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Evaluating a Primary Care Mental Health Integration Project in Burera District, Rwanda: A mixed methods outcome evaluation

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-014067
Article Type:	Protocol
Date Submitted by the Author:	29-Aug-2016
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Primary Subject Heading:	Global health
Secondary Subject Heading:	Health services research, Mental health, Public health
Keywords:	MENTAL HEALTH, Schizophrenia & psychotic disorders < PSYCHIATRY, PUBLIC HEALTH, International health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Title: Evaluating a Primary Care Mental Health Integration Project in Burera District, Rwanda: A mixed methods outcome evaluation

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Abstract

Introduction Integrating mental health care into primary care has the potential to reduce the global burden of mental disorders. Yet data on the effective implementation of task-shared, integrated mental health programs in real world settings is limited. We propose one of the first studies in a rural low-income country to assess the implementation and clinical outcomes of a program integrating mental health care for severe mental disorders into the public primary care system.

Methods and analysis In 2012, the Rwandan Ministry of Health and the international health care organization Partners In Health collaboratively adapted the Mentoring and Enhanced Supervision at Health Centers (MESH) program, a successful program of supported supervision based on task shifting for HIV/AIDS care, to include care of severe mental disorders within a primary care setting (MESH MH). This study will assess the process of the program implementation through routine data and quality of care data. In addition, we will employ sequential quantitative and qualitative research methodology to assess clinical outcomes for patients receiving care at primary care clinics supported by the program, and primary nurse reception of the program.

Ethics and Dissemination This evaluation aims to associate changes in uptake of services and quality of mental health care provided by primary care nurses with quantitative and qualitative patient clinical outcomes. Although the data will be unique to the program, information and the methodology used during this evaluation could be used to inform other implementation studies designed to assess the implementation and outcomes of mental health services in other resource limited areas.

Key messages
- Data on the effective integration of mental health care into real world primary care settings is limited
- The proposed study protocol will be one of the first to assess the implementation process and outcomes of a program capacitating front line public primary care health workers in a resource limited setting to care for patients with severe mental disorders
- Data from the study could inform other studies on the implementation and effectiveness of integrated mental health services in resource limited areas, as well as generate evidence that can be adopted by policy makers, program developers and clinicians.

Strengths and limitations of this study
- This prospective cohort study is limited by a lack of a control group, but will be among the first to link program implementation processes with clinical outcomes for patients with severe mental disorders being cared for in a resource limited primary care setting

INTRODUCTION
Mental disorders account for the highest proportion of years lived with disability across the globe.[1] Addressing this burden through effective clinical and social programs is a global imperative. One strategy to improve access to mental health care is to integrate mental health care into primary care. Rather than using specialized care settings to address mental disorders,

integrated primary care settings optimize health worker interventions for mental health through 'task-shifting'– delegating tasks and responsibilities from more specialized mental health clinicians to less specialized health workers.[2]

Although integrating mental health care into primary care settings has the potential to significantly reduce the burden of mental disorders,[3-6] few real-world models exist to show how evidence-based mental health care can be implemented in primary health care settings in resource-limited areas, especially for severe mental disorders. Most primary care personnel in low resource settings have little or no training or expertise in mental health care.[7] For those who have received some training in recognizing mental disorders, the training is usually brief and does not necessarily focus on patients' care.[8] Programs are also hampered by a lack of prioritization of mental health care within the primary care system, and the over-reliance on lower skilled individuals for providing the bulk of mental health care without supervision and support. There is even less known about clinical and functional outcomes of such programs occurring in real world settings.

This study will describe and assess the implementation and clinical outcomes of an innovative program to integrate mental health care for severe mental disorders into public primary care services in a resource limited area. Partners In Health (PIH), a non-profit organization working in ten countries, has supported the public health delivery system in three rural districts of Rwanda for eleven years. In 2012, the Rwandan Ministry of Health (MoH) and PIH collaboratively designed the MESH MH (Mentoring and Enhanced Supervision at Health Centers for Mental Health) program, a systematic approach to integrated mental health care that capacitates front line public primary care health providers to care for patients with severe mental disorders. The model is based on an existing program of mentorship and enhanced clinical supervision at health centers to improve the quality of care provided by nurses at first level health facilities in PIH supported districts of Rwanda.[9] The model follows closely with World Health Organization (WHO) clinical mentoring guidelines developed for effective task shifting of HIV care.[10]

To evaluate the process and outcomes of our integrated program, we will use mixed qualitative and quantitative implementation research methods. This design will allow for multiple data sources to be used to evaluate the MESH MH program in its context. Implementation research such as this holds high promise for reducing the gap between the evidence base for effective services and clinical practice.[11] Such research can inform future multisite studies to study the MESH MH model as a scalable model of care for mental health services in resource limited areas, as well as generate evidence that can be adopted by policy makers, program developers and clinicians.

METHODS AND ANALYSIS
Site
The program was implemented in Burera district, northern Rwanda. The district is served by Butaro Hospital, a 150-bed public hospital with approximately thirty-five general nurses, thirteen full time general practitioners, four psychiatric nurses and one psychologist. The hospital houses an outpatient mental health specialty clinic which operates five days a week. Patients in need of acute psychiatric services are transferred from the mental health clinic or directly from district health centers to Butaro Hospital under the care of the hospital-based mental health workers, in collaboration with general physicians. The hospital is the primary referral center for seventeen district health centers, and serves an overall population of approximately 340,000 people. The public mental health services in Burera district were supported by a three-member PIH Mental Health team, including one psychiatric nurse-manager, one community coordinator, and an expatriate psychiatrist based in the district.

MESH MH Implementation

Three health centers in Burera district were initially chosen to participate in the program, with a plan for scale-up to the remaining health centers in the district over several years, for a total of eighteen health centers. Four major neuropsychiatric disorders were chosen for clinical focus based on needs perceived by district mental health staff and health center directors, informal observation of diagnoses as listed in health center registers, and evidence of disease burden and treatment effectiveness as defined by the World Health Organization (WHO): schizophrenia; bipolar disorder; major depressive disorder; and epilepsy.

After an intensive, forty-hour training designed to teach primary care nurses how to identify and manage these four disorders, a program of regular supervision by a trained Rwandan psychiatric nurse was initiated. Weekly health center supervisory visits included clinical observation, individual case review, documentation review, and brief didactic sessions. A mental health supervision checklist was adapted from checklists used in other areas of clinical focus, to assist with clinical mentoring and to ensure standardization of activities across clinical domains. The mentor nurse used the case observation checklist to ensure that health center nurses were performing key elements of basic psychiatric evaluations, accurately diagnosing patients, and offering appropriate treatment and support. The successful completion of checklist items during mental health clinical evaluations was used to define basic quality of care provided by health center nurses. During each supervision session, the nurse-mentor also discussed systems-based performance issues and "quality gaps" with the health center director and the health center nurses, and formulated specific plans to improve patient care, referral pathways, coordination between services, and other systems-level issues.

Overall Objectives*:* A mixed-methods outcomes evaluation with a pre- and post-test design will be performed at four purposively selected health facilities newly participating in the MESH MH program. Qualitative and quantitative outcome evaluations will be conducted to determine whether patients who receive mental health care at supported health centers experience clinical and functional improvement and to explore the perspectives and experiences of health workers and patients who receive care through this program. As an adjunct to these evaluations, a process evaluation will be conducted using service utilization data to assess changes in uptake of mental health services at participating health facilities within the district, and using MESH MH supervision checklists to determine whether participating health center nurses adequately provide basic quality mental health care.

Process Evaluation Aim 1*:* Assess changes in uptake of mental health care by assessing the quantity and quality of mental health diagnoses at Burera district health centers in relation to the implementation of the MESH MH program.

Routine program monitoring data will be collected from the paper registries for all patients attending mental health services at participating health centers for three months prior to and six months following the implementation of the MESH MH program, to assess whether increases in mental health diagnoses occur in relation to implementation of MESH MH. All health centers participating in the MESH MH program in Burera district will be surveyed. Patient diagnoses and visit data are currently routinely recorded in the daily register by clinicians at all health facilities in the district. A subset of these routinely recorded data will be collected as indicators of program implementation process (Table 1).

Table 1. Routine health center program monitoring indicators

- Total number of mental health visits per month

| - Total number of unique patients with a mental disorder seen per month |
| - Number of new patients seen per month |
| - Number of new patients who receive any follow up over six months |

Each month, a research data officer will travel to participating health facilities and record these process indicators. The data will be entered into a password protected electronic patient database currently in use by the IMB MH team for tracking routine process indicators.

Data analysis: We will compare the number of new patients diagnosed with a mental disorder, the number of new mental health diagnoses, the number of mental health follow-up visits, and % of patients with specific diagnoses pre- and post- MESH MH program implementation. We hypothesize that we will observe an increase in the number of mental health diagnoses and follow-up visits at health centers post-MESH MH implementation, representing an increase in uptake of mental health services and recognition of mental health morbidity among providers. We further hypothesize that MESH MH training will lead to improvements in the number of individuals with specific mental health diagnoses post-MESH MH.

Process Evaluation Aim 2: Assess whether participating non-specialist health center nurses offer basic quality mental health care as specified in MESH MH program objectives.

Specific indicators of quality have been developed to track each nurse's provision of mental health care at health centers as an integral routine part of the MESH MH program. These quality of care indicators will be routinely collected over one year using the MESH MH supervision checklist, completed by mentors. Each month, all MESH MH mentor observation checklists are collected from the MESH MH nurse mentor and entered into a database. The quantitative process indicators for purposes of this evaluation will include the number of MESH MH checklists completed weekly, as well as a subset of supervision checklist items (Table 2).

Table 2. Quality of Care Process Indicators

| Checklist items for **new** patients: |
| 1) Summary score of correctly completed mental health intake questions |
| 2) Diagnostic agreement between the psychiatric nurse-mentor and the primary care nurse |
| 3) Summary score of correctly completed treatment planning tasks |
| 4) Completed safety planning questions |

Data analysis: For each nurse mentee from each health center, we will calculate the change in checklist item scores each month relative to baseline and test whether the mean change is different than zero. We hypothesize that within person change will increase with time since MESH MH implementation. For binary variables, we will examine whether proportions increase with time since MESH MH enrollment. We will adjust for correlation resulting from repeated measures from the same individuals.

Quantitative Outcomes Specific Aim: Assess whether patients who receive mental health care at select health centers experience clinical and functional improvement, including improvements in economic status.

Study Population/Recruitment: All consecutive adults presenting to the mental health clinics at the four selected health centers for an initial visit over the course of approximately six months, who have been diagnosed with a major mental or neurologic disorder, will be invited to participate in the quantitative outcomes evaluation. Patients who need to be transferred to the

district hospital for an acute medical or psychiatric emergency and patients with a primary alcohol or substance use disorder will be excluded from the evaluation. The mental health clinic day occurs once weekly as designated by the health center schedule. On that day, the clinician researcher will be available at the health center for enrollment in the research evaluation. Additionally, patients with a mental disorder who arrive at the clinic on a non-designated mental health clinic day will also be informed of the program evaluation by the health center nurse, and will be invited to return to participate the following week on the day that the clinician researcher will be present. Written informed consent from the patient and his/her designated proxy will be obtained before data collection begins.

Data collection, measures and outcomes: The primary outcomes will be clinical symptoms and daily functioning, measured at first visit, eight weeks and six months after beginning participation in the MESH MH program using the scales listed in Table 3. A brief economic status questionnaire for patients with mental disorders, adapted with permission from other resource limited contexts [12], will also be administered (Table 3).

Table 3. Outcome measurement tools

Domain	Instrument
Clinical Symptoms	General Health Questionnaire (GHQ-12) [13]
Functioning and Disability	WHO-Disability Assessment Scale (WHO-DAS) 12 item version [14]
Individual and Household Economic Status	PIH-adapted economic questionnaire

All instruments will be translated into Kinyarwanda and back translated prior to implementation. The symptom and functioning scales will be pilot-tested among a small convenience sample of patients to ensure face validity.

Questionnaires will be administered by the trained clinician researcher. If the clinician researcher determines that a patient is unable to offer adequate answers to questions secondary to severe mental illness (e.g. the patient exhibits clinical signs of severe psychosis such as disorganized thinking), the primary family member in attendance at the clinic with the patient will be used as a proxy to answer questions, and the fact that a proxy has been used will be recorded. Demographic information as well as self-reported treatment status (new to treatment or received previous treatment) will be recorded.

Follow up: Patients will be re-interviewed at eight week and six month follow up, on their return for follow up to the health center. For patients who do not return to follow-up, a community health worker in their village will be contacted to visit the patient and encourage the patient to return to care (as is routine practice in the current health system). Patients who return will be re-interviewed at eight week and six month follow up.

Analysis: All participating patients will be included in the analysis. Among patients who receive a score of > 2 on the WHO DAS-II (indicating non-zero baseline disability) and a score of ≥ 3 on the GHQ-12 (indicating psychiatric caseness), [15-16] we will calculate within-person score change at eight weeks and six months and test whether any mean change is different than zero. We will calculate the percent of patients who experience clinically significant reductions in score (25% for the GHQ-12 and 20% for WHO-DAS-II Brief). We will use multivariable logistic regression to identify covariates associated with improved scores. We will also calculate the percentage of patients who report improvements on the economic questionnaire and calculate within person changes in their economic score. To account for any patients who do not return for follow-up (and therefore do not complete a follow-up interview), we will conduct analyses in

which we (1) assume no change in their baseline scores or (2) use inverse probability weighting to calculated a weighted mean change in score.

Sample size: Conservatively estimating that 50% of individuals will achieve a 25% score reduction within our population, a sample size of 96 patients will allow us to calculate 95% confidence intervals with precision of +/-10%. Assuming a drop-out rate of 20%, the minimum sample size for enrollment in the study will be 116. In order to stratify outcomes by characteristics such as age, gender, health center, diagnosis, and whether the patient is newly diagnosed or has previously been treated for a mental disorder, we will enroll as many patients are willing to participate (an estimated 200 patients).

Qualitative outcomes evaluation specific aim:
To explore the perspectives and experiences of health center nurses, families and patients who receive care at select health centers where the MESH MH program has been implemented

Study Population/Recruitment: A subset of patients recruited for the quantitative program evaluation will be selected by stratified purposeful selection for the qualitative program evaluation. Approximately 40-50 "information rich" (e.g. willing and able to speak freely about their experiences) participants will be chosen by the clinician researcher or recommended by the health center nurse or the MESH MH mentor. Patients will be chosen to represent the continuum of quantitative outcome scores (including those who did not see significant clinical improvement, those who achieved average improvement, and those who achieved maximal clinical improvement), as well as a maximal variety of patients assessed by demographics including age, gender, health center, and diagnosis.

Nurses: All health center nurses (approximately eight nurses) participating in the MESH MH program at the four selected health centers will be invited to participate in the qualitative program evaluation.

Data Collection and Measurement: Demographic data of participants will be obtained. Semi-structured interviews will be conducted by the mental health clinician researcher. The interviews will be conducted in Kinyarwanda and audio-recorded, and the interviewer will take notes for context and non-verbal communication. The interview guide will be developed through an emergent design including insights gained from the investigator's experience working as a psychiatrist in Burera district for two years, as well as insights from other mental health workers in Rwanda and the literature on primary care integration models for mental health.

The semi-structured interviews will include sections to discuss access to and uptake of care, quality of care and outcomes for patients of the MESH MH program, as well as the health center nurse as an agent of delivery and overall experiences of the MESH MH mentorship model of care, including perceived needs for improvement. Interview guides will be tailored to the nurses, users and families, probing for experiences and opinions in each section. Interviews will be translated into English and transcribed for analysis.

Data Analysis: A content analysis will be conducted. Each transcript will be analyzed and coded for the themes of access to and quality of mental health care at the health center level, the health center nurse as an agent of delivery and the mentorship model of mental health care. Illustrative examples of any associations found in the quantitative outcome evaluation will also be identified and synthesized.

ETHICS AND DISSEMINATION

The program outcomes evaluation will take place within the context of mental health service provision at health centers. Potential participants are those enrolled in care for a mental health diagnosis at the health centers, and each participant will be provided follow-up care indefinitely both during and after the program evaluation is completed, as in the course of routine services.

Data collection consists of quantitative and qualitative interviews. Although answering questions about current clinical status and opinions about care provision is low risk for patients, families and nurses, there is a possibility that such discussions may cause an increase in distress for participants. To mitigate this risk, the research assistant will emphasize during the informed consent process that patients or family members can return to the health center for support should they experience such distress. Health Center nurses who may feel distress after participation will have access to support from the MESH mentor associated with their health center. If any acute safety risks are identified during or after the quantitative or qualitative interview processes (e.g. patient expression of an acute risk of harm to self or others), the participant will be referred to district mental health services at Butaro hospital for clinical evaluation.

To maintain participant confidentiality, all quantitative evaluation questionnaires will be completed in pen and paper format or on a password protected tablet and stored in a locked storage cabinet at Butaro hospital. Data will be entered from these questionnaires into a database on a password-protected computer which is also stored in the locked cabinet. Qualitative interviews will be recorded and transcribed onto the same computer by the research assistant or certified translator. Audio recorders will also be held in the locked cabinet and erased after the study is completed.

This proposal has been deemed exempt by the Institutional Review Board of Harvard University and approved by the Rwanda National Ethics Committee (RNEC). As patients with mental disorders are considered a vulnerable population, a more intensive consent process will be used to ensure that appropriate consent for participation in the outcomes evaluation is obtained. Evidence suggests that when systematic and thorough informed consent processes are implemented, patients with severe psychiatric disorders can understand and retain critical components of informed consent.[17] The following consent process has been adapted according to the recommendations of RNEC.

Patients:
Quantitative/Qualitative Evaluation: The initial consent process will occur at the four selected health centers following patients' routine appointments for a mental disorder. In cases where patients are potentially interested in participating as determined by the recruitment procedure, the research assistant will describe the quantitative evaluation process in some detail, including the purpose of the study, the anticipated benefits and risks, and voluntariness issues, to both the patient and his/her accompanying family member, and answer any questions which may arise. Purposively selected "information rich" patients will be asked with their family members by the research assistant if they are both willing to participate in a qualitative evaluation consisting of the longer semi-structured interview. If the patient and family member then agree to participate, the research assistant will then obtain assent from the patient and consent from the accompanying family member.

Nurses:
Qualitative Evaluation: The research assistant will describe the qualitative evaluation process in some detail to all prospective participant nurses, including the purpose, anticipated risks and

benefits, voluntariness and confidentiality issues, and obtain written consent from all participating nurses.

DISCUSSION

This prospective cohort study will be among the first to link program implementation processes with clinical outcomes for patients with severe mental disorders being cared for in a resource limited primary care setting. Although integration of mental health care into general medical settings is a common policy prescription across the globe, there is currently little real-world evidence that resource limited primary care settings can effectively care for patients with severe mental disorders. This proposal aims to fill an urgent need to assess the impact of a systematic program which capacitates front line public primary care health providers to care for patients with severe mental disorders. If results are positive, recommendations for scale-up of the MESH MH program will be developed and presented to key community, government, and NGO stakeholders.

There are limitations to the study design. This proposal endeavors to evaluate whether the MESH MH program contributes to improved clinical and functional outcomes among patients participating in the program, but it does not include a control group. For this reason, we will not be able to quantify the improvement that is directly attributable to MESH MH versus improvement that would have happened in the absence of MESH MH. The use of program process indicators as an adjunct to the qualitative and quantitative outcome assessment will help to ensure confidence that the MESH MH program has been implemented as intended at studied health centers. The addition of the process evaluation will strengthen the plausibility that observed clinical changes can be attributed to the MESH MH program.

A second limitation is that the MESH mental health program is currently being implemented in public health centers in only one district in Rwanda which is well supported by PIH. Whether our results are generalizable across all settings or at scale remains to be determined. For example, more intensive supervision and monitoring of the program may not be feasible in all districts and could influence the quality of delivery of the program, as well as patient outcomes. However, this implementation research evaluation will be the first report on a newly implemented supervised mental health program at the health center level, which may lead to further rigorous testing of the effectiveness of the intervention and its potential to scale to other health centers and districts in Rwanda.

Authors Contributions

SLS developed the proposal concept, drafted the proposal, and is a co-principal investigator of the study. CNM is a co-principal investigator of the study and provided critical revisions to the manuscript. JDI, JAD and AM manage different aspects of the national mental health program in Rwanda, and revised the manuscript critically for content. MA provided contextual inputs and critical revisions; RAO was a technical advisor for the IMB MH program and revised critically for content, MFF provided statistical analysis support and revised critically for content, YK leads the national mental health program in Rwanda and revised critically for content; GJR supported the initial development and strategic focus of the IMB mental health program leading to the current intervention, leads the PIH mental health program, mentored and supervised SLS as principal investigator, advised the IMB mental health team, advised the proposal creation, and provided critical revisions to the manuscript.

Conflict of Interest

The authors declare no conflict of interests

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Abstract

Introduction Integrating mental health care into primary care can reduce the global burden of mental disorders. Yet data on the effective implementation of real-world task-shared mental health programs is limited. In 2012, the Rwandan Ministry of Health and the international health care organization Partners In Health collaboratively adapted the Mentoring and Enhanced Supervision at Health Centers (MESH) program, a successful program of supported supervision based on task sharing for HIV/AIDS care, to include care of neuropsychiatric disorders within primary care settings (MESH Mental Health). We propose one of the first studies in a rural low-income country to assess the implementation and clinical outcomes of a program integrating neuropsychiatric care into a public primary care system.

Methods and Analysis: A mixed-methods evaluation will be conducted. First we will conduct a quantitative outcomes evaluation using a pre- and post-test design at four purposively selected MESH MH participating health centers. At least 96 consecutive adult patients with schizophrenia, bipolar disorder, depression or epilepsy will be enrolled. Primary outcomes are patients' symptoms and functioning measured at baseline, eight weeks and six months using clinician-administered scales: the General Health Questionnaire and the World Health Organization Disability Assessment Scale, brief version. We hypothesize that patients will experience at least a 25% improvement in symptoms and functioning from baseline after MESH MH program participation. To understand any outcome improvements under the intervention, we will evaluate program processes using (1) quantitative analyses of routine service utilization data and supervision checklist data and (2) qualitative semi-structured interviews with primary care nurses, patients and family members.

Ethics and Dissemination This evaluation was approved by the Rwanda National Ethics Committee (Protocol #736/RNEC/2016) and deemed exempt by the Harvard University Institutional Review Board. Results will be submitted for peer-reviewed journal publication, presented at conferences, and disseminated to communities served by the program.

Strengths and Limitations of this study
- The proposed study protocol will be one of the first to assess the implementation process and outcomes of a program capacitating front line public primary care health workers in a resource limited setting to care for patients with neuropsychiatric disorders, including severe mental disorders.

- We use a prospective pre- and post- study design to evaluate patient outcomes. In this design the pre-intervention period serves as the control group. A strength of this approach is that each person serves as his/her own control and there is no confounding by patient-level characteristics.

- Our outcomes evaluation is limited by the lack of an external control group that did not receive the intervention and the potential for bias due to trends in outcomes over time. Additionally, our ability to associate program quality (nurse supervisory checklist scores) with care delivery is limited by the use of routine data to measure quality of care.

- To overcome these limitations we coupled the pre- and post- outcomes evaluation with multiple data sources for the process evaluation (service use, checklist scores and qualitative interviews) to establish a plausible causal link for improvements in patient outcomes with program implementation.

Keywords:

Mental health, Public Health, International Health Services, Organization of Health Services, Quality in Health Care

INTRODUCTION

Mental disorders account for the highest proportion of years lived with disability across the globe.[1] Addressing this burden through effective clinical and social programs is a global imperative. One strategy to improve access to mental health care is to integrate mental health care into primary care. Rather than using specialized care settings to address mental disorders, integrated primary care settings optimize health worker interventions for mental health through 'task-sharing'– delegating tasks and responsibilities from more specialized mental health clinicians to less specialized health workers.[2]

Although integrating mental health care into primary care settings has the potential to significantly reduce the burden of mental disorders,[3-6] few real-world models exist to show how evidence-based mental health care can be implemented in primary health care settings in resource-limited areas, especially for severe mental disorders. The World Health Organization has created mental health care implementation guidelines for non-specialist providers [7], yet most primary care personnel in low resource settings have had little or no training in the delivery of mental health services.[8] For those who have received some training in recognizing mental disorders, the training is usually brief and does not necessarily focus on patients' care.[9] Programs are also hampered by a lack of prioritization of mental health care within the primary care system, and the over-reliance on lower skilled individuals for providing the bulk of mental health care without supervision and support. Globally, there are several new research initiatives to test innovative models of task-sharing in mental health system development [10-12], but there is currently little known about the clinical and functional outcomes patients participating in such programs in real world settings.

Partners In Health (PIH), a non-profit organization working in ten countries, has supported the public health delivery system in three rural districts of Rwanda for eleven years. In 2012, the Rwandan Ministry of Health (MoH) and PIH collaboratively designed the MESH MH (Mentoring and Enhanced Supervision at Health Centers for Mental Health) program, a systematic approach to integrated mental health care that capacitates front line public primary care health providers to care for patients with mental disorders and epilepsy. The model is based on an existing program of mentorship and enhanced clinical supervision at health centers to improve the quality of care provided by nurses at first level health facilities in PIH supported districts of Rwanda.[13] The model follows closely with World Health Organization (WHO) clinical mentoring guidelines developed for effective task shifting of HIV care.[14]

MESH MH Program

The MESH MH program focuses on four major neuropsychiatric disorders: schizophrenia; bipolar disorder; major depressive disorder; and epilepsy. The program consists of a five day training by public psychiatric nurse-mentors, designed to capacitate primary care nurses to engage practically in the clinical care of patients with these mental disorders. The training is followed by a program of regular supervision of the primary care nurses by the psychiatric-nurse mentors. Training materials and basic guidelines were created primarily from the Mental Health Gap Action Program (mhGAP) of the WHO [15], in addition to existing Partners In Health curriculum. The training curriculum includes: basic communication skills and showing empathy; recognition of delirium; diagnosis and treatment protocols for selected major mental disorders and epilepsy; psychoeducation; crisis interventions; and referral pathways to specialist mental health services when appropriate.

The program is designed to ensure weekly supervisory visits with a taper to monthly by one year after the initial training, and includes a refresher training midway through the first year. Primary care nurse supervisory visits by psychiatric nurses include clinical observation, individual case review, documentation review, and brief didactic sessions. A mental health supervision checklist was developed to assist with clinical mentoring and to ensure standardization of activities across clinical domains. The mentor nurse uses the case observation checklist to ensure that health center nurses are performing key elements of basic psychiatric evaluations, accurately diagnosing patients, and offering appropriate treatment and support. The successful completion of checklist items during mental health clinical evaluations is used to define basic quality of care provided by health center nurses. In addition, a facilities checklist has been adapted from other clinical areas, to assist with systems-based quality improvement projects. During each supervision session, the nurse-mentor uses this checklist to stimulate discussion of systems-based performance issues and "quality gaps" with the health center director and nurses. After gaps are identified, the mentor works together with the health center staff to formulate specific solutions to improving quality gaps. The problem and proposed solution(s) are recorded on the facilities checklist, and are returned to frequently by the mentor until the identified gaps are adequately addressed.

The program also includes basic training for Community Health Workers (CHWs) in case finding, treatment adherence, psychoeducation and stigma reduction. Training for CHWs begins several months after services are rolled out at health centers. CHWs are supported by a PIH community coordinator and a public community health nurse at each participating health center. The MESH MH program began initially at three health centers, and will be rolled out in phases to all health centers in the district over a several year period to ensure complete district coverage.

Study Rationale

This study will describe and assess program process indicators, and patient clinical outcomes and experiences in the MESH MH program, using mixed qualitative and quantitative research methods. This approach will allow for multiple data sources to be used to evaluate the MESH MH program in its context. Implementation research such as this holds high promise for reducing the gap between the evidence base for effective services and clinical practice.[16] Such research can inform future multisite studies to study the MESH MH model as a scalable model of care for mental health services in resource limited areas, as well as generate evidence that can be adopted by policy makers, program developers and clinicians.

Study Objectives

Primary Outcome Aim: Assess whether patients who receive mental health care at select health centers participating in the MESH MH program experience clinical and functional improvement.
Process Aim 1: Assess changes in uptake of mental health care by assessing the quantity and quality of mental health diagnoses at all district health centers in relation to the implementation of the MESH MH program.
Process Aim 2: Assess whether participating non-specialist health center nurses offer basic quality mental health care as specified in MESH MH program objectives.
Process Aim 3: Explore the perspectives and experiences of health center nurses, families and patients who receive care at select health centers where the MESH MH program has been implemented.

METHODS AND ANALYSIS
Site

The MESH MH program is based in Burera district, northern Rwanda. The district is served by Butaro Hospital, a 150-bed public hospital with approximately thirty-five general nurses, thirteen full time general practitioners, four psychiatric nurses and one psychologist. The hospital houses an outpatient mental health specialty clinic which operates five days a week. Patients in need of acute psychiatric services are transferred from the mental health clinic or directly from district health centers to Butaro Hospital under the care of the hospital-based mental health workers, in collaboration with general physicians. The hospital is the primary referral center for nineteen district health centers, and serves an overall population of approximately 340,000 people. The public mental health services in Burera district are supported by a three-member PIH Mental Health team, including one program manager, one community coordinator, and an expatriate psychiatrist based in the district.

Study Design: A mixed-methods evaluation will be performed at four purposively selected health facilities newly participating in the MESH MH program. A quantitative outcome evaluation with a pre-and post test design will be conducted to determine whether patients who receive mental health care at supported health centers experience clinical and functional improvement. As an adjunct to this evaluation, a process evaluation will be conducted using service utilization data to assess changes in uptake of mental health services at participating health facilities within the district, using MESH MH supervision checklists to determine whether participating health center nurses adequately provide basic quality mental health care, and using qualitative interviews to explore the perspectives and experiences of health workers and patients who receive care through this program.

Outcomes Evaluation (Quantitative Pre- and Post- Intervention Analysis): Assess whether patients who receive mental health care at select health centers participating in the MESH MH program experience clinical and functional improvement.

Study Population/Recruitment: All consecutive adults presenting to the mental health clinics at the four selected health centers for an initial visit over the course of approximately six months, who have been diagnosed with a major mental or neurologic disorder, will be invited to participate in the quantitative outcomes evaluation. Patients who need to be transferred to the district hospital for an acute medical or psychiatric emergency and patients with a primary alcohol or substance use disorder will be excluded from the evaluation. The mental health clinic day occurs once weekly as designated by the health center schedule. On that day, a clinician researcher will be available at the health center for enrollment in the outcomes evaluation. Additionally, patients with a mental disorder who arrive at the clinic on a non-designated mental health clinic day will also be informed of the outcomes evaluation by the health center nurse, and will be invited to return to participate the following week on the day that the clinician researcher will be present. Written informed consent from the patient and his/her designated proxy will be obtained before data collection begins.

Data collection, measures and outcomes: The primary outcomes will be clinical symptoms and daily functioning, measured at first visit, eight weeks and six months after beginning participation in the MESH MH program, using the scales listed in Table 1.

Table 1. Outcome measurement tools

Domain	Instrument
Clinical Symptoms	General Health Questionnaire (GHQ-12) [17]
Functioning and Disability	WHO-Disability Assessment Scale (WHO-DAS II) 12 item version [18]

The General Health Questionnaire (GHQ-12) is a general measure of psychological distress, frequently used in primary care settings. This scale was chosen, rather than a symptom specific scale, given the anticipated diagnostic heterogeneity of the study population. The World Health Organization Disability Assessment Scale Brief (WHO-DAS II Brief) scale was chosen as a general measure of functioning and disability across a variety of domains relevant to mental illness. Although neither scale has yet been validated specifically in Rwanda, both scales have demonstrated high levels of validity and reliability across multiple cultures and languages [19,20]. All instruments will be translated into Kinyarwanda and back translated prior to implementation. The symptom and functioning scales will be pilot-tested among a small convenience sample of patients to ensure face validity.

Questionnaires will be administered by the trained clinician researcher. If the clinician researcher determines that a patient is unable to offer adequate answers to questions secondary to severe mental illness (e.g. the patient exhibits clinical signs of severe psychosis such as disorganized thinking), the primary family member in attendance at the clinic with the patient will be used as a proxy to answer questions, and the fact that a proxy has been used will be recorded. Demographic information as well as self-reported treatment status (new to treatment or received previous treatment) will be recorded.

Follow up: Patients will be re-interviewed on their return for routine follow up to the health center. For patients who do not return to follow-up, a community health worker in their village will be contacted to visit the patient and encourage the patient to return to care (as is routine practice in the current health system).

Analysis: All participating patients will be included in the analysis. Among patients who receive a score of > 2 on the WHO DAS-II Brief (indicating non-zero baseline disability) and a score of ≥ 3 on the GHQ-12 (indicating psychiatric caseness), [21-22] we will calculate within-person score change at eight weeks and six months and test whether any mean change is different than zero. We will calculate the percent of patients who experience clinically significant reductions in score (25% for the GHQ-12 and 20% for WHO-DAS-II Brief). We will use multivariable logistic regression to identify covariates associated with improved scores. To account for any patients who do not return for follow-up (and therefore do not complete a follow-up interview), we will conduct analyses in which we (1) assume no change in their baseline scores or (2) use inverse probability weighting to calculated a weighted mean change in score.

Sample size: Conservatively estimating that 50% of individuals will achieve a 25% score reduction within our population, a sample size of 96 patients will allow us to calculate 95% confidence intervals with precision of +/-10%. Assuming a drop-out rate of 20%, the minimum sample size for enrollment in the study will be 116. In order to stratify outcomes by characteristics such as age, gender, health center, diagnosis, and whether the patient is newly diagnosed or has previously been treated for a mental disorder, we will enroll as many patients are willing to participate (an estimated 200 patients).

Process Evaluation Aim 1*:* Assess changes in uptake of mental health care by assessing the quantity and quality of mental health diagnoses at all district health centers in relation to the implementation of the MESH MH program.

Routine program monitoring data will be collected from the paper registries for all patients attending mental health services at MESH MH participating health centers each month for six months following the implementation of the program, to assess whether increases in mental health diagnoses occur in relation to implementation of MESH MH. All health centers

participating in the MESH MH program in Burera district will be surveyed beginning at time of entry into the MESH MH program. Patient diagnoses and visit data are currently routinely recorded in the daily register by clinicians at all health facilities in the district. A subset of these routinely recorded data will be collected as indicators of program implementation process (Table 2).

Table 2. Routine health center program monitoring indicators

- Total number of mental health visits per month
- Total number of unique patients with a mental disorder seen per month
- Number of new patients seen per month
- Number of new patients who receive any follow up over six months

Each month, a research data officer will travel to participating health facilities and record these process indicators. The data will be entered into a password protected electronic patient database currently in use by the IMB MH team for tracking routine process indicators.

Data analysis: We will compare the number of new patients diagnosed with a mental disorder, the number of new mental health diagnoses, the number of mental health follow-up visits, and percent of patients with specific diagnoses at baseline and monthly for six months post- MESH MH program implementation. We hypothesize that we will observe an increase in the number of mental health diagnoses and follow-up visits at health centers post-MESH MH implementation, representing an increase in uptake of mental health services and recognition of mental health morbidity among providers. We further hypothesize that MESH MH supervision will lead to improvements in the number of individuals with specific mental health diagnoses post-MESH MH.

Process Evaluation Aim 2: Assess whether participating non-specialist health center nurses offer basic quality mental health care as specified in MESH MH program objectives.

Specific indicators of quality have been developed to track each nurse's provision of mental health care at health centers as an integral routine part of the MESH MH program. These quality of care indicators will be routinely collected over six months using the MESH MH supervision checklist, completed by mentors. Each month, all MESH MH mentor observation checklists are collected from the MESH MH nurse mentor and entered into a database. The quantitative process indicators for purposes of this evaluation will include the number of MESH MH checklists completed weekly, as well as a subset of supervision checklist items (Table 3).

Table 3. Quality of Care Process Indicators

Checklist items for **new** patients:
- Summary score of correctly completed mental health intake questions
- Diagnostic agreement between the psychiatric nurse-mentor and the primary care nurse
- Summary score of correctly completed treatment planning tasks
- Completed safety planning questions

Data analysis: For each nurse mentee from each health center, we will calculate the change in checklist item scores each month relative to baseline and test whether the mean change is different than zero. We hypothesize that within person change will increase with time since MESH MH implementation. For binary variables, we will examine whether proportions increase with time since MESH MH enrollment. We will adjust for correlation resulting from repeated measures from the same individuals.

Process Evaluation Aim 3: Explore the perspectives and experiences of health center nurses, families and patients who receive care at select health centers where the MESH MH program has been implemented

Study Population/Recruitment: A subset of patients recruited for the quantitative program evaluation will be selected by stratified purposeful selection for the qualitative program evaluation. Approximately 40-50 participants will be chosen by the clinician researcher or recommended by the health center nurse or the MESH MH mentor. Patients will be chosen to represent the continuum of quantitative outcome scores (including those who did not see significant clinical improvement, those who achieved average improvement, and those who achieved maximal clinical improvement), as well as a maximal variety of patients assessed by demographics including age, gender, health center, and diagnosis. Family members of patients will also be included in interviews to understand the family's perspective and experiences of care at health centers as well.

Nurses: All health center nurses (approximately eight nurses) participating in the MESH MH program at the four selected health centers will be invited to participate in the qualitative program evaluation.

Data Collection and Measurement: Demographic data of participants will be obtained. Semi-structured interviews will be conducted by the mental health clinician researcher. The interviews will be conducted in Kinyarwanda and audio-recorded, and the interviewer will take notes for context and non-verbal communication. The interview guide will be developed through an emergent design including insights gained from the investigators' clinical and programmatic mental health care experiences as well as insights from other mental health workers in Rwanda and the literature on primary care integration models for mental health.

The semi-structured interviews will include sections to discuss access to and uptake of care, acceptability of care, quality of care and outcomes for patients of the MESH MH program, as well as the health center nurse as an agent of delivery and overall experiences of the MESH MH mentorship model of care, including perceived needs for improvement. Interview guides will be tailored to the nurses, users and families, probing for experiences and opinions in each section. Interviews will be translated into English and transcribed for analysis.

Data Analysis: A thematic analysis will be conducted. Each transcript will be analyzed and coded for the themes of access to and quality of mental health care at the health center level, the health center nurse as an agent of delivery and the mentorship model of mental health care. Illustrative examples of any associations found in the quantitative outcome evaluation will also be identified and synthesized.

ETHICS AND DISSEMINATION
The quantitative outcomes evaluation will take place within the context of mental health service provision at health centers. Potential participants are those enrolled in care for a mental health diagnosis at the health centers, and each participant will be provided follow-up care indefinitely both during and after the evaluation is completed, as in the course of routine services.

Data collection consists of quantitative and qualitative interviews. Although answering questions about current clinical status and opinions about care provision is low risk for patients, families and nurses, there is a possibility that such discussions may cause an increase in distress for participants. To mitigate this risk, the research assistant will emphasize during the informed

consent process that patients or family members can return to the health center for support should they experience such distress. Health Center nurses who may feel distress after participation will have access to support from the MESH mentor associated with their health center. If any acute safety risks are identified during or after the quantitative or qualitative interview processes (e.g. patient expression of an acute risk of harm to self or others), the participant will be referred to district mental health services at Butaro hospital for clinical evaluation.

To maintain participant confidentiality, all quantitative evaluation questionnaires will be completed in pen and paper format or on a password protected tablet and stored in a locked storage cabinet at Butaro hospital. Data will be entered from these questionnaires into a database on a password-protected computer which is also stored in the locked cabinet. Qualitative interviews will be recorded and transcribed onto the same computer by the research assistant or certified translator. Audio recorders will also be held in the locked cabinet and erased after the study is completed.

This proposal has been deemed exempt by the Institutional Review Board of Harvard University and approved by the Rwanda National Ethics Committee (RNEC). As patients with mental disorders are considered a vulnerable population, a more intensive consent process will be used to ensure that appropriate consent for participation in the outcomes evaluation is obtained. Evidence suggests that when systematic and thorough informed consent processes are implemented, patients with severe psychiatric disorders can understand and retain critical components of informed consent.[23] The following consent process has been adapted according to the recommendations of RNEC.

Patients:
Quantitative/Qualitative Evaluation: The initial consent process will occur at the four selected health centers following patients' routine appointments for a mental disorder. In cases where patients are potentially interested in participating as determined by the recruitment procedure, the research assistant will describe the quantitative evaluation process in some detail, including the purpose of the study, the anticipated benefits and risks, and voluntariness issues, to both the patient and his/her accompanying family member, and answer any questions which may arise. Purposively selected patients will be asked with their family members by the research assistant if they are both willing to participate in a qualitative evaluation consisting of the longer semi-structured interview. If the patient and family member then agree to participate, the research assistant will then obtain written assent from the patient and consent from the accompanying family member.

Nurses:
Qualitative Evaluation: The research assistant will describe the qualitative evaluation process in some detail to all prospective participant nurses, including the purpose, anticipated risks and benefits, voluntariness and confidentiality issues, and obtain written consent from all participating nurses.

DISCUSSION
This mixed methods evaluation will be among the first to link program implementation processes with clinical outcomes for patients with neuropsychiatric disorders, including severe mental disorders such as schizophrenia, being cared for in a resource limited primary care setting. Although integration of mental health care into general medical settings is a common policy prescription across the globe, there is currently little real-world evidence that resource limited public primary care settings can effectively care for patients with mental disorders, especially

with severe mental disorders. This protocol aims to fill an urgent need to assess the impact of a systematic program which capacitates front line public primary care health providers to care for such patients. If results are positive, recommendations for scale-up of the MESH MH program will be developed and presented to key community, government, and non-governmental stakeholders.

There are limitations to the study design. This proposal endeavors to evaluate whether the MESH MH program contributes to improved clinical and functional outcomes among patients participating in the program, but it does not include a control group. For this reason, we will not be able to draw a definitive causal relationship between clinical and functional changes and the MESH MH program implementation. In addition, our measurement of program quality, the nurse supervisory checklist scores, will be taken from routinely collected data, which limits our ability to associate these data with actual care delivery. However, the use of multiple program process indicators (service use data, supervision checklist data, and qualitative interviews) as an adjunct to the quantitative outcome assessment will help to ensure confidence that the MESH MH program has been implemented as intended at studied health centers. The addition of the process evaluation will strengthen the plausibility that observed clinical changes can be attributed to the MESH MH program.

A second limitation is that the MESH mental health program is currently being implemented in public health centers in only one district in Rwanda which is well supported by PIH. Whether our results are generalizable across all settings or at scale remains to be determined. For example, more intensive supervision and monitoring of the program may not be feasible in all districts and could influence the quality of delivery of the program, as well as patient outcomes. However, this mixed methods evaluation will be the first report on a newly implemented supervised mental health program at the health center level, which may lead to further rigorous testing of the effectiveness of the intervention and its potential to scale to other health centers and districts in Rwanda.

Authors Contributions

SLS developed the proposal concept, drafted the proposal, and is a co-principal investigator of the study. CNM is a co-principal investigator of the study and provided critical revisions to the manuscript. JDI, JAD and AM manage different aspects of the national mental health program in Rwanda, and revised the manuscript critically for content. MA provided contextual inputs and critical revisions; RAO was a technical advisor for the IMB MH program and revised critically for content, MFF provided statistical analysis support and revised critically for content, YK leads the national mental health program in Rwanda and revised critically for content; GJR supported the initial development and strategic focus of the IMB mental health program leading to the current intervention, leads the PIH mental health program, mentored SLS as principal investigator, advises the IMB mental health team, and provided critical revisions to the manuscript.

Conflict of Interest

The authors declare no conflict of interests

Funding

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Evaluating Process and Clinical Outcomes of a Primary Care Mental Health Integration Project in rural Rwanda: a Prospective Mixed-Methods Protocol.

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Title: Evaluating Process and Clinical Outcomes of a Primary Care Mental Health Integration Project in rural Rwanda: a Prospective Mixed-Methods Protocol

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Abstract

Introduction Integrating mental health care into primary care can reduce the global burden of mental disorders. Yet data on the effective implementation of real-world task-shared mental health programs is limited. In 2012, the Rwandan Ministry of Health and the international health care organization Partners In Health collaboratively adapted the Mentoring and Enhanced Supervision at Health Centers (MESH) program, a successful program of supported supervision based on task sharing for HIV/AIDS care, to include care of neuropsychiatric disorders within primary care settings (MESH Mental Health). We propose one of the first studies in a rural low-income country to assess the implementation and clinical outcomes of a program integrating neuropsychiatric care into a public primary care system.

Methods and Analysis: A mixed-methods evaluation will be conducted. First we will conduct a quantitative outcomes evaluation using a pre- and post-test design at four purposively selected MESH MH participating health centers. At least 112 consecutive adults with schizophrenia, bipolar disorder, depression or epilepsy will be enrolled. Primary outcomes are symptoms and functioning measured at baseline, eight weeks and six months using clinician-administered scales: the General Health Questionnaire and the brief World Health Organization Disability Assessment Scale.. We hypothesize that service users will experience at least a 25% improvement in symptoms and functioning from baseline after MESH MH program participation. To understand any outcome improvements under the intervention, we will evaluate program processes using (1) quantitative analyses of routine service utilization data and supervision checklist data and (2) qualitative semi-structured interviews with primary care nurses, service users and family members.

Ethics and Dissemination This evaluation was approved by the Rwanda National Ethics Committee (Protocol #736/RNEC/2016) and deemed exempt by the Harvard University Institutional Review Board. Results will be submitted for peer-reviewed journal publication, presented at conferences, and disseminated to communities served by the program.

Strengths and Limitations of this study

- The proposed study protocol will be one of the first to assess the implementation process and outcomes of a program capacitating front line public primary care health workers in a resource limited setting to care for people with neuropsychiatric disorders, including severe mental disorders.

- We use a prospective pre- and post- study design to evaluate clinical outcomes. In this design the pre-intervention period serves as the control group. A strength of this approach is that each person serves as his/her own control and there is no confounding by service user-level characteristics.

- Our outcomes evaluation is limited by the lack of an external control group that did not receive the intervention and the potential for bias due to trends in outcomes over time. Additionally, our ability to associate program quality (nurse supervisory checklist scores) with care delivery is limited by the use of routine data to measure quality of care.

- To overcome these limitations we coupled the pre- and post- outcomes evaluation with multiple data sources for the process evaluation (service use, checklist scores and qualitative interviews) to establish a plausible causal link for improvements in clinical outcomes with program implementation.

Keywords:

Mental health, Public Health, International Health Services, Organization of Health Services, Quality in Health Care

INTRODUCTION

Mental disorders account for the highest proportion of years lived with disability across the globe.[1] Addressing this burden through effective clinical and social programs is a global imperative. One strategy to improve access to mental health care is to integrate mental health care into primary care. Rather than using specialized care settings to address mental disorders, integrated primary care settings optimize health worker interventions for mental health through 'task-sharing'– delegating tasks and responsibilities from more specialized mental health clinicians to less specialized health workers.[2]

Although integrating mental health care into primary care settings has the potential to significantly reduce the burden of mental disorders,[3-6] few real-world models exist to show how evidence-based mental health care can be implemented in primary health care settings in resource-limited areas, especially for severe mental disorders. The World Health Organization has created mental health care implementation guidelines for non-specialist providers [7], yet most primary care personnel in low resource settings have had little or no training in the delivery of mental health services.[8] For those who have received some training in recognizing mental disorders, the training is usually brief and does not necessarily focus on clinical care.[9] Programs are also hampered by a lack of prioritization of mental health care within the primary care system, and the over-reliance on lower skilled individuals for providing the bulk of mental health care without supervision and support. Globally, there are several new research initiatives to test innovative models of task-sharing in mental health system development [10-12], but there is currently little known about the clinical and functional outcomes of service users participating in such programs in real world settings.

Partners In Health (PIH), a non-profit organization working in ten countries, has supported the public health delivery system in three rural districts of Rwanda for eleven years. In 2012, the Rwandan Ministry of Health (MoH) and PIH collaboratively designed the MESH MH (Mentoring and Enhanced Supervision at Health Centers for Mental Health) program, a systematic approach to integrated mental health care that capacitates front line public primary care health providers to care for people with mental disorders and epilepsy. The model is based on an existing program of mentorship and enhanced clinical supervision at health centers to improve the quality of care provided by nurses at first level health facilities in PIH supported districts of Rwanda.[13] The model follows closely with World Health Organization (WHO) clinical mentoring guidelines developed for effective task shifting of HIV care.[14]

MESH MH Program

The MESH MH program focuses on four major neuropsychiatric disorders: schizophrenia; bipolar disorder; major depressive disorder; and epilepsy. The program consists of a five day training by public psychiatric nurse-mentors, designed to capacitate primary care nurses to engage practically in the clinical care of people with these mental disorders. The training is followed by a program of regular supervision of the primary care nurses by the psychiatric-nurse mentors. Training materials and basic guidelines were created primarily from the Mental Health Gap Action Program (mhGAP) of the WHO [15], in addition to existing Partners In Health curriculum. The training curriculum includes: basic communication skills and showing empathy; recognition of delirium; diagnosis and treatment protocols for selected major mental disorders and epilepsy; psychoeducation; crisis interventions; and referral pathways to specialist mental health services when appropriate.

The program is designed to ensure weekly supervisory visits with a taper to monthly by one year after the initial training, and includes a refresher training midway through the first year. Primary care nurse supervisory visits by psychiatric nurses include clinical observation, individual case review, documentation review, and brief didactic sessions. A mental health supervision checklist was developed to assist with clinical mentoring and to ensure standardization of activities across clinical domains. The mentor nurse uses the case observation checklist to ensure that health center nurses are performing key elements of basic psychiatric evaluations, accurately diagnosing service users, and offering appropriate treatment and support. The successful completion of checklist items during mental health clinical evaluations is used to define basic quality of care provided by health center nurses. In addition, a facilities checklist has been adapted from other clinical areas, to assist with systems-based quality improvement projects. During each supervision session, the nurse-mentor uses this checklist to stimulate discussion of systems-based performance issues and "quality gaps" with the health center director and nurses. After gaps are identified, the mentor works together with the health center staff to formulate specific solutions to improving quality gaps. The problem and proposed solution(s) are recorded on the facilities checklist, and are returned to frequently by the mentor until the identified gaps are adequately addressed.

The program also includes basic training for Community Health Workers (CHWs) in case finding, treatment adherence, psychoeducation and stigma reduction. Training for CHWs begins several months after services are rolled out at health centers. CHWs are supported by a PIH community coordinator and a public community health nurse at each participating health center. The MESH MH program began initially at three health centers, and will be rolled out in phases to all health centers in the district over a several year period to ensure complete district coverage.

Study Rationale

This study will describe and assess program process indicators, and clinical outcomes and experiences of service users in the MESH MH program, using mixed qualitative and quantitative research methods. This approach will allow for multiple data sources to be used to evaluate the MESH MH program in its context. Implementation research such as this holds high promise for reducing the gap between the evidence base for effective services and clinical practice.[16] Such research can inform future multisite studies to study the MESH MH model as a scalable model of care for mental health services in resource limited areas, as well as generate evidence that can be adopted by policy makers, program developers and clinicians.

Study Objectives

Primary Outcome Aim: Assess whether service users who receive mental health care at select health centers participating in the MESH MH program experience clinical and functional improvement.

Process Aim 1: Assess changes in uptake of mental health care by assessing the quantity and quality of mental health diagnoses at all district health centers in relation to the implementation of the MESH MH program.

Process Aim 2: Assess whether participating non-specialist health center nurses offer basic quality mental health care as specified in MESH MH program objectives.

Process Aim 3: Explore the perspectives and experiences of health center nurses, families and service users who receive care at select health centers where the MESH MH program has been implemented.

METHODS AND ANALYSIS
Site

The MESH MH program is based in Burera district, northern Rwanda. The district is served by Butaro Hospital, a 150-bed public hospital with approximately thirty-five general nurses, thirteen full time general practitioners, four psychiatric nurses and one psychologist. The hospital houses a mental health specialty clinic which operates five days a week. Persons in need of acute psychiatric services are transferred from the mental health clinic or directly from district health centers to Butaro Hospital under the care of the hospital-based mental health workers, in collaboration with general physicians. The hospital is the primary referral center for nineteen district health centers, and serves an overall population of approximately 340,000 people. The public mental health services in Burera district are supported by a three-member PIH Mental Health team, including one program manager, one community coordinator, and an expatriate psychiatrist based in the district.

Study Design: A mixed-methods evaluation will be performed at four purposively selected health facilities newly participating in the MESH MH program between November 2014 and July of 2017. A quantitative outcome evaluation with a pre-and post test design will be conducted to determine whether service users who receive mental health care at supported health centers experience clinical and functional improvement. As an adjunct to this evaluation, a process evaluation will be conducted using service utilization data to assess changes in uptake of mental health services at participating health facilities within the district, using MESH MH supervision checklists to determine whether participating health center nurses adequately provide basic quality mental health care, and using qualitative interviews to explore the perspectives and experiences of health workers and service users who receive care through this program.

Outcomes Evaluation (Quantitative Pre- and Post- Intervention Analysis): Assess whether service users who receive mental health care at select health centers participating in the MESH MH program experience clinical and functional improvement.

Study Population/Recruitment: All consecutive adults presenting to the mental health clinics at the four selected health centers for an initial visit over the course of approximately nine months, who have been diagnosed with a major mental or neurologic disorder, will be invited to participate in the quantitative outcomes evaluation. Persons who need to be transferred to the district hospital for an acute medical or psychiatric emergency, or who have a primary alcohol or substance use disorder and no other diagnosed mental disorder, will be excluded from the evaluation. The mental health clinic day occurs once weekly as designated by the health center schedule. On that day, a clinician researcher will be available at the health center for enrollment in the outcomes evaluation. Additionally, service users with a mental disorder who arrive at the clinic on a non-designated mental health clinic day will also be informed of the outcomes evaluation by the health center nurse, and will be invited to return to participate the following week on the day that the clinician researcher will be present. Written informed consent from the service user and his/her designated proxy will be obtained before data collection begins.

Data collection, measures and outcomes: The primary outcomes will be clinical symptoms and daily functioning, measured at first visit, eight weeks and six months after beginning participation in the MESH MH program, using the scales listed in Table 1.

Table 1. Outcome measurement tools

Domain	Instrument
Clinical Symptoms	General Health Questionnaire (GHQ-12) [17]
Functioning and Disability	WHO-Disability Assessment Scale (WHO-DAS II) 12 item version [18]

The General Health Questionnaire (GHQ-12) is a general measure of psychological distress, frequently used in primary care settings. This scale was chosen, rather than a symptom specific scale, given the anticipated diagnostic heterogeneity of the study population. The World Health Organization Disability Assessment Scale Brief (WHO-DAS II Brief) scale was chosen as a general measure of functioning and disability across a variety of domains relevant to mental illness. Although neither scale has yet been validated specifically in Rwanda, both scales have demonstrated high levels of validity and reliability across multiple cultures and languages [19,20]. All instruments will be translated into Kinyarwanda and back translated prior to implementation. The symptom and functioning scales will be pilot-tested among a small convenience sample of service users to ensure face validity.

Questionnaires will be administered by the trained clinician researcher. If the clinician researcher determines that a service user is unable to offer adequate answers to questions secondary to severe mental illness (e.g. the person exhibits clinical signs of severe psychosis such as disorganized thinking), the primary family member in attendance at the clinic with the service user will be used as a proxy to answer questions, and the fact that a proxy has been used will be recorded. Demographic information as well as self-reported treatment status (new to treatment or received previous treatment) will be recorded.

Follow up: Service users will be re-interviewed on their return for routine follow up to the health center. For service users who do not return to follow-up, a community health worker in their village will be contacted to perform a home visit and encourage the service user to return to care (as is routine practice in the current health system).

Analysis: All participants will be included in the analysis. Among service users who receive a score of > 2 on the WHO DAS-II Brief (indicating non-zero baseline disability) and a score of ≥ 3 on the GHQ-12 (indicating psychiatric caseness), [21-22] we will calculate within-person score change at eight weeks and six months and test whether any mean change is different than zero. We will calculate the percent of service users who experience clinically significant reductions in score (25% for the GHQ-12 and 20% for WHO-DAS-II Brief). We will use multivariable logistic regression to identify covariates associated with improved scores at six months. To account for those who do not return for follow-up (and therefore do not complete a follow-up interview), we will conduct analyses in which we (1) assume no change in their baseline scores or (2) use inverse probability weighting to calculated a weighted mean change in score.

Sample size: Conservatively estimating that 50% of individuals will achieve a 25% score reduction within our population, a sample size of 96 service users will allow us to calculate 95% confidence intervals with precision of +/-10%. Assuming a drop-out rate of 20%, the minimum sample size for enrollment in the study will be 116. In order to stratify outcomes by characteristics such as age, gender, health center, diagnosis, and whether the service user is newly diagnosed or has previously been treated for a mental disorder, we will enroll as many adults as are willing to participate (an estimated 200 service users).

Process Evaluation Aim 1*:* Assess changes in uptake of mental health care by assessing the quantity and quality of mental health diagnoses at all district health centers in relation to the implementation of the MESH MH program.

Routine program monitoring data will be collected from the paper registries for all persons attending mental health services at MESH MH participating health centers each month for six months following the implementation of the program, to assess whether increases in mental

health diagnoses occur in relation to implementation of MESH MH. All health centers participating in the MESH MH program in Burera district will be surveyed beginning at time of entry into the MESH MH program. Service user diagnoses and visit data are currently routinely recorded in the daily register by clinicians at all health facilities in the district. A subset of these routinely recorded data will be collected as indicators of program implementation process (Table 2).

Table 2. Routine health center program monitoring indicators

- Total number of mental health visits per month
- Total number of unique service users with a mental disorder seen per month
- Number of new service users seen per month
- Number of new service users who receive any follow up over six months

Each month, a research data officer will travel to participating health facilities and record these process indicators. The data will be entered into a password protected electronic database currently in use by the IMB MH team for tracking routine process indicators.

Data analysis*:* We will compare the number of new service users diagnosed with a mental disorder, the number of new mental health diagnoses, the number of mental health follow-up visits, and percent of service users with specific diagnoses at baseline and monthly for six months post- MESH MH program implementation. We hypothesize that we will observe an increase in the number of mental health diagnoses and follow-up visits at health centers post-MESH MH implementation, representing an increase in uptake of mental health services and recognition of mental health morbidity among providers. We further hypothesize that MESH MH supervision will lead to improvements in the number of individuals with specific mental health diagnoses post-MESH MH.

Process Evaluation Aim 2*:* Assess whether participating non-specialist health center nurses offer basic quality mental health care as specified in MESH MH program objectives.

Specific indicators of quality have been developed to track each nurse's provision of mental health care at health centers as an integral routine part of the MESH MH program. These quality of care indicators will be routinely collected over six months using the MESH MH supervision checklist, completed by mentors. Each month, all MESH MH mentor observation checklists are collected from the MESH MH nurse mentor and entered into a database. The quantitative process indicators for purposes of this evaluation will include the number of MESH MH checklists completed weekly, as well as a subset of supervision checklist items (Table 3).

Table 3. Quality of Care Process Indicators

Checklist items for **new** service users:
- Summary score of correctly completed mental health intake questions
- Diagnostic agreement between the psychiatric nurse-mentor and the primary care nurse
- Summary score of correctly completed treatment planning tasks
- Completed safety planning questions

Data analysis*:* For each nurse mentee from each health center, we will calculate the change in checklist item scores each month relative to baseline and test whether the mean change is different than zero. We hypothesize that within person change will increase with time since MESH MH implementation. For binary variables, we will examine whether proportions increase

with time since MESH MH enrollment. We will adjust for correlation resulting from repeated measures from the same individuals.

Process Evaluation Aim 3: Explore the perspectives and experiences of health center nurses, families and service users who receive care at select health centers where the MESH MH program has been implemented

Study Population/Recruitment: A subset of service users recruited for the quantitative program evaluation will be selected by stratified purposeful selection for the qualitative program evaluation. Approximately 40-50 participants will be chosen by the clinician researcher or recommended by the health center nurse or the MESH MH mentor. Service users will be chosen to represent the continuum of quantitative outcome scores (including those who did not see significant clinical improvement, those who achieved average improvement, and those who achieved maximal clinical improvement), as well as a maximal variety of demographics including age, gender, health center, and diagnosis. Family members of service users will also be included in interviews to understand the family's perspective and experiences of care at health centers as well.

Nurses: All health center nurses (approximately eight nurses) participating in the MESH MH program at the four selected health centers will be invited to participate in the qualitative program evaluation.

Data Collection and Measurement: Demographic data of participants will be obtained. Semi-structured interviews will be conducted by the mental health clinician researcher. The interviews will be conducted in Kinyarwanda and audio-recorded, and the interviewer will take notes for context and non-verbal communication. The interview guide will be developed through an emergent design including insights gained from the investigators' clinical and programmatic mental health care experiences as well as insights from other mental health workers in Rwanda and the literature on primary care integration models for mental health.

The semi-structured interviews will include sections to discuss access to and uptake of care, acceptability of care, quality of care and outcomes for service users of the MESH MH program, as well as the health center nurse as an agent of delivery and overall experiences of the MESH MH mentorship model of care, including perceived needs for improvement. Interview guides will be tailored to the nurses, users and families, probing for experiences and opinions in each section. Interviews will be translated into English and transcribed for analysis.

Data Analysis: A thematic analysis will be conducted. Each transcript will be analyzed and coded for the themes of access to and quality of mental health care at the health center level, the health center nurse as an agent of delivery and the mentorship model of mental health care. Illustrative examples of any associations found in the quantitative outcome evaluation will also be identified and synthesized.

ETHICS AND DISSEMINATION
The quantitative outcomes evaluation will take place within the context of mental health service provision at health centers. Potential participants are those enrolled in care for a mental health diagnosis at the health centers, and each participant will be provided follow-up care indefinitely both during and after the evaluation is completed, as in the course of routine services.

Data collection consists of quantitative and qualitative interviews. Although answering questions about current clinical status and opinions about care provision is low risk for service users,

families and nurses, there is a possibility that such discussions may cause an increase in distress for participants. To mitigate this risk, the research assistant will emphasize during the informed consent process that service users or family members can return to the health center for support should they experience such distress. Health Center nurses who may feel distress after participation will have access to support from the MESH mentor associated with their health center. If any acute safety risks are identified during or after the quantitative or qualitative interview processes (e.g. expression of an acute risk of harm to self or others), the participant will be referred to district mental health services at Butaro hospital for clinical evaluation.

To maintain participant confidentiality, all quantitative evaluation questionnaires will be completed in pen and paper format or on a password protected tablet and stored in a locked storage cabinet at Butaro hospital. Data will be entered from these questionnaires into a database on a password-protected computer which is also stored in the locked cabinet. Qualitative interviews will be recorded and transcribed onto the same computer by the research assistant or certified translator. Audio recorders will also be held in the locked cabinet and erased after the study is completed.

This proposal has been deemed exempt by the Institutional Review Board of Harvard University and approved by the Rwanda National Ethics Committee (RNEC). As service users with mental disorders are considered a vulnerable population, a more intensive consent process will be used to ensure that appropriate consent for participation in the outcomes evaluation is obtained. Evidence suggests that when systematic and thorough informed consent processes are implemented, people with severe psychiatric disorders can understand and retain critical components of informed consent.[23] The following consent process has been adapted according to the recommendations of RNEC.

Service users:
Quantitative/Qualitative Evaluation: The initial consent process will occur at the four selected health centers following service users' routine appointments for a mental disorder. In cases where a user is potentially interested in participating as determined by the recruitment procedure, the research assistant will describe the quantitative evaluation process in some detail, including the purpose of the study, the anticipated benefits and risks, and voluntariness issues, and answer any questions which may arise. Purposively selected service users will be asked with their family members by the research assistant if they are both willing to participate in a qualitative evaluation consisting of the longer semi-structured interview. If the service user and family member then agree to participate, the research assistant will then obtain written assent from the service user and consent from the accompanying family member. Non-literate service users and family members will use a stamped fingerprint as is customary within the health system in Rwanda. Although obtaining assent from service users and consent from family members is not common current practice for studies involving persons with mental disorders, the Rwanda National Ethics Committee reports that Rwandan legislation around mental disorders remains under review and until updates are finalized, the current legislation requires the above described processes of assent/consent for persons with mental disorders.

Nurses:
Qualitative Evaluation: The research assistant will describe the qualitative evaluation process in some detail to all prospective participant nurses, including the purpose, anticipated risks and benefits, voluntariness and confidentiality issues, and obtain written consent from all participating nurses.

DISCUSSION

This mixed methods evaluation will be among the first to link program implementation processes with clinical outcomes for persons with neuropsychiatric disorders, including severe mental disorders such as schizophrenia, being cared for in a resource limited primary care setting. Although integration of mental health care into general medical settings is a common policy prescription across the globe, there is currently little real-world evidence that resource limited public primary care settings can effectively care for people with mental disorders, especially with severe mental disorders. This protocol aims to fill an urgent need to assess the impact of a systematic program which capacitates front line public primary care health providers to care for such persons. If results are positive, recommendations for scale-up of the MESH MH program will be developed and presented to key community, government, and non-governmental stakeholders.

There are limitations to the study design. This proposal endeavors to evaluate whether the MESH MH program contributes to improved clinical and functional outcomes among service users participating in the program, but it does not include a control group. For this reason, we will not be able to draw a definitive causal relationship between clinical and functional changes and the MESH MH program implementation. Secondly, the criterion-related validity of our scaled clinical and functional scales are not known in Rwanda, although both have been widely used internationally, including in multiple African countries. In addition, our measurement of program quality, the nurse supervisory checklist scores, will be taken from routinely collected data, which limits our ability to associate these data with actual care delivery. However, the use of multiple program process indicators (service use data, supervision checklist data, and qualitative interviews) as an adjunct to the quantitative outcome assessment will help to ensure confidence that the MESH MH program has been implemented as intended at studied health centers. The addition of the process evaluation will strengthen the plausibility that observed clinical changes can be attributed to the MESH MH program.

A second limitation is that the MESH mental health program is currently being implemented in public health centers in only one district in Rwanda which is well supported by PIH. Whether our results are generalizable across all settings or at scale remains to be determined. For example, more intensive supervision and monitoring of the program may not be feasible in all districts and could influence the quality of delivery of the program, as well as clinical outcomes. However, this mixed methods evaluation will be the first report on a newly implemented supervised mental health program at the health center level, which may lead to further rigorous testing of the effectiveness of the intervention and its potential to scale to other health centers and districts in Rwanda.

Authors Contributions
SLS developed the proposal concept, drafted the proposal, and is a co-principal investigator of the study. CNM is a co-principal investigator of the study and provided critical revisions to the manuscript. JDI, JAD and AM manage different aspects of the national mental health program in Rwanda, and revised the manuscript critically for content. MA provided contextual inputs and critical revisions; RAO was a technical advisor for the IMB MH program and revised critically for content, MFF provided statistical analysis support and revised critically for content, YK leads the national mental health program in Rwanda and revised critically for content; GJR supported the initial development and strategic focus of the IMB mental health program leading to the current intervention, leads the PIH mental health program, mentored SLS as principal investigator, advises the IMB mental health team, and provided critical revisions to the manuscript.

Conflict of Interest
The authors declare no conflict of interests

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