BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-051015
Article Type:	Original research
Date Submitted by the Author:	10-Mar-2021
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Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Tropical medicine < INFECTIOUS DISEASES, Community child health < PAEDIATRICS, PRIMARY CARE

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Long-term quality of Integrated Community Case Management care: a retrospective observational study in Bugoye Subcounty, Uganda

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Word count: 3442

Keywords: Village health workers, Integrated Community Case Management, quality of health care, Uganda

Abstract

Objectives: We examine quality of Integrated Community Case Management (iCCM) care provided by two cohorts of village health workers (VHW), as well as trends over time in quality of care as VHWs gain clinical experience but are also further from their initial iCCM training.

Setting: community-based care at a single rural site. The first cohort of VHWs began providing iCCM care in March 2013, the second cohort in July 2016.

Participants: all patients receiving iCCM care in 18,430 clinical encounters occurring between April 2014–December 2018.

Primary and secondary outcome measures: Primary outcome measures include proportion of patients receiving overall correct care and trends over time in quality of care (assessed using logistic regression models with generalized estimating equations). Secondary outcome measures include VHWs' adherence to correct diagnostic protocol, correct prescribing practices, and correct referral of patients to a health facility. Pre-planned and final measures were the same.

Results: Overall, 74% of patients received correct management. Quality of care was higher for uncomplicated malaria (93%), presumed pneumonia (90%), and diarrhea (92%). For patients with danger signs for severe illness, 77% received appropriate referral to a health facility, while only 60% received appropriate pre-referral treatment. VHWs commonly failed to refer patients with subjective fever and a negative malaria test. Inappropriate use of medications was generally low. For the first cohort of VHWs, regression modeling demonstrated a modest increase in quality of care until approximately 3 years after their initial iCCM training, followed by a modest decrease in quality of care. For the second cohort, quality of care was essentially constant over time.

Conclusions: Quality of care was high for uncomplicated malaria, presumed pneumonia, and diarrhea. Quality of care was relatively constant over time, though the trend toward decreasing quality of care after 3 years of providing iCCM care requires further monitoring.

Strengths and limitations of this study

- We use a record review approach to examine quality of care for all Integrated Community Case Management clinical encounters over a nearly 5-year period
- We assessed trends in quality of care over time using logistic regression models with generalized estimating equations (GEE) with robust standard errors to account for correlation by VHW
- A record review approach cannot assess all aspects of appropriate care, and may overestimate quality of care

- While this study assesses a large number of patient encounters, it includes a fairly small number of VHWs in a single geographic area, limiting its generalizability

INTRODUCTION

In Integrated Community Case Management (iCCM) care, village health workers (VHW) or other lay workers provide protocol-based care for priority pediatric health conditions—often malaria, pneumonia, and diarrhea—usually in a community setting rather than at a health facility. In some parts of Uganda, volunteer VHWs provide iCCM care, either in the patient's home or at the VHW's home, as part of the national Village Health Teams system[1–3]. These VHWs also retain their existing roles in health promotion efforts. In Bugoye Subcounty, Uganda, a rural, mountainous area on the western edge of the country, VHWs from the national program have provided iCCM care since 2013, with financial and operational support from a longstanding collaboration with Mbarara University of Science and Technology and the Massachusetts General Hospital.

Prior studies have employed several different approaches to assess iCCM quality of care, including direct observation of VHWs (with or without reexamination of the patient by a trained clinician), review of VHWs' clinical records, and surveys of patients' caregivers. In Uganda, prior studies using direct observation[4], record review[5], and surveys of caregivers[6] have generally demonstrated excellent quality of care. However, there are few evaluations examining changes in iCCM care quality over time. One prior study in Kenya used direct observation of VHWs and reexamination of patients, with 3 evaluations conducted over the 4-year period after VHWs' initial iCCM training. This study demonstrated improvement in some quality measures and worsening of other measures over time but did not assess for an overall trend in quality over time[7]. We previously examined trends in quality of care over the first 2 years of the iCCM program in Bugoye using a record review approach, showing improvement over the initial 6 months after iCCM care initiation and stable quality of care for the remaining 18 months[8]. Several other studies have examined quality of care provided by VHWs with differing levels of experience but have not provided results stratified by experience level[9,10]. Studies by our group and others have also examined the specific iCCM skills of performing and interpreting RDTs for malaria, finding that VHWs are able to maintain these skills over a 1–4 year period[11–13].

Since iCCM programs provide frontline care for common but potentially fatal childhood illnesses, programs must be able to monitor and ensure quality of care over time. Here we describe quality of iCCM care over a nearly 5-year period, as VHWs gain clinical experience but are also further from their initial iCCM training.

METHODS

Study design

In this retrospective, observational study, we examine overall iCCM quality of care as well as specific components of iCCM care for two cohorts of VHWs using a record review approach for all clinical encounters occurring between April 2014–December 2018. For each cohort we also examine trends in quality of care over time. For the first cohort of VHWs, we sought to assess long-term trends in quality of care, building on the prior evaluation of the first 2 years of iCCM care provided by this cohort[8]. For the second cohort of VHWs, we sought to assess quality of care over the initial 2.5 years of iCCM care provided by this cohort, using a larger dataset of all clinical encounters rather than sampled encounters to further evaluate our prior findings on quality of iCCM care after initial training.

Study setting

VHWs in Bugoye are selected by community members in their villages as part of the national Village Health Teams program and serve their communities as part-time volunteers. All VHWs are required to have achieved basic literacy, and most have completed primary school. VHWs receive 3 days of initial general training, 5 days of initial iCCM training, and half-day refresher trainings on a quarterly basis. In addition to their other responsibilities, VHWs provide iCCM care for malaria, pneumonia, and diarrhea in children between 2 months and 5 years old, including performing rapid diagnostic tests for malaria (RDT) and treating with artemisinin combination therapy (ACT), measuring respiratory rate and treating presumed pneumonia with amoxicillin, and evaluating children with diarrhea and treating with oral rehydration solution (ORS) and zinc. VHWs also refer children with other conditions or with danger signs of severe illness to a formal health facility. The first cohort (24 VHWs) began providing iCCM care in March 2013 in 5 villages; one VHW was added in 2016 to replace a VHW who had moved away. The second cohort (14 VHWs) began providing iCCM care in July 2016 in 3 additional villages. Both cohorts received the same initial training, refresher trainings, and supervision.

Data collection

During the time period assessed in this study, VHWs in Bugoye used paper records to record information from each clinical encounter. At the end of each month, program staff collected the paper records and entered information from each clinical encounter into a customized Epidata clinical database[14].

Deidentified data for all encounters from April 2014–December 2018 (reflecting all available months in the electronic clinical database) were extracted to create the research dataset used for this study. Data were then cleaned, with comparison to paper records in case of a mismatch between similar variables (e.g., report month and visit date) or other suspected inaccuracies. Infants under 2 months of age were excluded from analysis as they were likely seen for newborn wellness checks separate from iCCM care. Stata Version 15 (StataCorp, College Station, TX) was used to check for presumed duplicate entries in the database. Decision rules in Stata were used to determine whether each patient received correct care according to the iCCM protocol, within the limits of the data recorded on the paper record form.

Data analysis

The analytic methods for this study are quite similar to our prior study of iCCM care quality over the initial 2 years of this program[8]. In brief, along with overall correct management, we assessed several specific domains of quality of care, including correct diagnostic protocol (measuring respiratory rate for all patients presenting with cough or respiratory distress, performing a malaria RDT for all patients presenting with subjective fever), correct prescribing practices (both provision of correct treatment and avoidance of providing medications not indicated by the protocol), and correct referral of patients needing clinician assessment or other facility-based care. Since failure to refer a patient with subjective fever and a negative RDT was a common and likely low-consequence error [15], we also examined the overall proportion of patients receiving correct care if this error is excluded.

We also examined the proportion of VHWs providing correct care for each of the main iCCM conditions, using thresholds of 70% and 84% of encounters with correct care. These thresholds were chosen to accord with our prior findings which employed a lot quality assurance sampling approach[8].

We assessed trends in quality of care over time using logistic regression models with generalized estimating equations (GEE) with robust standard errors to account for correlation by VHW. For this analysis, we used a dichotomous outcome variable representing correct or incorrect care according to the iCCM protocol, with time since the VHW began providing iCCM care as the exposure variable. We used the quasi-likelihood under the independence criterion (QIC) to assess model fit. The VHW who was added at a later time in an initial village was excluded from this portion of analysis.

Ethics approval

Ethical approval for this study was granted by the Partners Healthcare IRB and the Research Ethics Committee at the Mbarara University of Science and Technology. Because the study involved only analysis of deidentified clinical records, individual patients' caregivers were not consented for the study.

Patient and public involvement

While patients' families were not directly involved in developing the research question or outcome measures for this study, community members play a key role in selecting the VHWs who provide care in their communities. In a separate study we have also sought to understand families' experience of and satisfaction with iCCM care to identify program strengths and areas for improvement[16]. Evaluation of iCCM quality of care has also helped tailor the content of VHW refresher trainings and other quality improvement efforts.

RESULTS

After exclusion of 48 encounters for children under 2 months old and 339 presumed duplicate entries, VHWs completed a total of 18,430 clinical encounters between April 2014–December 2018. VHWs in the first cohort accounted for 74% of these encounters (Table 1). The proportion of female patients and mean age of patients were similar between the first cohort and second cohort of VHWs. Subjective fever was the most common presenting complaint, followed by

cough/fast breathing, and then diarrhea (59%, 45%, and 28%, respectively; percentages add to >100% because some patients presented with multiple complaints). In both cohorts, VHWs recorded the presence of danger signs in 1% of clinical encounters.

Table 1: Patient demographic information and summary of all Integrated Community Case Management clinical encounters (April 2014–December 2018 for first cohort VHWs, July 2016–December 2018 for second cohort VHWs)

Measure	n (%) or mean (range)		
	First cohort VHWs	Second cohort VHWs	Overall
Total encounters*	13,650 (74%)	4,780 (26%)	18,430
Female	6,780 (50%)	2,325 (49%)	9,105 (49%)
Age in months**	28.5 (2–60)	27.0 (2–60)	28.1 (2–60)
*Presenting complaints****			
Fever	8,418 (62%)	2,394 (50%)	10,812 (59%)
Cough/fast breathing	5,890 (43%)	2,449 (51%)	8,339 (45%)
Diarrhea	3,818 (28%)	1,352 (28%)	5,170 (28%)
Other/not recorded	600 (4%)	149 (3%)	749 (4%)
Patients with danger signs	171 (1%)	58 (1%)	229 (1%)
Actions/outcomes			
Respiratory rate measured	6,377 (47%)	2,472 (52%)	8,849 (48%)
Respiratory rate elevated	5,756 (90%)	2,293 (93%)	8,049 (91%)
RDT performed	9,316 (68%)	2,715 (57%)	12,031 (65%)
RDT positive	7,060 (76%)	1,719 (63%)	8,779 (73%)
Patients treated with ACT	7,022 (51%)	1,706 (36%)	8,728 (47%)
Patients treated with amoxicillin	5,972 (44%)	2,457 (51%)	8,429 (46%)
Patients treated with ORS and zinc	3,841 (28%)	1,331 (28%)	5,172 (28%)
Patients treated with rectal artesunate	95 (1%)	38 (1%)	133 (1%)
Patients referred to health center	783 (6%)	303 (6%)	1,086 (6%)
Medication reactions	2 (0.01%)	0 (0%)	2 (0.01%)
Deaths	1 (0.01%)	1 (0.02%)	2 (0.01%)

Abbreviations: ACT, artemisinin combination therapy; ORS, oral rehydtration solution; RDT, rapid diagnostic test for malaria; VHW, village health worker

*339 presumed duplicate encounters as well as 76 encounters with no clinical information recorded are excluded from the analysis

**48 infants under 2 months of age were excluded from the analysis as they were likely seen for newborn assessments rather than iCCM care

***Percentages add to >100%, as some patients presented with multiple complaints

For patients with measured respiratory rate, 91% had a respiratory rate above age-based cutoffs. VHWs performed a total of 12,031 malaria RDTs, of which 8,879 (73%) were positive. There were 8,728 patients treated with ACT, 8,429 patients treated with amoxicillin, and 5,172 patients treated with oral rehydration salts and zinc. Higher proportions of patients treated by

VHWs in the first cohort presented with fever (62% vs. 50%), received an RDT (68% vs. 57%), and had positive RDTs (76% vs. 63%). Correspondingly, a higher proportion of patients treated by VHWs in the first cohort received ACT (51% vs. 36%). There were 133 patients (1%) treated with rectal artesunate, and 1,086 (6%) referred to the health center. There were 2 patients recorded as having adverse reactions to medications, and 2 recorded deaths (Table 1).

Regarding quality measures, 97% of patients presenting with subjective fever correctly received an RDT (98% of those treated by VHWs in the first cohort vs. 94% of those treated by VHWs in the second cohort). Of patients diagnosed with malaria by RDT, 93% received correct management (94% vs. 88%). However, of patients with a negative RDT, only 23% were appropriately referred to the health center (21% vs. 26%). Of patients presenting with cough or subjective fast breathing, 96% had their respiratory rate recorded (97% vs. 94%). Of those with an elevated respiratory rate and thus presumed pneumonia based on the iCCM algorithm, 90% received correct treatment (92% vs. 90%). Of patients with danger signs, 77% were appropriately referred to the health center (80% vs 69%), and 60% received appropriate pre-referral treatment (56% vs. 72%); see Table 2.

Table 2: Integrated Community Case Management quality of care measures

Measure	First cohort VHWs n (%)	Second cohort VHWs n (%)	Overall n (%)
RDT performed for patient presenting with fever	8,278 (98%)	2,258 (94%)	10, 536 (97%)
Malaria patients receiving correct management	6,864 (94%)	1,617 (88%)	8,841 (93%)
Patients with negative RDT receiving correct management	323 (21%)	172 (26%)	495 (23%)
Respiratory rate recorded for patient presenting with cough or subjective fast breathing	5,693 (97%)	2,305 (94%)	7,998 (96%)
Patients with elevated respiratory rate receiving correct treatment	5,625 (92%)	2,200 (86%)	7,825 (90%)
Patients with diarrhea receiving ORS and zinc	3,699 (92%)	1,281 (90%)	4,980 (92%)
Patients inappropriately treated with ACT (out of total patients)	182 (1%)	100 (2%)	282 (2%)
Inappropriate ACT prescriptions (out of total ACT prescriptions)	182 (3%)	100 (6%)	282 (3%)
Patients inappropriately treated with amoxicillin (out of total patients)	343 (3%)	256 (5%)	599 (3%)
Inappropriate amoxicillin prescriptions (out of total amoxicillin prescriptions)	343 (6%)	256 (10%)	599 (7%)
Patients inappropriately treated with ORS, zinc, or both (out of total patients)	188 (1%)	73 (2%)	261 (1%)
Inappropriate ORS or zinc prescriptions (out of total ORS and zinc prescriptions)	188 (5%)	73 (5%)	261 (5%)

Patients with danger signs appropriately referred to health center	137 (80%)	40 (69%)	177 (77%)
Patients with danger signs receiving appropriate pre-referral treatment	96 (56%)	42 (72%)	138 (60%)
Patients receiving overall correct management (all months)*	10,455 (77%)	3,244 (68%)	13,699 (74%)
Patients receiving overall correct management (July 2016 - December 2018)	5,560 (75%)	3,244 (68%)	8,804 (72%)
Patients receiving overall correct management, excluding referral of patients with negative RDT (all months)*	11,486 (84%)	3,654 (76%)	15,140 (82%)

Abbreviations: ACT, artemisinin combination therapy; ORS, oral rehydtration solution; RDT, rapid diagnostic test for malaria; VHW, village health worker

*April 2014 - December 2018 for original VHWs; July 2016 - December 2018 for expansion VHWs

Overall, 74% of patients received correct management (77% vs. 68%). When comparing only the time period in which the second cohort of VHWs was providing iCCM care, 72% of patients received correct management (75% vs 68%). Excluding the common error of failing to refer patients with a negative malaria RDT, 82% of patients received correct management (84% vs 76%).

Inappropriate use of medications was fairly low, with 2% of patients receiving ACT inappropriately, 3% of patients receiving amoxicillin inappropriately, and 1% of patients receiving ORS, zinc, or both inappropriately (Table 2). This constituted 3%, 7%, and 5% of prescriptions for those medications, respectively. These proportions were similar between the two cohorts of VHWs.

Regarding individual VHWs' performance, of the 38 VHWs, all 38 VHWs provided correct care for at least 70% of patients with malaria, and 34 VHWs provided correct care for least 84% of patients with malaria, compared with 35 and 30 VHWs (respectively) for patients with presumed pneumonia, 36 and 29 VHWs (respectively) for patients with diarrhea, and 24 and 7 VHWs (respectively) for all patients. If failure to refer patients with a negative RDT is excluded, then 35 VHWs met the 70% threshold for overall correct care, and 16 VHWs met the 84% threshold for overall correct care (Table 3).

Table 3: Village health worker-level quality of care measures

Measure	In >70% of encounters n (%)*	In >84% of encounters n (%)*
VHWs providing correct care for malaria	38 (100%)	34 (89%)
VHWs providing correct care for presumed pneumonia	35 (92%)	30 (79%)
VHWs providing correct care for diarrhea	36 (95%)	29 (76%)

VHWs providing overall correct care	24 (63%)	7 (18%)
VHWs providing overall correct care, excluding referral of patients with negative RDT	35 (92%)	16 (42%)

Abbreviations: RDT, rapid diagnostic test for malaria; VHW, village health worker

*The 70% and 84% thresholds were chosen to accord with our prior lot quality assurance sampling approach, allowing for comparison between the two studies

Graphical depiction of overall correct care over time for the first cohort of VHWs appeared to show a gradual increase until approximately March 2016 (3 years after iCCM care initiation), followed by gradual decrease (Figure 1). Modelling time as a continuous variable (months since iCCM care initiation) estimated a 0.6% decreased odds of correct care for each month (OR 0.994, 95% CI 0.988-0.999, p=0.032). The addition of a spline knot at the 3-year mark demonstrated a slight trend toward increasing correctness of care up until the 3-year mark (OR 1.022, 95% CI 1.005-1.038, p=0.009), followed by decreasing correctness of care after that point (OR 0.978, 95% CI 0.970-0.986, p<0.001), with an improvement in model fit based on the QIC values (Table 4).

Table 4: GEE logistic regression models for quality of care over time

Measure	OR	95% CI	p-value	Model QIC*
*First cohort VHWs, overall correct care***				14587
Months since iCCM services initiation	0.994	0.988–0.999	0.032	
*First cohort VHWs, overall correct care, with spline knot at 3 years after iCCM care initiation***				14524
Months since iCCM services initiation - Months 14–36	1.022	1.005–1.038	0.009	
Months since iCCM services initiation - Months 36–70	0.978	0.970–0.986	<0.001	
*First cohort VHWs, overall correct care excluding referral of patients with negative RDT***				11747
Months since iCCM services initiation	0.999	0.993–1.004	0.632	
*First cohort VHWs, overall correct care excluding referral of patients with negative RDT, with spline knot at 3 years after iCCM care initiation***				11718
Months since iCCM services initiation - Months 14–36	1.023	1.005–1.043	0.015	
Months since iCCM services initiation - Months 36–70	0.984	0.976–0.993	<0.001	
Second cohort VHWs, overall correct care				6057
Months since iCCM services initiation	1.007	0.989–1.025	0.475	
Second cohort VHWs, overall correct care, with spline knot at 6 months after iCCM care initiation				6061
Months since iCCM services initiation - Months 1–6	1.068	0.971–1.175	0.175	
Months since iCCM services initiation - Months 7–30	0.998	0.973–1.022	0.845	
Second cohort VHWs, overall correct care, with spline knot at 18 months after iCCM care initiation				6047
Months since iCCM services initiation - Months 1–18	1.027	1.004–1.050	0.023	
Months since iCCM services initiation - Months 19–30	0.963	0.926–1.000	0.053	

Second cohort VHWs, overall correct care excluding referral of patients with negative RDT				5272
Months since iCCM services initiation	1.026	1.007–1.045	0.006	

Abbreviations: CI, confidence interval; iCCM, Integrated Community Case Management; OR, odds ratio; QIC, quasi-likelihood under the independence model criterion; RDT, rapid diagnostic test for malaria; VHW, village health worker

*Quasi-likelihood under the independence model criterion. This is a modification of the Akaike information criterion (AIC) so that it can be applied to GEE regression models to assess goodness of fit of different models. A lower QIC term reflects a better-fitting regression model.

**One VHW joined the first cohort of VHWs later, and is thus excluded from this analysis

Graphical depiction of correct referral of patients with a negative RDT for the first cohort of VHWs appeared to show worse performance over time; exclusion of this error appeared to moderate the trend toward decreasing quality of care in later months (Figure 1). Repeating the model with the outcome variable as correct care excluding referral of patients with negative RDT estimated essentially constant correctness of care over time (OR 0.999, 95% CI 0.993-1.004, p=0.632). The addition of a spline knot at the 3-year mark resulted in similar findings to using the main outcome variable of overall correct care (slightly increasing correctness of care up until the 3-year mark, followed by slightly decreasing correctness of care); see Table 4 and Figure 2.

Graphical depiction of overall correct care over time for the second cohort of VHWs appeared to show a slight increase in correct care over approximately the first 6 months after iCCM program initiation, followed by a plateau and then a further increase until approximately 18 months, followed by a gradual decline (Figure 1). Modelling time as a continuous variable estimated essentially constant correctness of care over time (OR 1.007, 95% CI 0.989, 1.025, p=0.475); see Table 4. Based on the graphical appearance as well as our prior findings [8], we created two additional models, one with a spline knot at 6 months, and one with a spline knot at 18 months. The model with the spline knot at 6 months did not meaningfully change the result (months 1-6: OR 1.068, 95% CI 0.971-1.175, p=0.175; months 7-30: OR 0.998, 95% CI 0.973-1.022, p=0.845). The model with the spline knot at 18 months showed some evidence of a trend toward increasing correctness of care over the first 18 months and decreasing correctness of care over the remaining 12 months (months 1-18: OR 1.027, 95% CI 1.004-1.050, p=0.023; months 18-30: OR 0.963, 95% CI 0.926-1.000, p=0.053), with an improvement in model fit based on the QIC values (Table 4).

Similar to the first cohort, graphical depiction of correct referral of patients with a negative RDT by VHWs in the second cohort appeared to show worse performance over time; exclusion of this error resulted in a relatively linear-appearing trend toward increasing correctness of care over time, followed by a slight decline over the final 6 months (Figure 1). Repeating the model with the outcome variable as correct care excluding referral of patients with negative RDT demonstrated a trend toward increasing correctness of care over time (OR 1.026, 95% CI 1.007-1.045, p=0.006); see Table 4.

DISCUSSION

Patient demographic data and presenting complaints were broadly similar between patients treated by the two cohorts of VHWs. Overall quality of care was slightly higher for the first cohort of VHWs compared with the second cohort (77% vs 68%). Both cohorts demonstrated high quality of care for uncomplicated malaria, pneumonia, and diarrhea (>90% on all measures for the first cohort, and >85% for all measures for the second cohort). Encouragingly, overuse of medications was fairly low in both cohorts as well. To the best of our knowledge, the program never experienced stockouts of medications, so VHWs' ability to provide correct care would not have been affected by unavailability of the necessary medication.

These findings are broadly similar to our prior evaluation of quality of care in Bugoye as well as other studies in Uganda[4–6,8]. Studies on iCCM care in other countries in Sub-Saharan Africa have demonstrated greater heterogeneity. Some have documented correct care for 70–90% of encounters[9,17–19]. Others have documented lower quality of care overall[10,20] or in the control group or pre-assessment evaluation in several intervention studies[21,22].

In both cohorts, the proportion of patients with fever and negative RDT for malaria appropriately referred to the health center was quite low. Our prior evaluation identified this common error as well[8], which prompted refresher training on this topic. The persistence of this error despite refresher training might indicate that this represents an intentional decision by VHWs rather than an unintentional error; perhaps VHWs have observed that such patients often have self-limiting viral illnesses and recover without intervention. Some iCCM programs advise symptomatic management and at-home follow-up rather than referral for patients with subjective fever and a negative malaria RDT[15]. When this error is excluded, overall quality of care for all other patients was 84% and 76% in the first and second cohorts respectively.

VHWs did not perform as well for appropriate referral and pre-referral treatment of patients with danger signs. This finding is somewhat concerning as these patients are likely at highest risk of poor outcomes or even death. Very few deaths were reported, though deaths might be underreported as VHWs might not update their clinical encounter record if a child later dies during that illness episode. Additionally, deaths may have occurred in children who were never evaluated by a VHW.

The analytic results of this study for the first cohort of VHWs showed a modest increase in quality of care until approximately 3 years after their initial iCCM training, followed by a gradual decrease in quality of care. While the magnitude of change is small, the trend toward decreasing quality of care in the later years requires further monitoring. Uganda relies on an all-volunteer VHWs workforce, which could result in decreased motivation over time. Alternatively, as VHWs gain experience and are further from their initial training, they may begin to rely more on clinical judgment and follow the iCCM protocol less closely.

For the second cohort of VHWs, quality of care was essentially constant over time. This finding is in contrast to our prior study demonstrating increasing quality of care over the first 6 months in the first cohort of VHWs[8]. When referral of patients with a negative RDT was excluded, quality of care for the second cohort appeared to gradually improve over time.

This study has at least 5 limitations. First, while we conducted some data cleaning and assessed for duplicate entries as detailed above, these data were not double-entered. Given the large volume of clinical encounters, some data entry errors likely persist. However, such errors are less likely to cause systematic bias. Second, some elements of correct care are not captured on the paper registers, and thus cannot be assessed here (e.g., correct drug dosages), which may overestimate quality of care. Third, this study assesses quality of recorded care rather than quality of actual care. In some instances, this may overestimate quality of care—e.g., we cannot assess whether a VHW correctly performed and read a malaria RDT or measured respiratory rate correctly. In other cases, a VHW could provide correct care but have the encounter classified as incorrect due to incomplete record-keeping. For instance, because the words for "fever" and "malaria" are often used interchangeably in the local language, some VHWs seem to have recorded a patient as having subjective fever only if the malaria RDT was positive. For a patient with a negative RDT, this misunderstanding would make it appear that the VHW had incorrectly performed an RDT for a patient without subjective fever. Overall however, prior research suggests that record review somewhat overestimates quality of care when compared with direct observation of VHWs with reexamination by a clinician[23,24]. Fourth, because the data are deidentified and lack a reliable unique identifier variable, two or more illness episodes for the same child may be included. However, this issue is unlikely to affect the results significantly, as quality of care for different episodes of illness for a given individual are not necessarily correlated (beyond the addressed correlation of receiving care from the same VHW). Fifth, while this study assesses a large number of patient encounters, it includes a fairly small number of VHWs in a single geographic area, limiting its generalizability.

CONCLUSION

Overall, this study suggests that VHWs continue to provide high quality of care for uncomplicated malaria, pneumonia, and diarrhea nearly 5 years after initial training, with lower quality of care for patients with danger signs. Further qualitative evaluation may help elucidate why VHWs persistently fail to refer patients with subjective fever and a negative malaria RDT. To the best of our knowledge, this is the first study to track overall quality of care over an extended timeframe. The modest trend toward decreasing quality of care after 3 years of providing iCCM care in the first cohort of VHWs requires further monitoring.

List of abbreviations

ACT: artemisinin combination therapy; GEE: generalized estimating equations; iCCM: Integrated Community Case Management; ORS: oral rehydration solution; QIC: quasi-likelihood under the independence criterion; RDT: rapid diagnostic test for malaria; VHW: village health worker

Acknowledgments:

We are grateful to Sarah Masika, Rapheal Mbusa, Stephen Baguma, Sara Mian-McCarthy, and Emily Cable for their work in administering and supporting the village health worker program in

Bugoye. We are grateful to all the village health workers for volunteering to provide critical services to their communities.

Competing interests: The authors declare that they have no competing interests

Funding: This work was supported by the Mooney-Reed Charitable Foundation (Award/Grant number is not applicable) and the Massachusetts General Hospital Department of Medicine (Award/Grant number is not applicable).

Ethical review: Ethical approval for this study was granted by the Partners Healthcare IRB (2016P001423) and the Research Ethics Committee at the Mbarara University of Science and Technology (14/06-16). Because the study involved only analysis of deidentified clinical records, individual patients' caregivers were not consented for the study.

Authors' contributions: JSM, EMM, JK, RR, and GSS conceived and designed the study. ACW and EMM led data collection, with contributions from NM, JM, MM, MN, DAG, PRP, SB, and JSM. JSM led data analysis, with contributions from ACW and EMM. JSM and EMM drafted initial versions of the manuscript. All authors contributed to manuscript writing and approved the final manuscript.

Data sharing statement: Data are available for non-commercial use from the corresponding author (jsmiller@post.harvard.edu) upon reasonable request.

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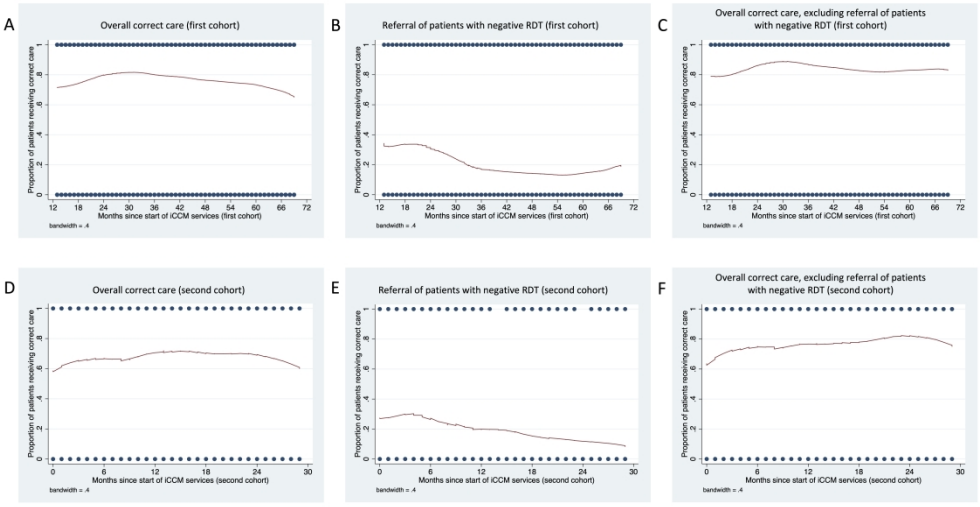
Figure 1: Lowess smoothing plots for correct management over time. Plots A–C correspond to the first cohort of VHWs. Plot A shows overall correct care over time. Plot B shows correct referral of patients with a negative malaria RDT over time. Plot C shows overall correct care over time, excluding the error of failing to refer patients with a negative malaria RDT. Plots D–F depict the second cohort of VHWs. Plot D shows overall correct care over time. Plot E correct

referral of patients with a negative malaria RDT over time. Plot F shows overall correct care over time, excluding the error of failing to refer patients with a negative malaria RDT.

Figure 2: Post-estimation margins plots for GEE logistic regression models with spline knots. Plots A and B depict the first cohort of VHWs. Plot A shows overall correct care over time, with a spline knot 3 years after iCCM care initiation for this group. Plot B shows overall correct care over time, excluding the error of failing to refer patients with a negative malaria RDT, again with a spline knot at 3 years. Plots C and D depict the second cohort of VHWs. Plot C shows overall correct care over time, with a spline knot 6 months after iCCM care initiation for this group. Plot D again shows overall correct care over time, but with a spline knot at 18 months.



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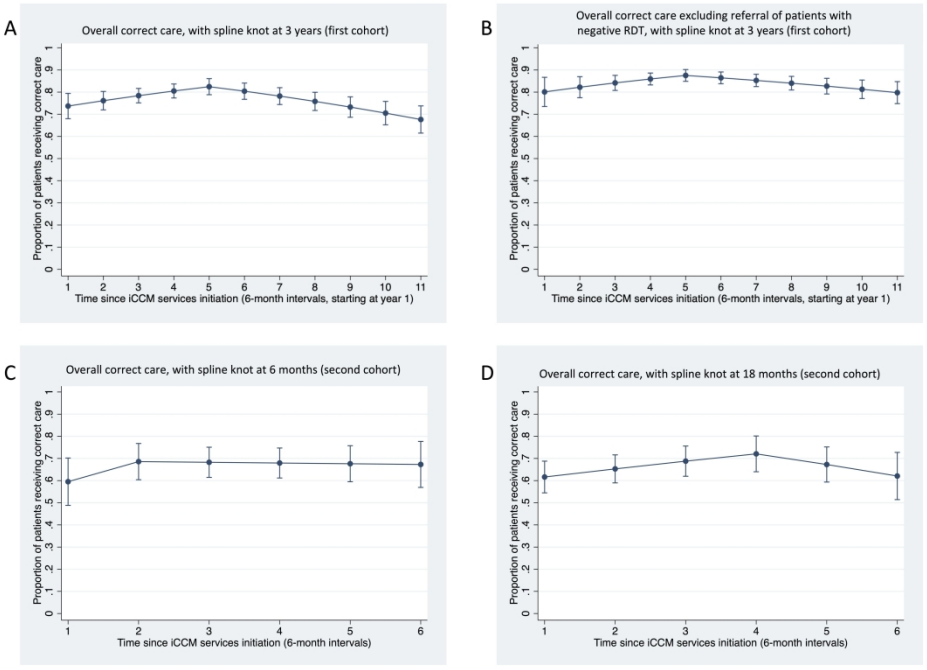

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STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	n/a
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	n/a
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	5
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	6
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	6
Outcome data	15*	Report numbers of outcome events or summary measures over time	6-7

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	9-10
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-10
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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Long-term quality of Integrated Community Case Management care for children in Bugoye Subcounty, Uganda: a retrospective observational study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-051015.R1
Article Type:	Original research
Date Submitted by the Author:	17-Nov-2021
Complete List of Authors:	Miller, James S.; Massachusetts General Hospital; Harvard Medical School Mulogo, Edgar; Mbarara University of Science and Technology Faculty of Medicine, Community health; Bugoye Community Health Collaboration Wesuta, Andrew ; Bugoye Community Health Collaboration ; Global Health Collaborative—MUST Uganda Mumbere, Nobert; Bugoye Community Health Collaboration ; Global Health Collaborative—MUST Uganda Mbaju, Jackson; Bugoye Community Health Collaboration ; Global Health Collaborative—MUST Uganda Matte, Michael; Bugoye Community Health Collaboration ; Global Health Collaborative—MUST Uganda Ntaro, Moses; Mbarara University of Science and Technology Faculty of Medicine, Community health; Bugoye Community Health Collaboration Guiles, Daniel; Indiana University School of Medicine Patel, Palka; Indiana University School of Medicine Bwambale, Shem; Bugoye Health Center; Bugoye Community Health Collaboration Kenney, Jessica; Massachusetts General Hospital; Bugoye Community Health Collaboration Reyes, Raquel ; University of North Carolina at Chapel Hill, 5039 Old Clinic Building, CB 7110, Chapel Hill, 27599, USA., Division of General Medicine & Clinical Epidemiology Stone, Geren; Massachusetts General Hospital; Harvard Medical School
Primary Subject Heading:	Global health
Secondary Subject Heading:	Health services research, Infectious diseases
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Tropical medicine < INFECTIOUS DISEASES, Community child health < PAEDIATRICS, PRIMARY CARE, Paediatric infectious disease & immunisation < PAEDIATRICS

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Long-term quality of Integrated Community Case Management care for children in Bugoye Subcounty, Uganda: a retrospective observational study

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Word count: 4362

Keywords: Village health workers, Integrated Community Case Management, quality of health care, Uganda

Abstract

Objectives: Integrated community case management (iCCM) of childhood illness in Uganda involves protocol-based care of malaria, pneumonia, and diarrhea for children under 5 years old. This study assessed volunteer village health workers' (VHW) ability to provide correct iCCM care according to the national protocol and change in their performance over time since initial training.

Setting: VHWs affiliated with the Ugandan national program provide community-based care in 8 villages in Bugoye Subcounty, a rural area in Kasese District. The first cohort of VHWs began providing iCCM care in March 2013, the second cohort in July 2016.

Participants: All children receiving iCCM care in 18,430 clinical encounters occurring between April 2014–December 2018.

Primary and secondary outcome measures: The descriptive primary outcome measure was the proportion of patients receiving overall correct care, defined as adherence to the iCCM protocol for the presenting condition (hereafter quality of care). The analytic primary outcome was change in the odds of receiving correct care over time, assessed using logistic regression models with generalized estimating equations. Secondary outcome measures included a set of binary measures of adherence to specific elements of the iCCM protocol. Pre-planned and final measures were the same.

Results: Overall, VHWs provided correct care in 74% of clinical encounters. For the first cohort of VHWs, regression modeling demonstrated a modest increase in quality of care until approximately 3 years after their initial iCCM training (OR 1.022 per month elapsed, 95% CI 1.005–1.038), followed by a modest decrease thereafter (OR 0.978 per month, 95% CI 0.970–0.986). For the second cohort, quality of care was essentially constant over time (OR 1.007 per month, 95% CI 0.989–1.025).

Conclusions: Quality of care was relatively constant over time, though the trend toward decreasing quality of care after 3 years of providing iCCM care requires further monitoring.

Strengths and limitations of this study

- We used a record review approach to examine quality of care for all Integrated Community Case Management clinical encounters over a nearly 5-year period
- A retrospective record review approach cannot assess all aspects of appropriate care, and may overestimate quality of care
- While this study assessed a large number of patient encounters, it included a fairly small number of VHWs in a single geographic area, limiting its generalizability

INTRODUCTION

In integrated community case management (iCCM) of childhood illness, village health workers (VHW) or other lay workers provide care for pediatric malaria, pneumonia, and diarrhea, usually in a community setting rather than at a health facility[1]. VHWs follow a defined protocol that directs specific diagnostic and therapeutic steps based on the patient's presenting complaint and clinical exam findings. In some parts of Uganda, volunteer VHWs provide iCCM care, either in the patient's home or at the VHW's home, as part of the national Village Health Teams system[2–4]. These VHWs also retain their existing roles in health promotion efforts. In Bugoye Subcounty, Uganda, a rural, mountainous area in Kasese District (on the western border of Uganda), VHWs from the national program have provided iCCM care since 2013, with financial and operational support from a longstanding collaboration with Mbarara University of Science and Technology (Mbarara, Uganda) and the Massachusetts General Hospital (Boston, Massachusetts, USA).

Prior studies have employed several different approaches to assess iCCM quality of care, including direct observation of VHWs (with or without reexamination of the patient by a trained clinician), review of VHWs' clinical records, case scenarios, and surveys of patients' caregivers. Each approach comes with certain risks of bias and with different ability to measure the varied aspects of quality of care. Direct observation of VHWs with reexamination of patients allows for the most comprehensive assessment of quality of care, though the presence of an observer may alter VHWs' clinical practice (Hawthorne effect). A record review approach cannot assess all elements of quality of care and measures quality of recorded care rather than quality of actual care. However, record review has the benefit of easier repeated or widespread implementation. Prior studies comparing different methods of assessing quality of iCCM care, with direct observation of VHWs and reexamination of patients as the gold standard, have found that record review, case scenarios, and direct observation alone all tend to overestimate quality of care somewhat[5,6]. While acknowledging that limitation, in this study we employ a record review approach because it feasibly allows for continuous assessment of quality of care over years.

In Uganda, prior studies using direct observation[7], record review[8], and surveys of caregivers[9] have generally demonstrated high quality of iCCM care, within the limits of each approach. However, there are few evaluations examining changes in iCCM care quality over time. One prior study in Kenya used direct observation of VHWs and reexamination of patients, with 3 evaluations conducted over the 4-year period after VHWs' initial iCCM training. This study demonstrated improvement in some quality measures and worsening of other measures over time but did not assess for an overall trend in quality over time[10]. We previously examined trends in quality of care over the first 2 years of the iCCM program in Bugoye using a record review approach, showing improvement in the proportions of patients receiving correct care (quality of care) over the initial 6 months after iCCM care initiation and stable quality of care for the remaining 18 months[11]. Several other studies have examined quality of care provided by VHWs with differing levels of experience but have not provided results stratified by experience level[12,13]. Prior studies in Bugoye and other settings have also examined the

specific iCCM skills of performing and interpreting rapid diagnostic tests (RDT) for malaria, finding that VHWs are able to maintain these skills over a 1–4 year period[14–16].

Since iCCM programs provide frontline care for common but potentially fatal childhood illnesses, programs must be able to monitor and ensure quality of care over time. Here we describe quality of iCCM care over a nearly 5-year period, as VHWs gain clinical experience but are also further from their initial iCCM training.

METHODS

Study design

In this retrospective, observational study, we examined overall iCCM quality of care as well as specific components of iCCM care for two cohorts of VHWs using a record review approach for all clinical encounters occurring between April 2014–December 2018. For each cohort we also examined trends in quality of care over time. For the first cohort of VHWs, we sought to assess long-term trends in quality of care, building on the prior evaluation of the first 2 years of iCCM care provided by this cohort[11]. For the second cohort of VHWs, we sought to assess quality of care over the initial 2.5 years of iCCM care provided by this cohort, using a larger dataset of all clinical encounters rather than sampled encounters to further evaluate our prior findings on quality of iCCM care after initial training.

The descriptive primary outcome measure was the proportion of patients receiving overall correct care, defined as adherence to all elements of the iCCM protocol for the presenting condition (further description of the iCCM protocol is provided below). We have termed this outcome measure quality of care, acknowledging that a retrospective record review approach cannot assess all domains of quality of care. The analytic primary outcome measure examined trends over time in quality of care, again using a binary classification of overall correct or incorrect care. Secondary outcome measures also used a binary correct or incorrect classification, and included VHWs' adherence to correct diagnostic protocol, correct prescribing practices, and correct referral of patients to a health facility. Pre-planned and final measures were the same.

Study setting

VHWs in Bugoye are selected by community members in their villages as part of the national Village Health Teams program and serve their communities as part-time volunteers. All VHWs are required to have achieved basic literacy, and most have completed primary school. All VHWs received 3 days of initial general training, 5 days of initial iCCM training, and half-day refresher trainings on a quarterly basis throughout the time period examined here. Clinical staff members at the government-funded health center in Bugoye are trained as iCCM instructors and lead the quarterly training sessions as well as providing field-based individual supervision. In addition to their other responsibilities, VHWs provide iCCM care for malaria, pneumonia, and diarrhea in children between 2 months and 5 years old. In keeping with World Health Organization/UNICEF standards, VHWs perform rapid diagnostic tests for malaria (RDT) and

provide artemisinin combination therapy (ACT) if indicated, measure respiratory rate and treat presumed pneumonia with amoxicillin, and evaluate children with diarrhea and treat with oral rehydration solution (ORS) and zinc, as well as assessing children for signs of severe illness (danger signs) and providing health education[1]. VHWs refer children with other conditions or with danger signs to a health facility. The first cohort (24 VHWs) began providing iCCM care in March 2013 in 5 villages; one VHW was added in 2016 to replace a VHW who had moved away. The second cohort (14 VHWs) began providing iCCM care in July 2016 in 3 additional villages. Both cohorts received the same initial training, refresher trainings, and supervision. In this program, Mbarara University of Science and Technology and Massachusetts General Hospital fund program administration and the purchase medications and malaria rapid diagnostic tests as well as providing staff support to enhance data collection and quality improvement efforts. During the time period examined here, iCCM care had not yet been implemented throughout the national Village Health Teams program.

Data collection

During the time period assessed in this study, VHWs in Bugoye used paper records to record information from each clinical encounter. At the end of each month, program staff collected the paper records and entered information from each clinical encounter into a customized Epidata form[17] (implemented separately from national reporting systems) and stored in a Research Electronic Data Capture (REDCap) database[18]. The paper record forms contain basic information about the patient (age, sex, presenting complaints), clinical assessment data (presence of danger signs, respiratory rate, and malaria rapid diagnostic test result), and actions taken (medications administered and/or referral to the health facility).

Deidentified data for all encounters from April 2014–December 2018 (reflecting all available months in the electronic clinical database) were extracted to create the research dataset used for this study. Data were then cleaned, with comparison to paper records in case of a mismatch between similar variables (e.g., report month and visit date) or other suspected inaccuracies. Infants under 2 months of age were excluded from analysis as they were likely seen for newborn wellness checks separate from iCCM care. Stata Version 15 (StataCorp, College Station, TX) was used to check for presumed duplicate entries in the database. Decision rules in Stata were used to determine whether the care each patient received (based on the paper record form) matched with correct care according to the iCCM protocol. For patients presenting with fever, elements of correct care include performing a rapid diagnostic test for malaria and recording the result, treatment with artemisinin combination therapy if the test is positive, and referral to a health facility if the test is negative. For patients presenting with cough/fast breathing, elements of correct care include measuring and recording the respiratory rate and treatment with oral amoxicillin if the respiratory rate is above age-based cutoffs (based on patients' recorded age and respiratory rate we could assess whether the VHW made this determination appropriately). For patients presenting with diarrhea, correct care constituted treatment with oral rehydration solution (ORS) and zinc. For patients recorded as having danger signs, we assessed whether the patient was referred to a health facility and received appropriate pre-referral treatment (if indicated). Certain elements of correct care (e.g.,

medication dosage, specific elements of health education provided) could not be assessed because they are not included on the paper record form.

Data analysis

The analytic methods for this study are quite similar to our prior study of iCCM care quality over the initial 2 years of this program[11]. In addition to the measures above, we also examined the proportion of VHWs providing high-quality care for each of the main iCCM conditions, using thresholds of 70% and 84% of encounters with correct care. These thresholds were chosen to accord with our prior findings which employed a lot quality assurance sampling approach[11]. Since failure to refer a patient with subjective fever and a negative RDT was a common and likely low-consequence error[19], we also examined the overall proportion of patients receiving correct care if this error is excluded.

We assessed population average trends in quality of care over time using logistic regression models with generalized estimating equations (GEE) with robust standard errors to account for correlation by VHW (and potential clustering resulting from inclusion of multiple visits for the same child). For this analysis, we used a binary outcome variable representing correct or incorrect care according to the iCCM protocol, with time in months since the VHW began providing iCCM care as the exposure variable, to examine changes in the odds of receiving correct care over time. After graphical depiction of the data, we fit models with and without splines for each cohort of VHWs. We used the quasi-likelihood under the independence criterion (QIC) to compare model fit between the models with and without splines. The VHW who joined the program later in a village from the first cohort was excluded from this portion of analysis.

Ethics approval

Ethical approval for this study was granted by the Partners Healthcare IRB and the Research Ethics Committee at the Mbarara University of Science and Technology. Because the study involved only analysis of deidentified clinical records, individual patients' caregivers were not consented for the study.

Patient and public involvement

While patients' families were not directly involved in developing the research question or outcome measures for this study, community members play a key role in selecting the VHWs who provide care in their communities. In a separate study we have also sought to understand families' experience of and satisfaction with iCCM care to identify program strengths and areas for improvement[20]. Evaluation of iCCM quality of care has also helped tailor the content of VHW refresher trainings and other quality improvement efforts.

RESULTS

After exclusion of 48 encounters for children under 2 months old and 339 presumed duplicate entries, VHWs completed a total of 18,430 clinical encounters between April 2014–December 2018. VHWs in the first cohort accounted for 74% of these encounters (Table 1). Because the data are deidentified and do not contain a unique identifier variable like a medical record

number, it was not possible to determine how many unique children received care from a VHW during this period. For brevity, hereafter we refer to "patients" rather than clinical encounters. The proportion of female patients and mean age of patients were similar between the first cohort and second cohort of VHWs. Subjective fever was the most common presenting complaint, followed by cough/fast breathing, and then diarrhea (59%, 45%, and 28%, respectively; percentages add to >100% because some patients presented with multiple complaints). In both cohorts, 1% of patients were noted to have danger signs.

Table 1: Patient demographic information and summary of all Integrated Community Case Management clinical encounters (April 2014–December 2018 for first cohort VHWs, July 2016–December 2018 for second cohort VHWs)

Measure	n (%) or mean (range)		
	First cohort VHWs	Second cohort VHWs	Overall
Total encounters*	13,650 (74%)	4,780 (26%)	18,430
Female	6,780 (50%)	2,325 (49%)	9,105 (49%)
Age in months**	28.5 (2–60)	27.0 (2–60)	28.1 (2–60)
*Presenting complaints****			
Fever	8,418 (62%)	2,394 (50%)	10,812 (59%)
Cough/fast breathing	5,890 (43%)	2,449 (51%)	8,339 (45%)
Diarrhea	3,818 (28%)	1,352 (28%)	5,170 (28%)
Other/not recorded	600 (4%)	149 (3%)	749 (4%)
Patients with danger signs	171 (1%)	58 (1%)	229 (1%)
Actions/outcomes			
Respiratory rate measured	6,377 (47%)	2,472 (52%)	8,849 (48%)
Respiratory rate elevated	5,756 (90%)	2,293 (93%)	8,049 (91%)
RDT performed	9,316 (68%)	2,715 (57%)	12,031 (65%)
RDT positive	7,060 (76%)	1,719 (63%)	8,779 (73%)
Patients treated with ACT	7,022 (51%)	1,706 (36%)	8,728 (47%)
Patients treated with amoxicillin	5,972 (44%)	2,457 (51%)	8,429 (46%)
Patients treated with ORS and zinc	3,841 (28%)	1,331 (28%)	5,172 (28%)
Patients treated with rectal artesunate	95 (1%)	38 (1%)	133 (1%)
Patients referred to health facility	783 (6%)	303 (6%)	1,086 (6%)
Medication reactions	2 (0.01%)	0 (0%)	2 (0.01%)
Deaths	1 (0.01%)	1 (0.02%)	2 (0.01%)

Abbreviations: ACT, artemisinin combination therapy; ORS, oral rehydration solution; RDT, rapid diagnostic test for malaria; VHW, village health worker

*339 presumed duplicate encounters as well as 76 encounters with no clinical information recorded are excluded from the analysis

**48 infants under 2 months of age were excluded from the analysis as they were likely seen for newborn assessments rather than iCCM care

***Percentages add to >100%, as some patients presented with multiple complaints

For patients with measured respiratory rate, 91% had a respiratory rate above age-based cutoffs. VHWs performed a total of 12,031 malaria RDTs, of which 8,879 (73%) were positive. There were 8,728 patients treated with ACT, 8,429 patients treated with amoxicillin, and 5,172 patients treated with oral rehydration salts and zinc. Higher proportions of patients treated by VHWs in the first cohort presented with fever (62% vs. 50%), received an RDT (68% vs. 57%), and had positive RDTs (76% vs. 63%). Correspondingly, a higher proportion of patients treated by VHWs in the first cohort received ACT (51% vs. 36%). There were 133 patients (1%) treated with rectal artesunate, and 1,086 (6%) referred to a health facility. There were 2 patients recorded as having adverse reactions to medications, and 2 recorded deaths (Table 1).

Regarding quality measures, 97% of patients presenting with subjective fever correctly received an RDT (98% of those treated by VHWs in the first cohort vs. 94% of those treated by VHWs in the second cohort). Of patients diagnosed with malaria by RDT, 93% received correct management (94% vs. 88%). However, of patients with a negative RDT, only 23% were appropriately referred to a health facility (21% vs. 26%). Of patients presenting with cough or subjective fast breathing, 96% had their respiratory rate recorded (97% vs. 94%). Of those with an elevated respiratory rate and thus presumed pneumonia based on the iCCM algorithm, 90% received correct treatment (92% vs. 90%). Of patients with danger signs, 77% were appropriately referred to a health facility (80% vs 69%), and 60% received appropriate pre-referral treatment (56% vs. 72%); see Table 2.

Table 2: Integrated Community Case Management quality of care measures

Measure	First cohort VHWs n (%)	Second cohort VHWs n (%)	Overall n (%)
RDT performed for patient presenting with fever	8,278 (98%)	2,258 (94%)	10, 536 (97%)
Malaria patients receiving correct management	6,864 (94%)	1,617 (88%)	8,841 (93%)
Patients with negative RDT receiving correct management	323 (21%)	172 (26%)	495 (23%)
Respiratory rate recorded for patient presenting with cough or subjective fast breathing	5,693 (97%)	2,305 (94%)	7,998 (96%)
Patients with elevated respiratory rate receiving correct treatment	5,625 (92%)	2,200 (86%)	7,825 (90%)
Patients with diarrhea receiving ORS and zinc	3,699 (92%)	1,281 (90%)	4,980 (92%)
Patients inappropriately treated with ACT (out of total patients)	182 (1%)	100 (2%)	282 (2%)
Inappropriate ACT prescriptions (out of total ACT prescriptions)	182 (3%)	100 (6%)	282 (3%)
Patients inappropriately treated with amoxicillin (out of total patients)	343 (3%)	256 (5%)	599 (3%)
Inappropriate amoxicillin prescriptions (out of total amoxicillin prescriptions)	343 (6%)	256 (10%)	599 (7%)

Patients inappropriately treated with ORS, zinc, or both (out of total patients)	188 (1%)	73 (2%)	261 (1%)
Inappropriate ORS or zinc prescriptions (out of total ORS and zinc prescriptions)	188 (5%)	73 (5%)	261 (5%)
Patients with danger signs appropriately referred to health facility	137 (80%)	40 (69%)	177 (77%)
Patients with danger signs receiving appropriate pre-referral treatment	96 (56%)	42 (72%)	138 (60%)
Patients receiving overall correct management (all months)*	10,455 (77%)	3,244 (68%)	13,699 (74%)
Patients receiving overall correct management (July 2016 - December 2018)	5,560 (75%)	3,244 (68%)	8,804 (72%)
Patients receiving overall correct management, excluding referral of patients with negative RDT (all months)*	11,486 (84%)	3,654 (76%)	15,140 (82%)

Abbreviations: ACT, artemisinin combination therapy; ORS, oral rehydration solution; RDT, rapid diagnostic test for malaria; VHW, village health worker

*April 2014 - December 2018 for original VHWs; July 2016 - December 2018 for expansion VHWs

Overall, 74% of patients received correct management (77% vs. 68%). When comparing only the time period in which the second cohort of VHWs was providing iCCM care, 72% of patients received correct management (75% vs 68%). Excluding the common error of failing to refer patients with a negative malaria RDT, 82% of patients received correct management (84% vs 76%).

Inappropriate use of medications was fairly low, with 2% of patients receiving ACT inappropriately, 3% of patients receiving amoxicillin inappropriately, and 1% of patients receiving ORS, zinc, or both inappropriately (Table 2). This constituted 3%, 7%, and 5% of prescriptions for those medications, respectively. These proportions were similar between the two cohorts of VHWs.

Regarding individual VHWs' performance, of the 38 VHWs, all 38 VHWs provided correct care for at least 70% of patients with malaria, and 34 VHWs provided correct care for least 84% of patients with malaria, compared with 35 and 30 VHWs (respectively) for patients with presumed pneumonia, 36 and 29 VHWs (respectively) for patients with diarrhea, and 24 and 7 VHWs (respectively) for all patients. If failure to refer patients with a negative RDT is excluded, then 35 VHWs met the 70% threshold for overall correct care, and 16 VHWs met the 84% threshold for overall correct care (Table 3).

Table 3: Village health worker-level quality of care measures

Measure	In >70% of encounters n (%)*	In >84% of encounters n (%)*
VHWs providing correct care for malaria	38 (100%)	34 (89%)
VHWs providing correct care for presumed pneumonia	35 (92%)	30 (79%)
VHWs providing correct care for diarrhea	36 (95%)	29 (76%)
VHWs providing overall correct care	24 (63%)	7 (18%)
VHWs providing overall correct care, excluding referral of patients with negative RDT	35 (92%)	16 (42%)

Abbreviations: RDT, rapid diagnostic test for malaria; VHW, village health worker

*The 70% and 84% thresholds were chosen to accord with our prior lot quality assurance sampling approach, allowing for comparison between the two studies

Graphical depiction of overall correct care over time for the first cohort of VHWs appeared to show a gradual increase until approximately March 2016 (3 years after iCCM care initiation), followed by gradual decrease (Figure 1). Modelling time as a continuous variable (months since the cohort began providing iCCM care) estimated a 0.6% decreased odds of correct care for each month (OR 0.994, 95% CI 0.988-0.999, p=0.032). Based on the graphical depiction, the addition of a spline knot at the 3-year mark demonstrated a slight trend toward increasing correctness of care up until the 3-year mark (OR 1.022, 95% CI 1.005-1.038, p=0.009), followed by decreasing correctness of care after that point (OR 0.978, 95% CI 0.970-0.986, p<0.001), with an improvement in model fit based on the QIC values (Table 4).

Table 4: GEE logistic regression models for quality of care over time

Measure	OR	95% CI	p-value	Model QIC*
*First cohort VHWs, overall correct care***				14587
Months since iCCM services initiation	0.994	0.988–0.999	0.032	
*First cohort VHWs, overall correct care, with spline knot at 3 years after iCCM care initiation***				14524
Months since iCCM services initiation - Months 14–36	1.022	1.005–1.038	0.009	
Months since iCCM services initiation - Months 36–70	0.978	0.970–0.986	<0.001	
*First cohort VHWs, overall correct care excluding referral of patients with negative RDT***				11747
Months since iCCM services initiation	0.999	0.993–1.004	0.632	
*First cohort VHWs, overall correct care excluding referral of patients with negative RDT, with spline knot at 3 years after iCCM care initiation***				11718
Months since iCCM services initiation - Months 14–36	1.023	1.005–1.043	0.015	
Months since iCCM services initiation - Months 36–70	0.984	0.976–0.993	<0.001	
Second cohort VHWs, overall correct care				6057
Months since iCCM services initiation	1.007	0.989–1.025	0.475	

Second cohort VHWs, overall correct care, with spline knot at 6 months after iCCM care initiation				6061
Months since iCCM services initiation - Months 1–6	1.068	0.971–1.175	0.175	
Months since iCCM services initiation - Months 7–30	0.998	0.973–1.022	0.845	
Second cohort VHWs, overall correct care, with spline knot at 18 months after iCCM care initiation				6047
Months since iCCM services initiation - Months 1–18	1.027	1.004–1.050	0.023	
Months since iCCM services initiation - Months 19–30	0.963	0.926–1.000	0.053	
Second cohort VHWs, overall correct care excluding referral of patients with negative RDT				5272
Months since iCCM services initiation	1.026	1.007–1.045	0.006	

Abbreviations: CI, confidence interval; iCCM, Integrated Community Case Management; OR, odds ratio; QIC, quasi-likelihood under the independence model criterion; RDT, rapid diagnostic test for malaria; VHW, village health worker

*Quasi-likelihood under the independence model criterion. This is a modification of the Akaike information criterion (AIC) so that it can be applied to GEE regression models to assess goodness of fit of different models. A lower QIC term reflects a better-fitting regression model.

**One VHW joined the first cohort of VHWs later, and is thus excluded from this analysis

Graphical depiction of correct referral of patients with a negative RDT for the first cohort of VHWs appeared to show worse performance over time; exclusion of this error appeared to moderate the trend toward decreasing quality of care in later months (Figure 1). Repeating the model with the outcome variable as overall correct care excluding referral of patients with negative RDT estimated essentially constant correctness of care over time (OR 0.999, 95% CI 0.993-1.004, p=0.632). The addition of a spline knot at the 3-year mark resulted in similar findings to using the main outcome variable of overall correct care (slightly increasing correctness of care up until the 3-year mark, followed by slightly decreasing correctness of care); see Table 4 and Figure 2.

Graphical depiction of overall correct care over time for the second cohort of VHWs appeared to show a slight increase in correct care over approximately the first 6 months after iCCM program initiation, followed by a plateau and then a further increase until approximately 18 months, followed by a gradual decline (Figure 1). Modelling time as a continuous variable (months since the cohort began providing iCCM care) estimated essentially constant correctness of care over time (OR 1.007, 95% CI 0.989, 1.025, p=0.475); see Table 4. Based on the graphical appearance as well as our prior findings [11], we created two additional models, one with a spline knot at 6 months, and one with a spline knot at 18 months. The model with the spline knot at 6 months did not meaningfully change the result (months 1-6: OR 1.068, 95% CI 0.971-1.175, p=0.175; months 7-30: OR 0.998, 95% CI 0.973-1.022, p=0.845). The model with the spline knot at 18 months showed some evidence of a trend toward increasing correctness of care over the first 18 months and decreasing correctness of care over the remaining 12 months (months 1-18: OR 1.027, 95% CI 1.004-1.050, p=0.023; months 18-30: OR 0.963, 95% CI 0.926-1.000, p=0.053), with an improvement in model fit based on the QIC values (Table 4).

Similar to the first cohort, graphical depiction of correct referral of patients with a negative RDT by VHWs in the second cohort appeared to show worse performance over time; exclusion of this error resulted in a relatively linear-appearing trend toward increasing correctness of care

over time, followed by a slight decline over the final 6 months (Figure 1). Repeating the model with the outcome variable as correct care excluding referral of patients with negative RDT demonstrated a trend toward increasing correctness of care over time (OR 1.026, 95% CI 1.007-1.045, p=0.006); see Table 4.

DISCUSSION

Patient demographic data and presenting complaints were broadly similar between patients treated by the two cohorts of VHWs. Overall quality of care was slightly higher for the first cohort of VHWs compared with the second cohort (77% vs 68%). Both cohorts demonstrated high quality of care for uncomplicated malaria, pneumonia, and diarrhea (>90% on all measures for the first cohort, and >85% for all measures for the second cohort). Encouragingly, overuse of medications was fairly low in both cohorts as well. To the best of our knowledge, the program never experienced stockouts of medications, so VHWs' ability to provide correct care would not have been affected by unavailability of the necessary medication.

These findings are broadly similar to our prior evaluation of quality of care in Bugoye as well as other studies in Uganda[7–9,11]. Studies on iCCM care in other countries in Sub-Saharan Africa have demonstrated greater heterogeneity. Some have documented correct care for 70–90% of encounters[12,21–23]. Others have documented lower quality of care overall[13,24] or in the control group or pre-assessment evaluation in several intervention studies[25,26]. Local context might explain some of the variation in quality of care. In this setting, all scheduled trainings took place (to the best of our knowledge), external funding ensured a consistent supply of diagnostic tests and medications, and monthly collection of paper record forms might have helped provide accountability. These factors might result in higher quality of care compared with settings in which iCCM is implemented more broadly.

In both cohorts, the proportion of patients with fever and negative malaria RDT appropriately referred to a health facility was quite low. Our prior evaluation also identified this as a common error[11], which prompted refresher training on this topic. The persistence of this error despite refresher training might indicate that this represents an intentional decision by VHWs rather than an unintentional error; perhaps VHWs have observed that such patients often have self-limiting viral illnesses and recover without intervention. For this error (as well as other errors), caregiver preferences or requests might also have influenced VHWs. For instance, caregivers might not wish to be referred to the health facility because of the time spent traveling to the facility and waiting to be seen. Some iCCM programs advise symptomatic management and at-home follow-up rather than referral for patients with subjective fever and a negative malaria RDT[19]. When this error was excluded, overall quality of care for all other patients was 84% and 76% in the first and second cohorts respectively. While inappropriate use of medications was fairly low, pressure from caregivers to provide a medication could also have influenced VHWs' treatment decisions.

VHWs did not perform as well for appropriate referral and pre-referral treatment of patients with danger signs. This finding is somewhat concerning as these patients are likely at highest risk of poor outcomes or death. Very few deaths were reported, though deaths might be

underreported as VHWs might not update their clinical encounter record if a child later dies during that illness episode. Additionally, deaths might have occurred in children who were never evaluated by a VHW; caregivers who recognize that a child has severe illness might proceed directly to a health facility rather than seeking care from a VHW.

We employee GEE regression models to examine trends in quality of care over time (GEE models estimate a population average effect, so these trends should be interpreted as such). For the first cohort of VHWs, quality of care appeared to increase modestly until approximately 3 years after their initial iCCM training, followed by a gradual decrease in quality of care. While the magnitude of change is small, the trend toward decreasing quality of care in the later years requires further monitoring. Uganda relies on an all-volunteer VHWs workforce, which could result in decreased motivation over time. Alternatively, as VHWs gain experience and are further from their initial training, they may begin to rely more on clinical judgment and follow the iCCM protocol less closely.

For the second cohort of VHWs, quality of care was essentially constant over time. This finding is in contrast to our prior study demonstrating increasing quality of care over the first 6 months in the first cohort of VHWs[11]. When referral of patients with a negative RDT was excluded, quality of care for the second cohort appeared to gradually improve over time.

This study has at least 5 limitations. First, while we conducted some data cleaning and assessed for duplicate entries as detailed above, these data were not double-entered. Given the large volume of clinical encounters, some data entry errors likely persist. However, such errors are less likely to cause systematic bias. Second, some elements of correct care are not captured on the paper registers, and thus cannot be assessed here (e.g., correct drug dosages), which may overestimate quality of care. More broadly, a record review approach cannot capture whether or how much health education is provided, or VHWs' ability to assess children's overall health and identify more chronic issues such as malnutrition. Third, this study assesses quality of recorded care rather than quality of actual care. In some instances, this may overestimate quality of care—e.g., we cannot assess whether a VHW correctly performed and interpreted a malaria RDT or measured respiratory rate correctly. In other cases, a VHW could provide correct care but have the encounter classified as incorrect due to incomplete record-keeping. For instance, because the words for "fever" and "malaria" are often used interchangeably in the local language, some VHWs seem to have recorded a patient as having subjective fever only if the malaria RDT was positive. For a patient with a negative RDT, this misunderstanding would make it appear that the VHW had incorrectly performed an RDT for a patient without subjective fever (when in fact the RDT was appropriately performed). Overall however, prior research suggests that record review somewhat overestimates quality of care when compared with direct observation of VHWs with reexamination by a clinician[5,6]. Fourth, because the data are deidentified and lack a reliable unique identifier variable, two or more illness episodes for the same child may be included. However, this issue is unlikely to affect the results significantly, as quality of care for different episodes of illness for a given individual are not necessarily correlated (beyond the correlation of receiving care from the same VHW). Fifth, while this study

assesses a large number of patient encounters, it includes a fairly small number of VHWs in a single geographic area, limiting its generalizability.

CONCLUSION

Overall, this study suggests that VHWs continue to provide high quality of care for uncomplicated malaria, pneumonia, and diarrhea nearly 5 years after initial training, with lower quality of care for patients with danger signs. Further qualitative evaluation may help elucidate why VHWs persistently fail to refer patients with subjective fever and a negative malaria RDT. To the best of our knowledge, this is the first study to track overall quality of care over an extended timeframe. The modest trend toward decreasing quality of care after 3 years of providing iCCM care in the first cohort of VHWs requires further monitoring.

List of abbreviations

ACT: artemisinin combination therapy; GEE: generalized estimating equations; iCCM: Integrated Community Case Management; ORS: oral rehydration solution; QIC: quasi-likelihood under the independence criterion; RDT: rapid diagnostic test; VHW: village health worker

Acknowledgments:

We are grateful to Sarah Masika, Rapheal Mbusa, Stephen Baguma, Sara Mian-McCarthy, and Emily Cable for their work in administering and supporting the village health worker program in Bugoye. We are grateful to all the village health workers for volunteering to provide critical services to their communities.

Competing interests: The authors declare that they have no competing interests

Funding: This work was supported by the Mooney-Reed Charitable Foundation (Award/Grant number is not applicable) and the Massachusetts General Hospital Department of Medicine (Award/Grant number is not applicable).

Ethical review: Ethical approval for this study was granted by the Partners Healthcare IRB (2016P001423) and the Research Ethics Committee at the Mbarara University of Science and Technology (14/06-16). Because the study involved only analysis of deidentified clinical records, individual patients' caregivers were not consented for the study.

Authors' contributions: JSM, EMM, JK, RR, and GSS conceived and designed the study. ACW and EMM led data collection, with contributions from NM, JM, MM, MN, DAG, PRP, SB, and JSM. JSM led data analysis, with contributions from ACW and EMM. JSM and EMM drafted initial versions of the manuscript. All authors contributed to manuscript writing and approved the final manuscript.

Data sharing statement: Data are available for non-commercial use from the corresponding author (jsmiller@post.harvard.edu) upon reasonable request.

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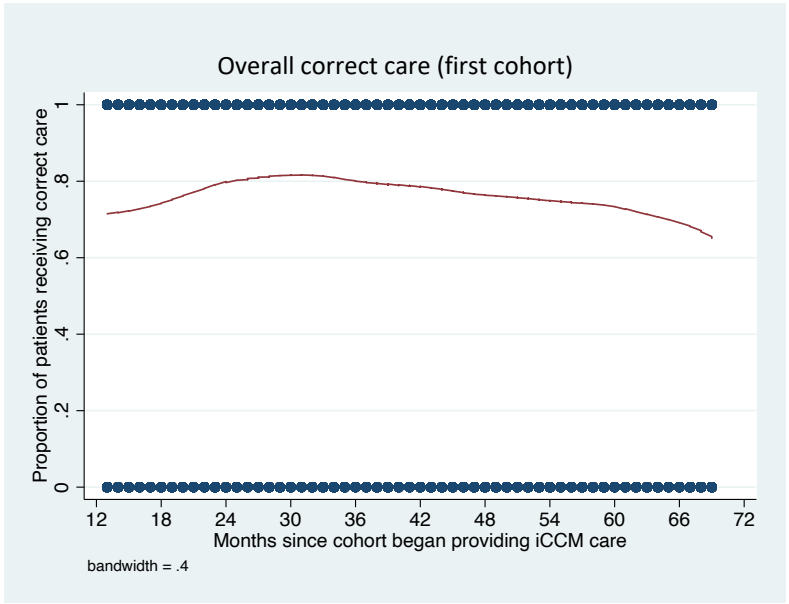
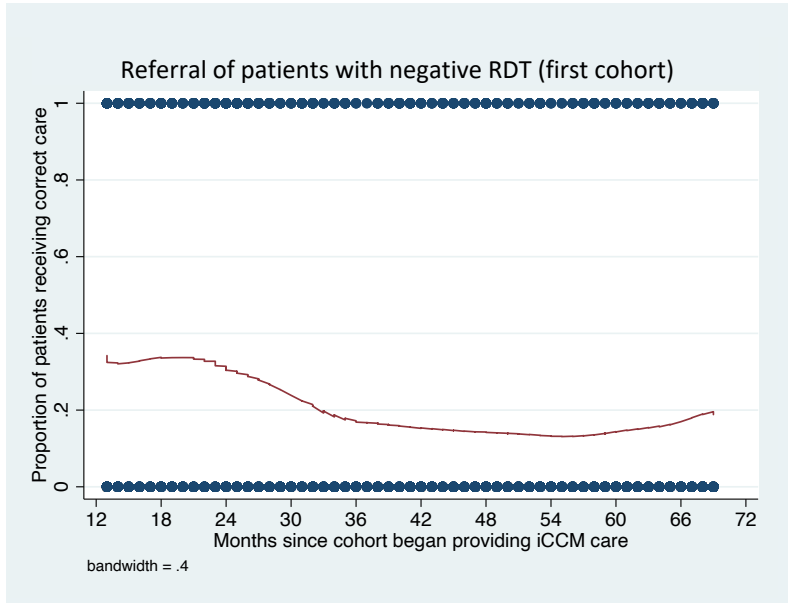
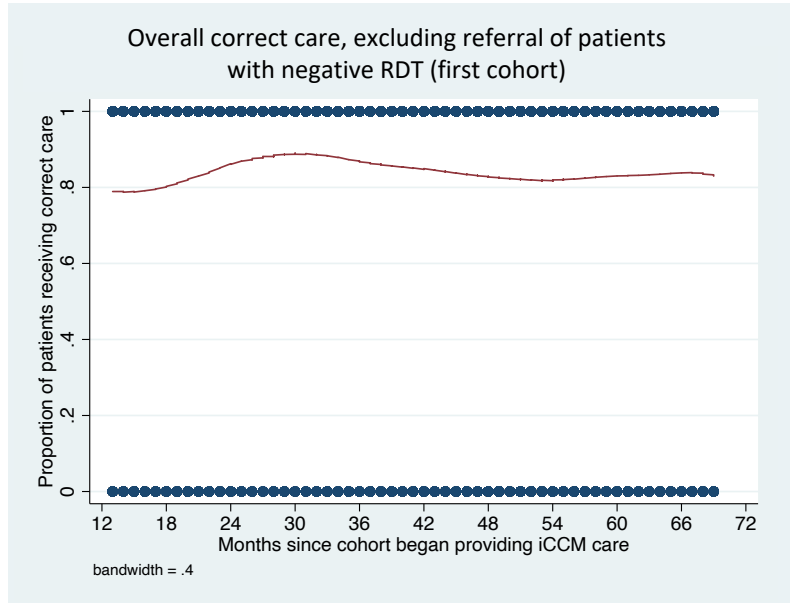
Figure 1: Lowess smoothing plots for correct management over time. Plots A–C correspond to the first cohort of VHWs. Plot A shows overall correct care over time. Plot B shows correct referral of patients with a negative malaria rapid diagnostic test (RDT) over time. Plot C shows overall correct care over time, excluding the error of failing to refer patients with a negative malaria RDT. Plots D–F depict the second cohort of VHWs. Plot D shows overall correct care over time. Plot E correct referral of patients with a negative malaria RDT over time. Plot F shows overall correct care over time, excluding the error of failing to refer patients with a negative malaria RDT.

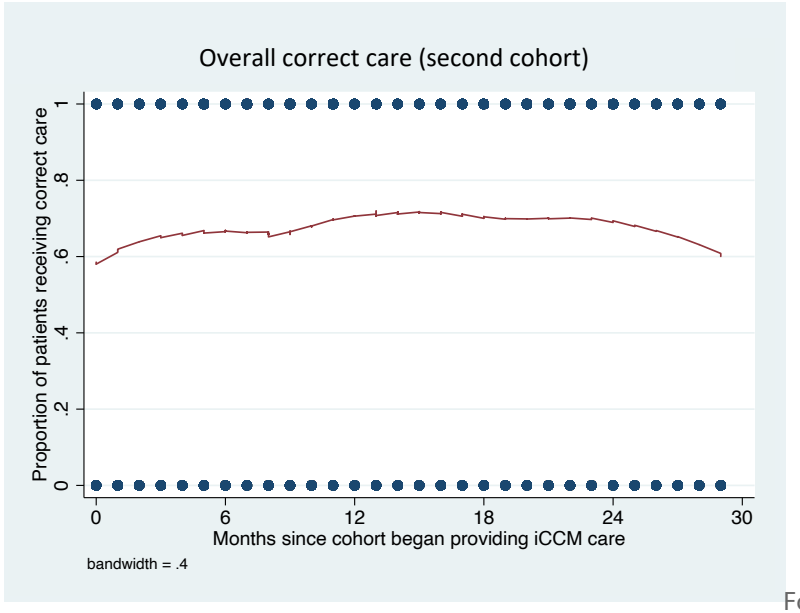
Figure 2: Post-estimation margins plots for GEE logistic regression models with spline knots, which display the predicted probability of receiving correct care at specified time points (6-month intervals). Plots A and B depict the first cohort of VHWs. Plot A shows the predicted probability of overall correct care, with a spline knot 3 years after the first cohort began providing iCCM care. Plot B shows the predicted probability of overall correct care excluding the error of failing to refer patients with a negative malaria rapid diagnostic test (RDT), again with a spline knot at 3 years. Plots C and D depict the second cohort of VHWs. Plot C shows the predicted probability of overall correct care, with a spline knot 6 months after the second

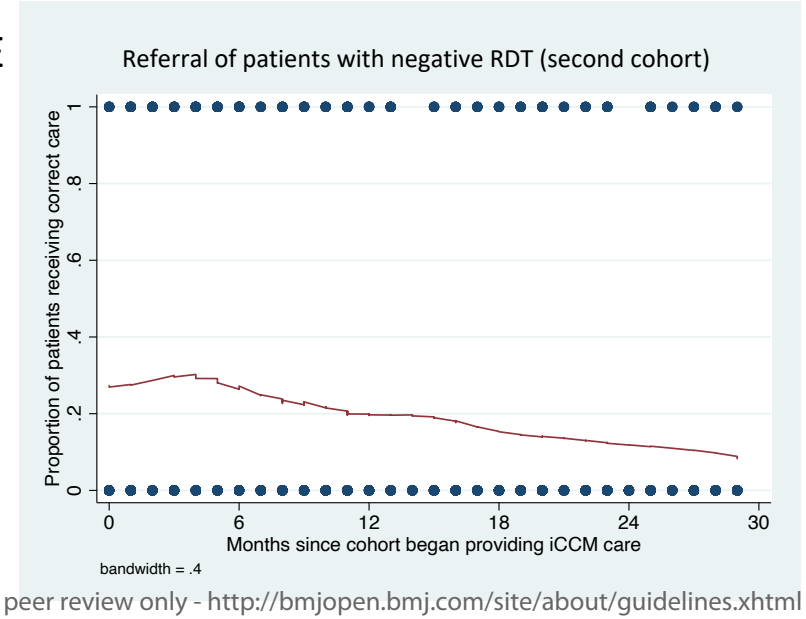
cohort began providing iCCM care. Plot D again shows the predicted probability of overall correct care, but with a spline knot at 18 months.

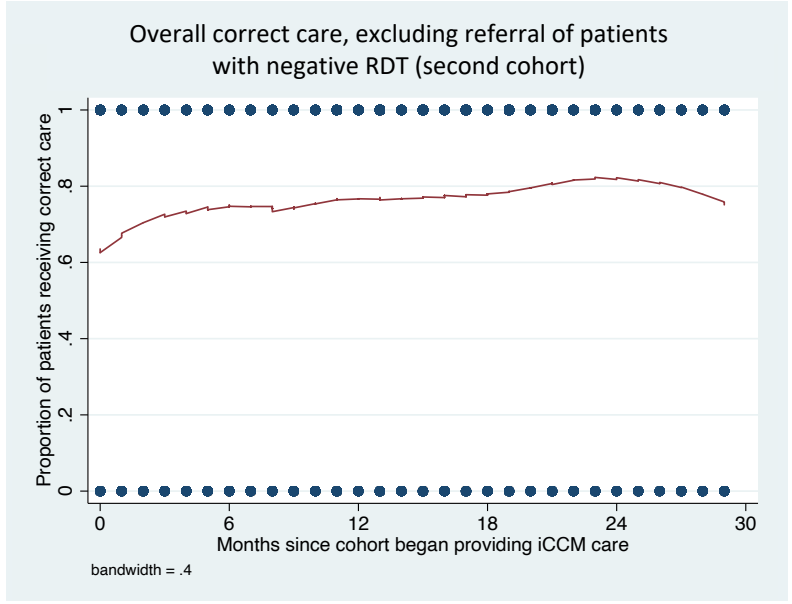












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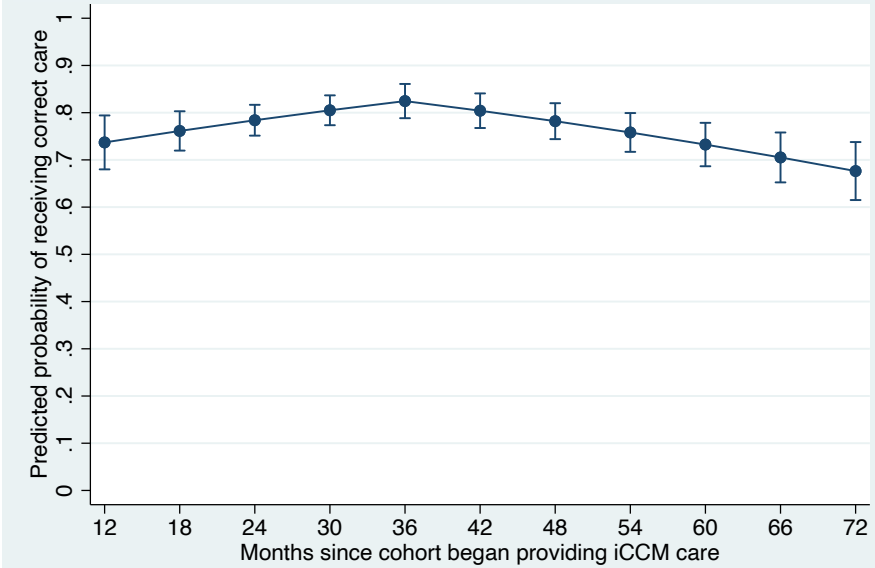

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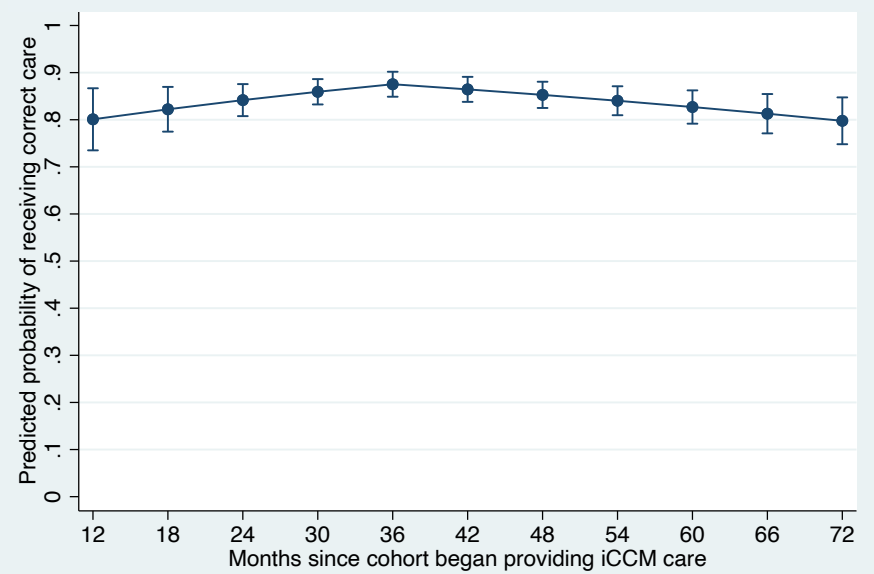

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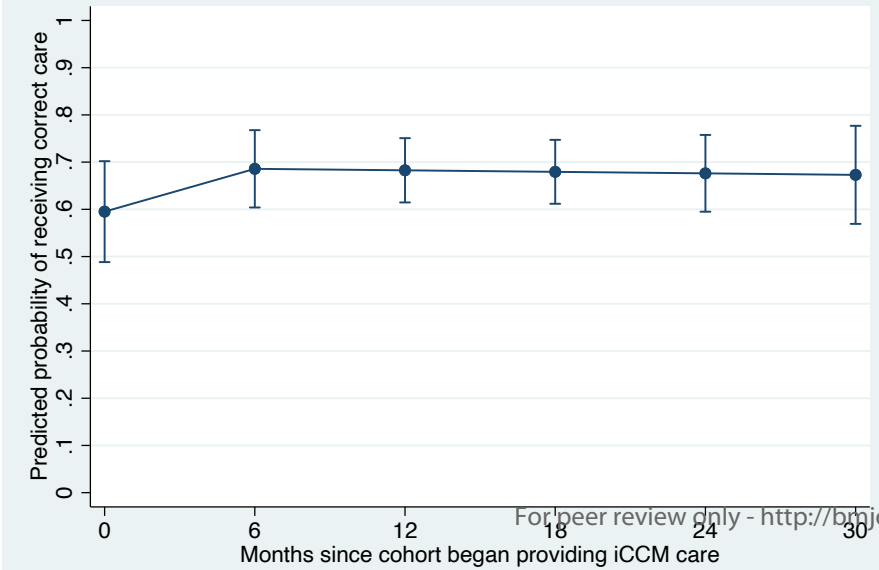

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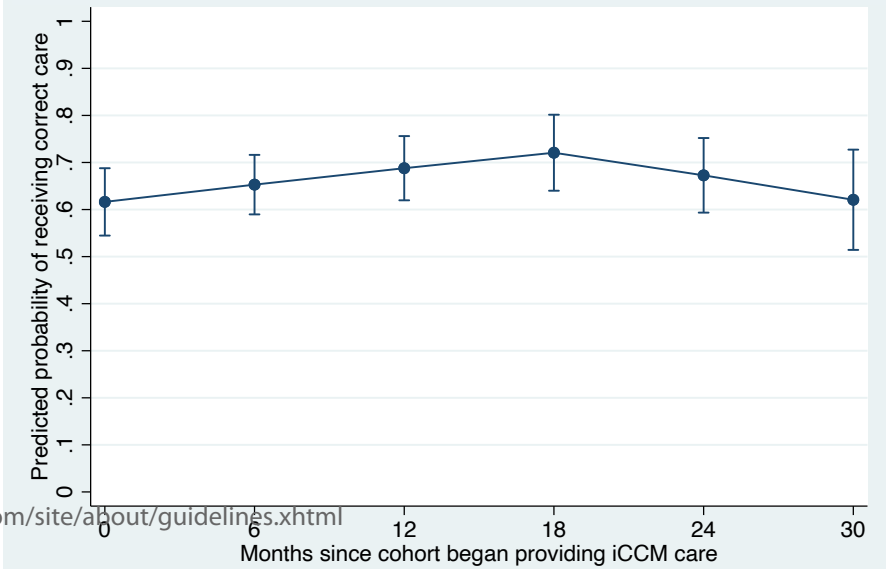

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	n/a
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	n/a
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	5
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	6
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	6
Outcome data	15*	Report numbers of outcome events or summary measures over time	6-7

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	9-10
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-10
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

BMJ Open

Long-term quality of Integrated Community Case Management care for children in Bugoye Subcounty, Uganda: a retrospective observational study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-051015.R2
Article Type:	Original research
Date Submitted by the Author:	11-Mar-2022
Complete List of Authors:	Miller, James S.; Massachusetts General Hospital; Harvard Medical School Mulogo, Edgar; Mbarara University of Science and Technology Faculty of Medicine, Community health; Bugoye Community Health Collaboration Wesuta, Andrew ; Bugoye Community Health Collaboration ; Global Health Collaborative—MUST Uganda Mumbere, Nobert; Bugoye Community Health Collaboration ; Global Health Collaborative—MUST Uganda Mbaju, Jackson; Bugoye Community Health Collaboration ; Global Health Collaborative—MUST Uganda Matte, Michael; Bugoye Community Health Collaboration ; Global Health Collaborative—MUST Uganda Ntaro, Moses; Mbarara University of Science and Technology Faculty of Medicine, Community health; Bugoye Community Health Collaboration Guiles, Daniel; Indiana University School of Medicine Patel, Palka; Indiana University School of Medicine Bwambale, Shem; Bugoye Health Center; Bugoye Community Health Collaboration Kenney, Jessica; Massachusetts General Hospital; Bugoye Community Health Collaboration Reyes, Raquel ; University of North Carolina at Chapel Hill, 5039 Old Clinic Building, CB 7110, Chapel Hill, 27599, USA., Division of General Medicine & Clinical Epidemiology Stone, Geren; Massachusetts General Hospital; Harvard Medical School
Primary Subject Heading:	Global health
Secondary Subject Heading:	Health services research, Infectious diseases
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Tropical medicine < INFECTIOUS DISEASES, Community child health < PAEDIATRICS, PRIMARY CARE, Paediatric infectious disease & immunisation < PAEDIATRICS

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Long-term quality of Integrated Community Case Management care for children in Bugoye Subcounty, Uganda: a retrospective observational study

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Word count: 4874

Keywords: Village health workers, Integrated Community Case Management, quality of health care, Uganda

Abstract

Objectives: Integrated community case management (iCCM) of childhood illness in Uganda involves protocol-based care of malaria, pneumonia, and diarrhea for children under 5 years old. This study assessed volunteer village health workers' (VHW) ability to provide correct iCCM care according to the national protocol and change in their performance over time since initial training.

Setting: VHWs affiliated with the Ugandan national program provide community-based care in 8 villages in Bugoye Subcounty, a rural area in Kasese District. The first cohort of VHWs began providing iCCM care in March 2013, the second cohort in July 2016.

Participants: All children receiving iCCM care in 18,430 clinical encounters occurring between April 2014–December 2018.

Primary and secondary outcome measures: The descriptive primary outcome measure was the proportion of patients receiving overall correct care, defined as adherence to the iCCM protocol for the presenting condition (hereafter quality of care). The analytic primary outcome was change in the odds of receiving correct care over time, assessed using logistic regression models with generalized estimating equations. Secondary outcome measures included a set of binary measures of adherence to specific elements of the iCCM protocol. Pre-planned and final measures were the same.

Results: Overall, VHWs provided correct care in 74% of clinical encounters. For the first cohort of VHWs, regression modeling demonstrated a modest increase in quality of care until approximately 3 years after their initial iCCM training (OR 1.022 per month elapsed, 95% CI 1.005–1.038), followed by a modest decrease thereafter (OR 0.978 per month, 95% CI 0.970–0.986). For the second cohort, quality of care was essentially constant over time (OR 1.007 per month, 95% CI 0.989–1.025).

Conclusions: Quality of care was relatively constant over time, though the trend toward decreasing quality of care after 3 years of providing iCCM care requires further monitoring.

Strengths and limitations of this study

- We used a record review approach to examine quality of care for all Integrated Community Case Management clinical encounters over a nearly 5-year period
- A retrospective record review approach cannot assess all aspects of appropriate care, and may overestimate quality of care
- While this study assessed a large number of patient encounters, it included a fairly small number of VHWs in a single geographic area, limiting its generalizability

INTRODUCTION

In integrated community case management (iCCM) of childhood illness, village health workers (VHW) or other lay workers provide care for pediatric malaria, pneumonia, and (in some settings) diarrhea, usually in a community setting rather than at a health facility[1]. VHWs follow a defined protocol that directs specific diagnostic and therapeutic steps based on the patient's presenting complaint and clinical exam findings. In some parts of Uganda, volunteer VHWs provide iCCM care, either in the patient's home or at the VHW's home, as part of the national Village Health Teams system[2–4]. These VHWs also retain their existing roles in health promotion efforts. In Bugoye Subcounty, Uganda, a rural, mountainous area in Kasese District (on the western border of Uganda), VHWs from the national program have provided iCCM care since 2013, with financial and operational support from a longstanding collaboration with Mbarara University of Science and Technology (Mbarara, Uganda) and the Massachusetts General Hospital (Boston, Massachusetts, USA).

Prior studies have employed several different approaches to assess iCCM quality of care, including direct observation of VHWs (with or without reexamination of the patient by a trained clinician), review of VHWs' clinical records, case scenarios, and surveys of patients' caregivers. Each approach comes with certain risks of bias and with different ability to measure the varied aspects of quality of care. Direct observation of VHWs with reexamination of patients allows for the most comprehensive assessment of quality of care, though the presence of an observer may alter VHWs' clinical practice (Hawthorne effect). A record review approach cannot assess all elements of quality of care and measures quality of recorded care rather than quality of actual care. However, record review has the benefit of easier repeated or widespread implementation. Prior studies comparing different methods of assessing quality of iCCM care, with direct observation of VHWs and reexamination of patients as the gold standard, have found that record review, case scenarios, and direct observation alone all tend to overestimate quality of care somewhat[5,6]. While acknowledging that limitation, in this study we employ a record review approach because it feasibly allows for continuous assessment of quality of care over multiple years.

In Uganda, prior studies using direct observation[7], record review[8], surveys of caregivers[9], and a combination of approaches[10] have generally demonstrated high quality of iCCM care, within the limits of each approach. In other countries in Sub-Saharan Africa, some studies have found similar quality of care[11,12], while others documented lower quality of care overall[13] or for specific areas such as severe illness[14] or antibiotic overuse[15]. However, there are few evaluations examining changes in iCCM care quality over time; most studies have assessed quality of care at a point in time or cumulatively for a single time period, or examined the impact of a particular intervention[7–15].

One prior study in Kenya examined quality of care at multiple time points using direct observation of VHWs and reexamination of patients, with 3 evaluations conducted over the 4-year period after VHWs' initial iCCM training. This study demonstrated improvement in some quality measures and worsening of other measures over time but did not assess for an overall trend in quality of care over time[16]. We previously examined trends in quality of care over the

first 2 years of the iCCM program in Bugoye using a record review approach, showing improvement in the proportions of patients receiving correct care (quality of care) over the initial 6 months after iCCM care initiation and stable quality of care for the remaining 18 months[17]. Several other studies have examined quality of care provided by VHWs with differing levels of experience but did not examine the relationship between experience level and quality of care provided[18,19]. Prior studies in Bugoye and other settings have also examined the specific iCCM skills of performing and interpreting rapid diagnostic tests (RDT) for malaria, finding that VHWs are able to maintain these skills over a 1–4 year period[20–22].

Since iCCM programs provide frontline care for common but potentially fatal childhood illnesses, programs must be able to monitor and ensure quality of care over time. Here we describe quality of iCCM care over a nearly 5-year period, as VHWs gain clinical experience but are also further from their initial iCCM training.

METHODS

Study design

In this retrospective, observational study, we examined overall iCCM quality of care as well as specific components of iCCM care for two cohorts of VHWs using a record review approach for all clinical encounters occurring between April 2014–December 2018. For each cohort we also examined trends in quality of care over time. For the first cohort of VHWs, we sought to assess long-term trends in quality of care, building on the prior evaluation of the first 2 years of iCCM care provided by this cohort[17]. For the second cohort of VHWs, we sought to assess quality of care over the initial 2.5 years of iCCM care provided by this cohort, using a larger dataset of all clinical encounters rather than sampled encounters to further evaluate our prior findings on quality of iCCM care after initial training.

The descriptive primary outcome measure was the proportion of patients receiving overall correct care, defined as adherence to all elements of the iCCM protocol for the presenting condition (further description of the iCCM protocol is provided below). We have termed this outcome measure quality of care, acknowledging that a retrospective record review approach cannot assess all domains of quality of care. The analytic primary outcome measure examined trends over time in quality of care, again using a binary classification of overall correct or incorrect care. Secondary outcome measures also used a binary correct or incorrect classification, and included VHWs' adherence to correct diagnostic protocol, correct prescribing practices, and correct referral of patients to a health facility. Pre-planned and final measures were the same.

Study setting

VHWs in Bugoye are selected by community members in their villages as part of the national Village Health Teams program and serve their communities as part-time volunteers. In general, VHWs are working age adults and have a paid job or practice subsistence farming, sometimes with an additional cash crop such as coffee, in addition to their work as VHWs. All VHWs are

required to have achieved basic literacy, and most have completed primary school. In addition to iCCM care, VHWs also provide health education and collect demographic and health data. All VHWs received 3 days of initial general training, 5 days of initial iCCM training, and half-day refresher trainings on a quarterly basis throughout the time period examined here. Clinical staff members at the government-funded health center in Bugoye are trained as iCCM instructors (as part of a Ministry of Health-supported training of trainers approach) and lead the quarterly training sessions as well as providing field-based individual supervision. VHWs provide iCCM care for malaria, pneumonia, and diarrhea in children between 2 months and 5 years old. In keeping with World Health Organization/UNICEF standards, VHWs perform rapid diagnostic tests for malaria (RDT) and provide artemisinin combination therapy (ACT) if indicated, measure respiratory rate and treat presumed pneumonia with amoxicillin, and evaluate children with diarrhea and treat with oral rehydration solution (ORS) and zinc, as well as assessing children for signs of severe illness (danger signs) and providing health education[1]. VHWs refer children with other conditions or with danger signs to a health facility. The first cohort (24 VHWs) began providing iCCM care in March 2013 in 5 villages; one VHW was added in 2016 to replace a VHW who had moved away. The second cohort (14 VHWs) began providing iCCM care in July 2016 in 3 additional villages. Both cohorts received the same initial training, refresher trainings, and supervision. In this program, Mbarara University of Science and Technology and Massachusetts General Hospital fund program administration and the purchase medications and malaria rapid diagnostic tests as well as providing staff support to enhance data collection and quality improvement efforts. During the time period examined here, iCCM care had not yet been implemented throughout the national Village Health Teams program.

Data collection

During the time period assessed in this study, VHWs in Bugoye used a paper form to record information from each clinical encounter. The form used was based on a Ministry of Health template and was modified to address local context and translated into the local language of Lukonjo. At the end of each month, program staff collected the paper records and entered information from each clinical encounter into a customized Epidata form[23] (implemented separately from national reporting systems) and stored in a Research Electronic Data Capture (REDCap) database[24]. The paper record forms contain basic information about the patient (age, sex, presenting complaints), clinical assessment data (presence of danger signs, respiratory rate, and malaria rapid diagnostic test result), and actions taken (medications administered and/or referral to the health facility).

Deidentified data for all encounters from April 2014–December 2018 (reflecting all available months in the electronic clinical database) were extracted to create the research dataset used for this study. Data were then cleaned, with comparison to paper records in case of a mismatch between similar variables (e.g., report month and visit date) or other suspected inaccuracies. Infants under 2 months of age were excluded from analysis as they were likely seen for newborn wellness checks separate from iCCM care. Stata Version 15 (StataCorp, College Station, TX) was used to check for presumed duplicate entries in the database. Decision rules in Stata were used to determine whether the care each patient received (based on the paper record form) matched with correct care according to the iCCM protocol. For patients presenting

with fever, elements of correct care include performing a rapid diagnostic test for malaria and recording the result, treatment with artemisinin combination therapy if the test is positive, and referral to a health facility if the test is negative. For patients presenting with cough/fast breathing, elements of correct care include measuring and recording the respiratory rate and treatment with oral amoxicillin if the respiratory rate is above age-based cutoffs (based on patients' recorded age and respiratory rate we could assess whether the VHW made this determination appropriately). For patients presenting with diarrhea, correct care constituted treatment with oral rehydration solution (ORS) and zinc. For patients recorded as having danger signs, we assessed whether the patient was referred to a health facility and received appropriate pre-referral treatment (if indicated). Certain elements of correct care (e.g., medication dosage, specific elements of health education provided) could not be assessed because they are not included on the paper record form.

Data analysis

The analytic methods for this study are quite similar to our prior study of iCCM care quality over the initial 2 years of this program[17]. In addition to the measures above, we also calculated the proportion of VHWs providing high-quality care for each of the main iCCM conditions, using thresholds of 70% and 84% of encounters with correct care. These thresholds were chosen to accord with our prior findings which employed a lot quality assurance sampling approach[17]. Since failure to refer a patient with subjective fever and a negative RDT was a common and likely low-consequence error[11], we also calculated the overall proportion of patients receiving correct care if this error is excluded.

We assessed population average trends in quality of care over time using logistic regression models with generalized estimating equations (GEE) with an exchangeable correlation structure and with robust standard errors to account for clustering by VHW, but otherwise without adjustment for demographic variables. For this analysis, we used a binary outcome variable representing correct or incorrect care according to the iCCM protocol, with time in months since the VHW began providing iCCM care as the exposure variable, to examine changes in the odds of receiving correct care over time. For each cohort, we initially fit a base model without a spline. Based on graphical depiction of the data as well as our prior findings suggesting that quality of care improved over the initial 6 months of providing iCCM care[17], we then fit models that included a spline, as the relationship between experience, i.e., time providing iCCM care, and provision of correct care might not be constant (e.g., provision of correct care might initially improve with experience but eventually reach a point at which further experience does not correlate with further improvement). We used the quasi-likelihood under the independence criterion (QIC) to compare model fit between the models with and without splines. The VHW who joined the program later in a village from the first cohort was excluded from this portion of analysis.

Ethics approval

Ethical approval for this study was granted by the Partners Healthcare IRB and the Research Ethics Committee at the Mbarara University of Science and Technology. Because the study

involved only analysis of deidentified clinical records, individual patients' caregivers were not consented for the study.

Patient and public involvement

While patients' families were not directly involved in developing the research question or outcome measures for this study, community members play a key role in selecting the VHWs who provide care in their communities. In a separate study we have also sought to understand families' experience of and satisfaction with iCCM care to identify program strengths and areas for improvement[25]. Evaluation of iCCM quality of care has also helped tailor the content of VHW refresher trainings and other quality improvement efforts.

RESULTS

After exclusion of 48 encounters for children under 2 months old and 339 presumed duplicate entries, VHWs completed a total of 18,430 clinical encounters between April 2014–December 2018. VHWs in the first cohort accounted for 74% of these encounters (Table 1). Because the data are deidentified and do not contain a unique identifier variable like a medical record number, it was not possible to determine how many unique children received care from a VHW during this period. For brevity, hereafter we refer to "patients" rather than clinical encounters. The proportion of female patients and mean age of patients were similar between the first cohort and second cohort of VHWs. Subjective fever was the most common presenting complaint, followed by cough/fast breathing, and then diarrhea (59%, 45%, and 28%, respectively; percentages add to >100% because some patients presented with multiple complaints). In both cohorts, 1% of patients were noted to have danger signs.

Table 1: Patient demographic information and summary of all Integrated Community Case Management clinical encounters (April 2014–December 2018 for first cohort VHWs, July 2016–December 2018 for second cohort VHWs)

Measure	n (%) or mean (range)		
	First cohort VHWs	Second cohort VHWs	Overall
Total encounters*	13,650 (74%)	4,780 (26%)	18,430
Female	6,780 (50%)	2,325 (49%)	9,105 (49%)
Age in months**	28.5 (2–60)	27.0 (2–60)	28.1 (2–60)
*Presenting complaints****			
Fever	8,418 (62%)	2,394 (50%)	10,812 (59%)
Cough/fast breathing	5,890 (43%)	2,449 (51%)	8,339 (45%)
Diarrhea	3,818 (28%)	1,352 (28%)	5,170 (28%)
Other/not recorded	600 (4%)	149 (3%)	749 (4%)
Patients with danger signs	171 (1%)	58 (1%)	229 (1%)
Actions/outcomes			
Respiratory rate measured	6,377 (47%)	2,472 (52%)	8,849 (48%)
Respiratory rate elevated	5,756 (90%)	2,293 (93%)	8,049 (91%)
RDT performed	9,316 (68%)	2,715 (57%)	12,031 (65%)

RDT positive	7,060 (76%)	1,719 (63%)	8,779 (73%)
Patients treated with ACT	7,022 (51%)	1,706 (36%)	8,728 (47%)
Patients treated with amoxicillin	5,972 (44%)	2,457 (51%)	8,429 (46%)
Patients treated with ORS and zinc	3,841 (28%)	1,331 (28%)	5,172 (28%)
Patients treated with rectal artesunate	95 (1%)	38 (1%)	133 (1%)
Patients referred to health facility	783 (6%)	303 (6%)	1,086 (6%)
Medication reactions	2 (0.01%)	0 (0%)	2 (0.01%)
Deaths	1 (0.01%)	1 (0.02%)	2 (0.01%)

Abbreviations: ACT, artemisinin combination therapy; ORS, oral rehydration solution; RDT, rapid diagnostic test for malaria; VHW, village health worker

*339 presumed duplicate encounters as well as 76 encounters with no clinical information recorded are excluded from the analysis

**48 infants under 2 months of age were excluded from the analysis as they were likely seen for newborn assessments rather than iCCM care

***Percentages add to >100%, as some patients presented with multiple complaints

For patients with measured respiratory rate, 91% had a respiratory rate above age-based cutoffs. VHWs performed a total of 12,031 malaria RDTs, of which 8,879 (73%) were positive. There were 8,728 patients treated with ACT, 8,429 patients treated with amoxicillin, and 5,172 patients treated with oral rehydration salts and zinc. Higher proportions of patients treated by VHWs in the first cohort presented with fever (62% vs. 50%), received an RDT (68% vs. 57%), and had positive RDTs (76% vs. 63%). Correspondingly, a higher proportion of patients treated by VHWs in the first cohort received ACT (51% vs. 36%). There were 133 patients (1%) treated with rectal artesunate, and 1,086 (6%) referred to a health facility. There were 2 patients recorded as having adverse reactions to medications, and 2 recorded deaths (Table 1).

Regarding quality measures, 97% of patients presenting with subjective fever correctly received an RDT (98% of those treated by VHWs in the first cohort vs. 94% of those treated by VHWs in the second cohort). Of patients diagnosed with malaria by RDT, 93% received correct management (94% vs. 88%). However, of patients with a negative RDT, only 23% were appropriately referred to a health facility (21% vs. 26%). Of patients presenting with cough or subjective fast breathing, 96% had their respiratory rate recorded (97% vs. 94%). Of those with an elevated respiratory rate and thus presumed pneumonia based on the iCCM algorithm, 90% received correct treatment (92% vs. 90%). Of patients with danger signs, 77% were appropriately referred to a health facility (80% vs 69%), and 60% received appropriate pre-referral treatment (56% vs. 72%); see Table 2.

Table 2: Integrated Community Case Management quality of care measures

Measure	First cohort VHWs n (%)	Second cohort VHWs n (%)	Overall n (%)
RDT performed for patient presenting with fever	8,278 (98%)	2,258 (94%)	10, 536 (97%)
Malaria patients receiving correct management	6,864 (94%)	1,617 (88%)	8,841 (93%)

Patients with negative RDT receiving correct management	323 (21%)	172 (26%)	495 (23%)
Respiratory rate recorded for patient presenting with cough or subjective fast breathing	5,693 (97%)	2,305 (94%)	7,998 (96%)
Patients with elevated respiratory rate receiving correct treatment	5,625 (92%)	2,200 (86%)	7,825 (90%)
Patients with diarrhea receiving ORS and zinc	3,699 (92%)	1,281 (90%)	4,980 (92%)
Patients inappropriately treated with ACT (out of total patients)	182 (1%)	100 (2%)	282 (2%)
Inappropriate ACT prescriptions (out of total ACT prescriptions)	182 (3%)	100 (6%)	282 (3%)
Patients inappropriately treated with amoxicillin (out of total patients)	343 (3%)	256 (5%)	599 (3%)
Inappropriate amoxicillin prescriptions (out of total amoxicillin prescriptions)	343 (6%)	256 (10%)	599 (7%)
Patients inappropriately treated with ORS, zinc, or both (out of total patients)	188 (1%)	73 (2%)	261 (1%)
Inappropriate ORS or zinc prescriptions (out of total ORS and zinc prescriptions)	188 (5%)	73 (5%)	261 (5%)
Patients with danger signs appropriately referred to health facility	137 (80%)	40 (69%)	177 (77%)
Patients with danger signs receiving appropriate pre-referral treatment	96 (56%)	42 (72%)	138 (60%)
Patients receiving overall correct management (all months)*	10,455 (77%)	3,244 (68%)	13,699 (74%)
Patients receiving overall correct management (July 2016 - December 2018)	5,560 (75%)	3,244 (68%)	8,804 (72%)
Patients receiving overall correct management, excluding referral of patients with negative RDT (all months)*	11,486 (84%)	3,654 (76%)	15,140 (82%)

Abbreviations: ACT, artemisinin combination therapy; ORS, oral rehydration solution; RDT, rapid diagnostic test for malaria; VHW, village health worker

*April 2014 - December 2018 for original VHWs; July 2016 - December 2018 for expansion VHWs

Overall, 74% of patients received correct management (77% vs. 68%). When comparing only the time period in which the second cohort of VHWs was providing iCCM care, 72% of patients received correct management (75% vs 68%). Excluding the common error of failing to refer patients with a negative malaria RDT, 82% of patients received correct management (84% vs 76%).

Inappropriate use of medications was fairly low, with 2% of patients receiving ACT inappropriately, 3% of patients receiving amoxicillin inappropriately, and 1% of patients receiving ORS, zinc, or both inappropriately (Table 2). This constituted 3%, 7%, and 5% of prescriptions for those medications, respectively. These proportions were similar between the two cohorts of VHWs.

Regarding individual VHWs' performance, of the 38 VHWs, all 38 VHWs provided correct care for at least 70% of patients with malaria, and 34 VHWs provided correct care for least 84% of patients with malaria, compared with 35 and 30 VHWs (respectively) for patients with presumed pneumonia, 36 and 29 VHWs (respectively) for patients with diarrhea, and 24 and 7 VHWs (respectively) for all patients. If failure to refer patients with a negative RDT is excluded, then 35 VHWs met the 70% threshold for overall correct care, and 16 VHWs met the 84% threshold for overall correct care (Table 3).

Table 3: Village health worker-level quality of care measures

Measure	In >70% of encounters n (%)*	In >84% of encounters n (%)*
VHWs providing correct care for malaria	38 (100%)	34 (89%)
VHWs providing correct care for presumed pneumonia	35 (92%)	30 (79%)
VHWs providing correct care for diarrhea	36 (95%)	29 (76%)
VHWs providing overall correct care	24 (63%)	7 (18%)
VHWs providing overall correct care, excluding referral of patients with negative RDT	35 (92%)	16 (42%)

Abbreviations: RDT, rapid diagnostic test for malaria; VHW, village health worker

*The 70% and 84% thresholds were chosen to accord with our prior lot quality assurance sampling approach, allowing for comparison between the two studies

For the first cohort of VHWs, modelling time as a continuous variable (months since the cohort began providing iCCM care) estimated a 0.6% decreased odds of correct care for each month (OR 0.994, 95% CI 0.988-0.999, p=0.032). Graphical depiction of overall correct care over time for the first cohort appeared to show a gradual increase until approximately March 2016 (3 years after iCCM care initiation), followed by gradual decrease (Figure 1). Based on the graphical depiction, the addition of a spline knot at the 3-year mark demonstrated a slight trend toward increasing correctness of care up until the 3-year mark (OR 1.022, 95% CI 1.005-1.038, p=0.009), followed by decreasing correctness of care after that point (OR 0.978, 95% CI 0.970-0.986, p<0.001), with an improvement in model fit based on the QIC values (Table 4).

Table 4: GEE logistic regression models for quality of care over time

Measure	OR	95% CI	p-value	Model QIC*
*First cohort VHWs, overall correct care***				14587

Months since iCCM services initiation	0.994	0.988–0.999	0.032	
*First cohort VHWs, overall correct care, with spline knot at 3 years after iCCM care initiation***				14524
Months since iCCM services initiation - Months 14–36	1.022	1.005–1.038	0.009	
Months since iCCM services initiation - Months 36–70	0.978	0.970–0.986	<0.001	
*First cohort VHWs, overall correct care excluding referral of patients with negative RDT***				11747
Months since iCCM services initiation	0.999	0.993–1.004	0.632	
*First cohort VHWs, overall correct care excluding referral of patients with negative RDT, with spline knot at 3 years after iCCM care initiation***				11718
Months since iCCM services initiation - Months 14–36	1.023	1.005–1.043	0.015	
Months since iCCM services initiation - Months 36–70	0.984	0.976–0.993	<0.001	
Second cohort VHWs, overall correct care				6057
Months since iCCM services initiation	1.007	0.989–1.025	0.475	
Second cohort VHWs, overall correct care, with spline knot at 6 months after iCCM care initiation				6061
Months since iCCM services initiation - Months 1–6	1.068	0.971–1.175	0.175	
Months since iCCM services initiation - Months 7–30	0.998	0.973–1.022	0.845	
Second cohort VHWs, overall correct care, with spline knot at 18 months after iCCM care initiation				6047
Months since iCCM services initiation - Months 1–18	1.027	1.004–1.050	0.023	
Months since iCCM services initiation - Months 19–30	0.963	0.926–1.000	0.053	
Second cohort VHWs, overall correct care excluding referral of patients with negative RDT				5272
Months since iCCM services initiation	1.026	1.007–1.045	0.006	

Abbreviations: CI, confidence interval; iCCM, Integrated Community Case Management; OR, odds ratio; QIC, quasi-likelihood under the independence model criterion; RDT, rapid diagnostic test for malaria; VHW, village health worker

*Quasi-likelihood under the independence model criterion. This is a modification of the Akaike information criterion (AIC) so that it can be applied to GEE regression models to assess goodness of fit of different models. A lower QIC term reflects a better-fitting regression model.

**One VHW joined the first cohort of VHWs later, and is thus excluded from this analysis

Failure to refer patients with a negative RDT to a health facility was a common error. We conducted a secondary analysis to assess whether the trends observed in the main models were driven solely by this error. Graphical depiction of correct referral of patients with a negative RDT for the first cohort of VHWs appeared to show worse performance over time; exclusion of this error appeared to moderate the trend toward decreasing quality of care in later months (Figure 1). Repeating the model with the outcome variable as overall correct care excluding referral of patients with negative RDT estimated essentially constant correctness of care over time (OR 0.999, 95% CI 0.993-1.004, p=0.632). The addition of a spline knot at the 3-year mark resulted in similar findings to using the main outcome variable of overall correct care (slightly increasing correctness of care up until the 3-year mark, followed by slightly decreasing correctness of care); see Table 4 and Figure 2.

For the second cohort of VHWs, modelling time as a continuous variable (months since the cohort began providing iCCM care) estimated essentially constant correctness of care over time (OR 1.007, 95% CI 0.989, 1.025, p=0.475); see Table 4. Graphical depiction of overall correct care over time for the second cohort appeared to show a slight increase in correct care over approximately the first 6 months after iCCM program initiation, followed by a plateau and then a further increase until approximately 18 months, followed by a gradual decline (Figure 1). Based on the graphical appearance as well as our prior findings [17], we created two additional models, one with a spline knot at 6 months, and one with a spline knot at 18 months. The model with the spline knot at 6 months did not meaningfully change the result (months 1-6: OR 1.068, 95% CI 0.971-1.175, p=0.175; months 7-30: OR 0.998, 95% CI 0.973-1.022, p=0.845). The model with the spline knot at 18 months showed some evidence of a trend toward increasing correctness of care over the first 18 months and decreasing correctness of care over the remaining 12 months (months 1-18: OR 1.027, 95% CI 1.004-1.050, p=0.023; months 18-30: OR 0.963, 95% CI 0.926-1.000, p=0.053), with an improvement in model fit based on the QIC values (Table 4).

We again conducted a secondary analysis using the outcome variable of overall correct care excluding referral of patients with negative RDT. Similar to the first cohort, graphical depiction of correct referral of patients with a negative RDT by VHWs in the second cohort appeared to show worse performance over time; exclusion of this error resulted in a relatively linear-appearing trend toward increasing correctness of care over time, followed by a slight decline over the final 6 months (Figure 1). Repeating the model with the outcome variable as correct care excluding referral of patients with negative RDT demonstrated a trend toward increasing correctness of care over time (OR 1.026, 95% CI 1.007-1.045, p=0.006); see Table 4.

DISCUSSION

Patient demographic data and presenting complaints were broadly similar between patients treated by the two cohorts of VHWs. Overall quality of care was slightly higher for the first cohort of VHWs compared with the second cohort (77% vs 68%). Both cohorts demonstrated high quality of care for uncomplicated malaria, pneumonia, and diarrhea (>90% on all measures for the first cohort, and >85% for all measures for the second cohort). Encouragingly, overuse of medications was fairly low in both cohorts as well. To the best of our knowledge, the program never experienced stockouts of medications, so VHWs' ability to provide correct care would not have been affected by unavailability of the necessary medication.

These findings are broadly similar to our prior evaluation of quality of care in Bugoye as well as other studies in Uganda[7–9,17]. Studies on iCCM care in other countries in Sub-Saharan Africa have demonstrated greater heterogeneity. Some have documented correct care for 70–90% of encounters[18,26–28]. Others have documented lower quality of care overall[19,29] or in the control group or pre-assessment evaluation in several intervention studies[30,31]. Local context might explain some of the variation in quality of care. In this setting, all scheduled trainings took place (to the best of our knowledge), external funding ensured a consistent supply of diagnostic tests and medications, and monthly collection of paper record forms might have

helped provide accountability. These factors might result in higher quality of care compared with settings in which iCCM is implemented more broadly.

In both cohorts, the proportion of patients with fever and negative malaria RDT appropriately referred to a health facility was quite low. Our prior evaluation also identified this as a common error[17], which prompted refresher training on this topic. The persistence of this error despite refresher training might indicate that this represents an intentional decision by VHWs rather than an unintentional error; perhaps VHWs have observed that such patients often have self-limiting viral illnesses and recover without intervention. For this error (as well as other errors), caregiver preferences or requests might also have influenced VHWs. For instance, caregivers might not wish to be referred to the health facility because of the time spent traveling to the facility and waiting to be seen. Some iCCM programs advise symptomatic management and at-home follow-up rather than referral for patients with subjective fever and a negative malaria RDT[11]. When this error was excluded, overall quality of care for all other patients was 84% and 76% in the first and second cohorts respectively. While inappropriate use of medications was fairly low, pressure from caregivers to provide a medication could also have influenced VHWs' treatment decisions.

VHWs did not perform as well for appropriate referral and pre-referral treatment of patients with danger signs. This finding is somewhat concerning as these patients are likely at highest risk of poor outcomes or death. Very few deaths were reported, though deaths might be underreported as VHWs might not update their clinical encounter record if a child later dies during that illness episode. Additionally, deaths might have occurred in children who were never evaluated by a VHW; caregivers who recognize that a child has severe illness might proceed directly to a health facility rather than seeking care from a VHW.

We employee GEE regression models to examine trends in quality of care over time (GEE models estimate a population average effect, so these trends should be interpreted as such). For the first cohort of VHWs, quality of care appeared to increase modestly until approximately 3 years after their initial iCCM training, followed by a gradual decrease in quality of care. For the second cohort of VHWs, quality of care was essentially constant over time. This finding is in contrast to our prior study demonstrating increasing quality of care over the first 6 months in the first cohort of VHWs[17]. There are several potential explanations for the trend toward decreasing quality of care for the first cohort in the later years. Uganda relies on an all-volunteer VHWs workforce, which could result in decreased motivation over time or a need to focus on income-generating activities instead of volunteer work. Alternatively, as VHWs gain experience and are further from their initial training, they may begin to rely more on clinical judgment and follow the iCCM protocol less closely. However, based on the secondary analysis, the decline in quality of care persists even when the error of failing to refer patients with a negative RDT is excluded. Another potential explanation for this trend would be higher engagement and interest from supervisors in the earlier years of the program, though we are not aware of any concrete changes in frequency of trainings, supervision schedule, incentives, or other such factors in this program. Alternatively, there could have been changes in care-seeking behaviors or expectations over time (e.g., caregivers bringing children with a broader

range of illnesses to VHWs as the program became more established); we could not meaningfully examine this using the available records.

More broadly, several years represents a substantial follow-up period for a study but not such a substantial period for a health system. From this standpoint, the modest decline in quality of care over time might point to the challenge of relying on a volunteer workforce to fill a critical role in the health system. Some prior studies examining Integrated Management of Childhood Illness and long-term trends in quality of facility-based care for malaria or other life-threatening pediatric illnesses have documented consistent improvements in quality of care[32,33], though other factors apart from the paid status of these healthcare workers could explain this discrepancy. While iCCM has the potential to increase access to potentially lifesaving care, broader implementation and longer-term reliance on this approach should be accompanied by monitoring and evaluation of quality of care.

This study has at least 5 limitations. First, while we conducted some data cleaning and assessed for duplicate entries as detailed above, these data were not double-entered. Given the large volume of clinical encounters, some data entry errors likely persist. However, such errors are less likely to cause systematic bias. Second, some elements of correct care are not captured on the paper registers, and thus cannot be assessed here (e.g., correct drug dosages), which may overestimate quality of care. More broadly, a record review approach cannot capture whether or how much health education is provided, or VHWs' ability to assess children's overall health and identify more chronic issues such as malnutrition. Third, this study assesses quality of recorded care rather than quality of actual care. In some instances, this may overestimate quality of care—e.g., we cannot assess whether a VHW correctly performed and interpreted a malaria RDT or measured respiratory rate correctly. In other cases, a VHW could provide correct care but have the encounter classified as incorrect due to incomplete record-keeping. For instance, because the words for "fever" and "malaria" are often used interchangeably in the local language, some VHWs seem to have recorded a patient as having subjective fever only if the malaria RDT was positive. For a patient with a negative RDT, this misunderstanding would make it appear that the VHW had incorrectly performed an RDT for a patient without subjective fever (when in fact the RDT was appropriately performed). Overall however, prior research suggests that record review somewhat overestimates quality of care when compared with direct observation of VHWs with reexamination by a clinician[5,6]. Fourth, because the data are deidentified and lack a reliable unique identifier variable, two or more illness episodes for the same child may be included. However, this issue is unlikely to affect the results significantly, as quality of care for different episodes of illness for a given individual are not necessarily correlated (beyond the correlation of receiving care from the same VHW). Fifth, while this study assesses a large number of patient encounters, it includes a fairly small number of VHWs in a single geographic area, limiting its generalizability.

CONCLUSION

Overall, we found that VHWs continue to provide quality care for uncomplicated malaria, pneumonia, and diarrhea nearly 5 years after initial training, though with a trend toward decreasing quality of care during the later period and with lower quality of care for patients

with danger signs. The trend toward decreasing quality of care starting several years after iCCM care initiation points to the importance of long-term monitoring of quality of care by iCCM programs.

List of abbreviations

ACT: artemisinin combination therapy; GEE: generalized estimating equations; iCCM: Integrated Community Case Management; ORS: oral rehydration solution; QIC: quasi-likelihood under the independence criterion; RDT: rapid diagnostic test; VHW: village health worker

Acknowledgments:

We are grateful to Sarah Masika, Rapheal Mbusa, Stephen Baguma, Sara Mian-McCarthy, and Emily Cable for their work in administering and supporting the village health worker program in Bugoye. We are grateful to all the village health workers for volunteering to provide critical services to their communities.

Competing interests: The authors declare that they have no competing interests

Funding: This work was supported by the Mooney-Reed Charitable Foundation (Award/Grant number is not applicable) and the Massachusetts General Hospital Department of Medicine (Award/Grant number is not applicable).

Ethical review: Ethical approval for this study was granted by the Partners Healthcare IRB (2016P001423) and the Research Ethics Committee at the Mbarara University of Science and Technology (14/06-16). Because the study involved only analysis of deidentified clinical records, individual patients' caregivers were not consented for the study.

Authors' contributions: JSM, EMM, JK, RR, and GSS conceived and designed the study. ACW and EMM led data collection, with contributions from NM, JM, MM, MN, DAG, PRP, SB, and JSM. JSM led data analysis, with contributions from ACW and EMM. JSM and EMM drafted initial versions of the manuscript. All authors contributed to manuscript writing and approved the final manuscript.

Data sharing statement: Data are available for non-commercial use from the corresponding author (jsmiller@post.harvard.edu) upon reasonable request.

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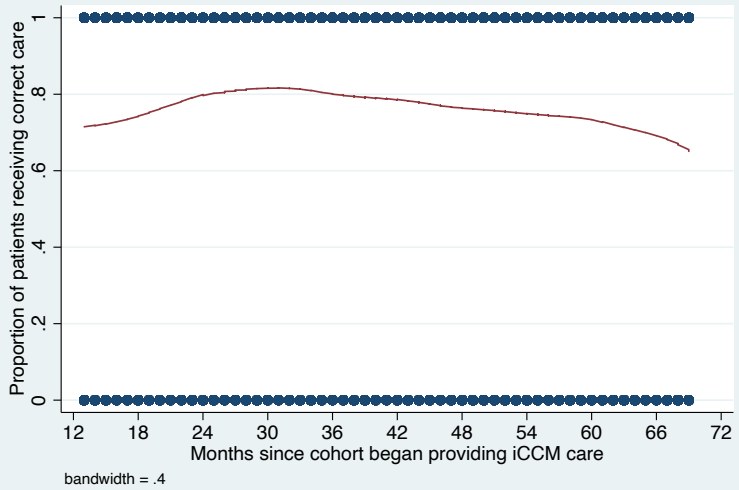
Figure 1: Lowess smoothing plots for correct management over time. Plots A–C correspond to the first cohort of VHWs. Plot A shows overall correct care over time. Plot B shows correct

referral of patients with a negative malaria rapid diagnostic test (RDT) over time. Plot C shows overall correct care over time, excluding the error of failing to refer patients with a negative malaria RDT. Plots D–F depict the second cohort of VHWs. Plot D shows overall correct care over time. Plot E correct referral of patients with a negative malaria RDT over time. Plot F shows overall correct care over time, excluding the error of failing to refer patients with a negative malaria RDT.

Figure 2: Post-estimation margins plots for GEE logistic regression models with spline knots, which display the predicted probability of receiving correct care at specified time points (6-month intervals). Plots A and B depict the first cohort of VHWs. Plot A shows the predicted probability of overall correct care, with a spline knot 3 years after the first cohort began providing iCCM care. Plot B shows the predicted probability of overall correct care excluding the error of failing to refer patients with a negative malaria rapid diagnostic test (RDT), again with a spline knot at 3 years. Plots C and D depict the second cohort of VHWs. Plot C shows the predicted probability of overall correct care, with a spline knot 6 months after the second cohort began providing iCCM care. Plot D again shows the predicted probability of overall correct care, but with a spline knot at 18 months.

A



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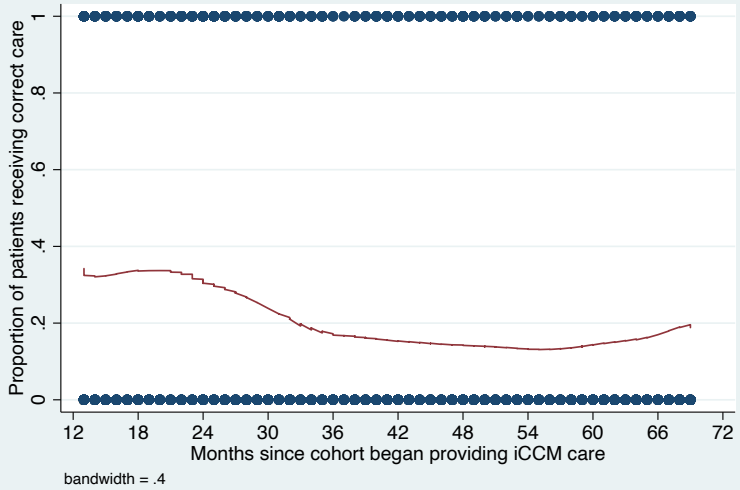

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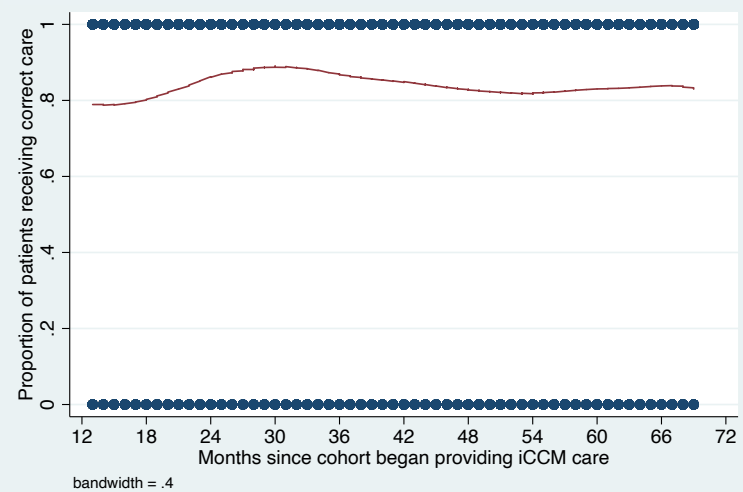

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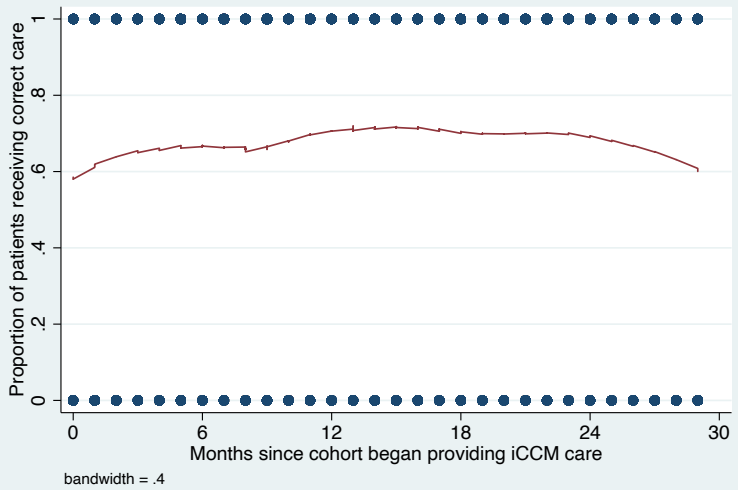

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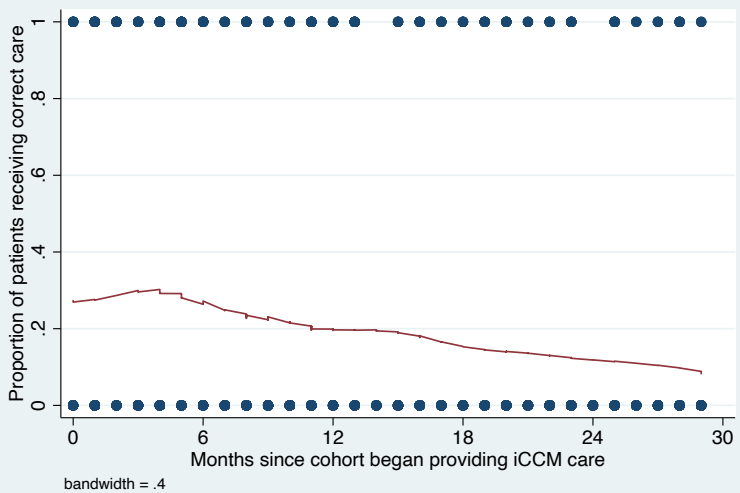

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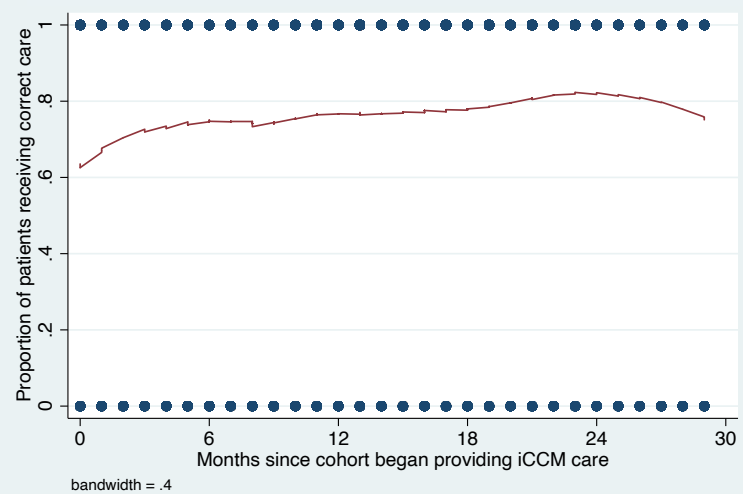

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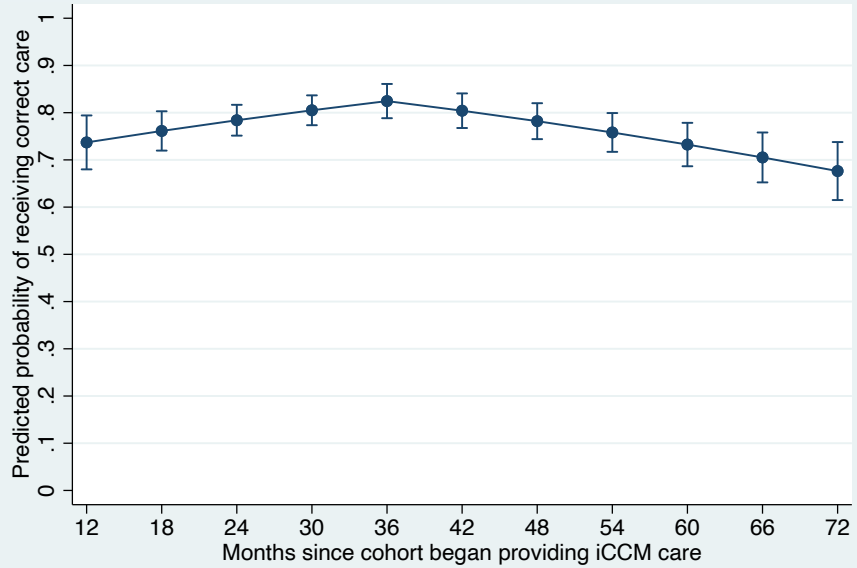

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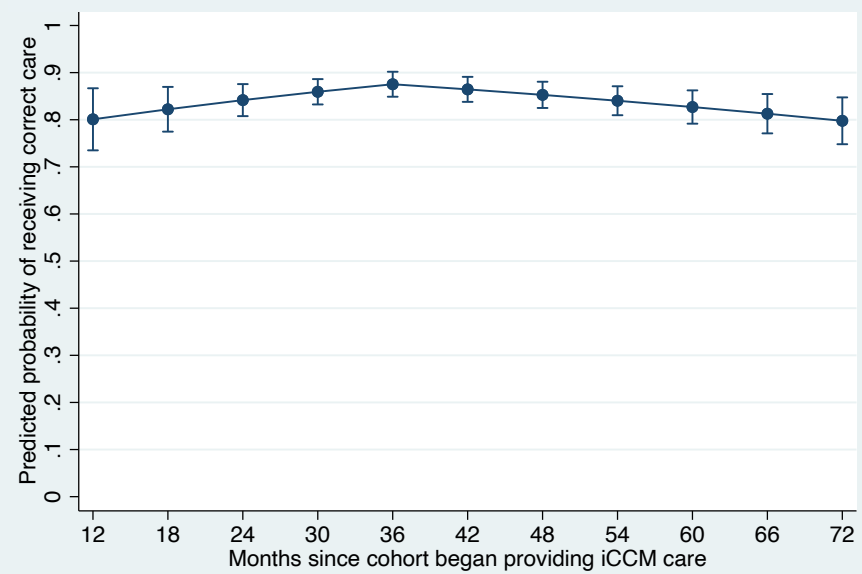

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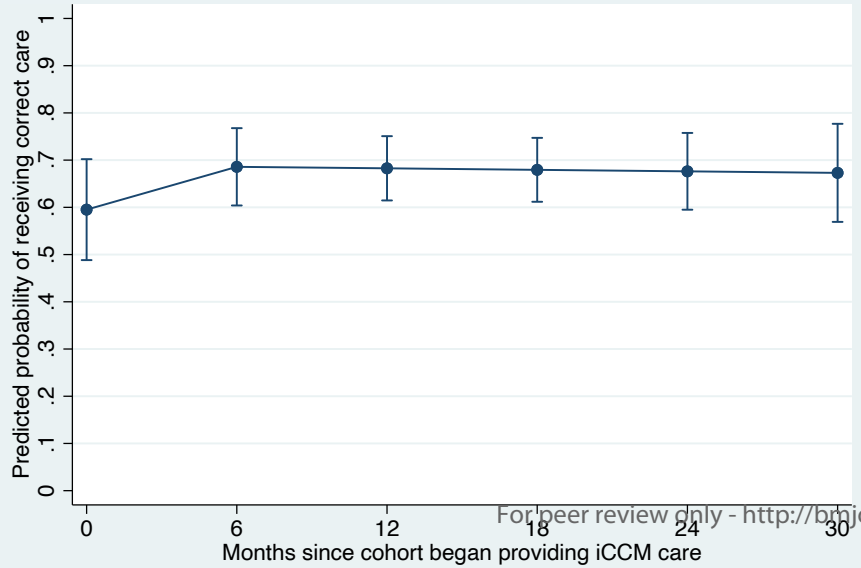

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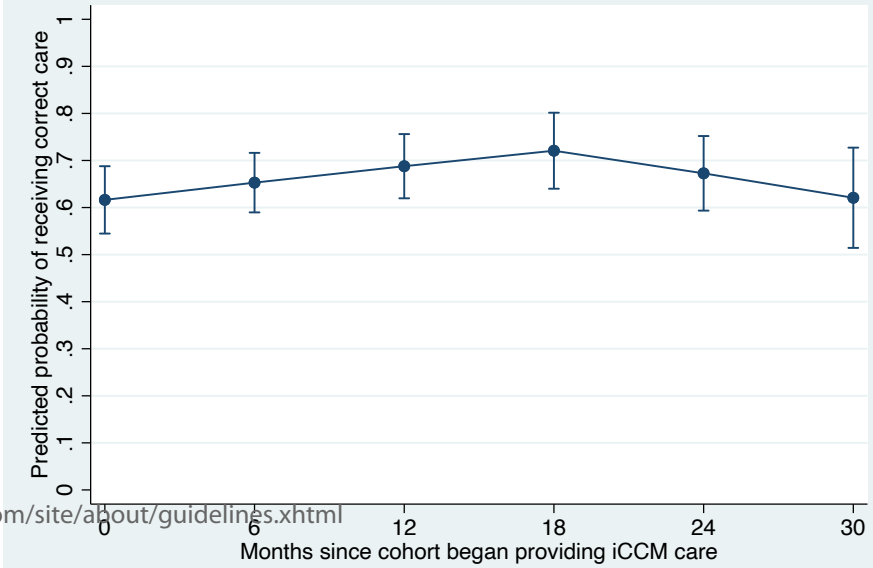

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	n/a
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	n/a
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	5
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	6
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	6
Outcome data	15*	Report numbers of outcome events or summary measures over time	6-7

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	9-10
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-10
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.