Chronic obstructive pulmonary disease self-management in three LMICs: a pilot randomized trial

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Scientific Knowledge on the Subject
COPD is projected to become the third leading cause of death by 2030. A significant proportion of COPD cases in low- and middle-income countries (LMICs) remains undiagnosed and untreated due to several challenges including a lack of health system resources and capacity. Guideline-based interventions for COPD, such as action plans, have been demonstrated to improve COPD outcomes in high-income settings. In addition, task-shifting strategies, such as community health worker models, have shown success in LMICs in addressing chronic diseases such as hypertension and diabetes. CHW models may also represent effective models for delivering evidence-based care for chronic respiratory diseases.

What This Study Adds to the Field
In this pilot effectiveness-implementation trial of adults with moderate-to-severe COPD, we assessed the feasibility of testing a CHW-supported self-management intervention for COPD on respiratory-related quality of life, moderate-to-severe exacerbations, and all-cause hospitalizations. We carried out this intervention across three low-resource community settings in three continents that varied in culture, urbanization, and healthcare resources. We did not observe significant improvements in effectiveness outcomes. However, this pilot trial provides insight into the important considerations for implementing COPD self-management interventions in such contexts, where availability and access to evidence-based care is limited.

This article has an online data supplement, which is accessible from this issue's table of content online at www.atsjournals.org.

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ABSTRACT

Introduction: Chronic obstructive pulmonary disease (COPD) disproportionately affects low- and middle-income countries (LMICs). Health systems are ill-prepared to manage the increase in COPD cases.

Methods: We carried out a pilot effectiveness-implementation randomized field trial of a community health worker (CHW)-supported, one-year self-management intervention in individuals with COPD grade B-D. The study took place in low-resource settings of Nepal, Peru, and Uganda. The primary outcome was the St. George's Respiratory Questionnaire (SGRQ) at one year. We evaluated differences in moderate-to-severe exacerbations, all-cause hospitalizations and the EuroQol score (EQ5D-3L) at 12 months.

Results: We randomly assigned 239 participants (119 control, 120 intervention) with grade B-D COPD to a multi-component, CHW-supported intervention or standard of care and COPD education. 25 participants (21%) died or were lost to follow-up in the control arm compared to 11 (9%) in the intervention arm. At 12 months, there was no difference in mean total SGRQ scores between intervention and control arms (34.7 vs. 34.0 points; adjusted mean difference 1.0, 95% CI -4.2-6.1; p=0.71). The intervention arm had a higher proportion of hospitalizations (10% vs. 5.2%; adjusted odds ratio 2.2, 95% CI 0.8-7.5; p=0.15) at 12 months compared to controls.

Conclusion: A CHW-based intervention to support self-management of acute exacerbations of COPD in three resource-poor settings did not result in differences in SGRQ scores at one year. Fidelity was high, and intervention engagement was

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moderate. While results cannot differentiate between a failed intervention or implementation, it nonetheless suggests that we need to revisit our strategy.

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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a progressive, life-threatening lung disease that was estimated to be responsible for 3.2 million deaths worldwide in 2019. COPD is projected to become the third leading cause of death by 2030, and more than 90% of COPD deaths occur in low- and middle-income countries (LMICs) [1]. Health systems in these countries are ill-prepared to diagnose, treat, and manage the growing burden of COPD due to lack of resources and capacity. Indeed, a significant proportion of COPD cases in LMICs remains undiagnosed and untreated [2,3].

Effective treatments and self-management interventions for COPD such as action plans have been demonstrated to reduce symptoms, prevent exacerbations, and improve health-related quality of life in high-income settings [4]. Self-management interventions comprise multi-component behavioral strategies that allow individuals to play a central role in managing their own health behaviors and treatments, often in collaboration with caregivers or other support in their social networks [5]. COPD Action Plans serve as tools to guide individuals to monitor and recognize changes in symptoms and use appropriate, evidence-based therapies and healthcare-seeking behaviors to manage COPD exacerbations [6].

In LMICs, task-shifting strategies have been used to address the limited resources for training of healthcare workers [7]. Community health worker (CHW) models have shown success in allowing the health system to provide care more directly and effectively to communities, including in LMICs. These models show promise for diseases requiring

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chronic care such as hypertension and diabetes [8,9]. Because of their potential for scalability and leveraging existing infrastructure and personnel from ongoing programs, CHW models may also represent effective models for delivering evidence-based, self-management-based care for respiratory diseases such as COPD. Multi-component, community health worker (CHW)-based strategies for obstructive lung diseases have shown mixed results for improving quality of life, respiratory admissions, and mortality in high-income settings [10]. However, these task shifting models may be particularly useful in LMIC settings, where existing infrastructure for COPD treatment and management is limited.

In this pilot effectiveness-implementation trial of adults with moderate-to-severe COPD, we sought to assess the feasibility of testing a multi-component, CHW-supported self-management intervention for COPD on respiratory-related quality of life [11], health-related quality of life, and moderate-to-severe exacerbations, and all-cause hospitalizations over 12 months.

METHODS

Study setting

The protocol for the Global Excellence in COPD outcomes trial (GECo2) has been published previously [12], and the trial was registered at clinicaltrials.gov (NCT03359915). Briefly, the trial took place in three geographically, economically, and culturally diverse regions in Asia, South America, and Sub-Saharan Africa (Table 1). Sites were selected to test the performance of a CHW-supported action plan for COPD

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management in different continents and at sites with different degrees of urbanization, prevalence of COPD, and economic development. Trial participants were recruited from a random, age-and sex-stratified sample of adults aged 40-95 years who underwent spirometry [13], as part of an earlier study reporting the discriminative accuracy of COPD screening instruments in the same three settings [14].

Study design

The GECo2 study was a single-blind, individually randomized controlled pilot trial carried out between March 9, 2018 and July 17, 2020. Before testing the multi-component intervention, we carried out eight months of formative research consisting of qualitative interviews with individuals with COPD, health providers, and CHWs, to adapt COPD education material and the COPD Action Plan for patients, allow instrument development, gain an understanding of pathways to care for COPD, and tailor CHW training. Formative research informed content and adaptation of the COPD education materials and Action Plan (instruments found in the protocol paper) [12,15].

We consecutively approached and enrolled eligible individuals from an age- and sex-stratified, population-based sample of adults aged ≥40 years who underwent spirometry testing [13] and were identified to have COPD by post-bronchodilator spirometry with severity grade B-D [16]. Participants were considered to have COPD if they had a post-bronchodilator FEV_1/FVC below the lower 5^{th} percentile of the 2012 Global Lung Function Initiative mixed ethnic population for their given age, sex, and height (i.e., an FEV_1/FVC Z-score less than -1.645); and grade B-D spirometry based on 2017 GOLD

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guidelines [16]. Exclusion criteria were self-reported pregnancy, self-reported active pulmonary tuberculosis, or receiving medications for pulmonary tuberculosis, or contraindications to spirometry (eye surgery, thoracic surgery, abdominal surgery, or myocardial infarction in the 3 months prior to study visit or measured blood pressure >180/100 mm Hg at the research assessment). Participants were randomly selected from study area censuses irrespective of respiratory symptoms, a prior diagnosis of COPD, St. George's Respiratory Questionnaire (SGRQ) scores or exacerbation history at baseline. We made a pragmatic choice to not require guideline-recommended maintenance therapy due to the extremely low availability and affordability of these therapies in these settings [17].

We aimed to randomize 240 adults (80 in each country) with COPD who met eligibility criteria over 12 months and follow them quarterly for one year to evaluate primary and secondary outcomes. Participants were randomized 1:1 to either the intervention or control arm using an online system [18], stratified by country. We used randomly permuted block sizes between 2 and 6. Principal investigators and data analysts were blinded to treatment allocation. Due to the nature of the intervention, it was not feasible to blind participants or data collectors to treatment assignment. Although we planned to enroll 80 participants from each site, we found that the prevalence of COPD in Lima, Peru, was lower than originally anticipated in the parent study [14]. Given that enrollment was done consecutively and across study settings, once we realized that our site in Lima had fewer eligible grade B-D COPD cases, we increased the number of participants enrolled in Uganda and Nepal to meet our recruitment targets and timeline.

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Intervention and control conditions

Individuals were randomized to receive either a CHW-based self-management intervention or usual care with COPD education. The intervention consisted of four components surrounding prevention and self-management of COPD and monthly CHW visits over one year. Selection of intervention components was guided by the Capacity, Opportunity, and Motivation of behavior (COM-B) framework [19] and based on formative research related to key barriers and facilitators to adopting COPD self-management practices [12,15]. These components included: COPD education at enrollment; training and ongoing support in self-management of acute exacerbations using a context-adapted Action Plan, which included training and support on recognition of symptoms; rescue packs delivered or refilled by a CHW consisting of antibiotics and steroids for use during exacerbations; and, continuous and iterative reinforcement and feedback on COPD educational concepts and self-management behaviors, such as smoking cessation and home-based exercise. Rescue packs consisted of 30 mg of prednisolone taken once daily for 5 days, and 500 mg of amoxicillin taken three times per day for 5 days. If amoxicillin was not available or the participant was allergic to penicillin, it was replaced with either 500 mg of azithromycin taken daily for 3 days (Peru and Uganda) or 200 mg of doxycycline on the first day followed by 100 mg for the remaining 4 days (Nepal). CHWs also served as a source of support for navigating the healthcare system. In Peru, eight intervention participants received their final monthly CHW visits via telephone during the months of March through June 2020 due to the COVID-19 pandemic.

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Participants randomly assigned to the control arm received basic COPD education from a CHW and were offered access to the same medications at designated local clinics or pharmacies for acute exacerbations free of charge. The study teams in each country ensured that the medications were available at these designated locations.

CHW training and roll-out

CHWs at each site were recruited from local catchment areas and trained on delivery of the COPD education tool, the COPD Action Plan, use of rescue packs, referral to higher levels of care, provision of patient navigation services, and longitudinal reinforcement of COPD education concepts and self-management behaviors. They were also trained on distribution of antibiotics and steroids during home visits, building patient rapport and effective communication. The training included a combination of didactic instruction and role-playing activities over the course of two weeks, with regular feedback. We conducted refresher trainings as needed and after any protocol adaptations (see Online Supplement). A total of eight CHWs were recruited in Nepal, three in Peru, and 13 in Uganda.

Standardization and assessment of fidelity to the intervention protocol

We assessed fidelity to the intervention using direct observations of CHW visits and fidelity checklists (Online Supplement). Field team supervisors completed fidelity checks to observe key standardized competencies of CHWs and adherence to the study

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protocol during home visits. We observed CHWs three times: at an initial participant visit, a 4-6 month visit, and a 10-12 month visit.

To standardize the content of the CHW visits, we created a standard training and re-training protocol across all three sites (Online Supplement). CHWs met with site leaders weekly to discuss any issues that arose and to provide an opportunity for re-training as needed based on the fidelity observation visits.

Study Outcomes

The primary outcome for this trial was respiratory-related quality of life, defined as St. George's Respiratory Questionnaire (SGRQ) total score at 12 months [11]. The SGRQ has been previously validated in Spanish [20] and our research team previously conducted validation studies of the SGRQ in both Luganda and Nepali [21,22]. We also examined differences between treatment arms in SGRQ score at earlier follow-up visits. Secondary outcomes included the proportions of moderate-to-severe exacerbations and all-cause hospitalizations over 12 months, SGRQ sub-scores, the five-dimension, three-level EuroQol health-related quality life scale (EQ5D) at 12 months, and the EQ5D visual analog scale score [23]. Moderate exacerbations were defined as having taken a rescue pack in the follow-up period without hospitalization. Severe exacerbations were defined as having been hospitalized for COPD during the follow-up period.

Study procedures

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Participants were visited in person at their homes by independent data collectors at baseline and quarterly thereafter over one year, for a total of five visits. We evaluated engagement with intervention components and fidelity to the intervention using a mixed-methods approach. First, we measured indicators of engagement with the intervention, including use of the Action Plan by participants and rescue pack use, at each of the quarterly follow-up visits via questionnaire. We also carried out semi-structured interviews with 17 participants (five in Nepal, five in Peru, seven in Uganda) and 11 CHWs (two in Nepal, two in Peru, seven in Uganda) during the follow-up period and with three field supervisors (one in Nepal, one in Peru, and one in Uganda). Each interview lasted between 30 and 60 minutes. Interviews with participants were carried out in the local language and translated into English by qualified translators for analyses. CHWs completed visit logs after each monthly visit. During initial and monthly home visits, CHWs recorded notes about their interactions with participants, including whether the participant was receptive to the visit, topics discussed during the education session, and observations regarding participants' use of the action plans and rescue packs.

Biostatistical methods

We took the approach recommended by Cocks and Torgerson [24] for sample size calculation of a pilot trial. We calculated that 112 participants per arm would be needed to produce an 80% one-sided confidence interval that excluded a 4-point difference in total SGRQ score and a standard deviation of 25 points under the scenario of no difference in means [25]. A final sample size of 240 participants would thus allow for

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greater precision while accounting for a 5-10% loss to follow-up. We conducted analyses in R version 4.2.2 [26] based on a pre-defined statistical analysis plan.

All analyses were intention-to-treat. We compared the total SGRQ score at 12 months between trial arms using a linear regression model adjusted for baseline SGRQ score and study site. We conducted a similar analysis for SGRQ sub-scores. In sensitivity analyses, we adjusted for age, sex, the modified Medical Research Council (mMRC) Dyspnea Scale score, and pre-bronchodilator FEV_1 (in L). In a sensitivity analysis that included data for all 239 participants, we estimated mean differences in total SGRQ scores between the intervention and control arms at 3, 6, 9, and 12 months post-randomization using a linear mixed effects regression model, which included an evaluation of intervention arm by time-point interactions and adjusted for site and a random intercept by subject.

In secondary analyses, we compared the proportions of participants who experienced all-cause hospitalization and moderate-to-severe COPD exacerbations at 12 months between study arms using a log-binomial regression. We used linear regression to estimate differences in mean EQ5D scores at 12 months adjusted for baseline scores and study. Missing data were assumed to be missing at random. We therefore used complete case analyses.

Qualitative data analysis

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In-depth interviews were digitally recorded, transcribed, and translated into English by bilingual professionals as needed. Handwritten CHW observation notes from each home visit were translated into English for coding purposes. We developed a codebook that included several thematic codes relevant to engagement with the intervention components and fidelity through a process of initial line-by-line coding followed by group discussion and consensus. We then used the codebook to interpret the interview transcripts and field notes and identified quotations relevant to engagement with the Action Plan.

Ethical considerations

This trial was approved by the ethics review boards of Johns Hopkins University School of Medicine (IRB00139901) in Baltimore, USA: University College London (#9661/001) in London, UK; A.B. PRISMA in Lima, Peru (CE2147.17); Makerere University in Kampala, Uganda (REC 2017-096); and the Nepal Health Research Council (Reg No.136/2017) in Kathmandu, Nepal. All participants provided written informed consent.

Role of funding source

The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

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RESULTS

Participant characteristics

A total of 10,664 participants (3,534 in Nepal, 3,550 in Peru and 3,580 in Uganda) participated in the parent study and 467 (147 Nepal, 73 Peru, 247 Uganda) were identified as having grade B-D COPD [14]. Of these, we consecutively enrolled the first 241 participants who agreed to participate in the trial. Two participants were later found to not have grade B-D COPD. We therefore randomized 239 participants, 120 were assigned to the intervention and 119 to the control arm (Figure 1). Intervention participants were on average 3 years older when compared to controls but otherwise had similar characteristics (Table 2). Intervention participants had similar lung function at baseline when compared to controls and low use of COPD medications at baseline. A total of 33 participants were lost to follow-up (20 in the control and nine in the intervention arm) and four died (three in the control and one in the intervention arm) over the 12 months of follow-up (Figure 1).

Difference in total St. George's Respiratory Questionnaire score

There were no differences in total SGRQ score between the intervention and control arms at 12 months (Table 3) or at any quarterly visit (Figure 2). After adjusting for total SGRQ score at baseline and study site, the difference remained small (mean difference 1.0, 95% CI -4.2 to 6.1; p=0.71). In a sensitivity analysis that included all participants (120 intervention and 119 controls) and used all SGRQs collected between 3 and 12 months, the difference in total mean SGRQ score between the intervention and control

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arms was 0.2 (95% CI -4.3 to 4.6). We did not identify an interaction between intervention arm and time-point in this multiple time-point analysis (p=0.54).

Differences in secondary outcomes

There were no differences in SGRQ sub-scores between intervention and control arms at 12 months (Table 3) or at any other quarterly visit (Figure 2). Models adjusting for age, sex, and disease severity, and sensitivity analyses adjusting for predictors of missingness gave similar results. There were also no differences in EQ5D scores or in the EQ5D visual analog scale score at 12 months (Table 3). At 12 months, intervention participants had a higher proportion of hospitalizations and moderate-to-severe exacerbations that received treatment when compared to controls (Table 3).

Indicators of engagement with the intervention

The overall percentage of individuals in the intervention arm who reported using their Action Plans at each follow-up period (3, 6, 9, and 12 months) was 46.6%, 53.0%, 44.7%, and 43.6%, respectively (Figure 3). We also show the mean (SD) number of rescue packs used by intervention arm in Table 4. Field notes were consistent with survey results in that few participants, across sites, referred directly to the COPD Action Plan for their COPD management. Some participants reported memorizing the Action Plan contents instead of consulting the plan directly. Others used them only for the pulmonary rehabilitation exercises, whereas some did not use them at all.

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> "I know everything from the Action Plan booklet by reading it many times, that's why I don't read it anymore…" (Field notes; Nepal).

There was also evidence that understanding of the Action Plan zones did not always align with what the intervention was intended to communicate.

> "When I'm in the yellow zone…it's because I'm improving, right?...So if I don't improve, I'd be in the red zone, the red zone is danger, right? So now, I've been taking my pills and all, I'm improving, I'm in the amber [yellow] zone and I want to get to the green zone,…I hope I get there. (Participant; Peru)

Finally, low literacy in Nepal was cited as a barrier to use of the Action Plan.

The percent of intervention participants who reported using rescue packs during the previous 3 months was 48.3%, 45.2%, 41.2%, and 31.8% (3, 6, 9, and 12 months) in the intervention arm, and 10%, 11.5%, 18.4%, and 10.4% in the control arm (Figure 3). Results from interviews and field notes across all three sites suggested that some participants were taking rescue medications every month, irrespective of whether they had an exacerbation. We observed that some participants were taking the rescue packs preventatively or not completing the full course of medications.

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> "One [CHW] mentioned how one of the patients...always takes the medicine as soon as he is given them and takes them irrespective of whether he has an exacerbation or not" (Meeting notes; Uganda).

> "[Participant] doesn't understand rescue pack usage and purpose. Wants to take steroids preventatively to help him when he leaves home" (Field notes; Nepal)

Fidelity

Results from the fidelity checklists demonstrate that CHWs had good adherence to protocol standards during observation visits (Online Supplement). Field notes and interviews showed that CHWs sometimes had challenges or forgot to emphasize the differences between the two yellow zones on the Action Plan. Furthermore, while some CHWs felt comfortable correcting medication misuse, others did not have confidence to correct those behaviors. Overall, the CHWs exhibited excellent interpersonal skills and work ethic, and excelled most at providing emotional and social support during the visits.

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DISCUSSION

We conducted a pilot effectiveness-implementation randomized field trial of a multi-component, CHW-supported self-management COPD action plan in a group of 239 participants with grade B-D COPD living in three low-resource settings in Nepal, Peru, and Uganda to improve respiratory health quality of life, and reduce hospitalizations and exacerbations. We found no evidence of differences in respiratory health quality of life between intervention and control arms, suggesting that proceeding to a larger trial with the currently proposed strategy is not warranted. Moderate-to-severe exacerbations, as defined by use of treatment, were more commonly documented in the intervention arm as compared to controls. While the results of our trial cannot differentiate between a failed intervention or a failed implementation of the intervention, it suggests that the strategy across our settings should be revised.

Self-management interventions for COPD that include Action Plans have shown variable results for improving respiratory-disease related quality of life and respiratory-related hospital admissions. However, pooled analyses have shown that such interventions can lead to improvements in these outcomes [3,27]. Aboumatar and colleagues examined the effect of a transitional care and long-term self-management support intervention after discharge for individuals hospitalized due to COPD in Baltimore, USA [28]. Like our study, the investigators found a higher proportion of COPD-related hospitalizations and emergency room visits in the intervention arm, without improvement in quality of life. One possible explanation for the higher number of hospitalizations in the intervention arm in both studies is a heightened awareness of symptoms, as well as increased self-initiated healthcare utilization. In our study, close

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communication with a CHW may have led to increased referrals to acute care services and appropriately higher use of rescue packs. The higher dropout rate in controls when compared to intervention participants may also have led to attrition bias, whereby individuals in the control arm with more severe illness and higher hospitalization rate were lost to follow-up and therefore not captured in our analyses. One potential explanation for the differential dropout is that individuals in the control condition may have lost interest and perceived less of a direct benefit given that they only received the initial COPD education visit and access to medications by going to a local distribution point. A second potential explanation is that individuals in the control arm had poorer COPD control, and thus their ability to continue in the study was compromised.

Administrative records, interviews, and field notes suggested that rescue packs were used more often by intervention participants as compared to controls. The availability of rescue packs in the home has the potential to facilitate access to timely treatment for a COPD exacerbation, particularly for individuals with functional limitations that might restrict their ability to leave their homes to procure medications. However, this availability increases the likelihood of medication overuse. It is challenging to differentiate appropriate use from overuse in community-based studies. Midway through the trial, in response to several reports of suspected rescue pack overuse, we instituted a protocol whereby individuals requesting a rescue pack for three consecutive months no longer received automatic refills for rescue packs, but rather had to request one from their CHW. The CHW would provide further rescue pack education and then refer the participant to the physician for evaluation to ensure a refill was appropriate. Of note, the medications included in the rescue packs (antibiotics, steroids) are generally available

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and comparatively affordable in local pharmacies in all three settings [17]. This occurrence highlights the importance of training CHWs to provide oversight of medication use, and availability of a qualified clinician to provide additional expertise as needed. Considering the limited healthcare infrastructure for treating COPD in these settings and the challenges with providing clinical oversight, the role of the CHW and clinician in overseeing treatment should be carefully delineated. In addition, as demonstrated by the low baseline use of inhaled preventative medications in this population, there is a clear need for expanded, facilitated access to long-term COPD medications in low-resource settings in LMICs [17, 29] at the health system level.

Our study has several strengths. This is one of few studies to implement a COPD self-management intervention in LMICs. Evaluating the multi-component self-management intervention in multiple settings allows for exploration of clinical outcomes as well as implementation across diverse communities in LMICs. Given the context-specific challenges and the disproportionate burden of disease in LMICs, this is an important strength. However, our study also had important limitations. Our study was not powered to detect differences in clinical outcomes at each of the study sites; rather, the study was designed to inform the decision to proceed to a larger future trial. Furthermore, the higher percentage with group D in the intervention arm could have led to a bias toward the null; future studies should stratify enrollment by disease severity. We did not collect data on availability of primary care and pulmonary physicians. While there was a suggestion that antibiotics and steroids may have been overused among some participants, we were not able to evaluate whether there was increased risk of infection as a result. The intervention did not include inhalers, but rather focused on training and

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support to identify COPD exacerbations and make informed decisions on when to seek care. The addition of inhaler education would be beneficial for any future iterations of this program, although access to affordable medications at these sites is limited. Finally, there was a larger proportion of participants who died or were lost to follow-up in the control when compared to the intervention arm. Despite following standard of care practices for controls, it is possible that disparities in services offered to participants between the intervention and controls arms may have contributed to differential dropout. Future studies should provide incentives to mitigate this problem.

There are aspects to our intervention design and strategies for implementation that merit discussion. In-depth interviews with participants and CHWs suggested that the regular visits and follow-up provided by CHWs was, for many participants, a welcome source of support and education. Many CHWs found satisfaction in providing this support, while others saw it as an additional burden on their existing responsibilities. Self-reported adoption of the COPD Action Plan across settings was moderate (generally less than 50%), highest in Peru and lowest in Nepal. Given that we measured use of the Action Plan via self-report, it is likely that actual use was lower. Interviews, observations, and administrative records taken as part of the process evaluation (forthcoming) suggest that the design and mode of delivery for the Action Plan (e. g. didactic vs. interactive), as well as the user interface of our rescue packaging, could have benefited from a more rigorous, iterative design process that employs methods and principles from user-centered design.

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Inclusion of task shifting strategies to support individuals in self-management and linkage to care has the potential to overcome many structural limitations in the health system. However, the effectiveness of self-management interventions such as the one tested in this study, whether delivered via task shifting or otherwise, will be limited by the health system, economic, and geopolitical contexts in which they are implemented. For example, both Nepal and Uganda have larger CHW networks that perform home visits as part of their regular duties and are compensated. In Peru, CHW networks are smaller and often hired for shorter-term programs, such as vaccination campaigns or care of the elderly. These and other factors, such as existing workload and specific role within the overall health system, would influence intervention fit or required adaptations in a particular setting. Furthermore, in the absence of COPD medication availability [3,17], CHWs would be unable to carry out their duties in distribution of evidence-based treatments. As such, task shifting strategies should complement larger-scale structural reforms to improve the quality and accessibility of chronic disease treatment and care.

Conclusions

We found that a multi-component COPD self-management intervention supported by CHWs did not improve disease-specific quality of life and resulted in a higher proportion of treated moderate-to-severe exacerbations defined by use of rescue packs, with the suggestion of overuse, compared to standard of care plus COPD education. We carried out this intervention across three low-resource community settings in three different continents that varied in culture, level of urbanization, and healthcare infrastructure and resources. Interventions and accompanying implementation strategies should be

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carefully adapted to the social, structural, and systemic contexts in which they are carried out. This pilot trial, while not definitive, provides insight into the important considerations and challenges for implementing COPD self-management interventions in such contexts, where diagnosis and treatment gaps are vast, and availability and access to evidence-based treatments is limited. Special attention should be paid to the potential for antibiotic and oral steroid overuse in self-management interventions for COPD. CHW or other task shifting models have potential to improve detection, linkage, and treatment outcomes for people living with COPD in LMICs. However, their effectiveness will be limited without complementary structural and system-level interventions to address inequities in the quality, availability, and affordability of COPD care across the globe.

Acknowledgements

We gratefully acknowledge the contributions of the field research teams, participants in the trial, the communities in which the trial took place, the trial steering committee, the Medical Research Council, and the Global Alliance for Chronic Disease research network. We also acknowledge Dr. Lindsay J Underhill for providing insightful comments on this manuscript.

Data Sharing

Individual participant data that underlie the results reported in this article, after deidentification, will be shared upon request by study authors with researchers who

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provide a methodologically sound proposal. The data will be available beginning 9 months and ending 36 months following article publication.

List of Abbreviations

Chronic obstructive pulmonary disease (COPD); low- and middle-income countries (LMICs); community health worker (CHW), St. George's Respiratory Questionnaire (SGRQ); Global Excellence in COPD outcomes trial (GECo-2); EuroQol-5 Dimension (EQ-5D)

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Table 1. Economic and demographic characteristics of study sites. Data from the World Bank [30].

	Nepal	Peru	Uganda
Classification by income level	Low-income	Upper-Middle-Income	Low-income
Country region	South Asia	South America	East Africa
Country population (2018)	26.5 million	32.2 million	41.5 million
% rural population	80%	22%	76%
Gross Domestic Product	33 billion USD	223 billion USD	40.5 billion USD
% living below the poverty line (2019)	15%	20%	21% (2016)
Study site (urbanization status)	Bhaktapur (peri-urban)	San Juan de Miraflores, Lima (urban)	Nakaseke (rural)

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Table 2. Baseline characteristics of participants in the intervention and control arms.

Characteristic	Intervention	Control
Age in years, mean (SD)	68.0 (10.9)	65.1 (10.8)
Number of females (%)	52 (43.3%)	45 (37.8%)
Income in USD/month, mean (SD)	116.8 (156.8)	133.8 (184.6)
Number of current smokers (%)	29 (24.2%)	25 (21.0%)
Previous diagnosis of pulmonary tuberculosis (%)	13 (10.8%)	16 (13.4%)
Uses biomass daily to cook %	51 (42.5%)	52 (43.7%)
Body mass index in kg/m^2, mean (SD)	22.5 (4.3)	22.9 (5.0)
Lung function		
Post-bronchodilator FEV_1 Z-score L, mean (SD)	-2.08 (1.23)	-2.19 (1.16)
Post-bronchodilator FEV_1 % predicted, mean (SD)	64.5% (21.5%)	63.5% (20.2%)
Post-bronchodilator FEV_1/FVC Z-score, mean (SD)	-2.87 (0.95)	-2.94 (1.04)
Post-bronchodilator FEV_1/FVC, mean (SD)	0.56 (0.10)	0.56 (0.11)
COPD category		
B	79 (66.4%)	97 (80.8%)
C	3 (2.5%)	3 (2.5%)
D	31 (26.1%)	17 (14.2%)
Site		
Nepal	49 (41.2%)	51 (42.5%)
Peru	20 (16.8%)	20 (16.7%)
Uganda	50 (42.0%)	49 (40.8%)
Prior chronic respiratory disease diagnosis, n (%)		
COPD	10 (8.3%)	10 (8.4%)
Chronic bronchitis	40 (33.3%)	39 (32.8%)
Emphysema	1 (0.8%)	1 (0.8%)
Comorbidities, n (%)		
Hypertension	32 (26.7%)	23 (19.3%)
Heart disease	6 (5.0%)	4 (3.4%)
Angina	4 (3.3%)	1 (0.8%)
Diabetes	8 (6.7%)	7 (5.9%)

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	Lung cancer	0 (0%)	0 (0%)
	Tuberculosis	13 (10.8%)	16 (13.4%)
Regular medication use, n (%)			
	Inhaled corticosteroids	1 (0.8%)	2 (1.7%)
	Short-acting beta agonists	9 (7.5%)	8 (6.7%)
	Short-acting anti-muscarinic	3 (2.5%)	6 (5.0%)
	Long-acting beta-agonists	5 (4.2%)	4 (3.4%)
	Long acting anti-muscarinic	4 (3.3%)	4 (3.4%)
	Xanthines	0 (0.0%)	1 (0.8%)
	Non-inhaled steroids	1 (0.8%)	2 (1.7%)

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Table 3. Unadjusted and adjusted differences in primary and secondary outcomes by study arm at 12 months of follow-up. These include the St. George's Respiratory Questionnaire (SGRQ) scores (adjusted for site and baseline value), the percentages of participants experience hospitalizations or moderate-to-severe exacerbations (adjusted for site), and the five-dimension, three-level EuroQol health-related quality of life (EQ5D) and the EQ5D visual analog scale scores (adjusted for site and baseline values). *SGRQ scores are 12-months were missing in 3 participants (1 intervention, 2 controls).

Outcome	Intervention (n=110)	Control (n=96)	Mean unadjusted difference (95% CI) or RR (95% CI)	Mean adjusted difference (95% CI) or RR (95% CI)
Total SGRQ score, mean (SD)*	34.7 (20.2)	34.0 (20.8)	0.6 (-5.1 to 6.3)	1.0 (-4.2 to 6.1)
SGRQ sub-scores*				
Impact, mean (SD)	26.2 (21.6)	27.8 (22.6)	-1.6 (-7.8 to 4.5)	-1.0 (-6.5 to 4.5)
Activity, mean (SD)	50.6 (25.4)	45.3 (24.7)	5.3 (-1.6 to 12.3)	5.2 (-1.1 to 11.4)
Symptoms, mean (SD)	32.3 (18.0)	32.9 (24.1)	-0.6 (-6.6 to 5.4)	-0.2 (-5.7 to 5.3)
Participants experiencing at least one hospitalization, % (n)	11 (10.0%)	5 (5.2%)	1.9 (0.7 to 5.2)	2.2 (0.8 to 7.5)
Participants receiving treatment for at least one moderate-to-severe exacerbation, % (n)	78 (70.9%)	26 (27.1%)	1.4 (0.8 to 1.9)	3.0 (0.7 to 2.1)
EQ5D score, mean (SD)	7.5 (1.8)	7.8 (2.2)	-0.03 (-0.9 to 0.3)	-0.02 (-0.7 to 0.3)
EQ5D visual analog scale score, mean (SD)	69.1 (14.8)	71.3 (15.1)	-2.1 (-6.2 to 2.1)	-1.7 (-5.4 to 2.1)

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Table 4. Mean (standard deviation) number of rescue packs used over 3 months by intervention arm and time-point.

	Mean (SD) number of rescue packs used in 3-month intervals							
	Intervention				Control			
	Overall	Uganda	Peru	Nepal	Overall	Uganda	Peru	Nepal
3 months	1.1 (1.6)	1.4 (1.9)	1.2 (1.1)	0.7 (1.4)	0.2 (0.8)	0.4 (1.1)	0.2 (0.6)	0.0 (0.0)
6 months	1.1 (1.7)	1.5 (1.8)	1.4 (1.7)	0.5 (1.4)	0.2 (0.6)	0.5 (0.9)	0.1 (0.3)	0.0 (0.0)
9 months	0.7 (1.2)	1.0 (1.4)	1.2 (1.2)	0.2 (0.4)	0.3 (0.9)	0.8 (1.2)	0.0 (0.0)	0.0 (0.0)
12 months	0.6 (1.1)	0.9 (1.2)	0.8 (1.0)	0.2 (0.8)	0.2 (0.5)	0.4 (0.8)	0.0 (0.0)	0.0 (0.0)

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Figure Legends

Figure 1. CONSORT Diagram of Participant Flow Through the GECo 2 Study.

Figure 2. Comparison of differences in SGRQ total score and sub-scores (activity, impacts, symptoms) at baseline and 3, 6, 9, and 12-month follow-up visits between intervention and control arms. The blue lines represent the intervention arm, and the red lines represent the control arm. The diamond point estimates indicate the means, the thicker lines represent the 80% one-sided confidence intervals, and the thinner lines represent the 95% confidence intervals.

Figure 3. Indicators of engagement with the intervention among intervention arm participants. The top panel displays the percentage of participants, overall and in each site, at 3, 6, 9, and 12-months follow-up, that answered “yes” to the question, “During the last three months, have you used your action plan?” The second panel displays the percentage of participants who answered “yes” to the question, “[Among those who did use the action plan], did your action plan help guide your decision to take medications or seek medical care? The third panel displays the percentage of participants who answered “yes” to the question, “During the last three months, did you use a rescue pack?”

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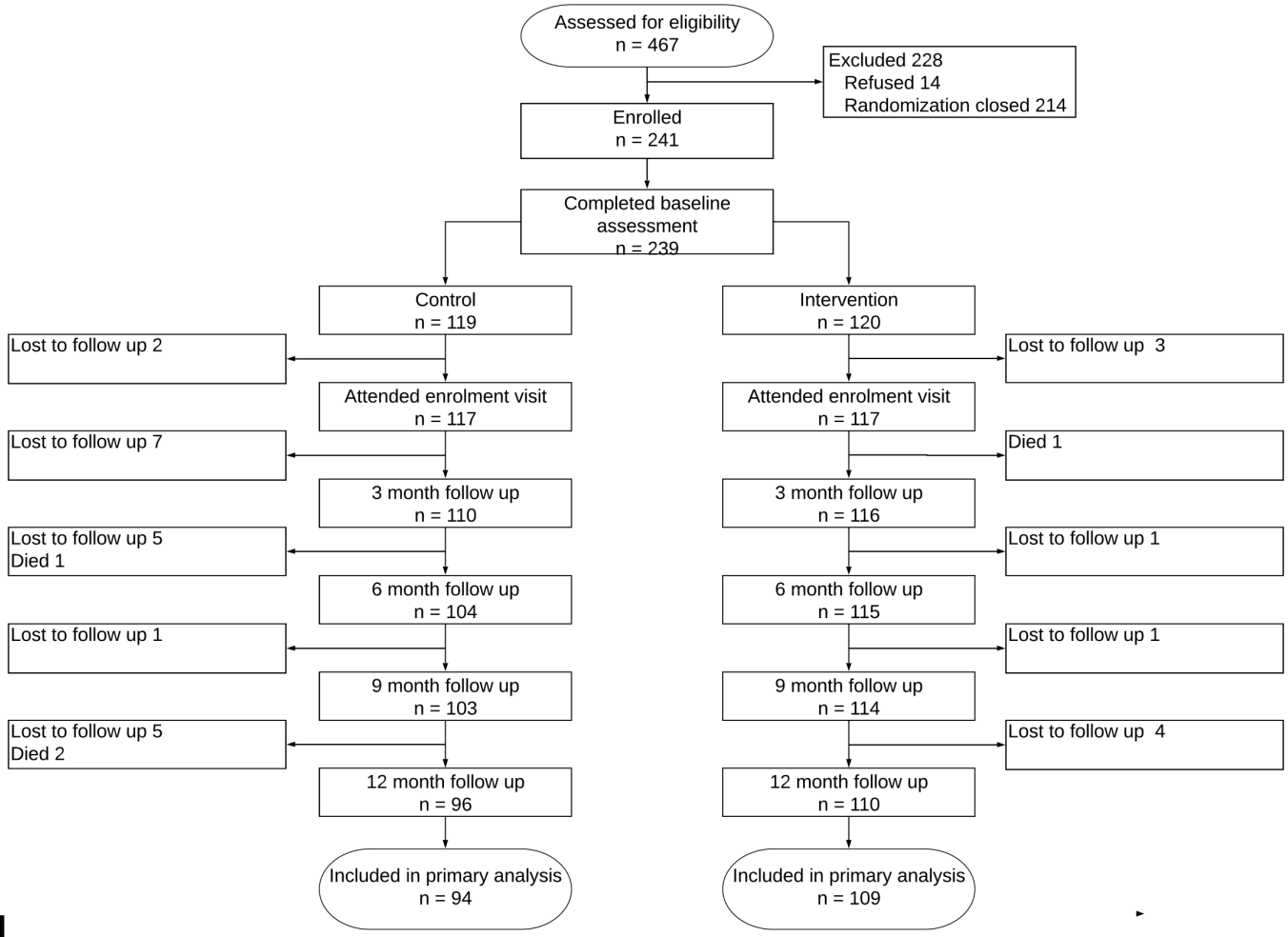

Figure 1.

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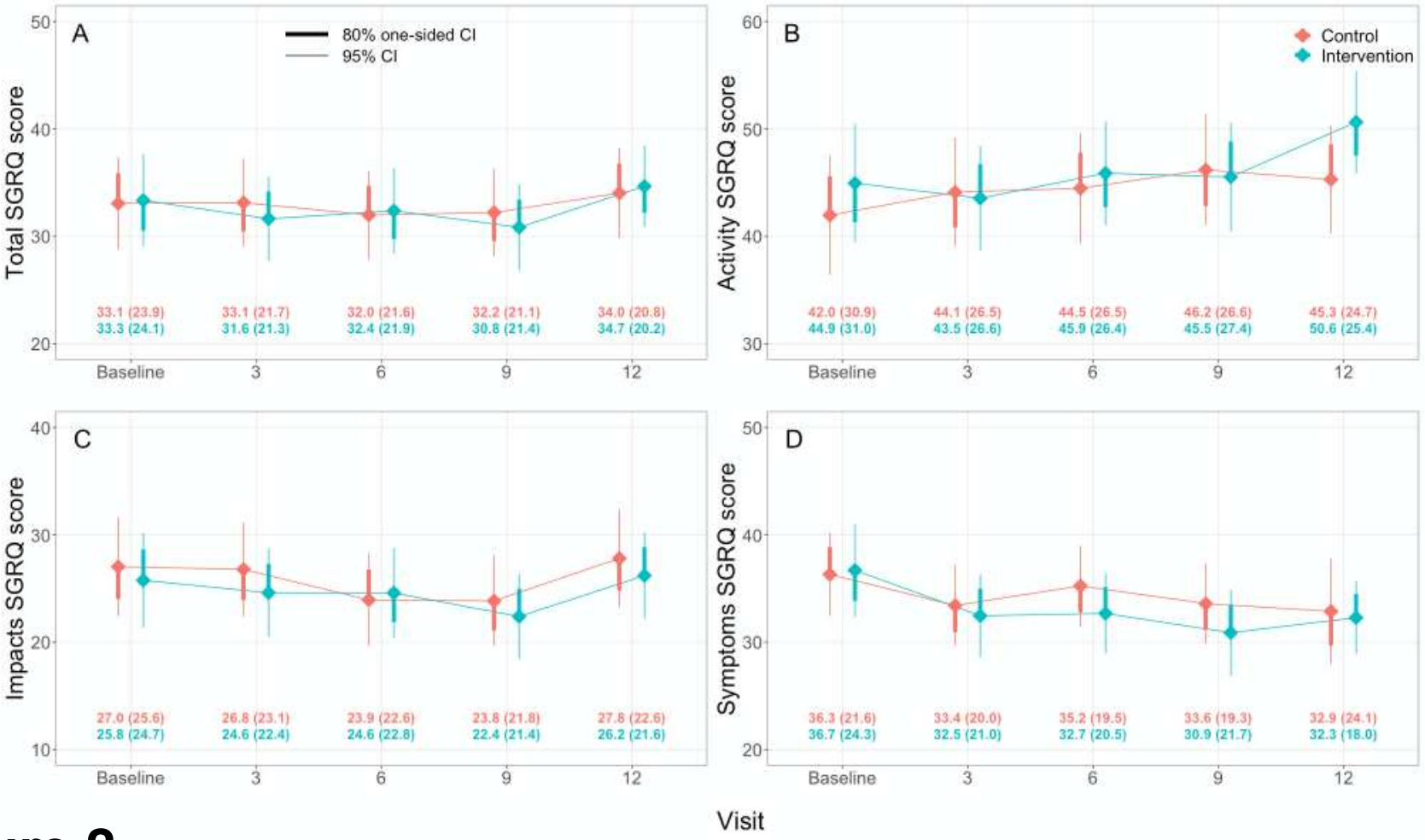

Figure 2.

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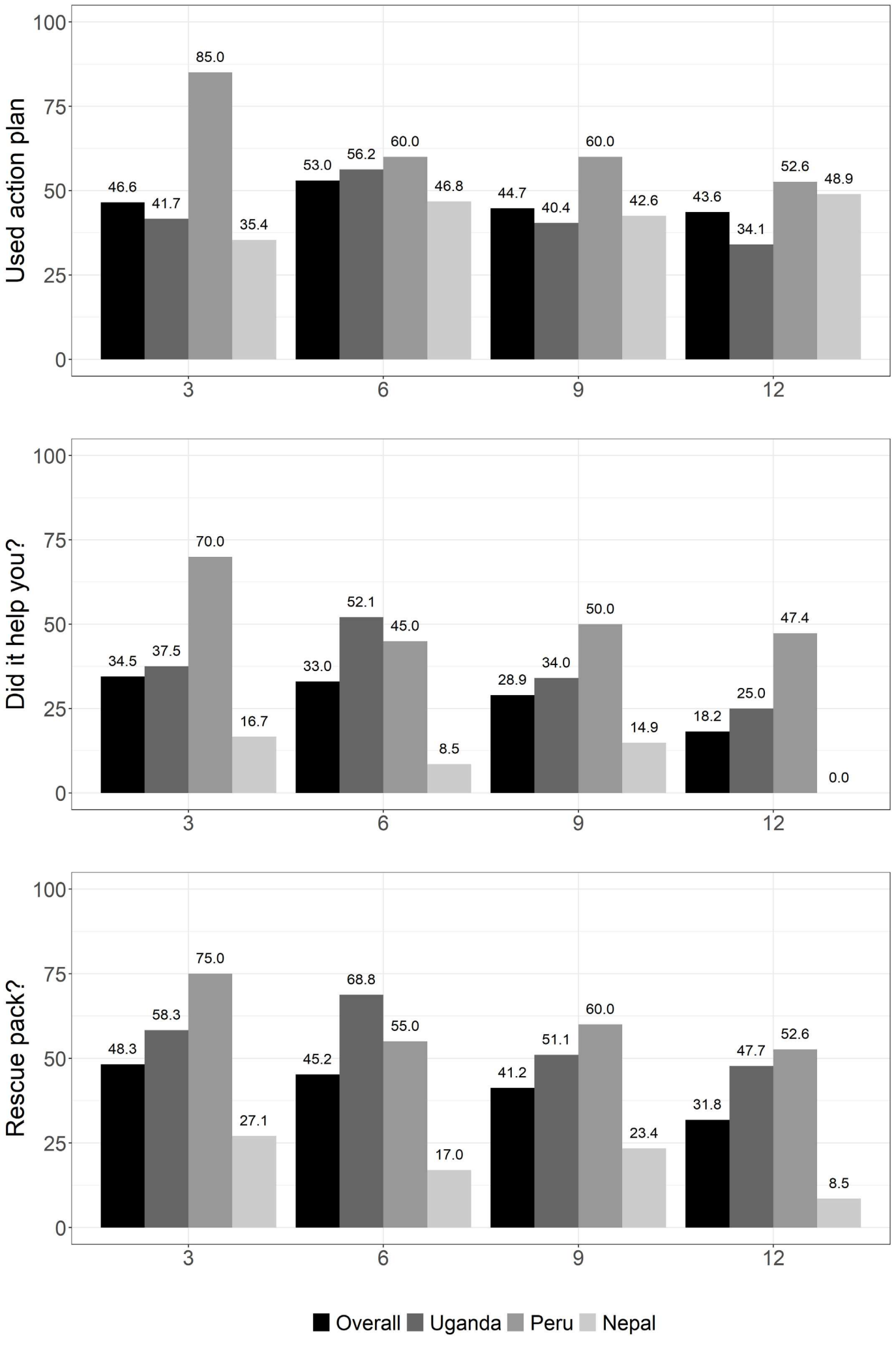

Figure 3.

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Chronic obstructive pulmonary disease self-management in three LMICs: a pilot randomized trial

Suzanne L Pollard, Trishul Siddharthan, Shakir Hossen, Natalie A Rykiel, Oscar Flores-Flores, Patricia Alupo, Shumonta Quaderi, Ivonne Ascencio, Julie A Barber, Ram Chandyo, Santa Kumar Das, Gonzalo Gianella, Bruce Kirenga, Kelli Grunstra, J Jaime Miranda, Sakshi Mohan, Federico Ricciardi, Arun K Sharma, Laxman Shrestha, Marta O Soares, Adaeze C Wosu, John R Hurst, William Checkley; for GECo-2 trial investigators

ONLINE DATA SUPPLEMENT

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Flipchart Manual for CHW Training across sites (in detail)
CHW Training Manual: Researchers training CHWs

Equipment needed:

- Flip Chart
- Board, large notepad or somewhere to write
- Large straws and thin straws, small cup
- Notepads & pens for CHWs
- Refreshments

Step 1: Introduction

- *Name:* Hello I am X, and I work as a X
- *Where From:* I live in X
- *Why Here:* I am part of a team of researchers who want to improve lung health in this country by finding easier ways to diagnose a lung problem called COPD. You will learn about COPD today and then part of this research will be to work together, to try and help people who have this condition in (mention where you are) understand what it is, and manage their symptoms better.

*Distribute **COPD Knowledge Questionnaire**. Explain that this is to assess their baseline understanding of COPD, it is just to give our team an idea of how well our training will be conducted.*

Step 2: Role and motivations of CHWs

- "Why did you become a CHW?"
- "Why have you continued your work as a CHW?"
- Importance of CHWs:
    - We can see that you as a CHW are a valuable person within your community. You help connect people to health care and help provide them health education.
- Why involved:
    - As said before, we hope you, as a CHW, can work with us to help people in the community understand and manage their symptoms of COPD.
- Benefits/Motivation:
    - *For you:* You will learn about COPD and be able to offer people guidance on their care and help them better deal with their symptoms.
    - *For the community:* This means people with COPD will be able to care for their symptoms at home and sooner. Then they will hopefully avoid ending up in the hospital and having many costs, will miss less work and will feel better faster!
- Your role:
    - You will help us educate people with COPD about their disease using this tool, the flipchart
    - You will be taking it to peoples' homes to help you teach people about COPD. The front side with pictures will be facing the patient. The backside will have the text as a guide for you.
    - You do not need to read this word-for-word. It is meant to help you in your teaching.

Step 3: Review with first image

Role of Lungs: What are your lungs and what do they do?

- Your lungs make up one of the largest organs in your body and are found in the chest.
- Your lungs allow you to breathe, talk, sing, laugh, cry.

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- Your lungs are controlled by your brain to help you breathe in and out.
- Your lungs are where exchange of air takes place. They take in fresh air (oxygen) and get rid of stale air (carbon dioxide).
- Instruct everyone: "To feel how powerful your lungs are: Put your hands on your chest and breathe very deeply. You will feel your chest getting slightly bigger. Now breathe out the air, and feel your chest return to its regular size."

- **What do you know about COPD?**
  - Explore CHW perceptions and potential misconceptions
  - Ask CHWs to write their thoughts about COPD on paper and put the papers in a bowl. This can cover; the disease, treatment, if they have met anyone with COPD, etc.
  - Read out the anonymized suggestions and discuss.

** * Can show educational video here if need be. Depends on site's baseline COPD knowledge.*

Step 4: Flipchart
Page 4: What Is COPD?

- Write out the acronym then fill in words.
  - C = Chronic O = Obstructive P =Pulmonary D = Disease.
  - This allows you to focus on the chronic portion. "Chronic means long-term, not that it is particularly bad."
- "A chronic lung disease that is preventable and treatable"
- "Chronic Obstructive Pulmonary Diseases = chronic bronchitis ***and/or*** emphysema. They usually occur together but can occur separately.
- The airways within your lungs become narrow, making it hard for your lungs to do their job."
  - Have big straw and thin straw to illustrate obstruction. Explain- narrow airways/ flattened alveoli= mucous settles, therefore higher chance of infection and exacerbations.
- Show image of lungs:
  - Healthy lung (pink, left), Diseased from smoke (black, right).
  - "Patients can look different but have similar signs/symptoms"

Page 4 (text) and Page 5 (picture of woman): Symptoms of COPD

- **"When you are getting sick from COPD, what do you feel like?"**
- Ask what kinds of symptoms someone would have if they had trouble with their lungs; trouble getting air into them. Help it to seem logical. "How do you feel when you walk around/run?" to get them to relate to feeling out of breath, tired, etc.
- Suggested Order of Logic
  - Fatigue/Tired – lower energy due to lower oxygen
  - Breathlessness- a need for air
  - Chronic cough
  - Excessive sputum/mucus production
  - Add: Infections?

- (Keep Symptoms up on Flipchart but leading to causes) "What things may cause these symptoms? When you are healthy what makes you cough?"

Page 6 and 7: Causes of COPD

- "Why do you think people get COPD?" Review their understanding of causes.

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- "Keeping your lungs looking and feeling healthy is a smart idea, and the best way to keep your lungs healthy is not to smoke. Smoking isn't good for any part of your body, and your lungs especially hate it. Cigarette smoke damages:

  1) Cilia (tiny hairs that line the airway that help get rid of mucus) in the trachea (your windpipe) so they can no longer keep dirt and other substances out of the lungs. In COPD the alveoli get hurt too, because the chemicals in cigarette smoke can cause the walls of the alveoli to break down, making it much harder to breathe.

  2) Alveoli (small sacs in your lungs that allow oxygen from the air to pass into your blood). In COPD the alveoli get hurt too, because the chemicals in cigarette smoke can cause the walls of the alveoli to break down, making it much harder to breathe."

  If going into detail: " All the cells in the body need oxygen every minute of the day. Oxygen passes through the walls of each alveolus into the tiny blood vessels that surround it. The oxygen enters the blood in the capillaries, attaches to red blood cells and travels through the heart. The heart then sends the blood full of oxygen out to all the cells in the body."

  "Finally, cigarette and indoor smoke/ air pollution (explain here that's it's all smoke, so can focus on the biomass relevant to each site) can damage the cells of the lungs so much that sometimes the healthy cells go away, only to be replaced by cancer cells. Lungs are normally tough and strong, but when it comes to cigarettes, they can be hurt easily — and it's often very difficult or impossible to undo any damage. "

- Suggested Order:
  - Tobacco Smoking: (*picture of people smoking*): Number one thing that you can change to improve your health
  - Smoke from Cooking and Heating: (*picture of indoor cooking, gas*)
    - "What kinds of smoke would you see in your home?"
    - Focus on the smoke portion of it as relating between all items. Include smoke from candles, mosquito coils, etc.
  - Smoke from Outside (*factories, trash burning)*:
    - "What looks like smoke when you are outside? What air pollution do you see outside?" (Cars, Trucks, motorcycles, dust, burning trees, trash etc.)
  - Vapours are like smoke:
    - Example: cleaning solution/detergent and if too close it goes up your nose and makes you cough. Most people have cleaned something and then can use that to expand to occupational
    - To relate: "Do you ever smell gas from the stove in your home?"
  - Infections: Infections are both a cause and a symptom.
    - To help patients, advise that they take the full amount of meds and take care of infections when they first see signs so they don't become worse or long-term.

- **Page 8, 9 (picture of man): Timeline & Consequences**: As per the flip chart.
  - Preventable and treatable, progressively worsening symptoms (breathless, cough, mucus, fatigue), functional limitation (unable to work or take care of self, stop leisure activities), susceptible to repeat chest infections
  - Leads directly into how to avoid

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- **Page 10: Treatment and Management**- How to avoid: As per the flipchart
    - Ask them to brainstorm: "What can we do to avoid further harm to our lungs?"
        - Offer alternatives vs. just saying do or don't. Offer ways to improve or ask the focus group what are the available options?
    - Stop burning trash, wear a mask when around dust, if lighting candles etc. do it in an open area (windows or outside)
    - Focus on exercise, sleeping or eating well. "These are free"
        - Brainstorm: "What are some healthy foods?"
    - "Being active doesn't need to be difficult, I will show some easy ways later"
    - End with vaccinations because you can loop back to infections again as a way to prevent (this may be more relevant at some sites than others depending on what is offered as part of usual care)

- **Page 11 (Before/After Cessation picture)**:
    - Discuss briefly how basic COPD education can help to get to this stage. (Can go through the basic physical activities on page 17).

- **Page 12, 13: Exposure reduction**
    - Quit smoking—will read benefits on page 14
    - How to control biomass: (Cover in brief as not very relevant to site)
        - "Most people have LPG, these are other good options to help limit smoke and indoor air pollution"
        - As seen in picture: We want to encourage having a "separate cooking area if not already there and to try have open windows/doors when cooking to allow air to pass through"

- **Page 14, 15: Exposure reduction—Quit Smoking**
    - Slide 14: BENEFITS of QUITTING
        - From an education standpoint, it makes sense to go into why quit smoking both with reasons it *helps* you and reasons it *harms* you… People motivated by different reasons and <u>often will do it to help others</u>.
        - Passive /second hand smoking should be mentioned here too
    - Slide 15: HARMS OF SMOKING
        - Read through pregnancy impacts as well
        - Buergers disease: Inflammation, swelling and thrombosis (clotting) of blood vessels, typically in legs and hands. Can lead to infection and gangrene

- **Page 16, 17: Exercises!**
    - "You can also show your love for your lungs by exercising! Exercise is good for every part of your body, and especially for your lungs and heart. When you exercise, your lungs work harder and become stronger and better at doing their job (supplying your body with the air it needs). Keep your lungs healthy and they will thank you for life."
    - Read thru page 16 and practice
    - To keep it interactive – Ask group to actually get up and do exercises. Get them moving and have them experience it.

- **Page 18: When to see your doctor**
  (Note: the symptoms here vary from the AP—"mucus colored" we say, "change in mucus" in the AP I believe and we do not mention weight loss or coughing up blood as "YELLOW" stage (or ever, for weight loss)

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- Mention each of the red flag symptoms and reiterate to the CHW that it's very important that when they teach the participants, they must stress that these are worry signs and symptoms and they must seek medical care
- Remind them of their local health care providers and also which hospital to attend

Step 5: Role-Play

- In pairs, take turns acting as a patient and as a trainer. Practice training one another.
- Suggestions to act out: Patient who is hesitant to quit smoking, patient who does not follow inhaler regimen (wants to save money/believes they are addictive), patient who has excuses for not exercising, patient who doesn't want to eat "cold fruits"
    - What are our solutions?

Step 6: How to teach the patients

- Ask CHWs to brainstorm different ways of teaching the patients
    - Ideas: Rearrange furniture in the house, draw on paper, demonstrate exercises, use timeline for effects of smoking, get whole family involved

RECAP: At the end of the teaching session:

1. Any Questions?
2. Anything you'd like me to go over?
3. Get feedback from the CHWs about any changes they would like to incorporate to aid in their teaching to participants
4. Would they like another session?
5. Would they to practice on teaching other CHWs before educating participants?
6. Would they like to practice teaching to us (research staff at sites) before educating participants?

*Distribute and administer the **post- COPD Knowledge Questionnaire** at the conclusion.*

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Action Plan Training Manual across sites (in detail)
(For researchers to teach CHWs and CHWs to teach participants)

Equipment needed: The Action Plan Booklet for each relevant country, a small cup equivalent to the size of an egg-cup and then a board or somewhere to write to keep it interactive.

The CHWs should all be given a pad and writing tools so they can make notes as required.

This document is an add on to the CHW training manual we have created for the COPD Education Flip-Charts so there is no need to introduce ourselves again, however if we would like to…

- **Step 1:** Introduction
  - *Name:* Hello I am X, and I work as a X
  - *Where From:* I live in X
  - *Why Here:* I am part of a team of researchers who want to improve lung health in this country by finding easier ways to diagnose a lung problem called COPD. You will learn about COPD today and then part of this research will be to work together, to try and help people who have this condition in (mention where you are) understand what it is, and manage their symptoms better.

- **Front Page**

  Explain what our Action Plan is.

"If you have a long-term condition like COPD, you'll feel better if you self-manage your condition and take some control of your life. Our Action Plan will help guide you to understand and recognize your own symptoms. You will understand what is 'normal' for you and what it means when your symptoms change and what you need to do about it. By understanding this, you will be taking control of your chronic condition, you will be able to manage your condition and symptoms better on a day to day basis, and most importantly try to stop your lung disease from progressing.

People with COPD are more at risk of getting 'flares' of their symptoms and associated chest infections. We have already spoken about ways to minimize this, but unfortunately, sometimes these still occur, and when they do, it is very important that we recognize the symptoms and then treat these 'flares' or infections as early as possible. By doing this, we can help to prevent our lungs from being damaged further."

- **Page 1**

  CHW's to help participants fill out demographics

- **Page 2**

  Reiteration of Education tool.
  Role of CHW to is to remind participant that every day they should:
  1. Stop Smoking
  2. Try to minimize HAP by cooking in well ventilates areas, and spending as little time as possible in smoky indoor environments
  3. Remember to try and stay active (Pulmonary Rehab exercises) to keep their lungs strong
  4. To rest and try and sleep well
  5. To eat healthily with vitamin enriched food (site dependent what they choose as an example)

- **Page 3 & 4** (**green zone** over a double page spread)

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To talk through each point in this zone

IF:

- I can do my usual activities (eg. Walking) without feeling more short of breath OR breathing faster - *Visually show them someone who is panting*
- I have my usual amount of cough
- I have my usual amount of sputum/phlegm (expectoration) – *show them an egg cup and emphasize if USUALLY they fill this up in a 24hr period then this is their 'normal'. Need to illustrate that 'normal' is different for each individual*
- My sputum/ phlegm is the usual colour – *emphasize if they cough up clear or slightly creamy/white coloured sputum up every day, this is likely their baseline and what we mean by "usual"*

THEN: I am in the **Green** Zone – This Zone represents that they are doing well and don't need to take any action other than trying to incorporate healthy lifestyle changes such as: being active, avoid cigarette smoke, eating healthily and continue taking their usual medications if they are on any.

➢ **Page 4 & 5** (**yellow zone** over a double page spread)

To talk through each point in the zone

IF:

- I feel more short of breath or breathe faster doing my usual activities (e.g. walking), or
- The medicines I take for COPD, if I take any, aren't working so well today

THEN: I am in the **Yellow Zone** – I am having a bad day or a COPD flare / attack /crisis / 'exacerbation'. This zone represents that are having a COPD 'flare' and they quicker it is addressed the sooner they will hopefully get better, and the less long term damage it will do. Based on the exact symptoms they are having, they should be able to recognize if they are having a 'flare' and then start self-treatment. Explain to the CHWs that at this stage the participants may call them for advice and say should I start my medication?". If the symptoms they describe, mean they fall into the yellow zone then they should encourage the participants to start their 'flare' medication –steroids.

Actions:

- Keep taking your daily medication if you use any (re-start them if you stopped)
- Use a 'quick relief' inhaler called ___(SPECIFY DRUG/DOSE/DAYS – site dependent)___ every 6 hours if you have one
- Start oral steroid tablets ___(SPECIFY DRUG/DOSE/DAYS - site dependent)
- Avoid smoke
- Contact your CHW if the symptoms don't improve

IF:

- I feel more short of breath or breathe faster doing my usual activities (e.g. walking), or
- The medicines I take for COPD, if I take any, aren't working so well today

AND (must emphasize that these symptoms are also for a 'flare' and within the yellow zone, but if the added symptoms of more sputum, or the colour of their sputum is darker, then along with the steroids they should start antibiotics too, as it is likely they have an underlying chest infection)

- I am coughing more sputum / phlegm than usual (expectoration)
- My sputum / phlegm is darker than usual

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THEN: I am in the **Yellow Zone** – I am having a bad day or a COPD flare / attack /crisis / 'exacerbation'
Picture of man coughing - *illustrative version of having a 'flare'*
Actions:

- Keep taking your daily medication if you use any (re-start them if you stopped)
- Use a 'quick relief' inhaler called ___(SPECIFY DRUG/DOSE/DAYS - site dependent)___ every 6 hours if you have one
- Start oral steroid tablets___(SPECIFY DRUG/DOSE/DAYS - site dependent)_____
- Start antibiotics tablets___(SPECIFY DRUG/DOSE/DAYS - site dependent)__
- Avoid smoke
- Contact your CHW if the symptoms don't improve

➢ **Page 6 & 7 (red zone** over a double page spread**)**

To talk through each point in the zone

IF:

- I have severe shortness of breath / fast breathing at rest/ feel I am suffocating
- And one or more of
- Bad chest pain – *Here we should explain both cardiac chest pain and Pleuritic chest pain*
- high fever (more than 38^{O}C) and or chills – *Explain they may feel 'hot and cold'*
- coughing blood
- other people notice I have become confused or drowsy

THEN: **I am in the Red Zone -** This zone represents that they need urgent medical advice and they should not be calling their CHW but instead presenting to their nearest equivalent of a local hospital. If they do call the CHW and the CHW feels they are in the red zone, then should advise the participants to present to their nearest equivalent of a local hospital.
Picture of a doctor with a stethoscope - *illustrative version of they need to see a doctor*
Action: Seek urgent medical care at your local clinic or hospital

➢ **Page 8 and 9:**

Exercises to do at home: To reinforce the **same** Pulmonary Rehabilitation exercises as what is in the COPD Education Flipcharts
Pursed Lip Breathing - 3 x pictures and instructions
Sit to Stand – 3 x pictures and instructions
Arm punches – 3 x pictures and instructions

➢ **Page 10:** Each CHW will be assigned participants – they should highlight this page at the back and show them that their contact details are on there and where the nearest Local health care provider for the red zone is.

- Contacts
- CHW
- Local health Care Provider
- Local hospital

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RESPONSES TO THE FIDELITY OBSERVATION CHECKLISTS
(% yes)

FLIP CHART DELIVERY: TO WHAT EXTENT DID THE CHW…	PERU (N=6)	NEPAL (N=50)	UGANDA (N=13)
INTRODUCE SELF, STUDY AND ROLE AS CHW FOR THIS PARTICIPANT	100%	94%	85%
EXPLAIN THE PURPOSE OF FLIPCHART, HOW AND WHY IT'S USED	0%	94%	38%
INTRODUCE COPD SYMPTOMS, CAUSES, HEALTH CONSEQUENCES	67%	84%	92%
DISCUSS COPD TREATMENT AND MANAGEMENT	100%	96%	92%
• **AVOID BIOMASS EXPOSURE AND AIR POLLUTION**	100%	96%	92%
• **CONTINUE MEDICATIONS, RECOGNIZE CHANGE IN SYMPTOMS**	83%	96%	92%
DISCUSS EXPOSURE REDUCTION AND OFFER PRACTICAL SOLUTIONS: SITE-SPECIFIC	100%	98%	69%
DISCUSS THE EFFECTS OF SMOKING	100%	92%	92%
• **REINFORCE THE IMPORTANCE OF: EXERCISES, EAT WELL, SLEEP WELL**	100%	96%	77%
• **DEMONSTRATE PULMONARY REHABILITATION EXERCISES**	100%	96%	77%
REITERATE WHEN TO SEE THE DOCTOR, RED-FLAG SYMPTOMS	17%	96%	54%

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ACTION PLAN DELIVERY: TO WHAT EXTENT DID THE CHW…	PERU (N=4)	NEPAL (N=33)	UGANDA (N=7)
INTRODUCE SELF, STUDY AND ROLE AS CHW FOR THIS PARTICIPANT	100%	85%	86%
EXPLAIN PURPOSE OF ACTION PLAN, HOW AND WHY IT'S USED	100%	85%	71%
ASSIST IN FILLING IN PARTICIPANT-SPECIFIC INFO	100%	76%	14%
OBSERVE PATIENT ENVIRONMENT AND OVERALL PATIENT HEALTH	100%	79%	86%
• **NOTE ANY HEALTH OR ENVIRONMENTAL CONCERNS (*IMPORTANT TO COMPARE TO IN FOLLOW-UPS)**	100%	79%	71%
REITERATE IMPORTANCE OF PREVENTION FOR COPD:	100%	79%	71%
• **OFFER PRACTICAL SOLUTIONS TO LIMIT BIOMASS EXPOSURE**	100%	79%	71%
• **ENCOURAGE: EXERCISE, EAT WELL, SLEEP WELL, SMOKING CESSATION**	100%	79%	71%
• **ASK IF ANYONE IN HOUSEHOLD SMOKES (MEASURE FOR LATER)**	100%	79%	71%
EXPLAIN GREEN ZONE, YELLOW ZONE, RED ZONE	100%	82%	71%
• **IFS → ACTIONS**	100%	85%	71%
• **DIFFERENTIATE BETWEEN YELLOW ZONES: TAKING STEROIDS VS. STEROIDS & ANTIBIOTICS**	0%	85%	71%
REVIEW RESCUE PACK MEDICATIONS: DOSAGE, REFILL PROCESS,	100%	76%	100%

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DIFFERENTIATING BETWEEN ANTIBIOTICS AND STEROIDS			
ANSWER ANY QUESTIONS, OFFER AVAILABILITY FOR GUIDANCE/ASSISTANCE WITH ACTION PLAN	100%	85%	71%
EXPLAIN ONE-MONTH FOLLOW-UP PROCESS	100%	85%	43%

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