

BMJ Open 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 healthcare into primary care can reduce the global burden of mental disorders. Yet data on the effective implementation of real-world task-shared mental health programmes are limited. In 2012, the Rwandan Ministry of Health and the international healthcare organisation Partners in Health collaboratively adapted the Mentoring and Enhanced Supervision at Health Centers (MESH) programme, a successful programme 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 1 of the first studies in a rural low-income country to assess the implementation and clinical outcomes of a programme 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 pretest and post-test design at 4 purposively selected MESH MH participating health centres. At least 112 consecutive adults with schizophrenia, bipolar disorder, depression or epilepsy will be enrolled. Primary outcomes are symptoms and functioning measured at baseline, 8 weeks and 6 months using clinician-administered scales: the General Health Questionnaire and the brief WHO Disability Assessment Scale. We hypothesise that service users will experience at least a 25% improvement in symptoms and functioning from baseline after MESH MH programme participation. To understand any outcome improvements under the intervention, we will evaluate programme processes using (1) quantitative analyses of routine service utilisation data and supervision checklist data and (2) qualitative semistructured 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

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 programme 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 prestudy and poststudy design to evaluate clinical outcomes. In this design, the preintervention 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 programme 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 preoutcomes and postoutcomes 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 programme implementation.

publication, presented at conferences and disseminated to communities served by the programme.

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 programmes is a global imperative. One strategy to improve access to mental healthcare is to integrate mental healthcare into primary care. Rather than using specialised care settings to address mental disorders, integrated primary care settings optimise health worker interventions for mental health through ‘task-sharing’—delegating tasks and responsibilities from more specialised mental health clinicians to less specialised health workers.²

Although integrating mental healthcare 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 healthcare can be implemented in primary healthcare settings in resource-limited areas, especially for severe mental disorders. The WHO has created mental healthcare 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 recognising mental disorders, the training is usually brief and does not necessarily focus on clinical care.⁹ Programmes are also hampered by a lack of prioritisation of mental healthcare within the primary care system, and the over-reliance on lower skilled individuals for providing the bulk of mental healthcare 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 programmes in real-world settings.

Partners in Health (PIH), a non-profit organisation working in 10 countries, has supported the public health delivery system in 3 rural districts of Rwanda for 11 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) programme, a systematic approach to integrated mental healthcare 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 programme of mentorship and enhanced clinical supervision at health centres 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 WHO clinical mentoring guidelines developed for effective task shifting of HIV care.¹⁴

MESH MH programme

The MESH MH programme focuses on four major neuropsychiatric disorders: schizophrenia; bipolar disorder; major depressive disorder and epilepsy. The programme consists of a 5-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 programme 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,⁷ in addition to existing PIH 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 programme is designed to ensure weekly supervisory visits with a taper to monthly by 1 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 standardisation of activities across clinical domains. The mentor nurse uses the case observation checklist to ensure that health centre 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 centre 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 centre director and nurses. After gaps are identified, the mentor works together with the health centre 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 programme 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 centres. CHWs are supported by a PIH community coordinator and a public community health nurse at each participating health centre. The MESH MH programme began initially at three health centres, and will be rolled out in phases to all health centres in the district over a several year period to ensure complete district coverage.

Study rationale

This study will describe and assess programme process indicators, and clinical outcomes and experiences of service users in the MESH MH programme, using mixed qualitative and quantitative research methods. This approach will allow for multiple data sources to be used

to evaluate the MESH MH programme 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.¹⁵ 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 policymakers, programme developers and clinicians.

Study objectives

Primary outcome aim

Assess whether service users who receive mental healthcare at select health centres participating in the MESH MH programme experience clinical and functional improvement.

Process aim 1

Assess changes in the uptake of mental healthcare by assessing the quantity and quality of mental health diagnoses at all district health centres in relation to the implementation of the MESH MH programme.

Process aim 2

Assess whether participating non-specialist health centre nurses offer basic quality mental healthcare as specified in MESH MH programme objectives.

Process aim 3

Explore the perspectives and experiences of health centre nurses, families and service users who receive care at select health centres where the MESH MH programme has been implemented.

METHODS AND ANALYSIS

Site

The MESH MH programme is based in Burera district, northern Rwanda. The district is served by Butaro Hospital, a 150-bed public hospital with ~35 general nurses, 13 full-time general practitioners, 4 psychiatric nurses and 1 psychologist. The hospital houses a mental health specialty clinic which operates 5 days a week. Persons in need of acute psychiatric services are transferred from the mental health clinic or directly from district health centres to Butaro Hospital under the care of the hospital-based mental health workers, in collaboration with general physicians. The hospital is the primary referral centre for 19 district health centres, and serves an overall population of ~340 000 people. The public mental health services in Burera district are supported by a three-member PIH Mental Health team, including one programme 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 programme between November 2014 and July 2017. A quantitative outcome evaluation with a pretest and post-test design will be conducted to determine whether service users who receive mental healthcare at supported health centres experience clinical and functional improvement. As an adjunct to this evaluation, a process evaluation will be conducted using service utilisation data to assess changes in the uptake of mental health services at participating health facilities within the district, using MESH MH supervision checklists to determine whether participating health centre nurses adequately provide basic quality mental healthcare, and using qualitative interviews to explore the perspectives and experiences of health workers and service users who receive care through this programme.

Outcomes evaluation (quantitative preintervention and postintervention analysis)

Assess whether service users who receive mental healthcare at select health centres participating in the MESH MH programme experience clinical and functional improvement.

Study population/recruitment

All consecutive adults presenting to the mental health clinics at the four selected health centres for an initial visit over the course of ~9 months, who have been diagnosed with a major mental or neurological 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 centre schedule. On that day, a clinician researcher will be available at the health centre for enrolment 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 centre 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, 8 weeks and 6 months after beginning participation in the MESH MH programme, using the scales listed in table 1.

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 WHO Disability Assessment Scale Brief (WHO-DAS

Table 1 Outcome measurement tools

Domain	Instrument
Clinical symptoms	General Health Questionnaire (GHQ-12) ¹⁶
Functioning and disability	WHO-Disability Assessment Scale (WHO-DAS II) 12-item version ¹⁷

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.^{18 19} 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 (eg, the person exhibits clinical signs of severe psychosis such as disorganised 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 reinterviewed on their return for routine follow-up to the health centre. For service users who do not return to follow-up, a CHW 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),^{20 21} we will calculate within-person score change at 8 weeks and 6 months and test whether any mean change is different from zero. We will calculate the per cent 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 6 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 calculate 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% CIs with precision of $\pm 10\%$. Assuming a dropout rate of 20%, the minimum sample size for enrolment in the study will be 116. In order to stratify outcomes by characteristics such as age, gender, health centre, diagnosis and whether the service user is newly diagnosed or has previously been treated for a mental disorder, we will enrol as many adults as are willing to participate (an estimated 200 service users).

Process evaluation aim 1

Assess changes in the uptake of mental healthcare by assessing the quantity and quality of mental health diagnoses at all district health centres in relation to the implementation of the MESH MH programme.

Routine programme monitoring data will be collected from the paper registries for all persons attending mental health services at MESH MH participating health centres each month for 6 months following the implementation of the programme, to assess whether increases in mental health diagnoses occur in relation to implementation of MESH MH. All health centres participating in the MESH MH programme in Burera district will be surveyed beginning at the time of entry into the MESH MH programme. 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 programme implementation process (box 1).

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 per cent of service users with specific diagnoses at baseline and monthly for 6 months post-MESH MH programme implementation. We hypothesise that we will observe an increase in the number of mental health

Box 1 Routine health centre programme 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 6 months

diagnoses and follow-up visits at health centres post-MESH MH implementation, representing an increase in the uptake of mental health services and recognition of mental health morbidity among providers. We further hypothesise 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 centre nurses offer basic quality mental healthcare as specified in MESH MH programme objectives.

Specific indicators of quality have been developed to track each nurse's provision of mental healthcare at health centres as an integral routine part of the MESH MH programme. These quality of care indicators will be routinely collected over 6 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 (box 2).

Data analysis

For each nurse mentee from each health centre, we will calculate the change in checklist item scores each month relative to baseline and test whether the mean change is different from zero. We hypothesise 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 enrolment. We will adjust for correlation resulting from repeated measures from the same individuals.

Process evaluation aim 3

Explore the perspectives and experiences of health centre nurses, families and service users who receive care at select health centres where the MESH MH programme has been implemented.

Study population/recruitment

A subset of service users recruited for the quantitative programme evaluation will be selected by stratified purposeful selection for the qualitative programme evaluation. Approximately 40–50 participants will be chosen

by the clinician researcher or recommended by the health centre 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 centre 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 centres as well.

Nurses

All health centre nurses (approximately eight nurses) participating in the MESH MH programme at the four selected health centres will be invited to participate in the qualitative programme evaluation.

Data collection and measurement

Demographic data of participants will be obtained. Semistructured 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 healthcare experiences as well as insights from other mental health workers in Rwanda and the literature on primary care integration models for mental health.

The semistructured 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 programme, as well as the health centre 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 analysed and coded for the themes of access to and quality of mental healthcare at the health centre level, the health centre nurse as an agent of delivery and the mentorship model of mental healthcare. Illustrative examples of any associations found in the quantitative outcome evaluation will also be identified and synthesised.

DISSEMINATION

The quantitative outcomes evaluation will take place within the context of mental health service provision at health centres. Potential participants are those enrolled in care for a mental health diagnosis at the health

Box 2 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

centres, and each participant will be provided follow-up care indefinitely 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 emphasise during the informed consent process that service users or family members can return to the health centre for support should they experience such distress. Health centre nurses who may feel distress after participation will have access to support from the MESH mentor associated with their health centre. If any acute safety risks are identified during or after the quantitative or qualitative interview processes (eg, 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.

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.²² 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 centres 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 semistructured 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 finalised, 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 programme 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 healthcare 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 programme 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 programme will be developed and presented to key community, government and non-governmental stakeholders.

There are limitations to the study design. This proposal endeavours to evaluate whether the MESH MH programme contributes to improved clinical and functional outcomes among service users participating in the programme, 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 programme implementation. Second, the criterion-related validity of our scaled clinical and functional scales is not known in Rwanda, although both have been widely used internationally, including in multiple African countries. In addition, our measurement of programme 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 programme 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 programme has been implemented as intended at studied health centres. The addition of the process evaluation will strengthen the plausibility that observed clinical changes can be attributed to the MESH MH programme.

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

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

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