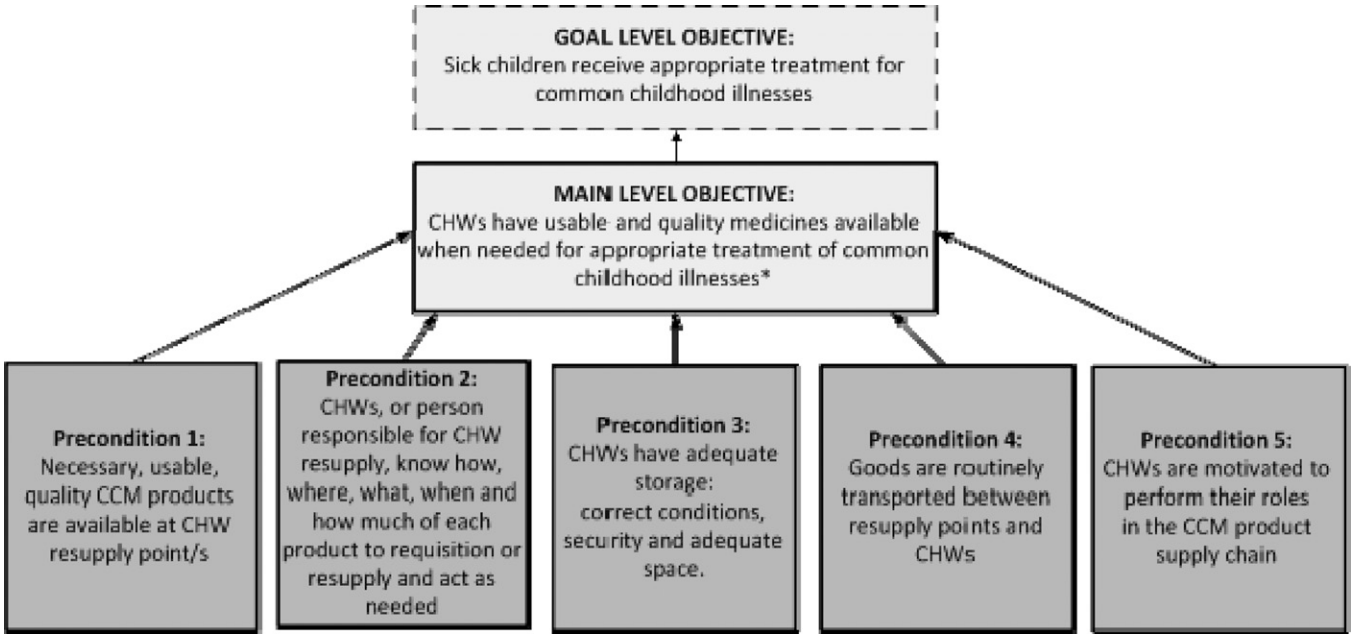

FIGURE 1. The five preconditions of product availability in the Improving Supply Chains for Community Case Management of Pneumonia and Other Common Diseases of Childhood Project. CCM = community case management; CHW = community health worker.

of discussion with internal experts and field staff, and informed by a review of literature and other conceptual frameworks on the subject.[8] The TOC was then validated by an external group of international supply chain and evaluation experts and used as a foundation for country-specific, results-based TOCs. Given the varying country contexts, country-specific TOCs were needed to identify specific causal pathways for each unique CCM supply chain, and were created with aid from baseline data. The TOC includes five key preconditions that affect CCM product availability among CHWs, the proximal (main-level) objective of SC4CCM (Figure 1). This objective feeds the more distal goal-level objective of increased appropriate treatment of sick children. The hypothesized causal pathways to each of these key preconditions can be found at http://sc4ccm.jsi.com/about-sc4ccm/theory-of-change (Supplemental Framework SC4CCM Theory of Change, 2011).

Baseline surveys. The project baseline surveys used complementary quantitative and qualitative tools that were field-tested and adapted for each country to assess supply chain challenges at the community level.[9] Permissions for the surveys were obtained from Ministries of Health in all countries and the National Ethics Committee of Rwanda. Samples were not intended to be nationally representative, but rather chosen to diagnose major CCM supply chain strengths and weaknesses in a cross-section of districts served by key CCM partners, and to follow the supply chain from the central level to the community level. Purposeful selection at higher administrative levels (i.e., region and zone) was conducted on the basis of existence of a functioning CCM program, geographic spread, and balance of CCM partner support. Probability proportional to size sampling was used to randomly select health centers and CHWs at lower levels of the supply chain. Qualitative data were gathered using focus groups and key informant interviews. In Malawi, the survey covered 10 of 28 districts; in Ethiopia 12 of approximately 68 zones, and in Rwanda 10 of 30 districts. The CHWs were the unit of analysis in all cases. The sample of CHWs included 245 in Ethiopia, 321 in Rwanda and 248 in Malawi. This information is shown in Table 1. However, in Malawi the full sample of CHWs was reduced from 248 to 139 cases for most analyses because the national CCM program was not fully implemented at the time of survey, and a large portion of CHWs sampled had not yet begun managing health products.

Local evaluation partners were selected through a competitive process in each country to lead data collection activities. Enumerators were trained to interview CHWs and other staff managing supplies of medicines, conduct product inventories,

TABLE 1
Sample size by country and system level, Ethiopia, Malawi, and Rwanda*

Ethiopia		Malawi		Rwanda	
System level	Achieved	System level	Achieved	System level	Achieved
Regional medical stores	6				
Zonal medical stores	9	Regional medical stores	3	Central warehouse (CAMERWA, now MPDD)	1
Woreda (district) medical stores	26	District health office and pharmacy	10	District pharmacies	10
Health centers	74	Health centers	81	Health centers	100
Health extension workers	245	Health surveillance assistants	248	Community health workers	321

* Country-specific names for community health workers include health extension workers in Ethiopia, health surveillance assistants in Malawi, and community health workers in Rwanda. All are referred to as community health workers in the report. CAMERWA = Rwanda Drug, Consumables and Equipment Central Procurement Agency; MPDD = Medical Procurement and Distribution Division.

TABLE 2
Key indicators, Ethiopia, Malawi, and Rwanda*

Key indicator*	Definition	Measurement method	Comment
Country-specific key product availability	Numerator: no. CHWs with all tracer products (primary CCM medicines defined for each country) in stock, unexpired and in good condition. Denominator: no. CHWs who reported that they managed all those tracer products, on day of inspection visit.	Quantitative survey, direct observation of stocks	Includes different products in each country, based on each country's CCM program
Standardized key product availability	Numerator: no. CHWs with ORS and AL (both doses), unexpired and in good condition. Denominator: no. of CHWs who reported that they managed ORS and AL, on day of inspection visit.	Quantitative survey, direct observation of stocks	Includes only ORS and AL (both doses), as those were the only drugs in common managed by CHWs in all three countries
% Of CHWs trained in supply chain management	Numerator: no. CHWs who reported they had been trained in supply chain topics. Denominator: no. CHWs interviewed.	Quantitative survey, CHW interview	
% Of CHWs with standard operating procedures	Numerator: no. CHWs with standard operating procedures available. Denominator: no. CHWs who managed CCM products.	Quantitative survey, CHW interview and observation to confirm	
Main method of transport	% CHWs using each mode of transport (CHWs answered from a list of transport options)	Quantitative survey, CHW interview	
Distance to CHW from resupply point	Mean amount of time it took to travel by car from the CHW resupply point to each CHW visited (as timed by data collectors)	Quantitative survey, interviewer reported	
Key obstacles reported by CHWs to obtaining CCM supplies	% CHWs reporting each type of obstacle (coded from open-ended and multiple responses)	Quantitative survey, CHW interview	

* CHWs = community health workers; CCM = community case management; ORS = oral rehydration salts; AL = artemether/lumefantrine. The Improving Supply Chains for Community Case Management of Pneumonia and Other Common Diseases of Childhood Project collects other key indicators, such as training on reporting and storage that are not highlighted in this report.

and rate storage conditions.[10] Data collectors used Nokia (Espoo, Finland) e71 and e63 smart phones loaded with the EpiSurveyor application (DataDyne, Chicago, IL), which enabled streamlined data entry and immediate review of data after uploading records to a web-based system.

Survey instruments. Quantitative and qualitative tools were adapted from tools originally developed by the USAID | DELIVER Project,[11,12] including questionnaires, inventory assessment forms, storage assessment forms, and key informant interview guides. Tools were tailored to each level of the supply chain from central medical stores down to the community level, to capture processes, behaviors and product availability along each step in the chain. Questions were designed to capture information related to the hypothesized change pathways of the TOC. Responses to these questions were customized by country. The project's key indicator of product availability was only measurable at one point in time (on the day of visit) because of limited or non-existent logistics records from which data on duration and frequency of stock outs could be derived. Although many indicators were measured, this report focuses on some key indicators, which are shown in Table 2 and discussed in the Results.

Analysis of survey results. Frequencies, cross-tabulations and bivariate tests of significance were carried out by using SPSS version 18 (SPSS Inc., Chicago, IL) and STATA version 11 (StataCorp LP, College Station, TX), and qualitative results were synthesized from workshop notes. After assembling preliminary results, the project presented baseline findings to in-country stakeholders and representatives of all levels of the supply chain in a series of participatory data validation workshops. Factors affecting product availability were identified and verified for each TOC precondition and supply chain strengths and weaknesses were discussed. Strategies were designed to address supply chain bottlenecks, areas correlated with low product availability, and areas with greatest potential for improvement and scale up, all tailored to each country's context.

RESULTS

On the basis of qualitative work and quantitative surveys in each country, preconditions 1, 2, and 4 had the strongest empirical evidence supporting their TOC pathways. Precondition 3 played an important role in ensuring product quality, but there was little evidence that it contributed to availability. Precondition 5, CHW motivation, is a complex concept to measure because most metrics tend to be subjective and/or qualitative.[13] Because of this complexity and space limitations, it is beyond the scope of this report to include this analysis. Therefore, this report will focus on preconditions 1, 2, and 4. Baseline results are presented by the key preconditions needed to achieve the main project outcome (CCM product availability with CHWs), and stratified by country.

Main level objective: overall CCM product availability. Product availability measures in the three SC4CCM focus countries are shown in Table 3. The key indicators are shown in the bottom two rows. For country-specific and standardized measures (see Table 2 for definitions), product availability was found to be weak in each country, with more than half of CHWs stocked out of at least one tracer product on the day of the assessment.

The CCM product availability at the CHW level was generally highest in Rwanda and lowest in Ethiopia. The figures largely reflect the progress and maturity of the CCM program at the time of each survey in 2010; Rwanda began implementing CCM nationwide in 2008, Malawi in 2009, and Ethiopia added treatment of pneumonia to the health extension program in 2011 (Table 4). It should be noted that these countries are contextually different, and the Ethiopia context is more complicated than those of Rwanda and Malawi because of

TABLE 3
Percentage of CHWs with essential CCM medicines in stock on day of visit, Ethiopia, Malawi, and Rwanda*

Products	Ethiopia (n = 240),† % CHWs	Malawi (n = 139),† % CHWs	Rwanda (n = 321),† % CHWs
Antibiotics for pneumonia‡	NA	87 (n = 133)	88 (n = 238)
Oral rehydration salts	67 (n = 204)	64 (n = 129)	83 (n = 238)
Zinc	NA	NA	85 (n = 240)
AL 1 × 6	18 (n = 138)	54 (n = 119)	76 (n = 305)
AL 2 × 6	31 (n = 141)	43 (n = 114)	79 (n = 302)
AL 1 × 6 and 2 × 6§	10 (n = 130)	39 (n = 111)	66 (n = 294)
Ready-to-use therapeutic food	61 (n = 144)	NA	NA
Mean no. tracer products in stock at CHW level¶	1.9 of 4	2.4 of 4	4 of 5
Country-specific key product availability#	6 (n = 69)	28 (n = 109)	49 (n = 208)
Standardized key product availability**	7 (n = 122)	29 (n = 110)	61 (n = 215)

* CHWs = community health workers; CCM = community case management; NA = product will vary by number of CHWs managing that particular product; AL = artemether/lumefantrine.
† Total number of CHWs who reported that they manage any of the tracer products.
‡ Cotrimoxazole in Malawi and amoxicillin in Rwanda.
§ Constitutes the two dosages of AL that are provided to children depending on their age and weight. Both dosages are important from a quality of care perspective.
¶ Tracer products in Ethiopia included oral rehydration salts, AL (both doses), and ready-to-use therapeutic food; Malawi included cotrimoxazole, oral rehydration salts, and AL (both doses); Rwanda included amoxicillin, oral rehydration salts, zinc, and AL (both doses).
# Percentage of CHWs with all country-specific tracer products available.
** Percentage of CHWs with oral rehydration salts and AL (both 1 × 6 and 2 × 6) available.

geography, population size, and diversity, and more specifically due to an additional supply chain management level and greater number of products managed by CHWs (Table 4). Differences in product availability will also be influenced by these factors. Also, none of the CHWs in the three countries managed all CCM products of interest. Overall, availability was high for most individual products except artemether/lumefantrine. More than 60% of CHWs who managed antibiotics, oral rehydration salts, zinc, and ready-to-use therapeutic food had those products in stock in all three countries, but most CHWs reported stockouts of at least one product on the day of the assessment. Artemether/lumefantrine was the CCM product most likely to be out of stock.

Precondition 1: Product availability at CHW resupply points. Individual product availability at resupply points (typically nearby health centers) for the two products that were standard (oral rehydration salts and artemether/lumefantrine) across countries paired with the same measures for their associated CHWs is shown in Figure 2. There was a statistically significant correlation between product availability at resupply points and CHWs in Malawi, but not for Ethiopia and Rwanda. For all products shown, the percentage of resupply points with the item in stock was higher than for CHWs, especially in the case of artemether/lumefantrine in Ethiopia. In the three countries, as was the case among CHWs, artemether/lumefantrine was typically the product most often out of stock at resupply points.

Precondition 2: Supply chain knowledge and capacity among CHWs and their supervisors. Results varied substantially across and within countries. For example, more than 95% of CHWs who manage health products in Malawi and Rwanda had received training in supply chain topics, but only 10% of CHWs in Ethiopia reported being trained. In all three countries, even those CHWs trained in supply chain topics were often unaware of standard operating procedures or did not have them available for reference. In Malawi, 47% of CHWs had standard operating procedures available compared with 4% of CHWs in Ethiopia and Rwanda. The percent of CHWs with standardized stock keeping records such as bin cards or stock cards was low, and reporting forms used by CHWs were often incomplete. There were no significant correlations between each of the CHW capacity measures and standardized CHW product availability. Findings related to this area are shown in Table 5.

Having data available for decision making is also an intermediary precondition (or a precondition to the precondition) to preconditions 1 and 2. In all three countries, data availability was inadequate. In Malawi, only 14% of CHW logistics data are reportedly sent to higher levels of the system. In Ethiopia, Logistics System Assessment Tool respondents reported that not all essential logistics data are sent to higher levels, and the quality is questionable. In Rwanda, participants in data validation workshops confirmed that logistics data are not always available at the right place to inform resupply decisions.

TABLE 4
Country profiles for Ethiopia, Malawi, and Rwanda*

Indicator	Ethiopia	Malawi	Rwanda
Population (2009) (thousands)†	82,825	15,263	9,998
Population, % rural	83	81	81
Health worker density/1,000 person†	0.26	0.3	0.47
CHW density/1,000 persons†	0.3	0.73	1.48
Community health policy with full CCM package‡§	2010 (pneumonia added)	2006	2008
CCM implementation commenced¶	2011	2009	2008
No. CHWs nationwide who manage CCM products	≥ 30,000	≥ 3,000	≥ 30,000
No. products managed per CHW (2010)	~≥ 50	~19	~5–8
Push or pull CCM product supply mechanism to CHW level#	Push	Push	Push

* CHW = community health worker; CCM = community case management.
† World Health Organization Global Health Observatory worker densities from 2007, 2008, and 2004–2005, respectively.
‡ U.S. Agency for International Development/Malawi Community Case Management Evaluation, May 2011.
§ Full CCM package is defined as CHWs providing treatment of uncomplicated pneumonia, diarrhea, and malaria in children less than five years of age.
¶ Rwanda National Community Health Policy, 2008.
# In a pull system, CHWs calculate their own resupply quantities and order from their resupply point. In a push system, resupply quantities are calculated by personnel at a higher level, ideally using reported logistics data or a standard calculation, but in some cases issuing standard quantities.

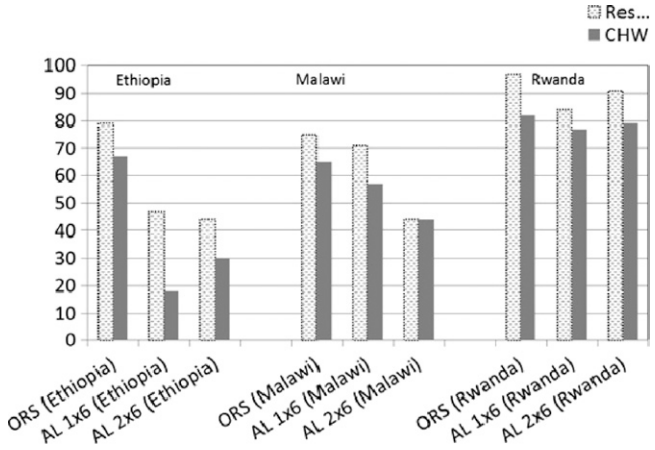

FIGURE 2. Availability of oral hydration solution (ORS) and Coartem (artemether/lumefantrine) (AL) at resupply points (Res) and community health worker (CHW) service points in Ethiopia, Malawi, and Rwanda.

Precondition 4: Availability of appropriate transportation. In almost all cases, CHWs are responsible for collecting supplies themselves, usually on foot or by bicycle. Mode of transport used by CHWs by country is shown in Table 6. In Malawi, almost 80% of CHWs depended on bicycles, whereas in Ethiopia and Rwanda, most CHWs traveled by foot. In addition in Ethiopia, 23% of CHWs used public transport. In Rwanda, although distances were shorter, the terrain was often hilly. However, during data validation workshops, CHWs in Rwanda reported that the primary challenge with transportation were the lack of incentives to pick up products because of lack of travel reimbursement, rather than the terrain. Overall, CHWs cited the lack of adequate or reliable transport as a major obstacle to obtaining products, although the mode of transport was only found to have a statistically significant effect on standardized product availability in Ethiopia, where CHWs who travel by foot were significantly less likely to have key products in stock compared with those using public transport.

Approximately half of the CHWs surveyed in Ethiopia and Malawi (66% and 46% respectively), were one hour or greater by car away from their resupply point (based on interviewer driving time from the resupply point), while in Rwanda, 11% of CHWs were an hour or more away. Actual CHW travel time was not measured but can be assumed to be longer because most CHWs traveled by foot or bike and not car. When CHWs were asked how long their trips were to resupply points, 45–90% reported trips of an hour or longer, depending on the country and whether it was dry or rainy season. In all three countries, CHWs primarily used dirt (or partial dirt) roads. Distance was only a statistically significant factor in Ethiopia and Rwanda, where CHWs located farther away from their resupply points had significantly lower standardized product availability.

The biggest obstacles CHWs said they faced in maintaining CCM product availability are shown in Table 7. The CHWs in every country named various transport related challenges as the top obstacles, (no transport available, transport always broken down, resupply point too far away, rainy season). These were aggregated into one response relating to transport. In Ethiopia, nearly two-thirds of CHWs mentioned this topic. In Rwanda, where CHWs are unpaid, the most common specific response was remuneration, and most responses referred to remuneration to pay for transport to reach resupply points.

TABLE 5
Community health worker capacity in selected aspects of supply chain management, Ethiopia, Malawi, and Rwanda*

Indicator	Ethiopia (n = 239)	Malawi (n = 139)	Rwanda (n = 321)
% Of CHWs trained in key aspects of supply chain (ordering, receiving, or reporting)	9	95	99
% Of CHWs with SOPs available	4	47	4
% Of CHWs who keep any stock records (stock card, bin card, tally sheet)	13	90	72
% Of CHW reports that included stock on hand and quantities dispensed (based on visual inspection)	43	63	89

* CHW = community health worker; SOPs = standard operating procedures.

TABLE 6
Percentage of community health workers using various transport means to collect supplies, Ethiopia, Malawi, and Rwanda

Mode of transport	Ethiopia* (n = 235)	Malawi (n = 139)	Rwanda (n = 320)
By foot	54	11	88
Bicycle	< 1	79	10
Public transport	23	9	< 1
Other†	22	1	1

* Respondents were able to choose more than one response in Ethiopia and only one response in Malawi and Rwanda.
† In Ethiopia, this response includes multiple responses.

DISCUSSION

Across all the countries, the use of the TOC framework and corresponding indicators enabled a comprehensive approach to identifying and designing SC improvement strategies while accommodating country contexts. By developing country specific TOCs to define hypothetical pathways to improved product availability, we were able to use the baseline data to identify and validate the most critical pathways in the three focus countries.

The baseline data support that product availability at resupply points (precondition 1) has an important effect on CHW CCM product availability (significant correlation in Malawi). The correlation is logical; if supplies are not available at resupply points, they are not likely to reach CHWs. Although data do not show significant correlations in Ethiopia and Rwanda for precondition 1, CHWs in both countries reported in data validation workshops that this was a major obstacle to increasing

TABLE 7
Main obstacles reported by CHWs to obtaining CCM supplies, Ethiopia, Malawi, and Rwanda*

Percentage of CHWs reporting the following main obstacles	Ethiopia (n = 240)†	Malawi (n = 139)†	Rwanda (n = 320)†
Products not available at resupply point/higher levels	15	17	3
Transport-related obstacles	32	15	27
Lack of remuneration (especially for public transport)	0	0	33
Long time between sending report and receiving supplies	> 1	17	0
Other‡	1	7	37

* CHWs = community heath workers; CCM = community case management.
† In Rwanda, CHWs, regardless of whether they reported having problems related to supplies, were asked to name the main obstacle they had experienced in obtaining CCM supplies. However the method was changed for Ethiopia and Malawi where only CHWs who answered yes when asked if they had any problems related to supplies were asked to list the main obstacle.
‡ In Rwanda, Other included the response no problem.

product availability. The lack of significance in Rwanda and Ethiopia is likely related to small subsamples: namely, CHWs who do not have products in stock, and at least for artemether/lumefantrine in Ethiopia, CHWs who work in malarial areas. Further investigation will be conducted as monitoring data and subsequent surveys are collected.

Precondition 1 underlines the vulnerability of CHWs at the last mile of the supply chain. If CCM supplies fail to reach CHW resupply points, or if those resupply points use CCM supplies to meet the needs of their facility-based patients, CHWs will continue to experience chronic shortages of CCM supplies for treating children in their communities. Supply chain strategies to improve CCM product availability at the community level must take place in concert with strengthening the entire supply chain and improving product availability at the national level, or first mile, of the CCM supply chain pipeline and at all intermediary levels.

The hypothesized relationship between CHW capacity measures (precondition 2) and product availability was not found to be statistically significant in the baseline perhaps because of the multi-faceted components of supply chain capacity, which interact in complex ways, and were not all measured in the surveys. Simply having been trained was not significantly correlated with CHW product availability in any one of the countries. These relationships will need to be explored further once more data have been collected to see if this holds true once confounders like length of time as a CHW and other related factors can be included. In general, capacity variables were substantially higher in Malawi and Rwanda than in Ethiopia, potentially because Ethiopia was still developing a logistics system for the community level at the time. There was still room for improvement in all countries.

Although not significantly correlated with product availability in our assessment, training is clearly necessary to create foundational supply chain knowledge, practices, and skills before strategies addressing other factors in the supply chain can be implemented. The CHWs in all three countries were generally operating in an environment characterized by a lack of standardized processes and reporting forms and this fragmentation affected CHW capacity and performance. Another consequence of the system fragmentation was the lack of visibility into CHW-level logistics data at higher levels of the supply chain. Because poor data hamper effective decision making, CHWs are unlikely to obtain the correct quantity of supplies, and national level procurement occurs without sufficient data to define the actual community level need. Therefore, data visibility plays an important role in ensuring that the product requirements for the last mile are accounted for in the supply chain.

Precondition 4 showed the strongest relationship to product availability in Ethiopia, which stands to reason because the CHWs sampled in Ethiopia had the longest travel times and were by far more likely to travel by foot, the slowest form of transport with the least capacity to carry bulky and/or heavy items. The CHWs in Ethiopia also manage 50 products, compared with 5–8 in Rwanda. In all three countries, transporting supplies was almost exclusively the responsibility of the CHW; products were rarely if ever delivered to them. Although geographic barriers and distance were the primary obstacles in Ethiopia, in Rwanda, transportation as an obstacle related more to a lack of motivation to travel, given that CHWs are volunteers and are not compensated for their travel time or costs. The main implication for addressing transport barriers is that each country will likely require a unique solution that is based on existing infrastructure and accommodates the specific aspects of transportation that pose key challenges to resupply at community level.

The cumulative effect of obstacles within these preconditions all contribute to lower CCM product availability at the community level. Slow rollout of CCM programs in terms of products and trainings in Ethiopia, Malawi, and Rwanda, and country-level policies defining limited CCM packages meant that no single community health worker in the three focus countries managed all products needed to treat all conditions generally considered as part of CCM: pneumonia, malaria, diarrhea, and malnutrition. Availability of the combined package of country-specific key CCM products that CHWs did manage in each country was also low, ranging from 6% to 49%, which poses a serious constraint to effective treatment of childhood disease at the community level. The poor concurrent availability of both strengths of artemether/lumefantrine had a strong downward effect on the country-specific and standardized product availability. Both strengths of artemether/lumefantrine are important because children require different dosages on the basis of age and weight, and substitution of doses introduces questions related to quality of care. Further analysis not included here showed that availability by product and by district varied substantially, with some products and districts greatly outperforming others, implying that inconsistency in the supply chain is also a challenge.

Evidence from the baseline surveys informed country-specific TOCs and identified areas where supply chain performance was strong or weak, and variables significantly correlated with standardized product availability. Together, this helped develop and tailor different sets of strategies to the needs of the three countries. For example, low product availability at the resupply point was a challenge in Malawi and Ethiopia, but addressing this issue was only a priority in Malawi. In Ethiopia, the immediate priority was the supply chain in transition, which to address requires training large numbers of CHWs and resupply point staff in supply chain essentials so that procedures directing the flow of products and information can be well executed.

There are some limitations of our data that should be noted. Small sample sizes indicated that we likely did not capture all variables significantly correlated with CCM product availability at CHWs. Nevertheless, a number of correlations were found to be significant, and others were identified through key informant interviews and other qualitative methods. Given that the baseline surveys were tailored to capture the varied CCM and supply chain contexts in each country, not all indicators for all preconditions are precisely comparable across countries. Day of visit results may present a more optimistic picture than actually exists because they do not show if products have been in stock continuously, nor whether supply levels are too low or too high to avoid future stockouts or expirations.

In conclusion, product availability is a challenge for all CCM programs and finding affordable, simple, and sustainable supply chain solutions must be guided by evidence, country context and program structure. Although it is important to note again that the surveys were small and not nationally representative, in general, the baselines confirmed that preconditions 1, 2, and 4 from the TOC must be in place for products to consistently reach the last mile of the supply chain. Although not all preconditions are equally influential as enabling or constraining factors to product availability at community levels, these preconditions provide a framework for a program to

assess, identify and address the factors affecting the availability of products at the community level. Improving availability of essential medicines among community health workers is vital if CCM is going to be successful at treating childhood illness, and ultimately, reducing child mortality.

Received December 16, 2011. Accepted for publication August 12, 2012.

Note: Supplemental Framework appears at www.ajtmh.org.

Acknowledgments: We thank the Ministry of Health leaders in all three countries for their support of the baseline studies, especially those colleagues leading the national CCM or child health programs and overseeing the public sector supply chains; our evaluation partners (JaRco Consulting, Addis Ababa, Ethiopia; Malaria Alert Center, Blantyre, Malawi; and National University of Rwanda School of Public Health, Kigali, Rwanda) and the teams of data collectors for their diligence and hard work; and the SC4CCM field office technical staff in Ethiopia, Malawi, and Rwanda for their work in data collection. The study was implemented by JSI Research & Training Institute, Inc.

Disclaimer: The views in this article are those of the authors and do not necessarily reflect those of the JSI Research and Training Institute, Inc.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 127–136
doi:10.4269/ajtmh.2012.12-0389

Comparison of Methods for Assessing Quality of Care for Community Case Management of Sick Children: An Application with Community Health Workers in Malawi

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Abstract. Direct observation (DO) with re-examination (RE) by a skilled clinician is a rigorous method for assessing health worker performance, but is not always feasible. We assessed the performance of 131 community health workers in Malawi in community case management of sick children with cough and fast breathing, fever, and diarrhea. We compared estimates of correct treatment measured through DO with RE (n = 382 cases) to DO only (n = 382 cases), register review (n = 1,219 cases), and case scenarios (n = 917 cases). Estimates of correct treatment of uncomplicated fever and diarrhea measured through DO only, register review, and case scenarios were within 9 percentage points of DO with RE estimates, while estimates for uncomplicated cough and fast breathing, and severe illness were substantially higher than DO with RE (12–51 percentage points above the estimate). Those planning for community health worker assessments in community case management can use these results to make an informed choice of methods on the basis of their objectives and the local context.

INTRODUCTION

Programs to train community health workers (CHWs) in resource-poor settings to deliver life-saving interventions to sick children have grown in number and scale, increasing the importance of assessing the quality of the care they deliver.[1,2] The assessment methods used to measure quality of care should be valid, feasible, and an accurate reflection of performance of CHWs.[3] However, few studies have examined the methods used to assess quality of health worker performance, and most previous studies focused on facility-level care.[3–6] Assessments of CHW performance pose unique challenges because of their remote locations, diverse responsibilities, and variable caseloads,[7] and it remains unclear which method provides the optimal balance between data validity, reliability and feasibility of implementation at the community level.

Methods that have been used to assess health workers' performance in community case management (CCM) of sick children delivered by CHWs are summarized in Table 1. Direct observation (DO) with re-examination (RE) by a higher-level trained clinician is a common and well-regarded method to assess clinical performance of health workers at first-level health facilities.[3,5,6] Direct observation enables assessment of clinical cases by the CHW in the presence of a silent observer, and DO with RE involves independent verification of the case by a skilled clinician. One disadvantage of DO is the influence of an observer, known as the Hawthorne effect,[8,9] which can introduce a positive bias in quality of care assessments.[7,10,11]

Although DO with or without RE can be feasible at facilities, assessment of a CHW stationed hours or days in travel time from a referral center can be time-consuming, expensive, and logistically challenging, especially because in many settings CHWs have responsibilities that require leaving their post.[12] Caseloads seen by each CHW can also vary widely[7] depending on disease burden, catchment area size, geographic barriers, and other factors; in low caseload settings, DO can be resource intensive. As a result, few studies to date have attempted DO or RE in the community.[13–18] Instead, many choose to bring CHWs to a central location, such as a district hospital, for DO or role-play assessments.[7,19–24] However, removing CHWs from their home environment changes the physical space in which they work (e.g., lighting and facility structure) and the resources they have at hand (e.g., timers, drug supply), removes the interaction with the caretaker as a respected member of the community, and may bias the case mix towards more severely ill children.

Many researchers have avoided these practical problems by using other assessment methods, such as reviewing clinical records or registers (register review [RR]) or assessing CHW knowledge using case scenarios (CS) that present a vignette, followed by a series of questions.[7,13,14,19,21,25] Register review is less time-consuming and resource-intensive than DO[5] and could be an ideal proxy for clinical actions, but records of CHWs are often incomplete, subject to reporting bias (e.g., CHWs may only record uncomplicated illnesses they can manage and not record others), and may only be possible in settings with high CHW literacy. Case scenarios can measure CHW knowledge and cover selected illnesses representative of those in the community, including rare cases that are difficult to observe directly, but do not document performance in real clinical cases.

As part of an assessment of quality of CCM services in Malawi,[26] we measured CHW performance in classification and treatment of cough and fast breathing (suspected pneumonia), fever (suspected malaria), and diarrhea cases using various measurement methods. This report examines the bias associated with measuring CHW performance in CCM by using RR, CS, and DO only methods compared with direct observation with re-examination (DO with RE) by a higher-level clinician, and discusses the relative strengths and weaknesses of the four assessment methods in the Malawi CCM context.

MATERIALS AND METHODS

Assessment tool development. We adapted detailed checklists for DO and RE from the World Health Organization (WHO) Health Facility Survey[27] to include required CCM

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TABLE 1

Methods used to assess community health worker technical performance in case management of sick children in the community, Malawi*

Method	Description	Advantages	Disadvantages
Observation of clinical encounter with re-examination	In person, silent observation of real case by surveyor with independent re-examination by higher level clinician	Complete picture of provider's actions in real setting, including steps in case management process where errors occur; collection of real-time data	Intrusive; observer influence (Hawthorne effect); time consuming, complex, and generally more expensive because of need for careful training and clinical staff; usually cross-sectional, trend analysis less feasible
Observation of clinical encounter with actor simulation	In person, observation of simulated case played by an actor unbeknownst to CHW	Complete picture of provider's actions in real setting, including steps in case management process where errors occur; reduction of Hawthorne effect compared with known observation	Usually cross-sectional, trend analysis less feasible; time consuming, complex, and generally more expensive because of need for careful training of actors/observers; may be difficult in CCM programs where CHWs know their patients from the community
Observation of clinical encounter	In person, silent observation of real case by surveyor	Complete picture of provider's actions in real setting, can be ideal for actions required regardless of classification, such as counseling	Careful training needed for observers; no independent re-examination makes it difficult to determine ideal, gold-standard management actions
Register review	Review of register or other records of individual cases and summaries	Review large number of cases relatively quickly; able to perform in any setting; inexpensive, can be performed by non-clinical staff at different points in time for trend analysis	Quality and quantity of documentation varies; data subject to health worker accuracy in reporting
Provider knowledge testing	Test of knowledge using 1) oral or written examination; 2) case scenarios/vignettes; or 3) scenario using video/audio recording of case	Assessment of knowledge relatively quickly; transferable between settings (can adjust questions/cases to reflect local case mix); focus on severe disease or broaden scope to include more common cases; can take place in any setting (community vs. facility based)	Questions and cases must accurately reflect child illnesses; measure of health worker knowledge, which may be different than practice
Exit interview with child's caretaker	Oral or written questionnaire of health worker performance	Determination of patient satisfaction; allows collection of additional data (such as costs incurred with visit or understanding of counseling messages)	Subject to recall bias, especially depending on timing of interview after consultation; tendency to over-report tasks
Provider self report	Questions/checklist of items performed on a routine basis	Ability to conduct in any setting; inexpensive and simple to administer	Biased assessment of one's own performance; potential for large bias means it may only be able to identify large performance gaps
Re-examination of child (without observation)	Gold-standard clinician re-examines child after CHW	Allows for accurate determination of child's clinical status for signs and symptoms that have not changed since the CHW consultation	Examination can change dramatically from initial presentation to CHW, especially if treatment is administered in the interim

*CHW = community health worker; CCM = community case management.

tasks according to the WHO manual *Caring for the Sick Child in the Community*.[28] A standard form for RR abstracted the child's age, sex, classification, treatment and referral decision from CCM patient registers. At the time of the assessment, Malawi's CHWs (known as Health Surveillance Assistants [HSAs]) were using ad hoc registers; often these were old diarrhea management registers that included the name, age and sex of child, classification and management decisions. Eight case scenarios were designed based on the WHO Health Facility Survey, reviewed by independent CCM experts, and adapted to reflect common and rare clinical illness expected in children in the community in Malawi (five scenarios required referral, three could be managed by the HSA in the community, three included diarrhea, three included cough and fast breathing, and three included fever). Copies of all assessment forms are available at www.jhsph.edu/dept/ih/IIP/projects/catalyticinitiative.html.[29] All data collection tools were piloted over a one-week period and revised accordingly.

Study setting. In 2008, Malawi's Ministry of Health started to train and equip a cadre of community-based health workers (HSAs), to provide CCM for sick children 2 months up to 5 years of age by using the WHO strategy in which CHWs assess symptoms, briefly examine the patient, classify and treat disease, and refer complex cases to a health facility.[28] The HSAs

are a paid cadre of CHWs who are required to have a 10th grade education and work in communities in water and sanitation and other programs such as child vaccination, tuberculosis treatment, family planning, or assisting at a health facility.[30] The CCM six-day training course, comprising three days of clinical practice, trained HSAs to treat cough and fast breathing (suspected pneumonia) with cotrimoxazole, fever (suspected malaria) with artemether/lumefantrine and paracetamol, and diarrhea with oral rehydration salts. For more complicated cases, HSAs were taught to recognize signs and symptoms and refer to the nearest health facility.[30] The Ministry of Health CCM strategy first targeted the training and deployment of HSAs to serve hard-to-reach communities (> 8 km from a health facility). The HSAs treat sick children in their communities at a village health clinic site designated by the community, often a central structure or outdoor place in the village, or sometimes located at the home of an HSA. The caseload of HSAs is relatively high; an average of > 40 sick children are seen per month.[26,30]

The HSAs were randomly sampled from a listing of CCM-trained HSAs with available drug supply and serving in hard-to-reach areas in 6 of the 28 districts in Malawi with early CCM implementation, resulting in a total sample of 132 HSAs. A detailed description of the sampling methods has been reported.[26]

Surveyor training and data collection. We trained surveyors, nurses, or clinical officers who were CCM master trainers in the use of the tools and methods for one week. Inter-observer reliability measurements were made for the direct observation tool during the initial training period and halfway through the assessment, continuing until 90% agreement was reached for all surveyors. Teams of three surveyors visited HSAs at their village health clinics in their communities and collected data for five weeks during October–November 2009.

The teams spent one day for each HSA visit, and carried out the following steps. First, the survey team obtained written consent from the HSA for all data collection methods. Second, as caretakers brought sick children to the HSA, typically early morning, surveyor 1 identified eligible children (sick children 2–59 months of age presenting for initial consultation) and obtained oral consent from their caretakers for DO and RE. Direct observation and RE were conducted for ≤ 5 sick children per HSA. Third, surveyor 2 observed sick child consultations and recorded whether specific steps in the CCM algorithm were carried out for each child. The classification of the HSA was determined by what the HSA wrote in the register; in instances where this was unclear, surveyors were instructed to ask the HSA for the classification. Treatments were determined by observing those given to the sick child. Fourth, without witnessing the initial encounter between the HSA and the sick child, surveyor 3 (also the team leader) re-examined the sick child privately and recorded his or her gold-standard assessment. Fifth, after all sick children had been seen by the HSA, surveyor 3, with help from the other surveyors, abstracted required data from the clinical registers for the last 10 cases seen by the HSA before the assessment. Surveyor 3 also read eight case scenarios to each HSA, who held a written copy. After each scenario, the HSA was asked open ended questions about what he or she would do for the child. The scenarios were administered without prompting and answers were recorded on a checklist of possible responses including HSA treatment and referral decisions. The HSAs were allowed to use any job aids available at their site to formulate their responses.

Definitions. We focused our analyses on three classifications (cough with fast breathing [suspected pneumonia and referred to as fast breathing throughout this report], fever [suspected malaria], and diarrhea) because collectively fast breathing, fever and diarrhea formed most clinical diagnoses seen by HSAs[26] and together are estimated to account for 45% of all deaths in children 1–59 months of age in Malawi.[31] We divided these cases into uncomplicated illness and severe illness, the latter defined as any illness with danger signs (Figure 1).

Measures and statistical analyses. Measures used to define correct classification and treatment of each method are shown in Table 2. These same methods were used to calculate misuse of antibiotics and antimalarial drugs; incorrect performance was defined as giving an antimicrobial drug in cases in which treatment was not indicated. In this analysis, we excluded cases for DO with RE and DO only in which the HSA was experiencing a stock-out of the drug needed to treat a classification correctly. Children who were not able to tolerate oral medications (i.e., vomiting everything or not able to drink or eat anything) were also excluded from analysis because the CCM guidelines recommend against treatment with drugs in these cases. We calculated correct treatment across the methods for all HSAs and cases and for a restricted sample of HSAs that had managed fast breathing, fever, or diarrhea during the DO. We present the former here because we found no appreciable differences in the results produced.

We considered the DO with RE as our gold-standard method. We first examined the classification and treatment decisions by the HSAs collected by DO compared with the independent re-examiner for uncomplicated illness and severe illness and report sensitivity and specificity estimates. Agreement between DO and RE was assessed by percent agreement and kappa statistics, with values < 0, 0.00–0.20, 0.21–0.40, 0.41–0.60, 0.61–0.80, and 0.81–1.00 considered as poor, slight, fair, moderate, substantial, and almost perfect agreement, respectively.[31] We calculated point estimates of the proportion of cases correctly treated as measured by DO only, RR and CS for uncomplicated and severe illness using the measurement definitions above. We then compared estimates of correct treatment measured by DO only, RR (historical cases) and CS (fictional cases) to cases with the same classifications as measured by DO with RE, calculating the arithmetic difference in point estimates and testing for significant differences by using chi-square or Fisher's exact, as appropriate.

Proportions, 95% confidence intervals, and P values were calculated by using Stata version 11 (StataCorp LP, College Station, TX) with adjustments for HSA clustering.[32] Differences were considered statistically significant if $P < 0.05$. The Institutional Review Board at the Johns Hopkins Bloomberg School of Public Health and the Malawi National Health Sciences Review Committee provided ethical review and approval for the study.

RESULTS

A total sample of 131 HSAs was visited; 1 HSA could not be found by the survey team and was dropped from the sample. One HSA did not consent to participate in the study; this HSA and seven others who did not have initial drugs stocks (3) or were absent (4) were replaced during the assessment by

Definitions

Uncomplicated illness includes cough and fast breathing (referred to throughout as fast breathing), diarrhea or fever without any danger signs.

Severe illness includes fast breathing, diarrhea or fever with one or more danger signs requiring referral according to community case management (CCM) guidelines. Danger signs included chest indrawing, cough for ≥ 21 days, fever for ≥ 7 days, diarrhea for ≥ 14 days, blood in stool, inability to drink or feed, vomits everything, convulsions, palmar pallor, red on mid-upper arm circumference (MUAC) tape, or bipedal enema.

Classification is the presumptive illness assigned to the child after examination. Fast breathing, diarrhea and fever are included in this analysis.

Correct classification is identification or recording by the Health Surveillance Assistant (HSA) of the same classification as recorded by the re-examiner, and is based on the application of the Malawi adaptation of the World Health Organization CCM guidelines.

Correct treatment[a] for uncomplicated illness is prescription of the appropriate medicine by the HSA according to CCM guidelines for the classification. Children with cough and fast breathing are treated with cotrimoxazole, children with fever are treated with antimalarials, and children with diarrhea are treated with oral rehydration salts.[b] Correct treatment for severe illness is defined as correct treatment by the HSA for the classification, as well as appropriate referral to a health facility, based on the CCM guidelines. Referral is required for any danger signs reported by the caretaker or identified by the HSA.

Misuse of antibiotics or antimalarials refers to a medication given to a child by the HSA that is not indicated in CCM guidelines for that classification.

Sensitivity and specificity

Classification of Illness

Sensitivity: proportion of children who truly had a classification (e.g., fever) as defined by the gold-standard re-examiner that were classified as such by the HSA.
Specificity: proportion of children who did not have the classification (e.g., did not have fever) who were correctly identified as not having that classification by the HSA.

Treatment of Uncomplicated Illness

Sensitivity: proportion of children who truly had a classification as defined by the gold-standard re-examiner who were treated correctly by the HSA.
Specificity: proportion of children who did not have the classification as defined by the gold standard re-examiner who were not treated by the HSA as if they did have that classification (e.g., child does not have fever, HSA did not give Antimalarial Combination Therapies (ACTs)).

Treatment of Severe Illness

Sensitivity: proportion of children who truly had an illness (fast breathing, fever, or diarrhea) with danger sign as defined by the gold-standard re-examiner who were treated correctly and referred for that illness by the HSA.
Specificity: proportion of children who did not have the illness (fast breathing, fever, or diarrhea), but did have a danger sign, as defined by the gold standard re-examiner, who were not treated by the HSA with a drug as if they had that illness (fast breathing, fever, or diarrhea), but were referred.

[a] Dose, frequency, and duration were not included in this analysis because this information was not available from register reviews or case scenarios.
[b] Zinc is also included as treatment for diarrhea in CCM guidelines, but was not available for any HSAs at the time of this assessment.

FIGURE 1. Definitions used in comparison of methods for assessing quality of care for community case management of sick children, Malawi.

TABLE 2
Measures used to define correct classification and treatment of each method, Malawi*

Measure	HSA performance measure	Standard for correct performance
Direct observation with reexamination (DO with RE)	Classification given by HSA as directly observed; treatment given by HSA as directly observed	RE classification; treatment recommended in CCM guidelines, according to RE classification
Direct observation (DO) only	Treatment given by HSA as directly observed	Treatment recommended in CCM guidelines, given HSA's classification observed
Register review (RR)	Treatment given by HSA as recorded in register	Treatment recommended in CCM guidelines, given HSA's classification recorded in register
Case scenarios (CS)	Treatment recommended by HSA in response to CS	Treatment recommended in CCM guidelines, given signs and symptoms of child included in CS

*HSA = health surveillance assistant; DO = direct observation; RE = re-examination; CCM = community case management; CS = case scenarios.

using random selection. Data from 382 sick child consultations with DO and RE were available for analysis after exclusion of six cases that did not meet eligibility criteria or had incomplete documentation. All caretakers approached to participate in the study consented. Surveyors directly observed and re-examined a median of 3 (range = 1–5) sick child consultations for each of 131 HSAs. Of 1,310 RR sick child cases recorded, 91 (6.9%) were excluded because they lacked information on the classification assigned by the HSA. Two of the eight scenarios administered to all HSAs were excluded from this analysis because they lacked analogous cases in RE, resulting in a total of 262 suspected pneumonia, 262 fever, and 393 diarrhea cases.

The percentage of cases by type of classified illness included in our sample for each method is shown in Table 3. Fever was the most common (59–75%) uncomplicated illness in DO with RE, DO only, and RR. A higher percentage of uncomplicated fast breathing cases were recorded in RR (32%) than observed in DO only (21%) or DO with RE (15%). Many fewer severe illnesses (with danger signs) were recorded in RR than observed in DO only or DO with RE. The most common danger signs classified by RE were fever for ≥ 7 days, palmar pallor, and blood in the stool. Most cases of uncomplicated fast breathing, fever, or diarrhea seen were classified with one (74–92%) or two of these illnesses (28–34%). A smaller proportion of cases were recorded as referred in RR (1–3%) than observed in DO only (19–22%) or DO with RE (19–21%).

TABLE 3
Percentage cases by type of illness and referral, by measurement method, Malawi*

	Direct observation with re-examination (n = 382)		Direct observation only (n = 382)		Register review (n = 1,219)	
Illness or referral	%	95% CI	%	95% CI	%	95% CI
Uncomplicated illness						
Fast breathing	15	11–19	21	16–27	32	27–37
Fever	63	58–69	59	53–65	75	72–79
Diarrhea	25	21–29	23	19–27	19	16–22
Severe illness						
Fast breathing	5	3–7	6	3–8	0.2	0–0.4
Fever	13	10–17	12	8–16	0.5	0–1
Diarrhea	4	2–6	4	2–6	0.1	0–0.2
No. uncomplicated illnesses†						
1	74	69–78	75	70–80	92	89–99
2	29	24–33	28	23–33	34	29–38
3	3	1–5	7	0.3–2.8	1	0.5–2
Referrals‡						
Fast breathing	20	71–90	19	10–27	1	0–3
Fever	21	15–26	19	14–25	2	0.3–4
Diarrhea	19	12–27	22	14–31	3	0.6–6

*CI = confidence interval. Case scenarios were designed by investigators as described in the text and included cases of fast breathing, fever, and diarrhea.
†One classification includes either fast breathing, fever, or diarrhea. Two is any combination of two of these illnesses per child; three is all three illnesses. Danger signs excluded.
‡Children referred for any reason.

Sensitivity, specificity, percent agreement, and kappa. The sensitivity, specificity, percent agreement, and kappa for HSA classification and treatment through DO relative to RE are shown in Table 4. For uncomplicated fever and diarrhea cases, sensitivity and specificity of HSA's classification and treatment (DO) compared with RE were high (87–99%), and kappa estimates indicated substantial or almost perfect agreement (0.70–0.92). Sensitivity was lower for classification and treatment of uncomplicated fast breathing (59% and 63%), as was specificity (82% and 75%). In further exploration, a contributing factor to the low sensitivity of classification and treatment of fast breathing cases was co-morbid fever and/or diarrhea. The HSAs more frequently missed the fast-breathing classification (18 of 24 cases incorrectly classified) or giving cotrimoxizole (19 of 21 cases with incorrect treatment) in the presence of other illnesses. For treatment of cases that did not have fast breathing, most errors leading to low specificity (46 of 57) were caused by incorrect classification with fast breathing.

For severe illness, sensitivity and specificity of HSA classification of fever with danger signs was highest (86% and 94%, respectively) (Table 4); sensitivity of fast breathing with danger signs (68%) and diarrhea with danger signs (57%) were lower. For treatment of severe illnesses, sensitivity and specificity were low for all three illnesses, ranging from 32% sensitivity for fast breathing to 65% for specificity for fever. Percent agreement and kappa estimates correlated with sensitivity and specificity estimates. Errors for fast breathing cases with danger signs were often caused by lack of referral (9 of 13) and or lack of treatment with cotrimoxazole (6 of 13). For fever cases with danger signs, 23 of 30 were not referred and 11 of 30 were not treated with artemether/lumefantrine.

Correct treatment of illness: comparisons of methods. Correct treatment of cases as measured by DO only, RR, and CS compared with DO with RE is shown in Table 5. For uncomplicated fast breathing, the proportion of cases with correct treatment as measured by DO only (100%), RR (97%), and CS (85%) were all more than 20 percentage points significantly higher than that recorded by DO with RE (63%). Measured levels of correct treatment by HSAs for uncomplicated fever and diarrhea cases in DO, RR, and CS were all within 9 percentage points of the DO with RE estimate. The aggregate indicator, correct treatment of fast breathing, fever and/or diarrhea, was different for DO only and RR compared with the gold-standard DO with RE (79%).

TABLE 4

Sensitivity specificity, percent agreement, and kappa for direct observation of health surveillance assistant classification and treatment of illness compared with re-examination, Malawi*

Illness		Sensitivity No.	Sensitivity % (95% CI)	Specificity No.	Specificity % (95% CI)	% Agreement†	Kappa statistic (95% CI)
Uncomplicated illness							
Fast breathing	Classification	34/58	59 (46–72)	209/256	82 (75–88)	77	0.35 (0.23–0.47)
	Treatment	36/57	63 (50–77)	173/230	75 (68–83)	73	0.31 (0.19–0.43)
Fever	Classification	226/242	93 (90–97)	71/72	99 (96–100)	95	0.86 (0.79–0.92)
	Treatment	198/229	87 (81–92)	52/53	98 (94–100)	89	0.70 (0.60–0.79)
Diarrhea	Classification	86/94	92 (86–97)	218/220	99 (98–100)	97	0.92 (0.88–0.97)
	Treatment	63/70	90 (82–98)	149/150	99 (98–100)	96	0.91 (0.86–0.97)
Severe illness							
Fast breathing	Classification	13/19	68 (41–95)	42/49	86 (75–96)	81	0.53 (0.31–0.76)
	Treatment	6/19	32 (3–60)	23/45	51 (35–67)	45	–0.15 (–0.38 to 0.07)
Fever	Classification	44/51	86 (76–96)	16/17	94 (82–100)	88	0.72 (0.54–0.90)
	Treatment	17/47	36 (22–51)	11/17	65 (38–91)	44	0.01 (–0.18 to 0.19)
Diarrhea	Classification	8/14	57 (26–89)	46/54	85 (74–96)	79	0.40 (0.14–0.66)
	Treatment	5/10	50 (12–88)	18/43	42 (23–61)	43	–0.05 (–0.24 to 0.15)

*CI = confidence interval. See Figure 1 for definitions of sensitivity and specificity for classification and treatment.
†Percent agreement is a weighted average of sensitivity and specificity. For example, 77% agreement for uncomplicated fast breathing (first row) was calculated as (34 + 209)/(58 + 256).

For fast breathing, fever, or diarrhea with danger signs, DO only (56–83%) and CS (37–70%) showed higher levels of correct treatment than DO with RE (24–40%) (Table 5). As the number of uncomplicated illness cases treated by HSAs increased from one to two to three per child, correct treatment by HSAs significantly decreased as measured by DO with RE, RR, and CS (one illness = 79–96%, two illnesses = 37–80%, and three illnesses = 11–60%). The proportion of cases managed correctly as measured by DO only did not decrease in the same manner and always remained ≥ 89%.

Misuse of antibiotics and antimalarial drugs. The proportion of cases that should not have received antibiotics or antimalarial drugs is shown in Table 6. The DO only, RR, and CS methods all showed lower proportions of cases without fast breathing that received cotrimoxazole compared with DO with RE; i.e., misuse of this antibiotic was recorded as lower (2–18%) for DO only, RR, and CS than for DO with RE (24%). A high percentage of cases with cough but not fast breathing received cotrimoxazole, as measured by the DO with RE (48%). RR measured an even higher level of misuse of antibiotics in the cases with cough (73% and +25 points from DO with RE), and DO only measured a lower proportion (16%); both were significantly different from the DO with RE.

DISCUSSION

We found that directly observed HSA classification and treatment of uncomplicated fever and diarrhea had high validity and reliability compared with RE, as indicated by high sensitivity, specificity, and kappa estimates. The DO only, RR, and CS methods provided estimates of the proportion of children correctly treated for uncomplicated fever and diarrhea that were similar to those from DO with RE (within nine absolute percentage points). In contrast, directly observed HSA classification and treatment of uncomplicated fast breathing showed lower sensitivity, specificity, and fair kappa estimates compared with RE. The DO only, RR, and CS methods also estimated significantly higher correct treatment of uncomplicated fast breathing compared with DO with RE. The same trend was true for HSA performance in severe illness cases for fast breathing, fever, and diarrhea, in which HSAs directly observed treatment had particularly low sensitivity, specificity, and kappa as compared with RE, and the proportion of correctly treated cases in DO only and CS were higher compared with DO with RE. Collectively, these results suggest that HSA performance for uncomplicated fever and diarrhea cases, but not fast breathing or severe illness, can be accurately reported through assessments using DO only, RR, or CS in the Malawi CCM context.

Using DO with RE enabled exploration of errors made by HSAs through an in-person, direct assessment of HSA performance in real-world clinical cases. We identified that most classification and treatment errors for uncomplicated fast breathing in DO were associated with a co-classification of fever, and most errors in severe illness cases were caused by a lack of appropriate referral. In addition, DO with RE and RR identified significant misuse of antibiotics. These errors would have been missed if only using the HSA classifications seen in DO, without the independent RE classifications.

Despite these advantages, DO with RE has been used in few published CHW assessments,[15,22–24] perhaps because it is resource intensive.[5,7] In our assessment, it required removal of clinicians from regular duties for a six-week period. In settings with chronic health worker shortages, this limitation poses a temporary drain on resources. The DO method is also subject to the Hawthorne effect.[6,8–11] Despite the limitations of DO with or without RE, ideally the long-term benefits from valid and reliable information gained from DO with RE on program improvements will outweigh the upfront costs.

Register review enabled us to retrospectively analyze data from a larger number of cases than was possible through DO. Register review identified a high proportion of HSAs giving cotrimoxazole inappropriately for children with cough but no fast breathing (73%). However, DO with RE also indicated a lower, but still high proportion (48%) of HSAs making this error, and DO only did not (16%). In addition, substantially more fast breathing cases were recorded and abstracted in RR than were directly observed. Before introduction of the WHO CCM algorithm, guidelines in Malawi indicated that giving antibiotics for cough was appropriate. Although CCM guidelines no longer endorse this policy,

TABLE 5

Correct treatment of illness, by method, Malawi*

Feature		Uncomplicated illness, correct treatment				Severe illness, correct treatment				No. uncomplicated illness classifications†		
		Fast breathing	Fever	Diarrhea	Fast breathing, fever, and/or diarrhea	Fast breathing	Fever	Diarrhea	Fast breathing, fever, and/or diarrhea	One	Two	Three
Direct observation with re-examination	No.	57	229	70	265	17	44	10	50	167	71	9
	% correct (95% CI)	63 (49–76)	87 (80–91)	90 (79–96)	79 (73–84)	24 (0.06–58)	32 (20–46)	40 (13–76)	26 (15–40)	89 (80–94)	65 (53–75)	11 (0.01–63)
Direct observation only	No.	88	229	66	287	8	27	12	35	164	79	4
	% correct (95% CI)	100	92 (87–95)	97 (88–99)	93 (88–96)	75 (19–98)	56 (35–74)	83 (44–97)	63 (43–79)	94 (87–97)	89 (76–95)	100
	Difference in % points from DO with RE	+37	+5	+7	+14	+51	+24	+43	+37	+5	–24	+89
	P‡	< 0.001	< 0.001	0.012	< 0.001	0.008	0.004	0.028	< 0.001	0.002	< 0.001	0.005
Register review	No.	384	898	225	1098	–	–	–	–	688	387	15
	% correct (95% CI)	97 (94–98)	93 (89–95)	82 (74–88)	89 (86–92)	–	–	–	–	96 (93–97)	80 (73–85)	60 (33–82)
	Difference in % points from DO with RE	+34	+6	–8	+10	–	–	–	–	+7	+15	+49
	P‡	< 0.001	0.030	0.183	< 0.001	–	–	–	–	0.014	0.016	0.030
Case scenarios	No.	131	131	131	131	131	131	131	131	131	131	
	% correct (95% CI)	85 (79–91)	95 (90–98)	99 (94–99.6)	79§ (72–96)	37 (4–29)	44 (35–52)	70 (61–78)	25§ (18–33)	79§ (72–96)	37 (29–46)	
	Difference in % points from DO with RE	+22	+8	+9	0	+13	+12	+30	–1	–10	–28	–
	P‡	0.003	0.005	0.008	0.973	0.323	0.132	0.057	0.912	< 0.001	< 0.001	

* CI = confidence interval; DO= direct observation; RE = re-examination.
† One classification is either fast breathing, fever, or diarrhea. Two is any combination of two of these illnesses per child; three is all three. Danger signs excluded.
‡ *P* value represents chi-square test, or Fisher's exact test as appropriate, for difference in proportions of the method to direct observation with re-examination adjusting for health surveillance assistant clustering.
§ Aggregate indicator (fast breathing, fever, and/or diarrhea) for case scenarios calculated at the health surveillance assistant level, i.e., health surveillance assistant correctly treated all three case scenarios for uncomplicated illness.

TABLE 6
Misuse of antibiotics and antimalarial drugs, by method, Malawi*

Feature		Misuse of antibiotics and antimalarial drugs		
		No fast breathing, received cotrimoxazole	Cough (no fast breathing), received cotrimoxazole	No fever, received AL
Direct observation with re-examination	No.	272	113	64
	% Detected (95% CI)	24 (17–31)	48 (36–60)	3 (0–8)
Direct observation only	No.	247	84	80
	% Detected (95% CI)	6 (2–9)	16 (6–25)	2 (0–6)
	Difference in % points from DO with RE	–18	–32	–1
	P†	< 0.001	< 0.001	0.869
Register review	No	791	125	273
	% Detected (95% CI)	18 (13–23)	73 (59–87)	5 (3–8)
	Difference in % points from DO with RE	–6	+25	+2
	P†	0.192	< 0.001	0.746
Case scenarios	No.	131	NA	131
	% Detected (95% CI)	2 (0-5)	NA	9 (4–14)
	Difference in % points from DO with RE	–22	NA	+6
	P†	< 0.001	NA	0.15

*AL = artemether/lumefantrine; CI = confidence interval; DO = direct observation; RE = re-examination; NA = no case scenarios tested this classification or combination of classifications.
†*P* value represents chi-square test, or Fisher's exact test as appropriate, for difference in proportions of the method to direct observation with re-examination adjusting for health surveillance assistant clustering.

HSAs may feel pressured to include a diagnosis of cough with fast breathing and dispense antibiotics either because of previous habits or because the caregiver expects it, as reported in studies of patient influence on prescribing practices for acute respiratory infections.[33,34] Therefore, the HSAs might justify prescribing antibiotics when not indicated and record these cases, but change their behavior in the presence of an observer.

Unfortunately, registers do not exist in all settings where CHWs work, and the quality and quantity of documentation varies in those that are available.[5,35] Although most HSAs did have registers, minimal information was recorded and did not enable a complete assessment of decisions made. For example, we found that fewer severe cases but more uncomplicated fast-breathing cases were recorded in RR compared with DO, and cannot be sure if this is associated with poor documentation or is a true difference. We directly observed substantial errors in recognizing and referring severe illness and HSAs may not have recorded severe cases in registers because of lack of recognition and/or discomfort managing more severe cases. Our assessment took place early in the CCM implementation in Malawi and extracted data from ad hoc registers created by each HSA for his or her own records. Since the time of our assessment, new, standardized registers have been introduced that include more detailed information on classifications, counted breaths per minute, danger signs, and treatments given. These registers could increase the validity of information gleaned from the registers, and serve as a job aid that could improve HSA performance.

Case scenarios assess clinical knowledge of CHWs, rather than actual practice, which is their primary limitation. Conversely, one advantage in our assessment was that our CS included more severe cases requiring complex management; DO of presenting cases could not capture substantial numbers of rare, severe illnesses, and RR also had small sample sizes and potential documentation bias for severe cases. Also, CS were not resource intensive to administer and can elucidate gaps in CHW knowledge in management of severe illnesses. Although training is still required for surveyors, scenarios can be applied in any setting (community or facility) and in CHW programs with low patient volume. A study directly comparing knowledge of CHWs in the management of severe cases to their actual practice in clinical settings would provide useful further information on the value of this method.

Our comparison of correct treatment across all methods indicated that increasing complexity of illness led to lower HSA performance. First, HSAs performed better for uncomplicated illnesses than severe illnesses in DO with RE, DO only, and CS methods. Second, HSAs performed better in managing cases with a single classification than cases with two or three classifications across DO with RE, RR, and CS methods. Compared with DO with RE, these results suggest that RR and CS, and in some cases DO only, may be able to detect a large decrease in HSA performance caused by the presence of danger signs or increasing number of classifications. A difference in CHW performance by severity of disease has been reported.[20] However, the correlation between increasing number of classifications and decreasing CHW performance should be confirmed in future studies.

This analysis has limitations. The study was not specifically designed to compare these methods, especially for severe illnesses, and small sample sizes limit the conclusions that can be drawn in some cases. For RR, we did not abstract the registers for the directly observed cases, which would have enabled more robust estimates of the reliability and validity of RR compared with DO with RE. This additional process should be considered in future studies of this kind. Case scenarios, by necessity, must be designed ahead of time, and therefore the comparison to actual cases seen is inflexible once the assessment begins. Finally, we were not able to assess the relative costs of these methods because all were implemented simultaneously as a part of a larger research study.

The results reported are based on one application in Malawi, and may differ in other settings. First, HSAs saw a median of three sick children per day in their communities during our observations, which is a relatively high caseload not always seen in other CHW programs. Second, HSAs were observed in the same settings where they practice, and they were assessed managing sick children from their

communities who were likely to reflect a case mix similar to the routine practice of the HSA. Although our assessment did not directly compare HSA performance in the community versus their performance if brought to a health facility for the assessment, we believe that conducting this quality of care assessment in the community likely produced results with higher validity. In other settings with lower care-seeking to CHWs, DO at the community level may not be feasible or affordable, given that surveyors will need to spend long periods in the field. Third, HSAs in Malawi have more education than CHWs providing CCM in other countries in Africa, and receive a government salary, and may therefore have conceptual skills to handle CS and be better motivated to perform their jobs well. Fourth, HSAs maintain relatively detailed clinical registers, but such documentation is not standard practice in all CHW settings. Fifth, CCM in Malawi focuses on fast breathing, fever, and diarrhea cases, but other CHWs may be trained in one disease only or have other responsibilities that require adaptation of the assessment method. Future assessments should investigate these methods, and any alternatives, in different contexts.

Calls for greater accountability in maternal, newborn, and child health programs[36] present new challenges to governments and their development partners about how to conduct regular assessments of the quality of health services delivered at community level. In this study, we aimed to assess the quality of care received by sick children and HSA performance at the community level, and the added validity and reliability of information gained by using DO with RE outweighed the intensity of resources required to carry out this method. However, if the objective is to determine effectiveness of a training program in developing knowledge, CS may be sufficient, or for skills building or reinforcement, DO with RE in a centralized setting may be sufficient. In all settings, if written documentation of cases is available, RR can provide additional information on historical cases, and CS can supplement assessment of routine clinical cases with more severe, rare cases with danger signs. In our assessment, a more comprehensive, valid and reliable picture of HSA performance was created by using all methods together in the community, but use of all methods together may not always be feasible for program managers or researchers. Our analysis of method alternatives to assess the performance of CHWs in delivering community case management of childhood illnesses indicates that the assessment objectives and feasibility of each method should be considered carefully in the context of the CHW program being assessed before making a selection.

Received June 20, 2012. Accepted for publication August 19, 2012.

Acknowledgments: We thank the health surveillance assistants and surveyors for participating in this assessment, the CCM-Malawi Quality of Care Working Group for their contributions, and Agbessi Amouzou for assistance during the analysis and write-up. The CCM-Malawi Quality of Care Working group includes Samira Aboubaker, Agbessi Amouzou, Enoch Bonongwe, Jennifer Bryce, Jennifer Callaghan, Cristina Cardemil, Bernadette Daelmans, Kate Gilroy, Asha George, Timothy Kachule, Susan Kambale, Regis Katsande, Leslie Mgalula, Angella Mtimuni, Edwin Nkhono, Humphreys Nsona, Thoko, Sambakunsi, Newton Temani, and Texas Zamasiya.

Financial support: This study was supported by the Bill and Melinda Gates Foundation through a contract to the World Health Organization to support the independent evaluation of the Maternal Newborn Child Health Rapid Scale-Up in Malawi. Cristina V. Cardemil received additional support from the Child Health Center Board and the Robert H. Parrott REACH Program.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 137–143
doi:10.4269/ajtmh.2012.12-0242

Household Costs for Treatment of Severe Pneumonia in Pakistan

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Abstract. Current World Health Organization (WHO) guidelines for severe pneumonia treatment of under-5 children recommend hospital referral. However, high treatment cost is a major barrier for communities. We compared household costs for referred cases with management by lady health workers (LHWs) using oral antibiotics. This study was nested within a cluster randomized trial in Haripur, Pakistan. Data on direct and indirect costs were collected through interviews and record reviews in the 14 intervention and 14 control clusters. The average household cost/case for a LHW managed case was $1.46 compared with $7.60 for referred cases. When the cost of antibiotics provided by the LHW program was excluded from the estimates, the cost/case came to $0.25 and $7.51 for the community managed and referred cases, respectively, a 30-fold difference. Expanding severe pneumonia treatment with oral amoxicillin to community level could significantly reduce household costs and improve access to the underprivileged population, preventing many child deaths.

INTRODUCTION

Pneumonia is one of the leading causes of childhood mortality globally, with estimated 1.25 million deaths per year.[1] Of the estimated 150 million new cases of pneumonia reported every year, 7–13% are severe enough to be life threatening and require hospitalization.[2,3] Globally, care seeking for pneumonia is low and the proportion of children receiving appropriate antibiotics for pneumonia is only 27%.[4] Pneumonia is a leading cause of death in children in Pakistan,[1] however, only 50% of children with pneumonia receive antibiotics.[5]

Meta-analysis by Sazawal and Black[6] estimated that community case management (CCM) of suspected pneumonia with oral antibiotics can reduce pneumonia-specific mortality by 35%. Current World Health Organization (WHO) guidelines recommend that health workers refer children with severe pneumonia (chest in-drawing) to a hospital for treatment with an injectable antibiotic.[7] In many developing countries, this is not feasible or practiced because of poor transportation, cost,[8] distance, lack of child care at home, or cultural perceptions.[9,10] Evidence shows that treatment of WHO-defined severe pneumonia on an outpatient basis with oral antibiotics is safe and efficacious.[11,12] Expanding oral treatment of severe pneumonia to the community level may not only improve access and compliance, but also significantly reduce economic burden on the poor families.

The economic burden of a disease can be viewed from a health system or a household perspective. In addition to the direct medical costs, composed of expenses on medicines, investigations, consultation, and hospital stay, households of sick children incur non-medical expenses for transportation, food, child care, and lost income in the form of caregiver time and/or lost wages. Data from developing countries on cost of severe pneumonia treatment of children < 5 years of age is scant, more so for studies estimating household costs. A study conducted in Northern Pakistan[13] reported a total cost of $142 and household cost of $17.61 for inpatient treatment of one episode of severe pneumonia. Another study in India[14] estimated provider cost of US$83.89 and US$146.59 and household cost of $41.35 and $134.62 for inpatient treatment of severe pneumonia in secondary and tertiary level hospitals, respectively. In a Kenyan study,[15] mean provider cost for inpatient treatment of pneumonia was $197.54 at the national hospital, $135.26 at the mission hospital, and $76.64 at the district hospital. Within these facilities, household direct and indirect costs amounted to $27.28, $18.82, and $12.54 for national, mission, and district hospital, respectively. The previous findings show the overall high cost of inpatient treatment of severe pneumonia and the financial burden on the families.

Outpatient and community treatment has been found effective and safe in the treatment of severe pneumonia.[11,12,16,17] Data on cost of community treatment of severe pneumonia and the resulting savings to households would help policymakers to prioritize strategies for severe pneumonia treatment.

The objective of this study was to estimate and compare household costs for current WHO and LHW program recommended management-diagnosis by a community health worker (CHW), give first dose of oral antibiotic, and refer to a health facility versus community treatment by the CHW with oral amoxicillin given for 5 days. We estimated the total and average direct and indirect costs to households for both treatment options.

MATERIALS AND METHOD

Study site. The study was conducted in district Haripur, Khyber Pakhtunkhwa province, Pakistan. Eighty-eight percent of the district's 856,921 people live in rural areas. Haripur has a wide range of topography with plains, mountains, and lakes. Although most people live in the central plain, a sizeable proportion lives in relatively remote mountainous areas. For these communities, travel to health facilities may mean walking for an hour or more to a road, followed by a drive in a vehicle, which may be only occasionally available. The overall literacy rate in Haripur is 53.7%, with a female literacy rate of only 37.4% compared with a male literacy rate of 63.6%. Agriculture is the primary occupation of a majority of the population.

Haripur is located in northern Pakistan comprising 327 villages grouped in 44 union councils (UC), the smallest administrative unit with 15,000–25,000 population. Each UC has at least one primary care health facility called a Basic Health

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Unit (BHU) or a Rural Health Center (RHC). Haripur has one district Hospital, 5 RHCs, 41 BHUs, and 14 other health centers in the public sector. There are several hospitals and clinics in the private sector. The LHWs are the most peripheral health providers. In 2009, there were 750 LHWs working in the district.

Lady Health Workers Program. Pakistan's well-established National Program for Family Planning and Primary Health Care, commonly referred to as Lady Health Workers (LHWs) Program was launched in 1994. In 2008, there were ~90,000 LHWs nationwide, serving a population of ~90 million.[18] The LHWs require an 8th grade school attainment and undergo an extensive 3-month classroom training with 12 months of field supervision. Once deployed, LHWs provide preventive, promotive care to children and mothers, and basic curative services for children. Linked to the nearest public health facility, they are clinically supervised by a lady health visitor and administratively supervised by a lady health supervisor. The LHWs visit their assigned health facility every month for supervision, replenishment of supplies, and in-service training. The LHW works from a health house established in her home and serves around 1,000 individuals (150–200 families). She conducts 5–8 household visits per day and visits all the households every month, and is available for sick child visits whenever needed.

Study design and participants. The costing study was nested within a cluster randomized clinical trial conducted (April 2008–December 2009) in district Haripur to determine equivalency in clinical treatment failure rates among children 2–59 months of age with WHO-defined severe pneumonia in the clusters receiving community treatment with oral amoxicillin versus children in the control clusters who received standard of care.[16]

For the cluster randomized trial (RCT), the union council was defined as a study cluster. Of the 44 UCs, 28 were randomized to 14 intervention and 14 control clusters. Sixteen UCs were excluded because they were either in urban areas or were inaccessible. Five hundred eleven (511) LHWs from the 28 clusters were enlisted into the study (for a detailed methodology see Bari and others[16]). The costing study sample population included all severe pneumonia cases enrolled in the 14 intervention and 14 control clusters in the RCT during December 2009.

For the RCT, LHWs were trained to screen every child 2–59 months of age presenting to her with fast breathing and or lower chest in-drawing for enrollment. Children who met the study inclusion criteria were enrolled by the LHW (Box 1). In the intervention clusters, LHWs gave oral amoxicillin (80–90 mg/kg per day or 375 mg twice a day to infants 2–11 months of age and 625 mg twice a day for those aged 12–59 months) for 5 days. In the control clusters, LHWs gave one dose of oral co-trimoxazole (age 2–11 months, sulfamethoxazole 200 mg plus trimethoprim 40 mg; 12 months to 5 years of age, sulfamethoxazole 300 mg plus trimethoprim 60 mg), and referred the children to a health facility (standard of care). The primary outcome was the development of clinical treatment failure up to Day 6 with clinical relapse between Day 6 and 14.

Children were followed up by the LHW either at the child's home or the LHW health house on Days 2, 3, 6, and 14 for assessment and recording of clinical outcomes, medicine compliance, change of medicines, visits to health providers, hospitalization, etc. Data collection assistants (DCA) trained in pneumonia case management and study procedures independently verified each case of severe pneumonia within 48 hours of enrollment by LHWs. In addition, DCAs also conducted follow-up on Days 2, 3, 6, and 14 in both arms to verify her findings.

Data collection. Data for cost of treatment of severe pneumonia episode was collected from a household perspective. For clinical data, sources of care and treatment, case report forms (CRFs) completed by the LHWs and the DCAs as part of the RCT were reviewed. Data on household demographics, income, and out-of-pocket expenses incurred by the households during the treatment of a severe pneumonia episode in the intervention and control clusters was collected through caregiver interviews. Data was collected by a team of 11 DCAs. A structured questionnaire was developed to transcribe information from the CRFs and recording information on costs. Two-day training was organized for the DCAs with field practice in two interventions and two control clusters in November 2009. Appropriate changes in the questions were made after pretesting and piloting.

The DCAs completed the questionnaire on Day 14 follow-up of the enrolled child. They transcribed the data from the case report forms completed on enrollment, and Days 2, 3, 6, and 14 follow-up visits. They interviewed the head of the household or the caregiver to verify the information in the CRFs on provider consultations, services availed (laboratory, radiology, or other tests), hospital stay, medicine prescription filled, and out-of-pocket expenses for each of the previous items. She also asked about the sources of travel to the provider/facility, travel time in minutes, cost of transportation, time spent on child care, and lost wages.

Household costs. We estimated the following costs associated with treatment of a severe pneumonia episode in children < 5 years of age in the intervention and control clusters from a household perspective (Box 2).

Direct medical costs. The actual amount paid by the households for consultation, laboratory test, radiology, and hospital admissions were obtained from the payment receipts for these services. For medicines, the retail price on the label was used for calculating direct costs. In case receipts were not available, retail market rates for previous services and medicines were applied.

Although oral amoxicillin in the intervention clusters and the first dose of cotrimoxazole in the control clusters were provided free of cost to the patients, a cost equivalent was included in calculations for determining household costs.

Direct non-medical costs. Costs incurred for transportation, meals for caregivers at the health facility, and under-the-table payments made for services at the health facility.

Indirect costs. Opportunity cost of caregiver time and foregone wages was measured at the household level. Opportunity cost was estimated as the approximate value of non-wage household activity to account for time spent on care seeking and child care based on the assumption that if the person was working, how much will be the expected earnings. For calculating time cost, lost minutes were recorded and converted into number of working days. Mean monthly income of the head of the household, for the intervention and control clusters, were converted into daily income and opportunity cost in rupees was calculated as—days lost × mean daily income of

Box 1

Definitions of pneumonia, inclusion/exclusion, and treatment failure criteria in a cluster randomzized control trial of community treatment of severe pneumonia in children 2–59 months of age in Haripur, Pakistan

Definitions

- ***Pneumonia***: Child 2-59 months old having cough and/or difficult breathing with respiratory rate of 50 breaths per minute or more.
- ***Severe pneumonia***: Lower chest in-drawing regardless of respiratory rate in children with history of cough and/or difficult breathing
- ***Very severe disease***: Presence of any of danger sign (unable to drink/breast feed, convulsions, vomits every thing, abnormally sleepy/difficult to wake) in a child with history of cough and/or difficult breathing

Inclusion Criteria

- Child aged 2 to 59 months presented to LHWs with severe pneumonia
- Residing in the study area (i.e. intervention or control clusters)

Exclusion Criteria

- Very severe disease
- Diarrhea with severe dehydration
- Severely malnourished
- Children who were part of the study in the past two weeks
- Care-taker refusal to participate in the study
- Children who are already on antibiotic treatment

Treatment Failure

Day 3

- Appearance of a danger sign (unable to drink/breast feed, convulsions, vomits every thing, abnormally sleepy/difficult to wake)
- Temperature ≥100 ºF and lower chest in-drawing
- Change of antibiotic*

Day 6

- Appearance of a danger sign (unable to drink/breast feed, convulsions, vomits every thing, abnormally sleepy/difficult to wake)
- Temperature ≥100 ºF
- Lower chest in-drawing
- Change of antibiotic*

Relapse

After child was cured at day 6, reappearance through day 7-14 of any one of the following:

- Temperature ≥100 ºF
- Lower chest in-drawing

* Self-referral and or medication (antibiotic) by caregivers

the head of the household for the intervention and control groups. Foregone earning was self-reported by the households because of absence from work to take a child to the health facility and for child care.

Data entry. Data were entered and analyzed in SPSS version 15 (SPSS, Inc., Chicago, IL). We used an exchange rate of US$ 1 equal to 85.30 Pakistani rupees (PKR).

RESULTS

Sample characteristics. A total of 423 (212 intervention, 211 control) cases of severe pneumonia were enrolled in the study. The two treatment groups were similar with regards to gender distribution of patients and educational attainment of parents of the enrolled children. The mean household monthly income was Pakistani rupees (PKR) 7,844 (median 8,400) and PKR 8,435 (median 9,000) in the intervention and control clusters, respectively. Only six women in the intervention clusters and 16 women in the control clusters reported earnings Therefore, a majority of household income share was contributed by the head of the households. Approximately 12% households in intervention clusters and 17% in control clusters earned < PKR 3,000 per month.

Source of treatment. Of the 212 severe pneumonia cases enrolled in the intervention group, 198 (93.4%) were successfully treated by LHWs with a 5-day course of oral amoxicillin. The LHWs referred 14 (6.6%) cases to the appropriate health facility for further treatment. Most referred cases sought treatment from private practitioners. No case was hospitalized.

Box 2

Variables for ascertaining direct and indirect out-of-pocket expenses incurred by the household for an episode of severe pneumonia in the intervention and control clusters

Direct Costs
A. Medical Costs
1. Consultations
2. Medicine
3. Lab tests
4. Radiology
5. Hospital admissions
6. Others (Specify)
B. Non-Medical Costs
1. Costs of Transportation
2. Costs of Food
3. Miscellaneous
Indirect Costs
A. Reported loss in earnings (Self, Caregiver)
B. Opportunity cost of time spent on care seeking and child care (Household, Caregiver)

In the control cluster, all 211 cases were referred by LHWs to a health facility after giving the first dose of cotrimoxazole. Caregivers of 131 (62%) children sought treatment from private practitioners, 53 (25%) were treated at government health facilities, and 11 (5.2%) went to other health providers; 6 (2.8%) cases were hospitalized.

Direct costs. The total direct medical cost for the intervention group was PKR 23,464 compared with PKR 86,221 for the control group (Table 1). In the intervention group, medicines constituted the major (98.3%) cost. The only other cost was the consultation fee (1.7%) for the referred patients. There were no costs for hospitalization, laboratory tests, and radiology. Although the cost of the LHW dispensed oral amoxicillin (PKR 21,792) was borne by the health system/research project, it is included in the calculation to reflect cost equivalence in absence of this support in other programs. In the control group, medicines amounted to 74.9% of the direct medical cost, followed by 13.8% for consultation, and 9.3% for hospital bed charges. The total expense for the six hospitalized patients was PKR 16,013. In the control group, households had to pay all the costs (98.2%) out of their own pocket, except the first dose of cotrimoxazole dispensed by the LHW.

Indirect costs. These costs for the households (Table 2) were estimated under two heads: 1) opportunity cost of caregiver and other household member's time; and 2) loss of wages and earnings for caregiver and other household members for care seeking and child care. The total time lost by households in intervention clusters was 8.8 days and the opportunity cost was PKR 2,276. In the intervention group, only one caregiver reported an earnings loss of PKR 250. For the control group, the total time lost by households was 32.2 days and the opportunity cost was PKR 9,005. Loss of earnings in the control group was PKR 16,313. There was an 11-fold difference (PKR 10.73. versus 120) in average indirect cost for households for the two treatment groups.

Table 2

Indirect household costs for treatment of severe pneumonia episode by treatment group

	Intervention $N = 212$	Control $N = 211$
Total time lost minutes	12,707	46,313
Total time lost in days*	8.82	32.16
Opportunity cost of time spent on care seeking and child care† (PKR)	2,276	9,005
Self reported loss of earnings/wages ‡ (PKR)	250	16,313
Total indirect costs (PKR)	2,526	25,318
Average indirect costs (PKR)	10.73	120

*Time lost in days - minutes/60/24.
Mean daily income (PKR) for head of households: control clusters – 8,413/30 = 280; intervention clusters – 7,765/30 = 258.
†Total opportunity cost of time during the severe pneumonia episode for all visits was calculated as - days lost × mean daily income for head of the holds in the treatment groups.
‡Loss of actual wages or earnings reported by the caregiver or a member of the household.

Direct and indirect household costs. Cost of transportation, meals, and other expenses incurred during the treatment of a severe pneumonia episode were considered direct non-medical costs. Because 198 (93.4%) cases in the intervention clusters were treated by LHWs, transportation cost was negligible, and the total for the 14 referred cases was only PKR 316 (Table 3). In comparison, the control group households incurred transportation costs of PKR 17,439 for seeking care for the sick children. The average cost of travel for the intervention group was PKR 1.5 compared with PKR 83 for the control group. Only one household reported PKR 20 as cost for food in the intervention clusters, whereas total cost of food in control clusters was PKR 7,415 for cases who sought care from hospital, private practitioners, and public health facilities.

In the intervention group the total household cost for the treatment of 212 severe pneumonia episodes was PKR 26,326 and the average cost was PKR 124.17. Cost of medicines constituted the highest proportion of costs (87.60%). Because

Table 1

Direct medical costs for intervention and control group by source and services*

	Consultation		Medicines		Diagnostics†		Bed charges		Total	
Source of Treatment	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
LHW	–	–	21,792	1,596	–		–	–	21,792	1,596
Hospitalization	–	210	–	6,874	–	900	–	8,029	–	16,013
Private practitioner	400	10,422	1,070	39,783		600	–	–	1,470	50,805
Public facility	2	1,200	200	12,214		150	–	–	202	13,564
Homeopath	–	1,200	–	–	–	–	–	–	–	1,200
Chemist	–	50	–	1,052	–	–	–	–	–	1,102
Others	–	9	–	1,932	–	–	–	–	–	1,941
Total (PKR)	402	11,891	23,062	64,581		1,650	–	8,029	23,464	86,221

*Numbers in the boxes are cost in Pakistani Rupees (PKR).
†Diagnostics includes laboratory tests and radiology.
Number of cases: intervention = 212; control = 211.

TABLE 3
Breakdown of direct and indirect household cost for severe pneumonia treatment of intervention and control groups

	Intervention PKR (% of total)	Control PKR (% of total)
A. DIRECT COSTS		
1. Medical		
Consultation	402 (1.53)	11,891 (8.70)
Medicines	23,062 (87.60)	64,581 (47.23)
• LHW	21,792 (82.78)	1,596 (1.17)
• Other providers	1,270 (4.82)	62,985 (46.06)
Laboratory and Radiology		1,650 (1.21)
Hospital Admission		8,020 (5.86)
Other		79 (0.058)
Sub-total medical costs	23,464 (89.12)	86,221 (63.05)
2. Non-medical		
Transportation	316 (1.28)	17,439 (12.75)
Food	20 (0.07)	7,415 (5.42)
Other	0	350 (0.26)
Sub-total non-medical costs	336 (1.28)	25,204 (18.43)
Sub-total direct cost (1 + 2)	23,800 (90.40)	111,425 (81.48)
B. INDIRECT COSTS		
Opportunity cost of time	2,276 (8.64)	9,005 (6.58)
Lost wages and earnings	250 (0.95)	16,313 (11.93)
Sub-total indirect costs	2,526 (9.59)	25,318 (18.51)
Total direct and indirect costs (A+B)	26,326	136,743
Average cost for treatment of severe pneumonia episode* (PKR)	124.17	648.07
Average cost for treatment of severe pneumonia episode in US dollars†	1.46	7.60

*Average cost: Sum of direct and indirect costs/number of cases.
†Exchange rate: 1 US $ = PKR 85.30.
Percentages are based on totals for intervention and control group.
Number of cases: intervention = 212; control = 211.

amoxicillin was provided free to the patients, only 4.82% of the total cost was borne by the households for medicines for the 14 cases that had to be referred by LHWs for further treatment. Deducting PKR 21,792 for the cost of amoxicillin provided by the LHWs from the total cost of PKR 26,326, the average household cost for treatment of one episode of severe pneumonia was PKR 21.39.

In the control group the total household cost for the treatment of 211 severe pneumonia episodes was PKR 136,743 and the average cost was PKR 648.07. Medicines constituted 47.23% of the cost followed by 18.51% for opportunity cost and lost earnings for child care and 18.43% for transportation and food expenses. Because all 211 children were referred by the LHWs for treatment, 98.83% of the cost (except the cost of the first dose of cotrimoxazole) was borne by the household. As a result, the average household cost for treatment of one episode of severe pneumonia was PKR 640.50. The average cost per episode for the six hospitalized patients was PKR 2669, which was 31.64% of the average household monthly income of the control cluster population.

DISCUSSION

To our knowledge, this is the first study to estimate the cost of severe pneumonia treatment at community level from the household perspective. Our findings show a substantial difference in household out-of-pocket expenses for treatment of a severe pneumonia episode by LHWs with oral amoxicillin versus current standard of care.

The average household cost for the community managed cases was PKR 124.17 ($1.46) compared with PKR 648.07 ($7.60) for those referred to health facilities. The difference is quite important for poor households with limited resources. The difference was caused by both direct (consultation, medicines, bed charges, and transportation) and indirect (opportunity cost and lost earnings) costs. When cost of medicines provided by the LHW program is excluded from the two treatment group estimates the average cost incurred by the households comes to PKR 21.39 ($0.25) and PKR 640.50 ($7.51) for the community managed and referred cases, respectively, a 30-fold difference. The per capita health expenditure in Pakistan in 2009[19] was $23, of which 32.8% was public expenditure. The rest was ($15.5) private out-of-pocket expenditure. This means families in the control clusters end up spending 39.9% of their annual per capita expenditure on health for treatment of single episode of severe pneumonia.

The average household cost of $1.46 for community managed cases in our study is substantially lower than the household cost of $17.61, $12.54, and $41.35 for inpatient treatment of severe pneumonia reported in the earlier studies.[13–15] The cost of $7.60 for the control group in our study was less than half of the $17.61 estimated by Hussain and others[13] for a severe pneumonia episode in Northern Pakistan. The higher expenditure reported in their study could be caused by the remoteness of the study district with a higher cost of medicines, transportation, and opportunity costs. The average cost of treatment of a severe pneumonia episode in the control group in our study may also be lower because LHWs in the community are available for prompt diagnosis and counseling of care givers to take the child to a nearby appropriate facility. This may have influenced care seeking behavior of families in the control population, thus lowering the cost of treatment.

Mehnaz and others[20] reported that 12% of children with pneumonia develop severe pneumonia in Pakistan. Applying this figure to Rudan and others[3] estimate of 10 million new pneumonia cases per year in Pakistan, ~1.2 million new cases of severe pneumonia per year would need hospital treatment, with an economic impact on the health system and the households. Hussain and others[13] estimated that in 2002, Pakistan spent $236 million for treatment of pneumonia and severe pneumonia. Our study findings show that treatment of severe pneumonia with oral amoxicillin by a first-level health facility and community health workers would reduce the overall economic burden of pneumonia treatment not only in Pakistan but in other countries with a high incidence of pneumonia. Bari and others[16] and Soofi and others[17] found that severe pneumonia patients referred to health facilities were given a variety of oral and injectable antibiotics. Treatment of severe pneumonia at peripheral health facility and community level with standard reference antibiotic, oral amoxicillin will help promote rational use of drugs as well.

Because our research was nested within the larger cluster randomized control trial, it benefited from the rigor and quality of data collection. The information on type and duration of medicine, health facility visits, etc., were collected during a follow-up visit by study personnel for the disease episode, ensuring accuracy and better estimation of direct medical and direct non medical costs. One of the study limitations may have been underestimation of head of household monthly income that was used to calculate indirect costs.

Households in Pakistan often report lower incomes as they are suspicious that this information may be passed on to the revenue department. Because the lower income reporting would be the same in intervention and control groups, we feel that the large difference in average costs found in our study was not affected by under-reporting of household income.

CONCLUSIONS

Pneumonia is one of the major killers of children < 5 years of age in developing countries, including Pakistan. Community case management for non-severe pneumonia is already recommended in the WHO and UNICEF joint statement[21] and Global Action Plan for Pneumonia Technical Consensus Statement.[22] Our study shows that extending severe pneumonia treatment to the community level will not only improve access, and better treatment outcomes,[16,17] but will decrease economic burden on the families. Extending services to the community will also decrease pressure and cost on the already overburdened public health system.

The LHWs are already providing pneumonia case management in Pakistan. Extending case management to severe pneumonia for in-service training for treating severe pneumonia with oral amoxicillin and ensuring availability of the drug will go a long way in making services available to remote and underprivileged populations, preventing thousands of child deaths and accelerating Pakistan's progress toward achieving MDG 4 goal.

Received April 14, 2012. Accepted for publication September 7, 2012.

Acknowledgments: We thank Ayaz Imran, (National Program of Family Planning and Primary Health Care [NPFPPHC], Khyber Pakhtoonkhawa, Pakistan), Farhat Yasmeen NPFPPHC, Haripur, Pakistan), Habib ur-Rehaman (District Head Quarter Hospital, Haripur), Ihsan Turabi (NPFPPHC, Khyber Pakhtoonkhawa), Inamullah Khan (NPFPPHC, Khyber Pakhtoonkhawa), Mohammad Idrees (Executive District Officer Health, Department of Health, Haripur), Ali Asghar Khan (NPFPPHC, Islamabad), Yousaf Ayub Khan (Haripur), Rasheda Parveen (Save the Children, Haripur.), and all the staff of Save the Children, Haripur office and LHWs working in district Haripur.

Financial support: The Department of Maternal Newborn Child and Adolescent Health, WHO, Geneva, Switzerland through a USAID grant and a sub-grant from University of Edinburgh, UK supported through grant 51285 by Bill & Melinda Gates Foundation.

Disclaimer: The opinions expressed are those of the authors and do not necessarily reflect the views of USAID or WHO.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 144–150
doi:10.4269/ajtmh.2012.12-0106

Insights from Community Case Management Data in Six Sub-Saharan African Countries

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Abstract. There is strong research evidence that community case management (CCM) programs can significantly reduce mortality. There is less evidence, however, on how to implement CCM effectively either from research or regular program data. We analyzed monitoring data from CCM programs supported by the International Rescue Committee (IRC), covering over 2 million treatments provided from 2004 to 2011 in six countries by 12,181 community health workers (CHWs). Our analysis yielded several findings of direct relevance to planners and managers. CCM programs seem to increase access to treatment, although diarrhea coverage remains low. In one country, the size of the catchment area was correlated with use, and increased supervision was temporally and strongly associated with improved quality. Planners should use routine data to guide CCM program planning. Programs should treat all three conditions from the outset. Other priorities should include use of diarrhea treatment and insurance of adequate supervision.

BACKGROUND

In most high-mortality countries, many families do not have adequate access to treatment of fatal childhood diseases. Community case management (CCM) is a strategy used to increase access to such treatment in countries with inadequate access to curative services by empowering community health workers (CHWs) to identify and treat children with life-threatening illnesses. Multicountry evidence reviews have shown that CHWs provided with adequate training, supervision, tools, and logistics support can identify and appropriately treat children with diarrhea, pneumonia, and malaria.[1,2] Typically, communities select CHWs, who are then trained in a simplified version of the Integrated Management of Childhood Illness (IMCI) curriculum to counsel parents, identify, and treat sick children under 5 years of age or refer them if they have danger signs. The World Health Organization (WHO), United Nations Children's Fund (UNICEF), and major donors are promoting CCM as a key strategy to meet Millennium Development Goal 4 of reducing under 5 years mortality from 1990 levels by two-thirds by 2015, and an increasing number of countries have incorporated CCM in their national strategies.[3]

However, nearly all the evidence for the impact of CCM is based on single disease models. Meta-analyses of studies conducted in the 1980s and 1990s found that management and treatment of pneumonia in the community could lead to significant reductions in pneumonia-specific and overall mortality among children under 5 years of age.[4,5] Presumptive treatment of fever with effective antimalarial drugs in the community and the home has been shown to increase the number of patients receiving treatment,[6,7] decrease malaria morbidity and parasitological indices,[6] and reduce overall and malaria-specific mortality.[8] The impact of use of oral rehydration salts/therapy in the home on child mortality and incidence of severe diarrhea has been well-documented,[9] and a community-based trial showed that zinc for diarrhea management can reduce diarrhea morbidity, antibiotic use, and overall mortality.[10,11]

There is also a large body of literature that examines operational components of programs based on CHWs, including selection and training, program supervision, health information systems, sustainability, and scalability.[12] However, much of this literature comes from Asia and Latin America and focuses on single disease management, and this information is merely descriptive. There are only a handful of studies that assess the effect of operational choices on program results in a quantitative fashion. One systematic review of intervention models involving CHWs recommended integrated multiple disease case management in sub-Saharan Africa.[13]

More specific evidence on the effect of different implementation strategies for CCM is scarce. A few studies conducted in Africa have formally investigated operational aspects of programs, in which CHWs used integrated guidelines to manage children sick with multiple illnesses at the community level.[14–16] In Siaya district, Kenya, CHWs used a modified IMCI algorithm to classify and treat malaria, pneumonia, and diarrhea/dehydration concurrently. An evaluation showed that CHWs adequately treated 90.5% of malaria cases but had difficulties in classifying and treating sick children with pneumonia and severe illness.[15] In Sudan, an evaluation of a CHW program found that CHW classification rates were consistent with facility-based IMCI evaluation studies.[14] A cluster randomized controlled trial in Zambia showed the feasibility and effectiveness of using CHWs to provide integrated management of pneumonia and malaria at the community level.[16] Except the latter, these studies were not comparative and do not provide evidence to decision-makers about which CCM operational strategies are most effective in improving access to treatment, use, quality, and mortality reduction. This gap is problematic given that implementation choices in areas such as CHW selection, training, and supervision are often the difference between success and failure.

Randomized trials would be expensive and impractical. In contrast, monitoring data, collected on a regular basis—usually monthly—in the course of program implementation, is a rich source of learning about the most effective ways to implement CCM. In this paper, we present findings and lessons learned from monitoring data collected by the International Rescue Committee (IRC) in its CCM programs.

THE IRC GLOBAL CCM PROGRAM

The IRC has been implementing CCM in sub-Saharan Africa since December of 2004. It started in Rwanda and

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progressively added programs in South Sudan, Sierra Leone, Uganda, Ethiopia, and Ivory Coast. By June of 2011, the IRC was supporting CCM in 17 underserved, rural districts in those countries, covering a population of over 3.6 million people, including close to 646,000 children under the age of 5 years who are served by a network of 12,181 CHWs referring to 304 health facilities. IRC-supported CHWs have provided over 2 million treatments.

The IRC's methodology in Rwanda, developed in collaboration with the Ministry of Health (MoH), has been scaled up nationally, and the IRC's CCM program is also being scaled up nationally in Sierra Leone in collaboration with the Ministry of Health and Sanitation, UNICEF, and other nongovernmental organizations (NGOs). Some aspects of the program methodology are similar in all countries, whereas there is variation between and within country programs for other parameters. In all six countries, communities select CHWs according to criteria set by the MoHs. It is important to note that CHWs in Ethiopia are a different cadre than Health Extension Workers. Initial training of CHWs lasts from 5 to 7 days, consists of variations of the WHO's CHW IMCI treatment manual, and focuses on management of malaria, diarrhea, and pneumonia. The training curriculum occasionally includes other skills, such as nutrition screening in Rwanda and newborn care in Uganda, depending on ministry policy. Literacy is an MoH criterion for CHW selection in Rwanda, Ethiopia, and Ivory Coast but not Sierra Leone and South Sudan. Literacy is a requirement in Uganda, except in some areas with extremely low literacy levels. A large proportion of the IRC-supported CHW network in Sierra Leone, South Sudan, and Uganda is composed of illiterate CHWs. Except in Ethiopia, supplies to CHWs are channeled through the health facilities to which CHWs refer. Replenishment of CHWs' drug stocks usually occurs one time per month and is facilitated by a supervisor that acts as a link between communities and health facilities. CHWs are supported through non-financial incentives, with the exception of Rwanda. In Rwanda, CHWs are unsalaried but receive financial support through a contract between the government and CHW cooperatives. CHWs treat fever presumptively with antimalarials with the exception of CHWs in Rwanda, where rapid diagnostic tests were introduced in 2010. CHWs in all six countries treat diarrhea with zinc and low osmolarity oral rehydration salts (ORSs) and pneumonia with amoxicillin or cotrimoxazole.

MATERIALS AND METHODS

Data collection. For all six countries, CHWs record the children visited and treatments given in patient and drug registers (patient register in Figure 1). These registers provide information on the name, age, and sex of the child, village where the child lives, classification of the condition of the child, treatment given, and whether the child was referred.

Community Based Distributor Patient Register

Community Case Management Program

Name of CBD: _____ **Month:** _____

Village: _____ **Year:** _____

PHU: _____ **CBD No:** _____

No.	Date	Patient's Name	Village	Sex		Age		Fever	Diarrhea	Cough	Pneumonia	Breaths per minute	Referred
						2-11 months	1-5 years						
1.													
2.													
3.													
4.													
5.													
6.													
7.													
8.													
9.													
10.													
11.													
12.													

FIGURE 1. CHW patient register in Sierra Leone.

The registers also contain information about each CHW's drug stock, including drugs received, used, and remaining for any given 1 month. On a monthly basis, a peer supervisor compiles all the information from the patient and drug registers used by the CHW in his/her catchment area into a CHW compiled report (data flow in Figure 2).

Peer supervisors are responsible for conducting a home visit to each CHW under their catchment area each month. During this visit, peer supervisors review the patient and drug registers to identify possible errors, check availability of supplies and storage conditions, assess how CHWs manage drugs, and assess whether CHWs can count breathing rates correctly. In addition, the supervisor and the CHW pay a visit to one of the children who recently sought care from the CHW. During this visit, the peer supervisors ask the caregiver why the child was taken to the CHW, what treatment, if any, was provided by the CHW, and how much of each treatment the caregiver actually gave to the sick child. The peer supervisor then compares the information obtained from the caregiver with what was recorded by the CHW in the patient and drug registers. At the end of the patient visit, the peer supervisor provides feedback to the CHW on any performance issues identified during the supervision and documents the findings in a supervision checklist. Information from the supervision checklist is included in the CHW compiled report.

In turn, field officers used by the IRC compile the CHWs' data in collaboration with health center and district staff, and they also collect data about peer supervision. Each IRC officer supports several health facilities and peer supervisors and is based in the field. An IRC officer or the health facility in charge will collect the totals from the CHW compiled report and the numbers of treatments for fever, diarrhea, and pneumonia in children under 5 years at the health facility and prepare a CCM health facility report. This information is then entered into a database at the district level. For the purposes of the project, private clinics are not classified as health facilities.

The database is an Excel worksheet with built in data validation and completeness checks. An IRC manager checks district data for completeness and quality before submitting it to a monitoring and evaluation officer/manager in charge of compiling all district data into a national database. The IRC coordinator in the country will check the national database for completeness and quality before submission to the IRC headquarters technical unit for inclusion into IRC's global database.

The Excel database holds updated information on population, treatments given, and stock levels. For treatments, the database also holds data from health facilities. A full list of database elements is included in Table 1. If a CHW experiences a stock out, the standard procedure involves referring the child to the health facility and documenting that referral in the patient register. A full course of treatment is never given with a referral, and therefore, no information would be recorded for a referral case in the drug register.

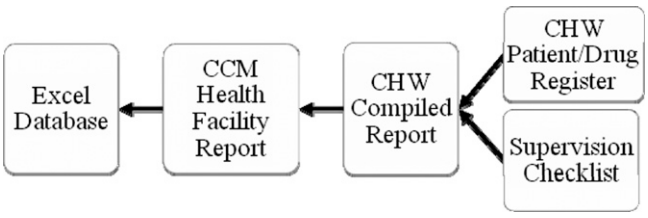


FIGURE 2. Data flow in IRC-supported CCM programs.

TABLE 1
Main data elements in the Excel database

Reference information	Community data	Health facility data
Country	Number of active CHWs	Number of malaria treatments
Year	Number of reporting CHWs	Number of diarrhea treatments
Month	Number of children visited	Number of pneumonia treatments
District	Number of malaria treatments	
Health facility	Number of diarrhea treatments	
Total population	Number of pneumonia treatments	
Under 5 years population	Number of referred children	
	Number of CHWs with antimalarials stock outs	
	Number of CHWs with ORS and zinc stock outs	
	Number of CHWs with antibiotics stock outs	
	Number of CHWs supervised	

At the time of this analysis, the database contained information from October of 2004 to June of 2011 for 2,023,984 CHW treatments in 304 health facility catchment areas in supported districts from six sub-Saharan countries.

Analysis. The analysis presented in this paper was done in Excel. Numbers were aggregated and stratified using pivot tables, and simple correlation coefficients were calculated. Table 2 lists the main outcome and stratification variables used in the analysis.

Our main outcome variable was use, which was expressed as the number of treatments per child per year. Population figures are obtained from either the district-level health office in country or the health facility, because they are aware of the population covered by their catchment area. Use can be used as a proxy for coverage by following it across time, comparing different areas, or comparing the number to an expected incidence (in which case, it is referred to as the treatment ratio).[17] This indicator assumes that, in the intervention areas where IRC is implementing CCM, all children have equal access to CHWs. In addition, use focuses on treatments and not encounters, and it is possible for a child to receive more than one treatment (e.g., if the child had malaria and diarrhea) during a single encounter. The treatment ratio can also be used as a proxy for quality, particularly for pneumonia, for which the expected incidence is reasonably consistent and backed by solid data. The treatment ratio provides an average number of treatments that each child receives per year and includes children who may have repeated episodes of a certain condition throughout the year. High or low treatment ratios can indicate poor quality, although such a determination can only be made with other contextual information. The incidence of childhood clinical pneumonia has been obtained from estimates published in 2008 in developing countries.[18] The most recent estimates of diarrhea morbidity among children under 5 years in Africa are based on reviews of five published studies conducted over 20 years ago, with limitations because of the small number of data points and the lack of representativeness.[19] However, a structured literature

TABLE 2
Main outcome and stratification variables used in the analysis

Indicator	Formula	Units	Notes
Use	12 × number of treatments for a particular disease/ (number of children < 5 years in the area × number of months covered by the data)	Treatments per child per year	A proxy for coverage compared over time among different areas or to an expected incidence. It gives an indication of the proportion of children in need receiving treatment.
Treatment ratio	Use/expected incidence	Unit or percentage	The expected incidence is an estimate, the precision of which varies by disease. For pneumonia, there is small but solid amount of literature on expected incidence rates. There is some evidence about rates for diarrhea. Malaria treatment is the most difficult to evaluate in this way, because malaria incidence varies widely across time and geography.
Treatment mix	Number of treatments for each condition/total treatments	Percentage	As with the treatment ratio, this number would be expected to vary according to local epidemiology. As with use and treatment ratio, however, in practice, major variations are associated with program issues rather than epidemiological variation.
Size of catchment area	Number of under 5 year children in the area/number of CHWs	Number of households per CHW	This information can be calculated for a program globally or individual CHWs depending on the analysis needs. The number of under 5 years of age children is estimated using a percentage fixed in national statistics of the total population.
Supervision intensity	Supervisions done each month/number of CHWs in the area	Supervisions per CHW per month	Although it is theoretically possible for one CHW to receive multiple supervisions while another CHW might receive none, this case is rarely a problem.

review of 27 studies looking into diarrhea morbidity by prospective surveillance in the work by Kosek and others[20] estimated a global median incidence of diarrhea to be 3.2 episodes per child per year in the year 2000, which is similar to those results found in previous reviews by Snyder and Merson[21] and Bern and others.[22] It is not practical to use a similar benchmark for fever treatments, because malaria incidence varies widely across time and place.

RESULTS

The analysis of these data, covering over 6 years of treatments in six very different countries, has yielded several findings. First, the data show that CHWs provide many more treatments than health facilities; Figure 3 presents the number of treatments per child per year for malaria, pneumonia, and diarrhea. The extent to which this finding is true varies across countries from Uganda, where community workers provide 11% more treatments than health facilities, to South Sudan, where community workers provide 10 times as many treatments as health facilities. There are good indications that community workers are providing new treatments rather than replacing treatments previously provided by health facilities. As Figure 4 illustrates for Sierra Leone, the increase in treatments by the introduction of CCM was far greater than any decrease in health facility treatments. The data also suggest that the CCM treatments are needed rather than excessive; Figure 3 shows that total use rates with CCM remain at or below what would be expected in areas with a high incidence of malaria, diarrhea, and pneumonia.

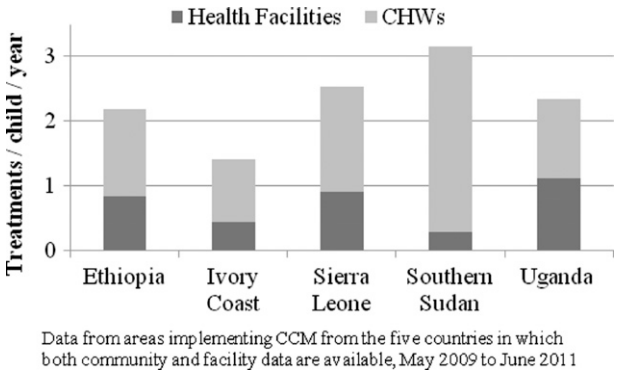


FIGURE 3. Health facility and community use rates by country.

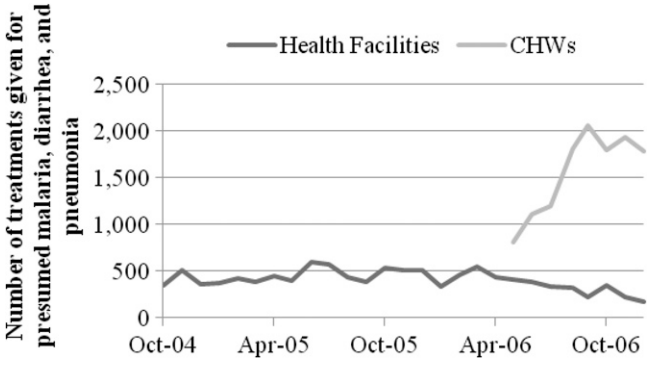


FIGURE 4. Health facility versus community treatments in Sierra Leone before and after the introduction of CCM.

The data also indicate, however, that, despite relatively high overall use rates, fewer children are receiving treatment for diarrhea than would be expected. Treatment rates for diarrhea ranged from 0.1 treatments per child per year in Rwanda to 0.8 treatments per child per year in South Sudan, whereas young children in sub-Saharan Africa would be expected to have more than three bouts of diarrhea per 1 year.[20]

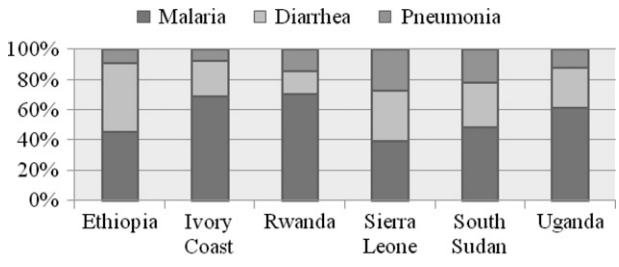
As Figure 3 indicates, use varies considerably between countries along with the balance between different treatments, which we refer to as the treatment mix (Figure 5). Sierra Leone and South Sudan started their programs treating all three conditions—fever, diarrhea, and pneumonia—at the outset, and they have continued to show a balanced treatment mix, with relatively good use of pneumonia treatment in particular. In Rwanda, the program started off providing only fever treatment. Although treatments of diarrhea and pneumonia were introduced within a couple of years after the launch in 2004, the imbalance in treatment has persisted, with treatments for fever representing more than two-thirds of the total. In Ethiopia and Ivory Coast, pneumonia treatment was initially not allowed at community level. This imbalance has persisted even after pneumonia treatment was accepted and implemented, with much lower treatment rates for pneumonia.

Another finding is that there is a strong and negative correlation between the number of children in a CHW's catchment area and use, which is shown in Figure 6. This finding is based only on data from Sierra Leone, which has the greatest variability between different CHWs in the size of the catchment area. The data show a correlation across the entire range, with CHWs who have above 50 children in their care in particular showing se rates well below what would be expected, suggesting low coverage.

Finally, using data from Sierra Leone, where supervision was reintroduced after a period of neglect, we found that a sharp increase in supervision, close to one supervision visit per CHW per month, was associated with a decreased and more regular use of pneumonia treatment. Pneumonia treatments were initially variable, with peaks at more than three times the expected incidence; they went down rapidly to almost exactly the expected incidence shortly after supervisions were reintroduced, which is shown in Figure 7. The decrease in variability and decrease to expected levels suggest a marked improvement in quality of screening.

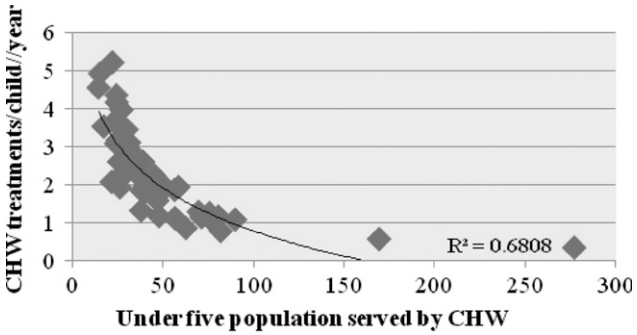
DISCUSSION

This analysis of routine data generated by a long-standing CCM program generated several findings of direct relevance for international policy advocates, national decision-makers, and field-level implementers.



Monitoring programmatic data from 8 to 64 months between February 2006 and June 2011

FIGURE 5. Treatment mix.



Data from areas implementing CCM for 2010 in 55 health facility catchment areas in Kono District in Sierra Leone

FIGURE 6. CHW use versus under 5 years population served by CHW in Sierra Leone.

These findings should be applied with an awareness of the limitations of the programmatic data. Although the IRC has focused on data quality, dedicating resources at both field and headquarters level to audit and otherwise check the validity of information, these resources cannot match the resources of research programs. Population data, in particular, are usually derived from official estimates rather than from an individual census, and they may, in some cases, be significantly inaccurate, particularly in countries with limited infrastructure. However, in South Sudan, where there were strong indications of major errors in the population figures, the IRC did count the number of households in each village using an estimated average household size to translate this count into population estimates. Another limitation of program data is that data collection methods varied from country to country according to MoH policy or simply program evolution. The data are observational and influenced by many factors outside of the IRC's control. The IRC does not collect data regarding the private sector and cannot estimate its contribution in terms of coverage. Conclusions about causation can only be made tentatively and with relevant contextual information from other sources.

The data show that community providers have higher use rates than health facilities. This finding is consistent with published research on CCM, but it is noteworthy that it seems to be confirmed in the setting of large-scale programs. The data suggest that the increased treatments are filling a treatment gap, in part at least, between the low number of

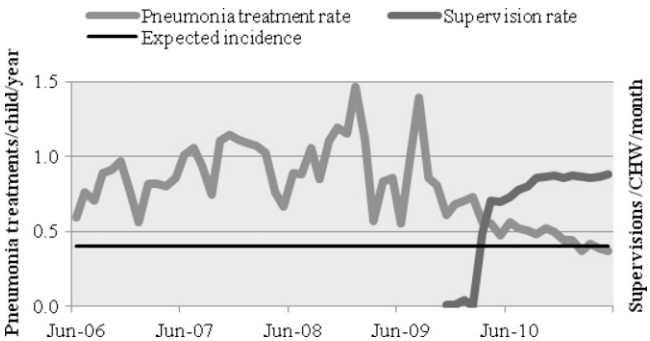


FIGURE 7. Pneumonia treatment and supervision intensity in Kono District (Sierra Leone).

treatments being provided by health facilities in these low-resource settings and the high need given the burden of these conditions. Unfortunately, treatments for diarrhea remain low, although CCM represents an improvement over facility-only use, whereas for pneumonia, they are low in some places and have been at times excessive in other settings. There are a number of possible policy and program actions that can be taken to address this issue, ranging from improving the packaging and supply of drugs to increasing education and other behavior change activities for conditions such as diarrhea, which may be perceived as routine rather than a real threat to life. There is also evidence that broader roles for CHWs, including curative treatment of malnutrition, acute respiratory infection, and diarrhea, improve use of CHW services.[23]

The data in Sierra Leone also show a strong correlation between use and the size of the catchment area the CHWs cover. It is hard to rule out, with observational data, that this correlation might be attributable to a confounding factor, such as having more CHWs put in areas with expected higher incidence of disease. A closer look at the program showed that, in general, larger villages had fewer CHWs per children under 5 years than smaller villages. However, it also suggested an alternative explanation: drugs were supplied in quantities that were fixed per CHW rather than according to the size of their catchment area. Thus, CHWs with larger catchment areas had fewer drugs available per child. This finding would suggest that the proper program or policy response would not necessarily be to increase the density of CHWs —although it may help—but rather, to ensure that drugs supplies are determined on the basis of catchment area and need. This step has been taken in Sierra Leone. In any case, this finding suggests that national and local planners must be aware of CHW catchment areas and ensure that any variability does not result in variable access to treatment. Indeed, national planners may want to try different catchment areas to determine if they affect use. Currently, the size of CHW catchment areas in many country CCM programs is based on arbitrary criteria rather than evidence about the optimal balance between proximity to treatment and program cost.

The finding that supervision is strongly and temporally associated with improved quality is consistent with other research showing that regular supervision is associated with better project outcomes[24] and more accurate classification and treatment of childhood illness by CHWs.[25] Our data suggest that one supervision per CHW per month is a necessary and feasible standard; currently, many, if not most, national CCM programs fall far short of this standard.

CONCLUSIONS

This analysis of routine CCM program data in several countries has yielded several findings with implications for policy and practice. The analysis supports, although it does not prove, that integrated CCM dramatically increases the number of children treated for fever, diarrhea, and pneumonia. These findings are consistent with research showing the benefits of CCM in reducing mortality, and they should be considered by national planners deciding whether to adopt or scale-up CCM as well as donors looking to make the most of their investment in saving lives. National as well as local planners should also analyze use rates by disease and act on their analysis given the finding in all six countries that treatment rates for diarrhea fall well short of expected incidence.

Our analysis also suggests that planners should give preference to integrating CCM programs from the outset rather than introducing treatment of each condition at a separate time. We found that countries that started programs without treatment of all three conditions suffered from persistent imbalances in the treatment mix, even after the three conditions were eventually introduced.

Our analysis showed a strong correlation between the size of CHW catchment areas and use of treatment. The reasons for this correlation may be complex, and our analysis did not yield a specific policy recommendation. At the least, however, national and local planners should follow this parameter and be aware of the possibility that the size of CHW catchment areas may significantly influence access to treatment.

Finally, our analysis strongly suggested that regular supervision—at a more intense level than most current CCM programs—significantly improves quality. Planners should track the number of supervisions given and ensure that they are of good quality, and we propose that they aim for a standard of one supervision for CHW per month.

Received February 15, 2012. Accepted for publication April 18, 2012.

Acknowledgments: The authors would like to thank the people who did most of the work collecting these data, and whose work has built up the CCM programs. These include the MoH staff at national, district, and health facility level; IRC field program staff; and, last but not least, the CHWs whose daily work most directly contributes to saving lives. The work presented in the paper was completed primarily with funds from the Canadian International Development Agency, with substantial additional support from United States Agency for International Development and the United Nations Children's Fund.

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Am. J. Trop. Med. Hyg., 87(Suppl 5), 2012, pp. 151–153
doi:10.4269/ajtmh.2012.12-0505

Integrated Community Case Management: Next Steps in Addressing the Implementation Research Agenda

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Integrated community case management (iCCM) of malaria, pneumonia, and diarrhea has been increasingly adopted as a strategy to improve the access of children to treatment of these diseases in underserved areas. iCCM offers a way forward both from the perspective of the sick child and from the perspective of rational drug use, by providing diagnostics-guided, evidence-based treatment of the sick child. Attesting to the importance of this approach, a United Nations Children's Fund/World Health Organization (UNICEF/WHO) joint statement justifying the need for iCCM and making recommendations on its implementation was released this year and republished in this special supplement.[1] However, there are many facets to this approach that need to be optimized for iCCM to have the greatest impact on morbidity and mortality of children less than five years of age. Well-designed implementation research and rigorous monitoring and evaluation of programs have been and will continue to be important sources of evidence for improvement of iCCM policies and program implementation.

A first global operations research agenda was developed at a WHO–Tropical Disease Research/UNICEF Joint Meeting for Community Case Management of Fever in June 2006,[2] and a CCM Operations Research Group (ccm.org) was created. The group further refined the agenda at a UNICEF meeting in New York in October 2008 and at a Program for Global Pediatric Research workshop on CCM for pneumonia in Vancouver in May 2010.[3] Many of the studies reported in this supplement were designed to fill in the research knowledge gaps identified by CCM.ORG and are ready to be shared with the wider CCM community. However, there remain many gaps in our understanding of the optimal approaches to the implementation, scale-up, and sustainability of iCCM programs, and new questions have arisen.

For example, there remain many questions on the effect of iCCM on community health workers, including their capacity to absorb increasing amounts and complexity of disease management tasks, their role in surveillance and reporting of routine disease burden from the community level, optimal approaches for supervision, and the best strategies for remuneration (Table 1).[4] There is also a need for more data on the impact of iCCM on child health outcomes, both reduction of morbidity and mortality, and the cost-effectiveness of this strategy. Similarly, how can adequate coverage be achieved and how can the private sector be effectively engaged in the delivery of iCCM, and conversely can iCCM bring order to and improve the quality of care in unregulated health markets?[5] Another pressing question is how the diagnosis of respiratory infections requiring antibiotic treatment can be improved. Although we need to better understand how iCCM modifies the use of antimicrobial agents in the community and the related therapeutic outcomes, we also need to monitor for adverse effects of the interventions and to assess the impact on antimicrobial resistance.

As many programs have implemented the use of rapid antigen-based diagnostic tests (RDTs) for malaria, there is a need to assess adherence of community-based health workers to the results given the problematic experiences with health workers at the primary health center level where treatment of malaria is often provided for febrile children and adults with RDT-negative test results.[6,7] What is the potential contribution of providing enhanced diagnostic and treatment approaches (especially for presumed pneumonia) through iCCM on adherence to RDT test results, rational use of drugs, and quality of care in public as well as private sectors, e.g. the Affordable Medicine Facility-malaria?[8]

As iCCM expands, there will be a role to test different algorithms in various ecological and system contexts (Table 1).[9] As the safety of treatment of severe disease with simple approaches is demonstrated, there is a need to understand how to scale these up while ensuring quality of care and outcomes. A key challenge will be to understand factors that influence adherence to therapy for malaria, pneumonia, or diarrhea. In addition, because infants in the first two months of life are especially vulnerable, regimens for community-based treatment or the utility of pre-referral therapy for serious infections need to be optimized. Part of the challenge there will be to ensure that mothers and other care providers are able to effectively recognize signs of illness, quickly seek appropriate care, and promptly accept recommended treatment and/or referral.

This special supplement of the American Journal of Tropical Medicine and Hygiene contains a number of excellent studies that fill in some of the gaps in the applied health research agenda for iCCM. The list provided in Table 1 includes a number of topics that were previously identified by CCM.ORG for which adequate evidence does not yet exist, and a number of new questions that have arisen during recent years as iCCM programs have expanded in many countries.

So, what are the next steps? We recommend that the operational and applied health research priorities for iCCM be systematically reviewed and updated using the methods developed by the Child Health and Nutrition Research Initiative.[10] This approach to research priority setting requires a well-defined context, transparent evaluation criteria, and independent input

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TABLE 1
Global iCCM implementation research agenda*

Front-line health workers
1. What is the effect on the performance of CHWs when management of one or more disease is added to their existing responsibilities?
2. Which is the effect of iCCM in improving adherence to RDT test results and rational use of drugs?
3. What are all of the roles that community-based health workers currently play apart from managing the 3 top killers, such as community-based surveillance, immunization, management of cholera, and preparing families for emergencies/outbreaks?
4. Are CHWs able to assess, classify, and treat various illnesses under integrated CCM?
5. What are the best ways to improve and sustain performance of CHWs?
6. What are the costs and performance of different training methods for (illiterate/literate) CHWs?
7. What are the best methods for evaluating the quality of services provided by CHWs?
8. What is the optimal number of CHWs to give near universal coverage to a given geographic area?
9. What are the roles of community-based volunteers (Red Cross, etc.) and how do they link to CHWs and formal health systems?
10. How do community-based volunteers fill gaps and can they take off some of the burden from CHWs?
11. What are the best ways of supervising CHWs?
12. Which factors increase recruitment and reduce attrition?
13. Which methods of remuneration/incentivization are effective and sustainable?
14. How can mobile telecommunication technology (mHealth) improve the quality of care and supervision of CHWs?

Implementation
15. What is the cost and cost-effectiveness of iCCM?
16. What are appropriate methods for cost recovery and financing?
17. How can effective coverage be achieved by CCM (equity, community effectiveness, etc.)?
18. Which is the role of community monitoring and local accountability in iCCM implementation?
19. How can the private sector become involved in delivering **iCCM and what role can iCCM play in improving the quality of care in the private and informal sectors?**
20. How acceptable are CHWs to the health system, and how can CCM requirements for drugs, supplies, supervision, etc. be met? **Which are the minimum and optimal health systems support for iCCM to be effective?**
21. What are health system effects of CCM on referral patterns to and caseload and case mix at first level health facilities?
22. What is the effect of iCCM on antibiotic resistance?
23. What is the impact of iCCM on drug use and therapeutic outcomes in the community?
24. How best can CCM be implemented in fragile or emergency settings? How it can be streamlined, accelerated, targeted, and monitored to reach emergency affected communities or improve resilience? How quickly can CHWs be trained and mobilized in an emergency?

Management of illness
25. How can available tools (RDTs, clinical signs, timers, drugs, pulse oximeters, etc.) be combined into clinical algorithms?
26. What is the algorithm performance in different epidemiologic and health system contexts?
27. Can mHealth applications play a role in improving the adherence of CHWs to clinical diagnostic and treatment algorithms?
28. What is the appropriate duration of antibiotic treatment of WHO-defined non-severe pneumonia in African settings?
29. Can CHWs treat WHO-defined severe pneumonia in the community?
30. How can age-dose regimens for different drugs be harmonized, and what are the effects on treatment of different packaging techniques?
31. What is the impact of pre-referral drugs on clinical outcomes of children with severe disease?
32. What treatment options are effective and safe in settings where referral is not possible?
33. What is the most appropriate antibiotic for treatment of pneumonia?
34. What is the most appropriate formulation of antibiotics?

Families and caregivers
35. Do family members recognize the disease and promptly seek care?
36. What are the elements that facilitate family members to use CCM services?
37. Do family members follow treatment recommendations properly?
38. How can timely referral completion be facilitated for severely ill children?
39. Can mHealth applications be used to help family members recognize disease, seek care, and adhere to treatment recommendations?
40. How does prescription of multiple medicines for multiple diseases (e.g., malaria and pneumonia) impact on adherence?
41. What key knowledge and tools can be provided by CHWs to families so they can care for themselves at home in the event of an emergency (home care) in the event that services are not accessible? How can families be best prepared for emergencies and outbreaks?

Impact
42. What is the impact of iCCM on health and survival of children?
43. Does iCCM lead to increased penetration in terms of reaching the poor? (effective coverage)
44. What is the impact of iCCM on building community and health system resilience (e.g., coping with an emergency)?

*New additions to the list of research priorities are indicated in **bold**. iCCM = integrated community case management; CHW = community health worker; RDT = rapid diagnostic test; WHO = World Health Organization.

from investors, technical experts, and other stakeholders.[11–13] Some elegant examples of the outcome of this approach have been recently published.[14,15] After a re-evaluation of research priorities for iCCM using the Child Health and Nutrition Research Initiative approach, there will be a need for donors, including international development agencies and foundations to provide funding to help address these gaps. Funding for implementation research on iCCM has been inconsistent and at times disappointing. Although it is encouraging that the interest for large-scale iCCM interventions is increasing, the iCCM community should realize there cannot be successful wide-scale iCCM implementation if it is not accompanied and supported by sound and rigorous research because many critical questions remain to be answered. Such research can and should be built into iCCM implementation. The medium- and long-term results of additional delivery science experiments will help inform program, policies, and ultimately improve the health of children living in challenging, resource-poor environments.

Received August 11, 2012. Accepted for publication August 17, 2012.

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