

This item is the archived peer-reviewed author-version of:

Synergistic impact of training followed by on-site support on HIV clinical practice : a mixed-design study in Uganda with pre/post and cluster-randomized trial components

Reference:

Burnett Sarah M., Mubiru Norbert, Imani Peace, Mbonye Martin K., Fisher Leigh, Colebunders Robert, Manabe Yukari C., Weaver Marcia R.- Synergistic impact of training followed by on-site support on HIV clinical practice : a mixed-design study in Uganda with pre/post and cluster-randomized trial components
JAIDS - ISSN 1525-4135 - 77:5(2018), p. 467-475
Full text (Publisher's DOI): <https://doi.org/10.1097/QAI.0000000000001630>
To cite this reference: <https://hdl.handle.net/10067/1537720151162165141>

Title: Synergistic impact of training followed by on-site support on HIV clinical practice: A mixed design study in Uganda with pre/post and cluster randomized trial components

Sarah Burnett, MPH, MPA, Norbert Mubiru, MD, MPH, Peace Imani, MBChB, MMED, MPH, Martin K. Mbonye, PhD, Leigh Fisher, PhD, Robert Colebunders, MD, PhD, Yukari C. Manabe, MD, PhD, Marcia R. Weaver, PhD

Authors' contributions: MKM and MRW conceived and designed the experiments. SMB, LF, PI, and MRW analyzed the data. SMB, NM, and MRW wrote the paper. RC and YM reviewed the manuscript to meet submission requirements. All authors reviewed and approved final submission.

Acknowledgements:

Accordia Global Health Foundation led an IDCAP partnership with Ugandan Ministry of Health, Infectious Diseases Institute, International Training and Education Center for Health, and University Research Co. LLC. The authors would like to thank the IDCAP Steering Committee for guidance, including: Drs. Geoffrey Bisoborwa, Alex Coutinho, Beatrice Crahay, Warner Greene, King Holmes, Nigel Livesley, Fred Wabwire-Mangen, M. Rachad Massoud, Alex Opio, W. Michael Scheld, and Gisela Schneider. The authors thank the IDCAP mobile team for providing OSS and clinical faculty for conducting the assessments, and the IDCAP trainees for their enthusiastic participation. The IDCAP investigators are grateful to the facility in-charges and hospital superintendents, and the HIV positive patients and their caregivers who accepted to participate in the clinical assessments. Special recognition goes to the District Health Offices who ensured that participating health professionals were not transferred out of the sites during the trial.

Acknowledgement of sources of support: This work was supported through grant number 94298 to Accordia Global Health Foundation from the Bill & Melinda Gates Foundation. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. The findings and conclusions contained within the manuscript are those of the authors and do not necessarily reflect positions or policies of the Bill & Melinda Gates Foundation.

Brief title (up to 40 characters): Impact of training and on-site support on HIV clinical practice

Corresponding Author: Sarah Burnett, MPH, MPAm, PATH, Washington, DC UNITED STATES

The authors report no conflicts of interest related to this work.

Summary:

Abstract (max 250): 250

Manuscript (max 3,500): 3,643

Figures & Tables (max 5)

Figures: 2; Tables: 3

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial License 4.0 (CCBY-NC) , where it is permissible to download, share, remix, transform, and buildup the work provided it is properly cited. The work cannot be used commercially without permission from the journal.

Abstract:

Background: Task-shifting can expand antiretroviral therapy access, but little is known about effective approaches to improve clinical practice among mid-level practitioners' (MLP) such as clinical officers, nurses, and midwives. The Integrated Infectious Diseases Capacity-Building Evaluation compared training alone to training combined with on-site support (OSS).

Methods: Two MLP each from 36 health facilities attended the five-week Integrated Management of Infectious Disease training. Following training, 18 facilities randomly assigned to arm A received OSS for nine months, while 18 arm B facilities did not. Clinical faculty assessed MLP HIV clinical practice on six tasks: history taking, physical examination, laboratory investigations, diagnosis, treatment, and patient education. We analyzed the effect of training alone and training combined with OSS as the pre/post change within each arm. We analyzed the incremental effect of OSS with a difference-in-difference analysis that compared changes between arms.

Results: Training alone and training combined with OSS significantly improved clinical practice in patient history taking (13% and 24% increase, respectively), physical examination (54% and 71%), laboratory investigations (32% and 20%) and diagnosis (31% and 51%). Combined training and OSS also improved patient education significantly (72% increase). Effect sizes for training combined with OSS were larger than for training alone except for laboratory investigations, and the effects were robust in sensitivity analyses. The incremental effect of OSS on diagnosis was significant (adjusted relative relative risk=1.23; 95% CI=1.00-1.50).

Conclusion: Combined training and OSS improved MLP HIV clinical practice over training alone and can contribute to continued expansion of access to antiretroviral therapy.

Key Words: Mid-level practitioners, Clinical practice, Quality of health care, Education, Capacity, HIV/AIDS care, Infectious diseases, Africa, South of the Sahara, Uganda

Introduction

Global efforts have rapidly increased access to antiretroviral therapy (ART); the percentage of people living with HIV on ART increased from 23% in 2010 to 53% by the end of 2016.¹ Despite more than doubling access in five years, one out of two people who need life-saving ARTs are not receiving them, and each year an estimated 2.1 million more people become infected. To reach the Fast-Track Target of 95% of people living with HIV receiving ART by 2030, access to ART must continue to expand rapidly.² While access to drugs, equipment and facilities has dramatically increased, lack of qualified human resources remains a major constraint.² To close the gap, a surge in the number of health professionals trained to provide high-quality HIV treatment is required over the next 10 years.³ Task-shifting from doctors to mid-level practitioners (MLP), which include clinical officers, nurses, and midwives, could support continued scale-up of ART and further implementation of WHO's test and treat guidelines.^{4,5} Not only are there more MLP than physicians within existing health systems, they are more likely to work in rural and underserved areas.⁶ Review have demonstrated that task-shifting can meet patient needs without sacrificing quality.^{7,8} However, few studies have compared the effectiveness of capacity-building interventions to prepare MLP to manage patients with HIV infection.

The Integrated Infectious Diseases Capacity Building Evaluation (IDCAP) project compared the effectiveness of two approaches to build capacity for the care and prevention of infectious diseases among MLP in sub-Saharan Africa: a training program for MLP on the integrated management of infectious diseases and IMID training combined on-site support (OSS).⁹ We report the results for HIV clinical practice; results on clinical competence, pediatric clinical practice, and facility performance were previously reported.¹⁰⁻¹⁴

Methods

Study Design:

The evaluation of clinical practice was conducted between January 2010 and March 2011, and used a mixed design with pre/post and cluster randomized trial components. Among 36 selected health facilities, two MLP from each facility attended a five-week IMID training. In addition to IMID, 18 facilities randomly assigned to arm A participated in OSS for nine months, while 18 facilities in arm B did not. We assessed HIV clinical practice before (time 0) and after (time 1) the interventions and compared changes within and across arms. The full protocol is available as a supplementary file in Weaver et al.¹² A consort checklist is available as S1 Table.

Participants and eligibility:

Health Facilities. The 36 health facilities (31 health centers IV, five hospitals) were drawn from the six regions of Uganda. Health centers IV are the health subdistrict referral facilities and provide preventive and curative outpatient services to catchment populations of 100,000.^{12,15} Two key facility inclusion criteria were accreditation to provide ART and a laboratory with the capability to perform six laboratory tests: HIV rapid test, tuberculosis (TB) sputum smear, haemoglobin estimation, malaria blood smear, urinalysis, and stool analysis.^{9,16}

Trainees. Two MLP were selected from each of the 36 health facilities. To be eligible for participation in the evaluation, the MLP had to be a clinical officer, registered nurse or registered midwife, devote at least 80% of their time to clinical care in outpatient and ART clinics, and available to participate throughout the evaluation. Clinical officers received first priority, followed by registered nurses then registered midwives.

Patients. Patients were a convenience sample who attended the HIV clinics on days that the clinical faculty conducted the assessments.

Interventions:

The 72 selected MLPs attended IMID training, a three-week core course, followed by two one-week boost courses 12 and 24 weeks after the initial training. The course was based on content from the World Health Organization's (WHO) Integrated Management of Adult Illness and Integrated Management of Childhood Illness courses, Infectious Disease Institute's Comprehensive Management of HIV including ART and Joint Uganda Malaria Training Program courses, and updated national and WHO guidelines for HIV/AIDS, tuberculosis and malaria treatment.^{17,18} The case-based course covered a range of HIV-related issues, from HIV testing and routine HIV patient care to treating pregnant women and children, and managing complex cases.

Following the IMID, arm A facilities received monthly two-day OSS visits for nine months from a team of four clinical faculty: medical officer with CQI experience, clinical officer, laboratory technologist, and registered nurse. During OSS, the MLP and other health facility staff participated in multidisciplinary training, cadre-specific breakout sessions, one-on-one mentoring, and continuous quality improvement (CQI) sessions. The multidisciplinary training was designed to foster teamwork between clinical and laboratory staff while building capacity. The CQI sessions used facility-based data to identify areas for quality improvement and then monitor the improvements. During one-on-one mentoring, the OSS faculty developed the MLPs' clinical skills by observing MLP practice and providing individualized feedback. Each month the OSS visit focused on a new topic. Four of the nine OSS visits focused on HIV management with the following topics: Comprehensive HIV care, ART follow-up and monitoring, pediatric ART, and prevention of mother-to-child transmission. To receive a certificate of completion, MLP had to attend at least seven of the nine OSS sessions. A detailed description of the IMID and OSS content is reported in Miceli et al.¹⁶

Outcomes:

The outcomes were HIV clinical practice on six tasks. Clinical faculty used a standardized HIV Clinical Observation Form (Supplementary File 2, <http://links.lww.com/QAI/B111>), based on Brentlinger et al., to record information on patients and MLPs' clinical practice.^{19,20} Patients were heterogeneous, so some items were required for all patients, and additional follow-up items were required based on information learned about the patient during the consultation. It was necessary to record patient information to document that additional items were required. For example, a question about history of fever was required for all patients, and the patient's response was recorded. When a patient had a history of fever, a follow-up question was required about the duration of fever. The number of required items varied across patients, and all items were weighted equally for the required items for each patient. For example, a trainee with a score of 5 out of 7 items for a patient would have a higher score than a trainee with 7 out of 11 items for a different patient.

After the MLP completed the patient history and physical examination, the clinical faculty asked additional history questions or examined additional systems to complete missing information or correct errors made by the MLP. To distinguish patient information obtained by the MLP from that obtained by the clinical faculty on the same form, the MLPs' clinical findings were recorded in blue or black ink and the faculty members' were recorded in red ink. The items that were required for all patients are described below, and a full list of items is in Supplementary File 2.

History taking (7-11 items). Number of questions asked given each patient's history and presenting symptoms, including weight, current cotrimoxazole and ART status, history of fever and cough, functional status, and other symptoms and concerns.

Physical examination (5-6 items). Number of physical systems examined given each patients' history, and initial findings of physical examination, including a general examination, examination of four systems (mouth, skin, lungs, abdomen), and other systems.

Laboratory tests (1 item). Summary score for laboratory and other tests based on the differential diagnosis.

Diagnosis (2 items). The first item was on diagnosing eligibility for ART for patients not on ART, and treatment failure for patients on ART. The second item was a summary score for diagnosis of opportunistic infections and other diagnoses for all patients, plus ART side effects for patients on ART.

Treatment (2-3 items). Number of treatments correctly prescribed among cotrimoxazole, and other treatments for all patients, plus ART for patients on ART.

Patient/caregiver education (2 items). Number of patient/caregiver education messages provided correctly among positive prevention and recommendations to use a mosquito net.

Changes after trial commencement. There were no major changes to the study outcomes however, there were modifications to the items included for each task due to missing data at baseline, as noted under data management.

Sample size:

Trainees were each assessed on five HIV patients per time point. The number of facilities was based on testing the effect of OSS on facility performance using two malaria indicators as reported in Naikoba et al.⁹ The number of MLP participating in IMID training and the number of patients observed were based on budget and program feasibility. With a sample size of 180 patients in each arm and time point (36 MLP with five patient each) we could detect an increase in tasks performed correctly from 60% to 75% with a power of 0.84, and 70% to 85% with a power of 0.91.

Randomization:

Health facilities were assigned to the two study arms after baseline data collection (1:1 balance) by stratified random selection, with stratification for two on-site interventions that would have potentially contaminated the trial: (1) prior experience with the Health Care Improvement Program, a CQI program for HIV prevention, care and treatment vs. CQI naïve; and (2) current or prior participation in the Baylor International Pediatric AIDS Initiative on-site intervention. Randomization was done using random

number generation in Stata 10.1 following the completion of the baseline assessment. This study was not blinded during the intervention or endline assessments.

Data Collection:

At baseline and endline, clinical faculty were trained to conduct the clinical assessments with a one-day training and two days of pilot testing at non-study facilities. Fourteen of the 17 clinical faculty were trained in the IMID course. Two clinical faculty that participated at baseline left their positions and were replaced at endline.

Data Management and Statistical Methods:

Data were coded by two Ugandan medical doctors (NM and PI), and entered into Epi Info 3.2 (U.S. Centers for Disease Control and Prevention, Atlanta, GA). The data were checked for consistency and cleaned with reference to the paper forms, and analyzed using Stata 11.1 (StataCorp, 2009 College Station, TX). Descriptive statistics for patient characteristics were calculated by arm and time.

For each outcome we used the change in arm B from baseline to endline to test the effect of IMID, the change in arm A to test the combined effect of IMID and OSS, and the comparison of change between the two arms to test the incremental effect of OSS. The data were analyzed using a generalized linear model with a Poisson family and log link with main effects for arm, time, and their interaction to estimate relative risks (RR) and ratio of relative risks (RRR). The unit of analysis was the patient with the number of tasks performed correctly as the numerator, and the number of required tasks for that patient as the denominator. Regression analyses were clustered on the MLP with robust variance estimation to adjust for using the Poisson family and for over-dispersion. Random effects for MLP nested within health facility did not affect the results, and were not included in the reported models. Although there were multiple comparisons, a 5% level of significance was used.

To address any residual confounding, we adjusted for MLP cadre, case complexity as measured by whether the patient presented with an opportunistic infection, and the two strata (facility participation in the Health Care Improvement program and Baylor International Pediatric AIDS Initiative). Some MLP may have learned from the assessment and improved their practice on subsequent patients, so we controlled for patient order. Given the potential for differences across clinical faculty, we controlled for cadre, and whether they had attended IMID and the baseline and endline assessment trainings. To address the change in clinical faculty from baseline to endline, sensitivity analyses were conducted with the subsample for which clinical faculty were balanced across arms and time points.

The primary model included the complete cases for each task, where information was reported on each item within the task. For patient history, three items were not included because data were missing for 35 patients or more at baseline: night sweats, weight loss, and recent history of contact with a TB patient. For physical examination, four systems were not included because data were missing for 24 or more patients at baseline: cardiovascular, genital, muscle, and neurological. Additional sensitivity analyses were performed with two alternative assumptions about the missing values: 1) all missing values were interpreted as the item not being performed, i.e. missing values were equal to zero, and 2) all missing values were interpreted as being performed, i.e. missing values were equal to one. Regression diagnostics were also performed to identify outliers and influential observations and estimates were obtained excluding these observations.

Ethical Considerations:

IDCAP was reviewed and approved by the School of Medicine, Research and Ethics Committee of Makerere University (Reference Number 2009-175) and the Uganda National Council for Science and Technology (Reference HS-722). The University of Washington Human Subjects Division determined that the evaluation did not meet the regulatory definition of research under 45 CFR 46.102(d). During the evaluation, the MLP participating in the study gave written informed consent for secondary analysis of their training program data for the evaluation. On the day of the assessment, patients and their caregivers were introduced to the assessments and asked to provide verbal informed assent/consent prior to the consultation. The patient data were anonymous.

Results

Recruitment and Enrollment:

Thirty-eight health facilities were assessed for eligibility and met the inclusion criteria. However, one facility declined to participate and one facility was excluded because it was participating in another research project. Four of the five hospitals were randomized to arm B (Figure 1). Of the 72 selected MLP, there were 48 clinical officers, 20 registered nurses and 4 registered midwives. Seventy-two percent and 61% of the MLP were clinical officers in arm A and arm B respectively. All midwives were at arm B facilities. All 72 selected MLP participated in the three-week IMID course. One MLP in arm A and three MLP in arm B were not available to participate in at least one boost course. All 36 MLP in arm A participated in at least one OSS session and 29 (81%) attended at least seven out of nine sessions.

Clinical assessments were completed and forms were available for 35 health facilities. At baseline all 36 MLP in arm A and 33 MLP in arm B had analyzable clinical assessments. At endline, 35 MLP in arm A and 33 in arm B had analyzable clinical assessments. Thirty-five MLP in arm A and 32 in arm B had assessments at both time points and were included in the analysis. While the aim was to observe each MLP providing care to five HIV patients at each time point, four had fewer and nine had more, with a maximum of 15 patients across both time points. A total of 680 patients were included in the analysis. Most HIV patients in the sample were adults 18 years of age or older visiting for a cotrimoxazole and/or ART refill (Table 1). The most common presenting complaints were cough and fever.

Outcomes:

Figure 2 shows the unadjusted average proportion of items performed correctly by task comparing the two arms at baseline (time 0) and endline (time 1). Clinical practice was comparable at baseline. While both arms improved for all tasks over time, arm A had higher scores at endline in unadjusted analyses.

Testing the effect of IMID, clinical practice significantly improved in arm B by 13% for patient history (95% CI=1.03-1.24), 54% for physical examination (95% CI=1.29-1.83), 32% for laboratory investigations (95% CI=1.04-1.67) and 23% for diagnosis (95% CI=1.04-1.45) (Table 2).

Testing the combined effect of IMID and OSS, clinical practice significantly improved in arm A by 24% for patient history (95% CI=1.15-1.34), 71% for physical examination (95% CI=1.44-2.03), 20% for laboratory investigations (95% CI=1.01-1.43), 51% for diagnosis (95% CI=1.31-1.74), and 72% for patient education (95% CI=1.33-2.23). When compared to IMID alone, the combined effect of IMID and OSS was larger for four of these five tasks.

Assessing the incremental effect of OSS, there was a 23%, significant increase in diagnosis (95% CI=1.00-1.50). There were also increases in the percentage of correct history, physical examination, and patient education items that were not statistically significant.

The balanced sample included 30 MLP from arm A and 27 from arm B and 427 clinical assessments, 223 in arm A and 204 in arm B at baseline, and 215 and 212, respectively, at endline. At baseline arm A performed significantly better for treatment (Table 3). Adjusting for covariates, IMID was associated with an improvement of 30% in physical examination (95% CI=1.07-1.58) and 45% in patient education (95% CI=1.04-2.03).

As in the full sample, the combined effect of IMID and OSS was larger than IMID alone. Table 3 shows a 23% improvement in history taking (95% CI=1.13-1.35), 43% in physical examination (95% CI=1.22-1.68), 27% in laboratory investigations (95% CI=1.02-1.57), 57% in diagnosis (95% CI=1.31-1.89) and 69% in patient education (95% CI=1.19-2.40). OSS was associated with incremental improvement of 19% in history taking (95% CI=1.04-1.35) and 37% in diagnosis (95% CI=1.02-1.83).

In additional sensitivity analyses we imputed missing clinical items as equal to zero or one. The direction and significance of the changes in practice were the same for all tasks, with one exception. The effect of IMID on history taking was not statistically significant when missing data was assumed to mean the items were performed correctly (aRR=1.06; 95% CI=0.99-1.13).

Discussion

This is one of the first studies to use a cluster randomized trial to compare interventions to improve HIV clinical practice among MLP. This study included a direct comparison of arms with training alone and training combined with OSS. Training alone showed a significant improvement for four tasks. In sensitivity analyses with a balanced sample, only the findings for physical examination and patient education were robust. Results were more consistent for the combined effect of training and OSS, which showed a significant and robust improvement for five tasks. The MLP were already performing well in treatment with average scores above 70% at baseline, leaving less room for improvement. At endline, trainees in the combined training and OSS arm scored 80% or higher in five tasks, compared to only three tasks in the training alone arm. While a comparison of effect sizes between arms indicate an additional effect of OSS for four tasks, we were only able to definitively identify the incremental contribution of OSS for diagnosis.

A comprehensive history and physical examination are important components of the clinical practice. Long patient queues with few attending clinicians are often cited as reasons clinicians are not able to complete these tasks during consultation. However, in this study we observed that clinicians saw on average 5.5 or fewer patients per day, a finding that was replicated in the Institute for Health Metrics and Evaluation's Access, Bottlenecks, Cost, and Equity survey in Uganda.^{21,22} In cases of high patient loads, more skilled clinicians may be able to perform these tasks more efficiently, and mentors can support development of these skills.

In a recent review of task-shifting interventions, seven of the 10 studies focused on health facility staff and described the interventions used; three used training alone, three used training plus mentorship, and one used educational outreach alone.⁷ Six of the studies improved HIV patient management, the one that was not effective used training alone.

These results highlight the potential for OSS to build clinical officers', nurses' and midwives' capacity in HIV clinical practice. When planning to task shift HIV care, governments and program implementers should complement training with OSS by experienced clinical faculty to reinforce skills learned during training. Clinicians often face complicated cases that fall outside of the typical cases reviewed in the classroom setting. Managing HIV and related conditions requires complex clinical decision-making skills which take time and experience to develop. Combining training with longer-term support can help clinical staff to translate classroom-learning into their real-life work, strengthening their ability to adapt to situational constraints and devise new solutions to complex problems.¹⁶

Limitations:

This study was subject to several limitations. First, two clinical faculty at baseline did not conduct endline assessments and were replaced by new clinical faculty members. To address this, we conducted a sensitivity analysis with the balanced sample that no longer represented the full, randomized sample. Second, missing information on patient history and physical examination at baseline could have affected the results. While results in arm A were robust in sensitivity analyses, the effect of IMID on history taking was not statistically significant when missing data on that task was assumed to mean it was performed. Third, these findings are based on observations, and clinicians may behave differently when not being observed. Fourth, we controlled for two facility-based HIV programs that could have caused systematic differences across arms, but we did not control for all other training programs. However, the selection of 36 health facilities from 25 districts controlled for contamination from district-level trainings that would have affected only a few sites. The authors were not aware of any national HIV training programs during the trial. Fifth, the clinical faculty and MLP were not blinded to allocation of facilities at endline. To reduce observer bias, clinical faculty did not conduct endline assessments at facilities where they provided OSS, but could have been biased in favor of the intervention arm. Sixth, we used a convenience sample of patients rather than a random sample, although it is unclear how patient selection may have biased the results. Seventh, IDCAP's eligibility criteria focused on subdistrict referral facilities within Uganda. However, to the extent that these facilities are similar to health facilities throughout sub-Saharan Africa these results would be generalizable to task-shifting interventions in other settings. Finally, we maintained a 5% level of significance despite multiple comparisons and may have erred (Type 1 error) in concluding that the effects of the interventions were statistically significant.

Conclusion

Training and OSS were associated with improvements in history taking, physical examination, laboratory investigations, diagnosis, and patient education. OSS provided incremental improvements in diagnosis. Combined training and OSS improved HIV clinical practice among of MLP over training alone.

References

1. UNAIDS. *Ending AIDS: Progress towards the 90-90-90 Targets*. Geneva, Switzerland; 2017.
http://www.unaids.org/sites/default/files/media_asset/Global_AIDS_update_2017_en.pdf.
2. UNAIDS. *Fast-Track: Ending the AIDS Epidemic by 2030*. Geneva, Switzerland; 2014. doi:ISBN 978-92-9253-063-1.
3. Baernighausen T, Bloom DE, Humair S. Human resources for treating HIV/AIDS: Are the preventive effects of antiretroviral treatment a game changer? *PLoS One*. 2016;11(10):1-24. doi:10.1371/journal.pone.0163960.
4. Samb B, Celletti F, Holloway J, Van Damme W, De Cock KM, Dybul M. Rapid Expansion of the Health Workforce in Response to the HIV Epidemic. *N Engl J Med*. 2007;357(24):2510-2514. doi:10.1056/NEJMs071889.
5. World Health Organization. *Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV*. Geneva, Switzerland; 2015. doi:978 92 4 150956 5.
6. Soucat A, Scheffler R, Ghebrey TA. *The Labor Market for Health Workers in Africa*.; 2013. doi:10.1596/978-0-8213-9555-4.
7. Kredo T, Adeniyi FB, Bateganya M, Pienaar ED. Task shifting from doctors to non-doctors for initiation and maintenance of antiretroviral therapy. *Cochrane Database Syst Rev*. 2014;(7). doi:10.1002/14651858.CD007331.pub3.www.cochranelibrary.com.
8. Callaghan M, Ford N, Schneider H. A systematic review of task-shifting for HIV treatment and care in Africa. *Hum Resour Health*. 2010;8(1):8. doi:10.1186/1478-4491-8-8.
9. Naikoba S, Colebunders R, van Geertruyden J-P, et al. Design of a cluster randomized trial assessing integrated infectious diseases training and on-site support for midlevel practitioners in Uganda. *Int J Care Pathways*. 2012;16(4):152-159. doi:10.1177/2040402613479342.
10. Weaver MR, Crozier I, Eleku S, et al. Capacity-Building and Clinical Competence in Infectious Disease in Uganda: A Mixed-Design Study with Pre/Post and Cluster-Randomized Trial Components. *PLoS One*. 2012;7(12). doi:10.1371/journal.pone.0051319.
11. Imani P, Jakech B, Kirunda I, Mbonye MK, Naikoba S, Weaver MR. Effect of integrated infectious disease training and on-site support on the management of childhood illnesses in Uganda: a cluster randomized trial. *BMC Pediatr*. 2015;15(1):103. doi:10.1186/s12887-015-0410-z.
12. Weaver MR, Burnett SM, Crozier I, et al. Improving facility performance in infectious disease care in Uganda: A mixed design study with pre/post and cluster randomized trial components. *PLoS One*. 2014;9(8). doi:10.1371/journal.pone.0103017.
13. Mbonye MK, Burnett SM, Burua A, et al. Effect of integrated capacity-building interventions on malaria case management by health professionals in Uganda: A mixed design study with pre/post and cluster randomized trial components. *PLoS One*. 2014;9(1). doi:10.1371/journal.pone.0084945.
14. Burnett SM, Mbonye MK, Naikoba S, et al. Effect of educational outreach timing and duration on facility performance for infectious disease care in Uganda: A trial with pre-

- post and cluster randomized controlled components. *PLoS One*. 2015;10(9):1-17. doi:10.1371/journal.pone.0136966.
15. HSSP. Health Sector Strategic Plan 3. *Gov Uganda*. 2014:16-18. http://www.health.go.ug/docs/HSSP_III_2010.pdf.
 16. Miceli A, Sebuyira LM, Crozier I, et al. Advances in clinical education: A model for infectious disease training for mid-level practitioners in Uganda. *Int J Infect Dis*. 2012;16(10):e708-e713. doi:10.1016/j.ijid.2012.07.003.
 17. Ssekabira U, Bukirwa H, Hopkins H, et al. Improved malaria case management after integrated team-based training of health care workers in Uganda. *Am J Trop Med Hyg*. 2008;79(6):826-833. doi:10.1186/1528-7566-79-6-826 [pii].
 18. Weaver MR, Nakitto C, Schneider G, et al. Measuring the outcomes of a comprehensive HIV care course: pilot test at the Infectious Diseases Institute, Kampala, Uganda. *J Acquir Immune Defic Syndr*. 2006;43(3):293-303. doi:10.1097/QAI.0000243047.42827.97.
 19. Brentlinger PE, Torres J V, Martinez PM, et al. Clinical staging of HIV-related illness in Mozambique: performance of nonphysician clinicians based on direct observation of clinical care and implications for health worker training. *J Acquir Immune Defic Syndr JAIDS*. 2010;55(3):351-355. doi:http://dx.doi.org/10.1097/QAI.0b013e3181e3a4cd.
 20. Brentlinger PE, Assan A, Mudender F, et al. Task shifting in Mozambique: cross-sectional evaluation of non-physician clinicians' performance in HIV/AIDS care. *Hum Resour Health*. 2010;8(1):23. doi:10.1186/1478-4491-8-23.
 21. Mbonye MK, Burnett SM, Naikoba S, et al. Effectiveness of educational outreach in infectious diseases management: a cluster randomized trial in Uganda. *BMC Public Health*. 2016;16(1):714. doi:10.1186/s12889-016-3375-4.
 22. Institute for Health Metrics and Evaluation (IHME). Assessing Facility Capacity, Costs of Care, and Patient Perspectives. *Access, Bottlenecks, Costs and Equity (ABCE)*. 2014.

Figure Legends

Figure 1. Participant flow and recruitment for the HIV clinical assessments

Figure 1 describes the flow and recruitment of the health facilities and mid-level practitioners for the study. The blue boxes (Enrollment, Allocation, and Analysis) are the three phases that determined health facility and mid-level practitioner inclusion in the study. The white boxes describe the specific steps through enrollment, allocation and analysis, the total number of participants at each stage and reasons for their inclusion or exclusion.

Figure 2. Unadjusted average proportion of items performed correctly by task, arm and time point

Figure 2 describes the unadjusted average proportion of items performed correctly by mid-level practitioners by arm and time point for each of the six tasks – history taking, physical examination, laboratory tests, diagnosis, treatment and patient/caregiver education.

Tables

Table 1. Patient characteristics during clinic visits

Table 2. Relative risks (95% confidence intervals) for proportion of items performed correctly, by task, arm and time point, adjusted full sample

Table 3. Relative risks (95% confidence intervals) for proportion of items performed correctly, by task, arm and time point, adjusted balanced sample

ACCEPTED

Table 1. Patient characteristics during clinic visits*

	Baseline			Endline		
	Arm A	Arm B	Total	Arm A	Arm B	Total
	N=174	N=169	N=343	N=178	N=159	N=337
	N (%)					
Demographics						
Female	108 (62)	114 (68)	222 (65)	115 (65)	107 (67)	222 (66)
Age >18	167 (96)	164 (97)	331 (97)	166 (93)	150 (94)	316 (94)
Presenting complaints						
Fever	48 (28)	44 (26)	92 (27)	37 (21)	52 (33)	89 (26)
Cough	55 (33)	51 (31)	106 (32)	63 (35)	51 (32)	114 (34)
Night sweats	25 (19)	11 (9)	36 (14)	20 (11)	22 (14)	42 (13)
Weight loss	21 (17)	17 (14)	38 (16)	29 (16)	23 (15)	52 (16)
Abdominal pain	40 (23)	36 (21)	76 (22)	26 (15)	34 (21)	60 (18)
Chest pain	30 (17)	19 (11)	49 (14)	21 (12)	27 (17)	48 (14)
Genital sores	18 (10)	23 (14)	41 (12)	16 (9)	22 (14)	38 (11)
Headache	37 (21)	24 (14)	61 (18)	29 (16)	41 (26)	70 (21)
Loss of appetite	24 (14)	32 (19)	56 (16)	23 (13)	33 (21)	56 (17)
Muscle aches	6 (3)	4 (2)	10 (3)	13 (7)	21 (13)	34 (10)
Skin problems	32 (18)	33 (20)	65 (19)	41 (23)	25 (16)	66 (20)
Others**	53 (30)	47 (28)	100 (29)	37 (21)	43 (27)	80 (24)
Reason for visit						
Cotrimoxazole refill	160 (93)	144 (86)	304 (89)	149 (84)	144 (91)	293 (87)
ART refill	88 (89)	68 (81)	156 (85)	105 (83)	84 (79)	189 (81)
Any presenting opportunistic infection	63 (40)	43 (28)	106 (34)	46 (26)	43 (27)	89 (26)

*The total sample varies from item to item. Percentages are based out of the total with responses.

**The other category has all complaints with fewer than 20 patients per arm in every time period, and includes: diarrhea, shortness of breath, burning sensation, general malaise, oral sores, nausea, pain on swallowing, and vomiting.

Table 2. Relative risks (95% confidence intervals) for proportion of items performed correctly, by task, arm and time point, adjusted full sample

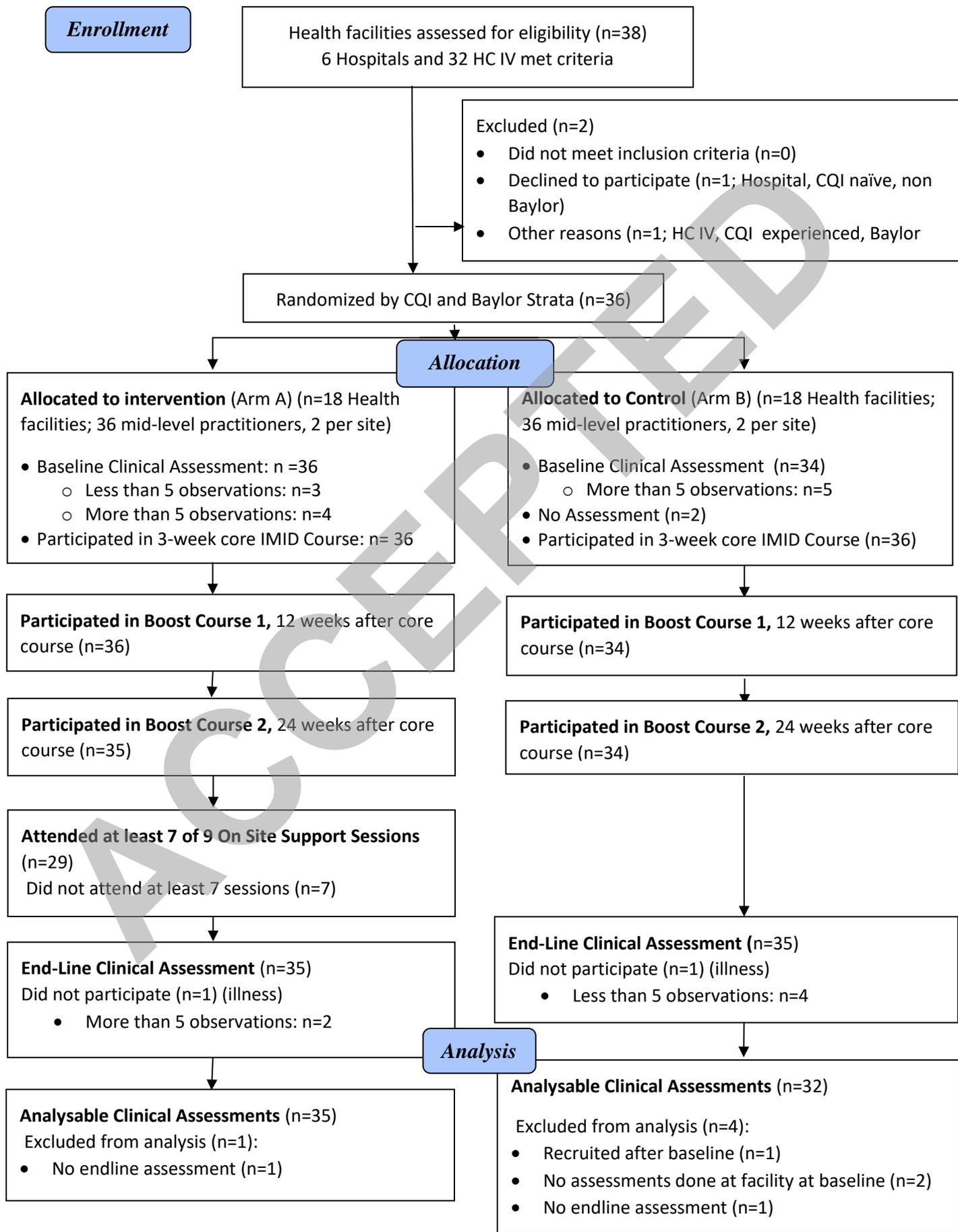
Effects	Sets of Clinical Tasks					
	History RR (CI)	Physical Exam RR (CI)	Laboratory Investigations RR (CI)	Diagnosis RR (CI)	Treatment RR (CI)	Patient Education RR (CI)
Sample Size	N=621	N=608	N=645	N=650	N=608	N=580
Arm A vs. Arm B at time 0	1.03 (0.93-1.14)	1.01 (0.83-1.22)	1.16 (0.93-1.45)	0.88 (0.74-1.04)	1.03 (0.98-1.09)	0.94 (0.68-1.29)
Arm B (IMID): Time 1 vs. time 0	1.13* (1.03-1.24)	1.54*** (1.29-1.83)	1.32* (1.04-1.67)	1.23* (1.04-1.45)	1.04 (0.99-1.09)	1.27 (0.99-1.64)
Arm A (IMID & OSS): Time 1 vs. time 0	1.24*** (1.15-1.34)	1.71*** (1.44-2.03)	1.20* (1.01-1.43)	1.51*** (1.31-1.74)	1.02 (0.96-1.08)	1.72*** (1.33-2.23)
Change in arm A vs. Arm B (OSS), RRR	1.10 (0.98-1.24)	1.11 (0.89-1.39)	0.91 (0.69-1.20)	1.23* (1.00-1.50)	0.98 (0.91-1.06)	1.36 (0.95-1.93)

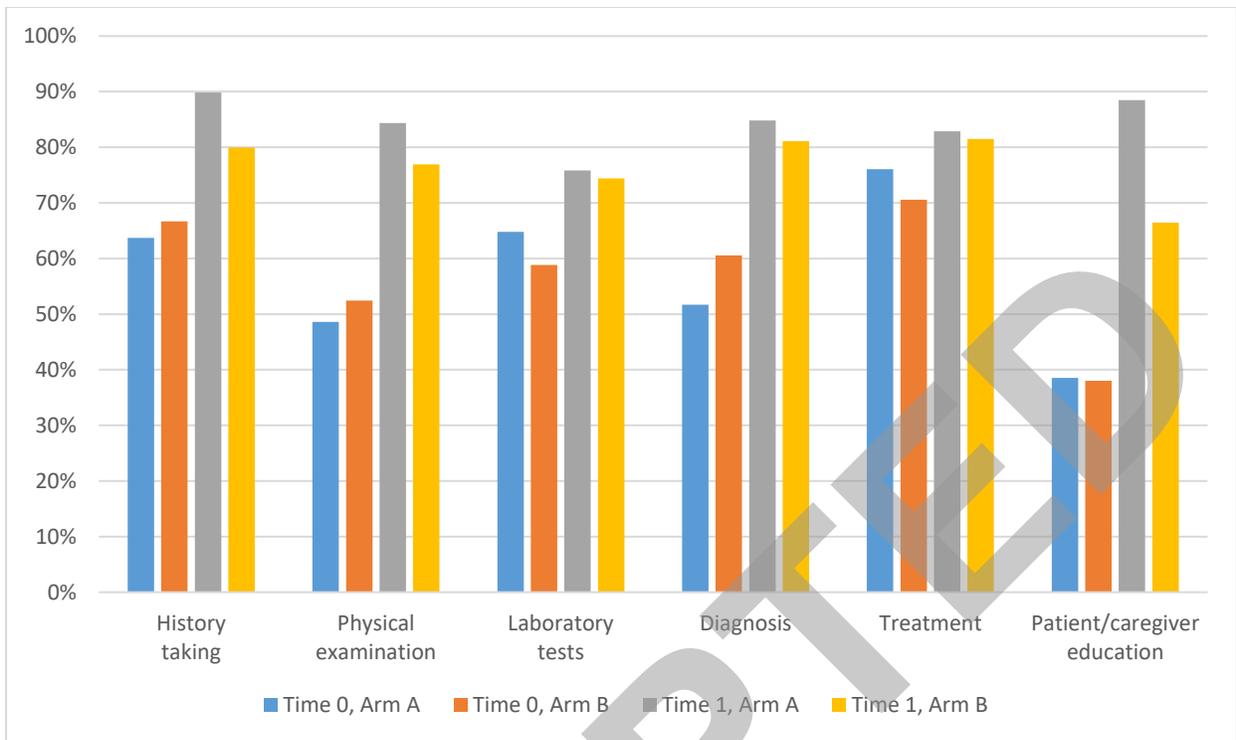
*p<0.05, **p<0.01, ***p<0.001

Table 3. Relative risks (95% confidence intervals) for proportion of items performed correctly, by task, arm and time point, adjusted balanced sample

Effects	Sets of Clinical Tasks					
	History RR (CI)	Physical Exam RR (CI)	Laboratory Investigations RR (CI)	Diagnosis RR (CI)	Treatment RR (CI)	Patient Education RR (CI)
Sample Size	N=393	N=372	N=403	N=407	N=371	N=379
Arm A vs. Arm B at time 0	0.98 (0.89-1.08)	1.00 (0.83-1.21)	1.02 (0.78-1.33)	0.88 (0.71-1.09)	1.10*** (1.04-1.15)	1.08 (0.73-1.62)
Arm B (IMID): Time 1 vs. time 0	1.04 (0.94-1.16)	1.30** (1.07-1.58)	1.19 (0.93-1.53)	1.15 (0.91-1.45)	1.01 (0.96-1.06)	1.45* (1.04-2.03)
Arm A (IMID & OSS): Time 1 vs. time 0	1.23*** (1.13-1.35)	1.43*** (1.22-1.68)	1.27* (1.02-1.57)	1.57*** (1.31-1.89)	0.97 (0.93-1.02)	1.69** (1.19-2.40)
Change in arm A vs. Arm B (OSS), RRR	1.19* (1.04-1.35)	1.10 (0.86-1.41)	1.07 (0.78-1.47)	1.37* (1.02-1.83)	0.97 (0.91-1.03)	1.16 (0.73-1.86)

*p<0.05, **p<0.01, ***p<0.001





ACCEPTED